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The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each month.

Title 5—Administrative Personnel

CHAPTER I—CIVIL SERVICE COMMISSION

PART 213—EXCEPTED SERVICE

Department of Labor; Correction

In the FEDERAL REGISTER of August 10, 1973, (FR Doc. 73-16524) appearing on page 21621, § 213.3315(a)(32) was revoked in error. Section 213.3315(a)(32) reads as follows:

§ 213.3315 Department of Labor.

(a) *Office of the Secretary.* * * *

(32) One Special Assistant to the Counselor to the Secretary.

(5 U.S.C. secs. 3301, 3302; E.O. 10577, 3 CFR 1954–58 comp. p. 218)

UNITED STATES CIVIL SERVICE COMMISSION

[SEAL] JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc.74-7296 Filed 3-28-74;8:45 am]

PART 213—EXCEPTED SERVICE

Action

Section 213.3359 is amended to show that one position of Director, Evaluation Division, and one position of Director, Policy Management Division, Office of Policy and Program Development are excepted under Schedule C.

Effective on March 29, 1974, § 213.3359 (m) and (n) are added as set out below.

§ 213.3359 Action.

* * * * *

(m) Director, Evaluation Division, Office of Policy and Program Development.

(n) Director, Policy Management Division, Office of Policy and Program Development.

(5 U.S.C. secs. 3301, 3302; E.O. 10577, 3 CFR 1954–58 Comp. p. 218)

UNITED STATES CIVIL SERVICE COMMISSION

[SEAL] JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc.74-7297 Filed 3-28-74;8:45 am]

Title 39—Postal Service

CHAPTER III—POSTAL RATE COMMISSION

PART 3002—ORGANIZATION

Change in Office Hours

APRIL 1, 1974.

The hours of the Postal Rate Commission will change effective April 1, 1974. Accordingly, § 3002.2(e) of the Code of Federal Regulations is changed to:

§ 3002.2 The Commission and its offices.

* * * * *

(e) *Hours.* The offices of the Commission will be open from 8:00 a.m. to 4:30 p.m. with the Docket Section open from 8:00 a.m. to 5:15 p.m. of each day except Saturdays, Sundays, and holidays, unless otherwise directed by Executive Order or officially declared, with appropriate notice.

* * * * *

By the Commission.

[SEAL] JOSEPH A. FISHER,
Secretary.

[FR Doc.74-7271 Filed 3-28-74;8:45 am]

Title 7—Agriculture

CHAPTER VIII—AGRICULTURAL STABILIZATION AND CONSERVATION SERVICE (SUGAR), DEPARTMENT OF AGRICULTURE

SUBCHAPTER B—SUGAR REQUIREMENTS AND QUOTAS

[Sugar Reg. 811, Amdt 3]

PART 811—CONTINENTAL SUGAR REQUIREMENTS AND AREA QUOTAS

Requirements, Quotas, and Quota Deficits for 1974

Basis and purpose and bases and considerations. This amendment is issued pursuant to the authority vested in the Secretary of Agriculture by the Sugar Act of 1948, as amended (61 Stat. 922, as amended; 7 U.S.C. 1101), hereinafter referred to as the "Act". The purpose of this amendment to sugar regulation 811, as amended, is to determine and prorate or allocate the deficits in quotas established pursuant to the Act.

Section 204(a) of the Act provides that the Secretary shall, as often as facts are ascertainable by him but in any event not less frequently than each 60 days after the beginning of each calendar year, determine whether any area or country will not market the quota for such area or country. On the basis of the quota established for Puerto Rico for the calendar year 1974, a finding was heretofore made (38 FR 31412) that Puerto Rico will be unable to market its quota by 700,000 short tons, raw value, and accordingly a quota deficit was determined for Puerto Rico for 700,000 tons. On the basis of the latest information on sugar production from the current Puerto Rican crop, it is herein found that Puerto Rico will be unable to fill its sugar quota by an additional 55,000 short tons, raw value. Therefore, a total deficit is herein determined in the 1974 quota for Puerto Rico of 755,000 short tons, raw value.

It has been determined that on the basis of the 1973 crop harvest and the probable marketing of the 1974 crop in 1974 that the Texas Cane Area will be unable to market its 1974 quota by an estimated 40,000 tons. A deficit, therefore, is herein determined in the 1974 quota of the Texas Cane Area of 40,000 tons.

If production exceeds the present estimates for Puerto Rico or the Texas Cane Area, the marketing opportunities for each area within the total mainland quota for such area will not be limited as a result of the deficit determination and proration provided herein.

On the basis of information available to the Department, Venezuela will not be able to market any sugar to the United States in 1974. Therefore a deficit of 63,540 tons is herein determined in the quota established for Venezuela which consists of 46,726 tons of its section 202 quota and 16,814 tons of deficit declarations previously prorated to it.

Deficits determined herein for Puerto Rico, the Texas Cane Area and Venezuela totaling 158,540 tons are allocated pursuant to section 204(a) of the Act by assigning 30.08 percent of the section 202 deficits or 42,631 tons to the Republic of the Philippines and prorating the balance of 115,909 tons to Western Hemisphere countries.

On the basis of evidence submitted to the Department from Haiti, Panama, and Honduras, it is hereby determined that the combined deficits and shortfalls in their 1973 quotas of 11,446 tons, 3,363 tons, and 10,351 tons, respectively, were due to crop disaster and the quotas of these countries for future years will not be subject to reduction pursuant to section 202(d)(4) of the Act. Peru, Guatemala, Argentina and India fell short of filling their 1973 quotas through combined deficits and shortfalls totaling 25,873 tons. It is hereby determined that such deficits and shortfalls were within reasonable tolerances under circumstances which prevailed last year and that the quotas of these countries for 1974 and subsequent years will not be subject to reduction pursuant to section 202(d)(4) of the Act.

It is hereby determined that deficits previously declared and those declared herein constitute all known deficits on which data are currently ascertainable by the Department.

On the basis of preliminary data a reduction of 179,309 tons was made in the 1974 quota established for the West Indies (38 FR 31412) pursuant to section 202(d)(4) of the Act. On the basis of final import data in 1973 such reduction in

the 1974 quota for the West Indies is reduced herein to 178,693 tons.

In 1973 Ireland was short of filling its quota by 4,244 tons while exporting to countries other than the United States. Therefore, pursuant to section 202(d)(4) of the Act the 1974 quota currently established for Ireland is hereby reduced by 4,244 tons, the amount of its shortfall. The quantity of 4,244 tons is allocated by assigning 30.08 percent to the Republic of the Philippines and prorating the balance to Eastern Hemisphere countries pursuant to section 202(d)(5) of the Act.

By virtue of the authority vested in the Secretary of Agriculture by the Act, part 811 of this chapter is hereby amended by amending §§ 811.31, 811.32, and 811.33 as follows:

1. Section 811.31 is amended by amending paragraph (a)(2) to read as follows:

§ 811.31 Quotas for domestic areas.

(a)(1) * * *

(2) It is hereby determined pursuant to section 204(a) of the Act that for the calendar year 1974 the Domestic Beet Sugar Area, the Texas Cane Area and Puerto Rico will be unable by 725,667, 40,000 and 755,000 short tons, raw value, respectively, to fill the quotas established for such areas in paragraph (a)(1) of this section. Pursuant to section 204 (b) of this Act, the determination of such deficits shall not affect the quotas established in paragraph (a)(1) of this section.

* * * * *

2. Section 811.32 is amended by amending paragraph (a) to read as follows:

§ 811.32 Proration and allocation of deficits in quotas.

(a) The total deficits determined in quotas established under section 202 of the Act in short tons, raw value, are as follows: Domestic Beet Sugar Area 725,667; Puerto Rico 755,000; the Texas Cane Area 40,000; and Venezuela 46,726. Such deficits totaling 1,567,393 short tons, raw value, are reallocated by (1) allocating 399,781 tons to the Republic of the Philippines; (2) prorating 929,278 tons to Western Hemisphere countries with quotas in effect in accordance with section 204(a) of the Act; and (3) assigning 238,334 tons to foreign countries on a first-come, first-served basis pursuant to paragraph (d)(2) of § 811.33 as set forth in Amendment 2 of this part.

3. Section 811.33 is amended by amending paragraphs (b) and (c) to read as follows:

§ 811.33 Quotas for foreign countries.

* * * * *

(b) For the calendar year 1974, the quota for the Republic of the Philippines is 1,599,081 short tons, raw value, representing 1,126,020 short tons, established pursuant to section 202(b) of the Act, 399,781 short tons established pursuant to section 204(a) of the Act and 73,280 short tons established pursuant to section 202(d) of the Act. Of the quantity of 1,126,020 short tons established pursuant to section 202(b) of the Act, only 59,920 short tons, raw value, may be filled by direct-consumption sugar pursuant to section 207(d) of the Act.

(c) For the calendar year 1974, the prorations to individual foreign countries other than the Republic of the Philippines pursuant to section 202 of the Act are shown in columns (1) and (2) of the following table. Deficit prorations previously established in this Sugar Regulation 811 are shown in column (3). New deficits and deficit prorations established herein are shown in column (4) and total quotas and prorations are shown in column (5).

Countries	Basic quotas	Temporary quotas and prorations pursuant to Sec. 202(d)[1]	Previous deficit prorations	New deficits and deficit prorations	Total quotas and prorations
	(1)	(2)	(3)	(4)	(5)
	(Short tons, raw value)				
Dominican Republic	427,345	184,303	174,977	24,935	811,560
Mexico	377,933	162,994	154,745	22,052	717,724
Brazil	368,585	158,960	150,918	21,506	699,969
Peru	254,228	87,224	107,994	15,389	464,835
West Indies	4,505	1,546	56,321	8,026	70,398
Ecuador	54,420	23,469	22,282	3,176	103,347
Argentina	51,081	22,030	20,915	2,981	97,007
Costa Rica	46,073	19,871	18,865	2,688	87,497
Colombia	45,405	19,583	18,591	2,650	86,229
Panama	43,068	18,574	17,634	2,513	81,789
Nicaragua	43,068	18,574	17,634	2,513	81,789
Venezuela	34,790	11,936	16,814	−63,540	0
Guatemala	39,396	16,990	16,131	2,298	74,815
El Salvador	28,712	12,383	11,756	1,676	54,527
Belize (British Honduras)	22,703	9,791	9,296	1,324	43,114
Haiti	20,699	8,928	8,475	1,208	39,310
Honduras	8,013	3,454	3,281	468	15,216
Bolivia	4,340	1,872	1,777	253	8,242
Paraguay	4,340	1,672	1,777	253	8,242
Australia	167,599	46,071			213,670
Republic of China	69,777	19,182			88,959
India	67,106	18,447			85,553
South Africa	47,408	13,032			60,440
Fiji Islands	36,725	10,096			46,821
Mauritius	24,706	6,792			31,498
Swaziland	24,706	6,792			31,498
Thailand	15,358	4,221			19,579
Malawi	12,353	3,395			15,748
Malagasy Republic	10,016	2,753			12,769
Ireland	1,107				1,107
Amendment 2 quotas [2]	131,572	43,428	238,334		413,334
Total	2,487,137	958,563	1,068,517	52,369	4,566,586

[1] Proration of the quotas withheld from Cuba, Southern Rhodesia, Bahamas, Uganda, West Indies, Peru, Venezuela, and Ireland.

[2] Quota made available to foreign countries on a first-come, first-served basis pursuant to section 202(d)(2) of the Act and in Sugar Regulation 811, Amendment 2 (39 F R 3945). Quantities shown in columns (1), (2), and (3) represent the amounts that would have been prorated to the Philippines and countries with quotas in the respective columns had proration been made in the usual manner under section 202 (b), (c), and (d)(1) of the Act.

* * * * *

(Secs. 201, 202, 204, and 403; 61 Stat. 923, as amended, 924, as amended, 925, as amended, 932; and (7 U.S.C. 1111, 1112, 1114, and 1153).)

Effective date. This action determines deficits in the Puerto Rican, the Texas Cane Area, and Venezuela quotas of 55,000, 40,000, and 63,540 tons, respectively, and prorates and allocates such deficit to the Republic of the Philippines and Western Hemisphere quota countries. In order to promote orderly marketing, it is essential that this amendment be effective immediately so that all persons selling and purchasing sugar for consumption in the continental United States can promptly plan and market under the changed marketing opportunities. Therefore, it is hereby determined and found that compliance with the notice, procedure, and effective date requirements of 5 U.S.C. 553 is unnecessary, impracticable and contrary to the public interest and this amendment shall be effective when filed for public inspection in the Office of the Federal Register.

Signed at Washington, D.C. on March 25, 1974.

GLENN A. WEIR,
Acting Administrator, Agricultural Stabilization and Conservation Service.

[FR Doc.74-7258 Filed 3-26-74;11:26 am]

CHAPTER IX—AGRICULTURAL MARKETING SERVICE (MARKETING AGREEMENTS AND ORDERS; FRUITS, VEGETABLES, NUTS), DEPARTMENT OF AGRICULTURE

[Lemon Reg. 632]

PART 910—LEMONS GROWN IN CALIFORNIA AND ARIZONA

Limitation of Handling

This regulation fixes the quantity of California-Arizona lemons that may be shipped to fresh market during the weekly regulation period Mar. 31–April 6, 1974. It is issued pursuant to the Agricultural Marketing Agreement Act of 1937, as amended, and Marketing Order No. 910. The quantity of lemons so fixed was arrived at after consideration of the total

available supply of lemons, the quantity of lemons currently available for market, the fresh market demand for lemons, lemon prices, and the relationship of season average returns to the parity price for lemons.

§ 910.932 Lemon Regulation 632.

(a) *Findings.* (1) Pursuant to the marketing agreement, as amended, and Order No. 910, as amended (7 CFR Part 910), regulating the handling of lemons grown in California and Arizona, effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and upon the basis of the recommendations and information submitted by the Lemon Administrative Committee, established under the said amended marketing agreement and order, and upon other available information, it is hereby found that the limitation of handling of such lemons, as hereinafter provided, will tend to effectuate the declared policy of the act.

(2) The need for this section to limit the quantity of lemons that may be marketed during the ensuing week stems from the production and marketing situation confronting the lemon industry.

(i) The committee has submitted its recommendation with respect to the quantity of lemons it deems advisable to be handled during the ensuing week. Such recommendation resulted from consideration of the factors enumerated in the order. The committee further reports the demand for lemons is easier so far this week because of unseasonal weather and the trade is clearing up stocks of fruit on hand. Average f.o.b. price was $5.94 per carton the week ended March 23, 1974 compared to $5.92 per carton the previous week. Track and rolling supplies at 152 cars were up 22 cars from last week.

(ii) Having considered the recommendation and information submitted by the committee, and other available information, the Secretary finds that the quantity of lemons which may be handled should be fixed as hereinafter set forth.

(3) It is hereby further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking procedure, and postpone the effective date of this section until 30 days after publication hereof in the FEDERAL REGISTER (5 U.S.C. 553) because the time intervening between the date when information upon which this section is based became available and the time when this regulation must become effective in order to effectuate the declared policy of the act is insufficient, and a reasonable time is permitted, under the circumstances, for preparation for such effective time; and good cause exists for making the provisions hereof effective as hereinafter set forth. The committee held an open meeting during the current week, after giving due notice thereof, to consider supply and market conditions for lemons and the need for regulation; interested persons were afforded an opportunity to submit information and views at this meeting; the recommendation and supporting information for regulation during the period specified herein were promptly submitted to the Department after such meeting was held; the provisions of this section, including its effective time, are identical with the aforesaid recommendation of the committee, and information concerning such provisions and effective time has been disseminated among handlers of such lemons; it is necessary, in order to effectuate the declared policy of the act, to make this section effective during the period herein specified; and compliance with this section will not require any special preparation on the part of persons subject hereto which cannot be completed on or before the effective date hereof. Such committee meeting was held on March 26, 1974.

(b) *Order.* (1) The quantity of lemons grown in California and Arizona which may be handled during the period March 31, 1974, through April 6, 1974, is hereby fixed at 240,000 cartons.

(2) As used in this section, "handled", and "carton(s)" have the same meaning as when used in the said amended marketing agreement and order.

(Secs. 1–19, 48 Stat. 31, as amended; (7 U.S.C. 601–674))

Dated: March 27, 1974.

FLOYD F. HEDLUND,
Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc.74-7416 Filed 3-28-74;8:45 am]

CHAPTER X—AGRICULTURAL MARKETING SERVICE (MARKETING AGREEMENTS AND ORDERS; MILK), DEPARTMENT OF AGRICULTURE

[Milk Order Nos. 32, 50, 62]

MILK IN THE SOUTHERN ILLINOIS, CENTRAL ILLINOIS AND ST. LOUIS-OZARKS MARKETING AREAS

Order Suspending Certain Provisions

This order of suspension is issued pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 et seq.), and of the orders regulating the handling of milk in the Southern Illinois, Central Illinois and St. Louis-Ozarks marketing areas.

Notice of proposed rulemaking was published in the FEDERAL REGISTER (39 FR 9387) concerning a proposed suspension of certain provisions of the orders. Interested persons were afforded opportunity to file written data, views, and arguments thereon.

After consideration of all relevant material, including the proposal set forth in the aforesaid notice, data, views, and arguments filed thereon, and other available information, it is hereby found and determined that for the months of March through December 1974, the following provisions of the orders do not tend to effectuate the declared policy of the Act:

PART 1032—MILK IN THE SOUTHERN ILLINOIS MARKETING AREA

1. In § 1032.71 that part of paragraph (f) which reads, "except for the months specified below, shall be", and the provisions contained in paragraphs (g) through (k) in their entirety.

PART 1050—MILK IN THE CENTRAL ILLINOIS MARKETING AREA

2. In § 1050.71 that part of paragraph (f) which reads, "except for the months specified below, shall be", and the provisions contained in paragraphs (g) through (k) in their entirety.

PART 1062—MILK IN ST. LOUIS-OZARKS MARKETING AREA

3. In § 1062.71 that part of paragraph (f) which reads, "except for the months specified below, shall be", and the provisions contained in paragraph (g) through (k) in their entirety.

STATEMENT OF CONSIDERATION

The suspension will make inoperative those provisions of Order Nos. 32, 50 and 62 that provide for the accumulation and disbursement of money due producers with the intent of encouraging seasonal adjustments in milk production. Under such provisions (the "takeout-payback" plan), money withheld from the pool during March through July (15 cents per hundredweight during March and July, and 25 cents per hundredweight during April, May, and June) is paid out to producers for deliveries of milk during September through December (20 percent in September and December and 30 precent in October and November).

Suspension in the Southern Illinois and St. Louis-Ozarks orders was requested by Mid-America Dairymen, Inc., and in the Southern Illinois and Central Illinois orders by Associated Milk Producers, Inc., Mississippi Valley Milk Producers and Prairie Farms Dairy, Inc.

In response to the invitation for written data, views, or arguments the National Farmers' Organization also requested that the respective provisions be suspended from the three orders for 1974. Also, a proprietary handler who obtains a substantial part of his milk from supply plants in Wisconsin supported petitioners' request as a means of preventing disorderly marketing conditions in the coming months.

The basis for the request by the petitioners is to provide the highest possible blend price to producers during the months of March through July 1974 to offset anticipated higher production costs. Also, blend prices zoned to the production areas of the respective orders could result in prices that are below competitive pay prices with other Federal order markets and with manufacturing plants competing for milk supplies. Without this suspension action the milk supply for the respective orders could be placed in jeopardy.

For the foregoing reasons, petitioners, who represent a substantial majority of

producers supplying the respective markets, request that the seasonal payment plan be suspended for this year in the Southern Illinois, Central Illinois and St. Louis-Ozarks markets. No opposition to the request was filed in response to the invitation for written data, views, or arguments. Accordingly, it is concluded that the specified provisions of the respective orders should be suspended for the months of March through December 1974.

It is hereby found and determined that thirty days' notice of the effective date hereof is impractical, unnecessary and contrary to the public interest in that:

(a) This suspension is necessary to reflect current marketing conditions and to maintain orderly marketing conditions in the marketing areas in that it is the only practical means of rendering the provisions inoperative for the period designated;

(b) This suspension does not require of persons affected substantial or extensive preparation prior to the effective date; and

(c) Notice of proposed rulemaking was given interested parties and they were afforded opportunity to file written data, views or arguments concerning this suspension.

Therefore, good cause exists for making this order effective for the months of March through December 1974.

It is therefore ordered, That the aforesaid provisions of the order are hereby suspended for the months of March through December 1974 effective.

(Secs. 1–19, 48 Stat. 31, as amended; (7 U.S.C. 601–674))

Effective date: March 29, 1974.

Signed at Washington, D.C., on March 26, 1974.

CLAYTON YEUTTER,
Assistant Secretary.

[FR Doc.74-7265 Filed 3-28-74;8:45 am]

[Docket No. AO-184-A34; Milk Order 98]

PART 1098—MILK IN THE NASHVILLE, TENNESSEE, MARKETING AREA

Order Amending Order

Findings and determinations. The findings and determinations hereinafter set forth are supplementary and in addition to the findings and determinations previously made in connection with the issuance of the aforesaid order and of the previously issued amendments thereto: and all of the said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein.

(a) *Findings upon the basis of the hearing record.* Pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 et seq.), and the applicable rules of practice and procedure governing the formulation of marketing agreements and marketing orders (7 CFR Part 900), a public hearing was held upon certain proposed amendments to the tentative marketing agreement and to the order regulating the handling of milk in the Nashville, Tennessee, marketing area.

Upon the basis of the evidence introduced at such hearing and the record thereof, it is found that:

(1) The said order as hereby amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the Act;

(2) The parity prices of milk, as determined pursuant to section 2 of the Act, are not reasonable in view of the price of feeds, available supplies of feeds, and other economic conditions which affect market supply and demand for milk in the said marketing area, and the minimum prices specified in the order as hereby amended, are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk, and be in the public interest; and

(3) The said order as hereby amended, regulates the handling of milk in the same manner as, and is applicable only to persons in the respective classes of industrial or commercial activity specified in, a marketing agreement upon which a hearing has been held.

(b) *Additional findings.* It is necessary in the public interest to make this order amending the order effective not later than April 1, 1974. Any delay beyond that date would tend to disrupt the orderly marketing of milk in the marketing area.

The provisions of this order are known to handlers. The recommended decision of the Deputy Administrator, Regulatory Programs, was issued February 15, 1974, and the decision of the Assistant Secretary containing all amendment provisions of this order was issued March 18, 1974. The changes effected by this order will not require extensive preparation or substantial alteration in method of operation for handlers. In view of the foregoing, it is hereby found and determined that good cause exists for making this order amending the order effective April 1, 1974, and that it would be contrary to the public interest to delay the effective date of this amendment for 30 days after its publication in the FEDERAL REGISTER. (Sec. 553(d), Administrative Procedure Act, 5 U.S.C. 551–559).

(c) *Determinations.* It is hereby determined that:

(1) The refusal or failure of handlers (excluding cooperative associations specified in Sec. 8c(9) of the Act) of more than 50 percent of the milk, which is marketed within the marketing area, to sign a proposed marketing agreement, tends to prevent the effectuation of the declared policy of the Act;

(2) The issuance of this order, amending the order, is the only practical means pursuant to the declared policy of the Act of advancing the interests of producers as defined in the order as hereby amended; and

(3) The issuance of the order amending the order is approved or favored by at least two-thirds of the producers who participated in a referendum and who during the determined representative period were engaged in the production of milk for sale in the marketing area.

ORDER RELATIVE TO HANDLING

It is therefore ordered, That on and after the effective date hereof, the handling of milk in the Nashville, Tennessee, marketing area shall be in conformity to and in compliance with the terms and conditions of the aforesaid order, as amended, and as hereby further amended, as follows:

1. Section 1098.7 is revised as follows:

§ 1098.7 Producer.

(a) Except as provided in paragraph (b) of this section, "producer" means any person who produces milk in compliance with the Grade A inspection requirements of a duly constituted regulatory agency, which milk is received at a pool plant or diverted pursuant to § 1098.13.

(b) "Producer" shall not include:

(1) A producer-handler as defined in any order (including this part) issued pursuant to the Act;

(2) Any person with respect to milk produced by him which is diverted to a pool plant from an other order plant if the other order designates such person as a producer under that order and such milk is allocated to a utilization other than Class I pursuant to § 1098.46(a)(4)(ii) and the corresponding step of § 1093.46(b); and

(3) Any person with respect to milk produced by him which is reported as diverted to an other order plant if any portion of such person's milk so moved is assigned to Class I under the provisions of such other order.

2. In § 1098.9, paragraph (a) is revised as follows:

§ 1098.9 Producer-handler.

* * * * *

(a) Produces milk and operates a distributing plant;

* * * * *

3. Section 1098.10 "Approved plant" is revoked and new §§ 1098.10 and 1098.10a are added as follows:

§ 1098.10 Distributing plant.

"Distributing plant" means a plant in which fluid milk products approved by a duly constituted regulatory agency for fluid consumption, or filled milk, are processed or packaged and from which there is route disposition in the marketing area during the month.

§ 1098.10a Supply plant.

"Supply plant" means a plant from which a fluid milk product acceptable to a duly constituted regulatory agency for fluid consumption, or filled milk, is shipped during the month to a pool plant.

4. Section 1098.11 is revised as follows:

§ 1098.11 Pool plant.

Except as provided in paragraph (d) of this section, "pool plant" means:

(a) A distributing plant that has route disposition, except filled milk, during

the month of not less than 50 percent of the fluid milk products, except filled milk, approved by a duly constituted regulatory agency for fluid consumption that are physically received at such plant or diverted as producer milk to a nonpool plant pursuant to § 1098.13 and that has route disposition, except filled milk, in the marketing area during the month of not less than 15 percent of its total disposition of fluid milk products, except filled milk, during the month.

(b) A supply plant from which not less than 50 percent of the total quantity of milk approved by a duly constituted regulatory agency for fluid consumption that is physically received from dairy farmers at such plant or diverted as producer milk to a nonpool plant pursuant to § 1098.13 during the month is shipped as fluid milk products, except filled milk, to pool plants pursuant to paragraph (a) of this section. A plant that was a pool plant pursuant to this paragraph in each of the immediately preceding months of August through February shall be a pool plant for the months of March through July unless the milk received at the plant does not continue to meet the requirements of a duly constituted regulatory agency or a written application is filed by the plant operator with the market administrator on or before the first day of any such month requesting that the plant be designated as a nonpool plant for such month and each subsequent month through July during which it would not otherwise qualify as a pool plant.

(c) A plant that is approved by a duly constituted regulatory agency to handle milk for fluid consumption in the marketing area that is operated by a cooperative association, for which pool plant status has been requested by the cooperative association, and from which during the month the quantity of fluid milk products (except filled milk) shipped to pool plants qualified pursuant to paragraph (a) of this section plus the milk physically received at such plants by direct delivery from the farms of producer members of the cooperative association is not less than two-thirds of the producer milk received at or diverted from pool plants of the cooperative association plus its members' producer milk received at or diverted from all other pool plants during the same month. If the cooperative association operating a plant qualified as a pool plant pursuant to this paragraph files with the market administrator prior to the first day of any month a written request for nonpool status for such month, the plant shall be a nonpool plant for such month and for each of the next 11 months in which it does not qualify as a pool plant pursuant to paragraph (a) or (b) of this section.

(d) The term "pool plant" shall not apply to the following plants:

(1) A producer-handler plant;

(2) A distributing plant qualified pursuant to paragraph (a) of this section which meets the requirements of a fully regulated plant pursuant to the provisions of another order issued pursuant to the Act and from which a greater quantity of fluid milk products, except filled milk, is disposed of during the month from such plant as route disposition in the marketing area regulated by the other order than as route disposition in the Nashville, Tenn., marketing area: *Provided*, That such a distributing plant which was a pool plant under this order in the immediately preceding month shall continue to be subject to all of the provisions of this part until the third consecutive month in which a greater proportion of its route disposition is made in such other marketing area, unless the other order requires regulation of the plant without regard to its qualifying as a pool plant under this order, subject to the proviso of this paragraph: *And provided further*, On the basis of a written application made either by the plant operator or by the cooperative association supplying milk to such operator's plant, at least 15 days prior to the date for which a determination of the Secretary is to be effective, the Secretary may determine that the route disposition in the respective marketing areas to be used for purposes of this paragraph shall exclude (for a specified period of time) route disposition made under limited term contracts to governmental bases and institutions;

(3) A distributing plant qualified pursuant to paragraph (a) of this section which meets the requirements of a fully regulated plant pursuant to the provisions of another Federal order and from which a greater quantity of Class I milk, except filled milk, is disposed of during the month in the Nashville, Tenn., marketing area as route disposition than as route disposition in the other marketing area, and such other order which fully regulates the plant does not contain provision to exempt the plant from regulation, even though such plant has greater route disposition in the marketing area of the Nashville, Tenn., order; and

(4) Any supply plant which would be subject to the classification and pricing provisions of another order issued pursuant to the Act unless such plant qualified as a pool plant pursuant to paragraph (b) of this section during the preceding August through January period.

5. In § 1098.13, paragraph (c) is revoked and paragraph (b) is revised as follows:

§ 1098.13 Producer milk.

* * * * *

(b) Diverted from a pool plant to a non-pool plant that is not a producer-handler plant. Such milk shall be accounted for as received by the diverting handler at the location of the nonpool plant.

6. In § 1098.18 the title "Route" is changed to "Route disposition" and § 1098.18 is revised as follows:

§ 1098.18 Route disposition.

"Route disposition" means any delivery (including delivery by a vendor or a sale from a plant store) of any fluid milk product classified as Class I milk other than a delivery to a milk or filled milk processing plant.

§ 1098.53 [Amended]

7. In § 1098.53, the word "pool" as it appears in paragraph (a) thereof is deleted.

8. In § 1098.81, a new paragraph (c) is added to read as follows:

§ 1098.81 Payments to market administrator.

* * * * *

(c) On or before the 25th day after the end of the month each handler who operated an other order plant that was regulated during such month under an order providing for individual-handler pooling shall pay to the market administrator an amount computed as follows:

(1) Determine the quantity of reconstituted skim milk in filled milk in route disposition from such plant in the marketing area which was allocated to Class I at such plant. If there is such route disposition from such plant in marketing areas regulated by two or more market-wide pool orders, the reconstituted skim milk allocated to Class I shall be prorated to each order according to such route disposition in each marketing area; and

(2) Compute the value of the reconstituted skim milk assigned in paragraph (c)(1) of this section to route disposition in this marketing area by multiplying the quantity of such skim milk by the difference between the Class I price under this part that is applicable at the location of the other order plant (but not to be less than the lowest price class) and the lowest price class.

9. In § 1098.83, paragraph (b) is revised as follows:

§ 1098.83 Butterfat and location differentials to producers and on nonpool milk.

* * * * *

(b) In making payments to producers pursuant to § 1098.82(b), the uniform price pursuant to § 1098.71 and the uniform base price pursuant to § 1098.72 for producer milk received at a plant shall be reduced according to the location of the plant, each at the rates set forth in § 1098.53; and

* * * * *

10. In § 1098.85, paragraph (c) is revised as follows:

§ 1098.85 Expense of administration.

* * * * *

(c) Class I milk disposed of from a partially regulated distributing plant as route disposition in the marketing area that exceeds Class I milk received during the month at such plant from pool plants and other order plants.

§ 1098.91 [Deleted]

11. Section 1098.91 is deleted.

12. In § 1098.92, paragraph (b) (1) and (3) is revised as follows:

§ 1098.92 Obligations of handler operating a partially regulated distributing plant.

* * * * *

(b) * * *

(1) Determine the respective amounts of skim milk and butterfat disposed of as route disposition in the marketing area;

(2) * * *

(3) Deduct the quantity of reconstituted skim milk in fluid milk products disposed of as route disposition in the marketing area;

* * * * *

(Secs. 1–19, 48 Stat. 31, as amended (7 U.S.C. 601–674))

Effective date: April 1, 1974.

Signed at Washington, D.C., on March 26, 1974.

CLAYTON YEUTTER,
Assistant Secretary.

[FR Doc.74–7264 Filed 3–28–74;8:45 am]

Title 9—Animals and Animal Products

CHAPTER I—ANIMAL AND PLANT HEALTH INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

SUBCHAPTER C—INTERSTATE TRANSPORTATION OF ANIMALS (INCLUDING POULTRY) AND ANIMAL PRODUCTS; EXTRAORDINARY EMERGENCY REGULATION OF INTRASTATE ACTIVITIES

PART 73—SCABIES IN CATTLE

Area Quarantined

This amendment quarantines a portion of Castro County in Texas because of the existence of cattle scabies. The restrictions pertaining to the interstate movement of cattle from quarantined areas as contained in 9 CFR Part 73 as amended, will apply to the area quarantined.

Accordingly, Part 73, Title 9, Code of Federal Regulations, as amended, restricting the interstate movement of cattle because of scabies is hereby amended as follows:

In § 73.1a, a new paragraph (a) relating to the State of Texas is added to read:

§ 73.1a Notice of quarantine.

(a) Notice is hereby given that cattle in certain portions of the State of Texas are affected with scabies, a contagious, infectious, and communicable disease; and therefore, the following area in such State is hereby quarantined because of said disease:

That portion of Castro County comprised of sections 1 through 4, Block 0–7, Abstract No. 999 through 1002 (G. W. Irwin Survey).

* * * * *

(Sec. 4–7, 23 Stat. 32 as amended; secs. 1 and 2, 32 Stat. 791–792, as amended; secs. 1–4, 33 Stat. 1264, 1265, as amended; secs. 3, 11, 76 Stat. 130, 132; (21 U.S.C. 111–113, 115, 117, 120, 121, 123–126, 134b, 134f); 37 FR 28464, 28477; 38 FR 19141.)

Effective date. The foregoing amendment shall become effective on March 26, 1974.

The amendment imposes certain further restrictions necessary to prevent the interstate spread of cattle scabies and must be made effective immediately to accomplish its purpose in the public interest. It does not appear that public participation in this rulemaking proceeding would made additional relevant information available to the Department.

Accordingly, under the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to the amendment are impracticable and contrary to the public interest, and good cause is found for making it effective less than 30 days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 26th day of March 1974.

J. K. ATWELL,
Acting Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service.

[FR Doc.74–7267 Filed 3–28–74;8:45 am]

PART 73—SCABIES IN CATTLE

Release of Area Quarantined

This amendment releases a portion of Logan County in Colorado from the areas quarantined because of cattle scabies. Therefore, the restrictions pertaining to the interstate movement of cattle from quarantined areas contained in 9 CFR Part 73, as amended, will not apply to the excluded area, but the restrictions pertaining to the interstate movement of cattle from nonquarantined areas contained in said Part 73 will apply to the excluded area. No areas in Colorado remain under quarantine.

Accordingly, Part 73, Title 9, Code of Federal Regulations, as amended, restricting the interstate movement of cattle because of scabies is hereby amended as follows:

In § 73.1a, paragraph (e) relating to the State of Colorado is deleted.

(Secs. 4–7, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791–792, as amended; secs. 1–4, 33 Stat. 1264, 1265, as amended; secs. 3, 11, 76 Stat. 130, 132; (21 U.S.C. 111–113, 115, 117, 120, 121, 123–126, 134b, 134f); 37 FR 28464, 28477; 38 FR 19141)

Effective date. The foregoing amendment shall become effective on March 26, 1974.

The amendment relieves restrictions no longer deemed necessary to prevent the spread of cattle scabies and should be made effective promptly in order to be of maximum benefit to affected persons. It does not appear that public participation in this rulemaking proceeding would make additional relevant information available to the Department.

Accordingly, under the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to the amendment are impracticable and unnecessary, and good cause is found for making the amendment effective less than 30 days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 26th day of March 1974.

J. K. ATWELL,
Acting Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service.

[FR Doc.74–7269 Filed 3–28–74;8:45 am]

PART 78—BRUCELLOSIS

Subpart D—Designation of Modified Certified Brucellosis Areas, Specifically Approved Stockyards, and Slaughtering Establishments

MODIFIED CERTIFIED BRUCELLOSIS AREAS

This amendment deletes the following area from the list of areas designated as Modified Certified Brucellosis Areas in 9 CFR 78.13 because it has been determined that this area no longer comes within the definition of § 78.1(i): Creek County in Oklahoma.

The following counties were deleted from the list of Modified Certified Brucellosis Areas in 9 CFR 78.13 on the specified date: Pittsburg and Pottawatomie Counties in Oklahoma on March 4, 1974. Since said date, it has been determined that these counties again come within the definition of § 78.1(i); and therefore, they have been redesignated as Modified Certified Brucellosis Areas.

Accordingly, § 78.13 of said regulations designating Modified Certified Brucellosis Areas is hereby revised to read as follows:

§ 78.13 Modified Certified Brucellosis Areas.

(a) All States of the United States are hereby designated as Modified Certified Brucellosis Areas except Oklahoma.

(b) The following State is hereby designated as a Modified Certified Brucellosis Area except for the counties named:

Oklahoma except Creek and Muskogee Counties.

Secs. 4–7, 23 Stat. 32, as amended, secs. 1 and 2, 32 Stat. 791–792, as amended; sec. 3, 33 Stat. 1265, as amended; sec. 2, 65 Stat. 693; and secs. 3 and 11, 76 Stat. 130, 132; (21 U.S.C. 111–113, 114a–1, 115, 117, 120, 121, 125, 134b, 134f); 37 FR 28464, 28477, 38 FR 19141, 9 CFR 78.16).

Effective date. The foregoing amendment shall become effective March 29, 1974.

The amendment imposes certain restrictions necessary to prevent the spread of brucellosis in cattle and relieves certain restrictions presently imposed. It should be made effective promptly in order to accomplish its purpose in the public interest and to be of maximum benefit to persons subject to the restrictions which are relieved. It does not appear that public participation in this rulemaking proceeding would make additional relevant information available to the Department.

Accordingly, under the administrative procedure provisions of 5 U.S.C., it is found upon good cause that notice and other public procedure with respect to

the amendment are impracticable, unnecessary, and contrary to the public interest, and good cause is found for making it effective less than 30 days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 26th day of March 1974.

J. K. ATWELL,
Acting Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service.

[FR Doc.74-7268 Filed 3-28-74;8:45 am]

Title 14—Aeronautics and Space

CHAPTER I—FEDERAL AVIATION ADMINISTRATION, DEPARTMENT OF TRANSPORTATION

[Airspace Docket No. 74-SW-11]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

Alteration of Control Zone

The purpose of this amendment to Part 71 of the Federal Aviation Regulations is to amend the Pine Bluff, Ark., control zone.

A new airport traffic control tower was commissioned on March 15, 1974, at Grider Field, Pine Bluff, Ark., and will operate from 0700–2000 local time daily. Concurrently, the Pine Bluff Flight Service Station will be part time from 0600–1800 local time daily. Weather observations will be taken either by the airport traffic control tower personnel or the flight service station personnel during the hours 0600–2000 local time daily. This will require an alteration of the Pine Bluff, Ark., control zone to part time effective 0600–2000 local time daily.

Since this amendment will impose no undue burden on any person, notice and public procedure hereon are unnecessary.

In consideration of the foregoing, Part 71 of the Federal Aviation Regulations is amended, effective on March 29, 1974, as hereinafter set forth.

In § 71.171 (39 FR 354), the Pine Bluff, Ark., control zone is amended to read:

PINE BLUFF, ARK.

That airspace within a 5-mile radius of Grider Field (latitude 34°10'35" N., longitude 91°55'55" W.) and within 2 miles each side of the Pine Bluff VORTAC 186° radial, extending from the 5-mile radius zone to 10.5 miles south of the VORTAC. This control zone is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airman's Information Manual.

Sec. 307(a), Federal Aviation Act of 1958, (49 U.S.C. 1348); sec. 6(c), Department of Transportation Act, (49 U.S.C. 1655(c))

Issued in Fort Worth, Tex., on March 19, 1974.

HENRY L. NEWMAN,
Director, Southwest Region.

[FR Doc.74-7236 Filed 3-28-74;8:45 am]

[Docket No. 13580; Amdt. 909]

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

Miscellaneous Amendments

This amendment to Part 97 of the Federal Aviation Regulations incorporates by reference therein changes and additions to the Standard Instrument Approach Procedures (SIAPs) that were recently adopted by the Administrator to promote safety at the airports concerned.

The complete SIAPs for the changes and additions covered by this amendment are described in FAA Forms 3139, 8260-3, 8260-4, or 8260-5 and made a part of the public rulemaking dockets of the FAA in accordance with the procedures set forth in Amendment No. 97-696 (35 FR 5609).

SIAPs are available for examination at the Rules Docket and at the National Flight Data Center, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, D.C. 20591. Copies of SIAPs adopted in a particular region are also available for examination at the headquarters of that region. Individual copies of SIAPs may be purchased from the FAA Public Document Inspection Facility, HQ-405, 800 Independence Avenue, SW., Washington, D.C. 20591 or from the applicable FAA regional office in accordance with the fee schedule prescribed in 49 CFR 7.85. This fee is payable in advance and may be paid by check, draft or postal money order payable to the Treasurer of the United States. A weekly transmittal of all SIAP changes and additions may be obtained by subscription at an annual rate of $150 per annum from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Additional copies mailed to the same address may be ordered for $30 each.

Since a situation exists that requires immediate adoption of this amendment, I find that further notice and public procedure hereon is impracticable and good cause exists for making it effective in less than 30 days.

In consideration of the foregoing, Part 97 of the Federal Aviation Regulations is amended as follows, effective on the dates specified:

1. Section 97.23 is amended by originating, amending, or canceling the following VOR-VOR/DME SIAPs, effective May 9, 1974:

Clinton, Okla.—Clinton-Sherman Arpt., VOR Rwy 35, Orig.
Grand Rapids, Mich.—Kent County Arpt., VOR Rwy 18, Amdt. 2.
Grand Rapids, Mich.—Kent County Arpt., VOR Rwy 36, Amdt. 6.
Oakdale, Calif.—Oakdale Arpt., VOR Rwy 10, Orig.

* * * effective April 11, 1974:

Pocahontas, Iowa—Pocahontas Municipal Arpt., VORTAC Rwy 29, Orig.

* * * effective March 20, 1974:

Eureka, Calif.—Murray Field, VOR-A, Amdt. 3.

2. Section 97.25 is amended by originating, amending, or canceling the following SDF-LOC-LDA SIAPs, effective May 9, 1974:

Clinton, Okla.—Clinton-Sherman Arpt., LOC (BC) Rwy 17, Orig.
Grand Rapids, Mich.—Kent County Arpt., LOC (BC) Rwy 8R, Amdt. 8.
Sioux City, Iowa—Sioux City Municipal Arpt., LOC (BC) Rwy 13, Amdt. 13.

* * * effective April 4, 1974:

Lewisburg, W. Va.—Greenbrier Valley Arpt., LOC Rwy 4, Amdt. 1, canceled.

3. Section 97.27 is amended by originating, amending, or canceling the following NDB/ADF SIAPs, effective May 9, 1974:

Clinton, Okla.—Clinton-Sherman Arpt., NDB Rwy 17, Orig.
Grand Rapids, Mich.—Kent County Arpt., NDB Rwy 26L, Amdt. 7.
Sioux City, Iowa—Sioux City Municipal, NDB Rwy 13, Amdt. 9.
Sioux City, Iowa—Sioux City Municipal, NDB Rwy 31, Amdt. 17.

* * * effective April 11, 1974:

Pocahontas, Iowa—Pocahontas Municipal Arpt., NDB Rwy 11, Orig.

* * * effective April 4, 1974:

Ashland, Ohio—Ashland County Arpt., NDB Rwy 18, Orig.
Calhoun, Ga.—Tom B. David Field, NDB Rwy 35, Orig.

* * * effective March 28, 1974:

Nome, Alaska—Nome Arpt., NDB Rwy 27, Amdt. 1.

* * * effective March 19, 1974:

Houghton Lake, Mich.—Roscommon County Arpt. NDB Rwy 27, Amdt. 3.

4. Section 97.29 is amended by originating, amending, or canceling the following ILS SIAPs, effective May 9, 1974:

Clinton, Okla.—Clinton-Sherman Arpt., ILS Rwy 35, Orig.
Grand Rapids, Mich.—Kent County Arpt., ILS Rwy 26L, Amdt. 8.
Sioux City, Iowa—Sioux City Municipal Arpt., ILS Rwy 31, Amdt. 17.

* * * effective April 4, 1974:

Lewisburg, W. Va.—Greenbrier Valley Arpt., ILS Rwy 4, Orig.

* * * effective March 20, 1974:

Louisville, Ky.—Standiford Field, ILS Rwy 1, Amdt. 1.

* * * effective March 19, 1974:

Atlantic City, N.J.—NAFEC, Atlantic City Arpt., ILS Rwy 31, Amdt. 1.

5. Section 97.31 is amended by originating, amending, or canceling the following RADAR SIAPs, effective May 9, 1974:

Sioux City, Iowa—Sioux City Municipal Arpt., RADAR-1, Orig.

Correction:

In Docket Nr. 13573, Amendment 908, to Part 97 of the Federal Aviation Regulations, published in the FEDERAL REGISTER under § 97.27, effective May 2,

1974—change effective date of Phoenix, Ariz.—Phoenix Sky Harbor Int'l. Arpt., NDB–A, Amdt. 1, Cancellation, to April 25, 1974.

(Secs. 307, 313, 601, 1110, Federal Aviation Act of 1948; (49 U.S.C. 1438, 1354, 1421, 1510); sec. 6(c) Department of Transportation Act, (49 U.S.C. 1655(c) and 5 U.S.C. 552(a)(1)))

Issued in Washington, D.C., on March 21, 1974.

JAMES M. VINES,
Chief, Aircraft Programs Division.

NOTE: Incorporation by reference provisions in §§ 97.10 and 97.20 (35 FR 5610) approved by the Director of the Federal Register on May 12, 1969.

[FR Doc.74-7239 Filed 3-28-74;8:45 am]

CHAPTER II—CIVIL AERONAUTICS BOARD

[Reg. ER-840; Amdt. 11]

PART 241—UNIFORM SYSTEM OF ACCOUNTS AND REPORTS FOR CERTIFICATED AIR CARRIERS

Fuel Consumption and Inventories; Reporting Requirements

Pursuant to Chairman Timm's letter of January 17, 1974, all route and supplemental air carriers have been reporting on an interim basis, fuel cost data on a form titled "CAB Form T-90, Fuel Consumption and Inventories." The letter also advised carriers to continue to file this report on a monthly basis, pending its inclusion as a schedule to the Form 41 reports of Part 241 of the Board's Economic Regulations. The reports received thus far, as well as the results of a survey conducted by the Air Transport Association of its 22 member carriers, have disclosed no substantial disagreement with the Board's need for the data nor any reason to believe that the imposition of this reporting requirement constitutes an undue burden on the carriers affected thereby.

The Board finds that it has an urgent regulatory need, so long as the present fuel situation remains basically unchanged, to have this data furnished by the carriers on a regular monthly basis. The Board therefore finds that, in view of the unquestioned need for the data to be furnished pursuant to this regulation and the demonstrated ability of the affected carriers to comply with this requirement, notice and public procedure hereon are unnecessary and would be contrary to the public interest. Accordingly, the Board has adopted the within amendment to Part 241.

The final rule incorporates substantially the same reporting requirements and instructions as were set forth in the interim reporting Form T-90. However, in light of certain questions and comments which have been raised with respect thereto, we have slightly revised the form and clarified the instructions for its completion, as more fully discussed hereinbelow.

To the extent that any of the within revisions, however minor, is regarded by an affected carrier as imposing an unnecessary reporting burden, we shall allow petitions for reconsideration with respect to such revisions. Twelve (12) copies of such petitions shall be filed with the Docket Section, Civil Aeronautics Board, Washington, D.C. 20428, on or before April 8, 1974. Copies of any petition filed will be available for inspection in the Docket Section. The filing of petitions shall not operate to stay the effective date of the within rules.

1. *Domestic and international operations.* All route and supplemental air carriers will continue to report on the new Form 41 Schedule P-5(b) (formerly designated as T-90) for fuel issued and acquired domestically for scheduled and nonscheduled operations. Such fuel as is consumed in "domestic" operations, as defined herein, is to be reported in columns (8) and (9), "Consumed By Carrier In Domestic Operations," indicating in the appropriate section of the report whether it came from the "Carrier's Storage Facilities" or was "Delivered Directly to the Aircraft by Others," as the case may be. In addition, we are adopting the suggestion of some carriers that, in order to conform to book inventories and thus make this report self-balancing, fuel drawn from domestic inventories for consumption in international operations should also be reported; this information is accordingly to be reported in columns (6) and (7), "Sold to Others and Consumed by Carrier in International Operations." [1] However, since the purpose of requiring information with respect to international operations is to facilitate balancing the carrier's inventory reports, this information is to be reported only with respect to fuel issued from "Carrier's Storage Facilities."

For the purposes of this rule, "domestic" operations are those flight stages with both terminals within the 50 States of the United States and the District of Columbia, just as the term is presently defined in section 03 of the Board's Economic Regulations. However, flight stages to and from Canada and Mexico, which are presently reported as domestic operations in the Form 41 reports, will be considered as international operations [2] for the purposes of this schedule.

It should also be noted that, although all bonded fuel will continue to be reported in Account 45.1, Aircraft Fuels, for the purposes of report Schedule P-5(b),[3] bonded fuels will be reported only to the extent that other fuel is reported.

The following examples illustrate the reporting of "domestic" and "international" operations:

EXAMPLE I

A carrier issues fuel from its "Carrier's Storage Facilities" for a flight to be operated Seattle/San Francisco/Mexico City and return to Seattle via San Francisco. The carrier would report on Schedule P-5(b), in the section for "Carrier's Storage Facilities":

1. The cost of all fuel loaded at Seattle with the next terminal to be San Francisco should be reported in columns (8) and (9), "Consumed by Carrier in Domestic Operations."

2. The cost of all fuel loaded at San Francisco with the next terminal to be Seattle should also be reported in columns (8) and (9), "Consumed by Carrier in Domestic Operations."

3. The cost of all fuel loaded at San Francisco with the next terminal to be Mexico City should be reported in columns (6) and (7), "Sold to Others and Consumed in International Operations," and the gallonage and costs so reported should be properly footnoted.

NOTE: Any fuel loaded in Mexico City is not from domestic storage facilities and information relating thereto is therefore excluded from this schedule.

EXAMPLE II

A carrier purchases fuel which is "Delivered Directly to Aircraft by Others" and operates the same flight sequence as set forth in Example I. The carrier would report on Schedule P-5(b), in the section for "Delivered Directly to Aircraft by Others":

1. The cost of all fuel loaded at Seattle with the next terminal to be San Francisco should be reported in columns (8) and (9), "Consumed by Carrier in Domestic Operations."

2. The cost of all fuel loaded in San Francisco with the next terminal to be Seattle should also be reported in columns (8) and (9), "Consumed by Carrier in Domestic Operations."

NOTE: Fuel purchased in San Francisco with the next terminal to be Mexico City would not be purchased for a "domestic" operation and would therefore not be reported.

2. *Miscellaneous clarifications.* Clarification has been requested as to which of various factors should be included or excluded in calculating the cost of fuel on Schedule P-5(b). Although shrinkage should be included in determining the cost of fuel, the following factors should be excluded from the cost of fuel:

a. "Through-put" and "in to plane" service fees,[4] and

b. Nonrefundable Federal and State excise taxes. Under the Uniform System of Accounts and Reports, "through-put" and "in to plane" service fees should be reflected in "Account 43.9, Other Services—Outside," and nonrefundable Federal and State excise taxes reflected in

[1] In order to facilitate analysis of the data reported under this heading, we are requiring annotation of that portion of fuel volume and cost which is attributable to international operations.

[2] For purposes of this regulation, international operations shall include "territorial operations," i.e., flight stages with both terminals within territory under U.S. jurisdiction where at least one of the terminals is not within a State or the District of Columbia.

[3] Filed as part of original document.

[4] Service charges or gallonage levies assessed by or against the fuel vendor or concessionaire and passed on to the carrier in a segregated and identifiable form.

[5] Commonly referred to as purchases.

"Account 69, Taxes—Other than Payroll."

Clarification has also been requested as to the method used to determine cost data reported on Schedule P–5(b). The fuel costs reporter in the section for "Delivered Directly to Aircraft by Others" should be stated in terms of total actual dollars. In the section for "Carrier's Storage Facilities," the total fuel costs are to be reported and calculated on the periodic average method. In applying this method, the total cost of Beginning Inventory, Column (3), plus Receipts,[5] column (5), is weighted by the total respective gallons, columns (2) and (4). The resulting quotient should then be applied to extend the gallons issued and in ending inventory. The following will illustrate the method:

	January			February		
	Gallons	Unit cost [1]	Cost	Gallons	Unit cost [1]	Cost
Beginning inventory	525,000		$145,000	420,000		$117,600
Receipts	1,750,000		492,000	1,740,000		519,600
Total	[2] 2,275,000		[2] 637,000	[3] 2,160,000		[3] 637,200
Issues:						
Sold to others and consumed by carrier in international operations	25,000	$0.28	7,000	6,000	$0.295	1,770
Consumed by carrier in domestic operations	1,830,000	.28	512,400	1,785,000	.295	526,575
Total issues	1,855,000		519,400	1,791,600		528,345
Ending inventory	420,000	.28	117,600	369,000	.295	108,855

[1] Shown merely for illustrative purposes.
[2] See the following equation:

$$\frac{\$637,000}{2,275,000 \text{ gal}} = \$0.28 \text{ per gallon}$$

[3] See the following equation:

$$\frac{\$637,200}{2,160,000 \text{ gal}} = \$0.295 \text{ per gallon}$$

3. *Technical revisions.* Certain carriers suggested that the Board give consideration to permit grouping station data under a specified amount rather than to require that each station be reported irrespective of quantity or cost. The Board believes this suggestion has merit and accordingly the form and instructions have been revised herein to permit grouping as "Miscellaneous" all stations where less than 5,000 gallons of fuel per month are issued in total, so long as the number of stations so grouped is indicated.

Also, where space on Schedule P–5(b) is not adequate to list all stations, copies of this schedule may be attached, so long as all stations reporting "Carrier's Storage Facilities" data and all stations reporting "Delivered Directly to Aircraft by Others" data are clearly identified in the attached copies.

Other carriers have suggested that a longer reporting deadline be granted, since the current reporting deadline of 10 days is inadequate in light of the coordination problem inherent when numerous stations are reporting data. The Board believes that this suggestion has merit and accordingly we are allowing Schedule P–5(b) to be filed 15 days after the close of the month.

Finally, the Cost of Living Council has recently advised the Board that it needs the data to be reported on Schedule P–5(b) and that the data would be even more useful if broken down by fuel type. While the Board believes that this data would facilitate its own analysis and evaluation, we recognize that most carriers use the basic Jet A fuel. Accordingly, we have changed the reporting instructions only to provide that, where the amounts reported for a station include other than Jet A fuel, a footnote should be added to Schedule P–5(b) indicating the number of gallons and applicable costs of such other fuel included in the amounts reported for that station.

In consideration of the foregoing, the Civil Aeronautics Board hereby amends Part 241 of its Economic Regulations (14 CFR Part 241) effective May 1, 1974 as follows:

1. Amend Section 22—General Reporting Instructions, as follows:

Section 22—[Amended]

A. By adding new Schedule P–5(b) in the list in paragraph (a), titled "List of Schedules in CAB Form 41" as follows:

List of schedules in CAB Form 41 report

Schedule No.	Schedule title	Filing frequency
*	*	*
P–5(a)	Components of flight equipment depreciation	Quarterly.
P–5(b)	Fuel consumption and inventories	Monthly.
P–6	Maintenance, passenger service, and general service and administrative expense functions—all carrier groups.	Quarterly.
*	*	*

B. By adding new Schedule P-5(b) to the list in paragraph (a) titled "Due Dates of Schedules in CAB Form 41 Report," as follows:

Due dates of schedules in CAB Form 41 report

Due date [1]	*Schedule No.*
Jan. 15	P-5(b).
Jan. 30	B-1, P-1(a), T-1, T-2, T-3, T-7, T-41.
Feb. 10 [2]	A, B-2, B-3, B-4, B-5, B-7, B-7(b), B-8, B-10, B-12, B-13, B-14, P-1.1, P-1.2, P-2, P-2(a), P-3, P-3(a), P-4, P-5.1, P-5.2, P-5(a), P-6, P-7, P-8, P-9.1, P-9.2, P-10, T-6.
Feb. 15	P-5(b).
Mar. 1	B-1, P-1(a), T-1, T-7.
Mar. 15	P-5(b).
Mar. 30	B-1, B-9, B-41, B-42, B-43, B-44, B-46, P-1(a), P-41, G-41, G-42, G-43, G-44, T-1, T-7.
Apr. 15	P-5(b).
Apr. 30	B-1, P-1(a), T-1, T-2, T-3, T-7.
May 10	A, B-1, B-2, B-3, B-4, B-5, B-7, B-7(b), B-8, B-10, B-12, B-13, B-14, P-1.1, P-1.2, P-2, P-(2)a, P-3, P-3(a), P-4, P-5.1, P-5.2, P-5(a), P-6, P-7, P-8, P-9.1, P-9.2, P-10, T-6.
May 15	P-5(b).
May 30	B-1, P-1(a), T-1, T-7.
June 15	P-5(b).
June 30	B-1, P-1(a), T-1, T-7.
July 15	P-5(b).
July 30	B-1, P-1(a), T-1, T-2, T-3, T-7.
Aug. 10	A, A-1, B-2, B-3, B-4, B-5, B-7, B-7(b), B-8, B-10, B-12, B-13, B-14, P-1.1, P-1.2, P-2, P-2(a), P-3, P-3(a), P-4, P-5.1, P-5.2, P-5(a), P-6, P-7, P-8, P-9.1, P-9.2, P-10, T-6.
Aug. 15	P-5(b).
Aug. 30	B-1, P-1(a), T-1, T-7.
Sept. 15	P-5(b).
Sept. 30	B-1, P-1(a), T-1, T-2, T-3, T-7.
Oct. 15	P-5(b).
Oct. 30	B-1, P-1(a), T-1, T-7, T-41.
Nov. 10	A, B-2, B-3, B-4, B-5, B-7, B-7(b), B-8, B-10, B-12, B-13, B-14, P-1.1, P-1.2, P-2, P-2(a), P-3, P-3(a), P-4, P-5.1, P-5.2, P-5(a), P-6, P-7, P-8, P-9.1, P-9.2, P-10, T-6.
Nov. 15	P-5(b).
Nov. 30	B-1, P-1(a), T-1, T-7.
Dec. 15	P-5(b).
Dec. 30	B-1, P-1(a), T-1, T-7.

[1] Due dates falling on a Saturday, Sunday, or national holiday will become effective the first following working day.

[2] B and P reporting dates are extended to Mar. 30, if preliminary schedules are filed at the Board by Feb. 10.

2. Amend Section 24—Profit and Loss Elements, as follows:

Section 24—[Amended]

A. By inserting, following the reporting instructions for Schedule P-5(a) and preceding the reporting instructions for Schedule P-6, reporting instructions for Schedule P-5(b), to read as follows:

SCHEDULE P-5(b)—

FUEL CONSUMPTION AND INVENTORIES

(a) This schedule shall be filed monthly by all route air carriers.

(b) A single copy (original only) of this schedule shall be filed for the fuel issued and acquired from domestic sources for scheduled and nonscheduled operations conducted by the air carrier.

(c) For the purpose of this schedule, fuel drawn for domestic operations is that fuel drawn for use between certificated flight stages with both terminals within the 50 States of the United States and the District of Columbia. The cost of fuel drawn within the United States and the District of Columbia for a flight stage outside of the United States and the District of Columbia is: (1) If drawn from "Carrier's Storage Facilities," included in columns (6) and (7), "Sold to Others and Consumed by Carrier in International Operations," footnoted as to that portion so reported therein, and (2) excluded from Schedule P-5(b) if it is "Delivered Directly to Aircraft by Others."

(d) The indicated data shall be grouped in alphabetical sequence by station as to: (1) Fuel issued from "Carrier's Storage Facilities," as reported in columns (2) through (11), and (2) fuel "Delivered Directly to Aircraft by Others," as reported in columns (8) and (9) only. Where the amounts reported for a station include other than Jet A fuel, a footnote should be added to this schedule indicating the number of gallons and applicable costs included in the amounts reported for that station. However, for stations where less than 5,000 gallons of fuel per month are issued in total, the aggregate fuel information for all such stations may be reported as "Miscellaneous," denoting the number of stations so reported.

(e) The cost of fuel shall include shrinkage, but shall exclude (1) "through-put" and "in to plane" fees, i.e., service charges or gallonage levies assessed by or against the fuel vendor or concessionaire and passed on to the carrier in a segregated and identifiable form, and (2) nonrefundable Federal and State excise taxes.

(f) All costs reported under the caption "Carrier's Storage Facilities," ex-

cept those actual costs which are to be reported in column (5), "Receipts," shall be computed on the periodic average method. Under this method, the average is computed by dividing the total cost of the Beginning Inventory plus Receipts during the period by the total number of units in these groups. The resulting quotient shall then be applied to extend the units issued and in ending inventory.

(g) Actual costs shall be used to report the cost of fuel under "Delivered Directly to Aircraft by Others."

(h) The beginning inventory of each schedule shall be the ending inventory of the prior period schedule. Differences shall be properly annotated and reconciled.

3. Amend Section 32—General Reporting Instructions, as follows:

Section 32 [Amended]

A. By adding new Schedule P-5(b) in the list in paragraph (a), titled "List of Schedules in CAB Form 41," as follows:

List of schedules in CAB Form 41 report

Schedule No.	Schedule title	Filing frequency
*	* * * * * * *	*
P-5(a)	Components of flight equipment depreciation	Quarterly.
P-5(b)	Fuel consumption and inventories	Monthly.
P-6	Maintenance, passenger service, and general service and administrative expense functions—all carrier groups.	Quarterly.
*	* * * * * * *	*

B. By adding new Schedule P-5(b) to the list in paragraph (a) titled "Due Dates of Schedules in CAB Form 41 Report," as follows:

Due dates of schedules in CAB Form 41 report

Due date [1]	*Schedule No.*
Jan. 15	P-5(b).
Jan. 30	B-11, T-3.1.
Feb. 10 [2]	A, B-1, B-2.1, B-7, B-8, B-10, B-12, B-13, B-14, P-1.1, P-1.2, P-2, P-3.1, P-4, P-5.1, P-5.2, P-5(a), P-6, P-7, T-6.
Feb. 15	P-5(b).
Mar. 1	B-11, T-3.1.
Mar. 15	P-5(b).
Mar. 30	B-11, B-41, B-43, B-44, B-46, G-41, G-42, G-43, G-44, T-3.1.
Apr. 15	P-5(b).
Apr. 30	B-11, T-3.1.
May 10	A, B-1, B-2.1, B-7, B-8, B-10, B-12, B-13, B-14, P-1.1, P-1.2, P-2, P-3.1, P-4, P-5.1, P-5.2, P-5(a), P-6, P-7, T-6.
May 15	P-5(b).
May 30	B-11, T-3.1.
June 15	P-5(b).
June 30	B-11, T-3.1.
July 15	P-5(b).
July 30	B-11, T-3.1.
Aug. 10	A, A-1, B-1, B-2.1, B-7, B-8, B-10, B-12, B-13, B-14, P-1.1, P-1.2, P-2, P-3.1, P-4, P-5.1, P-5.2, P-5(a), P-6, P-7, T-6.
Aug. 15	P-5(b).
Aug. 30	B-11, T-3.1.
Sept. 15	P-5(b).
Sept. 30	B-11, T-3.1.
Oct. 15	P-5(b).
Oct. 30	B-11, T-3.1.
Nov. 10	A, B-1, B-2.1, B-7, B-8, B-10, B-12, B-13, B-14, P-1.1, P-1.2, P-2, P-3.1, P-4, P-5.1, P-5.2, P-5(a), P-6, P-7, T-6.
Nov. 15	P-5(b).
Nov. 30	B-11, T-3.1.
Dec. 15	P-5(b).
Dec. 30	B-11, T-3.1.

[1] Due dates falling on a Saturday, Sunday, or national holiday will become effective the first following working day.

[2] B and P reporting dates are extended to Mar. 30, if preliminary schedules are filed at the Board by Feb. 10.

4. Amend Section 34—Profit and Loss Elements, as follows:

Section 34—[Amended]

A. By inserting, following the reporting instructions for Schedule P-5(a) and preceding the reporting instructions for Schedule P-6, reporting instructions for Schedule P-5(b), to read as follows:

SCHEDULE P-5(b)—FUEL CONSUMPTION AND INVENTORIES

(a) This schedule shall be filed monthly by all supplemental air carriers.

(b) A single copy (original only) of this schedule shall be filed for the fuel issued and acquired from domestic sources for scheduled and nonscheduled

operations conducted by the air carrier.

(c) For the purposes of this schedule, fuel drawn for domestic operations is that fuel drawn for use between certificated flight stages with both terminals within the 50 States of the United States and the District of Columbia. The cost of fuel drawn within the United States and the District of Columbia for a flight stage outside of the United States and the District of Columbia is: (1) If drawn from "Carrier's Storage Facilities," included in columns (6) and (7), "Sold to Others and Consumed by Carrier in International Operations," footnoted as to that portion so reported therein, and (2) excluded from Schedule P–5(b) if it is "Delivered Directly to Aircraft by Others."

(d) The indicated data shall be grouped in alphabetical sequence by station as to (1) fuel issued from "Carrier's Storage Facilities," as reported in columns (2) through (11) and (2) Fuel "Delivered Directly to Aircraft by Others," reported in columns (8) and (9) only. Where the amounts reported for a station include other than Jet A fuel, a footnote should be added to this schedule indicating the number of gallons and applicable costs included in the amounts reported for that station. However, for stations where less than 5,000 gallons of fuel per month are issued in total, the aggregate fuel information for all such stations may be reported as "Miscellaneous," denoting the number of stations so reported.

(e) The cost of fuel shall include shrinkage, but shall exclude (1) "through-put" and "in to plane" fees, i.e., service charges or gallonage levies assessed by or against the fuel vendor or concessionaire and passed on to the carrier in a segregated and identifiable form and (2) nonrefundable Federal and State excise taxes.

(f) All costs reported under the caption "Carrier's Storage Facilities," except those actual costs which are to be reported in column (5), "Receipts," shall be computed on the periodic average method. Under this method, the average is computed by dividing the total cost of the Beginning Inventory plus Receipts during the period by the total number of units in these groups. The resulting quotient shall then be applied to extend the units issued and in ending inventory.

(g) Actual costs shall be used to report the cost of fuel under "Delivered Directly to Aircraft by Others."

(h) The beginning inventory of each schedule shall be the ending inventory of the prior-period schedule. Differences shall be properly annotated and reconciled.

5. Amend CAB Form 41 by adding new Schedule P–5(b) as shown in Exhibit A below to the rule and made a part thereof.

(Secs. 204(a) and 407 of the Federal Aviation Act of 1958, as amended, 72 Stat. 743, 766 (49 U.S.C. 1324, 1377))

Effective: May 1, 1974.

Adopted: March 14, 1974.

By the Civil Aeronautics Board.

[SEAL] EDWIN Z. HOLLAND, *Secretary.*

NOTE: The reporting requirements herein have been approved by the General Accounting Office in accordance with the Federal Reports Act of 1942, as amended.

[FR Doc.74–7209 Filed 3–28–74;8:45 am]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER A—GENERAL

SUBCHAPTER C—DRUGS

SUBCHAPTER F—BIOLOGICS

RECODIFICATION EDITORIAL AMENDMENTS

The Commissioner of Food and Drugs, for the purpose of establishing an orderly development of informative regulations for the Food and Drug Administration, furnishing ample room for expansion of such regulations in years ahead, and providing the public and affected industries with regulations that are easy to find, read, and understand, has initiated a recodification program for Chapter I of Title 21 of the Code of Federal Regulations.

The fifth document in a series of recodification documents that will eventually include all regulations administered by the Food and Drug Administration appears elsewhere in this issue of the FEDERAL REGISTER. The regulations formerly under Parts 130, 131, 164, 165, and 167 of Subchapter C—Drugs, have been reorganized into Parts 310, 312, 314, 328, 329, 330, 369, and 429 of new Subchapter D—Drugs for Human Use, in an effort to provide greater clarity and adequate space for the development of future regulations.

These recodified regulations are referenced in Parts 1, 2, 3, 8, 132, 135, 144, 146, and 601 of this chapter.

Regulations pertaining to veterinary drugs have been left in Part 131.

To provide uniformity and continuity during the recodification the Commissioner concludes that the references to the recodified material should be revised at this time, and the title of Part 131 be revised to reflect its new composition. Therefore, Parts 1, 2, 3, 8, 131, 132, 135, 144, 146, and 601 of Chapter I of Title 21 of the Code of Federal Regulations are amended as follows:

PART 1—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND THE FAIR PACKAGING AND LABELING ACT

§ 1.102 [Amended]

1. In § 1.102(b) by changing the reference "§ 164.7" to read "§ 429.12."

§ 1.106 [Amended]

2. In § 1.106:

a. In paragraph (j), by changing the reference "§ 167.1(a)" to read "§ 328.3(a)"; and by changing the reference "Part 167" to read "Part 328."

b. In paragraph (l)(2) by changing the reference "§ 130.3" to read "§ 312.1."

§ 1.115 [Amended]

3. In § 1.115(b)(2) by changing the reference "Part 164" to read "Part 429."

PART 2—ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES

§ 2.65 [Amended]

4. In § 2.65(a) by changing the parenthetical reference "(21 CFR Parts 164 and 8, respectively)" to read "(21 CFR Parts 429 and 8, respectively)."

§ 2.121 [Amended]

5. In § 2.121:

a. In paragraph (u) (1) and (2) by changing the reference "§ 130.3" to read "§ 312.1"; and by changing the reference "§ 130.3a" to read "§ 312.9."

PART 3—STATEMENTS OF GENERAL POLICY OR INTERPRETATION

§ 3.15 [Amended]

6. In § 315(a)(2) by changing the reference "§ 130.4(c)" to read "§ 314.1(c)."

§ 3.29 [Amended]

7. In § 3.29(c)(3) by changing the reference "§ 130.4(c)" to read ""§ 314.1(c)."

§ 3.36 [Amended]

8. In § 3.36(d) by changing the reference "§ 130.4(c)" to read "§ 314.1(c)."

§ 3.48 [Amended]

9. In § 3.48(c) by changing the reference "§ 130.3" to read "§ 312.1."

§ 3.52 [Amended]

10. In § 3.52:

a. By changing the reference "§ 130.3" in the introductory text of paragraph (c) to read "§ 312.1."

b. In paragraph (d)(1) by changing the reference "§ 130.3a(a)" to read "§ 312.9(a)."

§ 3.53 [Amended]

11. In § 3.53(c) by changing the reference "§ 130.3" to read "§ 312.1."

§ 3.67 [Amended]

12. In § 3.67(d)(2) by changing the reference "§ 130.4(c)(2)" to read "§ 314.1(c)(2)."

§ 3.77 [Amended]

13. In § 3.77(b), by changing the phrase "Bureau of Narcotics and Dangerous Drugs" to read "Drug Enforcement Administration, Department of Justice" each time it appears; and by changing the reference "§ 130.44" to read "§ 310.505."

§ 3.81 [Amended]

14. In § 3.81(d) by changing the reference "§ 130.9 (d) and (e)" to read "§ 314.8(d) and (e)."

§ 3.90 [Amended]

15. In § 3.90(d) by changing the reference "§ 130.9(d)" to read "§ 314.8(d)."

§ 3.91 [Amended]

16. In § 3.91:

a. In paragraph (c)(4)(ii) by changing the reference "§ 130.9(d)" to read "§ 314.8(d)."

b. In paragraph (c)(4)(v) by changing the reference "§ 130.4" to read "§ 314.1" each time it appears.

PART 8—COLOR ADDITIVES

§ 8.28 [Amended]

17. In § 8.28(b) by changing in the last sentence the reference "§§ 130.14–130.26 of this chapter" to read "§§ 314.200 through 314.232 of this chapter."

PART 131—INTERPRETIVE STATEMENTS RE WARNINGS ON VETERINARY DRUGS FOR OVER-THE-COUNTER SALE

18. The heading for Part 131 is revised to read as set forth above.

PART 132—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

§ 132.1 [Amended]

19. In § 132.1(d) by changing the reference "§ 130.3" to read "§ 312.1."

§ 132.1 [Amended]

20. In § 132.31(b) by changing the reference "§ 130.3" to read "§ 312.1 of this chapter."

PART 135—NEW ANIMAL DRUGS

§ 135.1 [Amended]

21. In § 135.1(1) by changing the reference "§ 130.38" to read "§ 310.9."

§ 135.37 [Amended]

22. In the introductory text of § 135.37 by changing the reference "§ 130.38" to read "§ 310.9."

PART 144—ANTIBIOTIC DRUGS; EXEMPTIONS FROM LABELING AND CERTIFICATION REQUIREMENTS

§ 144.8 [Amended]

23. In § 144.8 by changing the reference "§ 130.3," each time it appears, to read "§ 312.1."

§ 144.26 [Amended]

24. In § 144.26(b)(18)(i), (22)(i), (32)(i), (35), (39), (42), (44), (45), (49), (50), (54), (56), (59), (60), (61), (62), and (63), by changing the reference "§ 130.4(c)(3)" to read "§ 314.1(c)(3)"; and by changing the reference "§ 130.9" to read "§ 314.8."

PART 146—ANTIBIOTIC DRUGS; PROCEDURAL AND INTERPRETIVE REGULATIONS

§ 146.1 [Amended]

25. In § 146.1(g)(2) by changing the reference "§ 130.12(a)(5)" to read "§ 314.111(a)(5)."

PART 601—LICENSING

§ 601.25 [Amended]

26. In § 601.25(d)(2) by changing the reference "§ 130.12(a)(5)(ii)" to read "§ 314.111(a)(5)(ii)."

The changes being made are nonsubstantive in nature and for this reason notice and public procedure are not prerequisites to this promulgation.

Dated: March 27, 1974.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.74-7384 Filed 3-28-74;8:45 am]

Chapter II—Drug Enforcement Administration; Department of Justice

Part 1301—Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

Part 1308—Schedules of Controlled Substances

Etorphine Hydrochloride Transfer to Schedule II

A notice dated November 15, 1973, and published in the FEDERAL REGISTER on November 23, 1973 (38 FR 32262) proposed the transfer of etorphine hydrochloride from Schedule I to Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Pub. L. 91–513). All interested persons were given 30 days after publication to submit their objections, comments, or requests for a hearing.

In response to the said notice, the Administration received two comments and one objection. The Department of Health and Social Services, State of Wisconsin by letter dated December 20, 1973, concurred in the proposed transfer. The Division of Wildlife, Department of Wildlife, State of Colorado, by letter dated December 10, 1973, suggested that the distribution of etorphine hydrochloride should not be limited to licensed veterinarians. The Food and Drug Administration has restricted the use of etorphine hydrochloride and diprenorphine by or on the order of a licensed veterinarian. The Drug Enforcement Administration shall transmit additional information to the Food and Drug Administration indicating its willingness to permit other qualified persons to use these substances if the Food and Drug Administration deems it proper and changes the labelling of the substances.

The American Pharmaceutical Association by letter dated December 20, 1973, objected to the restricted distribution of etorphine hydrochloride alleging that the Drug Enforcement Administration does not have the authority to deny any registrant the right to distribute controlled substances in schedules for which he is registered without deciding whether the American Pharmaceutical Association is an interested party with standing to object to the regulation, the Administration clearly has the authority to proscribe regulation, the Administration clearly has the authority to proscribe regulations restricting the distribution of etorphine hydrochloride. Section 871(b) of Title 21 of the United States Code provides that "the Attorney General may promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this title." Additional authority is found in Sections 301, 307, and 308 of the Controlled Substances Act (21 U.S.C. 827, 828 and 871(b)).

The Administration does acknowledge the necessity for codification of these procedures and amendments to Title 21 of the Code of Federal Regulations are published in this volume of the FEDERAL REGISTER.

Based upon the investigations of the Drug Enforcement Administration and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education, and Welfare, received pursuant to section 201(b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(b)), the Administrator of the Drug Enforcement Administration finds that etorphine hydrochloride:

(1) Has a high potential for abuse;

(2) Has a currently accepted medical use in treatment in the United States with severe restrictions; and

(3) May, if abused, lead to severe psychological or physical dependence.

On July 3, 1973 (38 FR 17717), the Administrator of the Drug Enforcement Administration ordered that § 1308.11(c) of Title 21 of the Code of Federal Regulations be amended by adding a new item, Drotebanol. The amendment to § 1308.11(c) renumbers the items therein to place Drotebanol in alphabetical order with the other controlled substances.

Therefore, under the authority vested in the Attorney General by section 201(a) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(a)), and delegated to the Administrator of the Drug Enforcement Administration by § 0.100 of Title 28 of the Code of Federal Regulations (see 38 FR 18380, July 2, 1973) the Administrator orders that:

a. Section 1301.02(b) of Title 21 of the Code of Federal Regulations be amended by inserting a new paragraph (b)(4)(iv) and renumbering paragraphs (b)(4)(iv)–(xiv) to read:

§ 1301.02 Definitions.

* * * * *

(b) * * *

(4) * * *

(iv) Etorphine hydrochloride;
(v) Ethylmorphine;
(vi) Hydrocodone;
(vii) Hydromorphone;
(viii) Metopon;
(ix) Morphine;
(x) Oxycodone;
(xi) Oxymorphone;
(xii) Thebaine;
(xiii) Mixed alkaloids of opium listed in § 1308.12(b)(2) of this chapter;
(xiv) Cocaine; and
(xv) Ecgonine;

b. Section 1308.11(c) of Title 21 of the Code of Federal Regulations be amended by revising subparagraphs (9)–(23) of paragraph (c) to read:

§ 1308.11 Schedule I.

* * * * *

(c) * * *

(9) Drotebanol	9335
(10) Etorphine (except hydrochloride salt)	9056
(11) Heroin	9200
(12) Hydromorphinol	9301
(13) Methyldesorphine	9302
(14) Methyldihydromorphine	9304
(15) Morphine methylbromide	9306
(16) Morphine methylsulfonate	9306
(17) Morphine-N-Oxide	9307
(18) Myrophine	9308
(19) Nicocodeine	9309
(20) Nicomorphine	9312
(21) Normorphine	9313
(22) Pholcodine	9314
(23) Thebacon	9315

(c) Section 1308.12(b) of Title 21 of the Code of Federal Regulations be amended by revising paragraph (b)(1) to read:

§ 1308.12 Schedule II.

* * * * *

(b) * * *

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium of opiate, excluding naloxone hydrochloride, but including the following:

(i) Raw opium	9600
(ii) Opium extracts	9610
(iii) Opium fluid extracts	9620
(iv) Powdered opium	9639
(v) Granulated opium	9640
(vi) Tincture of opium	9630
(vii) Apomorphine	9030
(viii) Codeine	9050
(ix) Ethylmorphine	9190
(x) Etorphine hydrochloride	9059
(xi) Hydrocodone	9193
(xii) Hydromorphone	9194
(xiii) Metopon	9260
(xiv) Morphine	9300
(xv) Oxycodone	9143
(xvi) Oxymorphone	9652
(xvii) Thebaine	9333

* * * * *

The requirements imposed on the substance controlled by this order are as follows:

1. *Registration.* Any person who manufactures, distributes, engages in research, imports or exports any of this substance or who proposes to engage in the manufacture, distribution, importation, or exportation of, or research with, this substance shall obtain a registration to conduct that activity on or before April 19, 1974.

2. *Security.* This substance must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72(a), 1301.73, 1301.74(a), 1301.75, and § 1301.76 of Title 21 of the Code of Federal Regulations. In addition, all registrants desiring to handle etorphine hydrochloride will be required to use a safe or steel cabinet equivalent to a U.S. Government Class V security container after August 1, 1974. In the event that this imposes special hardships, the Drug Enforcement Administration will entertain any justified requests for extensions of time.

3. *Labelling and packaging.* All labels on commercial containers of, and all labelling of, this substance which is packaged after April 19, 1974 shall comply with the requirements of §§ 1302.03–1302.05 and 1302.08 of Title 21 of the Code of Federal Regulations. In accordance with § 1302.08 of Title 21 of the Code of Federal Regulations, the Administrator finds that in order to protect the public health and safety early compliance with these requirements is necessitated by the high potential for abuse and the limited medical use of this substance. The shipment of etorphine hydrochloride should be under secure conditions using substantial packaging material with no markings on the outside of the package which would indicate the content. Shipment would be by the most secure means of transport available.

4. *Quotas.* Quotas for this substance have been established pursuant to section 1303 of Title 21 of the Code of Federal Regulations.

5. *Inventory.* Registrants possessing this substance will not be required to take an additional inventory.

6. *Records.* All registrants shall continue to keep records pursuant to §§ 1304.21–1304.27 of Title 21 of the Code of Federal Regulations. In addition, records for this substance shall be maintained separately from all other records on or before April 19, 1974.

7. *Reports.* All registrants are required to continue filing reports pursuant to Sections 1304.37–1304.41 of Title 21 of the Code of Federal Regulations. In addition, registrants supplying this substance are required to forward copies of the order forms received to the Drug Enforcement Administration on a weekly basis on or before April 19, 1974.

8. *Order forms.* Each distribution of this substance requires the use of an order form pursuant to Part 1305.03 of Title 21 of the Code of Federal Regulations. Order forms for etorphine hydrochloride shall contain this substance alone or with diprenorphine (but shall not contain any other substance) on or after April 19, 1974.

9. *Prescriptions.* The Food and Drug Administration has restricted the use of this substance by or on the order of a licensed veterinarian. Therefore, this substance is not to be obtained by use of a prescription.

10. *Importation and exportation.* All importation and exportation of any of this substance on or after April 19, 1974 shall be in compliance with Part 1312 of Title 21 of the Code of Federal Regulations.

11. *Criminal liability.* Any activity with etorphine hydrochloride not authorized by or in violation of the Controlled Substances Act or the Controlled Substances Import and Export Act before April 19, 1974 shall be unlawful. The applicable penalties shall be those of a Schedule I narcotic controlled substance. On April 19, 1974, etorphine hydrochloride for the purposes of criminal liability shall be treated as a Schedule II controlled substance. It should be noted that penalties of Schedule I or II narcotic controlled substances are the same. The only effect of the transfer will be for pleading purposes.

12. Other. In all other respects, this order is effective on April 19, 1974.

Dated: March 25, 1974.

JOHN R. BARTELS, Jr.,
Administrator,
Drug Enforcement Administration.

[FR Doc.74-7275 Filed 3-28-74;8:45 am]

Title 26—Internal Revenue

CHAPTER I—INTERNAL REVENUE SERVICE, DEPARTMENT OF THE TREASURY

SUBCHAPTER F—PROCEDURE AND ADMINISTRATION

[T.D. 7309]

PART 301—PROCEDURE AND ADMINISTRATION

Time for Performance of Acts Where Last Day Falls on a Legal Holiday

By a notice of proposed rulemaking appearing in the FEDERAL REGISTER for Monday, July 16, 1973 (38 FR 18897), an amendment to the regulations on Procedure and Administration (26 CFR Part 301) under section 7503 of the Internal Revenue Code of 1954 was proposed in order to conform such regulations to the changes made by Pub. L. 90–363, 82 Stat. 250, which amended 5 U.S.C. 6103(a), regarding the observance of certain legal holidays on Monday. The amendment of 5 U.S.C. 6103(a) was effective on January 1, 1971. After consideration of all such relevant matter as was presented by interested persons, certain changes were made, and the proposed amendment of the regulations, subject to the changes indicated below, is adopted by this document.

The amendment to the regulations is designed to conform § 301.7503-1(b)(1) to the present District of Columbia law regarding the date of observance of legal holidays. The District of Columbia now observes Washington's Birthday on the third Monday in February, Memorial Day on the last Monday in May, Veterans' Day on the fourth Monday in October, and Thanksgiving on the fourth Thursday in November. Columbus Day is also considered a legal holiday in the District of Columbia for all calendar years after 1970, and is observed on the

second Monday in October. Under the amendment of the regulations, the dates of observance of these holidays for purposes of the Internal Revenue Code of 1954 will correspond to the dates of observance of these holidays in the District of Columbia. So that the amendment to the regulations will not adversely affect certain taxpayers who relied on the current regulations, for the calendar years 1971, 1972, 1973, and 1974, taxpayers may, at their option (except with respect to the performance of any act relating to the jurisdiction of a court), treat Washington's Birthday as falling on either February 22 or the third Monday in February. For the calendar years 1971, 1972, and 1973, taxpayers may, at their option (except with respect to the performance of any act relating to the jurisdiction of a court), treat Memorial Day as falling on either May 30 or the last Monday in May, and Veterans' Day as falling on either November 11 or the fourth Monday in October. The option is denied to taxpayers in those cases where the performance of an act relates to the jurisdiction of a court in order to be consistent with William M. Winkler, 56 T.C. 844 (1971). In that case the United States Tax Court held that in computing the 150-day filing requirement of section 6213(a) of the Code, Monday, February 15, 1971, was a legal holiday (Washington's Birthday) in the District of Columbia. The Tax Court made no mention of the availability of an option in cases where the performance of an act relates to the jurisdiction of a court.

The proposed regulations did not extend optional treatment to Veterans' Day for 1973 or Washington's Birthday for 1974.

Pursuant to paragraph 4(a) of Treasury Order 221, published in the FEDERAL REGISTER for June 10, 1972 (37 FR 11696), certain regulations of the Internal Revenue Service continue in effect as regulations of the Bureau of Alcohol, Tobacco, and Firearms until superseded or revised. The regulations amended by this Treasury decision are among those that continue to apply for purposes of the laws administered by the Bureau in addition to applying for purposes of the laws administered by the Internal Revenue Service. The Director, Bureau of Alcohol, Tobacco, and Firearms has, for this reason, joined as a signatory to this Treasury decision.

Adoption of amendment to the regulations. On Monday, July 16, 1973, a notice of proposed rulemaking was published in the FEDERAL REGISTER (33 FR 18897) to amend the Regulations on Procedure and Administration (26 CFR Part 301) under section 7503 of the Internal Revenue Code of 1954 in order to conform such regulations to the changes made by Pub. L. 90-363, 82 Stat. 250, which amended 5 U.S.C. 6103(a), regarding the observance of certain legal holidays on Monday. After consideration of all such relevant matter as was presented by interested persons regarding the rules proposed, the following regulations are hereby adopted:

PARAGRAPH (b)(1) of § 301.7503-1 is amended as set forth below:

(This Treasury decision is issued under the authority contained in section 7805 of the Internal Revenue Code of 1954 (68A Stat. 917 (26 U.S.C. 7805)))

REX D. DAVIS,
Director, Bureau of Alcohol, Tobacco, and Firearms.

DONALD C. ALEXANDER,
Commissioner of Internal Revenue.

Approved: March 22, 1974.

JOHN H. HALL,
Deputy Assistant Secretary of the Treasury.

Paragraph (b)(1) of § 301.7503-1 is amended to read as follows:

§ 301.7503-1 Time for performance of acts where last day falls on Saturday, Sunday, or legal holiday.

* * * * *

(b) *Legal holidays.* (1) For the purpose of section 7503, the term "legal holiday" includes the legal holidays in the District of Columbia. Such legal holidays found in D.C. Code Ann. § 28-2701 (1967) and 5 U.S.C. 6103(a), as enacted and made effective by the Act of June 28, 1968 (82 Stat. 250), are—

(i) January 1, New Year's Day,

(ii) January 20, when such day is Inauguration Day,

(iii) Third Monday in February, Washington's Birthday,

(iv) Last Monday in May, Memorial Day,

(v) July 4, Independence Day,

(vi) First Monday in September, Labor Day,

(vii) Second Monday in October, Columbus Day,

(viii) Fourth Monday in October, Veterans' Day,

(ix) Fourth Thursday in November, Thanksgiving Day, and

(x) December 25, Christmas Day.

When a legal holiday in the District of Columbia falls on a Sunday, the next day is a legal holiday in the District of Columbia (see D.C. Code Ann. § 28-2701 (1967)). For the purpose of section 7503, when a legal holiday in the District of Columbia (other than Inauguration Day) falls on a Saturday it shall be treated as falling on the preceding Friday. For calendar years prior to 1971, Washington's Birthday will be treated as falling on February 22, Memorial Day on May 30, and Veterans' Day on November 11. For calendar years 1971, 1972, 1973, and 1974, the taxpayer may, at his option (except with respect to the performance of any act relating to the jurisdiction of a court), treat Washington's Birthday as falling on either February 22 or the third Monday in February. For calendar years 1971, 1972, and 1973, the taxpayer may, at his option (except with respect to the performance of any act relating to the jurisdiction of a court), treat Memorial Day as falling on either May 30 or the last Monday in May, and Veterans' Day as falling on either November 11 or the fourth Monday in October. Columbus Day is not a legal holiday in the District of Columbia in any calendar year prior to 1971.

* * * * *

[FR Doc.74-7342 Filed 3-27-74;8:45 am]

[T. D. 7310]

PART 301—PROCEDURE AND ADMINISTRATION

Disclosure or Use of Information by Preparers of Returns

By a notice of proposed rulemaking appearing in the FEDERAL REGISTER for December 20, 1972 (37 FR 28070), amendments to the Regulations on Procedure and Administration (26 CFR Part 301) were proposed in order to conform the regulations to section 7216 of the Internal Revenue Code of 1954, relating to the disclosure or use of information by preparers of returns, as added by section 316 of the Revenue Act of 1971 (85 Stat. 529). After consideration of all such relevant matter as was presented by interested persons regarding the rules proposed, the proposed amendments of the regulations, subject to the changes indicated below, are adopted by this document.

Section 7216(a) of the Code provides that any person who is engaged in the business of preparing, or providing services in connection with the preparation of, income tax returns or declarations of estimated tax and who discloses any tax return information or uses such information for any purpose other than to prepare, or assist in preparing, a return shall be guilty of a misdemeanor and, upon conviction thereof, shall be fined not more than $1,000, or imprisoned not more than 1 year, or both. Section 7216(a) also applies to any person who for compensation prepares any such return or declaration, whether or not such person is in the tax return preparer business.

Section 7216(b) provides certain exceptions to the new penalty rule. A tax return preparer may without penalty disclose tax return information if such disclosure is made pursuant to any other provision of the Internal Revenue Code or pursuant to an order of a court. The penalty does not apply to the use of information in the preparation of State and local tax returns. Furthermore, the Secretary or his delegate is authorized to prescribe regulations under which other disclosures or uses will not be subject to the penalty.

As published with the notice of proposed rule making, § 301.7216-1 contained in paragraph (a) the general rule for the application of section 7216 and in paragraph (b) detailed definitions of the terms "tax return", "tax return preparer", "tax return processor", and "tax return information". This document makes a technical change in paragraph (a) to make clear that the tax return referred to therein is the return of the taxpayer in respect of whom the information was furnished. Paragraph (b) is revised substantially by this document. The distinction between a tax return preparer and a tax return processor is eliminated. Persons who under the notice of

proposed rule making were defined as tax return processors are included within the new definition of tax return preparers. As a result of this revision, all of the disclosures or uses permitted without formal written consent under § 301.7216–2, and with formal written consent under § 301.7216–3, are applicable to all persons classified as tax return preparers.

Pursuant to the authority granted to the Secretary or his delegate, § 301.7216–2, as set forth in the notice of proposed rule making provided that certain disclosures or uses of tax return information were permitted without the formal written consent of the taxpayer. The taxpayer's attorney was permitted to disclose or use tax return information in connection with the rendering of legal services, such as estate planning, preparation of trial briefs, etc., to the taxpayer. Accountants were permitted to disclose or use tax return information in the preparation of books of account, working papers, and accounting statements or reports, or in the performance of other services for a taxpayer. In addition, other disclosures without the formal written consent of the taxpayer were permitted, such as a disclosure by a tax return preparer to a tax return processor, or a disclosure by one employee to another employee of a tax return preparer or a tax return processor.

A number of changes have been made by this document in proposed § 301.7216–2. Thus, a new paragraph (b) has been added to authorize in appropriate circumstances the disclosure or use, in the preparation of a tax return of one taxpayer, of tax return information furnished by another taxpayer. These situations are limited to those involving related taxpayers having no adverse interest. The rules governing attorneys and accountants have been combined and revised, and specifically extended to corporate fiduciaries, such as trust companies and bank trust departments, with the objective of permitting, without formal written consent of the taxpayer, the disclosure or use of tax return information in the customary and ordinary course of performing the professional or fiduciary services to or for the taxpayer. Another new rule makes clear that a tax return preparer may, without penalty, make tax return information available to the fiduciary of a taxpayer who, after furnishing the information, has become incompetent, insolvent, or bankrupt, or to the fiduciary of the estate of a deceased taxpayer. The rule on disclosure by one employee to another employee of a tax return preparer has been clarified and made applicable to officers and partners. The rule relating to use of information in the preparation of State returns has been expanded to apply to disclosure or use in the preparation or audit of State returns. In addition, the rules on retention of records and compiling of taxpayer lists have been made less restrictive.

Under the notice of proposed rule making, and pursuant to the authority granted to the Secretary or his delegate, certain disclosures or uses were permitted under § 301.7216–3 only with the formal written consent of the taxpayer. These consents were required to permit tax return preparers to use tax return information in connection with the solicitation of certain additional current business, to allow lawyers and accountants to disclose to third parties, and to permit tax return preparers to use the tax return information of one taxpayer in preparing the tax return of another taxpayer entering into a tax-related transaction with the first. These rules were intended to cover situations where tax return information could not be disclosed or used pursuant to § 301.7216–2.

Section 301.7216–3 has been revised in this document. The rule on solicitation of current business has been revised so that it applies only to matters not related to the Internal Revenue Service. Existing rules in Treasury Department Circular No. 230 (31 CFR 10.30) and Rev. Proc. 68–20, 1968–1 C.B. 812, govern the solicitation of employment in matters related to the Internal Revenue Service. The rule on disclosure to third parties has been expanded to apply to all tax return preparers; it will not apply where disclosure without formal written consent is permitted under § 301.7216–2 in the performance of professional or fiduciary services. The rule on use of tax return information in connection with another person's return has been revised to apply to disclosures or uses where the new § 301.7216–2(b) added by this document does not permit disclosure or use without formal written consent. A revised rule permits the formal consent to be signed by the taxpayer or his duly authorized agent or fiduciary. Two examples affecting certified public accountants have been eliminated from proposed § 301.7216–3(c) since the situations involved will be covered by revised § 301.7216–2(e).

In view of the foregoing, the amendments of the regulations as proposed are hereby adopted, subject to the changes set forth below:

PARAGRAPH 1. Section 301.7216–1, as set forth in the notice of proposed rule making, is changed by deleting subparagraph (3) of paragraph (b), by redesignating subparagraph (4) of paragraph (b) as subparagraph (3), and by revising paragraph (a), subparagraph (2) of paragraph (b), subparagraph (3) of paragraph (b), as so redesignated, and so much of paragraph (b) as precedes subparagraph (1) thereof, to read as set forth below:

PAR. 2. Section 301.7216–2, as set forth in the notice of proposed rulemaking, is changed to read as set forth below:

PAR. 3. Section 301.7216–3, as set forth in the notice of proposed rulemaking, is changed by revising the heading of such section, by revising paragraphs (a) and (b), by deleting examples (2) and (3) in paragraph (c), by redesignating examples (4) and (5) in paragraph (c) as examples (2) and (3), and by revising example (3) as so redesignated, as set forth below:

(This Treasury decision is issued under the authority contained in section 7805 of the Internal Revenue Code of 1954 (68A Stat. 917 (26 U.S.C. 7805)))

[SEAL] DONALD C. ALEXANDER,
Commissioner of Internal Revenue.

Approved: March 25, 1974.

FREDERIC W. HICKMAN,
Assistant Secretary of the Treasury.

§ 301.7216 Statutory provisions; disclosure or use of information by preparers of returns.

SEC. 7216. *Disclosure or use of information by preparers of returns*—(a) *General rule.* Any person who is engaged in the business of preparing, or providing services in connection with the preparation of, returns of the tax imposed by chapter 1, or declarations or amended declarations of estimated tax under section 6015, or any person who for compensation prepares any such return or declaration for any other person, and who—

(1) Discloses any information furnished to him for, or in connection with, the preparation of any such return or declaration, or

(2) Uses any such information for any purpose other than to prepare, or assist in preparing, any such return or declaration,

shall be guilty of a misdemeanor, and, upon conviction thereof, shall be fined not more than $1,000, or imprisoned not more than 1 year, or both, together with the costs of prosecution.

(b) *Exceptions*—(1) *Disclosure.* Subsection (a) shall not apply to a disclosure of information if such disclosure is made—

(A) Pursuant to any other provision of this title, or

(B) Pursuant to an order of a court.

(2) *Use.* Subsection (a) shall not apply to the use of information in the preparation of, or in connection with the preparation of, State and local tax returns and declarations of estimated tax of the person to whom the information relates.

(3) *Regulations.* Subsection (a) shall not apply to a disclosure or use of information which is permitted by regulations prescribed by the Secretary or his delegate under this section.

[Sec. 7216 as added by sec. 316, Rev. Act 1971 (85 Stat. 529)]

§ 301.7216–1 Penalty for disclosure or use of tax return information.

(a) *In general.* Section 7216(a) provides in effect that, except as provided in section 7216(b), any tax return preparer (as described in paragraph (b)(2) of this section) who on or after January 1, 1972, discloses or uses any tax return information (as described in paragraph (b)(3) of this section) other than for the specific purpose of preparing, assisting in preparing, or obtaining or providing services in connection with the preparation of, any tax return of the taxpayer by or for whom the information was made available to a tax return preparer, shall be guilty of a misdemeanor, and, upon conviction thereof, shall be fined not more than $1,000, or imprisoned not more than 1 year, or both, together with the costs of prosecution. Pursuant to section 7216(b), the provisions of section 7216(a) and this paragraph do not apply to any disclosure or use permitted under § 301.7216–2 or § 301.7216–3.

(b) *Definitions.* For purposes only of section 7216 and §§ 301.7216–1 through 301.7216–3—

(1) *Tax return.* The term "tax return" means any return (or amended return) of the income tax imposed by chapter 1 or 2 of the Code, or any declaration (or amended declaration) of estimated tax made under section 6015.

(2) *Tax return preparer.* (i) The term tax return preparer means any person—

(A) Who is engaged in the business of preparing tax returns,

(B) Who is engaged in the business of providing auxiliary services in connection with the preparation of tax returns,

(C) Who is remunerated for preparing, or assisting in preparing, a tax return for any other person, or

(D) Any individual who, as part of his duties or employment with any person described in (A), (B), or (C) of this subdivision, performs services which assist in the preparation of, or assist in providing auxiliary services in connection with the preparation of, a tax return.

For example, assume that a bank is a tax return preparer within the meaning of (A) of this subdivision and it employs one individual to solicit the necessary tax return information for the preparation of a tax return and another individual to prepare the return on the basis of the information that is furnished. Under these circumstances, both employees are tax return preparers. Also, for example, a secretary to a tax return preparer who types or otherwise works on returns prepared by the preparer is a tax return preparer.

(ii) A person is engaged in the business of preparing tax returns as described in subdivision (i)(A) of this subparagraph if, in the course of his business, he holds himself out to taxpayers as a person who prepares tax returns, whether or not tax return preparation is his sole business activity and whether or not he charges a fee for such services.

(iii) A person is engaged in the business of providing auxiliary services in connection with the preparation of tax returns as described in subdivision (i)(B) of this subparagraph if, in the course of his business, he holds himself out to tax return preparers or to taxpayers as a person who performs such auxiliary services, whether or not providing such auxiliary services is his sole business activity and whether or not he charges a fee for such services. For example, a person part or all of whose business is to provide a computerized tax return processing service based on tax return information furnished by another person is a tax return preparer.

(iv) A tax return preparer described in subdivision (i)(C) of this subparagraph includes any person who—

(A) For remuneration but not in the course of a business prepares a tax return for another person, or

(B) For remuneration and on a casual basis helps a relative, friend, or other acquaintance to prepare the latter's tax return.

(v) A person is not a tax return preparer merely because he leases office space to a tax return preparer, furnishes credit to a taxpayer whose tax return is prepared by a tax return preparer, or otherwise performs some service which only incidentally relates to the preparation of tax returns. For example, assume that a tax return preparer contracts with a department store for the rental of space in the store, and that the store advertises that taxpayers who use the tax return preparation service may charge the cost of having their tax return prepared to their charge account with the department store. Under such circumstances, the department store is not a tax return preparer.

(3) *Tax return information.* The term "tax return information" means any information, including but not limited to a taxpayer's name, address, or identifying number, which is furnished in any form or manner by a taxpayer for, or in connection with, the preparation of a tax return of such taxpayer. Information furnished by a taxpayer includes information which is furnished on behalf of the taxpayer by any person; for example, any person required under section 6012 to make a return for such taxpayer, such as a guardian for a minor, by a duly authorized agent for his principal, by a fiduciary for an estate or trust, or by a receiver, trustee in bankruptcy, or assignee for a corporation.

§ 301.7216–2 Disclosure or use without formal consent of taxpayer.

(a) *Disclosure pursuant to other provisions of Internal Revenue Code.* The provisions of section 7216(a) and § 301.7216–1 shall not apply to any disclosure of tax return information if such disclosure is made pursuant to any other provision of the Code or the regulations thereunder. Thus, for example, the provisions of such sections do not apply to a disclosure pursuant to section 7269 to an officer or employee of the Internal Revenue Service of information concerning the estate of a decedent or a disclosure pursuant to section 7602 to an officer or employee of the Internal Revenue Service of books, papers, records, or other data which may be relevant to the liability of any person for the income tax.

(b) *Disclosure or use of information in the case of related taxpayers.* (1) A tax return preparer may use, in preparing a tax return of a second taxpayer, and may disclose to such second taxpayer in the form in which it appears on such return, any tax return information which the preparer obtained from a first taxpayer if—

(i) The second taxpayer is related to the first taxpayer within the meaning of subparagraph (2) of this paragraph,

(ii) The first taxpayer's tax interest in such information is not adverse to the second taxpayer's tax interest in such information, and

(iii) The first taxpayer has not expressly prohibited such disclosure or use.

(2) For purposes of subparagraph (1)(i) of this paragraph, one taxpayer is related to another taxpayer if they have any one of the following relationships: husband and wife, child and parent, grandchild and grandparent, partner and partnership, trust or estate and beneficiary, trust or estate and fiduciary, corporation and shareholder, or members of a controlled group of corporations as defined in section 1563.

(3) See § 301.7216–3(a)(3) for disclosure or use of tax return information of the taxpayer in preparing the tax return of a second taxpayer where the requirements of this paragraph are not satisfied.

(c) *Disclosure pursuant to court order.* The provisions of section 7216(a) and § 301.7216–1 shall not apply to any disclosure of tax return information if such disclosure is made pursuant to the order of any court of record, Federal, State, or local, clearly identifying the information to be disclosed.

(d) *Disclosure for use in revenue investigations or court proceedings.* A tax return preparer may disclose tax return information (1) to his attorney, or to an employee of the Internal Revenue Service, for use in connection with an investigation of such tax return preparer conducted by the Internal Revenue Service or (2) to his attorney, or to any officer of a court, for use in connection with proceedings involving such tax return preparer before the court.

(e) *Attorneys and accountants.* A tax return preparer who is lawfully engaged in the practice of law or accountancy and prepares a tax return for a taxpayer to or for whom it renders legal or accounting services may disclose or use the tax return information of such taxpayer in the ordinary course of rendering such legal or accounting services to or for such taxpayer. Thus, for example, a lawyer who prepares a tax return for a taxpayer to or for whom he renders legal services may disclose or use the tax return information of the taxpayer for, or in connection with, the rendering of legal services, such as estate planning or administration, or preparation of trial briefs or trust instruments, to the taxpayer or his estate. In further illustration, an accountant who prepares a tax return for a taxpayer to or for whom he renders accounting services may disclose or use the tax return information of the taxpayer for, or in connection with, the preparation of books of account, working papers, or accounting statements or reports of the taxpayer and, in the normal course of rendering such accounting services to or for the taxpayer, may, with the express or implied consent of the taxpayer, make such tax return information available to stockholders, management, suppliers, lenders, or other third parties.

(f) *Corporate fiduciaries.* A trust company, trust department of a bank, or other corporate fiduciary which prepares a tax return for a taxpayer to or for whom it renders fiduciary, investment, or other custodial or management services may (1) disclose or use the tax return information of such taxpayer in the ordinary course of rendering such services to or for the taxpayer or (2), with

the express or implied consent of the taxpayer, make such information available to the taxpayer's attorney, accountant, or investment advisor.

(g) *Disclosure to taxpayer's fiduciary.* If after furnishing tax return information to a tax return preparer the taxpayer dies or becomes incompetent, insolvent, or bankrupt, or his assets are placed in conservatorship or receivership, the tax return preparer may disclose such information to the duly appointed fiduciary of the taxpayer or his estate, or to the duly authorized agent of such fiduciary.

(h) *Disclosure by tax return preparer to tax return processor.* A tax return preparer may disclose tax return information of a taxpayer to another tax return preparer described in § 301.7216–1(b)(2)(i)(B) for the purpose of having the second tax return preparer transfer that information to, and compute the tax liability on, a tax return of such taxpayer by means of electronic, mechanical, or other form of tax return processing service.

(i) *Disclosure by one officer, employee, or member to another officer, employee, or member.* An officer, employee, or member of a tax return preparer may transfer any tax return information to another officer, employee, or member of the same tax return preparer for the purpose of performing services which assist in the preparation of, or assist in providing auxiliary services in connection with the preparation of, the tax return of a taxpayer by or for whom the information was furnished.

(j) *Identical information obtained from other sources.* The provisions of section 7216(a) and § 301.7216–1 shall not apply to the disclosure or use by a tax return preparer of information which is identical to any tax return information which has been furnished to him if such identical information was obtained otherwise than in connection with the preparation of, or providing auxiliary services in connection with the preparation of, a tax return.

(k) *Disclosure or use of information in preparation or audit of State returns.* The provisions of section 7216(a) and § 301.7216–1 shall not apply to the disclosure or use by any tax return preparer of any tax return information in the preparation or audit of, or in connection with the preparation or audit of, any tax return or declaration of estimated tax required of the taxpayer under the law of any State or political subdivision therefor, of the District of Columbia, or of any possession of the United States.

(l) *Retention of records.* A tax return preparer may retain tax return information of a taxpayer, including copies of tax returns or data processing tapes prepared on the basis of such tax return information, and may use such information in connection with the preparation of other tax returns of the taxpayer or in connection with an audit by the Internal Revenue Service of any tax return. The provisions of paragraph (m) of this section respecting the transfer of a taxpayer list apply also to the transfer of any records and related workpapers to which this paragraph applies.

(m) *Lists for solicitation of tax return business.* Any tax return preparer may compile and maintain a separate list containing the names and address of taxpayers whose tax returns he has prepared or processed. This list may be used by the compiler solely to contact the taxpayers on the list for the purpose of offering tax information or additional tax return preparation services to such taxpayers. The compiler of the list may not transfer the taxpayer list, or any part thereof, to any other person unless such transfer takes place in conjunction with the sale or other disposition of the tax return preparation business of such compiler. A person who acquires a taxpayer list, or a part thereof, in conjunction with such a sale or other disposition shall be subject to the provisions of this paragraph with respect to such list as if he had been the compiler of such list. The term "list", as used in this paragraph, includes any record or system whereby the names and addresses of taxpayers are retained.

§ 301.7216–3 Disclosure or use only with formal consent of taxpayer.

(a) *Written consent to use or disclosure*—(1) *Solicitation of other business.* (i) If a tax return preparer has obtained from the taxpayer a consent described in paragraph (b) of this section, he may use the tax return information of such taxpayer to solicit from the taxpayer any additional current business, in matters not related to the Internal Revenue Service, which the tax return preparer provides and offers to the public. The request for such consent may not be made later than the time the taxpayer receives his completed tax return from the tax return preparer. If the request is not granted, no follow up request may be made. This authorization to use the tax return information of the taxpayer does not apply, however, for purposes of facilitating the solicitation of the taxpayer's use of any services or facilities furnished by a person other than the tax return preparer, unless such other person and the tax return preparer are members of the same affiliated group within the meaning of section 1504. Thus, for example, the authorization would not apply if the other person is a corporation which is owned or controlled directly or indirectly by the same interests which own or control the tax return preparer but which is not affiliated with the tax return preparer within the meaning of section 1504(a). Moreover, this authorization does not apply for purposes of facilitating the solicitation of additional business to be furnished at some indefinite time in the future, as, for example, the future sale of mutual fund shares or life insurance, or the furnishing of future credit card services. It is not necessary, however, that the additional business be furnished in the same locality in which the tax return information is furnished.

(ii) For prohibition against solicitation of employment in matters related to the Internal Revenue Service, see 31 CFR 10.30 (Treasury Department Circular No. 230) and § 7 of Rev. Proc. 68–20, 1968–1 C.B. 812.

(2) *Permissible disclosures to third parties.* If a tax return preparer has obtained from a taxpayer a consent described in paragraph (b) of this section, he may disclose the tax return information of such taxpayer to such third persons as the taxpayer may direct. However, see § 301.7216–2 for certain permissible disclosures without formal written consent.

(3) *Disclosure or use of information in connection with another person's return.* A tax return preparer may disclose or use any tax return information, which was obtained from a first taxpayer, in preparing a tax return of a second taxpayer if the tax return preparer has obtained from the first taxpayer a written consent described in paragraph (b) of this section. See § 301.7216–2(b) for disclosure or use in certain cases without formal consent.

(b) *Form of consent.* A separate written consent, signed by the taxpayer or his duly authorized agent or fiduciary, must be obtained for each separate use or disclosure authorized in paragraph (a)(1), (2) or (3) of this section and shall contain—

(1) The name of the tax return preparer,

(2) The name of the taxpayer,

(3) The purpose for which the consent is being furnished,

(4) The date on which such consent is signed,

(5) A statement that the tax return information may not be disclosed or used by the tax return preparer for any purpose (not otherwise permitted under § 301.7216–2) other than that stated in the consent, and

(6) A statement by the taxpayer, or his agent or fiduciary, that he consents to the disclosure or use of such information for the purpose described in subparagraph (3) of this paragraph.

(c) *Illustrations.* The application of this section may be illustrated by the following examples:

Example (1). In order to stimulate the making of loans, a bank advertises that it is in the business of preparing tax returns. A taxpayer goes to the bank to have his tax return prepared. After the return has been completed by the bank, the employee of the bank who obtained the tax return information from the taxpayer explains that the taxpayer owes an additional $400 in taxes and that the bank's loan department may be able to offer the taxpayer a loan to pay the tax due. If the taxpayer decides to accept the opportunity offered to apply for a loan, the bank must first have the taxpayer execute a written consent described in paragraph (b) of this section for the bank to use any of such information which is required in determining whether to make the tax loan.

Example (2). An individual who sells life insurance and shares in a mutual fund is

also in the business of preparing tax returns. A taxpayer who has gone to the individual to have his tax return prepared is requested, at the time he picks up his completed tax return, to give his consent to the individual's use of his tax return information in connection with such individual's solicitation of the taxpayer's purchasing a life insurance policy and shares in the mutual fund. Before the individual may use such tax return information as a basis for soliciting such additional business from the taxpayer, the taxpayer must execute separate written consents under paragraph (b) of this section, one authorizing the use of such information as a basis for soliciting the sale of the mutual fund shares and a second authorizing the use of such information as a basis for soliciting the sale of the life insurance.

Example (3). The facts are the same as in example (2) except that the individual does not sell life insurance but does sell shares in several mutual funds. If the request is for the purpose of using the tax return information as a basis for soliciting the sale at one time of shares in mutual funds A and B, only one written consent under paragraph (b) of this section is required of the taxpayer. If, however, the request is for the purpose of using the tax return information as a basis for soliciting the sale of shares in fund A at one time, and the sale of shares in fund B at a later time, two written consents under such paragraph are required of the taxpayer.

[FR Doc.74-7343 Filed 3-27-74;8:45 am]

Title 33—Navigation and Navigable Waters

CHAPTER I—COAST GUARD, DEPARTMENT OF TRANSPORTATION

[CGD 73-100R]

PILOT RULES FOR THE GREAT LAKES AND INLAND WATERS

Lights and Day Signals; Passing a Floating Plant; Pilot Vessels

These amendments to the Pilot Rules for the Great Lakes add regulations for—

a. Lights and day signals for vessels, dredges, and vessels working on wrecks and obstructions, etc.;

b. Passing a floating plant working in a navigable channel; and

c. Lights for Great Lakes pilot vessels.

These regulations are identical to the regulations in Part 201 of Title 33 which are administered by the U.S. Army Corps of Engineers. The Corps of Engineers has revoked Part 201 in the FEDERAL REGISTER of May 16, 1973 (38 FR 12804). The effective date of that revocation is the effective date of the regulations published in this document.

Though Part 201 applies to both the Great Lakes and Western Rivers, the regulations in this document apply only to the Great Lakes. Sections 95.52 through 95.66 of the Pilot Rules for Western Rivers already contain regulations similar to those in Part 201.

These amendments are based on a notice of proposed rulemaking published in the Wednesday, August 1, 1973, issue of the FEDERAL REGISTER (38 FR 20467). Interested parties were invited to comment on the proposal. No comments in response to the notice of proposed rulemaking were received. Accordingly, the proposed amendments are adopted in this document without substantive change.

The proposed regulations were numbered in the notice of proposed rulemaking as §§ 90.31 through 90.46. In this document they have been renumbered as §§ 90.22 through 90.37 to provide organization that is consistent with the organization of the Pilot Rules in Part 80 and Part 95 of Title 33. To accomplish the renumbering of these regulations, the present §§ 90.22 through 90.30 in Part 90 are renumbered as §§ 90.38 through 90.46.

This document also deletes the footnotes in Title 33 that immediately precede § 80.18 of Part 80 and § 95.51 of Part 95. These footnotes explained that some of the Pilot Rules for the Great Lakes were contained in Part 201. Notice and public procedure on these amendments to Part 80 and Part 95 are unnecessary because the amendments are clerical in nature and do not amend any regulations.

In accordance with the foregoing, Chapter I of Title 33 of the Code of Federal Regulations is amended as follows:

PART 80—PILOT RULES FOR INLAND WATERS

1. The Note immediately preceding § 80.18 and following the centerhead after § 80.17 entitled "Lights And Day Signals For Vessels, Dredges of All Types, And Vessels Working on Wrecks and Obstructions, Etc." is deleted.

(Sec. 1, Pub. L. 85-656, 72 Stat. 612 (33 U.S.C. 157); Sec. 6, Pub. L. 89-670, 80 Stat. 937 (49 U.S.C. 1655(b)(1)); 49 CFR 1.46(b))

PART 90—PILOT RULES FOR THE GREAT LAKES

2. Sections 90.22 through 90.30 grouped under the centerhead entitled MISCELLANEOUS are redesignated as §§ 90.38 through 90.46 and grouped under the same centerhead.

3. New §§ 90.22 through 90.37 to be grouped under the centerhead entitled "Lights and Day Signals for Vessels, Dredges, and Vessels Working on Wrecks and Obstructions, Etc." are added to read as follows:

LIGHTS AND DAY SIGNALS FOR VESSELS, DREDGES, AND VESSELS WORKING ON WRECKS AND OBSTRUCTIONS, ETC.

Sec.

90.22 Signals to be displayed by a towing vessel when towing a submerged or partly submerged object upon a hawser when no signals can be displayed upon the object which is towed.

90.23 Steam vessels, derrick boats, lighters, or other types of vessels made fast alongside a wreck, or moored over a wreck which is on the bottom or partly submerged, or which may be drifting.

90.24 Dredges held in stationary position by moorings or spuds.

90.25 Self-propelling suction dredges under way and engaged in dredging operations.

90.26 Vessels moored or anchored and engaged in laying cables or pipe, submarine construction, excavation, mat sinking, bank grading, dike construction, revetment, or other bank protection operations.

90.27 Lights to be displayed on pipelines.

90.28 Lights generally.

90.29 Vessels moored or at anchor.

PASSING FLOATING PLANT WORKING IN NAVIGABLE CHANNELS

90.30 Passing signals.

90.31 Speed of vessels passing floating plant working in channels.

90.32 Light-draft vessels passing floating plant.

90.33 Aids to navigation marking floating-plant moorings.

90.34 Obstruction of channel by floating plant.

90.35 Clearing of channels.

90.36 Protection of marks placed for the guidance of floating plant.

90.37 Lights for Great Lakes pilot vessels.

AUTHORITY: Sec. 3, 28 Stat. 649, as amended (33 U.S.C. 243); Sec. 6(b)(1), Pub. L. 89-670, 80 Stat. 937 (49 U.S.C. 1655(b)(1)); 40 CFR 1.46(b), unless otherwise noted.

LIGHTS AND DAY SIGNALS FOR VESSELS, DREDGES, AND VESSELS WORKING ON WRECKS AND OBSTRUCTIONS, ETC.

§ 90.22 Signals to be displayed by a towing vessel when towing a submerged or partly submerged object upon a hawser when no signals can be displayed upon the object which is towed.

(a) The vessel having the submerged object in tow shall display by day, where they can best be seen, two shapes, one above the other, not less than six feet apart, the lower shape to be carried not less than 10 feet above the deck house. The shapes shall be in the form of a double frustrum of a cone, base to base, not less than two feet in diameter at the center nor less than eight inches at the ends of the cones, and to be not less than four feet lengthwise from end to end, the upper shape to be painted in alternate horizontal stripes of black and white, eight inches in width, and the lower shape to be painted a solid bright red.

(b) By night the towing vessel shall display the regular side lights, but in lieu of the regular white towing lights shall display four lights in a vertical position not less than three feet nor more than six feet apart, the upper and lower of such lights to be white, and the two middle lights to be red, all of such lights to be of the same character as the regular towing lights.

§ 90.23 Steam vessels, derrick boats, lighters, or other types of vessels made fast alongside a wreck, or moored over a wreck which is on the bottom or partly submerged, or which may be drifting.

(a) Steam vessels, derrick boats, lighters, or other types of vessels made fast alongside a wreck, or moored over a wreck which is on the bottom or partly submerged, or which may be drifting, shall display by day two shapes of the same character and dimensions and displayed in the same manner as required by § 90.22(a), except that both shapes shall be painted a solid bright red, but where more than one vessel is working under the above conditions, the shapes need be displayed only from one vessel on each side of the wreck from which they can best be seen from all directions.

(b) By night this situation shall be indicated by the display of a white light from the bow and stern of each outside vessel or lighter not less than six feet above the deck, and in addition thereto there shall be displayed in a position where they can best be seen from all directions two red lights carried in a vertical line not less than three feet nor more than six feet apart, and not less than 15 feet above the deck.

§ 90.24 Dredges held in stationary position by moorings or spuds.

(a) Dredges which are held in stationary position by moorings or spuds shall display by day two red balls not less than two feet in diameter and carried in a vertical line not less than three feet nor more than six feet apart, and at least 15 feet above the deck house and in a position where they can best be seen from all directions.

(b) By night they shall display a white light at each corner, not less than six feet above the deck, and in addition thereto there shall be displayed in a position where they can best be seen from all directions two red lights carried in a vertical line not less than three feet nor more than six feet apart, and not less than 15 feet above the deck. When scows are moored alongside a dredge in the foregoing situation they shall display a white light on each outboard corner, not less than six feet above the deck.

§ 90.25 Self-propelling suction dredges under way and engaged in dredging operations.

(a) Self-propelling suction dredges under way and engaged in dredging operations shall display by day two black balls not less than two feet in diameter and carried in a vertical line not less than 15 feet above the deck house, and where they can best be seen from all directions. The term "dredging operations" shall include maneuvering into or out of position at the dredging site, but shall not include proceeding to and from the site.

(b) By night they shall carry, in addition to the regular running lights, two red lights of the same character as the white masthead light and in a vertical line beneath that light, the red lights to be not less than three feet nor more than six feet apart and the upper red light to be not less than four feet nor more than six feet below the masthead light, and on or near the stern two red lights in a vertical line not less than four feet nor more than six feet apart, to show through four points of the compass; that is, from right astern to two points on each quarter.

§ 90.26 Vessels moored or anchored and engaged in laying cables or pipe, submarine construction, excavation, mat sinking, bank grading, dike construction, revetment, or other bank protection operations.

(a) Vessels which are moored or anchored and engaged in laying cables or pipe, submarine construction, excavation, mat sinking, bank grading, dike construction, revetment, or other bank protection operations, shall display by day, not less than 15 feet above the deck, where they can best be seen from all directions, two balls not less than two feet in diameter, in a vertical line not less than three feet nor more than six feet apart, the upper ball to be painted in alternate black and white vertical stripes six inches wide, and the lower ball to be painted a solid bright red.

(b) By night they shall display three red lights, carried in a vertical line not less than three feet nor more than six feet apart, in a position where they can best be seen from all directions, with the lowermost light not less than 15 feet above the deck.

(c) Where a stringout of moored vessels or barges is engaged in the operations, three red lights carried as prescribed in paragraph (b) of this section shall be displayed at the channelward end of the stringout. Where the stringout crosses the navigable channel and is to be opened for the passage of vessels, the three red lights shall be displayed at each side of the opening instead of at the outer end of the stringout. There shall also be displayed upon such stringout one horizontal row of amber lights not less than six feet above the deck, or above the deck house where the craft carries a deck house, in a position where they can best be seen from all directions, spaced not more than 50 feet apart so as to mark distinctly the entire length and course of the stringout.

§ 90.27 Lights to be displayed on pipe lines.

Pipe lines attached to dredges, and either floating or supported on trestles, shall display by night one row of amber lights not less than eight feet nor more than 12 feet above the water, about equally spaced and in such number as to mark distinctly the entire length and course of the line, the intervals between lights where the line crosses navigable channels to be not more than 30 feet. There shall also be displayed on the shore or discharge end of the line two red lights, three feet apart, in a vertical line with the lower light at least eight feet above the water, and if the line is to be opened at night for the passage of vessels, a similar arrangement of lights shall be displayed on each side of the opening.

§ 90.28 Lights generally.

(a) All the lights required by §§ 90.22 to 90.27, except as provided in §§ 90.22 (b) and 90.25(b), shall be of such character as to be visible on a dark night with a clear atmosphere for a distance of at least two miles.

(b) The lights required by § 90.22(b) to be of the same character as the regular towing lights, and the lights required by § 90.25(b) to be of the same character as the masthead light, shall be of such character as to be visible on a dark night with a clear atmosphere for a distance of at least five miles.

(c) All floodlights or headlights which may interfere with the proper navigation of an approaching vessel shall be so shielded that the lights will not blind the pilot of such vessel.

§ 90.29 Vessels moored or at anchor.

Vessels of more than 65 feet in length when moored or anchored in a fairway or channel shall display between sunrise and sunset on the forward part of the vessel where it can best be seen from other vessels one black ball not less than two feet in diameter.

Passing Floating Plant Working in Navigable Channels

§ 90.30 Passing signals.

(a) Vessels intending to pass dredges or other types of floating plant working in navigable channels, when within a reasonable distance therefrom and not in any case over a mile, shall indicate such intention by one long blast of the whistle, and shall be directed to the proper side for passage by the sounding, by the dredge or other floating plant, of the signal prescribed in the local pilot rules for vessels under way and approaching each other from opposite directions, which shall be answered in the usual manner by the approaching vessel. If the channel is not clear, the floating plant shall sound the alarm or danger signal and the approaching vessel shall slow down or stop and await further signal from the plant.

(b) When the pipe line from a dredge crosses the channel in such a way that an approaching vessel cannot pass safely around the pipe line or dredge, there shall be sounded immediately from the dredge the alarm or danger signal and the approaching vessel shall slow down or stop and await further signal from the dredge. The pipe line shall then be opened and the channel cleared as soon as practicable; when the channel is clear for passage the dredge shall so indicate by sounding the usual passing signal as prescribed in paragraph (a) of this section. The approaching vessel shall answer with a corresponding signal and pass promptly.

(c) When any pipe line or swinging dredge shall have given an approaching vessel or tow the signal that the channel is clear, the dredge shall straighten out within the cut for the passage of the vessel or tow.

NOTE: The term "floating plant" as used in §§ 9.30 to 90.36, includes dredges, derrick boats, snag boats, drill boats, pile drivers, maneuver boats, hydraulic graders, survey boats, working barges, and mat sinking plant.

§ 90.31 Speed of vessels passing floating plant working in channels.

Vessels, with or without tows, passing floating plant working in channels, shall reduce their speed sufficiently to insure the safety of both the plant and themselves, and when passing within 200 feet of the plant their speed shall not exceed five miles per hour. While passing over lines of the plant, propelling machinery shall be stopped.

§ 90.32 Light-draft-vessels passing floating plant.

Vessels whose draft permits shall keep outside the buoys marking the ends of mooring lines of floating plant working in channels.

§ 90.33 Aids to navigation marking floating-plant moorings.

Breast, stern, and bow anchors of floating plant working in navigable channels shall be marked by barrel or other suitable buoys. By night approaching vessels shall be shown the location of adjacent buoys by throwing a suitable beam of light from the plant on the buoys until the approaching vessel has passed, or the buoys may be lighted by red lights, visible in all directions, of the same character as specified in § 90.28(a).

§ 90.34 Obstruction of channel by floating plant.

Channels shall not be obstructed unnecessarily by any dredging or other floating plant. While vessels are passing such plant all lines running therefrom across the channel on the passing side which may interfere with or obstruct navigation shall be slacked to the bottom of the channel.

§ 90.35 Clearing of channels.

When special or temporary regulations have not been prescribed and action under the regulations contained in §§ 90.30 to 90.34 will not afford clear passage, floating plant in narrow channels shall, upon notice, move out of the way of vessels a sufficient distance to allow them a clear passage. Vessels desiring passage shall, however, give the master of the floating plant ample notice in advance of the time they expect to pass.

NOTE: If it is necessary to prohibit or limit the anchorage or movement of vessels within certain areas in order to facilitate the work of improvement, application should be made through official channels for establishment by the Secretary of the Army of special or temporary regulations for this purpose.

§ 90.36 Protection of marks placed for the guidance of floating plant.

Vessels shall not run over anchor buoys, or buoys, stakes, or other marks placed for the guidance of floating plant working in channels; and shall not anchor on the ranges of buoys, stakes, or other marks placed for the guidance of such plant.

§ 90.37 Lights for Great Lakes pilot vessels.

(a) A power driven pilot vessel when engaged on pilotage duty and under way:

(1) Shall carry a white light at the masthead at a height of not less than 20 feet above the hull, visible all round the horizon at a distance of at least 3 miles and at a distance of 8 feet below it a red light similar in construction and character. If such a vessel is of less than 65 feet in length the vessel may carry the white light at a height of not less than 9 feet above the gunwale and the red light at a distance of 4 feet below the white light.

(2) Shall carry the sidelights prescribed by Great Lakes Rule 3 (33 U.S.C. 252) or by the Act of April 25, 1940 (46 U.S.C. 526b), as appropriate, and a white light at the stern showing an unbroken light over an arc of the horizon of 135°, so fixed as to show the light 67½° from right aft on each side of the vessel, and of such a character as to be visible at a distance of at least 2 miles.

(3) Shall show one or more flareup lights at intervals not exceeding 10 minutes. An intermittent white light visible all round the horizon may be used in lieu of flareup lights.

(b) A sailing pilot vessel when engaged on pilotage duty and underway:

(1) Shall carry a white light at the masthead visible all round the horizon at a distance of at least 3 miles.

(2) Shall be provided with the sidelights prescribed in paragraph (a)(2) of this section or the portable lanterns prescribed by Great Lakes Rule 8 (33 U.S.C. 257), as appropriate, and shall, on the near approach of or to other vessels, have such lights ready for use, and shall show them at short intervals to indicate the direction in which the pilot vessel is heading, but the green light shall not be shown on the port side nor the red light on the starboard side. The vessel shall also carry the stern light prescribed in paragraph (a)(2) of this section.

(3) Shall show one or more flareup lights at intervals not exceeding 10 minutes.

(c) A pilot vessel when engaged on pilotage duty and not under way shall carry the lights and show the flares prescribed in paragraph (a) (1) and (3) or (b) (1) and (3) of this section, as appropriate, and if at anchor shall also carry the anchor lights prescribed in Great Lakes Rule 9 (33 U.S.C. 253).

(d) A pilot vessel when not engaged on pilotage duty shall show the lights or shapes for a similar vessel of the same length.

PART 95—PILOT RULES FOR WESTERN RIVERS

4. The Note immediately preceding § 95.51 and following the centerhead after § 95.45 entitled "Lights and Day Signals for Vessels, Dredges of All Types, and Vessels Workin on Wrecks and Obstructions, Etc." is deleted.

Effective date. March 29, 1974.

Dated: March 22, 1974.

C. R. BENDER,
Admiral, U.S. Coast Guard,
Commandant.

[FR Doc.74-7288 Filed 3-28-74;8:45 am]

[CGD 73-124 R]

PART 110—ANCHORAGE REGULATIONS

Special Anchorage Area, Basin Point, Potts Harbor, Maine

This amendment to the Anchorage regulations is based on a notice of proposed rulemaking published in the June 19, 1973, issue of the FEDERAL REGISTER (38 FR 15970). The amendment establishes a special anchorage area in the vicinity of Basin Point in Potts Harbor near South Harpswell, Maine. In special anchorage areas, vessels under 65 feet in length, when at anchor, are not required to carry or exhibit anchor lights.

The establishment of a special anchorage area merely relaxes the lighting requirements of vessels at anchor, and does not impact on the use of the area in any other way.

Twelve comments were received as a result of the proposal. Eight of the comments expressed no objection to the proposal.

The United States Environmental Protection Agency, Boston, Massachusetts, recommended that the applicant be advised that he must conform at all times with applicable State and Federal Water Quality Standards. The Coast Guard issued a notice of proposed rulemaking on March 1, 1974 (39 FR 8038) concerning rules governing the design, construction, installation, and operation of marine sanitation devices. Comments were requested to be submitted prior to May 14, 1974. Under section 312 of the Federal Water Pollution Control Act (FWPCA), the Environmental Protection Agency (EPA) has promulgated Federal standards of performance for marine sanitation devices, which are required by the Act to be designed to prevent the discharge of untreated or inadequately treated sewage into or upon the navigable waters from new vessels and existing vessels, except vessels not equipped with installed toilet facilities.

Another comment was received objecting to the proposal on the grounds that more boats in the area would mean more pollution and more gas and oil spilled. The requirement of the Marine Sanitation Devices will overcome the pollution problem. There is a federal law which prohibits the discharge of gas and oil into the navigable waters of the United States.

The State of Maine, Department of Inland Fisheries and Game voiced no objection to the proposal provided no dredging is conducted. Any dredging planned in the area would require the approval of the Corps of Engineers and require an Environmental Impact Statement.

One person questioned the description of the anchorage and also suggested that opinions of the property owners in the vicinity of the special anchorage area be obtained. The individual also stated that he was not in favor of having a marina controlling waters beyond its land boundaries. The Commander, First Coast Guard District replied to the commenter explaining the description of the proposed anchorage area. The individual was further advised that the local control and administration of the anchorage would lie with the town of Harpswell Harbor Master and not with the local marina.

With respect to the opinions of local property owners, the Commander, First

Coast Guard District, has on file letters from 5 shoreline residents of the proposed anchorage area who do not express any dissatisfaction with the proposal provided their rights as property owners are protected.

In consideration of the foregoing, the proposed amendment is adopted without change, and is set forth below.

Effective date. This amendment is effective April 30, 1974.

Dated: March 21, 1974.

W. M. BENKERT,
Rear Admiral, U.S. Coast Guard, Chief, Office of Marine Environment and Systems.

Part 110 of title 33 of the Code of Federal Regulations is amended by adding a new § 110.5(c-1) to read as follows:

§ 110.5 Casco Bay, Maine.

* * * * *

(c-1) *Basin Point, Potts Harbor, east side of Basin Point.*—The water area east of Basin Point enclosed by a line beginning at the southernmost extremity of Basin Point at latitude 43°44'17" N., longitude 70°02'36" W.; thence easterly to latitude 43°44'17" N., longitude 70°02'10" W.; thence north northeasterly to a point on the shoreline at latitude 43°44'43" N., longitude 70°02'05" W.; thence following the shoreline to the point of beginning.

* * * * *

(Sec. 1, 30 Stat. 98, as amended; sec. 6(g)(1)(B), 80 Stat. 937 (33 U.S.C. 180), (49 U.S.C. 1655(g)(1)(B)), 49 CFR 1.46(c)(2).)

[FR Doc.74-7283 Filed 3-28-74;8:45 am]

Title 36—Parks, Forests, and Public Property

CHAPTER II—FOREST SERVICE, DEPARTMENT OF AGRICULTURE

PART 292—NATIONAL RECREATION AREAS

Subpart C—Sawtooth National Recreation Area—Private Lands

Proposed regulation was published in the FEDERAL REGISTER on May 25, 1973 (38 FR 13754), to add a new Subpart C to Part 292, Chapter II, Title 36, Code of Federal Regulations, concerning private lands within the Sawtooth National Recreation Area.

Interested persons were given the opportunity to participate in the rulemaking through the submission of comments. Comments were received from governmental agencies (national, State, and local), organizations, companies, and formal groups as well as many private landowners and individuals. The majority of the respondents expressed concern about existing private land uses that were in conflict with various portions of the proposed regulations and suggested numerous changes.

Several respondents felt definitions for designated communities and private property should be more specific to allow a better understanding of these classifications in the recreation area. The definition for a designated community was clarified to indicate that these areas are classified and shown on the Land Use Category Map dated December 15, 1973. The definition of private property was revised to specifically exclude unpatented mining claims. Many respondents felt the proposed private land classifications were too arbitrary and difficult to understand. The residential classifications (R-1, R-5, and R-10) have been eliminated and a single residential classification established for existing or future subdivision development outside designated communities. Some respondents felt the mineral classification was difficult to understand. Since mineral activity can occur in any one of the four land classifications, subject to certification, the mineral classification was not changed.

Many comments were received to include Obsidian and Sawtooth City as designated communities. Sawtooth City has been added as a designated community because the visual impact of this development can be controlled. Obsidian was not included as a designated community due to critical visual conflicts. A provision was added in the regulations to allow a phasing out period for existing, nonconforming uses in Obsidian and other locations in the recreation area to reduce the personal hardship. The area immediately east of U.S. Highway 93, in the vicinity of Obsidian, is classified to allow continuance of commercial and residential developments with some modifications.

A few respondents expressed a desire to have a committee formed to review and/or approve certification by the Area Ranger. Since the Secretary of Agriculture is directed to administer the recreation area, and appeal provisions are afforded to the Chief of the Forest Service for any landowner affected by a decision of the Area Ranger, provisions for such a committee were not provided.

Some respondents felt a time period should be established requiring the action of the Area Ranger on requests for certification. A 45-day period was established within which the Area Ranger will notify the applicant of his decision and/or need for additional information.

Some respondents suggested that provision for land exchanges be made to relocate nonconforming or conflicting uses. Some suitable lands in the National Recreation Area will be identified and classified in the general overall plan that will solve some problem conflicts. Federal lands located in or adjacent to designated communities will be considered for exchange only after acceptable community development plans and ordinances have been implemented.

Some landowners commented that specific standards were needed in the designated communities. Specific standards have been included for designated communities. In addition, the framework is provided for the preparation of acceptable community development plans and implementation of ordinances to assure proper use and development. The community development plan and ordinances, when approved, will replace the present standards.

Some respondents were in favor of the proposed regulations and expressed their support in adoption and implementation.

Part 292 is revised by adoption of the proposed Subpart C, as changed to read as follows:

Subpart C—Sawtooth National Recreation Area—Private Lands

Sec.

292.14 Introduction.
292.15 General provisions—procedures.
292.16 Standards.

AUTHORITY: Provisions of section 4(a), Act of August 22, 1972 (86 Stat. 613).

Subpart C—Sawtooth National Recreation Area—Private Lands

§ 292.14 Introduction.

(a) *Purpose.* In accordance with the provisions of the Act establishing the Sawtooth National Recreation Area (86 Stat. 612), the regulations of this subpart establish standards for the use, subdivision and development of privately owned property within the boundaries of the Sawtooth National Recreation Area. The standards are in furtherance of the preservation and protection of the natural, scenic, historic, pastoral, and fish and wildlife values and to provide for the enhancement of the recreational values of the Recreation Area. Unless, in the judgment of the Secretary, such property is being used, or is in imminent danger of being used, in a manner incompatible with such standards, the property or any interest therein may not be acquired by condemnation. However, private land or an interest therein, determined to be necessary for access to and utilization of public property, and for recreation and other facilities, may be condemned without regard to this restriction, subject however, to the limitation in § 292.15(j).

(b) *Amendment of regulations.* Amendments to these regulations shall be made in accordance with the Administrative Procedures Act (60 Stat. 238, 5 U.S.C. 553), including the publishing of the amendments as a notice of proposed rulemaking with final adoption after interested persons have been given an opportunity to participate in the rulemaking through submission of comments.

(c) *Definitions*—(1) *Cluster-type development.* Planned unit development which allows flexibility in neighborhood and subdivision lot design by dedicating or reserving the land so saved to open space.

(2) *Community development plan.* A narrative plan with maps which sets forth specific standards for desirable development of a community.

(3) *Designated community.* A populated area divided into lots, blocks and streets as platted and recorded in the official records of the county, containing residences and commercial establishments providing goods and services and retaining the atmosphere of a western frontier ranch-type town and so classified in § 292.15(a).

(4) *Dude ranching.* Development oriented to furnish an outdoor recreational or educational experience related to ranching. Facility development is compatible with the pastoral environment, rustic in nature and harmoniously colored.

(5) *Mineral operations.* All functions, work and activities in connection with exploration, development, mining or processing of mineral resources except prospecting which will not cause significant surface disturbance and will not involve removal of more than a reasonable amount of mineral deposit for analysis and study.

(6) *Private property.* Lands or interests in lands not owned by Federal, State, or local governments but not including unpatented mining claims.

(7) *Ranch-type character.* A low profile, rambling, well-proportioned, rustic appearing, rough-sawn wood or wood and stone structure or group of structures harmoniously situated within a natural environment.

(8) *Residential outbuilding.* Nonhabitable building detached from the residence, such as a garage, woodshed or storage building.

(9) *Secretary.* Secretary of Agriculture.

(10) *Area Ranger.* The Forest Officer having administrative authority for the Sawtooth National Recreation Area.

§ 292.15 General provisions—procedures.

(a) *Classification of private property.* For the purpose of establishing specific standards applicable to the several parcels of private land within the boundaries, such properties are classified and assigned to land use categories as shown on the Land Use Category Map, dated December 15, 1973, on file and available for public inspection in the office of the Area Ranger, Sawtooth National Recreation Area, Ketchum, Idaho. The classification of private properties is based on evaluation of scenic, natural, historic, pastoral, wildlife, and other values.

(b) *Land use categories.* Land use categories shown on the map referred to in paragraph (a) of this section are:

(1) *Designated community.* All properties inside a designated community.

(2) *Residential.* Areas for residential development outside designated communities.

(3) *Commercial.* Areas for commercial development outside designated communities.

(4) *Agriculture.* All properties outside designated communities not placed in a residential or commercial land use category.

(5) *Mineral.* Any areas in the land use in subparagraphs (1) through (4) of this paragraph, used for mineral operations.

(c) *Changes in classification.* The Secretary may make changes in the classification of private lands set forth in paragraph (a) of this section by incorporating such changes in an amendment of these regulations.

(d) *Certification of compliance with standards*—(1) *Present use.* Any owner of property may request in writing the Area Ranger to examine the present use of the property and issue a certification that such present use conforms to the applicable standards established in § 292.16 for the land use category in which the property is placed. If after examination the Area Ranger determines that the present use of the property does so conform, he will issue a certification to this effect.

(2) *Planned development or change in use.* Any owner of property who proposes to change the use or develop his property for other than agricultural use may submit to the Area Ranger a use or development plan setting forth the manner in which and the time by which the property is to be developed and the use to which the property is to be put. If the Area Ranger determines that the development and use plan conforms to the applicable standards established in § 292.16 for the land use category in which the property is placed, he will issue a certification to this effect.

(3) *Notification of action.* Within 45 days after receipt of request for certification, the Area Ranger shall:

(i) Issue the certification.

(ii) Notify applicant that additional information is needed before action can be taken on the application.

(iii) Notify applicant that certification is denied, and reasons for denial.

(iv) Notify applicant that action on the request is deferred for a specified period of time for stated reasons.

(e) *Qualified certifications.* (1) Any owner of a property classified residential or commercial under paragraph (a) of this section which had been improved and was being used for residential or commercial purposes on the effective date of these regulations, but which does not conform to the standards established for properties in the land use category in which the property is placed may nevertheless be issued a certification for period not to exceed 10 years so that the improvements may be made to conform to the standards. Such certification shall specify that it is only effective so long as the property is not subdivided, and is not further improved and the improvements existing on the effective date of these regulations, are not reconstructed, altered or relocated, except to meet standards. The certification shall specify the date on which it shall terminate.

(2) If the Area Ranger determines, prior to certification, that a part or all of a property, for which a request for certification is made, is needed for access to and utilization of public property or for recreation and other facilities, he may except from the certification that part of the property needed for these purposes.

(f) *Revocation of certification.* The Area Ranger will revoke a certification when he finds that the property is being used or developed not in conformance with the terms of the certification or the applicable standards established in § 292.16 or is in imminent danger of being so used or developed. Notice of such revocation will be in writing and delivered to the owner in person or by certified mail. A partial revocation may be made when a portion of a property covered by a certification is determined to be needed for access to and utilization of public property or for recreation and other facilities.

(g) *Effect of certification.* Property for which a certification is held by the owner shall not be acquired by the Secretary by condemnation.

(h) *Effect of noncompliance with standards.* Property for which a determination has been made that it is being used or developed not in conformance with the applicable standards established in § 292.16 for the land use category in which the property is placed may be acquired by the Secretary by condemnation.

(i) *Acquisition by negotiated purchase.* (1) Any privately owned land or interest in land determined by the Secretary to be needed in furtherance of the objectives and purposes for which the Sawtooth National Recreation Area was established may be acquired by negotiated purchase subject only to the limitation in paragraph (j) of this section.

(2) Property which has been developed for use prior to the effective date of these regulations, but which is not in conformance with applicable standards may be acquired by the Secretary through negotiated purchase and the Secretary may permit the owners, their successors or assigns to retain a right of use and occupancy of the improved property for a definite term not beyond December 31, 1988.

(j) *Limitation on acquisitions.* Acquisitions of lands or interests therein for access to and utilization of public property and for recreation and other facilities shall not exceed 5 percent of the total acreage of all private property within the Sawtooth National Recreation Area on August 22, 1972. A land acquisition plan shall be prepared by the Area Ranger and approved by the Regional Forester showing those properties needed for access to and utilization of public property or for recreation and other facilities. Said plan may be revised from time to time upon approval by the Regional Forester. Said plan shall be available for inspection by the public in the office of the Area Ranger.

(k) *Land exchanges.* Some parcels of Federal lands within the Sawtooth National Recreation Area are classfied or may be subsequently classified in the overall general plan for the Recreation Area as suitable for selection through land exchange. Using existing land exchange authorities, these Federal lands may be made available for selection by parties owning land within the boundaries of the National Recreation Area to resolve some existing or potential land use conflicts. The values of the properties so exchanged shall be approximately equal, or, if they are not approximately equal, they shall be equalized by the payment of cash. Federal lands which may be located within the boundaries of designated communities will be considered

for exchange only after acceptable community development plans and ordinances have been implemented.

(l) *Appeals.* (1) Any landowner who is adversely affected by a decision of the Area Ranger under these regulations may take an appeal to the Chief, Forest Service, by filing with the Area Ranger within 30 days a written notice of appeal and a written statement setting forth the reasons why the decision is contrary to, or in conflict with the facts, the law or these regulations; except a denial of a land exchange application is not appealable. Review and decision on the appeal shall be by the Chief or his designated representative: *Provided, however,* That if more than 45 days are required for a decision after receiving the notice of appeal and statement of reasons, the Chief or his designated representative shall notify the landowner and specify the reasons for the delay.

(2) Any landowner who is adversely affected by the decision of the Chief or his designated representative may take an appeal to the Secretary by filing with the Chief, within 30 days after such decision is made, a written notice of appeal and a written statement setting forth the reasons why the decision appealed from is contrary to, or in conflict with the facts, the law or these regulations. Upon receipt of the notice and statement the Chief shall prepare his own statement setting forth the facts and circumstances upon which his decision was based and shall transmit the record to the Secretary for his decision.

(m) *Judicial review.* The United States District Court for the District of Idaho shall have jurisdiction to review these regulations upon a complaint filed within 6 months after the effective date of these regulations, by any affected landowner in an action for a declaratory judgment as provided in the Act of August 22, 1972 (86 Stat. 612), section 4(a).

§ 292.16 Standards.

The standards established in these regulations are in furtherance of the preservation and protection of the natural, scenic, historic, pastoral, and fish and wildlife values and to provide for the enhancement of the recreation values of the Recreation Area.

(a) *Applicability.* The standards set forth in this section for each land use category shall apply to the private land in each such land use category as classified by the Secretary in accordance with § 292.15.

(b) *Changes in standards.* Changes in and addition to the standards may be made from time to time through amendment of these regulations.

(c) *General standards.* The following standards apply to properties in all land use categories.

(1) Use and development of the property will be in conformance with applicable Federal, State, and local laws, regulations and ordinances.

(2) Development, improvement and use of the property will not materially detract from the scenic, natural, historic, pastoral, and fish and wildlife values of the area.

(3) There will be adequate provision for disposal of solid and liquid waste originating on or resulting from use of the property.

(4) All new utilities will be underground.

(5) No structures or other improvements will be constructed in or encroaching upon streambeds, banks and flood plains of live or intermittent streams. Streambeds, banks, and flood plains will not be disturbed, except as may be necessary to construct, operate, and maintain irrigation, fisheries, utilities, roads, and similar facilities or improvements. Any such necessary encroachment will avoid impeding water flow, sedimentation of streams or entrance of deleterious material into streams.

(d) *Designated communities.* (1) The following standards are established until replaced as provided for in subparagraph (2) of this paragraph.

(i) No buildings or structures, or part thereof, erected, constructed, reconstructed, altered, moved, or used for any purpose, except in conformance with the standards established herein.

(ii) No excavation or topographic change, except that required for foundations, utilities, or roads, that would modify or change the scenic beauty of natural hillsides or mountain slope lands.

(iii) Minimum 100-foot frontage on new building sites.

(iv) All new buildings set in 10 feet from each side of property line.

(v) All new buildings set back 20 feet from front property line.

(vi) Only one single-family dwelling for each building site or lot.

(vii) No new building to exceed two stories in height as determined from ground level.

(viii) No building or structure erected with foundation pillars or stilts that exceeds 36 inches above ground level. Pillars or stilts if used, must be enclosed.

(ix) Minimum of 750 square feet for new residences.

(x) All new buildings constructed of logs, shakes, rough lumber, rough wood, and native stone.

(xi) Mobile or semimobile homes permitted only in existing mobile home parks.

(xii) Nonreflective roofs on new buildings.

(xiii) All new steps and walks constructed of wood.

(xiv) Paints or stains to be of earth tones common to the area.

(xv) All buildings and structures, including fences, to be maintained in a useable and serviceable condition or removed. Properties to be maintained in a clean and orderly condition.

(xvi) Existing plus new buildings or structures cannot occupy more than 30 percent of the land surface on a lot less than 20,000 square feet in area. On any lot larger than 20,000 square feet, existing plus new buildings cannot occupy more than 6,500 square feet. Existing properties exceeding this amount as of the effective date of these regulations may not be further developed.

(xvii) The standards in subdivisions (v), (vi), (ix), and (xvi) of this subparagraph shall not apply to properties developed for commercial purposes.

(2) The Area Ranger shall cooperate with each designated community in the preparation of a community development plan and implementing ordinances which will assure that use and development of the private properties within the community will be consistent with the purposes for which the Sawtooth National Recreation Area was established and with the overall general plan of the Recreation Area. The Secretary may then, by amendment of these regulations, replace the standards adopted pursuant to subparagraph (1) of this paragraph with the standards set forth in such community development plan and implementing ordinances as the standards applicable to that designated community.

(e) *Residential.* (1) Vegetative cover and screening requirements. Any combination of vegetative screening, topography, and structure design that renders the residence inconspicuous and not obtrusive as seen from main travel routes.

(2) Buildings.

(i) Not more than one residence on each separately owned contiguous property as recorded in the records of the appropriate county on date of publication of these regulations.

(ii) Not more than two outbuildings with each residence. Aggregate square foot area of outbuildings not to exceed 400 square feet.

(iii) Dwelling size not less than 750 square feet of floor space.

(iv) Building architecture compatible with location and the pastoral environment, rustic in nature, harmoniously colored or natural wood finish or suitable wood substitutes, nonreflective roofs and sidings.

(v) Height of buildings to be in keeping with site characteristics and normally not exceeding on-site tree height, or 30 feet.

(vi) Sufficient setback of buildings from centerline of public roads for safety and unhampered traffic flow.

(vii) Minimum building setback from property line—10 feet.

(3) No excavation or topographic change except that required for buildings, roads, and utilities.

(4) Removal of live trees and other vegetation limited to that necessary to accommodate buildings and roads to allow installation of utilities.

(5) Roads designed, located, and constructed to minimize adverse esthetic impact and soil erosion.

(6) Owner identification and sale or rental signs not to exceed 2 square feet in size.

(7) Buildings and structures, including fences, to be maintained in a usable and serviceable condition or removed.

(8) No further reduction in size of residential ownerships except that which will not impair the objectives for which the

Sawtooth National Recreation Area was established. A certification will be issued pursuant to § 292.15(d) upon application in such cases.

(f) *Commercial.* (1) General. Service provided must serve a need which cannot readily or adequately be provided in a designated community, and must be compatible with the purposes for which the Sawtooth National Recreation Area was established.

(2) Buildings.

(i) Building architecture to be compatible with the pastoral environment, rustic in nature, harmoniously colored or natural wood finish or suitable wood substitutes, nonreflective roofs and sidings.

(ii) Building height to be in keeping with building size, scale, setback from roads and property boundaries, site size, setting, building design and type of use.

(iii) Sufficient setback of buildings from centerline of public roads for safety and unhampered traffic flow.

(3) Only signs identifying the commercial enterprise being conducted on the property. Signs not to exceed 20 square feet in area, 6 feet in length and 15 feet maximum height. Signs to be subdued in appearance and harmonizing in design and color with the surroundings. Signs not complying with the standard may be approved by certifications issued pursuant to § 292.15(d) in special cases.

(4) No flashing lights.

(5) No new mobile or semimobile homes and mobile home parks except where they may be located without substantially impairing or detracting from the scenic, natural, historic, pastoral, and fish and wildlife values of the area.

(g) *Agriculture.* (1) Only structures which do not substantially impair or detract from the scenic, natural, historic, pastoral, and fish and wildlife values of the area and which are necessary for ranching or dude ranching such as dwellings, barns, storage buildings, fences, corrals, irrigation facilities, roads, and utilities.

(2) Buildings to be ranch-type character with log or other rustic exterior with harmoniously colored or natural wood finish and nonreflective surfaces.

(3) Fences and other improvements to be in harmony with the western ranching atmosphere.

(4) Minimum setback of new buildings to be 150 feet from public roads where determined feasible by the Area Ranger.

(5) No further reduction in size of agricultural ownerships except that which will not impair the objectives for which the Sawtooth National Recreation Area was established. A certification will be issued pursuant to § 292.15(d) upon application in such cases.

(6) No signs, billboards or advertising devices except a property identification sign and one sale or rental sign not to exceed 2 square feet in area, harmonious in design and color with the surroundings. Signs not complying with this standard may be approved by certifications issued pursuant to § 292.15(d) in special cases.

(7) Any tree removal and related slash disposal and soil erosion prevention measures to be conducted in a manner that will minimize detrimental effects to the site and adjoining lands.

(8) The general topography of the landscape to be unaltered except for incidental excavation or topographic change required by ranching activities.

(9) Structures and improvements, including fences, to be maintained in usable condition or removed. Those recognized as having historic or esthetic value may remain.

(10) Roads to be designed, located and constructed to minimize esthetic impact and soil movement.

(11) Agricultural practices to be limited to hay production and pasture and range grazing in a manner which does not degrade water quality or result in accelerated soil erosion.

(h) *Mineral operations.* The standards set forth in this paragraph shall apply to a private property or portion thereof in any land use category which is used for mineral operations. To aid in determining whether a planned mineral operation will conform to these standards, the owner of the property shall submit to the Area Ranger a proposed plan of operations. If the Area Ranger determines that the proposed operation conforms to the standards established herein he will approve the plan and such approval shall constitute the certification provided for in § 292.15(d).

(1) Operations will be confined to those locations where they may be conducted without substantially impairing or detracting from the scenic, natural, historic, pastoral, and fish and wildlife values of the area.

(2) The general standards set forth in paragraph (c) of this section shall apply to any mineral operations.

(3) The operations as described in the plan of operation and as they are carried out in accordance with the plan shall:

(i) Comply with Federal and State air and water quality and waste disposal standards.

(ii) Minimize adverse impacts on scenic values.

(iii) Provide for prompt stabilization and restoration of areas disturbed by the operations.

Effective date. These regulations take effect April 29, 1974.

Dated: March 25, 1974.

ROBERT W. LONG,
Assistant Secretary for Conservation, Research, and Education.

[FR Doc.74-7266 Filed 3-28-74;8:45 am]

Title 43—Public Lands: Interior

CHAPTER II—BUREAU OF LAND MANAGEMENT, DEPARTMENT OF THE INTERIOR

APPENDIX—PUBLIC LAND ORDERS

[Public Land Order 5418]

ALASKA

Amendment of Public Land Order No. 5180

By virtue of the authority vested in the President by the Act of June 25, 1910, as amended, 43 U.S.C. 141 (1970), and pursuant to Executive Order No. 10355 of May 26, 1952 (17 FR 4831), and by virtue of the authority vested in the Secretary of the Interior by section 17(d)(1) of the Alaska Native Claims Settlement Act of December 18, 1971, 43 U.S.C. 1616 (d)(1), 1970 Supplement II (hereinafter referred to as the Act), it is ordered as follows:

1. Subject to valid existing rights, Public Land Order No. 5180, of March 9, 1972, as amended, 37 FR 5583–5584, withdrawing lands for classification and for protection of the public interest in lands, is hereby further amended to add the following described lands:

All unreserved public lands in Alaska, or those which may become unreserved unless specified by order at that time.

The lands described above aggregate approximately 15,300,000 acres.

2. While the lands described in paragraph 1 of this order remain withdrawn, the lands shall be subject to administration by the Secretary of the Interior under applicable laws and regulations, and his authority to make contracts, to grant leases, permits, rights-of-way, or easements shall not be impaired by this withdrawal. Applications for leases under the Mineral Leasing Act will be rejected until this order is modified or the lands are appropriately classified to permit mineral leasing.

3. It is hereby determined that the promulgation of this order is not a major Federal action significantly affecting the quality of the human environment and that no detailed statement pursuant to

section 102(2)(C) of the National Environmental Policy Act of 1969, 42 U.S.C. 4332(2)(C), is not required.

ROGERS C. B. MORTON,
Secretary of the Interior.

MARCH 25, 1974.

[FR Doc.74-7261 Filed 3-28-74;8:45 am]

Title 50—Wildlife and Fisheries

CHAPTER I—BUREAU OF SPORT FISHERIES AND WILDLIFE, FISH AND WILDLIFE SERVICE, DEPARTMENT OF THE INTERIOR

PART 33—SPORT FISHING

Tawaukon National Wildlife Refuge, N. Dak.

The following special regulation is issued and is effective March 29, 1974.

§ 33.5 Special regulations; sport fishing, for individual wildlife refuge areas.

NORTH DAKOTA

TEWAUKON NATIONAL WILDLIFE REFUGE

Sport fishing on the Tewaukon National Wildlife Refuge, Cayuga, North Dakota, is permitted only on the areas designated by signs as open to fishing. These open areas are Lake Tewaukon, Mann Lake, and Sprague Lake, comprising 1,440 acres, and are shown on maps available at refuge headquarters and from the office of the Area Manager, Bureau of Sport Fisheries and Wildlife, Box 1897, Bismarck, North Dakota 58501. Sport fishing shall be in accordance with all applicable State regulations subject to the following special conditions:

(1) The open season for sport fishing on Sprague Lake and Mann Lake extends from May 4, 1974, through September 30, 1974, daylight hours only.

(2) The open season for sport fishing on Lake Tewaukon extends from May 4, 1974, through November 15, 1974, daylight hours only.

(3) Fishing on Lake Tewaukon will be limited to certain designated shoreline areas from October 1, 1974, through November 15, 1974, and fishing from boats is not permitted.

The provisions of this special regulation supplement the regulations which govern fishing on wildlife refuge areas generally which are set forth in Title 50, Code of Federal Regulations, Part 33, and are effective through November 15, 1974.

TYRUS W. BERRY,
Acting Refuge Manager.

MARCH 20, 1974.

[FR Doc.74-7259 Filed 3-28-74;8:45 am]

Title 6—Economic Stabilization

CHAPTER I—COST OF LIVING COUNCIL

PART 150—COST OF LIVING COUNCIL PHASE IV PRICE REGULATIONS

PART 152—COST OF LIVING COUNCIL PHASE IV PAY REGULATIONS

Exemption of Anthracite, Bituminous Coal, and Lignite

The purpose of these amendments is to exempt prices charged for anthracite, bituminous coal, and lignite by firms which manufacture those products, to add a further exemption for the prices charged by firms primarily engaged in providing mining services to the coal industry, and to add a parallel exemption to the Phase IV pay regulations.

The Council has determined that exemption of coal will encourage increased production to meet current energy problems, as the greatly increased world demand for coal has caused prices to rise and availability of supplies to decrease. Approximately 80 percent of coal sales are already exempt under § 150.54(n) which exempts sales of coal under long-term contracts to public utilities, under § 150.54(d) which exempts export prices, and § 150.60 which exempts firms with 60 or fewer employees. In addition, over 13 percent of the industry's production is accounted for by captive coal firms which are controlled by steel firms or electric utilities using the coal firms' products. Sales by these coal firms are generally intra-firm transfers and are not subject to direct price controls. Thus, average coal prices are not expected to be affected severely by this exemption. Most of the remaining 7 percent of coal sales are to steel mills, industrial establishments, and public utilities. The Council feels that this exemption should help to augment the domestic availability of coal by discouraging exports in the short run and by encouraging the opening of new mines which will increase production in the long run.

In return for decontrol the Council has received voluntary commitments from 10 of the leading bituminous coal producers (1) to increase bituminous coal production, (2) to request the Bituminous Coal Operators Association to begin negotiations on the present labor agreement which expires in November 1974, and (3) not to permit the weighted average price charged for coal to rise above $30 a ton before November 12, 1974.

Therefore, in accordance with the Council's policy of removing controls selectively where conditions warrant, the Council is today exempting the prices charged for the following products by manufacturers of those products: anthracite, bituminous coal, and lignite as listed in the Standard Industrial Classification Manual, 1972 edition, Industry Nos. 1111 and 1211. As a corresponding action the Council is also exempting the prices charged by firms that provide anthracite, bituminous coal, and lignite mining services as listed in the Standard Industrial Classification Manual, 1972 edition, in Industry Numbers 1112 and 1213. This exemption is an expansion of the already existing exemption of sales of coal under long-term contracts to public utilities, § 150.54(n).

Under §§ 150.11(e) and 150.161(b), a firm with revenues from the sale of exempt items remains subject to the profit margin constraints and reporting provisions of the Phase IV program unless during its most recent fiscal year it derived both less than $50 million in annual sales or revenues from the sale or lease of nonexempt items and 90 percent or more of its sales or revenues from the sale of exempt items or exempt sales.

As a complementary action to the exemption from price controls, the Council has also exempted pay adjustments affecting employees engaged on a regular and continuing basis in the operation of an establishment in the coal mining industry. The exemption is set forth in new § 152.39m. "Establishment in the coal mining industry" is defined as an establishment classified in the Standard Industrial Classification Manual, 1972 edition, under Major Group No. 11 (Anthracite Mining) or 12 (Bituminous Coal and Lignite Mining) and primarily engaged in mining or mining service activities classified under such Major Groups.

The exemption is inapplicable to any employee engaged in construction operations (within the meaning of § 152.102(f)), even if the employee works at an establishment classified under Major Group 11 or 12. This limitation on the exemption is necessary because the Council and the Construction Industry Stabilization Committee exercise mandatory control jurisdiction over pay adjustments in the construction industry and it would be inappropriate at this time to exempt construction pay adjustments.

The exemption is inapplicable to any employee who receives an item of incentive compensation, or who is a member of an executive control group. The exemption is also inapplicable to any employee whose duties and responsibilities are not of a type exclusively performed in or related to the coal mining industry and whose pay adjustments are historically related to the pay adjustments of employees performing such duties outside the industry and are not related to the pay adjustments of other employees that are within this or another industry exempted under Subpart D of Part 152. The exemption is further inapplicable to employees who are part of an appropriate employee unit where 25 percent or more of the members of such unit are not engaged on a regular and continuing basis in the operation of an establishment engaged in activities exempted under Subpart D. In cases of uncertainty of application, particularly with respect to mining activities that may be related to construction, inquiries concerning the scope or coverage of the pay exemption should be addressed to the Administrator, Office of Wage Stabilization, P.O. Box 672, Washington, D.C. 20044.

As with all exemptions from Phase IV controls, firms subject to these amendments remain subject to review for compliance with appropriate regulations in effect prior to these exemptions. A firm affected by these amendments will be held responsible for its pre-exemption compliance under all phases of the Economic Stabilization Program. A firm affected by these exemptions alleged to be in violation of stabilization rules in effect prior to these exemptions is subject to the same compliance actions as a non-exempt firm. These compliance actions include investigations, issuance of notices of probable violation, issuance of remedial

orders requiring rollbacks or refunds, and possible penalty of $2,500 for each stabilization violation.

The Council retains the authority to reestablish price and wage controls over any of the industries exempted by these amendments if price or wage behavior is inconsistent with the policies of the Economic Stabilization Program. The Council also has the authority, under §§ 150.162 and 152.6, to require firms to file special or separate reports setting forth information relating to the Economic Stabilization Program in addition to any other reports which may be required under the Phase IV controls program.

Because the purpose of these amendments is to grant an immediate exemption from the Phase IV price and pay regulations, the Council finds that publication in accordance with normal rulemaking procedure is impracticable and that good cause exists for making these amendments effective in less than 30 days. Interested persons may submit written comments regarding this amendment. Communications should be addressed to the Office of the General Counsel, Cost of Living Council, 2000 M Street NW., Washington, D.C. 20508.

(Economic Stabilization Act of 1970, as amended, Pub. L. 92-210, 85 Stat. 743; Pub. L. 93-28, 87 Stat. 27; E.O. 11695, 38 FR 1743; E.O. 11730, 38 FR 19345; Cost of Living Council Order No. 14, 38 FR 1489.)

In consideration of the foregoing, Parts 150 and 152 of Title 6 of the Code of Federal Regulations are amended as set forth herein, effective March 27, 1974.

Issued in Washington, D.C., on March 27, 1974.

JAMES W. MCLANE
Deputy Director,
Cost of Living Council.

1. In 6 CFR Part 150, § 150.54(n) is amended to read as follows:

* * * * *

§ 150.54 Certain price adjustments.

(n) *Anthracite, bituminous coal, and lignite.* Prices charged by firms engaged in providing anthracite, bituminous coal, and lignite mining services and firms engaged in the manufacturing of anthracite, bituminous coal, and lignite are exempt if those activities are within the scope of Major Groups 11 or 12 of the Standard Industrial Classification Manual, 1972 edition.

* * * * *

2. In 6 CFR Part 152, Subpart D is amended by adding thereto a new § 152.39m to read as follows:

§ 152.39m Coal mining industry.

(a) *Exemption.* Pay adjustments affecting employees engaged on a regular and continuing basis in the operation of an establishment in the coal mining industry or in support of such operation are exempt from and not limited by the provisions of this title.

(b) *Establishment in the coal mining industry.* For purposes of this section, "Establishment in the coal mining industry" means an establishment classified in the Standard Industrial Classification Manual, 1972 edition, under Major Group No. 11 (Anthracite Mining) or 12 (Bituminous Coal and Lignite Mining) and primarily engaged in mining or mining service activities classified under such Major Group.

(c) *Covered employees.* For purposes of this section, an employee is considered to be engaged on a regular and continuing basis in the operation of an establishment in the coal mining industry or in support of such operation only if such employee is employed at an establishment in the coal mining industry and only if such employee is employed by the firm which operates such establishment.

(d) *Limitation.* The exemption provided in paragraph (a) of this section shall not be applicable to—

(1) An employee engaged in construction operations (within the meaning of § 152.102(f)).

(2) An employee who receives an item of incentive compensation subject to the provisions of § 152.124, § 152.125, or § 152.126.

(3) An employee who is a member of an executive control group (determined pursuant to § 152.130).

(4) Employees whose occupational duties and responsibilities are of a type not exclusively performed in or related to the coal mining industry and whose pay adjustments are—

(i) Historically related to the pay adjustments of employees performing such duties outside the coal mining industry; and

(ii) Not related to pay adjustments of another unit of employees engaged on a regular and continuing basis in the operation of an establishment exempted under this subject, or in the operation of an establishment in the coal mining industry or in support of such operation within the meaning of paragraph (c) of this section.

(5) Employees who are members of an appropriate employee unit if 25 percent or more of the employees who are members of such unit are not engaged on a regular and continuing basis in the operation of an establishment engaged in activities exempted under this subpart.

(e) *Effective date.* The exemption provided in this section shall be applicable to pay adjustments with respect to work performed on and after March 27, 1974.

[FR Doc.74-7430 Filed 3-27-74;4:47 pm]

PART 155—PHASE IV PRICE PROCEDURAL REGULATIONS

Exceptions and Compliance Procedures

The purpose of this amendment is to further provide for the effective and orderly administration of compliance matters by precluding consideration of exceptions requests in cases which would more appropriately be resolved through compromise of civil penalties.

The Cost of Living Council recently took several steps to simplify and otherwise improve its procedural regulations in order to more effectively resolve compliance matters. Among other actions, the Council delegated full authority to the Internal Revenue Service to resolve price violations cases through the compromise of civil penalties procedures and to dispose of Phase I, II and III price violations matters through the use of the Phase IV price procedural regulations.

The present amendment is intended to further improve the Phase IV compliance effort by cutting off consideration of exception requests in those cases where the firm concerned has already violated the regulation from which an exception is sought and compliance actions have been initiated by the Council or the IRS. The Council believes that too much delay has been encountered in resolving violations cases where requests for retroactive exceptions have been permitted and that any mitigating factors such as inequity or hardship which the firm in violation may wish to assert are more properly raised under the compromise of civil penalties procedures.

Heretofore, a firm which violated a price rule (such as charging a price in excess of the freeze price or exceeding the profit margin limitation) was permitted after receiving a remedial order to file a request for exception from the regulation concerned. If the exception was granted, the effect was to retroactively nullify the violation and to revoke the remedial order. If the exception was denied the firm could seek reconsideration. If the relief requested was ultimately denied upon reconsideration the Council would resume its compliance effort through reactivation of the remedial order. However, review of such cases through the exceptions channels has unnecessarily burdened the Council's staff and in some cases as much as one year has elapsed before ultimate resolution of the matter.

Furthermore, review of the matter through the exceptions procedures appears inappropriate from other considerations. Based on experience to date in Phase IV, the Council believes that the practice of retroactively excusing violations through the exceptions procedures does not advance the goals of the Economic Stabilization Program. Instead, it tends to encourage non-compliance and is unfair to firms which are similarly situated but which faithfully adhere to the regulations for their duration or which, while complying with the regulations, seek exceptions prospectively.

Finally, this amendment will permit the Council to work more rapidly toward completion of pending exceptions cases which are unaffected by this amendment. At the same time this amendment will permit the IRS to more promptly dispose of pending violations cases. The amendment therefore is expected to significantly aid in the effort to complete action on exceptions and compliance matters remaining in Phase IV.

While now denied the possibility of relief through the exceptions procedures, a firm in violation may nevertheless obtain substantial relief, if merited, through compromise procedures. For example, a firm which received a remedial order to remit all revenues derived from charging prices in violation of the freeze regulations may request that due to inability to pay the amount involved or other extenuating circumstances the penalty be reduced to an appropriate amount to be mutually agreed in accordance with the compromise of civil penalties procedures. Under this method of disposition of the case, the payment of a civil penalty serves to strengthen the Council's compliance efforts by deterring unlawful pricing behavior while at the same time substantial relief is afforded in meritorious cases.

This amendment applies to profit margin violations as well as to more specific pricing violations. As a general rule, the fact that a profit margin violation was not realized or discovered until the financial statements for the fiscal year concerned were prepared does not excuse the violation. Most firms check profit margin compliance on a quarterly basis and a firm which has triggered the profit margin limitation by raising prices bears the affirmative responsibility to set prices at levels which will avoid a profit margin violation. If a violation is discovered by the IRS or the Council, it is too late to seek an exception to adjust the base period profit margin in order to avoid the violation for the fiscal year concerned. However, an exception with respect to the base period may be sought with respect to future profit margin compliance. In addition, any mitigating factors with respect to the profit margin violation for the year concerned may be raised under the appropriate violations procedures including compromise of civil penalties.

To carry out the Council's intent in this matter, a sentence is added to § 155.41 which provides that when a firm comes under investigation or receives a notice of probable violation or a remedial order it no longer qualifies to seek an exception which would nullify a violation covered by that investigation, notice or order. Pending exceptions requests affected by this amendment will be dismissed with notification to both the applicant and the IRS compliance division. However, any request for reconsideration which relates to an exception which was denied in whole or in part prior to the effective date of this amendment remains unaffected by this amendment and will continue to be processed.

Because the purpose of this amendment is to provide immediate guidance with respect to decisions of the Council, the Council finds that publication in accordance with normal rule making procedure is impracticable and that good cause exists for making this amendment effective in less than 30 days. Interested persons may submit written comments regarding this amendment. Communications should be addressed to the Office of the General Counsel, Cost of Living Council, 2000 M Street, NW., Washington, D.C. 20508.

(Economic Stabilization Act of 1970, as amended, Pub. L. 92-210, 85 Stat. 743; Pub. L. 93-28, 87 Stat. 27; E.O. 11695, 38 FR 1473; E.O. 11730, 38 FR 19345; Cost of Living Council Order No. 14, 38 FR 1489.)

In consideration of the foregoing, Part 155 of Title 6 of the Code of Federal Regulations is amended as set forth herein, effective March 27, 1974.

Issued in Washington, D.C., on March 27, 1974.

JAMES W. MCLANE,
Deputy Director,
Cost of Living Council.

The first paragraph of § 155.41 is amended to read as follows:

§ 155.41 Purpose and scope.

Exceptions from the provisions of Part 150 of this title may be granted for the purpose of preventing or correcting a serious hardship or gross inequity. However, a person who has violated the regulation with respect to which an exception is sought and who in connection with that matter is under investigation or has received a notice of probable violation or remedial order shall not qualify to obtain an exception which would nullify that violation in whole or in part.

* * * * *

[FR Doc.74-7393 Filed 3-27-74;2:46 pm]

PART 150—PHASE IV PRICE REGULATIONS

PART 152—PHASE IV PAY REGULATIONS

Exemption of Aluminum Production and Certain Aluminum Products

The purpose of these amendments is to exempt under the Phase IV price regulations the sale by producers, manufacturers and wholesalers of aluminum ores, alumina, aluminum ingot, basic shapes, castings, forgings and most aluminum products and to add a parallel exemption under the Phase IV pay regulations.

The Cost of Living Council has not permitted prices for aluminum and copper to rise in accordance with the general cost-justification and prenotification procedures in Phase IV. Instead, the Council has permitted price increases only upon special periodic review of prices and costs in these industries. In December 1973, the Council promulgated a special rule (§ 150.208) which permitted an upward adjustment in base prices to the level of May 1970. In explaining this action, the Council stated that proposed price increases above those levels would be held in abeyance pending a further review of these industries in March 1974.

Having now completed its review of current costs and prices in the aluminum industry, the Council has concluded that it is appropriate to extend price and pay exemption to this industry at this time. An exemption with respect to all nonferrous metals except aluminum and copper was previously granted, and the Council has not yet completed its review of costs and prices in the copper industry.

The Council has determined that price controls have contributed to the establishment of a two-tier pricing structure, in which the foreign and domestic spot price for aluminum ingot is approximately ⅓ higher than the price which domestic producers are able to charge. This situation has led to two undesirable developments. First, there is increased incentive to export metal for which strong demand is present in the U.S. Second, the smaller nonintegrated manufacturers of aluminum products, who make up about 20 percent of the market and who must buy a significant portion of their raw material needs (aluminum ingot or billet) from the foreign or domestic spot market, are unable to purchase metal at a price which would allow them to meet domestic competitive prices for finished products. It is anticipated that several plants of small nonintegrated firms will close within the next few weeks due to unavailability of billet unless these firms are permitted to charge prices for their products which more nearly reflect foreign and domestic spot metal prices.

In addition, industry production is now close to 100 percent capacity, due to increased worldwide demand. It is expected that decontrol will spur plans for the increased capacity which will be necessary to meet future domestic and foreign aluminum needs.

Finally, the Council has obtained individual and voluntary commitments for price restraint from four leading aluminum producers in return for decontrol at this time. First, the firms have separately committed to price ceilings for 99.5 percent primary aluminum ingot, the primary raw material for fabricated aluminum products. Compared with a current price under controls of 29 cents per pound and a current world price of about 34 cents to 35 cents and a spot price of over 40 cents per pound, the committing firms have agreed to charge no more than 31.5 cents through June 1 and no more than 33.5 cents per pound through August 1, 1974. Second, prices which may be charged for other primary basic shapes during these periods must not exceed price levels which reflect the established market relationships between 99.5 percent primary aluminum ingot and those other primary basic shapes. Third, through August 1, 1974, the historic rate of sales of primary aluminum basic shapes to unrelated domestic nonintegrated firms will be maintained in order to avoid market distortions. This applies only to sales not covered by existing contractual agreements.

Under these amendments, prices charged for aluminum ores (including bauxite), alumina, aluminum ingot, basic shapes and all other aluminum products at the manufacturing and wholesaling level are exempt as long as the product contains more than 50 percent by value of aluminum, aluminum alloy and other price-exempt metal. The exemption does not extend, however, to the sale of metal cans (SIC 3411) or automotive stampings (SIC 3465) which contain aluminum or aluminum alloy, or to the sale of chemicals (other than alumina) which contain aluminum. The aluminum products covered by this exemption are listed in Industry No. 1051 and in Major Groups 33 and 34 of the Standard Industrial Classification Manual, 1972 edition. The exemption of products under Major Group 33 includes, but is not limited to, the products listed under Industry Nos. 3334, 3353, 3354, 3355 and 3361. Although some of the aluminum products within Major Group 33 are listed under Industry Nos. 3341, 3357, 3398, and 3399, other products listed under those Industry Nos. are not exempted by these amendments. For example, "nonferrous insulated wire", listed under SIC Industry No. 3357, is not exempt under these amendments if it is copper wire or otherwise does not meet the content test stated above. The same consideration apply to the exemptions under Major Group 34.

Under §§ 150.11(e) and 150.161(b), a firm with revenues from the sale of exempt items remains subject to the profit margin constraints and reporting provisions of the Phase IV program unless during its most recent fiscal year it derived both less than $50 million in annual sales or revenues from the sale or lease of nonexempt items and 90 percent or more of its sales or revenues from the sale of exempt items or exempt sales.

As a complementary action to the exemption from price controls, the Council has also exempted pay adjustments affecting employees engaged on a regular and continuing basis in the operation of an establishment in the aluminum industry. The exemption is set forth in new § 152.39n. "Establishment in the aluminum industry" is defined as an establishment classified in the Standard Industrial Classification Manual, 1972 edition, under Major Group Number 33 or 34, and primarily engaged in the manufacturing or processing of items whose raw material content is, by value, greater than 50 percent aluminum or aluminum alloy or other price-exempt metal. The definition also includes an establishment engaged in the wholesaling of the aforementioned items, a manufacturer of alumina, and an establishment engaged in the mining of bauxite and other aluminum ores (SIC Industry Number 1051).

The definition expressly excludes manufacturers of aluminum containers classified under Industry Number 3411, and establishments engaged in the manufacture of automotive stampings, classified under Industry Number 3465.

The exemption is inapplicable to any employee who receives an item of incentive compensation, or who is a member of an executive control group. The exemption is also inapplicable to any employee whose duties and responsibilities are not of a type exclusively performed in or related to the aluminum industry and whose pay adjustments are historically related to the pay adjustments of employees performing such duties outside the industry and are not related to the pay adjustments of other employees that are within this or another industry exempted under Subpart D of Part 152. The exemption is further inapplicable to employees who are part of an appropriate employee unit where 25 percent or more of the members of such unit are not engaged on a regular and continuing basis in the operation of an establishment engaged in activities exempted under Subpart D. In cases of uncertainty of application, inquiries concerning the scope or coverage of the pay exemption should be addressed to the Administrator, Office of Wage Stabilization, P.O. Box 672, Washington, D.C. 20044.

As with all exemptions from Phase IV controls, firms subject to these amendments remain subject to review for compliance with appropriate regulations in effect prior to these exemptions. A firm affected by these amendments will be held responsible for its pre-exemption compliance under all phases of the Economic Stabilization Program. A firm affected by these exemptions alleged to be in violation of stabilization rules in effect prior to these exemptions is subject to the same compliance actions as a nonexempt firm. These compliance actions include investigations, issuance of notices of probable violation, issuance of remedial orders requiring rollbacks or refunds, and possible penalty of $2,500 for each stabilization violation.

The Council retains the authority to reestablish price and wage controls over any of the industries exempted by these amendments if price or wage behavior is inconsistent with the policies of the Economic Stabilization Program. The Council also has the authority, under §§ 150.162 and 152.6, to require firms to file special or separate reports setting forth information relating to the Economic Stabilization Program in addition to any other reports which may be required under the Phase IV controls program.

Because the purpose of these amendments is to grant an immediate exemption from the Phase IV price and pay regulations, the Council finds that publication in accordance with normal rulemaking procedure is impracticable and that good cause exists for making these amendments effective in less than 30 days. Interested persons may submit written comments regarding this amendment. Communications should be addressed to the Office of the General Counsel, Cost of Living Council, 2000 M Street NW., Washington, D.C. 20508.

(Economic Stabilization Act of 1970, as amended, Pub. L. 92-210, 85 Stat. 743; Pub. L. 93-28, 87 Stat. 27; E.O. 11695, 38 FR 1743; E.O. 11730, 38 FR 19345; Cost of Living Council Order No. 14, 38 FR 1489.)

In consideration of the foregoing, Parts 150 and 152 of Title 6 of the Code of Federal Regulations are amended as set forth herein, effective March 28, 1974.

Issued in Washington, D.C., on March 28, 1974.

JAMES W. MCLANE,
Deputy Director,
Cost of Living Council.

1. In Part 150, a new paragraph (k) is added to § 150.58 to read as follows:

§ 150.58 Additional price adjustments.

* * * * *

(k) *Aluminum Production and Certain Aluminum Products.*

The prices which manufacturers, producers, providers and wholesalers of the following aluminum ores, products, and services charge for those ores, products and services are exempt: the aluminum ores, products, and services listed in the SIC Manual, 1972 edition, under Industry No. 1051, Major Groups 33 and 34 (except Industry Nos. 3411 and 3465), and alumina. The exemption provided in the preceding sentence applies only to those products (other than aluminum ore and alumina) whose raw material content by value is greater than 50 percent aluminum, aluminum alloy, and other price-exempt metal. The exemption of products under Major Group 33 includes, but is not limited to, the products listed under Industry Nos. 3334, 3353, 3354, 3355, and 3361.

2. In 6 CFR Part 152, Subpart D is amended by adding thereto a new § 152.39n to read as follows:

§ 152.39n Aluminum industry.

(a) *Exemption.* Pay adjustments affecting employees engaged on a regular and continuing basis in the operation of an establishment in the aluminum industry or in support of such operation are exempt from and not limited by the provisions of this title.

(b) *Establishment in the aluminum industry.* For purposes of this section, "Establishment in the aluminum industry" means an establishment classified in the Standard Industrial Classification Manual, 1972 edition, under Major Group Number 33 (Primary Metal Industries) or 34 (Fabricated Metal Products, Except Machinery and Transportation Equipment), and primarily engaged in the activities classified under such

Numbers with respect to items whose raw material content is, by value, greater than 50 percent aluminum or aluminum alloy or other price-exempt metal. The term also means an establishment primarily engaged in the wholesaling of the aforementioned items, an establishment classified under Industry Number 1051 (Bauxite and Other Aluminum Ores) primarily engaged in the mining of such ores, and an establishment primarily engaged in the manufacture of alumina. Notwithstanding the provisions of the first sentence of this paragraph, the term does not mean an establishment primarily engaged in the manufacture of metal cans made of aluminum alloy and classified under Industry Number 3411 (Metal Cans) or primarily engaged in the manufacture of automotive stampings and classified under Industry Number 3465 (Automotive Stampings).

(c) *Covered employees.* For purposes of this section, an employee is considered to be engaged on a regular and continuing basis in the operation of an establishment in the aluminum industry or in support of such operation only if such employee is employed at an establishment in the aluminum industry and only if such employee is employed by the firm which operates such establishment.

(d) *Limitations.* The exemption provided in paragraph (a) of this section shall not be applicable to—

(1) An employee who receives an item of incentive compensation subject to the provisions of § 152.124, 152.125, or 152.126.

(2) An employee who is a member of an executive control group (determined pursuant to § 152.130 of this chapter).

(3) Employees whose occupational duties and responsibilities are of a type not exclusively performed in or related to the aluminum industry and whose pay adjustments are—

(i) Historically related to the pay adjustments of employees performing such duties outside the aluminum industry; and

(ii) Not related to pay adjustments of another unit of employees engaged on a regular and continuing basis in the operation of an establishment exempted under this subpart or in the operation of an establishment in the aluminum industry or in support of such operation within the meaning of paragraph (c) of this section.

(4) Employees who are members of an appropriate employee unit if 25 percent or more of the employees who are members of such unit are not engaged on a regular and continuing basis in the operation of an establishment exempted under this subpart.

(e) *Effective date.* The exemption provided in this section shall be applicable to pay adjustments with respect to work performed on and after March 28, 1974.

[FR Doc.74-7446 Filed 3-28-74;8:55 am]

Title 24—Housing and Urban Development

CHAPTER II—OFFICE OF ASSISTANT SECRETARY FOR HOUSING PRODUCTION AND MORTGAGE CREDIT—FEDERAL HOUSING COMMISSIONER (FEDERAL HOUSING ADMINISTRATION), DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

SUBCHAPTER B—MORTGAGE AND LOAN INSURANCE PROGRAMS UNDER NATIONAL HOUSING ACT

[Docket No. R-74-235]

PART 201—PROPERTY IMPROVEMENT AND MOBILE HOME LOANS

Factory Inspection of Mobile Homes

On September 4, 1973 a notice of proposed rulemaking was published in the FEDERAL REGISTER (38 FR 23803) by the Department of Housing and Urban Development proposing a new system for third party factory inspection of mobile homes financed with loans insured under this part.

Interested persons were given 30 days in which to submit written comments or suggestions. Comments and suggestions were received from trade associations, state agencies, mobile home manufacturers, testing laboratories, and other interested parties.

Comments germane to the proposal were favorable. Some respondents suggested clarification and improvements in the text.

Suggestions that have been adopted are as follows:

(1) In § 201.520, *Structural design and standards,* paragraph (b) has been amended to provide that compliance with specifications in effect at the time the home is manufactured is required, rather than compliance at the time the loan is made. This change is made by reason of the fact that at the time the loan is made the standards may have been changed from those in effect at the time the home was manufactured.

(2) The text of paragraph (b) of § 210.520 and the text of § 210.510 have also been amended to provide that the home shall bear the "label or seal" of the approved inspection agency.

Several respondents expressed doubts as to the requirements that the Secretary may set for approval of testing laboratories, the adequacy of the approval procedures of state agencies, and the effect that the Secretary's proposal may have on existing state requirements.

The regulation requires that as a condition of application for approval by the Commissioner a testing laboratory must be either an agency of a state, or if a private testing laboratory, have been approved by at least two states. Private testing laboratories meeting this condition would still be required to obtain approval of the Commissioner.

Testing laboratories would be required to meet all applicable state or local requirements and the Secretary's requirements would not preempt such requirements, or otherwise affect or modify these requirements.

A respondent suggested that there should be collaboration with the Veterans Administration on inspection procedures. Since inspection by the Veterans Administration of mobile home manufacturers is done by government employees rather than by "third parties", collaboration on this question would not be pertinent.

A respondent expressed concern that there might be a duplication of inspection of appliances that had been previously inspected and "labeled" or "listed" by an inspection organization.

Inspection under these regulations is confined to compliance with ANSI standards. ANSI standards provide for acceptance of "listed" or "labeled" products and therefore no re-inspection of "labeled" or "listed" appliances would be called for.

It was suggested § 201.521 be amended to substitute the term "testing program" for "quality control program". This change was not made as the term "quality control program" is most descriptive of the objective of this rule.

A respondent suggested that the requirement that inspection agencies be "independent" be omitted. Another respondent suggested that "independent" be defined in terms of financial strength and other criteria. These suggestions were not accepted. While some hardship may result, the requirement that an inspection agency be independent appears to be necessary to avoid real or apparent conflicts of interest. Measuring a testing agency's qualification in terms of its financial strength would appear not to be a clearly relevant criterion.

1. Accordingly, § 201.520(b) is amended to read as follows:

§ 201.520 Structural design and standards.

* * * * *

(b) *ANSI criteria.* The requirement of paragraph (b) of this section may be satisfied by compliance with the specifications in effect at the time the home is manufactured, which are prescribed in mobile home standard No. A119.1, as approved by the American National Standards Institute (formerly the United States of America Standards Institute), hereinafter referred to as "ANSI." A certification shall be obtained from the manufacturer stating that the mobile home was constructed in accordance with the ANSI requirements and that the home bears the label or seal of an independent inspecting agency certifying that the mobile home was constructed in accordance with the ANSI requirements.

* * * * *

2. A new § 201.521 is proposed to read as follows:

§ 201.521 Factory inspection.

The home shall display a seal or label certifying that it has been subject to representative inspections in accordance with a quality control program approved

by the Commissioner and is in compliance with the requirements of § 201.520. Inspections shall be made by a testing agency or organization approved by the Commissioner.

3. A new § 201.522 is proposed to read as follows:

§ 201.522 Private testing organization.

A private testing organization which applies for approval by the Commissioner, shall establish that it has been approved by at least two official state agencies to inspect and certify mobile homes and that it is actively engaged in the inspection and certification of mobile homes.

(Sec. 7(d), 79 Stat. 670 (42 U.S.C. 3535(d)); sec. 2, 48 Stat. 1246 (12 U.S.C. 1703))

Effective date. This amendment is effective April 29, 1974.

SHELDON B. LUBAR,
Assistant Secretary of Housing Production and Mortgage Credit, FHA Commissioner.

[FR Doc.74-7331 Filed 3-28-74;8:45 am]

Proposed Rules

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rulemaking prior to the adoption of the final rules.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[21 CFR Parts 1301, 1304, 1305]

ETORPHINE HYDROCHLORIDE AND DIPRENORPHINE

Proposed Controls

The Drug Enforcement Administration on November 23, 1973, published a notice in the FEDERAL REGISTER (38 FR 32262) proposing the transfer of etorphine hydrochloride from Schedule I to Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 821 et seq.). A final notice transferring etorphine hydrochloride to Schedule II is published this date in the FEDERAL REGISTER.

Etorphine hydrochloride is a derivative of the opium alkaloid Thebaine. It is a morphine-like agent with an analgesic potency, depending on test methods, that is 80 to 1,000 times greater than morphine. Because of its ability to produce narcosis at very low doses, etorphine hydrochloride has been approved by the Food and Drug Administration for the immobilization of wild and exotic animals (38 FR 15050).

Diprenorphine, a Schedule II controlled substance, is the only effective antidote to reverse the state of narcosis produced by etorphine hydrochloride. Diprenorphine has been approved by the Food and Drug Administration as an etorphine hydrochloride antagonist. (38 FR 15050.)

Due to the high potential for abuse of these substances with their limited medical uses and ability to produce severe psychological and physical dependence, the Drug Enforcement Administration, in concert with the Special Action Office of Drug Abuse Prevention and the Food and Drug Administration promulgated and agreed to specific procedures relating to their distribution. The American Cyanamid Co. (the holder of the New Animal Drug Application) and the D–M Pharmaceuticals Inc. (the firm marketing the product under the New Animal Drug Application) have agreed to abide by the following procedures to ensure against the abuse, diversion or misuse of these substances:

1. The distribution of etorphine hydrochloride and diprenorphine is restricted to licensed veterinarians engaged in zoo and exotic animal practice, wildlife management programs, and/or research. Only veterinarians who are directly engaged in zoo and exotic animal practice, wildlife management programs, and/or research may obtain etorphine hydrochloride or diprenorphine. These substances will not be available to other practicing veterinarians or other practitioners (except for authorized researchers). The Food and Drug Administration has restricted the use of etorphine hydrochloride and diprenorphine by or on the order of a licensed veterinarian. The Drug Enforcement Administration shall transmit additional information to the Food and Drug Administration indicating its willingness to permit other qualified persons to use these substances if the Food and Drug Administration deems it proper and changes the labelling of the substances.

2. In order to provide maximum security in the distribution, storage and use of etorphine hydrochloride and diprenorphine, all registrants submitting order forms for these substances will be checked by the Drug Enforcement Administration to ensure that they are properly authorized to handle these substances and are prepared to adhere to the special safeguards set forth in the regulations. [An amendment to § 1301.74 (g) to implement this requirement is proposed below.]

3. Registrants handling etorphine hydrochloride or diprenorphine shall be required to store these substances in a safe or steel cabinet equivalent to a United States Government Class V security container. The storage of these substances will be limited to reasonable quantities to avoid increased vulnerability of theft. [An amendment to § 1301.75(d) of the regulations to implement this requirement is proposed below.]

4. The order forms submitted by registrants desiring to purchase etorphine hydrochloride or diprenorphine must contain those substances only. If an order form for etorphine hydrochloride and diprenorphine is submitted to the supplier containing any other controlled substance it shall not be filled. [Amendments to § 1305.16 (Special procedure for filling certain order forms) and § 1305.06 (Procedure for executing order forms) to implement these requirements are proposed below.]

5. The supplier of etorphine hydrochloride and diprenorphine must maintain order forms for those substances separately from all other order forms and records required to be maintained by the registrant pursuant to 21 CFR Part 1304. [An amendment to § 1305.13 (Preservation of order forms) to implement this requirement is proposed below.]

6. An additional reporting requirement is imposed upon the manufacturer of etorphine hydrochloride and diprenorphine. The manufacturer is required to forward a copy of all order forms received for these subtances to the Drug Enforcement Administration for inspection on a weekly basis. [An amendment to § 1304.38(d) (Reports from manufacturers of bulk materials or dosage units) to implement this requirement is proposed below.]

7. Etorphine hydrochloride and diprenorphine shall only be shipped to the purchaser at the location printed by the Administration on the order form. Shipment is to be made by the most secure method using substantial packaging with no markings on the outside. [An amendment to § 1305.16(b)(ii) to implement this requirement is proposed below.]

Therefore, under the authority vested in the Attorney General by Sections 301, 307, 308, 501(b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 821, 827, 828 and 871(b)), and delegated to the Administrator of the Drug Enforcement Administration by § 0.100 of Title 21 of the Code of Federal Regulations, the Administrator proposes that:

1. Section 1301.74 of Title 21 of the Code of Federal Regulations be amended by adding a new paragraph (g) to read as follows:

§ 1301.74 Other Security Controls for Non-practitioners.

* * * * *

(g) Before the initial distribution of etorphine hydrochloride and/or diprenorphine to any person, the registrant must verify that the person is authorized to handle the substance(s) by contacting the Drug Enforcement Administration.

* * * * *

2. Section 1301.75 of Title 21 of the Code of Federal Regulations be amended by adding a new paragraph (d) to read as follows:

§ 1301.75 Physical Security Controls for Practitioners.

* * * * *

(d) Etorphine hydrochloride and diprenorphine shall be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container.

* * * * *

3. Section 1304.38 of of Title 21 of the Code of Federal Regulations be amended by adding a new paragraph (d) to read as follows:

§ 1304.38 Reports from the Manufacturers of Bulk Materials or Dosage Units.

* * * * *

(d) Registrants manufacturing etorphine hydrochloride or diprenorphine shall, on a weekly basis, forward a copy of

the order forms received for these substances to the Administration.

* * * * *

4. Section 1305.06(b) of Title 21 of the Code of Federal Regulations be amended by adding a new phrase to read as follows:

§ 1305.06 Procedure for Executing Order Forms.

* * * * *

(b) Only one item shall be entered on each numbered line. There are five lines on each order form. If one order form is not sufficient to include all items in an order, additional forms shall be used. Order forms for etorphine hydrochloride and diprenorphine shall contain only these substances. The total number of items ordered shall be noted on that form in the space provided.

* * * * *

5. Part 1305 of Title 21 of the Code of Federal Regulations be amended by adding a new § 1805.16 to read as follows:

§ 1305.16 Special Procedure for Filling Certain Order Forms.

(a) The purchaser of etorphine hydrochloride or diprenorphine shall submit copy 1 and 2 of the order form to the supplier and retain copy 3 in his own files.

(b) The supplier, if he determines that the purchaser is a veterinarian engaged in zoo and exotic animal practice, wildlife management programs and/or research and authorized by the Administrator to handle these substances shall fill the order in accordance with the procedures set forth in § 1305.09 except that: (i) Order forms for etorphine hydrochloride and diprenorphine shall only contain these substances in reasonable quantities and (ii) the substances shall only be shipped to the purchaser at the location printed by the Administration upon the order form under secure conditions using substantial packaging material with no markings on the outside which would indicate the content.

* * * * *

6. Section 1305.13 be amended by adding a new paragraph (d) to read as follows:

§ 1305.13 Preservation of Order forms.

* * * * *

(d) The supplier of etorphine hydrochloride and diprenorphine shall maintain order forms for these substances separately from all other order forms and records required to be maintained by the registrant.

In order to protect the public welfare by ensuring that etorphine hydrochloride and diprenorphine are manufactured, distributed, stored, and used in a proper manner, the foregoing provisions shall be effective on the date of publication as interim procedures until the proposals are finalized.

All interested persons are invited to submit their comments and objections in writing regarding this proposal. These comments or objections should state with particularity the issues concerning which the person desires to be heard. Comments and objections should be submitted in quintuplicate to the Hearing Clerk, Office of Chief Counsel, Drug Enforcement Administration, Department of Justice, Room 611, 1405 Eye Street NW., Washington, D.C. 20537, and must be received no later than April 26, 1974.

In the event that an interested party submits objections to this proposal which present reasonable grounds for this rule not to be finanlized and requests a hearing in accordance with 21 CFR 1308.45, the party will be notified by registered mail that a hearing will be held at the time and place set forth in the letter. A notice of hearing will simultaneously be published in the FEDERAL REGISTER. If objections submitted do not present such reasonable grounds, the party will so be advised by registered mail.

If no objections presenting reasonable grounds for a hearing on the proposal are received within the time limitations and all interested parties waive or deemed to waive their opportunity for the hearing or to participate in the hearing, the Administrator may cancel the hearing, and after giving consideration or written comments, issue his final order pursuant to 21 CFR 1308.48 without a hearing.

Dated: March 25, 1974.

JOHN R. BARTELS, Jr.,
Administrator,
Drug Enforcement Administration.

[FR Doc.74-7277 Filed 3-28-74;8:45 am]

DEPARTMENT OF LABOR

Office of Federal Contract Compliance

[41 CFR Parts 60-1, 60-50]

RELIGIOUS ENTITIES

Proposed Exemption

Notice is hereby given that pursuant to Executive Order 11246 (30 FR 12319), as amended by Executive Order 11375 (32 FR 14303), the Department of Labor proposes to clarify the employment obligations of religious corporations, associations, educational institutions and societies under Executive Order 11246 (as amended). This proposal is intended to establish consistency between the religious exemption provisions of section 702 of the Civil Rights Act of 1964, as amended by the Equal Employment Opportunity Act of 1972, and the rules and regulations of the Office of Federal Contract Compliance.

This proposed rulemaking concerns matters relating to public contracts. While public participation is not required, the Department of Labor, in keeping with the spirit of 5 U.S.C. 553, invites submission of written comments, suggestions or objections regarding these proposed amendments to Mr. Philip J. Davis, Director, Office of Federal Contract Compliance, U.S. Department of Labor, 14th Street and Constitution Avenue, NW., Washington, D.C. 20210, on or before April 29, 1974.

In consideration of the foregoing, it is proposed to amend Chapter 60 of Title 41, Code of Federal Regulations, as follows:

PART 60-1—OBLIGATIONS OF CONTRACTORS AND SUBCONTRACTORS

1. A new paragraph (a)(5) is proposed to be added to § 60-1.5 reading as follows:

§ 60-1.5 Exemptions.

(a) * * *

(5) *Contracts with religious entities.* The requirements of the equal opportunity clause shall not apply to a religious corporation, association, educational institution or society with respect to the employment of individuals of a particular religion to perform work connected with the carrying on by such corporation, association, educational institution, or society of its activities.

* * * * *

PART 60-50—GUIDELINES ON DISCRIMINATION BECAUSE OF RELIGION OR NATIONAL ORIGIN

2. A new paragraph (e) is proposed to be added to § 60-50.1 reading as follows:

§ 60-50.1 Purpose and scope.

* * * * *

(e) Nothing contained in this Part 60-50 is intended to supersede or otherwise limit the exemption set forth in § 60-1.5(a)(5) of this chapter for contracts with religious entities.

Signed at Washington, D.C., this 19th day of March 1974.

PETER J. BRENNAN,
Secretary of Labor.

BERNARD E. DELURY,
Assistant Secretary for Employment Standards.

PHILIP J. DAVIS,
Director, Office of Federal Contract Compliance.

[FR Doc.74-7318 Filed 3-28-74;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 1]

HYPOALLERGENIC COSMETICS

Proposed Definition

Correction

In FR Doc. 74-4305 appearing at page 7287 as the Part IV of the issue of Monday, February 25, 1974, make the following changes:

1. In the third column on page 7291, in the second line of paragraph 5., the word "Operations" should read "Opinions".

2. In column three on page 7292, in the second from the last paragraph, the date "April 26, 1973" should read "April 26, 1974".

Office of Education

[45 CFR Part 141]

STRENGTHENING INSTRUCTION IN ACADEMIC SUBJECTS IN PUBLIC SCHOOLS

Notice of Proposed Rule Making

In accordance with section 503 of the Education Amendments of 1972 (Pub. L. 92-318) and pursuant to the authority contained in Title III-A of the National Defense Education Act of 1958, as amended, 20 U.S.C. 441-444, the Commissioner of Education, with the approval of the Secretary of Health, Education, and Welfare, proposes to amend Title 45, Part 141 of the Code of Federal Regulations to read as set forth below.

At present, there will be guidelines under this program. Should guidelines be issued in the future, they would be limited to material in the nature of suggestions and recommendations for program management and operation.

1. *Program purpose.* Title III-A of the National Defense Education Act provides for assistance to States to strengthen academic subjects through the acquisition of laboratory and other special equipment, and minor remodeling.

2. *Section 503 procedures and effect.* Section 503 of the Education Amendments of 1972 requires the Commissioner to study all rules, regulations, guidelines, or other published interpretations or orders issued by him or by the Secretary after June 30, 1965, in connection with, or affecting, the administration of Office of Education programs; to report to the Committee on Labor and Public Welfare of the Senate and the Committee on Education and Labor of the House of Representatives concerning such study; and to publish in the FEDERAL REGISTER such rules, regulations, guidelines, interpretations, and orders, with an opportunity for public hearing on the matters so published. The regulations proposed below reflect the results of this study as it pertains to the program under Title III-A of the National Defense Education Act. Upon publication of revised Part 141 as a final regulation, after comments and hearing, all preceding rules, regulations, guidelines, and other published interpretations and orders issued in connection with or affecting the program will be superseded effective thirty days after such publication.

3. *Effect of Office of Education general provisions regulations.* The proposed regulations differ from the current regulations in that provisions have been deleted relating to general fiscal and administrative matters which are now covered in the overall Office of Education General Provisions Regulations published in the FEDERAL REGISTER at 38 FR 30654 (November 6, 1973), in connection with the same study under section 503 of the Education Amendments of 1972 of which this publication is a part. (Reference is made in particular to the provisions of proposed Part 100b of Title 45 CFR, containing general provisions for State administered programs, which would be applicable to the program under Title III-A of the National Defense Education Act.)

4. *Citations of legal authority.* As required by section 431(a) of the General Education Provisions Act (20 U.S.C. 1232(a)) and section 503 of the Education Amendments of 1972, a citation of statutory or other legal authority for each section of the regulations has been placed in parentheses on the line following the text of the section.

On occasion, a citation appears at the end of a subdivision of the section. In that case the citation is to all that appears in that section between the citation and the next preceding citation. When the citation appears only at the end of the section it applies to the entire section.

5. *Opportunity for public hearing.* Pursuant to section 503(c) of the Education Amendments of 1972, the Commissioner will provide interested parties an opportunity for a public hearing on these regulations as follows:

A hearing will take place at the U.S. Office of Education on April 25, 1974, in the auditorium of Regional Office Building Three (ROB-3) located at 7th and D Streets, SW, Washington, D.C., beginning at 10:00 a.m.

The purpose of the hearing is to receive comments and suggestions on the published materials.

Parties interested in attending the hearing should notify the Office of Education, 400 Maryland Avenue SW., Room 2079-G, Washington, D.C. 20202, Attention: Chairman, Office of Education Task Force on section 503, and are urged to submit a written copy of their comments with such notification. Each party planning to make oral comments at the hearing is urged to limit his presentation to a maximum of fifteen minutes.

Written comments and recommendations may also be sent to the above address. All relevant material received prior to the date of the hearing will be considered. Comments and suggestions submitted in writing will be available for review in the above office between the hours of 9 a.m. and 4:30 p.m., Monday through Friday of each week.

Dated: February 20, 1974

JOHN OTTINA,
U.S. Commissioner of Education.

Approved: March 15, 1974.

FRANK CARLUCCI,
Acting Secretary of Health, Education, and Welfare.

Subpart A—Definitions; General Provisions

Sec.

141.1 Definitions.
141.2 General provisions regulations.

Subpart B—State Plans

141.3 Purpose.
141.4 Effect of State plan.
141.5 Effect of Department plan.
141.6 Program and operational procedures.
141.7 Submission.
141.8 Certificate of the State Attorney General or other appropriate State legal officer.
141.9 Approval by the Commissioner.
141.10 Ineligibility to participate.
141.11 State plan assurances.

Subpart C—State Administration

141.19 Establishment of principles to govern priorities.
141.20 Administrative review and evaluation.
141.21 Advisory committees.
141.22 Continuing review by Commissioner of State administration.

Subpart D—Federal Financial Participation

141.30 Equipment and minor remodeling.
141.31 Supervision and administration.
141.32 Public nature of funds.
141.33 Reallotment.
141.34 Allotment to the Department of Interior and the Department of Defense.

Subpart E—Acquisition of Equipment and Minor Remodeling

141.46 Equipment and minor remodeling eligible for Federal financial participation.
141.47 Equipment and minor remodeling costs eligible for Federal financial participation.
141.48 Use of equipment in other subject areas.

Subpart F—Supervision and Administration

141.54 Programs for supervision and related services.
141.55 Expansion or improvement.
141.56 Time basis for measurement of activities.

AUTHORITY: Secs. 301-304, Pub. L. 85-864, as amended, 72 Stat. 1588 (20 U.S.C. 441-444), unless otherwise noted.

Subpart A—Definitions; General Provisions

§ 141.1 Definitions.

As used in this part:

"Academic subjects" means the following elementary and secondary school subjects: The arts, civics, economics, English geography, history, the humanities, industrial arts, mathematics, modern foreign languages, reading, and science.

"Act" means the National Defense Education Act of 1958, 20 U.S.C. Ch. 17.

"Arts" includes, but is not limited to, music (instrumental and vocal), dance, drama, folk art, creative writing, architecture and allied fields, painting, sculpture, photography, graphic and craft arts, industrial design, costume and fashion design, film, television, radio, tape and sound recording, and the arts related to the presentation, performance, execution and exhibition of such major art forms.

"Audiovisual library" means a facility used for the acquisition, preparation, maintenance, and circulation of audiovisual materials for education in academic subjects in public elementary and secondary schools, and controlled and operated by a State or local educational agency or other public school authority below the State level.

"Class" means a group of students assembled for instruction for a given period of time under a teacher or teachers.

"Electronic digital and analog computing equipment" means electronic devices capable of input (receiving information), memory (storing information),

programs (performing arithmetical and logical operations), and output (presenting the results of the processing). Input devices may be in the form of key or paper punches, magnetic tape impregnators, magnetic ink, printed characters, or keyboard. Memory devices may be in the form of magnetic drums, tapes, disks, cards, or cores. The term also includes output media which may be in the form of punch cards, magnetic or paper tape, printed copy, or visual display. (Special purpose computing devices and auxiliary equipment whose major application is in data processing and other business and administrative areas are not eligible except for those elements which may be essential for scientific problem solving or for mediating instruction in one of the academic subjects.)

"Equipment" means laboratory and other special equipment as defined in this section, including materials as defined in § 100.1 of this chapter.

"Humanities" includes, but is not limited to, the study of the following: Language, both modern and classic; linguistics; literature; history; jurisprudence; philosophy; archeology; the history, criticism, theory, and practice of the arts; and those aspects of the social sciences which have humanistic content and employ humanistic methods.

"Laboratory and other special equipment" (a) The term includes: (1) Fixed or movable articles, including electronic digital and analog computing equipment, which are particularly appropriate for use in providing education in academic subjects in a public elementary or secondary school and which are to be used either by teachers in connection with teaching or by students in learning in such subjects; (2) audiovisual equipment (including projectors, recorders, television cameras, television receivers, closed-circuit television distribution systems, and ancillary television projection and reception equipment to be used primarily for nonbroadcast purposes, except where broadcast takes the place of closed-circuit cable systems), to be used, either by teachers in connection with teaching or by students in connection with learning, primarily in providing education in academic subjects in a public elementary or secondary school; (3) materials (as defined in § 100.1 of this chapter) and devices (other than those used for printing, such as printing presses and offset printing machines) to be used for preparation of audiovisual and instructional materials for academic subjects; (4) storage equipment to be used solely for the care and protection of the items specified in paragraph (a) (1)–(3) of this definition, when used in laboratories or classrooms; (5) testgrading equipment to be used primarily in providing education in academic subjects in a public elementary or secondary school; and (6) specialized equipment for audiovisual libraries serving public elementary or secondary schools when such equipment is to be used primarily in providing education in academic subjects.

(b) The term excludes such items as general-purpose furniture, school public address systems, or items for the maintenance and repair of equipment. However, the term does include equipment for maintenance, repair, and storage of materials in audiovisual libraries.

"Local educational agency" means a public board of education or other public authority legally constituted within a State for either administrative control or direction of, or to perform a service function for, public elementary or secondary schools in a city, county, township, school district, or other political subdivision of a State, or such combination of school districts or counties as is recognized in a State as an administrative agency for its public elementary or secondary schools. It also includes any other public institution or agency having administrative control and direction of a public elementary or secondary school.

"Minor remodeling" (notwithstanding the definition set forth in § 100.1 of this chapter) means those minor alterations, in a previously completed building in space used or to be used a laboratory or classroom for education in academic subjects, which are needed to make effective use of equipment in providing education in such subjects. The term also includes those minor alterations in a previously completed building which are needed to make effective use of the items referred to in paragraph (a) (5)–(6) of the definition of "Laboratory and other special equipment" in this section. The term may also include the extension of utility lines, such as for water and electricity, from points beyond the confines of the space in which the minor remodeling is undertaken but within the confines of such previously completed building, to the extent needed to make effective use of equipment. The term does not include building construction, structural alterations to buildings, building maintenance, repair, or renovation.

"Project": (a) As applied to the acquisition of laboratory or other special equipment or minor remodeling the term means (1) a proposal submitted by a local educational agency, or agencies, or other public school authority below the State level, or (2) in cases where the State educational agency operates one or more public elementary or secondary schools or audiovisual libraries, a proposal submitted by the highest administrative officer of such school or audiovisual library.

(b) Proposals shall contain: (1) Description and current cost estimates of the equipment to be acquired or minor remodeling to be performed; (2) certification that the equipment is to be used primarily for providing education in academic subjects, except that in the case of storage equipment the certification shall be to the effect that the storage equipment will be used solely for the care and protection of equipment and materials used in providing such education; and (3) information showing the direct relationship of the proposed expenditures to the overall design for enriching the planned educational program and the achievement of desired curriculum goals in academic subjects.

"School" means a division of instructional organization consisting of a group of pupils comprised of one or more grade groups, organized on a class basis as one unit with one or more teachers to give instruction of a defined type, and housed in a school plant of one or more buildings. More than one school may be housed in one school plant as when elementary and secondary schools are so housed.

"Secondary school" means a school which provides secondary education, as determined under State law or, if such school is not in a State, as determined by the Commissioner. The term does not include any education provided beyond grade 12 except that (notwithstanding the definition set forth in § 100.1 of this chapter) it may include a public junior college when it is a part of or an extension of the secondary school system of the State as determined under State law.

"Services": (a) "Supervisory services" mean the services rendered by a qualified person in the promotion, maintenance, and improvement of instruction in one or more of the academic subjects;

(b) "Related Services" mean those technical activities which support supervisory services in academic subjects.

"Standards" are means for determining the suitability of equipment or minor remodeling as it relates to the improvement of instruction on one or more of the academic subjects in public elementary and secondary schools.

(a) With respect to equipment acquisition: "standards" mean criteria, categories of eligible equipment and materials, and such relevant information as the State wishes to use in determining eligibility, including any limitations, prohibitions, or minimum quality requirements developed by the State to encourage long-range planning and to ensure acquisition of equipment appropriate for a specific program of instruction.

(b) With respect to minor remodeling: "standards" are criteria for determining approvability of projects. Such standards shall include a requirement that there be a direct relationship between the minor remodeling and the improvement of instruction in the academic subjects.

"State" means a State of the Union, the District of Columbia, Puerto Rico, the Canal Zone, Guam, American Samoa, the Virgin Islands, and the Trust Territory of the Pacific Islands.

"State educational agency" or "State agency" means the State board of education or other agency or officer primarily responsible for the State supervision of public elementary and secondary schools, or, if there is no such officer or agency, an officer or agency designated by the Governor or by State law.

"Textbook" means a book, workbook, or manual which is used as the principal source of study material for a given class or group of students, a copy of which is

expected to be available for the individual use of each pupil in that class or group of students.

(20 U.S.C. 403, 443)

§ 141.2 General provisions regulations.

Assistance under this part is subject to applicable provisions contained in Subchapter A of this chapter (relating to fiscal, administrative, property management, and other matters.

(20 U.S.C. 443)

Subpart B—State Plans

§ 141.3 Purpose.

(a) *States.* A basic condition for the payment of Federal funds to a State under sections 301–304 of the Act is a State plan that meets the requirements of sections 303(a) and 1004(a) of the Act in providing a program under which funds paid to the State under its allotment under section 302(a) of the Act will be expended solely for projects approved by the State educational agency for the acquisition of laboratory and other special equipment suitable for use in providing education in academic subjects, and minor remodeling.

(b) *Departments of Interior and Defense.* The basic condition for the payment of funds under Title III–A of the Act to the Department of the Interior or the Department of Defense is a plan which describes the projects to be carried out with the funds together with such other information and assurances as the Commissioner may require.

(20 U.S.C. 443(a), 588 (B))

§ 141.4 Effect of State plan.

The State plan, when approved by the Commissioner, shall constitute the basis on which Federal grants will be made, as well as a basis for determining the propriety of State and local expenditures in which Federal participation is requested.

(20 U.S.C. 443(a))

§ 141.5 Effect of Department plan.

A plan from the Department of the Interior or the Department of Defense, when approved by the Commissioner, shall constitute the basis on which payments will be made to those Departments under Title III–A of the Act and the basis for determining the propriety of the expenditures of those funds by those Departments.

(20 U.S.C. 588(B))

§ 141.6 Program and operational procedures.

(a) The administration of the program shall be kept in conformity with the approved plan, the regulations in this part, and Title III–A of the Act.

(b) A description of the program and operational procedures shall be recorded and made available to the public upon request.

(c) Whenever there is any material change in the content or administration of the program, or when there has been any material change in pertinent State law or in the organization, policies, or operations of the State agency affecting the program under the plan, the plan shall be appropriately amended.

(20 U.S.C. 443(a))

§ 141.7 Submission.

(a) (1) A State plan shall be submitted to the Commissioner by a duly authorized officer of the State agency. (2) A plan submitted by the Department of the Interior or the Department of Defense shall be submitted by an officer of that Department.

(b) A State plan shall give the official name of the agency which will administer the plan and shall indicate that such agency meets the criteria for a State educational agency.

(20 U.S.C. 443(a), 584(a)(3), 588(B))

§ 141.8 Certificate of the State Attorney General or other appropriate State legal officer.

The State plan shall also include as an attachment a certificate by the appropriate State legal officer to the effect that the State educational agency named in the plan is the agency having authority to administer the State plan or to supervise the administration of the State plan; that the State educational agency has authority under State law to develop, submit, and administer or supervise the administration of the plan; and that the State has authority under State law to carry out the State plan.

(20 U.S.C. 443(a))

§ 141.9 Approval by the Commissioner.

The Commissioner will approve each plan which he determines meets the applicable requirements of Title III–A of the Act and regulations in this part, and will notify the applicant of the granting or withholding of approval in each such case. However, no final action, other than one of approval, will be taken by the Commissioner unless he first notifies the applicant of his proposed action and affords the applicant a reasonable opportunity for a hearing on whether the affected plan meets such requirements.

(20 U.S.C. 443(b), 584(b))

§ 141.10 Ineligibility to participate.

Whenever the Commissioner, after reasonable notice and opportunity for a hearing, finds:

(a) That the plan fails to comply with the requirements of Title III–A of the Act or the regulations in this part; or

(b) that in the administration of the plan there is a failure to comply substantially with any such provisions, the Commissioner will notify the applicant that the applicant will not be regarded as eligible to participate in the program under Title III–A of the Act until the Commissioner is satisfied that there is no longer any such failure to comply.

(20 U.S.C. 584(c))

§ 141.11 State plan assurances.

Each State plan shall contain the following assurances:

(a) *Authority.* That the State agency will administer the plan and has adequate authority to do so under State law.

(b) *Fiscal procedures.* That the State agency has provided for such fiscal control and fund accounting procedures as will assure proper disbursement of and accounting for Federal funds paid to the State under the plan, including the funds paid by the State to local educational agencies. Subject to the applicable provisions of Part 100b of this chapter, such administration shall be conducted in accordance with applicable State laws, policies, and procedures.

(c) *Reports.* That the State agency will participate in periodic consultations and will make reports to the Commissioner, at such time, in such form, and containing such information, as the Commissioner may consider reasonably necessary to enable him to perform his duties under the Act and will keep such records and afford such access thereto, and will comply with such other requirements as the Commissioner may find necessary to assure the correctness and verification of such reports.

(d) *Description of program.* That the State agency has developed a program under which funds paid to the State from its allotment under section 302(a) of Title III–A of the Act will be expended solely for (1) projects approved by the State agency for the acquisition of (i) laboratory and other special equipment (other than supplies consumed in use), including audiovisual materials and equipment, (ii) printed and published materials (other than textbooks), suitable for use in providing education in academic subjects in public elementary and secondary schools, and (iii) testgrading equipment for those schools and specialized equipment for audiovisual libraries serving those schools; and (2) projects approved by the State agency for minor remodeling of laboratory or other space used for those materials or equipment. In addition that the State agency has developed a program under which funds paid to the State from its allotment under section 302(b) will be expended solely for projects for (i) expansion or improvement of supervisory and related services in public elementary and secondary schools, including leadership and services to local educational agencies to improve instruction in academic subjects, and (ii) for the administration of the State plan. The programs developed pursuant to sections 302(a) and 302(b) must either be set forth in the State plan itself or be incorporated therein by reference as separate existing and identified documents available for inspection by the Commissioner.

(e) *Principles for determining priority of projects.* That the State agency has established the principles that will be applied in determining the priority of and order of undertaking of projects for assistance under the provisions of Title III–A of the Act. Such principles must either be set forth in the State plan itself or be incorporated therein by reference as a separate existing and identified document available for inspection by the Commissioner.

(f) *Opportunity for hearing.* That the State agency has provided for an opportunity for a hearing before the State

agency to any applicant for a project under Title III–A of the Act.

(g) *Standards.* That the State agency has established standards for laboratory and other special equipment to be acquired with assistance furnished under Title III–A of the Act and will advise the Commissioner of those standards. These standards are to be related to the State's program for improving instruction in academic subjects and shall be applied by the State in approving projects for the acquisition of equipment.

(h) *Financial participation.* Whether the State agency has established requirements to be imposed upon applicants for financial participation in projects assisted under Title III–A of the Act, including any provision for taking into account the resources available to any applicant for such participation relative to the resources for participation available to all other applicants. These requirements must either be set forth in the State plan itself or be incorporated therein by reference as a separate existing and identified document available for inspection by the Commissioner.

(20 U.S.C. 443, 584)

Subpart C—State Administration

§ 141.19 Establishment of principles to govern priorities.

In meeting the requirements contained in § 141.11(e), a State must provide a list of principles which reflect its major educational concerns in the academic subject fields and which have a bearing on the functioning of the Title III–A program. These principles are then to be used as a basis for the development of priorities. The priorities themselves, while not a required part of the State plan, must be prepared by the State to be used for the purpose of assigning relative importance and order of approval of projects submitted by local educational agencies under this part.

(20 U.S.C. 443(a)(2))

§ 141.20 Administrative review and evaluation.

The State agency and the Department of the Interior and the Department of Defense shall provide for the administration and supervision of all plan programs. Program and administrative review and evaluation shall be conducted by the State agency or the Department of the Interior or the Department of Defense, as the case may be, at least annually to appraise the status of the programs and their administration in terms of plan provisions and program objectives. The State agency shall include a report of such administrative review and evaluation in its annual report.

(20 U.S.C. 443, 584(a)(1), 588(B))

§ 141.21 Advisory committees.

If State advisory committees are used in one or more aspects of the State plan, the State agency shall establish policies for the establishment of the committees, for the qualification and selection of members, for the establishment of the duties of members and of the committee, and for the payment of committee expenses, if any.

(20 U.S.C. 443, 584)

§ 141.22 Continuing review by Commissioner of State administration.

In order to assist the State agency in adhering to statutory requirements and to the provisions of its approved State plan, the Commissioner will be responsible for conducting periodic reviews, including onsite reviews of the administration of programs under Title III–A of the Act. These reviews will involve analysis of activities and procedures used by State agencies to conduct the program, including the development and monitoring of management activities.

(20 U.S.C. 584)

Subpart D—Federal Financial Participation

§ 141.30 Equipment and minor remodeling.

The Federal Government will pay from each State's allotment an amount equal to one-half of the sums expended for the purchase of equipment and for minor remodeling, when expended for an approved project under an approved State plan. There can be no Federal financial participation in the expenditures for a project if the project, including any amendments thereto, had not been approved by the State agency prior to the incurrence of the expenditures.

(20 U.S.C. 444(a))

§ 141.31 Supervision and administration.

The Federal Government will pay from each State's allotment for Title III–A of the Act one-half of the total sum expended by the State for supervision, related services, and administration in programs established under the approved State plan.

(20 U.S.C. 444(b))

§ 141.32 Public nature of funds.

The expenditures to be used in computing Federal financial participation must be made from public funds. Public funds do not include contributions by private organizations or individuals unless such contributions are deposited in accordance with State law to the account of the unit or agency of State or local government without such conditions or restrictions as would negate their public character.

(20 U.S.C. 444)

§ 141.33 Reallotment.

(a) If the Commissioner determines that any part of the amount allotted to any State for any fiscal year under section 302(a) of the Act will not be required for that year, that part will be available on such dates during that year as the Commissioner may fix for reallotment to other States. The reallotment will be made in proportion to the amounts originally allotted to other States for that year, except that the total amount available to each State will be reduced to the extent it exceeds the sum the Commissioner determines that that State needs and will be able to use for that year, and the total of such reductions shall be similarly reallotted among the States whose allotments were not so reduced.

(b) The amounts to be so reallotted will be determined by the Commissioner on the basis of (1) reports filed by the States of the amounts required to carry out the State plan approved by the Commissioner, and (2) such other information as he may have available. Each State agency shall, if requested, submit to the Commissioner, on such date or dates as he may specify, a report or reports showing the anticipated need during the current fiscal year for the amount previously allotted or any amount needed in addition thereto, and such other information as the Commissioner may request.

(c) If the Commissioner determines that any amount reserved for any fiscal year for making loans under section 305 of the Act will not be required for that year, that part shall be available for allotment to the States in the manner provided for reallotment of Title III–A funds under paragraph (a) of this section.

(20 U.S.C. 442(c))

§ 141.34 Allotment to the Department of the Interior and the Department of Defense.

The Commissioner will make allotments, according to their respective needs for the types of programs authorized under Title III–A of the Act, to the Secretary of the Interior for elementary and secondary schools operated for Indian children by the Department of the Interior, and to the Secretary of Defense for elementary and secondary schools operated for overseas dependents by the Department of Defense.

(20 U.S.C. 588(B))

Subpart E—Acquisition of Equipment and Minor Remodeling

§ 141.46 Equipment and minor remodeling eligible for Federal financial participation.

A State educational agency may approve projects for the acquisition, with Federal financial participation, of items of equipment, or for minor remodeling, for education in academic subjects only to the extent that equipment or minor remodeling for such academic subjects are covered by the State plan current at the time of project approval.

(20 U.S.C. 443)

§ 141.47 Equipment and minor remodeling costs eligible for Federal financial participation.

(a) *Equipment.* (1) Acquisition of equipment includes the costs of delivery to the school and installation. (2) Expenditures in which Federal participation is claimed may include the cost of raw or processed materials or component parts to be made into finished products or complete equipment units for instruction in academic subjects, including the cost of making and assembling the equipment.

(b) *Minor remodeling.* A minor remodeling project may include the costs of

materials and the labor of local school or district personnel, provided that the costs are properly substantiated by documentation.
(20 U.S.C. 443)

§ 141.48 Use of equipment in other subject areas.

Equipment acquired under an approved project for academic subjects may be used when available and suitable in providing education in other subjects, if there exists a critical need therefor in the judgment of local school authorities. Equipment shall be deemed available only when it is not needed for the time being for use in academic subjects.
(20 U.S.C. 443)

[FR Doc.74-7273 Filed 3-28-74;8:45 am]

Public Health Service

[42 CFR Part 52]

EMERGENCY MEDICAL TECHNIQUES

Proposed Project Grants for Research

Notice is hereby given that the Assistant Secretary of Health, Office of the Secretary, with the approval of the Secretary of Health, Education, and Welfare, proposes to amend Part 52 of Title 42, CFR, "Grants for Research Projects."

The purpose of the proposed amendment is to implement section 1205 of the Public Health Service Act (42 U.S.C. 300d–4), which was added by section 2(a) of the Emergency Medical Services Systems Act of 1973, Pub. L. 93–154. Section 1205 of the Public Health Service Act authorizes the Secretary of Health, Education, and Welfare to make grants to public or private nonprofit entities for the support of research in emergency medical techniques, methods, devices, and delivery.

Interested persons are invited to submit written comments, suggestions, or objections regarding the proposed amendment of 42 CFR Part 52 to the Bureau of Health Services Research, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20852, on or before April 29, 1974. All comments received in response to this notice will be available for public inspection in the above-named office on weekdays between the hours of 8:30 a.m. and 5:00 p.m.

It is therefore proposed to amend 42 CFR Part 52 in the manner set forth below.

Dated: March 6, 1974.

CHARLES C. EDWARDS,
Assistant Secretary for Health.

Approved: March 25, 1974.

CASPAR W. WEINBERGER,
Secretary.

1. The citation of authority is amended by adding the words "sec. 1205, 87 Stat. 597; U.S.C. 300d–4." As amended, the citation of authority reads as follows:

AUTHORITY: The provisions of this Part 52 issued under secs. 215, 58 Stat. 690, as amended, 301, 81 Stat. 504; (42 U.S.C. 216, 1857g). Secs. 301, 58 Stat. 691, as amended; 303, 70 Stat. 929; 304, 81 Stat. 534; 396, 79 Stat. 1063; 103, 81 Stat. 486; 204, 79 Stat. 998; (42 U.S.C. 241, 242a, 242b, 280b–6, 1857b, 3253); sec. 1205, 87 Stat. 597; 42 U.S.C. 300d–4. Reorganization Plan No. 3 of 1966, 31 FR 8855, 80 Stat. 1610; 3 CFR 1966 Comp.; Reorganization Orders and Delegations of Mar. 13, Apr. 1, 1968 (33 FR 4894, 5426) and Jan. 17, 1969 (34 FR 1279).

2. Section 52.1 is amended by revoking the words "grants for studies in providing services outside hospitals." As amended, § 52.1 reads as follows:

§ 52.1 Applicability.

The regulations of this part apply to grants for the support of health related research projects as set forth in § 52.10. They do not apply to general research support grants, demonstration grants, or other grants as may be authorized by law, such as grants for the construction of research facilities (see Part 57 of this chapter), for the construction of hospital or other medical facilities (see Part 53 of this chapter), or the award of fellowships (see Part 61 of this chapter), traineeships (see Part 63 of this chapter), or training grants (see Part 64 of this chapter).

3. Section 52.10 is amended by deleting the period at the end of paragraph (e) and inserting in lieu thereof "; and", and by adding a new paragraph (f), to read as follows:

§ 52.10 Nature and purpose of research project grant.

* * * * *

(f) Emergency medical techniques, methods, devices, and delivery as authorized by section 1205 of the Public Health Service Act (42 U.S.C. 300d–4).

4. In § 52.13, paragraph (a) is amended by adding at the end of the second sentence the words "and in the case of applications for support of research in emergency medical services, special consideration shall be given to applications for grants for research relating to the delivery of emergency medical services in rural areas." As amended, § 52.13(a) reads as follows:

§ 52.13 Evaluation and disposition of applications.

(a) *Evaluation.* All applications filed in accordance with § 52.12 shall be evaluated by the Secretary through such officers and employees and such experts or consultants engaged for this purpose as he determines are specially qualified in the areas of research involved in the project, including review by an appropriate National Advisory Council or other body as may be required by law. The Secretary's evaluation shall take into account among other pertinent factors the scientific merit and significance of the project, the competency of the proposed staff in relation to the type of research involved, the feasibility of the project, the likelihood of its producing meaningful results, the proposed project period, and the adequacy of the applicant's resources available for the project and the amount of grant funds necessary for completion, and in the case of application for support of research in emergency medical services, special consideration shall be given to applications for grants for research relating to the delivery of emergency medical services in rural areas.

* * * * *

[FR Doc.74-7270 Filed 3-28-74;8:45 am]

DEPARTMENT OF TRANSPORTATION

Coast Guard

[33 CFR Part 117]

[CGD 74 72]

DRAWBRIDGE OPERATION REGULATIONS

Chesapeake and Delaware Canal, Del.

At the request of the U.S. Army Corps of Engineers, the Coast Gaurd is considering amending the regulations for the Penn Central lift bridge across the Chesapeake and Delaware Canal to allow the use of radiotelephones in lieu of sound and visual signals to request the opening of this bridge when communications have been satisfactorily established. This amendment is being considered to assure maximum safety of navigation. This section will only apply to the Penn Central Railroad bridge because the Reedy Point drawbridge has been replaced by a high level fixed bridge.

Interested persons may participate in this proposed rule making by submitting written data, views, or arguments to the Commander, Fifth Coast Guard District (oan), Federal Building, 431 Crawford Street, Portsmouth, Virginia 23705. Each person submitting comments should include his name and address, identify the bridge, and give reasons for any change in the proposal. Copies of all written communications received will be available for examination by interested persons at the office of the Commander, Fifth Coast Guard District.

The Commander, Fifth Coast Guard District, will forward any comments received before April 30, 1974, with his recommendations to the Chief, Office of Marine Environment and Systems, who will evaluate all communications received and take final action on this proposal. The proposed regulations may be changed in the light of comments received.

In consideration of the foregoing, it is proposed that Part 117 of Title 33 of the Code of Federal Regulations, be amended by:

1. Amending the heading of § 117.235a to read as follows:

§ 117.235a Chesapeake and Delaware Canal, Del.; Penn Central Railroad vertical lift bridge.

* * * * *

2. Adding a new paragraph (c) to § 117.235a to read as follows:

§ 117.235a Chesapeake and Delaware Canal, Del.; Penn Central Railroad vertical lift bridge.

* * * * *

(c) This bridge is equipped with an FM radiotelephone station and those vessels equipped with an FM radiotelephone

station may contact the bridge by radiotelephone via Channel 13 (or whatever channel is currently assigned by the Federal Communications Commission). Sound signals may be omitted if radiotelephone communications are satisfactorily established and maintained between the draw tender and the approaching vessel, until the vessel has passed through the lift span.

(Sec. 5, 28 Stat. 362, as amended, sec. 6(g)(2), 80 Stat. 937 (33 U.S.C. 499, 49 U.S.C 1655(g)(2)); 49 CFR 146(c)(5), 33 CFR 1.05-1(c)(4)).

Dated: March 21, 1974.

W. M. BENKERT,
Rear Admiral, U.S. Coast Guard, Chief, Office of Marine Environment and Systems.

[FR Doc.74-7280 Filed 3-28-74;8:45 am]

[33 CFR Part 117]

[CGD 74 71]

DRAWBRIDGE OPERATION REGULATIONS

Chuckatuck Creek, Va.

At the request of the Virginia Department of Highways, the Coast Guard is considering revising the regulations for the drawbridge at mile 1.0 across Chuckatuck Creek, Nansemond, Virginia. Present regulations require that the draw open on signal from 7:00 a.m. to 3:00 p.m., daily except Sunday and at all other times if at least 4 hours notice is given. The proposed regulations would require at least 2 hours notice at all times. The requirement that the bridge open on signal from 7:00 a.m. to 3:00 p.m. is being eliminated because of limited openings of the bridge (52 from July 1971 through April 1973). The reduced notice time would allow sufficient time for Highway Department personnel to travel to the bridge for draw openings. The emergency requirement is being reworded in order to clarify its meaning.

Interested persons may participate in this proposed rulemaking by submitting written data, views, or arguments to the Commander, Fifth Coast Guard District (oan), Federal Building, 431 Crawford Street, Portsmouth, Vrginia 23705. Each person submitting comments should include his name and address, identify the bridge, and give reasons for any recommended change in the proposal. Copies of all written communications received will be available for examination by interested persons at the office of the Commander, Fifth Coast Guard District.

The Commander, Fifth Coast Guard District, will forward any comments received before April 30, 1974, with his recommendations to the Chief, Office of Marine Environment and Systems, who will evaluate all communications received and take final action on this proposal. The proposed regulations may be changed in the light of comments received.

In consideration of the foregoing, it is proposed that Part 117 of Title 33 of the Code of Federal Regulations, be amended by revising subparagraph (23) of paragraph (f) of § 117.245 to read as follows:

§ 117.245 Navigable waters discharging into the Atlantic Ocean south of and including Chesapeake Bay and into the Gulf of Mexico, except the Mississippi River and its tributaries and outlets; bridges where constant attendance of draw tenders is not required.

* * * * *

(f) * * *

(23) Chuckatuck Creek, Va.; Virginia Department of Highways bridge on U.S. Route 17 between Nansemond and Isle of Wight County. The draw shall open on signal if at least 2 hours notice is given. If an emergency exists the draw shall open as soon as possible.

* * * * *

(Sec. 5, 28 Stat. 362, as amended, sec. 6(g)(2), 80 Stat. 937; (33 U.S.C. 499, 49 U.S.C. 1655(g)(2)); 49 CFR 1.46(c)(5), 33 CFR 1.05-1(c)(4))

Dated: March 21, 1974.

W. M. BENKERT,
Rear Admiral, U.S. Coast Guard, Chief, Office of Marine Environment and Systems.

[FR Doc.74-7279 Filed 3-28-74;8:45 am]

Federal Aviation Administration

[14 CFR Part 71]

[Airspace Docket No. 74-SO-34]

TRANSITION AREA

Proposed Alteration

The Federal Aviation Administration is considering an amendment to Part 71 of the Federal Aviation Regulations that would alter the Vidalia, Ga., transition area.

Interested persons may submit such written data, views or arguments as they may desire. Communications should be submitted in triplicate to the Federal Aviation Administration, Southern Region, Air Traffic Division, P.O. Box 20636, Atlanta, Ga. 30320. All communications received on or before April 29, 1974, will be considered before action is taken on the proposed amendment. No hearing is contemplated at this time, but arrangements for informal conferences with Federal Aviation Administration officials may be made by contacting the Chief, Airspace and Procedures Branch. Any data, views or arguments presented during such conferences must also be submitted in writing in accordance with this notice in order to become part of the record for consideration. The proposal contained in this notice may be changed in light of comments received.

The official docket will be available for examination by interested persons at the Federal Aviation Administration, Southern Region, Room 645, 3400 Whipple Street, East Point, Ga.

The Vidalia transition area described in § 71.181 (39 FR 440) would be amended as follows:

"* * * longitude 82°22'15" W.) * * *" would be deleted and "* * * longitude 82°22'15" W.); within a 6.5-mile radius of Reidsville Airport, Reidsville, Ga. (latitude 32°03'19" N., longitude 82°-09'19" W.); within 3 miles each side of the 295° bearing from Prison RBN (latitude 32°03'27" N., longitude 82°09'09" W.), extending from the 6.5-mile radius area to 8.5 miles northwest of the RBN * * *" is substituted therefor.

The proposed alteration is required to provide controlled airspace protection for IFR operations at Reidsville Airport. A prescribed instrument approach procedure to this airport, utilizing the Prison (private) Nondirectional Radio Beacon, is proposed in conjunction with the alteration of this transition area.

This amendment is proposed under the authority of section 307(a) of the Federal Aviation Act of 1958 (49 U.S.C. 1348(a)) and of section 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).

Issued in East Point, Ga., on March 21, 1974.

PHILLIP M. SWATEK,
Director, Southern Region.

[FR Doc.74-7238 Filed 3-28-74;8:45 am]

[14 CFR Part 75]

[Airspace Docket No. 74-SO-18]

RNAV ROUTE

Proposed Alteration

The Federal Aviation Administration (FAA) is considering an amendment to Part 75 of the Federal Aviation Regulations that would alter a segment of RNAV Route No. J812R in the vicinity of Atlanta, Ga.

Interested persons may participate in the proposed rule making by submitting such written data, views or arguments as they may desire. Communications should identify the airspace docket number and be submitted in triplicate to the Director, Southern Region, Attention: Chief, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Ga. 30320. All communications received on or before April 29, 1974, will be considered before action is taken on the proposed amendment. The proposal contained in this notice may be changed in the light of comments received.

An official docket will be available for examinaiton by interested persons at the Federal Aviation Administration, Office of the General Counsel, Attention: Rules Docket, 800 Independence Avenue, SW., Washington, D.C. 20591. An informal docket also will be available for examination at the office of the Regional Air Traffic Division Chief.

The proposed amendment would realign J812R between ALMA, Ga., and SHUTO as follows:

Waypoint	Latitude-longitude	Ref. Facility	Rho/Theta
ALMA	31°32'1" N., 82°30'30" W.	SAV	243.7° M/80.5.
SINCA	33°05'19" N., 83°33'03" W.	AGS	250.4° M/76.3.
CANTE	34°19'29" N., 84°25'39" W.	CHA	135.5° M/52.4.
SHUTO	37°14'52" N., 85°21'50" W.	TYS	320° M/107.3.

As presently aligned, the route creates points of conflict with inbound traffic at LANDS and SINCA, and with outbound traffic at CANTE and SOCLE. Realignment as proposed would move the route centerline westward as much as 27 miles, thereby eliminating the points of conflict.

This amendment is proposed under the authority of section 307(a) of the Federal Aviation Act of 1958 (49 U.S.C. 1348(a)) and section 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).

Issued in Washington, D.C., on March 25, 1974.

GORDON E. KEWER,
Acting Chief, Airspace and Air Traffic Rules Division.

[FR Doc.74-7237 Filed 3-28-74;8:45 am]

FEDERAL HOME LOAN BANK BOARD

[12 CFR Parts 545, 549]

[No. 74-59]

FEDERAL SAVINGS AND LOAN SYSTEM

Proosed Authorization and Limitations of Issuing Negotiable Certificates of Deposit

JANUARY 30, 1974.

The Federal Home Loan Bank Board considers it desirable to propose to amend various sections of Parts 545 and 549 of the rules and regulations for the Federal Savings and Loan System (12 CFR Parts 545 and 549) for the purpose of authorizing Federal associations to issue negotiable certificates of deposit as described below. By a companion Resolution (Resolution No. 74-60; January 30, 1974), the Board proposes collateral amendments to the rules and regulations for Insurance of Accounts (12 CFR Ch. V, Subchapter D).

The principal amendment to said Part 545 would be to add a new § 545.1-5 thereto which would authorize, and place limitations on, the issuance of negotiable certificates of deposit. Under paragraph (a) of proposed § 545.1-5, each Federal association which has adopted the charter provision set forth in § 545.1-3 (12 CFR 545.1-3)—a "deposit-type" association—could accept savings deposits for fixed periods of time and bearing fixed rates of interest which are evidenced by certificates which by their form are negotiable instruments under the law of the State where the home office of the association is located. Negotiable certificates of deposit would have the same status and priority as is provided under § 545.1-2 (12 CFR 545.1-2) for savings deposits authorized by that section.

Paragraph (b) of proposed § 545.1-5 would permit payment of interest on negotiable certificates of deposit either monthly, quarterly, semiannually or at the conclusion of the fixed-term.

Paragraph (c) of proposed § 545.1-5 would set forth limitations on negotiable certificates of deposit. In substance, Federal associations would not be permitted to issue a negotiable certificate of deposit: (1) Which has a principal amount of less than $100,000; (2) which has a term of less than 30 days or more than 10 years; (3) which permits the association to redeem or accelerate payment of the certificate before the end of its fixed-term; (4) which permits the holder to add to it, or withdraw principal from it, before the end of its fixed-term; (5) which permits any renewal or extension at the end of its fixed-term; or (6) which provides for the payment of any interest after the end of its fixed-term.

Also, paragraph (c) of proposed § 545.1-5 would require that before the association could issue negotiable certificates of deposit, the association must obtain an opinion by its legal counsel that the form of the certificate complies with the requirements of applicable law (including applicable State negotiable instruments law) and regulations and the association's charter, and must submit the form of certificate and the legal opinion to the Federal Savings and Loan Insurance Corporation. The legal opinion would not need to be obtained if the association uses a form of certificate which has already been approved by the Corporation for use by Federal associations. At this time it is not expected that the Corporation will approve certificate forms for general use by all Federal associations until sufficient experience is gained concerning the form of negotiable certificates of deposit. As a result, each association desiring to issue negotiable certificates of deposit would have to first submit its certificate forms and legal opinions to the Corporation. Specific Board or staff approval of the certificate form would not be required by the regulation, but it is expected that an association would wait for a reasonable period of time for staff comments before beginning to issue a certificate form submitted to the Corporation.

Paragraphs (d) and (e) of proposed § 545.1-5 are concerned with the provisions to be set forth on the face of the certificate form. Under paragraph (e), a certificate which meets the requirements of paragraphs (c), (d) and (f) could be in such form as the board of directors of the association may determine. For example, it could be registered or nonregistered, be payable to bearer or to the order of a specified person or entity, or be a coupon-type instrument. Under paragraph (d), a negotiable certificate of deposit form would be required in substance to include in its provisions and display in easily read type: (1) The amount of the deposit and the date on which it is made; (2) the rate of interest to be paid, the date or dates on which principal is payable, and the date or dates or the frequency of payment of interest; (3) a statement as to deposit and withdrawal restrictions; and (4) a statement that interest will not accrue on, or be credited to, the deposit after the end of its fixed term.

Also, paragraph (d) of proposed § 545.1-5 would require the certificate form to disclose whether the holder of the certificate has membership and voting rights in the association. Under paragraph (f) of proposed § 545.1-5 the association's board of directors may decide whether to grant membership and voting rights to holders of negotiable certificates of deposit or designated classes thereof. However, if membership and voting rights are granted, the certificate would have to be in registered form.

The issuance of negotiable certificates of deposit would be subject to the restrictions of § 563.25 of the rules and regulations for Insurance of Accounts (12 CFR 563.25) concerning sales commissions and the use of brokers. Such issuance would also be subject to § 526.5-1 of the regulations for the Federal Home Loan Bank System (12 CFR 526.5-1) which places a percentage of total savings accounts limitation on certificate accounts of $100,000 or more paying a return at a rate in excess of 6.75 percent.

The Board also proposes to amend §§ 545.1-4, 545.2 and 545.4-1 of said Part 545 (12 CFR 545.1-4, 545.2 and 545.4-1) in connection with permitting the issuance of negotiable certificates of deposit. Section 545.1-4(a) would be amended by adding "and § 545.1-5" after the phrase "In addition to the savings deposits authorized by § 545.1-2" at the beginning thereof. Section 545.4-1 would be amended by adding a new paragraph (c) which would provide in substance that § 545.4-1 does not limit the authority of Federal associations to issue negotiable certificates of deposit.

Authorizing Federal associations to issue negotiable certificates of deposit requires several changes to § 545.2, captioned "Evidence of ownership". Generally, these changes deal with what records and proof of ownership would be required in connection with the issuance of negotiable certificates of deposit. Paragraph (a) of § 545.2 would be revised so that a Federal association issuing a negotiable certificate of deposit would not be required to obtain a signature card from the owner of such deposit if it is not in registered form. This change is desirable in connection with the issuance of negotiable certificates of deposit which are in bearer form and in order to facilitate distribution of negotiable certificates of deposit through a dealer or broker.

Paragraph (b) of § 545.2 is revised to make clear that at least for the time being the Board will not prescribe negotiable certificates of deposit forms as discussed above. Said paragraph (b) would also be revised by deleting the last sentence thereof since there are no longer any Federal associations holding Charter E.

Similar conforming amendments would be made to paragraphs (c) and (d) of § 545.2. It should be noted, however, that the second sentence of paragraph (c)

would be revised and a new third sentence added to indicate that applicable State negotiable instruments law would determine the rules for valid and sufficient release of the association for any payment of a negotiable certificate of deposit.

Part 549 deals with the powers of a receiver and the conduct of a receivership. A new § 549.5–2 would be added thereto to make clear that written notifications required by §§ 549.5(a) and 549.5–1(b)(1) need not be sent to holders of negotiable certificates of deposit which are not in registered form.

Accordingly, the Board hereby proposes to amend said Parts 545 and 549 as set forth below.

Interested persons are invited to submit written data, views, and arguments to the Office of the Secretary, Federal Home Loan Bank Board, 101 Indiana Avenue, NW., Washington, D.C. 20552, by April 30, 1974, as to whether this proposal should be adopted, rejected, or modified. Written material submitted will be available for public inspection at the above address unless confidential treatment is requested or the material would not be made available to the public or otherwise disclosed under § 505.6 of the general regulations of the Federal Home Loan Bank Board (12 CFR 505.6).

1. Section 545.1–4(a) would be amended to read as follows:

§ 545.1–4 Other savings deposits.

(a) *General.* In addition to the savings deposits authorized by §§ 545.1–2 and 545.1–5, any Federal association which has a charter in the form of Charter N or Charter K (rev.) and which has adopted the charter provision set forth in § 545.1–3 may, subject to the provisions of this section, accept savings deposits for fixed periods of time and bearing fixed rates of interest, which savings deposits shall have the same status and priority as is provided under subparagraph (3) of paragraph (b) of § 545.1–2 for savings deposits authorized by that section. Holders of savings deposits authorized by this section shall, to the same extent as is provided in subparagraph (2) of paragraph (b) of § 545.1–2 for holders of savings deposits authorized by that section, be members of the association and have voting rights.

* * * * *

2. A new § 545.1–5 to read as follows would be added immediately after § 545.1–4:

§ 545.1–5 Negotiable certificates of deposit.

(a) *General.* In addition to the savings deposits authorized by §§ 545.1–2 and 545.1–4, any Federal association which has adopted the charter provision set forth in § 545.1–3 may, subject to the provisions of this section, accept savings deposits for fixed periods of time and bearing fixed rates of interest which are evidenced by certificates which by their form are negotiable instruments under the law of the State where the home office of the association is located (hereinafter referred to as "negotiable certificates of deposit"). Negotiable certificates of deposit issued pursuant to the authority contained in this section shall have the same status and priority as is provided under § 545.1–2(b)(3) for savings deposits authorized by that section.

(b) *Payment of interest.* Interest on negotiable certificates of deposit authorized by this section shall be paid at the rate fixed, or negotiated on an individual basis, by the association prior to the acceptance of the deposit; but such rate shall not exceed the applicable maximum rate prescribed in Part 526 of this Chapter. The board of directors of the association shall provide that interest on such deposits, or designated classes thereof, shall be paid either monthly, quarterly, semiannually, annually, at the conclusion of the fixed term, or on any dates on which interest may be paid on savings deposits authorized by § 545.1–2. The board of directors of the association may provide for the payment of interest on negotiable certificates of deposit authorized by this section on the same basis, terms, and conditions as is provided for the distribution of earnings by § 545.1–1.

(c) *Limitations on negotiable certificates of deposit.* In accepting savings deposits under the authority contained in paragraph (a) of this section, a Federal association shall not:

(1) Issue any negotiable certificate of deposit of less than $100,000;

(2) Issue any negotiable certificate of deposit for a term of less than 30 days or more than 10 years;

(3) Issue any negotiable certificate of deposit which by its terms is subject to redemption or acceleration by the association;

(4) Issue any negotiable certificate of deposit which by its terms permits the holder thereof to add to or withdraw principal from such certificate of deposit before the end of its fixed-term;

(5) Issue any negotiable certificate of deposit under this section unless the association has first (i) obtained a written opinion by its legal counsel that the form of the certificate complies with the requirements of applicable law and regulations and the association's charter, which opinion shall be retained by the association so long it continues to issue certificates in such form, and (ii) submitted a copy of such certificate, together with a copy of such legal opinion, to the Federal Savings and Loan Insurance Corporation: *Provided*, That such legal opinion need not be obtained if the association uses a form of negotiable certificate of deposit which has already been approved by the Corporation for use by Federal associations;

(6) Issue any negotiable certificate of deposit which by its terms permits any renewal or extension at the end of its fixed-term; or

(7) Issue any negotiable certificate of deposit which provides for the payment of any interest for any period during which the funds deposited remain with the association after the end of the fixed-term of the savings deposit evidenced by such certificate.

(d) *Provisions required in negotiable certificates of deposit.* Each negotiable certificate of deposit issued by a Federal association pursuant to the authority contained in paragraph (a) of this section shall include in its provisions and display in easily read type:

(1) The amount of the deposit and the date on which it is made;

(2) The rate of interest to be paid, the date or dates on which principal is payable, and the date or dates or the frequency of payment of interest;

(3) A statement that the holder of the certificate is not permitted to add to, or withdraw principal from, the savings deposit evidenced by the certificate before the end of its fixed-term;

(4) A statement that no interest shall accrue on, or be credited to, the savings deposit evidenced by the certificate after the end of its fixed-term; and

(5) A statement as to whether the holder of the certificate has membership and voting rights in the association.

(e) *Form of certificate.* Certificates evidencing savings deposits accepted pursuant to the authority contained in this section shall, subject to paragraphs (c), (d) and (f) of this section, be in such form as the board of directors of the association may determine. Such certificates shall not be incorporated in passbooks.

(f) *Membership and voting rights.* The board of directors of the Federal association shall determine whether holders of savings deposits evidenced by negotiable certificates of deposit issued pursuant to the authority contained in this section, or designated classes thereof, are membrs of the association and have voting rights as provided in § 545.1–2(b)(2) for holders of savings deposits authorized by that section. If the board of directors determines that holders of negotiable certificates of deposit are members of the association and have voting rights, such holders shall have membership and voting rights to the same extent provided in § 545.1–2(b)(2) for holders of savings deposits authorized by that section. If the holders of negotiable certificates of deposit are given membership and voting rights, the name and address of the owner of the certificate shall be registered on the books of the association and the certificate shall be made transferable only on such books.

Section 545.2 would be revised to read as follows:

§ 545.2 Evidence of ownership.

(a) *Signature card.* In connection with the issuance of a savings account other than a negotiable certificate of deposit issued under § 545.1–5 which is not in registered form, a Federal association shall obtain a card containing the signature of the owner of such account or his duly authorized representative and shall preserve such signature card in the records of the association.

(b) *Account books and certificates.* A Federal association that has Charter N or Charter K (rev.) shall issue to each holder of its savings accounts an account book, or a separate certificate, evidencing the ownership of the account and the interest of the holder thereof in the capital of such Federal association. Each such certificate shall be in form prescribed by the Board. (The Board has prescribed for use by all Federal associations that have Charter K, forms of certificates evidencing the ownership of savings share accounts, short-term savings share accounts, and investment share accounts; and has prescribed for use by all Federal associations that have Charter N or Charter K (rev.) forms of certificates, other than a negotiable certificate of deposit, evidencing ownership of savings accounts. Illustrative copies of these forms may be obtained from the Federal Home Loan Bank Board, Washington, D.C., or from any Federal Home Loan Bank.)

(c) *Ownership of record.* A Federal association may treat the holder of record of a savings account, including a negotiable certificate of deposit which is in registered form, as the owner for all purposes without being affected by any notice to the contrary unless such Federal association has acknowledged in writing notice of a pledge of such savings account or notice of a transfer or negotiation of such a negotiable certificate of deposit. The receipt or acquittance of any member, including a minor person or a married woman, who holds a savings account other than a negotiable certificate of deposit shall be a valid and sufficient release and discharge of the association for any payment to such person on any savings account. Valid and sufficient release and discharge of the association for any payment of a negotiable certificate of deposit shall be determined under applicable State negotiable instruments law. Savings accounts of a Federal association, other than negotiable certificates of deposit which are not in registered form, shall be transferable only upon the books of the association and upon proper application by the transferee and the acceptance of the transferee as a member upon terms approved by the board of directors.

(d) *Duplicate account books and certificates.* Upon filing with a Federal association by the holder of record as shown by the books of the association, by the holder of a negotiable certificate of deposit, or by a legal representative of either of such holders, of an affidavit to the effect that the certificate or account book evidencing his savings account with the association has been lost or destroyed, and that such certificate or account book has not been pledged or assigned in whole or in part, and in the case of a negotiable certificate of deposit has not been transferred by him, such Federal association shall issue a new certificate or account book evidencing such savings account in the name of the holder of record or such holder of a negotiable certificate of deposit: *Provided*, That the board of directors shall, if in its judgment it is necessary, require a bond in an amount sufficient to indemnify the association against any loss which might result from the issuance of such new certificate or account book.

4. A new paragraph (c) to read as follows would be added to § 545.4–1:

§ 545.4–1 Payments to third parties by withdrawals or transfer of savings accounts; checks and money orders.

* * * * *

(c) *Negotiable certificates of deposit.* Nothing in this section shall limit the authority of Federal associations under § 545.1–5 to accept savings deposits for fixed periods of time and bearing fixed rates of interest which are evidenced by certificates which by their form are negotiable instruments under the law of the State where the home office of the association is located.

5. A new § 549.5–2 to read as set forth below would be added immediately after § 549.5–1:

§ 549.5–2 Notifications required in this part.

The written notifications required by the fifth sentence of § 549.5(a) and the fifth sentence of § 549.5–1(b)(1) need not be sent to holders of negotiable certificates of deposit issued pursuant to § 545.1–5 of this chapter which are not in registered form.

(Sec. 5, 48 Stat. 132, as amended; 12 U.S.C. 1464. Reorg. Plan No. 3 of 1947, 12 FR 4981, 3 CFR, 1943–48 Comp., p. 1071)

By the Federal Home Loan Bank Board.

[SEAL] GRENVILLE L. MILLARD, Jr.,
Assistant Secretary.

[FR Doc.74–7335 Filed 3–28–74;8:45 am]

[12 CFR Parts 563, 564]

[No. 74–60]

FEDERAL SAVINGS AND LOAN INSURANCE CORPORATION

Proposed Approval of Issuing Negotiable Fixed-Rate, Fixed-Term Accounts

JANUARY 30, 1974.

The Federal Home Loan Bank Board considers it desirable to propose to amend various sections of Parts 563 and 564 of the rules and regulations for Insurance of Accounts (12 CFR Parts 563 and 564) for the purpose of approving the issuance of negotiable fixed-rate, fixed-term accounts by insured institutions as described below. By a companion Resolution (Resolution No. 74–59; January 30, 1974), the Board proposes collateral amendments to the rules and regulations of the Federal Savings and Loan System (12 CFR Ch. V, Subchapter C).

The principal amendment to said Part 563 would be to add a new § 563.3–3 thereto which would approve, and place limitations on, the issuance of negotiable fixed-rate, fixed-term accounts. Under paragraph (a) of proposed § 563.3–3, each insured institution could accept accounts bearing a definite rate of return for fixed periods of time evidenced by certificates which by their form are negotiable instruments under the law of the State where the principal office of the institution is located. A certificate which meets the provisions of paragraphs (b), (c) and (d) of proposed § 563.3–3 could be in such form as the board of directors of the institution may determine. For example, it could be registered or nonregistered, be payable to bearer or to the order of a specified individual or entity, or be a coupon-type instrument.

Paragraph (b) of proposed § 563.3–3 would set forth limitations on negotiable fixed-rate, fixed-term accounts. In substance, insured institutions would not be permitted to issue a negotiable fixed-rate, fixed-term account: (1) which has a principal amount of less than $100,000; (2) which has a term of less than 30 days or more than 10 years; (3) which permits the association to redeem or accelerate payment of the certificate before the end of its fixed-term; (4) which permits the holder to add to it, or withdraw principal from it, before the end of its fixed-term; (5) which permits any renewal or extension at the end of its fixed-term; or (6) which provides for the payment of any interest after the end of its fixed-term.

Also, paragraph (b) of proposed § 563.3–3 would require that before the insured institution could issue negotiable certificates of deposit, the institution must obtain an opinion by its legal counsel that the form of certificate complies with the requirements of applicable law (including applicable State negotiable instruments law) and regulations and the institution's charter, and must submit the form of certificate and the legal opinion to the Federal Savings and Loan Insurance Corporation. The legal opinion would not need to be obtained if the institution uses a form of certificate which has already been approved by the Corporation for use by institutions in the State where the institution is located. At this time it is not expected that the Corporation will approve certificate forms for general use by all insured institutions in a particular State until sufficient experience is gained concerning the form of negotiable certificates of deposit. As a result, each institution desiring to issue negotiable fixed-rate, fixed-term accounts would have to first submit its cretificate forms and legal opinions to the Corporation. Specific Board or staff approval of the certificate form would not be required by the regulation, but it is expected that an institution would wait for a reasonable period of time for staff comments before beginning to issue a certificate form submitted to the Corporation.

Paragraph (c) of proposed § 563.3–3 is concerned with the provsions to be set forth on the face of the certificate form. The certificate form would be required to include in its provisions and display in easily read type: (1) The amount of the deposit and the date on which it is made;

(2) the rate of interest to be paid, the date or dates on which principal is payable, and the date or dates or frequency of payment of interest; (3) a statement as to deposit and withdrawal restrictions; (4) a statement that interest will not accrue on, or be credited to, the deposit after the end of its fixed-term; and (5) whether the holder of the certificate has membership and voting rights in the institution.

Paragraph (d) of proposed § 563.3–3 would require that if the holders of negotiable fixed-rate, fixed-term accounts have membership and voting rights in the insured institution, the name and address of the owner of the account shall be registered on the books of the institution and the certificate evidencing the account shall be made transferable only on such books.

The issuance of negotiable fixed-rate, fixed-term accounts would be subject to the restrictions of § 563.25 of the rules and regulations for Insurance of Accounts (12 CFR 563.25) concerning sales commissions and the use of brokers. Such issuance would also be subject to § 526.5–1 of the regulations for the Federal Home Loan Bank System (12 CFR 526.5–1) which places a percentage of savings limitation on certificate accounts of $100,000 or more paying a return at a rate in excess of 6.75 percent.

The Board aslo proposes to amend §§ 563.3–1, 563.4, 563.7–2 and 563.17–1 (12 CFR 563.3–1, 563.4, 563.7–2 and 563.17–1) in connection with approving the issuance of negotiable fixed-rate, fixed-term accounts. Section 563.3–1(a) would be amended by adding the phrase "In addition to accounts approved by § 563.3–3" at the beginning thereof. Section 563.7–2(a) would be amended by adding § 563.3–3 to the list of sections referred to therein.

Section 563.4, captioned "Transfer of securities", presently requires that all securities issued by an insured institution shall be made transferable only on the books of the institution. This section would be revised so that negotiable fixed-rate, fixed-term accounts which are not in registered form would not be required to be made transferable only on the books of the institution.

Section 563.17–1(c)(5), captioned "Records with respect to insured accounts", would be revised so that the records of an insured institution would not be required to contain the signature of the holder of a negotiable fixed-rate, fixed-term account which is not in registered form. Such records would be required to reflect the balance in such account, however.

Part 564 of the rules and regulations for Insurance of Accounts (12 CFR Part 564) deals with settlement of insurance. Paragraph (a) of § 564.1 (12 CFR 564.1) captioned "Settlement of insurance upon default", would be amended to indicate that the Corporation need not send written notice of the time and place of payment of insurance to the holders of negotiable certificates of deposit and negotiable fixed-rate, fixed-term accounts which are not in registered form. If the institution has outstanding at the time of default such a deposit or account which is not in registered form, the Corporation would be required, however to publish, in a newspaper of general circulation in the area in which such institution's principal office is located, a notice to all account holders of such institution of the time and place of payment of insurance.

Section 564.2 (12 CFR 564.2) sets forth general principles applicable in determining the insured members of an insured institution and the amount of their insured accounts. Paragraph (b)(1) thereof states, in part, that "The account records of the insured institution shall be conclusive as to the existence of any relationship pursuant to which the funds in the account are invested and on which a claim for insurance coverage is founded * * *." A new paragraph (b)(5) would be added to § 564.2 which would provide that paragraph (b) does not apply with respect to negotiable certificates of deposit and negotiable fixed-rate, fixed-term accounts which are not in registered form. Paragraph (b)(5) would require that affirmative proof must be offered in all cases to substantiate a claim by the holder of such a deposit or account as to the existence of any relationship upon which a claim for insurance coverage is founded.

A new § 564.13, captioned "Accounts evidenced by negotiable certificates", would be added to Part 564 which would be comparable to a similar regulation of the Federal Deposit Insurance Corporation (12 CFR 330.11). In substance, new § 564.13 would provide that the holder of a negotiable certificate of deposit or a negotiable fixed-rate, fixed-term account which is not in registered form will be recognized for all purposes involving claims in connection with settlement of insurance upon default as if the name and interests of such holder could be determined from the books and records of the insured institution. However, the certificate must have been negotiated to such holder prior to the date of the closing of the institution and affirmative proof of such negotiation must be offered in all cases to substantiate the claim. In that connection, a new example of insurance coverage for negotiable certificates of deposit and negotiable fixed-rate, fixed-term accounts would be added to the Appendix to Part 564. The purpose of the example is to explain that the insurance coverage as to the holders of a certificate evidencing such a deposit or account is unaffected by the insurance coverage which was afforded to a previous holder of such certificate.

Accordingly, the Board hereby proposes to amend said Parts 563 and 564 as set forth below.

Interested persons are invited to submit written data, views, and arguments to the Office of the Secretary, Federal Home Loan Bank Board, 101 Indiana Avenue, NW., Washington, D.C. 20552, by April 30, 1974, as to whether this proposal should be adopted, rejected, or modified. Written material submitted will be available for public inspection at the above address unless confidential treatment is requested or the material would not be made available to the public or otherwise disclosed under § 505.6 of the General Regulations of the Federal Home Loan Bank Board (12 CFR 505.6).

1. Section 563.3–1(a) would be revised to read as follows:

§ 563.3–1 Fixed-rate, fixed-term accounts.

(a) *General approval.* In addition to accounts approved by § 563.3–3, a State-chartered institution which, in accordance with State law, may accept accounts bearing a definite rate of return for fixed periods of time (hereinafter referred to as "fixed-rate, fixed-term accounts") and whose board of directors has adopted a resolution providing for the issuance of such fixed-rate, fixed-term accounts may, subject to the limitations contained in paragraph (b) of this section and to the disclosure provisions contained in paragraph (c) of this section, issue certificates evidencing such fixed-rate, fixed-term accounts in such form as the board of directors of the institution may determine.

* * * * *

2. A new § 563.3–3 to read as follows would be added immediately following § 563.3–2:

§ 563.3–3 Negotiable fixed-rate, fixed-term accounts.

(a) *General approval.* In addition to accounts approved by § 563.3–1, a State-chartered institution which, in accordance with State law, may accept accounts bearing a definite rate of return for fixed periods of time evidenced by certificates which by their form are negotiable instruments under the law of the State in which the principal office of the institution is located (hereinafter referred to as "negotiable fixed-rate, fixed-term accounts") and whose board of directors has adopted a resolution providing for the issuance of such negotiable fixed-rate, fixed-term accounts may, subject to paragraphs (b), (c) and (d) of this section, issue certificates evidencing such negotiable fixed-rate, fixed-term accounts in such form as the board of directors of the institution may determine.

(b) *Limitations.* In issuing certificates evidencing negotiable fixed-rate, fixed-term accounts pursuant to the approval contained in paragraph (a) of this section, an insured institution shall not:

(1) Issue any negotiable fixed-rate, fixed-term account of less than $100,000;

(2) Issue any negotiable fixed-rate, fixed-term account for a term of less than 30 days or more than 10 years;

(3) Issue any negotiable fixed-rate, fixed-term account which by its terms is subject to redemption or acceleration by the institution;

(4) Issue any negotiable fixed-rate, fixed-term account which by its terms permits the holder thereof to add to or

withdraw principal from such account before the end of its fixed-term;

(5) Issue any negotiable fixed-rate, fixed-term account under the approval contained in this section unless the institution has first (i) obtained a written opinion by its legal counsel that that form of certificate evidencing such account complies with the requirements of applicable law and regulations and the institution's charter, which opinion shall be retained by the institution so long as it continues to issue certificates in such form, and (ii) submitted a copy of such form of certificate, together with a copy of such legal opinion, to the Federal Savings and Loan Insurance Corporation: *Provided*, That such legal opinion need not be obtained if the institution uses a form of certificate which has already been approved by the Corporation for use by insured institutions in the State where such institution is located;

(6) Issue any negotiable fixed-rate, fixed-term account which by its terms permits any renewal or extension at the end of its fixed-term; or

(7) Issue any negotiable fixed-rate, fixed-term account which provides for the payment of any interest for any period during which the funds in the account remain with the institution after the end of the fixed-term of such account.

(c) *Provisions required in negotiable fixed-rate, fixed-term accounts.* Each certificate evidencing a negotiable fixed-rate, fixed-term account accepted pursuant to the approval contained in paragraph (a) of this section shall include in its provisions and display in easily read type:

(1) The amount of the negotiable fixed-rate, fixed-term account and the date on which it is issued;

(2) The rate of interest to be paid, the date or dates on which principal is payable, and the date or dates or frequency of payment of interest;

(3) A statement that the holder of the certificate is not permitted to add to, or withdraw principal from, the savings account evidenced by the certificate before the end of its fixed-term;

(4) A statement that no interest shall accrue on, or be credited to, the savings account evidenced by the certificate after the end of its fixed-term; and

(5) A statement as to whether the holder of the certificate has membership and voting rights in the institution.

(d) *Membership and voting rights.* If the holders of negotiable fixed-rate, fixed-term accounts, or designated classes thereof, have membership and voting rights in the insured institution, the name and address of the owner of the account shall be registered on the books of the institution and the certificate evidencing the account shall be made transferable only on such books.

3. Section 563.4 would be revised to read as follows:

§ 563.4 Transfer of securities.

Except for negotiable certificates of deposit and certificates evidencing negotiable fixed-rate, fixed-term accounts which are not in registered form, all securities issued by an insured institution shall be made transferable only on the books of the insured institution.

4. Section 563.7–2 would be revised to read as follows:

§ 563.7–2 Form, return, and maturity of securities.

Securities of any insured institution which are (a) in conformity with § 563.3–1, § 563.3–2, § 563.3–3, or § 563.8–1 or § 545.24 of this chapter, (b) issued in connection with any borrowing which is in conformity with § 563.8, (c) issued in connection with any transaction which is not a borrowing or the issuance of a savings account and is not in nonconformity with the terms of any provision of this part which by its terms is applicable to such transaction, or (d) issued with specific prior approval of the Corporation are, as to form, return, and maturity (as referred to in those parts of the third sentence of subsection (b) of section 403 of the National Housing Act, as now or hereafter in effect, which refer to the form, return, and maturity of securities), hereby approved by the Corporation.

5. Section 563.17–1(c)(5) would be revised to read as follows:

§ 563.17–1 Examinations and audits; appraisals; establishment and maintenance of records.

* * * * *

(c) *Establishment and maintenance of records.* * * *

(5) *Records with respect to insured accounts.* Except as provided in the next sentence of this paragraph (c)(5), the records of an insured institution with respect to each withdrawable or repurchasable share, investment certificate, deposit, or savings account issued by such institution shall include the signature of the owner of such account or his duly authorized representative, together with a record reflecting the balance in such account. The records of an insured institution with respect to each negotiable certificate of deposit and certificate evidencing a negotiable fixed-rate, fixed-term account which are not in registered form need not include the signature of the holder of such certificate but shall reflect the balance in such account.

* * * * *

6. Section 564.1(a) would be revised to read as follows:

§ 564.1 Settlement of insurance upon default.

(a) *General.* In the event of a default by an insured institution, the Corporation will promptly determine, from the savings account contracts and the books and records of the institution, the insured members thereof and the amount of the insured account of each such member. The Corporation will give to each member (except holders of negotiable certificates of deposit and negotiable fixed-rate, fixed-term accounts which are not in registered form) written notice of the time and place of payment of insurance by mail at the last known address as shown on the books of the insured institution. If an insured institution has outstanding at the time of default any negotiable certificates of deposit or certificates evidencing negotiable fixed-rate, fixed-term accounts which are not in registered form, the Corporation shall also, concurrently with the mailing of such written notice, publish (in a newspaper printed in the English language and of general circulation in the city or county in which the principal office of such insured institution is located) a notice to all account holders of such insured institution of the time and place of payment of insurance.

* * * * *

7. Section 564.2(b) would be revised by adding a new subparagraph (5) thereto to read as follows:

§ 564.2 General principles applicable in determining insurance of accounts.

* * * * *

(b) *Records.* * * *

(5) The provisions of this paragraph shall not apply with respect to "negotiable certificates of deposit" issued pursuant to § 545.1–5 of this chapter and "negotiable fixed-rate, fixed-term accounts" issued pursuant to the approval contained in § 563.3–3 of this chapter which are not in registered form. Affirmative proof must be offered in all cases to substantiate a claim by the holder of such a deposit or account as to the existence of any relationship upon which a claim for insurance coverage is founded.

* * * * *

8. A new § 564.13 to read as follows would be added immediately after § 564.12:

§ 564.13 Accounts evidenced by negotiable certificates.

A "negotiable certificate of deposit" issued pursuant to § 545.1–5 of this chapter and a "negotiable fixed-rate, fixed-term account" issued pursuant to the approval contained in § 563.3–3 of this chapter which is not in registered form will be recognized for all purposes involving claims in connection with settlement of insurance upon default as if the name and interests of such holder could be determined from the books and records of the insured institution as required by this Part 564: *Provided*, That the certificate evidencing such deposit or account was in fact negotiated to such holder prior to the date of the closing of the insured institution. Affirmative proof of such negotiation must be offered in all cases to substantiate the claim.

9. A new Section H and a new example of insurance coverage would be added at the end of the Appendix following Part 564 to read as follows:

APPENDIX—EXAMPLES OF INSURANCE COVERAGE AFFORDED ACCOUNTS IN INSTITUTIONS INSURED BY THE FEDERAL SAVINGS AND LOAN INSURANCE CORPORATION

* * * * *

H. NEGOTIABLE CERTIFICATES OF DEPOSIT AND NEGOTIABLE FIXED-RATE, FIXED-TERM ACCOUNTS

Example 1

Question: A has $100,000 invested in a negotiable certificate of deposit. A transfers the certificate of deposit to B, who has $20,000 in a single-ownership account. B then transfers the certificate of deposit to C. What is the insurance coverage?

Answer: While A holds the certificate of deposit, it is insured for $20,000, leaving $80,000 uninsured. While B holds the certificate of deposit, it is added to his single-ownership account and his insurance coverage is $20,000, leaving $100,000 uninsured. While C holds the certificate of deposit, it is insured for $20,000 leaving $80,000 uninsured.

(Secs. 402, 403, 405, 48 Stat. 1256, 1257, 1259, as amended; (12 U.S.C. 1725, 1726, 1728). Reorg. Plan No. 3 of 1947, 12 FR 4981, 3 CFR, 1943–48 Comp., p. 1071)

By the Federal Home Loan Bank Board.

[SEAL] GRENVILLE L. MILLARD, Jr.,
Assistant Secretary.

[FR Doc.74–7336 Filed 3–28–74;8:45 am]

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[7 CFR Parts 1001, 1002, 1004, 1015, 1033, 1036, 1040, 1049]

[Docket Nos. AO–14–A53, etc.]

MILK IN THE BOSTON REGIONAL AND CERTAIN OTHER MARKETING AREAS

Partial Decision on Proposed Amendments

In the matter of:

7 CFR Part	Marketing area	Docket No.
1001	Boston Regional	AO 14–A53.
1002	New York-New Jersey	AO 71–A68.
1004	Middle Atlantic	AO 160–A51.
1015	Connecticut	AO 305–A31.
1033	Ohio Valley	AO 166–A44.
1036	Eastern Ohio-Western Pennsylvania.	AO 179–A39.
1040	Southern Michigan	AO 225–A28.
1049	Indiana	AO 319–A22.

A public hearing was held upon proposed amendments to the marketing agreements and the orders regulating the handling of milk in the aforesaid marketing areas. The hearing was held, pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 et seq.), and the applicable rules of practice (7 CFR Part 900), at Washington, D.C., on February 20–28, 1974, pursuant to notice thereof issued on February 14, 1974 (39 FR 5642).

The material issues on the record of the hearing relate to:

1. The immediate need for making inoperative the butter-powder formula under each order during the next few months.

2. Appropriate longer-term basis of pricing reserve milk under the eight orders.

3. Whether an emergency exists to warrant the omission of a recommended decision.

Sixteen proposals concerning the pricing of milk to which the butter-powder formula applies were submitted by interested parties for consideration at the hearing. Certain of the proposals called for either emergency suspension or immediate amendment action with respect to elimination of the butter-powder pricing formula. Other proposals involved adoption of new pricing formulas.

This partial decision deals with issues 1 and 3. Issue 2 is reserved for later decision.

FINDINGS AND CONCLUSIONS

The following findings and conclusions on the material issues are based on evidence presented at the hearing and the record thereof:

1. *The immediate need for making inoperative the butter-powder formula under each order during the next few months.* The price for reserve milk disposed of in manufacturing uses other than butter and nonfat dry milk in the eight markets under consideration should not be based on the butter-powder formula price but rather on the average of prices paid for manufacturing grade milk in Minnesota and Wisconsin. Milk utilized in butter and nonfat dry milk production in this April–July 1974 period should be priced below such Minnesota-Wisconsin price by the amount, not to exceed 50 cents, that the butter-powder formula price is less than the Minnesota-Wisconsin price.

Since mid-1968 in the four northeastern markets and for several years prior thereto in the other four markets, reserve milk (Class II milk under the Boston Regional, Connecticut, Indiana, Middle Atlantic, and New York-New Jersey orders and Class III milk under the Eastern Ohio-Western Pennsylvania, Ohio Valley, and Southern Michigan orders) has been priced at the lower of either the Minnesota-Wisconsin price or a butter-nonfat dry milk formula price. Except for a few occasions, these two pricing formulas have been in close alignment. Annually, the butter-powder formula price and the Minnesota-Wisconsin price have been in relative balance. For instance, the butter-powder formula price averaged 5 cents per hundredweight below the Minnesota-Wisconsin price in 1968, 17 cents below in 1969, 10 cents below in 1970, 6 cents above in 1971, 2 cents below in 1972, and 7 cents below in 1973.

Since January 1, 1969, there have been three periods when the Minnesota-Wisconsin price and the butter-powder formula price varied by more than 25 cents per hundredweight. The first period was October-December 1969 and January-April 1970 when the Minnesota-Wisconsin price varied from 31 to 42 cents over the butter-powder formula price; the second period was in August and September 1973 when the butter-powder formula price exceeded the Minnesota-Wisconsin price 36 and 33 cents, respectively; and finally, since October 1973, the Minnesota-Wisconsin price has exceeded the butter-powder formula price by $0.47, $0.78, $1.13, and $1.18 for October, November, and December 1973, and January 1974, respectively.

This current unprecedented price disparity between these two formulas is a result of a $2.32 increase since July 1973 in the prices paid for manufacturing grade milk as reflected in the Minnesota-Wisconsin pay price series compared to an increase of $1.00 in the butter-powder formula price. Substantive differences between the two price formulas are likely to continue at least through the immediate peak production months.

Substantial quantities of milk used to produce manufactured dairy products are associated with the eight orders. The annual volume of reserve milk supplies priced under the eight orders in 1971, 1972, and 1973 ranged from 26 to 28 billion pounds. Such reserve supplies have represented about 45 percent of the total volume of Class II and Class III milk priced under all Federal milk orders. Moreover, nearly 40 percent of the reserve supplies in the eight markets is produced during the four-month period, April–July.

When considered collectively for all eight markets, the principal regular outlets for reserve milk is in the so-called soft products such as cream, cottage cheese, ice cream, and ice milk mixes and condensed products. To a lesser extent, reserve milk in the eight markets is also used in hard cheese production. During the months of seasonally high production, significant quantities of butter and nonfat dry milk are processed since producer receipts exceed the volume of milk that can be utilized in the other lowest class use outlets.

The butter-powder formula was adopted under these orders principally on the basis that butter and nonfat dry milk plants were used to process milk in excess of Class I and soft product uses. Recently hard cheese production has increased in this northeastern region and such outlet for milk now accounts for a greater proportion of the market for seasonal reserve milk supplies.

A compelling reason that immediate action be taken is to eliminate the competitive disparity that currently exists between processors of reserve milk in the eight markets under consideration and similar processors in other Federal orders and unregulated processors of manufactured dairy products. The competitive market for products manufactured from reserve milk is essentially national in scope. Hence, dairy products manufactured from Federal order priced reserve milk compete with products made from unregulated manufacturing grade milk. In recognition of this fact, it is essential that prices for reserve milk be maintained at comparable levels among Federal order markets with prevailing competitive pay prices for manufacturing grade milk at plants buying such milk.

Under existing circumstances, the current prices of reserve milk as established by the butter-powder price formula in

the eight markets under consideration are substantially below the competitive market value of milk for similar uses in other Federal orders as well as the prices being paid by unregulated processors of manufacturing grade milk. Processors of reserve milk in the eight markets have a substantially lower milk cost and thus higher gross margins are available to them than for their competitors. This disparity, if permitted to continue, will lead to dislocation of normal production and processing patterns and disruption of normal efficient marketing channels. To achieve competitive equality it is necessary to provide uniform pricing of reserve milk under the eight orders herein considered and the adjacent nearby orders to the West as well as align such prices with the competitive pay prices being paid for the majority of unregulated manufacturing grade milk in the United States. It is concluded, therefore, that this objective can best be achieved through the use of the Minnesota-Wisconsin price series.

It is quite evident that current reserve milk prices in the eight markets herein considered are not providing producers a return for that portion of their milk utilized in manufactured dairy products reflecting its full use value. Producers should not be expected to continue to accept less for their milk not needed for Class I uses than its full use value.

The current lower reserve price levels are provided by the butter-powder price formula are significantly depressing the uniform price received by producers. The amount of this depressing effect on uniform prices varies among markets by the proportion of reserve milk for a particular market in a given month. However, the record evidence indicated that the relative impact on uniform prices of using the butter-powder formula price rather than the Minnesota-Wisconsin price in determining reserve milk prices for the four-month period, October 1973–January 1974, in five markets (New York-New Jersey, Boston Regional, Connecticut, Middle Atlantic, and Eastern Ohio-Western Pennsylvania) was a weighted average reduction of nearly 32 cents per hundredweight.

Under this price depressing situation, dairy farmers are not encouraged to maintain milk production at levels necessary to meet current and anticipated market needs for milk and milk products. For the eight markets under consideration, total producer receipts in 1973 decreased 4.8 percent from 1972. Receipts in December were 4.6 percent below a year ago. The percentage of producer milk utilized in Class I in the eight markets increased from 60.3 percent in 1972 to 62.4 percent in 1973. Utilization of Class I milk in December 1973 was 64.4 percent.

Under these market conditions, an immediate increase in reserve milk prices will help encourage the production of adequate supplies of milk since total U.S. milk production is less than domestic demand for milk and the markets represent a large proportion of total U.S. milk production.

Certain producer groups strongly urged that the current inequities in reserve milk pricing in the eight orders can best be achieved by immediately suspending the application of the butter-powder price formula. Under this proposal, all reserve milk would be priced at the Minnesota-Wisconsin price. This proposed course of action is not adopted since it fails to consider that some reserve milk during this flush period will have no other available market outlet than in butter and powder production which, at present, is a lower-valued use of reserve milk.

As indicated previously, this decision provides for a special price for reserve milk used to produce butter and nonfat dry milk for the April–July 1974 period at not more than 50 cents per hundredweight less than the price applicable to milk used in other manufactured dairy products. This special price is designed to recognize the lower use value of reserve milk utilized in butter and nonfat dry milk production. It should accommodate the orderly disposition of reserve milk that cannot be utilized in other manufactured products, which may occur during the seasonal flush.

The average prices paid at butter and by-product plants in the U.S. in recent months has not dropped more than 42 cents under the Minnesota-Wisconsin price. An amount in excess of the 50-cent limit adopted, such as the $1.18 which the butter-powder formula would provide, could result in a special butter-powder price sufficiently below the regular reserve milk price to encourage processors of ice cream and cottage cheese to displace producer milk with nonfat dry milk and butter made from milk priced at the lower special price. The net effect of this potential substitution, if practiced by handlers, would lower total returns to producers.

In order to facilitate and equitably apply this special butter-powder price, the accompanying amendatory orders provide an additional provision to the handler's pool obligation treating the 50 cent price differential as a credit.

To facilitate the marketing of excess milk supplies, milk and cream moved to a nonpool plant for processing into butter and nonfat dry milk should be eligible for the credit to the extent that the amount processed into such products in the plant is sufficient to account for the amount of milk moved to such plant. In the event that there is an insufficient quantity of butter and nonfat dry milk made in a plant to account for the receipts from more than one Federal order source, the quantity processed into butter and nonfat dry milk should be prorated among those Federal order sources for which a similar price credit is allowed.

Two of the orders, Middle Atlantic and Southern Michigan, contain a base-excess plan of payments to producers. Since the excess price under the orders is based on the lowest class price, the credits on milk used to produce butter and nonfat dry milk appropriately should be allocated against the value of excess milk to the extent that the volume of excess milk is sufficient to cover the volume of milk on which the credit is allowed.

3. *Whether an emergency exists to warrant the omission of a recommended decision.* The due and timely execution of the function of the Secretary under the Act imperatively and unavoidably requires the omission of a recommended decision and opportunity for exceptions thereto on Issue No. 1. The current marketing conditions in the aforesaid marketing areas are such that it is urgent that remedial action be taken as soon as possible. It is necessary to correct at the earliest opportunity the disparity in alignment of reserve milk prices under the eight orders with the order prices in the midwest as well as the prices being paid for manufacturing grade milk. Accordingly, the requests for a recommended decision are denied.

The notice of hearing stated that consideration would be given to economic and emergency marketing conditions relating to the proposed amendments. Certain parties at the hearing requested emergency action be taken. Interim emergency action is necessary pending a detailed review of new pricing formulas presented on the record.

It is therefore determined that good cause exists for the omission of the recommended decision and the opportunity for filing exceptions thereto.

Rulings on Proposed Findings and Conclusions

Briefs and proposed findings and conclusions were filed on behalf of certain interested parties. These briefs, proposed findings and conclusions and the evidence in the record were considered in making the findings and conclusions set forth above. To the extent that the suggested findings and conclusions filed by interested parties are inconsistent with the findings and conclusions set forth herein, the requests to make such findings or reach such conclusions are denied for the reasons previously stated in this decision.

On the record of the hearing, separate motions were presented to the Administrative Law Judge that (1) the scope of the hearing be broadened to consider the proposed revision of all classification provisions of the orders, as well as to include the proposed revision of many additional Federal milk orders; and (2) the Department provide information during the hearing as to the identity, type of operation, and market outlet of products

processed by plants handling manufacturing grade milk in the States of Minnesota and Wisconsin. The motions were denied.

In post-hearing briefs, it was requested that consideraiton be given to a reversal of the rulings.

The Administrative Law Judge's rulings have been reviewed in light of the arguments presented. The rulings, for the reasons stated by the Administrative Law Judge on the record, are hereby affirmed.

GENERAL FINDINGS

The findings and determinations hereinafter set forth are supplementary and in addition to the findings and determinations previously made in connection with the issuance of the aforesaid orders and of the previously issued amendments thereto; and all of said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein.

(a) The tentative marketing agreements and the orders, as hereby proposed to be amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the Act;

(b) The parity prices of milk as determined pursuant to section 2 of the Act are not reasonable in view of the price of feeds, available supplies of feeds, and other economic conditions which affect market supply and demand for milk in the marketing areas, and the minimum prices specified in the tentative marketing agreements and the orders, as hereby proposed to be amended, are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk, and be in the public interest; and

(c) The tentative marketing agreements and the orders, as hereby proposed to be amended, will regulate the handling of milk in the same manner as, and will be applicable only to persons in the respective classes of industrial and commercial activity specified in, marketing agreements upon which a hearing has been held.

MARKETING AGREEMENT AND ORDER

Annexed hereto and made a part hereof are two documents, a marketing agreement regulating the handling of milk,[1] and an order amending the orders regulating the handling of milk in the aforesaid specified marketing areas, which have been decided upon as the detailed and appropriate means of effectuating the foregoing conclusions.

It is hereby ordered, That this entire decision, except the attached marketing agreement, be published in the FEDERAL REGISTER. The regulatory provisions of the marketing agreements are identical with those contained in the orders as hereby proposed to be amended by the attached order which is published with this decision.

[1] Filed as part of original document.

DETERMINATION OF PRODUCER APPROVAL AND REPRESENTATIVE PERIOD

December 1973 (September 1973 for the New York-New Jersey order) is hereby determined to be the representative period for the purpose of ascertaining whether the issuance of the orders, as amended and as hereby proposed to be amended, regulating the handling of milk in the aforesaid specified marketing areas, is approved or favored by producers, as defined under the terms of each of the orders (as amended and as hereby proposed to be amended), who during such representative period were engaged in the production of milk for sale within the aforesaid marketing areas.

Signed at Washington, D.C., on: March 27, 1974.

CLAYTON YEUTTER,
Assistant Secretary.

ORDER[2] AMENDING THE ORDER, REGULATING THE HANDLING OF MILK IN THE CERTAIN SPECIFIED MARKETING AREAS.

FINDINGS AND DETERMINATIONS

The findings and determinations hereinafter set forth are supplementary and in addition to the findings and determinations previously made in connection with the issuance of each of the aforesaid orders and of the previously issued amendments thereto; and all of said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein. The following findings are hereby made with respect to each of the aforesaid orders.

(a) *Findings.* A public hearing was held upon certain proposed amendments to the tentative marketing agreements and to the orders regulating the handling of milk in the aforesaid specified marketing areas. The hearing was held pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 et seq.), and the applicable rules of practice and procedure (7 CFR Part 900).

Upon the basis of the evidence introduced at such hearing and the record thereof, it is found that:

(1) The said order as hereby amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the Act;

(2) The parity prices of milk, as determined pursuant to section 2 of the Act, are not reasonable in view of the price of feeds, available supplies of feeds, and other economic conditions which affect market supply and demand for milk in the said marketing area, and the minimum prices specified in the order as hereby amended, are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk, and be in the public interest; and

(3) The said order as thereby amended regulates the handling of milk in the same manner as, and is applicable only to persons in the respective classes of industrial or commercial activity specified in, a marketing agreement upon which a hearing has been held.

Order relative to handling. It is therefore ordered that on and after the effective date hereof the handling of milk in each of the specified marketing areas shall be in conformity to and in compliance with the terms and conditions of each of the orders, as amended, and as hereby amended, as follows:

PART 1001—MILK IN THE BOSTON REGIONAL MARKETING AREA

1. The introductory text of § 100.61(b) preceding the table is revised as follows:

§ 1001.61 Class prices.

* * * * *

(b) *Class II price.* Subject to the adjustment set forth below for the applicable month, the Class II price shall be the lesser of the basic formula price for the month or a butterpowder formula price for the month computed pursuant to paragraph (b)(1) through (3) of this section: *Provided*, That from the effective date hereof through July 1974, the price computed pursuant to paragraph (b)(1) through (3) of this section shall not be the Class II price.

* * * * *

2. In § 1001.64, a new paragraph (j) is added as follows:

§ 1001.64 Computation of value of fluid milk products at class prices.

* * * * *

(j) Deduct for each of the months from the effective date hereof through July 1974, an amount computed by multiplying the quantity of producer milk classified as Class II milk and used to produce butter or nonfat dry milk by the lesser of 50 cents per hundredweight or the amount that the basic formula price exceeds the price computed pursuant to § 1001.61(b)(1) through (3).

PART 1002—MILK IN THE NEW YORK-NEW JERSEY MARKETING AREA

1. The introductory text of § 1002.50a (c) preceding the table is revised as follows:

§ 1002.50a Class prices.

* * * * *

(c) Subject to the adjustment set forth below for the applicable month, the Class II price shall be the lesser of the basic formula price for the month or a butter-powder formula price computed pursuant to paragraph (c)(1) through (3) of this section: *Provided*, That from the effective date hereof through July 1974, the price computed pursuant to paragraph (c)(1) through (3) of this section shall not be the Class II price.

* * * * *

[2] This order shall not become effective unless and until the requirements of § 900.14 of the rules of practice and procedure governing proceedings to formulate marketing agreements and marketing orders have been met.

2. In § 1002.70, the introductory text is revised and a new paragraph (f) is added as follows:

§ 1002.70 Net pool obligation of handlers.

Each handler's net pool obligation for milk received at each plant and unit shall be computed separately pursuant to paragraphs (a) through (d) of this section and then combined into one total to be adjusted by any credit applicable pursuant to paragraphs (e) and (f) of this section to determine the handler's total net pool obligation.

* * * * *

(f) Deduct for each of the months from the effective date hereof through July 1974, an amount computed by multiplying the quantity of pool milk classified as Class II milk and used to produce butter or nonfat dry milk by the lesser of 50 cents per hundred-weight or the amount that the basic formula price exceeds the price computed pursuant to § 1002.50a(c) (1) through (3).

PART 1004—MILK IN THE MIDDLE ATLANTIC MARKETING AREA

1. The introductory text of § 1004.50(b) preceding the table is revised as follows:

§ 1004.50 Class prices.

* * * * *

(b) *Class II price.* Subject to the adjustment set forth below for the applicable month, the Class II price shall be the lesser of the basic formula price for the month or a butter-powder formula price computed pursuant to paragraph (b) (1) through (3) of this section: *Provided,* That from the effective date hereof through July 1974, the price computed pursuant to paragraph (b) (1) through (3) of this section shall not be the Class II price.

* * * * *

2. In § 1004.60, a new paragraph (f) is added as follows:

§ 1004.60 Pool obligation of each pool handler.

* * * * *

(f) Deduct for each of the months from the effective date hereof through July 1974 an amount computed by multiplying the quantity of producer milk classified as Class II milk used to produce butter or nonfat dry milk by the lesser of 50 cents per hundredweight or the amount that the basic formula price exceeds the price computed pursuant to § 1004.50(b) (1) through (3).

3. In § 1004.61, paragraph (b) (1) (i) is revised as follows:

§ 1004.61 Computation of weighted average price and uniform prices for base milk and excess milk.

(b) * * *

(1) * * *

(i) Multiply the quantity of such milk which does not exceed the total quantity of producer milk received by such handlers assigned to Class II milk by the Class II milk price less 5 cents: *Provided,* That for each month from the effective date hereof through July 1974, there shall be deducted from the value of such excess milk an amount determined pursuant to § 1004.60(f) that is not in excess of an amount determined by multiplying the quantity of excess milk by the lesser or 50 cents per hundredweight or the amount that the basic formula price exceeds the price computed pursuant to § 1004.50(b) (1) through (3);

* * * * *

PART 1015—MILK IN THE CONNECTICUT MARKETING AREA

1. The introductory text of § 1015.61 (b) preceding the table is revised as follows:

§ 1015.61 Class prices.

* * * * *

(b) *Class II price.* Subject to the adjustment set forth below for the applicable month, the Class II price shall be the lesser of the basic formula price for the month or a butter-powder formula price computed pursuant to paragraph (b) (1) through (3) of this section: *Provided,* That from the effective date hereof through July 1974 the price computed pursuant to paragraph (b) (1) through (3) of this section shall not be the Class II price.

* * * * *

2. In § 1015.63, paragraph (g) is revised and a new paragraph (h) is added as follows:

§ 1015.63 Value of each handler's fluid milk products.

* * * * *

(g) Add together the values resulting from the computations described in paragraphs (a) through (e) of this section and subtract therefrom the values resulting from the computations described in paragraphs (f) and (h) of this section. The remainder shall be known as the value of fluid milk products.

(h) Deduct from the effective date hereof through July 1974 an amount computed by multiplying the quantity of producer milk classified as Class II milk used to produce butter or nonfat dry milk by the lesser of 50 cents per hundredweight or the amount that the basic formula price exceeds the price computed pursuant to § 1015.61(b) (1) through (3).

PART 1033—MILK IN THE OHIO VALLEY MARKETING AREA

1. The introductory text of § 1033.51 (c) is revised as follows:

§ 1033.51 Class prices.

* * * * *

(c) *Class III price.* The Class III price shall be the basic formula price for the month, but not to exceed an amount computed as follows: *Provided,* That from the effective date hereof through July 1974, the price computed pursuant to paragraph (c) (1) through (3) of this section shall not be the Class III price:

* * * * *

2. In § 1033.60, a new paragraph (h) is added as follows:

§ 1033.60 Computation of the net pool obligation of each handler.

* * * * *

(h) Deduct for each of the months from the effective date hereof through July 1974, an amount computed by multiplying the quantity of producer milk classified as Class III milk and used to produce butter or nonfat dry milk by the lesser of 50 cents per hundredweight or the amount that the basic formula price exceeds the price computed pursuant to § 1033.51(c) (1) through (3).

PART 1036—MILK IN THE EASTERN OHIO-WESTERN PENNSYLVANIA MARKETING AREA

1. The introductory text of § 1036.50(c) is revised as follows:

§ 1036.50 Class prices.

* * * * *

(c) *Class III price.* The Class III price shall be the basic formula price for the month, but not to exceed an amount computed as follows: *Provided,* That from the effective date hereof through July 1974, the price computed pursuant to paragraph (c) (1) through (3) of this section shall not be the Class III price:

* * * * *

2. In § 1036.60, a new paragraph (f) is added as follows:

§ 1036.60 Handler's value of milk for computing uniform price.

* * * * *

(f) Deduct for each of the months from the effective date hereof through July 1974, an amount computed by multiplying the quantity of producer milk classified as Class III milk and used to produce butter or nonfat milk by the lesser of 50 cents per hundredweight or the amount that the basic formula price exceeds the price computed pursuant to § 1036.50(c) (1) through (3).

PART 1040—MILK IN THE SOUTHERN MICHIGAN MARKETING AREA

1. The introductory text of § 1040.50 (c) is revised as follows:

§ 1040.50 Class prices.

* * * * *

(c) *Class III price.* The Class III price shall be the basic formula price, but not to exceed an amount computed as follows: *Provided,* That from the effective date hereof through July 1974, the price computed pursuant to paragraph (c) (1) through (3) of this section shall not be the Class III price:

* * * * *

2. In § 1040.60, a new paragraph (h) is added as follows:

§ 1040.60 Handler's value of milk for computing uniform price.

* * * * *

(h) Subtract for each of the months from the effective date hereof through July 1974, an amount computed by multiplying the quantity of producer milk classified as Class III milk used to produce butter or nonfat dry milk by the

lesser of 50 cents per hundredweight or the amount that the basic formula price exceeds the price computed pursuant to § 1040.50(c) (1) through (3).

3. In § 1040.61, paragraph (d) is revised as follows:

* * * * *

§ 1040.61 Computation of uniform prices for base milk and excess milk (including uniform price and adjusted uniform price).

* * * * *

(d) The excess milk price which shall be the Class III price pursuant to § 1040.50(c): *Provided*, That for each month from the effective date hereof through July 1974, the excess milk price shall be determined as follows:

(1) Multiply the total pounds of excess milk for the month by the Class III price;

(2) Subtract the amount determined pursuant to § 1040.60(h) that is not in excess of an amount determined by multiplying the quantity of excess milk by the lesser of 50 cents per hundredweight or the amount that the basic formula price exceeds the price computed pursuant to § 1040.50(c) (1) through (3); and

(3) Divide the resultant value by the total hundredweight of excess milk. The resultant hundredweight price shall be the uniform price of excess milk of 3.5 percent butterfat content.

PART 1049—MILK IN THE INDIANA MARKETING AREA

1. The introductory text of § 1049.50(b) is revised as follows:

§ 1049.50 Class prices.

* * * * *

(b) *Class II price.* The Class II price shall be the basic formula price computed pursuant to § 1049.51, but not to exceed an amount computed as follows: *Provided*, That from the effective date hereof through July 1974, the price computed pursuant to paragraph (b) (1) through (3) of this section shall not be the Class II price:

* * * * *

2. In § 1049.60, a new paragraph (f) is added as follows:

§ 1049.60 Handler's value of milk for computing uniform price.

* * * * *

(f) Deduct for each of the months from the effective date hereof through July 1974, an amount computed by multiplying the quantity of producer milk classified as Class II used to produce butter or nonfat dry milk by the lesser of 50 cents per hundredweight or the amount that the basic formula price exceeds the price computed pursuant to § 1049.50(b) (1) through (3).

[FR Doc.74-7452 Filed 3-28-74;9:29 am]

Notices

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

ORGANIZATION AND FUNCTIONS

This material supersedes the statements on organization and functions published at 37 FR 20961–20990, 38 FR 23341 and 23342, and 38 FR 30011 and 30012.

Dated: March 25, 1974.

[SEAL] DONALD C. ALEXANDER,
Commissioner of Internal Revenue.

1100 ORGANIZATION AND STAFFING

1110 ORGANIZATION AND FUNCTIONS OF THE INTERNAL REVENUE SERVICE

SEC. 1111 *Establishment of the Internal Revenue Service.*

SEC. 1111.1 *Mission.*

The mission of the Service is to encourage and achieve the highest possible degree of voluntary compliance with the tax laws and regulations and to maintain the highest degree of public confidence in the integrity and efficiency of the Service. This includes communicating the requirements of the law to the public, determining the extent of compliance and causes of non-compliance, and doing all things needful to a proper enforcement of the law.

SEC. 1111.2 *Organic Act.*

(1) The Office of the Commissioner of Internal Revenue was established by an act of Congress (12 Stat. 432) on July 1, 1862, and the first Commissioner of Internal Revenue took office on July 17, 1862.

(2) The act of July 1 provided:

"* * * That, for the purpose of superintending the collection of internal duties, stamp duties, licenses, or taxes imposed by this Act, or which may be hereafter imposed, and of assessing the same, an office is hereby created in the Treasury Department to be called the Office of the Commissioner of the Internal Revenue; * * * Commissioner of Internal Revenue, * * * shall be charged, and hereby is charged, under the direction of the Secretary of the Treasury, with preparing all the instructions, regulations, directions, forms, blanks, stamps, and licenses, and distributing the same or any part thereof, and all other matters pertaining to the assessment and collection of the duties, stamp duties, licenses, and taxes, which may be necessary to carry this Act into effect, and with the general superintendence of his office, as aforesaid, and shall have authority, and hereby is authorized and required, to provide proper and sufficient stamps or dies for expressing and denoting the several stamp duties, or the amount thereof in the case of percentage duties, imposed by this Act, and to alter and renew or replace such stamps from time to time, as occasion shall require; * * *"

(3) By common parlance and understanding of the time, an office of the importance of the Office of Commissioner of Internal Revenue was a bureau. The Secretary of the Treasury in his report at the close of the calendar year 1862 stated that "The Bureau of Internal Revenue has been organized under the Act of the last session * * *" Also it can be seen that Congress had intended to establish a Bureau of Internal Revenue, or thought they had, from the act of March 3, 1863, in which provision was made for the President to appoint with Senate confirmation a Deputy Commissioner of Internal Revenue "who shall be charged with such duties in the bureau of internal revenue as may be prescribed by the Secretary of the Treasury, or as may be required by law, and who shall act as Commissioner of internal revenue in the absence of that officer, and exercise the privilege of franking all letters and documents pertaining to the office of internal revenue." In other words, "the office of internal revenue" was "the bureau of internal revenue," and the act of July 1, 1862 is the organic act of today's Internal Revenue Service.

SEC. 1111.3 *History.*

SEC. 1111.31 *Internal taxation.*

Madison's Notes on the Constitutional Convention reveal clearly that the framers of the Constitution believed for some time that the principal, if not sole, support of the new Federal Government would be derived from customs duties and taxes connected with shipping and importations. Internal taxation would not be resorted to except infrequently, and for special reasons. The first resort to internal taxation, the enactment of internal revenue laws in 1791 and in the following 10 years, was occasioned by the exigencies of the public credit. These first laws were repealed in 1802. Internal revenue laws were reenacted for the period 1813–1817 when the effects of the war of 1812 caused Congress to resort to internal taxation. From 1818 to 1861, however, the United States had no internal revenue laws and the Federal Government was supported by the revenue from import duties and the proceeds from the sale of public lands. In 1862 Congress once more levied internal revenue taxes. This time the establishment of an internal revenue system, not exclusively dependent upon the supplies of foreign commerce, was permanent.

SEC. 1111.32 *Background and evolution of present organization.*

(1) Before the establishment of the Office of Commissioner of Internal Revenue, taxes were collected by "Supervisors" of collection districts who were appointed by the President, subject to Senate confirmation. These Supervisors worked under the direct control of the Treasury Department. The Revenue Act of 1813 provided, for the first time, for a "Collector" and a "Principal Assessor" for each collection district, and for deputy collectors and assistant assessors. Collectors and Assessors appear to be the original forerunners of the twentieth century Collectors of Internal Revenue and Internal Revenue Agents in Charge.

(2) Since 1862, the Internal Revenue Service has undergone a period of steady growth as the means for financing Government operations shifted from the levying of import duties to internal taxation. Its expansion received considerable impetus in 1913 with the ratification of the Sixteenth Amendment to the Constitution under which Congress received constitutional authority to levy taxes on the income of individuals and corporations. With the enactment of income tax laws the work of the Revenue Service began to take on a highly technical character.

(3) From the World War I period through 1951, the basic organizational structure of the Internal Revenue Service remained essentially unchanged even though there were marked increases in the number of taxpayers serviced, revenue receipts, employees and the overall workload. The Service was organized, in Washington and the field, on a program or "type-of-tax" basis, with jurisdictionally separate organizations, or "Units," charged with the administration of different types of taxes.

SEC. 1111.4 *Reorganization Plan No. 1 of 1952 and other changes.*

(1) On January 14, 1952, the President of the United States submitted to Congress Reorganization Plan No. 1 of 1952, calling for a comprehensive reorganization of the Internal Revenue Service. On March 13, 1952, the last motion to defeat the Plan was voted down in the Senate, and the Plan became effective on March 15, 1952.

(2) Reorganization Plan No. 1 of 1952 brought about four basic changes in the Internal Revenue Service:

(a) The organization of the Service along functional lines—i.e., operations, administration, technical, planning, and inspection;

(b) The abandonment of the system of political appointments to positions below the Commissioner;

(c) The integration of most field revenue programs under District Directors of Internal Revenue; and

(d) The establishment of a system of regional administration under Regional Commissioners of Internal Revenue.

(3) The Reorganization Plan provided authority for the establishment of 25 Offices of Regional Commissioners (referred to as "District Commissioners" in the Plan). By December 1, 1952, the Offices of 17 Regional Commissioners had been established. The major field programs, including alcohol and tobacco tax enforcement, were integrated under District Directors; the appellate program and the permissive alcohol and tobacco tax functions were placed in the Offices of Regional Commissioners; and, in the National Office, all activities were placed under Assistant Commissioners for Inspection; Operations; and Technical; an Assistant to the Commissioner, and an Administrative Assistant to the Commissioner.

(4) In 1953, a number of organizational refinements were effected. The number of regions was reduced to 9; the field operations of Alcohol and Tobacco Tax were centralized at the regional level; and the delinquent accounts and returns program was transferred from the Audit Divisions in the Offices of District Directors to their Collection Divisions. In the National Office, the position of Deputy Commissioner was established and the Bureau of Internal Revenue was redesignated as the Internal Revenue Service.

(5) Other significant changes since 1953 include establishment of the Offices of Assistant Commissioners for Administration, Data Processing, and Planning and Research; redesignation of the Assistant Commissioner (Operations) as the Assistant Commissioner (Compliance); discontinuance of the Columbus and Toledo (Ohio) districts and consolidation of the Upper and Lower Manhattan districts, effective January 1, 1960; establishment of the Anchorage (Alaska) district on January 1, 1961; transfer on September 13, 1963 of the Director of Practice from the Internal Revenue Service to the Office of the Secretary of the Treasury to be under the immediate supervision of the General Counsel; effective January 1, 1964, reduction in the number of regions to 8 and discontinuance of the districts of Camden (New Jersey), Kansas City (Missouri), Scranton (Pennsylvania), and Syracuse (New York); and, effective January 4, 1965, reduction in the number of regions to 7. On December 19, 1968, Alcohol and Tobacco Tax Division was changed to Alcohol, Tobacco and Firearms Division. Effective July 1, 1971, the Office of Assistant Commissioner (Data Processing) was redesignated Office of Assistant Commissioner (Accounts, Collection, and Taxpayer Service). Effective November 14, 1971, the position of Assistant Commissioner (Stabilization) was established. Effective July 1, 1972, the Alcohol, Tobacco and Firearms activity was transferred from the Internal Revenue Service to be a separate bureau within the Department of the Treasury.

SEC. 1112 *Service Organization.*

(1) The Internal Revenue Service is a component part of the Treasury Department. The Service is headed by the Commissioner of Internal Revenue who serves under the direction of the Secretary of the Treasury.

(2) The Internal Revenue Service consists of a National Office in Washington, D.C., and a field organization. The latter consists of 7 Internal Revenue regions, each headed by a Regional Commissioner who reports to the Deputy Commissioner; 58 Internal Revenue districts, each headed by a District Director, and 10 service centers, each headed by a Director, who report to a Regional Commissioner; and a computer center and a data center under the direction of the Assistant Commissioner (Accounts, Collection, and Taxpayer Service) in the National Office. In addition, there are in the field 7 Regional Inspectors and 7 Regional Counsels, who report to the Assistant Commissioner (Inspection) and the Chief Counsel, respectively, in Washington, D.C.

(3) In administering the appellate functions direct from the regional office, the Regional Commissioner maintains and supervises branch offices headed by Chiefs, Appellate Branch Office, who report to the Assistant Regional Commissioner (Appellate) who also carries the title of Chief, Appellate Division. Chief, Appellate Branch Office, may also supervise sub-offices administered by an Assistant Chief or local representative of the Chief.

(4) The Regional Counsels also maintain and supervise branch offices.

(5) In each Internal Revenue district there are offices in communities where concentration of workload in audit, collection, intelligence, or stabilization activities requires the assignment of personnel.

SEC. 1113 *National Office.*

SEC. 1113.1 *Mission.*

The mission of the National Office is to develop broad nationwide policies and programs for the administration of the internal revenue laws and related statutes, and to direct, guide, coordinate, and control the endeavors of the Internal Revenue Service.

SEC. 1113.2 *Basic Organization.*

The principal offices which form the National Office are: The Office of the Commissioner; the Office of the Assistant Commissioner (Administration); the Office of the Assistant Commissioner (Compliance); the Office of the Assistant Commissioner (Accounts, Collection, and Taxpayer Service); the Office of the Assistant Commissioner (Inspection); the Office of the Assistant Commissioner (Planning and Research); the Office of the Assistant Commissioner (Technical); the Office of the Assistant Commissioner (Stabilization); and the Office of the Chief Counsel.

SEC. 1113.3 *Office of the Commissioner.*

The Commissioner of Internal Revenue, in conformity with policies and delegations of authority made by the Secretary of the Treasury, establishes the policies and administers the activities of the Internal Revenue Service. The Office of the Commissioner includes the Deputy Commissioner, the Assistant to the Commissioner, Assistant to the Commissioner (Public Affairs) and the Tax Administration Advisory Staff.

SEC. 1113.31 *Deputy Commissioner.*

The Deputy Commissioner assists and acts for the Commissioner in planning, directing, coordinating and controlling the policies and programs and in giving executive leadership to the activities of the Internal Revenue Service. The Deputy Commissioner also supervises the Regional Commissioners of Internal Revenue, and makes allocations of funds and personnel to them.

SEC. 1113.32 *Assistant to the Commissioner.*

The Assistant to the Commissioner reviews and takes final action for the Commissioner on documents involving technical matters prepared for the Commissioner's signature, including regulations, reports on proposed legislation, rulings, correspondence, compromises and reports to the Joint Committee on Internal Revenue Taxation involving refunds or credits of any income, war profits, excess profits, estate, or gift taxes in excess of $100,000. The Assistant to the Commissioner makes independent studies for the Commissioner.

SEC. 1113.33 *Assistant to the Commissioner (Public Affairs).*

The Assistant to the Commissioner (Public Affairs) counsels and advises the Commissioner, Deputy Commissioner and other levels of management on matters where public interest or response is involved in the determination of Service policies and the execution of Service programs. Plans, develops and coordinates the Service-wide policies and programs for providing information to the public through mass communication methods to help improve knowledge and understanding of Federal tax and related laws and their administration, for the primary purpose of encouraging and facilitating maximum voluntary compliance by the public. Conducts continuous studies of the Service's public affairs activities to identify and act on problems and opportunities for improvement. Maintains liaison with and provides functional supervision to regional and district offices in public affairs matters and carries out public affairs programs at the National Office and directs the activities of the Public Affairs Division. Evaluates for the Commissioner public response to Service policies and programs and recommends Service actions where indicated.

SEC. 1113.331 *Administrative Office.*

Provides administrative support for the public affairs function. Coordinates budget formulation and financial planning for the Division and assists in developing staffing, training, and personnel

plans for field public affairs activities. Provides the necessary administrative support to the internal operation of the Division, maintaining liaison with Personnel, Training, Facilities Management, and Fiscal Management personnel. Provides library and reference services for public affairs personnel and a daily newspaper clipping service for top Service and Department officials. Services requests for inspection and copies of exempt organization returns, Abstracts and Statements for accepted offers in compromise. Maintains the Freedom of Information Reading Room and services requests for documents on deposit therein.

SEC. 1113.332 *Operations Branch.*

Responsible for the continuing relationships and day-to-day contacts with national media and Washington bureaus of media serving local communities, on all aspects of the IRS mission and operations. Media include the press, radio, television, news services, trade associations, and other organizations that provide information to large segments of the public. Seeks out and develops new media outlets. Maintains a knowledge of all significant Service objectives, activities and problems; and an awareness of public interest and news developments which affect the Service. Conducts information activities both in response to media requests and as initiated in response to Service-recognized needs. The activities include answering queries, arranging interviews, reviewing articles, arranging news conferences, organizing public appearances, preparing news releases, radio and television announcements, fact sheets, feature articles, and conducting other information efforts to further Service objectives and assist the media in serving their audiences or members. Responsibilities also encompass assisting field officials in relationships with local media in situations where immediate action is required. Compiles the Commissioner's Letter, National Office Notes and other communications to employees. Responds to public correspondence relating to national news stories.

SEC. 1113.333 *Programs Branch.*

Responsible for formulating nationwide public affairs programs and providing the information materials, program guidance, coordination, and assistance necessary to implement those programs. Consults with operating officials to determine Service objectives and priorities, develops supporting information themes and objectives, and plans specific information actions, timetables and materials. Develops public affairs audio-visual materials and written materials for distribution to media through IRS field offices. Advises field offices of National Office information programs and projects; provides training, procedural guidance, and program assistance; supervises field visits; analyzes reports and other indicators of program effectiveness; prepares program evaluations and initiates action to improve programs where necessary. Serves as primary point of contact with field Public Affairs Officers and assures prompt National Office response to their inquiries, requests for disclosure guidance under Freedom of Information Act, and other needs. Compiles the Commissioner's Annual Report and the Service segment of the Secretary's Annual Report.

SEC. 1113.34 *Tax Administration Advisory Staff.*

The Tax Administration Advisory Staff provides leadership within the Service for the development and implementation of comprehensive programs of assistance in tax administration to developing nations, and on occasion, to the more developed nations, in line with the foreign policy of the United States and its commitments to the Organization of American States, the United Nations, and other international institutions. It is the central point of contact within the Service with foreign governments, the State Department and international organizations on all matters involving the exchange of technical assistance in tax administration. The Staff designs broad programs aimed at modernizing and strengthening tax administration in developing countries; it determines program requirements in terms of number and qualifications of advisors and selects, trains, and assigns such advisors. It provides technical leadership and direction, continually monitors, and periodically evaluates country programs to ensure maximum effectiveness of assistance efforts. The Staff develops and arranges study and observation programs in tax administration for foreign tax officials, which are conducted largely in the U.S. and occasionally at overseas sites. The Staff maintains close liaison with the Department of State and the Agency for International Development (AID), foreign governments, international organizations, and the Office of the Secretary on matters concerning the foreign tax assistance program, most of which is conducted cooperatively with AID. The Director, Tax Administration Advisory Staff, has been delegated authority to arrange for and authorize temporary assignment of personnel between the IRS and State and local governments and institutions of higher education. The Director is responsible for determining that requests for individual assignments or for projects of assistance involving several assignments are consistent with the intent of the Act and that the requirements for mutual benefit to the Service and the requesting organization are met. The Director is also authorized to set the amount of the financial support to be provided by the Service and to make such other determinations as are needed. The Staff will furnish or arrange for any necessary technical direction and support of employees on assignment to other organizations.

SEC. 1113.4 *Office of Assistant Commissioner (Administration).*

The Assistant Commissioner (Administration) is the principal assistant to the Commissioner in planning and executing the Administration program of the Internal Revenue Service, which includes fiscal management, personnel, facilities management, training, employment policy, and management improvement. Jointly, with other Assistant Commissioners, he participates in the general management of the Service by coordinating Administration with other functions to accomplish the objectives of a comprehensive and well-integrated Revenue program. On general administrative matters represents the Commissioner in relationships with the Congress; the Department of the Treasury Office of the Secretary and other components of the Department of the Treasury; and such agencies as the Office of Management and Budget, the Civil Service Commission and General Services Administration. Supervises the activities of the Fiscal Management, Personnel, Facilities Management, and Training Divisions in the National Office, and is responsible for functional supervision of Administration activities in the field.

SEC. 1113.41 *Facilities Management Division—Office of the Director.*

Develops, directs, coordinates, and evaluates policies and programs for providing essential support activities for the operating divisions' primary programs and carries them out in the National Office. Its programs are designed to increase the effectiveness of the Internal Revenue Service, reduce its operating costs, and improve taxpayer relations by tailoring Internal Revenue Service physical facilities and by providing support services to best meet the Service's total needs. These programs include information and records systems, space, property, supply, transportation, and telecommunications management, procurement and contracting, printing and distribution, national emergency planning, safety, document and physical security, and the settlement of tort claims. Develops the standards and procedures necessary for effective performance of its functions. This Division consists of five branches: National Office Facilities, Information Systems, Protective Programs, Space and Property, and Publishing Services.

SEC. 1113.411 *National Office Facilities Branch.*

Develops, coordinates, directs, and evaluates the Contracting and Procurement Programs of the Internal Revenue Service. Develops procurement policy and procedures, and provides guidelines and consultative assistance for all Internal Revenue Service Procurement Programs. Appraises procurement programs through a systematic program of visits to field offices and through review and analysis of reports and accomplishments. In addition, develops, coordinates, directs and evaluates all Facilities Management programs and activities (except printing and distribution and National Office emergency relocation planning) within the National Office, including the National Training Center and the National Computer Center, within the broad guidelines established by the Division Director. Thse activities include: Information and records systems, space management, transportation management,

property and supply management, telecommunications management, protective programs, and contracting and procurement. Maintains liaison with National Office officials, other Government agencies, public utilities, contractors, private carriers, and other private and public organizations to coordinate and improve service in all of these activities.

SEC. 1113.412 *Information Systems Branch.*

Plans, develops, promotes, coordinates, and evaluates programs designed to increase the effectiveness of Servicewide operations in the following areas: Records Management — documentation standards; correspondence; and the management of records creation, retrieval, retention, and disposal; Information Systems Analysis—internal mail and files management; management of information and records handling equipment and supplies; studies of information utilization and flow, and of paperwork management; analysis, either singly, or in collaboration with the Systems Development Division of the information needs of management at various levels of the Service, and the development of reporting and management information systems to effectively and economically meet those needs; guidelines and standards for application of microphotography (excepting microphotographic publishing), and other information handling and word processing technology; Reports Management—development of Servicewide reports management policies, procedures, and standards; control, review and evaluation of National Office generated reporting and management information systems; maintenance of a Servicewide information inventory and of the National Office Reports Catalogue; Mail and Transportation Management—coordination and planning for those services provided by the U.S. Postal Service, or private shippers and service units of IRS, for physically transporting, controlling, delivering, sorting and distributing material in solid forms such as correspondence, documents, receipts, microfilm, or magnetic tape; Telecommunications Systems—services and facilities for transmitting and receiving data and information and the operation of telephone, telegraph, facsimile, and data communications systems, equipment and circuitry. The Branch determines the need for program emphasis and goals, develops the programs and promotes and coordinates their acceptance and implementation with other components of the Service; provides standardized techniques, guidelines, and consultative services needed in these areas by the Service. Collaborates with the Systems Development Division in matters involving communications and information storage and retrieval systems. Acts as liaison for the Service with other Federal agencies and industry in matters concerning Branch program activities.

SEC. 1113.413 *Protective Programs Branch.*

Develops, coordinates, administers, and evaluates Servicewide programs of civil defense and emergency planning which includes contingency plans for coping with demonstrations, civil disorder and bomb threats; accident prevention; physical and document security and identification. Ensures continuity of operations by preventing or minimizing loss through acident, employee injury, fire, theft, enemy attack, natural disaster, and civil disturbance, and breaches of security of facilities, equipment, and documents. Exercises the authority to settle claims arising out of the activities of the Internal Revenue Service under the Federal Tort Claims Act, the Military Personnel and Civilian Employees' Claims Act and the Claims Collection Act, and administers the program to ensure equitable settlement and payment of claims.

SEC. 1113.414 *Publishing Services Branch.*

Plans, develops, coordinates, administers, and evaluates the policies, systems, procedures, and standards for the publishing needs of the Internal Revenue Service in consonance with the Congressional Joint Committee on Printing Regulations. Participates in agency-wide program planning and development. Responsible for the fiscal control, planning, analysis, graphic design, requirements determination, procurement, integrated scheduling, inventory maintenance, and distribution of all published material. Administers the Servicewide forms management program and the publishing systems for forms, publications and envelopes. Provides for comprehensive graphic presentation program assistance and services. Initiates, directs, and coordinates studies to develop or improve processes in the publishing and graphic arts fields including duplicating and printing equipment; office reproduction machines; electronic composition; visual media; inventory, storage, and mail and distribution systems for published material. Provides functional supervision and logistical support to field components for the management of printing (including procurement), forms, graphic design, and distribution. Represents IRS in liaison and negotiation with other governmental agencies, private industry groups, and the public on matters pertaining to IRS publishing activities.

SEC. 1113.415 *Space and Property Branch.*

Plans, develops, promotes, coordinates, and evaluates programs designed to increase the effectiveness of Servicewide operations in the following areas: Space Management—planning requirements for IRS space, providing standards for environmental quality programs and for the acquisition, maintenance, utilization and disposal of space to ensure an effective, efficient, and appropriate physical working environment for all Service employees, and a pleasing environment for public visitors; Property and Supply Management—conducts utilization studies, establishes requirements, designs, disposes of and maintains furniture, furnishings, certain non-capitalized and capitalized equipment including data processing auxiliary and accessory equipment; manages property accountability and the IRS motor vehicle fleet management; Electronic Support Systems—provides support services for the requirements, procurement, installation and inspection of electronic data processing systems and other electronic, electromechanical audiovisual and other computerized or automated devices, equipment and systems; analyzes and conducts power reliability studies for IRS buildings. The Branch determines the need for program emphasis and goals, develops the programs and promotes and coordinates their acceptance and implementation with other components of the Service; provides standardized techniques, guidelines, and consultative services needed in these areas by the Service. Confers and collaborates with the Systems Development Division and the Acounts and Data Processing Division in matters involving new systems and equipment related to branch functions, and with other government agencies and private industry to assure proper installation. Acts as liaison for the Service with other Federal agencies and industry in matters concerning Branch program activities.

SEC. 1113.42 *Fiscal Management Division.*

Develops, plans, coordinates and evaluates the financial management and budget policies and programs of the Internal Revenue Service. Develops and assists in the justification of the Service's budget; advises on its execution; establishes procedures covering the accounting system for appropriated funds; and directs the budget and fiscal activities carried out in the National Office. Counsels and advises the Commissioner, the Deputy Commissioner and all levels of management on matters concerning budget and the fiscal management of funds appropriated for the administration of the Service. The Division, under the direction of the Fiscal Management Officer, consists of two branches: Accounting Branch and Budget Branch.

SEC. 1113.421 *Accounting Branch.*

The Accounting Branch develops, prescribes, and installs the Service's financial accounting system to produce timely and accurate data for budgetary and fiscal management purposes. It also collaborates with Planning and Analysis and Facilities Management Divisions in developing and administering the financial reporting system, as it relates to IRS management information systems.

SEC. 1113.422 *Budget Branch.*

The Budget Branch develops the Service's budget in conformance with the established over-all program policies through consultation and cooperation with the responsible operating officials. It prescribes budget procedures and directs the preparation of budget estimates for the Service; participates in the development of standards for the measurements of work necessary in the justification of estimates or the evaluation of financial plans; prepares requests for the apportionment of reapportionment of

appropriations; allots funds in accordance with the approved financial plan and properly authorized revisions thereof; establishes the procedures and records necessary to properly reflect the execution of the budget; and collaborates with the Planning and Analysis and Facilities Management Divisions in developing and administering a reporting system reflecting the status of the budget and financial plan, as it relates to IRS management information systems.

SEC. 1113.43 *Personnel Division—Office of the Director.*

Plans, directs and leads in the development, coordination and evaluation of the personnel policies and programs of the Service. Provides functional supervision over personnel operations throughout the Service and personnel programs in the regions, districts and service centers, including long-range planning, organization and staffing studies, staff development and program evaluation. Administers centralized personnel activities including those for employees of the National Office. Acts as appellate office for the Commissioner on adverse action and grievance appeals and designates hearing officers when requested. Through the Technical Advisor directs appropriate personnel activities to promote effective manpower utilization. Prepares certain Servicewide personnel reports for the Civil Service Commission and other agencies. Exercises line supervision over the Eastern and Western Assessment Centers in their activities involving evaluation of candidates for supervisory, managerial and executive positions. Reviews and approves Servicewide security clearances for non-critical sensitive positions.

SEC. 1113.431 *Union Relations Branch.*

Develops and coordinates policies, procedures and instructions in the areas of union-management relationships, employee conduct, disciplinary actions and appeal procedures. Serves as IRS functional specialist; reviews, evaluates, assists, interprets, disseminates information and exercises functional supervision over Service activities in these program areas. Acts as liaison between the Service and the Office of the Secretary, Treasury Department Bureaus, and Civil Service Commission and other Federal agencies and provides comments on legislation, for these program areas. Responsible for liaison, consultation and negotiation with unions.

SEC. 1113.432 *Employment Branch.*

Develops and coordinates policies, procedures, and program instructions including technical training programs for the employee programs of the Service such as: recruitment; selection; placement; appointment; career status; details; veteran's preference; orientation and placement follow-up; reduction-in-force equal employment; separations; awards and incentive programs; high quality increases; pay administration; employee benefits and services; fitness for duty; and recreation and fund-raising. Develops and coordinates redeployment programs and procedures; coordinates, as required, personnel programs affecting service center installations. Develops and coordinates policies and procedures pertaining to participation of the Interagency Boards. Reviews and advises on budgetary and staffing proposals relative to recruitment, selection and utilization of personnel. Exercises functional supervision over counterpart operations throughout the Service, and participates as functional specialists in evaluation of field programs. Provides staff expertise in personnel management techniques for the development and application of automated processes to personnel management. Administers the Personnel Reports Management System. Processes Section 6(c) retirement cases.

Develops and maintains automated personnel data specifications; coordinates these specifications with the IRS Data Center and submits them to the Data Center for implementation.

SEC. 1113.433 *National Office Branch.*

Develops and executes policies, programs and procedures relating to recruitment, selection, placement, employee relations, position classification, discipline, performance evaluation promotion, manpower utilization, and other aspects of a complete personnel program for National Office and certain field positions with the exception of those requiring Treasury or Civil Service approval; reviews the budget for proposed position reallocations pertinent to the above positions. In addition, performs the following duties pertaining to Servicewide programs: renders support to the Tax Administration Advisory Staff; administers National Placement Program; reviews and processes regional employment cases for which authority has not been delegated to regions; processes proposals for Gallatin Awards; and answers general inquiries and other correspondence concerning applications for employment, reassignment, promotion, etc.

SEC. 1113.434 *Position Management Branch.*

Plans, develops and coordinates procedures and program instructions to enable line managers to most effectively establish and manage positions in their organization. Provides advice to managers as to job content, grade structure and organization design. Assists managers in assessing position management effectiveness in their organization. Working with functional representatives, develops occupational standards and guides such as case classification guides, rating schedules, classification and qualification guides. Coordinates with the Office of the Secretary on all classification, position management and occupational standards questions requiring the Secretary's Office's consideration. Exercises Servicewide functional supervision for position management operations. Provides program advice and assistance to Regional Offices and National Office Branch and assesses their program effectiveness. Performs such centralized services as classification of positions for which authority has not been delegated to the field, development of standard position descriptions, and preparation of recommendations and justifications for classification of supergrade positions. Adjudicates classification appeals and administers Wage Grade Systems. In collaboration with the Training Division, formulates and provides functional classification training courses to maintain and improve the level of technical excellence in the execution of the Servicewide position management program; and develops, negotiates and administers Servicewide training agreements.

SEC. 1113.435 *Careers Branch.*

Develops and coordinates policies, procedures, and program instructions for the Service's technical, supervisory, managerial, and executive career programs. Develops techniques and criteria for evaluating supervisory, managerial, and executive potential; exercises functional personnel direction, over implementation and follow-through on career programs; performs essential personnel services for career programs for supervisory and managerial positions; provides staff assistance to the Executive Resources Board which selects and assigns executive personnel; and administers the employee performance evaluation and promotion programs. Provides staff expertise in personnel management techniques including the conduct and direction of studies requiring the use of psychological and other social science methodology; coordinates and administers the IRS testing program (noncompetitive written test).

SEC. 1113.44 *Training Division—Office of the Director.*

The Director formulates and recommends overall training policies of the Internal Revenue Service and provides professional training leadership and guidance to Service Officials and personnel. Performs the following functions: Conducts research and special studies to determine the best methods of employee development for the Service, and provides expert advice and counsel on training techniques and methodology; in cooperation with IRS management, the Director identifies the need for, and administers Service training programs, approves and is responsible for development and preparation of training courses and program materials, and supports the Tax Administration Advisory Staff; determines program emphasis and goals, establishes standards and procedures for the effective and efficient administration of Service training programs, and evaluates training for effectiveness and economy; administers the Taxpayer Education Program and coordinates the efforts of the field and National Office divisions concerned; advises on and approves training costs estimates for all Servicewide training, and administers the special fiscal allotment (250) used to finance centralized training activities; carries out the training policies and programs of the Service in the National Office.

SEC. 1113.441 *Administrative Services Office.*

Provides administrative support for the Training function. Performs the following: Assists the Director in carrying

out Servicewide administrative management responsibilities related to the Training function; coordinates and maintains overall Servicewide training budget formulation and execution, and work and financial plans; develops, coordinates, and maintains the Training Manual System; coordinates and develops intra-divisional projects such as budget formulation, work and financial plans, and PPBS updatings; conducts studies of intra-divisional activities; conducts special intra-divisional projects of an administrative nature; provides all necessary administrative support for internal operations of the Training Division.

SEC. 1113.442 *Compliance Training Branch.*

Provides professional training support for the Compliance technical training program (Audit; Intelligence; and Appellate). Jointly and in cooperation with appropriate Compliance officials, performs the following functions: Determines training priorities and goals of the Compliance technical training programs; identifies training needs, and defines and articulates training objectives; plans, designs, develops, coordinates and conducts Compliance technical training programs; evaluates the implementation and effectiveness of the total Compliance technical training program; supports, coordinates, and evaluates field Compliance technical course development. In addition: Monitors all pilot Compliance technical training projects and administers those conducted centrally; reviews and updates training methods, instructional techniques, materials, and supervisory practices as they relate to training; keeps Compliance technical training materials current; in cooperation with Compliance officials, establishes and maintains criteria for employee performance evaluation as it relates to effective training programs; with assistance of National Training Center and Compliance, develops Compliance technical training guidelines and standards, and conducts experimental projects.

SEC. 1113.443 *ACTS Training Branch.*

Provides professional training support for the Accounts, Collection and Taxpayer Service technical training program. Jointly and in cooperation with appropriate ACTS officials, performs the following functions: Determines training priorities and goals of the ACTS technical training program; identifies training needs, and defines and articulates training objectives; plans, designs, develops, coordinates and conducts ACTS technical training programs; evaluates the implementation and effectiveness of the total ACTS technical training program; supports, coordinates, and evaluates field ACTS technical course development; monitors all pilot ACTS technical training projects and administers those conducted centrally; reviews and updates training methods, instructional techniques, materials and supervisory practices as they relate to training, keeps ACTS technical training materials current; in cooperation with ACTS officials, establishes and maintains criteria for employee performance evaluation as it relates to effective training programs; in cooperation with Taxpayer Service officials, plans, designs, coordinates and evaluates appropriate and useful informational and educational materials for public use; with assistance of National Training Center and ACTS, develops ACTS training guidelines and standards, and conducts experimental projects.

SEC. 1113.444 *Management Training Branch.*

Provides professional training support for the Service in areas of organizational and career development; executive management, and supervision; cross-functional; and Career Education Awards. Performs the following functions: In cooperation with key Service officials, determines general and functional supervisory, management, and executive training goals of the Service, identifies training needs and, in cooperation with the appropriate Service activities and functions, defines supervisory, management and executive training objectives; plans, designs, develops, coordinates and conducts supervisory, management and executive training programs; evaluates the implementation and effectiveness of total supervisory, management and executive training programs; supports, coordinates and evaluates field supervisory and management course development; monitors all pilot supervisory and management training projects and administers those conducted centrally; reviews and updates supervisory, management, and executive training methods, instructional techniques and materials; in cooperation with appropriate IRS officials, establishes and maintains criteria for employee performance evaluation as it relates to effective training programs; reviews, coordinates and evaluates Service's Organizational Development and Career Development Programs; establishes guidelines, coordinates and evaluates Servicewide Administration and Equal Employment Opportunity Training Programs; develops guidelines for and administers Career Education Awards; supports Tax Administration Advisory Staff in determining training needs of foreign tax officials and developing training programs to meet these needs; in cooperation with appropriate organizations, develops and conducts communications and cross-functional training programs.

SEC. 1113.445 *National Office Training Branch.*

Provides professional training support for the National Office, Inspection, Chief Counsel, National Computer Center and the Data Center. Performs the following functions: In cooperation with key National Office officials, determines clerical, technical, supervisory, and managerial training goals for National Office personnel; identifies training needs and, in cooperation with National Office officials, defines training objectives and establishes training priorities; plans, designs, develops, coordinates, conducts and evaluates all National Office intra-functional training programs, plus appropriate cross-functional training programs (e.g., supervisory, communications, instructor training, clerical skills); in cooperation with appropriate officials, determines training priorities, goals, and objectives for Inspection, Chief Counsel, National Computer Center and Data Center; plans, designs, develops, coordinates, conducts and evaluates Inspection Chief Counsel, National Computer Center and Data Center training programs; administers, reviews and monitors pilot training projects; keeps National Office Inspection, Chief Counsel, National Computer Center and Data Center training materials current; reviews and updates training methods, instructional techniques and materials; administers training facilities in the National Office.

SEC. 1113.446. *National Training Center.*

Provides the educational research and development and specialized techniques input to the Training Division. Performs the following functions: Conducts research in training methodology and techniques; monitors and conducts experimental projects utilizing advance training technology; evaluates and determines feasibility of experimental projects becoming operational training programs; establishes Servicewide standards in training methodology, techniques and equipment, and develops materials requiring specialized training staff support; develops Servicewide guidelines for instructor and course-developer training; establishes standards for Servicewide staff development in specialized skills of training profession, and coordinates training staff development; establishes the standards for and coordinates the administration of the Regional Training Center network; maintains library at NTC; coordinates development and production of Servicewide materials requiring specialized staff support (e.g., videotape, film strip); maintains control and oversees distribution of Servicewide printed materials; administers the National Training Center facility.

SEC. 1113.5 *Office of Assistant Commissioner (Compliance).*

The Assistant Commisioner (Compliance) is the principal assistant to the Commissioner on all matters pertaining to the compliance and appellate programs of the Service, in encouraging and achieving the highest possible degree of voluntary compliance by taxpayers, and in providing effective functional supervision of those activities in the field. These include audit and investigation of returns; criminal fraud investigations; the administrative system of tax appeals; administration of laws relating to alcohol, alcoholic beverages, tobacco, firearms, and explosives; and the receipt and processing of wagering, narcotics, alcohol and tobacco tax, and firearms returns and applications. Through the Disclosure Staff, in the immediate Office of the Assistant Commissioner, administers the disclosure provisions of the law and regulations concerning inspection of returns

and other matters of official record; administers the Freedom of Information Act and regulations; administers the regulations governing testimony of Service employees in nontax matters; administers the tax check program involving high level Federal employees; and certifies documents under the Treasury Department seal, furnishing copies where appropriate. The Assistant Commissioner (Compliance) directs, coordinates and evaluates the work of the Appellate Division, the Audit Division, the Intelligence Division, and the Office of International Operations.

SEC. 1113.51 [Reserved]

SEC. 1113.52 *Appellate Division—Office of the Director.*

Accomplishes the Appellate mission of resolving tax controversies without litigation, on a basis which is fair and impartial to both the Government and the taxpayer by developing and supervising (functional supervision) nationwide programs for final appeal consideration, within the Service, of cases involving income, profits, estate, gift, employment and excise taxes (other than alcohol, tobacco, narcotics, firearms, and wagering), offers-in-compromise, refund claims and overassessments, in which the taxpayer protests the decision of the District Director, and of cases docketed in the United States Tax Court (with concurrence of Regional Counsel and prior to the opening date of the Tax Court session concerned). Develops nationwide Appellate budget estimates and long-range plans; evaluates financial plans and budget execution of regional Appellate Divisions. Conducts Appellate Reports and Information Retrieval Activity (ARIRA) programs and nationwide Appellate reporting system. Collaborates with Planning and Research, Accounts, Collection, and Taxpayer Service; and other segments of the Service in a research effort to create a comprehensive information storage and retrieval system. Furnishes administrative services for the operation of the Appellate Division of the National Office. Also directs or performs certain centralized Appellate functions.

SEC. 1113.521 *Coordination and Management Staff.*

Assists in developing and recommending policies, plans, programs, and basic procedures and provides top-level managerial assistance through the following principal functions: Develops and recommends operations policies, plans, programs, and basic procedures relating to the Appellate function. Assists and advises regional Appellate offices on technical and administrative problems to enable them more effectively to accomplish their objectives. Establishes and conducts a field visitation program, and maintains continuous field liaison to assure that established policies, programs, plans, and instructions are carried out in a uniform, effective manner. Evaluates adequacy of staffing and managerial performance in regional Appellate offices. Performs coordination functions across regional lines and with other Service elements. Supervises task forces working on special projects such as training, position descriptions, offices systems, and management improvement. Represents the Director in meetings of National Office and regional officials, and staff members serve on various committees as designated. Analyzes and interprets program status and progress in accomplishing the overall Appellate mission. Originates statistical analyses and graphic presentations with explanations and interpretations to disclose program status and progress with trends and deviations highlighted. These analyses serve as the basis for program direction and long-range program planning for the Appellate activity.

SEC. 1113.522 *Programs and Procedures Branch.*

Conducts program and procedural studies concerning Appellate activity and recommends methods to efficiently accomplish Appellate mission. Reviews and analyzes operational reports, field issuances and compiled data (such as ARIRA tables) to identify significant trends, procedural problems, etc., and submits recommendations to Director, where appropriate. Provides procedural instructions and procedural advice to Appellate field organization to effectively implement policies, plans, and programs relating to Appellate function. Maintains Part VIII of the Internal Revenue Manual and related Handbooks and coordinates Appellate procedures with other functions concerned. Provides material for inclusion in Statement of Procedural Rules concerning Appellate activity. Supervises task forces working on special projects relating to Appellate programs and procedures. Develops and coordinates training programs to improve skills of Appellate personnel. Provides forms and form letters for use in Appellate operation. Considers and processes employee suggestions submitted under the Incentive Awards Program relating to Appellate and implements those that are adopted.

SEC. 1113.523 *Special Services Branch.*

Advises and assists in cases involving controversies as to valuation through the following principal functions: Participates in the development of Service position and procedures in complex valuation matters. Helps to maintain uniformity of treatment of valuation issues throughout the regional Appellate Divisions by furnishing advice, and conducting training sessions. Furnishes expert advice and assistance to the National Office, regional Appellate Division, and Regional Counsel on difficult valuation problems. Provides expert witnesses to testify at trials involving complex valuation issues. Develops programs and techniques aimed at eliminating, to the greatest extent possible, the need for time consuming trials of valuation issues in the Tax Court or other courts. Provides regional Appellate Divisions with technical assistance of a general nature through the following principal functions: Analyzes and processes requests for technical information and digests technical information and other technical communications for dissemination to Regional Offices when information is of general Appellate interest. Maintains liaison on matters relating to cases requiring submission to the Congressional Joint Committee on Internal Revenue Taxation. Develops and aids in formulation and presentation of Appellate technical seminar programs. Recognizes need for specialized technical workshops and prepares program materials for them. Post-reviews closing agreements approved by regional Appellate officials. Also reviews closing agreements prior to submission to the Assistant Commissioner (Compliance) for approval. Identifies troublesome technical or qualitative areas and trends; and recommends solutions to help Regional Offices meet their objectives. Conducts special studies (such as prime issues) to assist the Director and the Assistant Regional Commissioners (Appellate) in their programming and long-range planning. Administers a continuing progra mfor evaluating and analyzing regional post-review effectiveness.

SEC. 1113.53 *Audit Division—Office of the Director.*

Accomplishes the Audit mission of encouraging and achieving the highest possible degree of voluntary compliance by taxpayers and tax exempt organizations with the tax laws. This is accomplished through developing and functionally supervising well designed and executed examination programs which utilize appropriated resources effectively and through plans for optimum audit programs in the future. These programs and plans provide for determining types and degrees of noncompliance and taking effective action to increase compliance. Also supervises the performance of certain centralized audit functions.

SEC. 1113.531 *Office Services Staff.*

Furnishes services in support of the Audit Division. Maintains liaison with the Office of the Assistant Commissioner (Administration) on fiscal, personnel, training, and facilities matters. Provides centralized mail, files, distribution, messenger, and library services for the Division.

SEC. 1113.532 *Programs Branch.*

Plans, implements, and evaluates nationwide programs for the examination monitoring of Audit Division's portion of of income, excise, employment, and estate and gift tax returns. Responsible for the development, implementation, and monitoring of Audit Division's portion of other enforcement programs. Provides assistance to field components in the conduct of their returns examination programs. Develops long-range plans and strategies for the accomplishment of its portion of the Audit mission. Issues IRM and other procedural material required for the execution of examination programs. Participates with other Compliance activities. Technical, and ACTS in the development and implementation of examination programs. Participates in planning and is responsible for implementing the returns classification program. Prepares replies to correspondence

relating to income, excise, employment, and estate and gift tax matters.

SEC. 1113.533 *Exempt Organization Examination Branch.*

Plans, implements, and evaluates nationwide programs for the examination of exempt organization returns and records. Responsible for the development, implementation, and monitoring of the Audit Division's portion of the pension trust program. Plans and implements the program for issuance of exemption determination letters. Develops long-range plans and strategies for the accomplishment of its portion of the Audit mission. Maintains close communication and liaison with the Office of the Assistant Commissioner (Technical) on both exempt organization and pension trust matters. Reviews or post reviews revenue agent reports for quality and uniformity of exempt organization examinations. Issues IRM and other procedural material required for the execution of exempt organization and pension trust examinations. Determines uses to be made of the Exempt Organization Master File (EOMF) data and works with other Service activities in fulfilling their needs from the EOMF. Also determines uses for the Employees' Plans Master File (EPMF) and coordinates with the office of the Assistant Commissioner (ACTS) in such matters. Prepares replies to correspondence relating to exempt organization matters.

SEC. 1113.534 Centralized Activities *Branch.*

Provides technical coordination on complex Audit matters with other Compliance activities, Assistant Commissioner (Technical), and the Chief Counsel. Plans, implements, and monitors nationwide programs for Joint Committee, conference and review programs. Monitors and reports on cases docketed for Tax Court and assists Chief Counsel and Department of Justice in trial and settlement of cases. Performs centralized activities relating to qualification for enrollment and practice. Monitors the providing of necessary management services for the Audit activity and serves as liaison with the Office of the Assistant Commissioner (Administration) on administrative matters affecting the entire Audit activity.

Provides liaison with the Office of the Assistant Commissioner (Technical) and the Tax Forms Coordinating Committee on Audit matters. Conducts economic studies pertinent to Section 482 allocations and post reviews and provides expert testimony concerning such allocations. Issues IRM and other procedural material required for the execution of the branch's programs. Prepares answers to correspondence deemed to be nationally significant concerning field Audit operations (with the exception of exempt organization and pension trust matters).

SEC. 1113.535 *Resources and Analysis Branch.*

Responsible for integrating the program planning and evaluation activities, such as budget, PPB and NORP support for the Audit activity. Regulates all program research activities for the Division including TCMP, DIF development, and other special analytical studies. Responsible for providing the Director and the other Audit branches with timely analyses of overall program effectiveness with regard to both resource expenditure and results achieved. Prepares Division submissions for PFP and budget requests. Plans, implements, and monitors programs to provide management information such as SCRIP. Provides functional direction to the Audit Service activity. Plans the Audit classification of returns program. Issues IRM and other procedural material required to carry out the branch's programs. Provides coordination support for the Audit activity in respect to services provided by the ACTS organization.

SEC. 1113.54 [Reserved]

SEC. 1113.55 *Intelligence Division—Office of the Director.*

Accomplishes the Intelligence mission with reference to enforcement of the criminal statutes applicable to income, estate, gift, employment, and certain excise tax laws by developing and supervising (functional supervision—which includes evaluation) nationwide programs for the investigation of suspected criminal violations of such laws and the recommendation of prosecution and/or assertion of the 50% ad valorem addition to the tax, when warranted, development of information concerning the extent of criminal violations of all Federal tax laws (except those relating to alcohol, tobacco, narcotics, and firearms), and measurement of the effectiveness of the investigation process. The Division also conducts, coordinates, and directs the investigation of cases which have been centralized, and performs certain other centralized Intelligence functions.

SEC. 1113.551 *Administrative Office.*

Is responsible for furnishing administrative services for the operation of the Intelligence Division of the National Office by: developing and preparing budget requests and financial plans as well as supervising budget execution, providing for the administrative needs of the Division (such as providing and maintaining investigative and administrative central filing systems and processing mail, and maintaining liaison with the Office of Assistant Commissioner (Administration) on all National Office Intelligence Division matters (including fiscal management, personnel, training, and facilities management matters); developing and preparing projections of personnel costs and staffing charts; collaborating with Administration in the procurement of investigative equipment for field and National Office use, and maintaining inventory and current records as to location of Intelligence Division investigative equipment; and conducting special studies relating to personnel, space, budget and equipment.

SEC. 1113.552 *Staff Assistance (Visitation).*

Is responsible for: planning and conducting a visitation program for on-site evaluation, guidance, and assistance; coordinating with, and maintaining close liaison with each of the several branches of the Division for the purpose of inquiring into specific field activities of special interest to each of the branches and keeping each fully apprised of conditions and developments in the field.

SEC. 1113.553 *Operations Branch.*

Is responsible for: providing the field with operational assistance, and conducting, directing, and coordinating the investigation of centralized cases by: interviewing informants, maintaining liaison with Committees of Congress, representatives of the Service and other Government agencies in order to obtain, develop, and disseminate to the field pertinent information relating to tax evasion; coordinating, conducting, or directing investigations which are inter-regional in scope, of a sensitive nature, or of national interest; responding to communications on matters pertaining to operations; keeping Service and Treasury officials informed of significant developments in sensitive cases and those of national interest; identifying operational and management deficiencies in investigations coordinated, conducted, or directed by the National Office and initiating corrective action or referring identified deficiencies to the appropriate branch; and maintaining a program for case research and development including establishment of criteria for use in the automatic processing of returns to aid in identification of returns having criminal potential; and participating, as directed, in field visits.

SEC. 1113.554 *Program Branch.*

Is responsible for: providing effective management and technical programs, plans, and procedures for accomplishment of the Intelligence mission and identifying as well as correcting deficiencies in programming, planning, and procedural guidelines, including the Manual and the investigative handbook, through statistical analyses and studies, review of policies, management reports, reports of field visits and other issuances, and through consultation and coordination with other Service elements. Consulting and coordinating with other Service elements on such matters as the findings in internal audit reports, legislative proposals, development of organizational and staffing standards and personnel classification standards; collaborating with the Planning and Analysis Division in developing the Intelligence Division's long-term program objectives and resource requirements within the Service's Long Range Planning System; collaborating with the Fiscal Management Division in the evaluation of field financial proposals; submitting recommendations for the allocation of Intelligence personnel and funds; collaborating with the Information Systems Branch for the report of management and investigative accomplishments; consolidating, evaluating, and disseminating information reflecting accomplishments of programs and plans; preparing the Intelligence portion of the

Cost Reduction—Management Improvement Report and the Commissioners Annual Report; and participating, as directed, in field visits.

SEC. 1113.555 *Technical Development Branch.*

Is responsible for: developing and maintaining professionals skills of special agents, developing investigative techniques and performing certain support functions in the accomplishment of the Intelligence mission by: conducting studies and developing Intelligence training programs in collaboration with the Training Division; directing and conducting centralized Intelligence training programs; instructing at, and collaborating in the program development and conduct of the Criminal Investigators School; maintaining liaison and providing technical guidance on and participation in course development and instruction which is carried out at the National Training Center for the Intelligence Division; coordination and evaluating field training: identifying deficiencies in training programs and materials and initiating corrective action or referring identified deficiencies to the appropriate branch; developing Intelligence investigative equipment standards and allocating investigative equipment and automobiles to the field; keeping abreast of developments in the use of automatic data processing equipment by taxpayers and third parties, such as banks, brokerage houses, and insurance companies to determine the type and extent of training needed by special agents to obtain necessary financial information where automatic data processing equipment is used; cooperating with the Personnel Division in the development of guidelines and standards for recruitment, selection, and career development of Intelligence personnel; preparing final Intelligence recommendations in cases unresolved at regional level; evaluating and recommending disposition of Incentive Awards suggestions; maintaining a current record of special skills of individual special agents; disseminating information on current developments, such as legal decisions, unique defenses, and unusual investigative approaches, through the issuance, monthly, of the Intelligence Digest; collaborating with the Public Affairs Division in the preparation of news releases regarding closed cases; collaborating with the Tax Administration Advisory Staff and the National Training Center in orientation of enforcement officials of other Federal agencies and of State and foreign governments concerning Intelligence techniques, procedures and practices, and participating, as directed, in field visits.

SEC. 1113.56 *Office of International Operations—Director of International Operations.*

The Office of International Operations administers the Internal Revenue laws and related statutes (except those relating to alcohol, tobacco, narcotics and firearms) as they relate to citizen taxpayers residing or doing business abroad, foreign taxpayers deriving income from sources within the United States, and taxpayers who are required to withhold tax on income flowing abroad to nonresident aliens and foreign corporations; acts as staff advisor to the Assistant Commissioner (Compliance) in the international area on all compliance functions, and as the international specialist provides assistance and guidance to the Compliance Divisions and makes recommendations on all aspects of the international enforcement program to the Assistant Commissioner (Compliance) and the Division Directors concerned; acts as competent authority in administering the operating provisions of tax conventions; performs and coordinates for the Service all foreign investigations and requests for information (other than those relating to rulings, regulations or assistance in the field of foreign tax administration) from foreign countries and United States possessions. Also computes and collects taxes due from the Alien Property Custodian, administers the provisions of the Internal Revenue Code authorizing the acceptance of foreign currency in payment of United States tax liabilities, coordinates foreign travel of Service personnel, and maintains foreign posts.

SEC. 1113.561 *Administrative Office.*

Responsible for the personnel, training, budget and fiscal and general administrative services, including procurement and supply, printing and communication services and other administrative services necessary to the effective operation and management of the Office of International Operations, including Foreign Posts and the Puerto Rico Office. Coordinates and develops the management improvement and incentive awards programs and special projects. Initiates and administers the security, safety and records management program. Develops the financial plan and budget estimates, fiscal programs, cost estimates, and is responsible for control of funds, report on budget execution and International Transaction estimates. Coordinates in conjunction with the Facilities Management Division the printing requirements and distribution of special publications, documents and tax forms required by the Office of International Operations, and the distribution of all tax forms to the United States Embassies and Consulates.

SEC. 1113.562 *Collection and Taxpayer Service Division.*

The Collection and Taxpayer Service Division is responsible for the receipt and transmittal of tax returns and documents received in the Office of International Operations; filed by nonresident liens, foreign corporations, nonresident alien estates, withholding agents (Forms 1042), information returns with respect to foreign corporations (Forms 959), and information returns with respect to foreign personal holding companies (Forms 957 and 958); the deposit to the credit of the Service Center Director of tax remittances received in OIO. Authorizes extensions of time for filing; provides year round taxpayer service to citizens and aliens; administers the automatic exchange of information and reciprocal collection provisions of tax treaties with foreign countries. Is responsible for the collection of delinquent accounts through distraint, seizure, levy and other means; the securing of delinquent returns; examination of officers in compromise based on doubt as to collectibility of taxes (except alcohol, tobacco and firearm taxes), offers in compromise of statutory additions based on doubt as to liability (except alcohol, tobacco, firearms, employment and withholding taxes and specific penalties), and all offers in compromise of 100 percent penalties. The Division receives, acts on, and processes information pertinent to bankruptcies, receiverships, assignments, reorganizations, probate proceedings, foreclosures and redemptions after civil foreclosure, bulk sales, gifts and prizes, and dissolutions and initiates investigations for securing delinquent returns where necessary. The Division maintains files or control records of payments received in insolvency, bankruptcy, and decedent cases and of surety bonds and other collateral posted as security for tax liability. It also maintains files and control records of property seized under distraint authority and takes appropriate action with respect to seized property to ensure that proper legal action may be timely taken.

SEC. 1113.5621 *Special Procedures Staff.*

The Special Procedures Staff is responsible for furnishing advisory assistance on technical delinquent collection and returns matters to the Chief, Collection and Taxpayer Service Division, Chief, Field Branch, Chief, Office Branch and Group Supervisors; providing liaison for the Director of International Operations with the Department of Justice, including the U.S. Attorneys, the Chief Counsel and Regional Counsel on all collection matters; ascertaining tax liability and filing of proof of claims in insolvency and decedent's estate proceedings; recommending civil suits to enforce collection or to protect the Government's interests; processing civil suits against the United States or the Office of International Operations, examining, reviewing and processing seizure and sale reports; processing applications for discharge of property from the effect of Federal tax liens and for certificates of nonattachment of Federal tax liens and certificates of subordination of the Federal tax lien; processing filed notices of Federal Tax liens and certificates of release; processing and maintaining executed collection waivers; analyzing and determining the sufficiency of various forms of collateral offered as security for release of lien or postponement of collection action; furnishing technical advice and assistance and recommendations for or against entry into suitable escrow agreements for the collection of delinquent accounts; reviewing recommendations for and holding conferences on 100 percent penalty and transferee assessments; post reviewing of accounts reported as uncollectible; reviewing recommendations and holding conferences on offers in compromise cases

based on inability to pay; and maintaining files and control records on all the above type cases to ensure that proper legal and other collection actions are taken timely.

SEC. 1113.5622 *Office Branch.*

The Office Branch effects the collection of delinquent accounts and secures delinquent returns through demands made by correspondence, telephone or office interviews. It safeguards the Government's interest by causing the filing of notices of tax liens and serving or causing the service of notices of levies. It transfers to Revenue Officer groups those assignments which require field investigations or can be more efficiently completed by field Revenue Officers. The Branch carries out the Division's responsibility for district-wide execution of the year-round taxpayer service program. It provides taxpayer service to citizens and aliens, including responses to correspondence requests of tax information, and provides functional supervision of taxpayer service at other posts of duty. The Branch screens and assigns cases and maintains assignment files. It prepares periodic reports of collection and taxpayer service activities. It receives and deposits to the credit of the Service Center Director remittances received in the Office of International Operations. It receives and transmits other returns and documents received in the Office of International Operations.

SEC. 1113.5623 *Field Branch I (Headquarters).*

Field Branch I is responsible for the Officer groups in Headquarters. Within management and control of Revenue the assigned area, the Branch makes collections of delinquent accounts and conducts a continuing program for the security of delinquent returns. It safeguards the Government's interest through the filing of notices of tax liens, and enforces collection by the serving of levies, and seizure and sale of real and personal property. It recommends jeopardy assessment when deemed necessary to protect revenue, civil actions to secure payments, suits to enforce penalty for failure to honor levies, and penalty assessments as a means of collection or as a method of obtaining compliance with existing laws and regulations. The Branch recommends the issuance of certificates of discharge of property from the effects of tax liens, recommends issuances of certificates of subordination of Federal tax liens, and conducts the investigations necessary to support such recommendations. The Branch examines offers in compromise based on doubt as to collectibility of taxes (except alcohol, tobacco, and firearms taxes), offers in compromise of statutory additions based on doubt as to liability (except alcohol, tobacco, firearms, employment and withholding taxes and specific penalties), and all offers in compromise of 100% penalties.

SEC. 1113.5624 *Field Branch II (Puerto Rico).*

Field Branch II is responsible for the management and control of both Revenue Officer groups and an Office Group in Puerto Rico. Within the assigned area, the Branch makes collections of delinquent accounts and conducts a continuing program for the security of delinquent returns. It safeguards the Government's interest through the filing of notices of tax liens, and enforces collection by the serving of levies, and seizure and sale of real and personal property. It recommends jeopardy assessment when deemed necessary to protect revenue, civil actions to secure payments, suits to enforce penalty for failure to honor levies, and penalty assessments as a means of collection or as a method of obtaining compliance with existing laws and regulations. The Branch recommends the issuance of certificates of discharge of property from the effects of tax liens, recommends issuances of certificates of subordination of Federal tax liens, and conducts the investigations necessary to support such recommendations. The Branch examines offers in compromise based on doubt as to collectibility of taxes (except alcohol, tobacco, and firearms taxes), offers in compromise of statutory additions based on doubt as to collectibility of taxes (except alcohol, tobacco, and firearms taxes), offers in compromise of statutory additions based on doubt as to liability (except alcohol, tobacco, firearms, employment and withholding taxes and specific penalties), and all offers in compromise of 100 percent penalties.

SEC. 1113.563 *Audit Division.*

The Audit Division administers an international audit program involving the selection and examination of all types of Federal Tax returns filed with the Office of International Operations (except alcohol, tobacco, and firearms). Is responsible for the examination of certain offers in compromise, informant's claims for reward and related activities including the examination and approval of pension trusts and the issuance of determination letters. The audit program involves the classification of returns for field and office audits, the conduct of district conferences in unagreed cases, participation with special agents in the conduct of tax fraud investigations, and is responsible for providing manpower for the annual overseas taxpayer compliance program. Provides advice and guidance on audit work performed by the foreign posts and reviews for technical and procedural accuracy all reports of audit examinations prepared by these offices. Directs programs for the exchange of estate and gift tax data with foreign governments under the tax conventions. Performs audit functions relating to the Alien Property Custodian activity. Makes certain that Internal Revenue Agents' manpower will be applied to the most significant civil enforcement cases in the international area. Is responsible for the maintainance of good relationship with region and districts and is responsive to their requirements for assistance in the foreign area. The Audit Division consists of the Examination Branch, Service Branch, Review Staff, Conference Staff and Classification.

SEC. 1113.5631 *Conference Staff.*

The Conference Staff attains, to the maximum extent possible, the primary objective of the Conference Function—to give taxpayers ample opportunity to reach early agreement on disputed issues arising from audit examinations. Has responsibility for all OIO conference cases. Assigns, controls, coordinates, and reviews Office of International Operations jurisdictional conference cases including those in Puerto Rico, and foreign posts of duty. Holds conferences; provides direction and furnishes technical advice to other conferees; performs final district review of field audit conference reports; reviews and evaluates statistics and other records to strengthen conference function operations; and screens taxpayer protests which request Appellate hearings. Authorizes settlements in "pattern settlement cases;" reviews primary statistical forms in conference cases; coordinates and discusses with Chief, Review Staff, conference cases in which Review Staff has taken legal interpretative positions at variance with conference positions; reviews and answers dissents to conference determinations; reviews Appellate Division closings for guidance to conferees; and is responsible for protecting the statute of limitations for cases under his control. Undertakes special assignments received from Division and Office Superiors to the extent time permits.

SEC. 1113.5632 *Review Staff.*

Is responsible for reviewing for technical accuracy and policy and procedural adherence, reports of examination on income, estate, gift, and miscellaneous taxes, and offers in compromise. Prepares and issues preliminary letters and statutory notices. Grants extension of time for filing protests, and closes out statutory notices by sending the case file to the Appellate Division if a petition is filed or closing out for assessment if the time period expires on default. Receives taxpayer protests, refers protests to the Chief, Conference Staff, and closes protested cases to the Appellate Division upon recommendation of the Chief, Conference Staff. Furnishes technical advice to foreign and Puerto Rico posts and all examining personnel. Considers special problems relating to specific cases and prepares recommendations thereon. Prepares replies to technical inquiries from taxpayers from all over the world and issues determination letters as required. Considers applications for exemption from tax from foreign organizations, and issues determination letters or refers the case to the Assistant Commissioner (Technical), as appropriate. Prepares statistical reports and analyzes information on specific cases as required. Controls and reviews all forms used by the Audit Division. Controls and processes all informant's claims. Prepares requests for technical advice to the National Office on specific cases under examination.

SEC. 1113.5633 *Chief Classifying Officer.*

Is responsible for planning and executing the audit classification program including the selection of returns to be examined and the determination of the organizational units where the returns can best be examined. Is responsible for the planning and execution of procedures involving the classification of other documents used in connection with examinations such as transferred cases from other districts, information reports, etc.

SEC. 1113.5634 *Service Branch.*

Controls all income, estate and gift, and miscellaneous tax returns received for audit or investigation by the OIO Washington Office, Puerto Rico Office and the Foreign Programs and Research Division. Routes work to appropriate units; reproduces completed reports; provides typing service for the Audit Division; effects closing action on examined cases transmitting returns to the Collection and Taxpayer Service Division; assembles audit production and statistical data and maintains controls on statutory expirations for the entire Audit Division as well as the Foreign Programs and Research Division.

SEC. 1113.5635 *Examination Branch.*

Conducts field and office examinations relative to all types of taxes (except alcohol, tobacco, and firearms) to determine correct liabilities of citizen taxpayers residing or doing business abroad, foreign taxpayers deriving income from sources within the United States and taxpayers who are required to withhold tax on certain payments to non-resident aliens and foreign corporations. Conducts examinations of estate tax returns of U.S. citizens who died while residing abroad or non-resident aliens with substantial property or income in the U.S. and gift tax returns filed by non-resident aliens or U.S. citizens residing abroad. It also conducts examinations of offers in compromise based on doubt as to liability for taxes or for both taxes and statutory additions (except alcohol, tobacco, and firearms taxes) claims for refund, credit or abatement, and special examinations as requested including joint examinations with special agents where tax evasions may exist. Obtains information on suspected delinquent taxpayers and other tax information while in overseas areas. It furnishes technical advice and assistance on pension trust plans, processes informants' claims for reward, and recommends jeopardy assessments. Prepares memoranda to accompany closing agreements and closing letters and releases in estate and gift tax cases, and administers the program for exchange of estate and gift tax data with foreign governments under tax conventions. Audits employment tax returns of Puerto Rico residents and income tax returns of United States Government employees and Puerto Rico residents deriving income from sources outside Puerto Rico, Audits books and records of Puerto Rican affiliates of domestic taxpayers to secure information requested by districts. Examines Virgin Island corporations to determine correct subsidy allowances. Coordinates examination program on resident foreign corporations and other cases, where appropriate, with National and Regional enforcement programs. On assignment holds conferences with taxpayers and their representatives. Prepares tax returns for, and audits books of, foreign corporations and alien individuals whose property is controlled by the Alien Property Custodian and conducts conferences on these matters.

SEC. 1113.564 *Foreign Programs and Research Division.*

Plans, develops and coordinates the work programs and other activities of the foreign posts. Conducts the intelligence function with respect to taxpayers under jurisdiction of the Office of International Operations. Coordinates, directs and/or conducts all functions performed overseas by Appellate, Audit, Collection and Taxpayer Service, Intelligence and International Operations personnel. Coordinates all audit, collection and intelligence functions between the foreign posts and the Divisions of the Office of International Operations, other Service components and other Government agencies. Assists in the performance of functions under the treaties principally involving nonautomatic exchange of information. It is the focal point for all contacts with foreign governments either directly or through the foreign posts. Coordinates the foreign travel of personnel of the Internal Revenue Service. Maintains liaison with the Treasury, State, Defense, Commerce and Interior Departments concerning overseas operating matters. Plans coordinates and directs the Annual Taxpayer Compliance Audit and Collection Programs abroad. Plans and coordinates, in conjunction with the military services, the Annual Military Assistance School Program. Provides research and technical assistance and prepares guidance memoranda for other OIO Divisions. Assists the Director in performance of the Competent Authority functions. Maintains a continuing appraisal of the operation of the income and estate tax treaties for the purpose of identifying areas for renegotiation. Considers administrative and operational feasibility of proposed tax conventions regulations. Conducts analytical studies with the purpose of achieving effective tax compliance. Prepares recommendations for remedial legislation or regulatory amendments. Reviews or prepares suggested public use or internal forms and documents. Disseminates information regarding United States business activity abroad and foreign business activity in the United States. Determines the amount of administrative relief [offset] to be allowed under Revenue Procedures 64–54 and 69–13. Submits recommendations with respect to proposed changes in legislation regulations, revenue procedures, treaty provisions and other aspects of the international enforcement program.

SEC. 1113.5641 *Foreign Posts.*

Takes necessary action under division programs to establish and maintain satisfactory levels of voluntary compliance. Develops information indicating possible tax evasion, delinquency or non-compliance. Conducts audits of income, estate and gift tax returns of a type justifying field investigation or contact abroad and conducts investigations on tax evasion cases. Effects collection of delinquent taxes when personal contact or investigation abroad is required. Obtains information on audit, intelligence and collection matters for other service components on collateral requests. Holds taxpayer conferences and effects settlements in income, estate and gift tax cases, claims, offers in compromise, etc., including those referred abroad by International Operations headquarters for such purposes. Under specific direction assists in the exercise of the Competent Authority provisions of tax treaties by holding discussions with foreign government representatives. Maintains close liaison with foreign governments in tax treaty, enforcement, exchange of information, technical and other matters. Maintains close liaison with U.S. military authorities and taxpayer groups in the area. Develops and implements enforcement, taxpayer assistance and school programs, taxpayer-education releases, and similar measures designed to assure a high level of compliance. Is responsible for the development and maintenance of desirable public relations, initiating appropriate taxpayer-education programs in the area. Furnishes technical assistance to taxpayers on all tax matters.

SEC. 1113.5642 *Research and Technical Branch.*

Accumulates and analyzes data concerning foreign tax laws, U.S. Tax Treaties, U.S. law changes, revenue rulings and statements of Service policy in the international area. Prepares, coordinates and reviews guidance memoranda within the Office of International Operations. Assists in the performance of the Competent Authority functions. As directed, represents the United States Government at conferences with foreign Competent Authorities. Reviews drafts of proposed tax conventions and regulations thereunder regarding the administrative and operational feasibility of the convention and regulations. Seeks out operational and administrative problems in the tax treaty area. Prepares analytical studies of technical problems and tax avoidance schemes in the international area. Prepares plans and programs to combat tax avoidance and evasion in the international area. Reviews or prepares suggested tax forms and other material. Coordinates technical matters regarding proposed legislation and similar matters with the various Divisions of the National Office and other Government agencies. Accumulates data on the extent, nature, location of U.S. taxpayer business and trust interest outside of United States and similar data on foreign business entities doing business in the United States. Accumulates data on other foreign business operations of concern to U.S. Determines the amount of administrative relief (offset) to be allowed

under Revenue Procedures 64–54 and 69–13 and, where appropriate, prepares closing agreements. Submits recommendations on proposed changes in legislation, regulations, revenue procedures, treaty provisions and other aspects of the international enforcement program. Provides data on foreign tax laws to technical field personnel responsible for determining correct Subparts F and G income and earnings and profits of controlled foreign corporations under the 1962 Revenue Act. Prepares periodic reports of the progress and activity in the international area.

SEC. 1113.5643 *Foreign Programs Branch.*

Provides functional supervision of the work programs and other activities of the foreign posts. Conducts the intelligence function with respect to taxpayers under jurisdiction of the Office of International Operations. Coordinates all functions performed overseas by Appellate, Audit, Collection and Taxpayer Service, Intelligence and International Operations personnel. Coordinates all audit collection, and intelligence functions between the foreign posts and the Divisions of the Office of International Operations other Service components and other Government agencies. Evaluates foreign programs. Provides point of contact for foreign governments either directly or through the foreign posts. Coordinates Internal Revenue Service. Maintains liaison with the Treasury, State, Defense, Commerce and Interior Departments concerning overseas operating matters. Plans and coordinates, in conjunction with the military services, the Annual Military Assistance and School Program.

SEC. 1113.6 *Office of Assistant Commissioner (Accounts, Collection, and Taxpayer Service).*

The Assistant Commissioner (Accounts, Collection, and Taxpayer Service), is the principal assistant to the Commissioner on all matters pertaining to the development of programs, systems, methods and procedures for implementation and operation of the Internal Revenue Service Automatic Data Processing Plan, the accounting for the internal revenue, the receipt and integrated processing of tax returns and other documents, the review and coordination of all reports, the collection of delinquent accounts, obtaining delinquent returns, and providing responsive services to taxpayers. He exercises line supervision over the activities performed in the various Divisions in the National Office which are within his jurisdiction and the National Computer Center and the Internal Revenue Service Data Center, and is functionally responsible for ACTS activities in Regional Offices, District Offices and Service Centers. Confers and collaborates with officials of other Government agencies and private industry to ensure compatibility of data which will be integrated into the ADP system of each.

SEC. 1113.61 *Administrative Service Office.*

Plans, organizes, coordinates, and directs the administrative management activities of the Office of Assistant Commissioner (Accounts, Collection, and Taxpayer Service) at the National level, assisting and collaborating with Division Directors and the National Computer Center Director in providing budget, personnel, records and reports management, space management, duplication, supply, and other administrative services necessary for the internal administration, management, operation and functioning of the Office.

SEC. 1113.62 *Program Review and Analytical Services Staff.*

The Program Review and Analytical Services Staff provides the Assistant Commissioner (ACTS) with: in-depth evaluations of Service Center, Data Center and Regional Office operations, programs and effectiveness in the ACTS areas to meet his needs for NORP participation as well as for his day-to-day management appraisals and decisions; independent centralized and integrated analyses of all ACTS programs, including the identification of actual, emerging, and potential problems to management particularly as they impact on two or more ACTS Divisions or other IRS organizations; assessments of program accomplishments, trends, or developments of specific interest to the Assistant Commissioner; and design and the undertaking of advanced analytical research programs and projects (in conjunction with other ACTS Divisions and IRS offices) to improve operational effectiveness and/or to shed insight on program alternatives.

Provides analytical service support and assistance, including specialized statistical services, to the individual Directors of the Accounts and Data Processing, Collection, and Taxpayer Service Divisions and the Director of the Data Center by identifying, evaluating, interpreting, reporting, and assisting in reporting progress towards accomplishment of their respective missions and program objectives. Provides specialist and consultant services and assistance in analytical methods to these officials as well as to Regional personnel in understanding and utilizing techniques and data resulting from integrated analyses of relevant internal and external data.

Coordinates the need for, and advises individual ACTS Divisions on, information system requirements for data, reports and information systems design, reports management activities. Also, in conjunction with ACTS Divisions, develops input for the Annual Internal Audit Program to obtain additional data for evaluation of ACTS program management. Coordinates with Divisions and Internal Audit preparation of the Monthly Informal Report to the Commissioner on significant findings pertaining to ACTS activities.

SEC. 1113.63 *Planning Staff.*

The Planning Staff is the principal advisor to the Assistant Commissioner (ACTS) for insuring the optimal use of ACTS resources for the Service in both tax and non-tax related applications. Develops and administers, in cooperation with all other offices, long-range goals; identifies a budgeting and control system as it relates to goal setting; recommends policy or program decisions on the basis of feasibility or operations research studies; systematizes requests for ACTS services; prepares final ACTS PPBS documents; and performs general staff work on all high-level planning and resource allocations as directed by the Assistant Commissioner (ACTS).

Develops and consolidates long-range goals for the ACTS organization, recommends priorities of work and alternatives, insures that all facets of major work projects are recognized, and identifies the impacts of recommended or proposed actions. Monitors the resources expended in the attainment of established goals and participates in the final system acceptance.

Systematizes the activities relating to requests for ACTS services by: identifying, controlling and monitoring major requirements, requesting and assisting in cost/benefit analysis, presenting the recommendations and priority assignments to the resource allocation boards (ADP Review Board, Data Center Committee) and the appropriate Assistant Commissioners. Independently reconciles and evaluates the cost/manpower/computer accomplishments of ACTS.

Consolidates and finalizes the preparation and submission of PPBS documents to insure consistency with long-range plans and resource requirements commensurate with the objectives and goals of the Assistant Commissioner (ACTS) and top line officials of the Service.

SEC. 1113.64 *Accounts and Data Processing Division—Office of the Director.*

Plans, coordinates and directs the development of returns processing programs and revenue accounting functions. Directs the operation of the present tax administration system in service centers, the National Computer Center, and district offices, and will operate the new, integrated tax administration systems. This responsibility encompasses: The development of major tax administration programs and issuance of detailed systems requirements, forms, procedures, and computer programs for the receipt and processing of tax returns and related documents or data (except alcohol and tobacco tax and firearms returns and applications); accounting for revenue collections and tax deposits; fulfilling the related requirements of other Service activities and the Department of the Treasury; maintenance of taxpayer master file and non-master file accounts; required financial and operating reports; design of master file related management and data control systems; systems acceptability testing of manual procedures, machine instructions, computer inputs, processes and outputs before implementation; and the maintenance of all operational ADP master files and related systems. Functional supervision—including determining the effectiveness of on-going programs, procedures, systems to achieve Service objectives; and providing leadership in the installation or modifications

of assigned tax administration programs and processing systems; prompt identification of and follow-up with regional management and coordination with Director, Program Review and Analytical Services Staff, ACTS, on significant operational problems which could impair attaining Service goals and objectives—over accounts and data processing activities in the regional offices, service centers, and district offices. Line supervision over the National Computer Center and liaison between the Center and other organizational units of the Service.

SEC. 1113.641 *National Computer Center.*

Plans, directs, and coordinates the master file operations of the totally integrated tax administration system. Functions include: establishment, maintenance, and updating of the individual, business, employee plans and exempt organizations master files through around-the-clock operation of a large-scale computer system complex. Provides reciprocal controls with service centers of the receipt, processing, and shipment of tax account data. Produces output data for use in issuing refunds, bills or notices, answering inquiries, conducting delinquency checks, detecting fraudulent refund claims, classifying returns for audit purposes, preparing reports, and other matters concerned with processing and enforcement activities of the Service. Provides line supervision over National Office Computer Facility which is principally responsible for computer testing support for the totally integrated tax administration system. Responsible for scheduling and coordinating with Service Centers on production matters and receipts, control and servicing of file searches for Disclosure Staff, Intelligence, Internal Audit and other Service offices. Responsible for financial planning, recruitment, and training, and other administrative matters of the National Computer Center.

SEC. 1113.642 *Office of the Executive Assistant.*

Responsible for providing assistance to the Director in the general overall management and evaluation of Accounts and Data Processing operations both within the Division and functional areas in the field. Coordinates and monitors Division program plans in the areas of organization, personnel, training, security, space and furniture acquisition, financial planning and funding. Finalizes financial and Program-Planning and Budgeting System documents for Division programs covering field operations and the National Office. Coordinates with Internal Audit on program reviews and follows up on findings and corrective action pertaining to the programs and mission of Accounts and Data Processing. Coordinates the Division reports management program. Manages the Division Internal Work Planning and Control System. Prepares speeches and other required papers on Division activities. Represents the Division in the orientation of foreign tax officials and other dignitaries. Provides office management and directives management for the Accounts and Data Processing Division.

SEC. 1113.643 *Associate Director (Accounts and Services).*

Directs the data processing program management for the present tax administration system, and will direct the program management of the new, integrated tax administration systems. Develops programs for approval; and designs, implements, and evaluates systems and procedures for data processing applications. Functions include: participates in developing new systems or revision of existing systems, including a cost/benefit analysis; plans and coordinates resource requirements for accomplishments of programs (collaborates with involved client organizations); prepares, issues, and monitors program requirement packages (PRP's) and ADP Handbook procedures; participates in systems acceptability testing with approval authority for proprietary programs; evaluates program effectiveness through feedback from on-site review, field office communications, customers, and Internal Audit, promptly resolving program problems; develops management information and quality review systems applicable to activities in service centers and NCC; responsible for development and coordination of service center and master file requirements relating to special studies and other research activities; provides analyses and recommendations of action required by tax legislation; and coordinates participation of ACTS in the data exchange programs, e.g., requests from Federal, State, and municipal entities for non-report and non-statistical formatted data from the master file.

SEC. 1113.6431 *Compliance and Special Programs Branch.*

Managers data processing programs relating to Compliance and other Service components, and external customers for the totally integrated tax administration system. Develops programs for approval; and designs, implements and evaluates systems and procedures for data processing applications. Develops new systems or revises existing systems in area of responsibility, including a cost/benefit analysis. In collaboration with client organization, responsible for aggregate planning and coordination of resource requirements for accomplishment of programs; prepares, issues, and monitors program requirement packages (PRP's) and ADP Handbook procedures for area of responsibility. Participates in system acceptability testing for those systems related to its program area with final approval authority for proprietary programs. Evaluates program effectiveness through feedback from on-site review, field office communications, customers, and Internal Audit, promptly resolving program problems. Develops management information systems applicable to activities in service centers, district offices, and NCC. Responsible for development and coordination for service center and master file requirements relating to special studies and other research activities. Coordinates particiaption of ACTS in the data exchange programs, e.g., requests from Federal, State, and municipal entities for non-report and non-statistical formatted data from the master file.

SEC. 1113.6432 *Revenue Accounting and Processing Branch.*

Manages data processing programs relating to processing of tax returns and related documents from receipt through posting to the master file, including service center and district office deposit activities for the totally integrated tax administration system. Develops programs for approval; and designs, implements, and evaluates systems and procedures for data processing applications. Develops new systems or revises existing systems in area of responsibility, including a cost/benefit analysis. Responsible for aggregate planning and coordination of resource requirement packages (PRP's) and ADP Handbook procedures for area of responsibility. Participates in systems acceptability testing for those systems related to its program area with final approval authority for proprietary programs. Evaluates program effectiveness through feedback from on-site review, field office communications. customers, and Internal Audit, promptly resolving program problems.

SEC. 1113.6433 *Taxpayer Accounts Services Branch.*

Manages data processing programs of service center and district office activities relating directly with taxpayer's accounts occurring subsequent to master file posting of the return for the totally integrated tax administration system. Develops programs for approval; and designs, implements and evaluates systems and procedures for data processing applications. Programs include activities such as correspondence, adjustments, notice review, payment tracers and other IDRS related activities. Develops new systems or revises existing systems in area of responsibility, including a cost/benefit analysis. Responsible for aggregate planning and coordination of resource requirements for accomplishment of programs. Prepares, issues, and monitors program requirement packages (PRP's) and ADP Handbook procedures for area of responsibility. Develops quality review systems applicable to activities in Service Centers and NCC. Participates in systems acceptability testing for those systems related to its program area with final approval authoriy for proprietary programs. Evaluates program effectiveness through feedback from on-site review, field office communications, customers, and Internal Audit, promptly resolving program problems.

SEC. 1113.6434 *Accounting Operations Branch.*

Assures that accounting operations in Service Centers are performed in accordance with prescribed procedures and provides assistance in account balancing or other problems through field visitations, phone calls and correspondence. Provides Division Management with information gathered through field contact relating to the accounting function.

Suggests revisions to the Revenue Accounting System and assists in preparation of field instructions; engages in consultation and preparation of special accounting related projects such as those involved in new service center activation and apportionment of accountability. Also prepares specifications for the maintenance of the centralized accounting function which accounts for monies to be transferred to U.S. territories such as Puerto Rico, Guam and the Virgin Islands. Prepares annual financial statements and maintains accounting data necessary for the proper planning of receipts and cash flow by the Department of the Treasury.

Prepares reports of revenue receipts and refunds paid for management and various IRS publications. Reviews revenue and refunds paid data prepared by the National Computer Center and Service Centers and prepares quarterly certifications of trust fund collections, refunds and credits such as those for the Highway, Land and Water Conservation, Airport and Airway, and Railroad Retirement Trust Funds. Maintains administrative control over Joint Committee refund cases from time of receipt, through processing, to time of final dispatch to service center for preparation of refund check. Reviews pending and enacted legislation, government and other publications to keep current with all actions affecting the revenue. Acts as liaison with other agencies in the Department of the Treasury, Railroad Retirement Board, Joint Committee on Internal Revenue Taxation, Office of Business Economics, and other agencies, industries, individuals and associations involved in the Nation's revenue.

SEC. 1113.644 *Associate Director (Computer Systems).*

Directs and coordinates the operations of computer systems and processing programs for the present tax administration system and will operate the new, integrated tax administration systems, commensurate with established ACTS goals and recommends determination of supporting computer hardware, as well as auxiliary and accessory equipment, and software requirements for service centers, district offices and the National Computer Center. In addition, includes: participation in studies of proposed computer systems, including telecommunications and real time processing applications; develops and maintains computer software support; evaluates computer systems utilization and is responsible for outside agency computer systems reporting; coordinates installation of computer systems, evaluating planned operational effectiveness; develops standards and guidelines for uniformity by all programmers; develops application and scientific computer programs; participates in systems acceptability testing of all procedures and computer programs before systems acceptability testing of all procedures and computer programs before sysalysts located at service centers and the National Computer Center; provides technical advice and consulting services to other Service offices on computer systems problems; coordinates participation of ACTS in the Government-wide ADP Sharing program; and develops and coordinates the recruitment and training of programmer trainees.

SEC. 1113.6441 *Master File Programming Branch.*

Develops, documents, and maintains computer systems and processing programs to establish, update, analyze and produce required outputs from Master Files of taxpayer accounts and related data files at the National Computer Center for the totally integrated tax administration system. Analyzes new or revised computer-oriented systems requirements to develop required run schematics, detailed logic and block diagrams, machine coding and run tests, documentation and instructions for National Computer Center input, Master Files processing and output programs, including data controls and files extracts. Coordinates with Accounts and Services, and the Service Center Programming, Data Retrieval Programming and Systems Support Branches to ensure compatibility with computer input/output programs in the Internal Revenue Service Centers. Assists the Systems Testing Branch in conducting tests of computer programs and instructions prior to operational use. Identifies operational programming problems, recommends recovery action, if practicable, and makes required program changes. Participates in the review and analysis of proposed computer systems requirements to determine feasibility, completeness, and compatibility with related IRS systems. Provides functional supervision over Resident Programmer Analysts located at the National Computer Center.

SEC. 1113.6442 *Service Center Programming Branch.*

Develops, documents, and maintains computer systems and processing programs and related off-line equipment instructions for tax return and all related data transcription and processing operations including residual master files and data controls in the Internal Revenue Service Centers for the totally integrated tax administration system. Analyzes new or revised computer-oriented systems requirements to develop required run schematics, detailed logic and block diagrams, machine coding and run tests, documentation and instructions for Service Center computer input/output programs, data controls and related processes. Coordinates with the Accounts and Services, and the Master File Programming, Data Retrieval Programming and Systems Support Branches to ensure compatibility with all IRS computer processes particularly at the National Computer Center. Assists the Systems Testing Branch in conducting tests of computer programs and instructions prior to operational use. Identifies operational programming problems, recommends recovery action if practicable and makes required program changes. Participates in the review and analysis of proposed computer systems requirements to determine feasibility, completeness, and compatibility with related IRS systems. Develops and maintains computer programs to fulfill requirements for management information systems integrated or related with the tax processing system. Provides functional supervision of Resident Programmer Analysts located at the Service Centers.

SEC. 1113.6443 *Data Retrieval Programming Branch.*

Develops, documents, and maintains computer systems and processing programs for the Service Centers and district and local offices that are required for the Integrated Data Retrieval System (IDRS). Designs file structure and determines the need for individual computer runs and the relationship of these runs for IDRS. Requirements of the system are received from the branches under Associate Director, Accounts and Services and are coordinated for clarity and programming feasibility. The computer system is diagrammed; file content and format is determined; individual program logic is designed, coded and tested. Complete program documentation is prepared for distribution to all Service Centers and district and local offices including detailed operating instructions. Programs are all prepared to operate synchronously with the individual, business, and residual master files, and other automated and manual systems for the totally integrated tax administration system. Programming activities include real time processing of terminal inquiries and update action plus a large number of multiprogrammed batch runs. The batch processing, which also has related real time processing, includes such items as: updating the Account Data files on a daily and weekly basis with data from the National Computer Center and data from all of the various stages of processing in the Service Center; analysis of accounts notice output; maintenance of adjustment and correspondence case inventories; and various audit and collection related activities. Some principal subsystems that are a part of IDRS processing are: Correspondex System, Document Request System, Unidentified Remittance System, On-Line Adjustment System, System for Direct Deposit of Receipts. Participates in the review and analysis of proposed computer systems requirements to determine feasibility, completeness, and compatibility with related IRS system. Coordinates with the Master File Programming and Service Center Programming Branches in the functional supervision over Resident Programmer Analysts located at the service centers and the National Computer Center.

SEC. 1113.6444 *Systems Testing Branch.*

Plans, develops, schedules and conducts acceptability tests simulating live operation of new or revised systems, procedures, forms, instructions, and computer programs designed to process tax returns, related documents and data in the district offices, service centers, or National Computer Center, including accounting, document and other internal

controls over such operations for the totally integrated tax administration system. Coordinates with other ACTS operating and user organizations in testing the system as acceptable for implementation, analyzes total system requirements, develops appropriate tests documents and data, and establishes predetermined control and output results. Tests all manual procedures, machine processes and computer programs, under predetermined controls as planned, to determine readiness of the system to produce records and outputs meeting all requirements. Identifies any deficiencies of problem areas, recommends evident modification or clarification, and tests any changes. Recommends acceptability to the client organization for their certification.

SEC. 1113.6445 *Systems Support Branch.*

Develops, maintains and modifies all software products, required for the Service's totally integrated tax administration system as a service function to the programming branches within the Division. Studies and evaluates proprietary software packages for application on any IRS system. Provides technical advice and consulting services to other Service offices including development of scientific computer programs. Provides a systems "debug" service to application programmers within the Division. Maintains the variety of skills and knowledge necessary to support the several different computer systems and programming languages utilized in the Service. Maintains a current knowledge of computer equipment, including auxiliary and related equipment, software technology, and telecommunication and real time processing applications. Participates in determining immediate or long-range computer systems equipment requirements for data processing; develops plans and schedules for meeting those requirements, and recommends acceptance, modification, or rejection of suppliers proposals. Coordinates installation of computer systems and evaluates effectiveness compared with contract requirements. Evaluates computer systems utilization and is responsible for outside agency computer systems reporting. Responsible for computer operation support functions, (e.g., tape library, computer scheduling) including related procedures and programming, for the Service Centers, National Computer Center, and the National Office. Develops and Issues standards and techniques for uniform guidance and use by all programmers; coordinates participation of ACTS in the Government-wide ADP Sharing Program. In coordination with Training Division, assists in developing and conducting data processing functional training seminars, for Service personnel and specialized training courses for programmer trainees.

SEC. 1113.65 *Collection Division—Office of the Director.*

Accomplishes the Collection mission with reference to the filing and payment requirements of the internal revenue laws by providing and supervising (functional supervision) nationwide programs for issuance of Certificates of Compliance to departing aliens, disposition of certain offers in compromise, collection of unpaid accounts, determination and analysis of why accounts become delinquent, and prevention of accounts from becoming delinquent; obtaining of delinquent returns, measurement of the types and degrees of non-filing, determination and analysis of the reasons for non-filing and reduction of non-filing.

SEC. 1113.651 *Special Projects Branch.*

Exercises responsibility over projects and activities not directly identified with a program management branch or the Special Service Staff. Exercises continuing responsibility for the coordination of management processes which apply to all programs and activities of the Division by performing the following functions: Monitors, coordinates and integrates the planning activities of the Division, including the preparation of program planning document, PPBS Program Memoranda and Program and Financial Plan, Work Plans and budget and financial documents. Maintains Work Planning and Control System (including maintenance of the Operations List) current and compatible with procedural issuances and coordinates the establishment of work priorities within the System. Monitors, studies, coordinates and integrates field collection (DAR activities), organization functions, position responsibilities, staffing and related personnel matters. Serves as Division consultant on these matters. Collaborates and maintains liaison with the Office of the Assistant Commissioner (ACTS) on information system requirements for data and data processing, reports and information systems design, other reports management activities, and on information storage and retrieval matters (also collaborating and maintaining liaison with the Office of Assistant Commissioner (Planning and Research) on information storage and retrieval), and coordinates and maintains management surveillance over all these matters within the Collection Division. Collaborates and maintains liaison with the Office of Assistant Commissioner (Administration) in determining field Collection training needs, evaluating and administering Collection training programs, and providing Collection functional guidance and review for development of training materials at the National Training Center. Conducts general management and other special studies and performs other assignments, which are not within the specific jurisdiction of the program management branches, when authorized by the Director or Assistant Director. Assists Director in determining permanent functional assignments within the Division where such assignments are not clearly covered within the established functional responsibilities. Coordinates internal audit matters related to the Collection Division, and is responsible for completed action on internal audit reports, keeping branches informed on these matters. Responsible, on a continuing basis, for management improvement, work simplification, better utilization of resources, etc., with reference to assigned programs.

SEC. 1113.652 *Delinquent Accounts Branch.*

Exercises program management responsibility for Collection Division's functional supervision of the payment requirements of the Internal Revenue laws through the Delinquent Accounts Program (collection of unpaid accounts, determination and analysis of why accounts become delinquent, and prevention of accounts from becoming delinquent) and of the functional supervision of offers in compromise based on doubt as to collectibility of taxes (except alcohol, tobacco and firearms taxes), offers in compromise of statutory additions based on doubt as to liability or doubt as to collectibility (except alcohol, tobacco, firearms, employment, withholding and excise taxes and specific penalties) and all offers in compromise of 100% penalties, by performing the following functions with reference to the Delinquent Accounts and Offer in Compromise Programs: Formulates and recommends policies. Develops short, intermediate and long-range program content and activities. Relates these to program planning documents, preliminary work plans and budget and financial plans. Develops, reviews and revises as necessary, systems, procedures, methods and other instructions for Collection field personnel, including the development of techniques. Analyzes, evaluates and reports to Division Director on status, progress and trends with reference to assigned programs and takes appropriate action required. Evaluates and reports to Division Director on status and trends of Field Operations involving assigned programs. Collaborates with Office of Assistant Commissioner (ACTS) on substantive program and systems matters pertaining to assigned programs. Identifies the need for and seeks improvement (in collaboration with the Special Projects Branch) of reports and information systems and training guides. Identifies need for and seeks improvement of records and internal forms in collaboration with Facilities Management Division. Recommends appropriate action on Incentive Awards suggestions referred by the Administrative Services Office and on internal audit reports referred by the Special Projects Branch. Conducts studies required for problem identification, problem solving, planning, assistance to the regions, and engages in "troubleshooting" for assigned programs. Makes a performance evaluation of offers in compromise in certain district acceptance cases. Reviews offers in compromise within functional jurisdiction requiring the Commissioner's approval. Participates in Division visits to field offices and conducts special purpose visits as required. Serves as taxpayer liaison office for the Division by the performance of the following principal functions: Responds to inquiries (personal visits, correspondence and telephone) from sources external to the Internal Revenue Service (e.g. taxpayers, members of Congress, Treasury Department

and other Departments and Agencies) on matters pertaining to Collection Programs, activities and functions. Conducts correspondence and engages in conferences with taxpayers, officials of the Service, States, other Federal Agencies, members of Congress and Congressional Committees on Collection Division activities and functions. Monitors the Division's sensitive case program. Responsible on a continuing basis, for management improvement, work simplification, better utilization of resources, etc., with reference to assigned programs.

SEC. 1113.653 *Returns Compliance Branch.*

Exercises program management responsibility for Collection Division's functional supervision of the filing requirements of the Internal Revenue laws through the Returns Compliance and Delinquent Returns Programs (obtaining of delinquent returns, measurement of the types and degrees of non-filing, determination and analysis of the reasons for non-filing and reduction of non-filing) by performance of the following functions with reference to the Returns Compliance and Delinquent Returns Program. Formulates and recommends policies. Develops short, intermediate and long-range program content and activities. Relates these to program planning documents, preliminary work plans and budget and financial plans. Develops, reviews and revises as necessary: systems, procedures, methods and other instructions for Collection field personnel, including the development of techniques. Analyzes, evaluates and reports to Division Director on status, progress and trends with reference to assigned programs and takes appropriate action required. Evaluates and reports to Division Director on status and trends of field operations involving assigned programs. Collaborates with Office of Assistant Commissioner (ACTS) on substantive program and systems matters pertaining to assigned programs. Identifies the need for and seeks improvement (in collaboration with the Special Projects Branch) of reports and information systems and training guides. Identifies need for and seeks improvement of records and internal forms in collaboration with Facilities Management Division. Recommends appropriate action on Incentive Award suggestions referred by the Administrative Service Office and on internal audit reports referred by the Special Projects Branch. Conducts studies required for problem identification, problem solving, planning assistance to the regions, and engages in "trouble-shooting" for assigned programs. Participates in Division visits to field offices and conducts special purpose visits as required. Responsible, on a continuing basis, for management improvement, work simplification, better utilization of resources, etc., with reference to assigned programs.

SEC. 1113.66 *Taxpayer Service Division—Office of the Director.*

Plans, develops and directs a comprehensive Service-wide Taxpayer Service Program which recognizes that taxpayers must have the ability as well as the willingness to comply with Federal tax law. Ensures a consistent and uniform policy of service to all taxpayers.

Responsible for coordinating and integrating all field Taxpayer Service related activities (other than those requesting technical determinations), regardless of organizational boundaries. In this regard ensures that prompt, accurate, and responsive replies are made to taxpayer inquiries and that appropriate and useful informational and educational materials for public use are prepared and distributed. Participates in the formulation of policies affecting the taxpaying public. Assists (utilizing internal audits to the extent practical) in determining the effectiveness of taxpayer service activities in all areas and at all organizational levels. In this regard, recommends how procedures might be changed and resources increased, decreased, or shifted to provide better overall service to the taxpayer. Exercises functional supervision over regional and district taxpayer service activities. Conducts research on assessing and improving the effectiveness of various Taxpayer Service activities.

SEC. 1113.661 *Operations Branch.*

Exercises general program management responsibility to ensure prompt, accurate and responsive replies to taxpayer inquiries directed to district offices and service centers. This includes prompt replies to correspondence received from taxpayers, members of Congress, tax practitioners, and other regarding operations aspects of the ACTS organization.

Develops, reviews and modifies, as necessary, procedures, methods, and other instructions to assist field managers and employees in the accomplishment of Program objectives.

Reviews selected correspondence to identify problem areas within the Taxpayer Service Division or to have the matter referred so the appropriate activity may take necessary remedial action. Provides liaison between district office taxpayer service operations and service center data processing operations as they related to Service-generated output or taxpayer-initiated actions.

Provides input to the Planning and Development Branch for Program Management guidelines, PPBS materials, work plans, estimates of staff and budget requirements to meet Program goals and objectives.

In conjunction with the Training Division, develops or reviews materials for field and National Office training programs for Taxpayer Service personnel. Issues up-to-date tax information, e.g., handbooks, guidelines, TAX-NEWS, and the like, to ensure dissemination of accurate tax information to the public by TSR's.

Provides guidance and assistance in the implementation of a comprehensive Servicewide Taxpayer Service Program; and participates in the evaluation of its operational effectiveness. Responsible, on a continuing basis, for submitting recommendations for initiating studies and conducting field operational studies to improve the effectiveness of field operations, management improvement, work simplification and the like.

SEC. 1113.662 *Planning and Development Branch.*

Develops long-range plans and objectives for a comprehensive Taxpayer Service and Assistance Program and coordinates these plans with other activities assigned responsibility for various programs related to Taxpayer Service. Prepares, coordinates, and integrates the planning activities of the División, including the preparation of Program Planning documents, PPBS materials, Programs and Financial plan, Work Plans, and budget documents. Assist in the determination of staff requirements to meet program objectives and long-range plans.

Assesses taxpayer needs, conducts in-depth research studies to measure effectiveness of selected methods of providing taxpayer service as well as measure various related programs, and recommends effective and economical methods of informing and educating taxpayers in their rights and responsibilities. Related programs to be measured include telephone assistance, filing period publicity, taxpayer education, taxpayer publications, and the like, to determine how to most effectively meet taxpayer needs.

Represents both taxpayers and the Assistant Commissioner (ACTS) on the Forms Committee; and suggests alternative solutions to meet Service objectives with minimum inconvenience to taxpayers. Assures that the needs of taxpayers are considered in the design of tax forms and other Service publications; and that instructions are issued which make compliance simpler or more understandable for the public.

Identifies subject matter areas giving taxpayers problems and endeavors to alleviate these by coordinating with other National Office Divisions in the preparation of appropriate technical publications, news releases, institute training materials, et cetera. Review forms, form letters, computer notices, and other issuances to ensure that information or instructions contained therein are understandable to the public.

Provides assistance in personnel management activities and program evaluation. Collects and presents statistical data in an organized and readily usable form in measuring accomplishments against objectives. Prepares materials designed to aid field personnel in achieving the highest Program goals at a minimum cost. Serves as Taxpayer Service Division representative in TCMP matters. Develops and coordinates the issuance of Revenue Procedures on the use of "substitute" tax forms and schedules. Coordinates internal audit matters related to the Taxpayer Service Division and has responsibility for completing action on such reports and for collaboration with the Field Operations Branch on these matters.

SEC. 1113.67 *IRS Data Center.*

Responsible for the performance of Non-Master File data processing operations for the Service. This includes: design of manually and electronically oriented processing systems; detail design of computer programming requirements and instructions; writing of computer programs; testing and debugging of computer routines; systems acceptability testing; installation of new systems; and maintenance of systems after they become operational. Such systems provide for the preparation of Department of the Treasury payrolls; fiscal reports; statistics of income; Taxpayer Compliance Measurement Programs, including both work progress reports and special studies; special tax research; personnel analysis reports; work planning and control reports; data for PPBS and other purposes; special tabulations and comparisons for States and other Federal agencies; and statistical information for management control by National and Regional Office officials; and other special applications not included in the Business and Individual Master File systems.

SEC. 1113.7 *Office of Assistant Commissioner (Inspection).*

The Assistant Commissioner (Inspection) acts as the principal assistant to the Commissioner in planning and carrying out the inspection program of the Internal Revenue Service. This includes the independent review and appraisal of all Internal Revenue Service activities as a basis for protective and constructive service to management, and the carrying out of a program for assisting management to maintain the highest standards of honesty and integrity among its employees. The Assistant Commissioner (Inspection) plans and directs the inspection program at both the national and regional levels. At the National Office level he supervises two divisions: the Internal Audit Division and the Internal Security Division; and at the regional level he supervises the Regional Inspectors.

SEC. 1113.71 *Internal Audit Division—Office of the Director.*

The Internal Audit Division has responsibility for conducting a program providing for an independent review and appraisal of the operations of the Internal Revenue Service. This review provides information on the condition of all the functional activities of the Service at the National, regional and district levels and is sufficient in scope to provide a basis for constructive management action by the Service officials responsible for the activities involved. The Division is also responsible for a systematic verification and analysis of financial transactions and a review and appraisal of the protective measures and controls established at all operating levels. The organizational structure for program operations consists of the National Office Internal Audit Division, and the regional Internal Audit staffs which are headquartered in the same location as the Regional Inspectors. The Director of the Internal Audit Division, under the general supervision of the Assistant Commissioner (Inspection), is responsible for the development and execution of the Division's program.

SEC. 1113.711 *Operations Branch.*

The Operations Branch has responsibility for ensuring a continuing effective internal audit of the Service's Administration, Appellate, Audit, Counsel, Intelligence, Technical, Office of International Operations, and Economic Stabilization Program activities by developing guidelines for the annual internal audit plans; by reviewing and making recommendations on regional internal audit plans; by conducting National Office and coordinated nationwide audits; by carrying out special surveys, examinations, and projects as assigned by higher authority, such as audits of the Tax Division of the U.S. Virgin Islands Government, and the Treasury Department's Exchange Stabilization Fund and Alcohol, Tobacco and Firearms activities; by coordinating, evaluating, and reviewing and following through on audit findings; and by bringing significant audit disclosures to the attention of top National Office management officials including the Commissioner. Participates in the program of staff guidance, review and evaluation of the auditing activities of regional Internal Audit staffs. Consults with top officials in the Offices of the Assistant Commissioners and the Office of Chief Counsel on recommendations for improving procedures and controls. Carries out special assignments in cooperation with the Internal Security Division on cases requiring the specialized knowledge and training of personnel of the Internal Audit Division. Exercises continuing direction and control over all Internal Audit aspects of Inspection integrity assignments conducted nationwide, including on-job visitations. Maintains liaison with National Office Internal Security Division on Security cases pending in the regional offices. Analyzes and summarizes Internal Audit Division's annual accomplishments and prepares required internal and external reports.

SEC. 1113.712 *Program Development Branch.*

The Program Development Branch has responsibility for developing the Division's policy and procedural instructions and internal audit program guidelines for the continuing effective internal audit of all activities in the Revenue Service's field offices. Also has responsibility for developing and carrying out career development programs for Internal Audit staff members nationwide to increase staff management capability and professional auditing proficiency, including conducting basic and advanced Internal Audit training programs. Keeps abreast of new developments in Service programs to determine their effect on Internal Audit's responsibilities in the auditing of field operations. Coordinates with other functional areas of the Office of Assistant Commissioner (Inspection) as necessary, including participation in a program of on-site review and evaluation of the activities of the regional Internal Audit staffs. Maintains liaison with Officers of Assistant Commissioners and Chief Counsel, to determine operating problems or developments that should be given internal audit program attention. Keeps abreast of latest professional management auditing techniques and methods to ensure timely adaptation to the Service's internal audit program. Maintains the division's program of continuing review of special long-range Service projects, e.g., Taxpayer Compliance Measurement Program.

SEC. 1113.713 *Data Processing Activities Branch.*

The Data Processing Activities Branch has responsibility for ensuring a continuing effective internal audit of the Service's Accounting, Data Processing, Collection and Taxpayer Service activities by developing guidelines for the annual internal audit plans; by reviewing and making recommendations on regional internal audit plans; by conducting National Office and coordinated nationwide audits; by carrying out special surveys, examinations, and projects as assigned by higher authority; by coordinating, evaluating, and reviewing and following through on audit findings; and by bringing significant audit disclosures to the attention of top National Office management officials including the Commissioner. Participates with management during the development stages of new or improved ADP systems to ensure the incorporation of effective management controls. Develops systems and procedures to ultilize automatic data processing in carrying out principal segments of the Internal Audit Division's program. Participates in the program of staff guidance, review and evaluation of the auditing activities of regional Internal Audit staffs. Consults with top officials in the Offices of the Assistant Commissioners and the Office of Chief Counsel on recommendations for improving procedures and controls; keeps abreast of current data processing developments, including technological changes, so that proper consideration can be given to carrying out the Internal Audit Division's program. Coordinates with other functional areas of the Office of Assistant Commissioner (Inspection) in order to obtain data processing services requested by them or provide other information pertinent to the mission of these functions. Analyzes and summarizes Internal Audit Division's annual accomplishments and prepares required internal and external reports.

SEC. 1113.72 *Internal Security Division.*

The Internal Security Division plans, develops, and controls the Internal Security program for the Internal Revenue Service so as to assist management in assuring the highest standards of honesty, integrity and security among Service employees and maintain public confidence in the integrity of the Service. The program includes personnel background investigations and investigations of complaints or allegations of misconduct or irregularities, including criminal,

concerning Service employees; also investigations of non-Service persons when their actions may affect the integrity of the Service or safety of Service personnel, including attempts to bribe or otherwise corrupt Service personnel; this authority includes investigation of attempts to interfere with administration of Internal Revenue laws through threats, assaults or forcible interference, and also the unauthorized disclosure of Federal tax information. The program also includes background investigations of certain applicants for enrollment to practice before the Internal Revenue Service, investigations of charges against tax practitioners, formal investigations of accidents involving Service employees or property, investigations of complaints alleging discrimination because of race, creed, color or national origin; and the maintenance of records and case files relating to investigations conducted. The Division also conducts such special investigations, studies, and inquiries as required for the Commissioner, Office of the Secretary, or other components of the Treasury Department. The Division is composed of three branches: Field Coordination Branch, Investigations Branch, Planning and Programming Branch.

SEC. 1113.721 *Field Coordination Branch.*

The Field Coordination Branch controls and coordinates on a nationwide basis *all* investigations conducted by the Internal Security function. These investigations cover alleged violations of Federal criminal statutes and of the regulations and rules governing the conduct of Service personnel; actions of non-Service persons that may affect the integrity of the Service, including attempts to bribe or otherwise corrupt Service personnel; charges against persons enrolled or entitled to practice before the Internal Revenue Service; the investigation of the character and background of applicants for, or incumbents of, positions in the Service; enrollee applicant cases; formal investigations under the Federal Tort Claims Act; and other investigations as required for the Commissioner and other components of the Treasury Department. The Branch maintains a continuing review and control of all investigations to: assure that proper priorities are established and that the investigation workload is accomplished in an effective and efficient manner on an overall regional, as well as an individual Inspector basis; assure that the scope of the investigations and the facts and evidence are sufficient to provide a basis for conclusions by management, the Department of Justice or other authority; assure that established policies, procedures and techniques are being followed properly and uniformly; assure effective investigation accomplishments, uniformity in investigative coverage, and that there is proper form and quality of reports, as well as administrative and criminal dispositions; develops data and recommendations for improvement, simplification, and standardization of investigative operations, many of which are passed along for use by management in connection with directing program execution as well as planning and programming Internal Security activities; and directs the maintenance of records and case files relating to investigations conducted by the Internal Security function. The Branch maintains liaison on criminal and other investigative matters with the Office of the Chief Counsel, other law enforcement and security segments of the Treasury Department and the Internal Revenue Service, Department of Justice, Federal Bureau of Investigation and other Federal law enforcement agencies.

SEC. 1113.722 *Investigations Branch.*

The Investigations Branch, operating on a nationwide basis, is responsible for conducting extremely confidential investigations of complaints and allegations of misconduct or irregularities concerning high level officials of the Service and other special investigations which by reason of their complexity or sensitivity, or because of their potential effect on the maintenance of public confidence in the integrity of the Service, demand special handling. The Branch, as the investigative branch of the Internal Security Division for National Office personnel, is responsible for conducting background investigations of applicants for, or incumbents of, positions in the Service, certain applicants for enrollment to practice before the Internal Revenue Service, and for applicants for positions with certain other components of the Treasury Department. In addition the Branch conducts investigations of alleged violations of Federal criminal statutes and rules and regulations governing the conduct of Service personnel; actions of non-Service persons that may affect the integrity of the Service, including attempts to bribe or otherwise corrupt Service personnel; charges against persons enrolled to practice before the Internal Revenue Service; formal investigations under the Federal Tort Claims Act; investigations of alleged discrimination because of race, creed, color or national origin; and other special investigations as may be required for the Commissioner and other components of the Treasury Department. The Branch maintains liaison with the Regional Inspectors and Assistant Regional Inspectors (Internal Security) to coordinate joint activities and in special situations to render assistance in the handling of difficult investigations.

SEC. 1113.723 *Planning and Programming Branch.*

The Planning and Programming Branch is responsible for providing staff assistance to the Division Director in planning and programming the Internal Security Division program. This includes formulating policies; developing technical and administrative procedural instructions, including manual issuances and investigative handbooks; conducting inspections of the management and operation of the regional Internal Security Division; conducting special surveys of National Office Internal Security activities; developing and coordinating training programs for the Division; providing technical and staff assistance to the Treasury Law Enforcement Officer Training School; compiling and analyzing reports of operational costs, workload data, and statistics concerning criminal and administrative actions resulting from Internal Security investigations; evaluating manual issuances or proposals originating outside Inspection which are pertinent to Internal Security functions; conducting special staff studies; and maintaining liaison with other branches of the Internal Security Division, the Internal Audit Division, and other offices of the Service.

SEC. 1113.8 *Office of Assistant Commissioner (Planning and Research).*

The Assistant Commissioner (Planning and Research) acts as the principal assistant to the Commissioner and the Deputy Commissioner in the development and administration of the Long-Range Plan, related objectives and policies, and in the analysis of all Service programs for the purpose of promoting maximum effectiveness in the administration of the Internal Revenue Code with the most efficient and economical expenditure of resources; provides leadership and coordination in Federal-State cooperative tax administration; provides liaison with the States on administrative matters related to Federal collection of State individual income taxes; and is responsible for research, statistics, and systems development. The Assistant Commissioner (Planning and Research) represents the Commissioner on these matters in relations with the Department of the Treasury, the Congress, other Government agencies and outside organizations. He discharges these primary responsibilities in cooperation with the appropriate Assistant Commissioners (or other principal officials), each of whom exercises related responsibilities within his own functional area. The Assistant Commissioner (Planning and Research) is responsible for and supervises the activities of the Planning and Analysis Division, Research Division, Statistics Division, Systems Development Division, Tax Systems Redesign Division, and Internal Management Documents Division.

SEC. 1113.81 *Planning and Analysis Division.*

The Planning and Analysis Division develops and administers the systems for producing a comprehensive multi-year Long-Range Plan, for coordinating and integrating program objectives of the Service, and for analyzing all Service programs—with the aim of optimizing the collection of internal revenue taxes. To these ends, in cooperation with responsible offices, it develops the Service's Long-Range Plan; through Special Studies, approved by the Deputy Commissioner, evaluates the desirability and costs of existing and proposed plans, organizations, and program objectives; and develops criteria and presentations to measure accomplishments. It coordinates the preparation of the annual Program

Memoranda analyzing the objectives, costs and benefits of the Long-Range Plan. The Division, in cooperation with other responsible offices, determines the scope of operating data, needed for performance reporting and for marginal productivity and other kinds of operations research analyses in connection with the Long-Range Plan, Program Memoranda, and Special Studies.

SEC. 1113.82 *Research Division.*

The Research Division conducts advanced research (independently or in conjunction with other offices) into the Federal tax system to develop new approaches to improve the Service's operations and to reduce the compliance burden on the taxpayer; directs such research, within the framework of tax policy determined by the Office of the Secretary of the Treasury; furnishes leadership and coordination for the program of Federal-State cooperation in the field of tax administration; and serves as the liaison office for administrative matters with the States in connection with the Federal collection of State individual income taxes. The Division serves as the focal point of the Service for assistance to the Chief Counsel and the Office of the Secretary of the Treasury in the development of legislative proposals and in the identification and evaluation of administrative implications of such proposals; coordinates and works with other activities of the Service in assisting the Chief Counsel and Tax Legislative Counsel in the drafting of legislation; develops, coordinates and monitors plans to implement provisions of new legislation affecting tax administration; and keeps the Commissioner apprised of significant legislative developments and progress in implementing provisions of new legislation. The Division actively participates with other staffs of the Assistant Commissioners and of the Department of the Treasury in the preparation of legislative proposals and regulation revisions resulting from the research conducted; designs and carries out surveys, studies, polls, and other forms of research to provide basic data needed for the formulation of legislative proposals and operating programs and plans; and prescribes the nature and content of statistical analyses made by other offices but required for the research functions of the Division.

SEC. 1113.83 *Statistics Division.*

The Statistics Division conducts research and prepares statistics with respect to the operation of the income tax laws as required annually by the Internal Revenue Code to provide basic information for tax studies and legislation by the Congress and its committees, for administrative use by the Secretary of the Treasury and the Commissioner of Internal Revenue, and for the Federal benchmark statistical programs on income, wealth, and finance; and performs other related research and statistical functions. The Division provides support services for the Reports Management program. The Division consists of the Income, Finance, and Wealth Branch, the Statistical Techniques Branch, the Mathematical Statistics Branch, and the Program Management Branch.

SEC. 1113.831 *Administrative Office.*

Performs all administrative management activities, including personnel, budget, and fiscal programs, cost estimates, allocations and control of funds, records management, travel, space and equipment utilization. Coordinates and controls, in conjunction with the Facilities Management Division the printing requirements of the Division and statistical processing contracts, other office services required. Serves as a focal point for Division contacts with Personnel Fiscal Management, and Facilities Management Divisions.

SEC. 1113.832 *Income, Finance, and Wealth Branch.*

The Income, Finance, and Wealth Branch performs statistical and economic research with respect to the operations of the income tax laws as required by the Internal Revenue Code. It identifies and analyzes actual and prospective needs of users of income, wealth, and financial data reported on tax returns. The Branch plans, evaluates, and modifies these needs to develop an integrated statistical program and prepares specifications for data preparation. It interprets, analyzes, and presents the resulting statistics through publications of the Internal Revenue Service, such as the "Statistics of Income" series, and in consultation with appropriate policy and management officials.

SEC. 1113.833 *Statistical Techniques Branch.*

The Statistical Techniques Branch performs technical statistical services in support of the program of the Division. It prepares projections and estimates of tax return populations by type of return and geographic area, and produces other workload measures of the Service. It uses statistical techniques to analyze problems and improve efficiency in work programs. It plans, prepares the analysis, and presents the results of statistical studies for the Service, other Federal Agencies, and for approved reimbursable projects. It conducts research in the development and adaptation of statistical techniques designed to promote efficient operations. It prepares Service statistical guidelines and taxpayer aids. It supplies special statistical services in response to requests and advice on applications of statistical techniques to technical and administrative tax problems. It provides the technical service in development of management information and other reports.

SEC. 1113.834 *Mathematical Statistics Branch.*

The Mathematical Statistics Branch has the Statistics Division's responsibility for the probability sampling portions of the Service's research and operational programs and aiding, on request, other agencies with their sampling problems. This responsibility includes such things as the application of computer methods to sampling techniques used in such programs as Statistics of Income and Taxpayer Compliance Measurement; the use of area survey techniques to measure tax delinquency; assisting in the application of sample audit techniques to processing functions; using time samples to develop cost data for the Long-Range Plan; and review of sampling plans developed in other areas of the Service.

SEC. 1113.835 *Program Management Branch.*

Designs and develops operational plans for use in producing the statistics required by the Division's program, and prepares related procedures, forms, and instructions. Coordinates budget development for, and the planning, scheduling, and processing of the statistical work performed at decentralized locations. Conducts research into methods for controlling quality. Develops and applies operating techniques for quality control, providing standards of measurement and instituting methods developed through operations research. Evaluates statistics produced in terms of original specifications, costs, and procedures. Serves as the focal point for collaboration between National Office and field statisticians in the execution of continuing programs such as Statistics of Income, Taxpayer Compliance Measurement, and Statistical Quality Control. Guides and coordinates the activities of statisticians in the field processing centers to insure uniformity of method and adherence to common goals. Plans uniform statistical applications to be implemented by statisticians in the field processing centers. Provides the technical and clerical support for the manual compilation of management information and other reports.

SEC. 1113.84 *Systems Development Division.*

The Systems Development Division is concerned both with electronic systems and other systems, except for the implementation of the new integrated tax administration data processing systems. It conducts a continuing program relative to the availability and capability of electronic data processing systems and other electronic or automation equipment and systems, the feasibility and adaptability of electronic equipment to specific Service tasks, and the development of special modifications for Service purposes. The Division reviews and coordinates projects of other offices involving the adaptation of electronic equipment and participates in the selection and installation of electronic equipment and systems. With respect to other systems, the Division examines and makes recommendations for improvement or extension of internal systems (such as those reating to reporting, processing, accounting, enforcement, records management, and communications), reviews and coordinates system-improvement efforts of other offices, and initiates and develops projects of its own; furnishes other offices of the Service, on request, advisory and consultative services on

systems problems; studies possibilities of integrating paperwork and data-handling systems and equipment; and surveys, develops and tests equipment used or usable by the Service.

SEC. 1113.85 *Tax Systems Redesign Division.*

The Tax Systems Redesign Division is responsible for the development of requirements, preparing requests for proposals from vendors, evaluating vendors' proposals and recommending appropriate contract awards, and installing the new integrated tax administration data processing systems. These new systems replace not only the existing systems for revenue accounting and processing, with their limited capacity for serving other segments of the Service, but also provide an integrated data processing system available to all elements of the Service. Staffing and programs of the division represent all of the major organizational components, and close and continuous liaison is required with all users of the systems. The division is responsible for designing, implementing, and installing integrated tax administration systems which involve the service center, district offices, the National Computer Center, and the National and Regional offices. Responsibilities include such things as: development of major programs and procedural implementation instructions, preparation of detailed systems requirements and computer programs, design of systems acceptability tests, and design and management of data control systems. The division is also responsible for insuring the uninterrupted processing of returns, revenue accounting, and related activities while the original data processing system is being replaced by the new tax administration systems. While extensive coordination with user activities is required, and user skills are represented in the division staffing, the division is basically a self-contained organization (except for administrative support) having all the requisite skills and capable of expanding as the number and intensity of assignments increase. Subordinate organizational structure will be established as required at various stages, and the division will be absorbed into the continuing organization at the conclusion of the implementation stage.

SEC. 1113.86 *Internal Management Documents Division.*

The Internal Management Documents Division is responsible for designing and administering the Service's Internal Management Document System and for establishing standards for style and format of such National Office documents. The division reviews all Internal Management Documents, and memorandums and letters addressed to a group of field officials, issued from the National Office, for adequacy of coordination and clearance; determination of proper category for issuance; conformance with established Service policies, delegations of authority, and organizational titles and designations; effects coordination and clearance of such issuances as may be required; and arranges for publication in the Federal Register of statements of Service organization and functions, and Commissioner's delegations of authority which affect the rights and duties of taxpayers. The division is responsible for substantive review, evaluation and coordination of new and revised statements of Service policy, delegation orders, and organizational changes, prepared for the Commissioner's approval; and effects coordination for Planning and Research matters involving the Freedom of Information Act and liaison with the Tax Administration Advisory Staff.

SEC. 1113.9 *Office of Assistant Commissioner (Technical).*

The Assistant Commissioner (Technical) acts as the principal assistant to the Commissioner in providing basic principles and rules for the uniform interpretation and application of the Federal tax laws (other than alcohol, tobacco, and firearms taxes under Subtitle E of the Internal Revenue Code). In carrying out this mission, he: Publishes rulings to announce interpretative positions of the Service; publishes explanatory booklets, pamphlets and other materials for the guidance of taxpayers and Service officials; issues rulings and advisory statements to taxpayers and Service officials; issues opinion letters to sponsoring organizations on master and prototype pension, annuity, and profit-sharing plans; directs programs for clarification and simplification of tax rules; develops (and is responsible for the technical content of) all tax return forms and instructions (other than those relating to alcohol, tobacco and firearms taxes); reviews other public-use tax forms and form letters; acts as competent authority in matters involving interpretation or application of tax treaties; provides advice and assistance on technical matters throughout the Service, and to the Department of the Treasury, other Government agencies, and Congressional Committees; conducts a technical liaison program with Service field offices, conducts a Technical Field Conference program; coordinates with the Research Division of Planning and Research in providing advice and assistance on legislative matters; coordinates with the Office of Chief Counsel and the Department of the Treasury in providing advice and assistance on regulatory matters; reviews all new or amendatory regulations for administrative feasibility and adequacy; administers the activities of the Art Advisory Panel embracing a Service-wide program for providing guidance and direct assistance to field offices in the disposition of income, estate and gift tax cases involving fine arts valuation; coordinates with the Office of the Chief Counsel and the Department of Justice in providing advice and assistance in connection with matters in litigation; and coordinates with the other Assistant Commissioners, the Department of the Treasury, other Government agencies, and outside professional groups and industry and trade associations on matters of mutual concern. The Assistant Commissioner (Technical) is authorized to prescribe the extent, if any, to which any ruling issued by or pursuant to authorization from him, shall be applied without retroactive effect. He is also authorized to enter into and approve a written agreement (Closing Agreement) with any person relating to the internal revenue tax liability, other than certain excise taxes, of such person (or of the person or estate for whom he acts) in respect of any prospective transactions or completed transactions affecting returns to be filed. The Assistant Commissioner (Technical) is responsible for and supervises the activities of three divisions: Income Tax Division; Miscellaneous and Special Provisions Tax Division; and Technical Publications and Services Division.

SEC. 1113.91 *Income Tax Division—Office of the Director.*

Has primary responsibility for providing basic principles and rules for uniform interpretation and application of the Federal tax laws in those areas involving: Income and employment taxes to corporate and noncorporate taxpayers (including individuals, partnerships, estates, and trusts); depreciation depletion, and valuation issues; the taxable status of exchanges and distributions in connection with corporate organizations, reorganizations, and liquidations; taxes imposed on self-employment income; and exemption of farmers' cooperatives from tax under IRC 521. In carrying out these responsibilities, the Division: Issues rulings to taxpayers and technical advice and general technical information to District Directors and Regional Commissioners; advises the Appellate and Audit Divisions of the Service's position on particular issues; drafts Revenue Rulings, Revenue Procedures, Announcements and Releases to be published for the guidance and information of taxpayers and Service personnel; drafts, or reviews, IR-Manual issuances to be published for the guidance of Service personnel; reviews or assists in preparing technical booklets, training materials, pamphlets, and other materials prepared for the guidance of taxpayers and Service personnel; conducts special studies of technical problem areas, including reappraisals of current rules and practices, with a view toward reducing controversy and promoting uniformity; determines the status of certain organizations as agencies or instrumentalities of the United States, a State or political subdivision thereof, or the District of Columbia, or agencies or instrumentalities of governments of foreign countries or political subdivisions thereof; reviews Actions on Decisions announcing the Commissioner's position on adverse decisions of the United States Tax Court, prior to publication in the Internal Revenue Bulletin; initiates recommendations and coordinates with the Research Division of Planning and Research in providing advice and assistance on legislative matters; initiates recommendations and coordinates with the Office of Chief Counsel and the Department of the Treasury in providing advice and assistance on regulatory matters; coordinates with the Office of the Chief Counsel and the Department of

Justice in providing advice and assistance in connection with matters in litigation; reviews newly proposed and amendatory regulations for administrative feasibility and adequacy; analyzes and acts upon reports submitted by field offices under the Technical Coordination Program which disclose tax administrative problems, abuses, and inequities, as well as the views of field personnel as to the quality and effectiveness of regulations and tax return forms, the need for new or amendatory legislation or regulations, etc.; coordinates on matters of mutual concern with other Technical divisions, the Compliance organization, other offices of the Department of the Treasury, and other Government agencies; supplies the Audit Division with names or essential identifying characteristics of persons or organizations, and otherwise advises and assists the Audit Division in the selection of representative cases, involving issues on which Service position needs to be established, clarified, or otherwise developed; aids the Audit Division in developing the scope of and techniques needed in the examinations or investigations of such issues; supplies information for use by the Audit Division in programming, evaluating, and guiding audit operations throughout the Service; participates in the development of tax return forms and instructions and reviews pertinent portions of public-use forms and instructions; invites outside professional groups and industry and trade associations to participate in conferences and to submit comments, briefs, and suggestions in connection with tax problems and matters involving Revenue Rulings or Revenue Procedures proposed for the solution of tax problems; conducts conferences in the regional offices to discuss major programs of the Technical organization, to present papers on particular substantive technical areas, to discuss and explore possible solutions to technical areas of concern to field offices, and to discuss other matters of mutual concern; makes determinations with respect to earnings and profits of corporations and the taxable status of distributions to shareholders; acts on applications for changes in or adoption of accounting methods and periods; and acts as competent authority in matters involving interpretation or application of tax treaties. In areas involving the application of Federal tax laws in connection with provisions relating to depreciation, depletion and valuation issues, this Division also: Passes upon requests for approval of plans for the aggregation of nonoperating mineral interests as a single property; post-audits the depreciation, depletion, and valuation issues of cases on which engineering reports have been prepared and a sample of other large cases involving such issues; upon request, provides direct assistance to regional and district offices on cases involving depreciation, depletion, and valuation issues; provides, or secures, expert witnesses in support of the Government position in cases in litigation, and assists Government counsel in preparation and presentation of cases and in negotiations of settlements; prepares and presents material on professional and technical developments at engineering meetings, and upon request, in coordination with Compliance, develops, and conducts training programs for engineers; prepares material for inclusion in the Engineers' Coordination Digest calling attention to important new developments and to nonuniform treatment of issues; and administers the activities of the Art Advisory Panel embracing a Service-wide program for providing guidance and direct assistance to field offices in the disposition of income, estate, and gift tax cases involving fine arts valuation. This Division also post-reviews field determination letters relating to the status of farmers' cooperatives under IRC 521. The Director is responsible for and supervises the activities of four branches: Corporation Tax Branch; Individual Income Tax Branch; Engineering and Valuation Branch; and Reorganization Branch.

SEC. 1113.911 *Corporation Tax Branch.*

In matters involving the application of Federal income tax laws to corporate taxpayers, including the taxation of insurance companies and those relating to consolidated returns of affiliated groups, this Branch: Issues rulings, technical advice, and general technical information; drafts Revenue Rulings, Revenue Procedures, Announcements and Releases, and IR-Manual issuances, including material for the Exempt Organization Handbook relating to cooperatives; reviews or assists in preparing technical booklets, pamphlets, and other materials for the guidance of Service personnel and the public; conducts special studies directed toward resolving technical problem areas; reviews Actions on Decisions; provides advice and assistance to other offices of the Service (including the Office of the Chief Counsel), the Department of the Treasury, other Government agencies, and Congressional Committees; reviews proposed regulations for administrative feasibility and adequacy; analyzes and acts upon reports submitted by field offices under the Technical Coordination Program; coordinates with other Technical branches on matters of mutual concern; advises and assists the Audit Division in regard to the Service's audit program; participates in the development of tax return forms and instructions, and reviews pertinent portions of public-use forms and instructions; and participates in the Technical Field Conference Program. This Branch also performs the same functions involving either corporate or noncorporate taxpayers with respect to: Income of States, Municipalities, etc.; appearances, etc., with respect to legislation; amortization of pollution control facilities; research and experimental expenditures; inventories, including LIFO; allocation of income and deductions among related taxpayers; sales of low income housing projects; cooperatives and their patrons; exemption of farmers' cooperatives from tax under IRC 521; regulated investment companies and their shareholders; controlled foreign corporations and their U.S. shareholders; foreign tax matters which involve determination of sources of income; nonresident alien individuals and partnerships or of alien residents of Puerto Rico; compensation of employees of foreign governments or international organizations; income affected by treaty; foreign tax credit; earned income from sources without the United States; income from possessions; involuntary conversions; small business investment company stock losses; withholding of tax on nonresident aliens and foreign corporations; mitigation of effect of renegotiation of government contracts; requests for permission for change in or adoption of accounting periods and methods (except methods of accounting for depreciation and depletion); acts as competent authority in matters involving interpretation or application of tax treaties; and makes determinations with respect to earnings and profits of corporations and the taxable status of distributions to shareholders. This Branch also post-reviews field determination letters relating to the status of farmers' cooperatives under IRC 521.

SEC. 1113.912 *Engineering and Valuation Branch.*

In matters involving the application of Federal tax laws in engineering and valuation areas, this Branch: Issues rulings, technical advice, and general technical information; drafts Revenue Rulings, Revenue Procedures; Announcements and Releases, and IR-Manual issuances; reviews or assists in preparing technical booklets, pamphlets, and other materials for the guidance of Service personnel and the public; conducts special studies directed toward resolving technical problem areas; reviews Actions on Decisions; provides advice and assistance to other offices of the Service (including the office of the Chief Counsel), the Department of the Treasury, other Government agencies, and Congressional Committees; reviews proposed regulations for administrative feasibility and adequacy; analyzes and acts upon reports submitted by field offices under the Technical Coordination Program; coordinates with other Technical branches on matters of mutual concern; advises and assists the Audit Division in regard to the Service's audit program; participates in the development of tax return forms and instructions, and reviews pertinent portions of public-use forms and instructions; passes upon requests for permission to change methods of accounting for depreciation and depletion and for approval of plans for the aggregation of nonoperating mineral interests as a single property; conducts a post-audit review of field engineer reports and a sample of non-engineer reports which contain depreciation, depletion, and valuation issues for purposes of assessing the field treatment of engineering issues in order to provide uniform guidance, both on an individual basis by report, and on a Servicewide basis by publication in the Engineers'

Coordination Digest; provides direct assistance to regional and district offices, upon request; assists the Office of Chief Counsel and the Department of Justice in preparing and presenting cases in litigation, provides or secures expert witnesses in support of the Government's litigating position, and furnishes technical expertise in the negotiation of trial and pre-trial settlements; prepares and presents material on professional and technical developments at engineering meetings, and upon request, in coordination with Compliance, develops and conducts training programs for engineers; prepares material for inclusion in the Engineers' Coordination Digest calling attention to important new developments and to non-uniform treatment of issues; prepares and mantains an up-to-date Engineering Citator; and administers the activities of the Art Advisory Panel embracing a Servicewide program for providing guidance and direct assistance to field offices in the disposition of income, estatae and gift tax cases involving fine arts valuation.

SEC. 1113.913 *Individual Income Tax Branch.*

In matters involving the application of Federal income tax laws to noncorporate taxpayers (including partnerships, estates, and trusts), and with respect to the application of employment tax laws to both corporate and noncorporate taxpayers, and with respect to the taxes imposed on self-employment income, this Branch: Issues rulings, technical advice, and general technical information; drafts Revenue Rulings, Revenue Procedures, Announcements and Releases, and IR-Manual issuances; reviews or assists in preparing technical booklets, pamphlets, and other materials for the guidance of Service personnel and the public; conducts special studies directed toward resolving technical problem areas; reviews Actions on Decisions; provides advice and assistance to other offices of the Service (including the Office of the Chief Counsel), the Department of the Treasury, other Government agencies, and Congressional Committees; reviews proposed regulations for administrative feasibility and adequacy; analyzes and acts upon reports submitted by field offices under the Technical Coordination Program; coordinates with other Technical branches on matters of mutual concern; advises and assists the Audit Division in regard to the Service's audit program; participates in the development of tax return forms and instructions, and reviews pertinent portions of public-use forms and instructions; and participates in the Technical Field Conference Program. This Branch also performs the same functions involving either noncorporate or corporate taxpayers with respect to: Charitable contributions; tenant-stockholders of cooperative housing corporations; employee stock option and stock purchase plans; real estate investment trusts; and election of certain small business corporations as to tax status and related matters, except the rules relating to certain qualified pension plans.

SEC. 1113.914 *Reorganization Branch.*

In matters involving the application of Federal income tax laws to exchanges and distributions in connection with corporate organizations, reorganizations, liquidations, and spin-offs, to stock dividends, redemptions, exchanges in obedience to Securities and Exchange Commission orders, to distributions pursuant to the Bank Holding Company Act, and to losses on small business stock, this Branch: Issues rulings, technical advice, and general technical information; drafts Revenue Rulings, Revenue Procedures, Announcements and Releases, and IR-Manual issuances; reviews or assists in preparing technical booklets, pamphlets, and other materials for the guidance of Service personnel and the public; conducts special studies directed toward resolving technical problem areas; reviews Actions on Decisions; provides advice and assistance to other offices of the Service (including the Office of the Chief Counsel), the Department of the Treasury, other Government agencies, and congressional Committees; reviews proposed regulations for administrative feasibility and adequacy; analyzes and acts upon reports submitted by field offices under the Technical Coordination Program; coordinates with other Technical branches on matters of mutual concern; advises and assists the Audit Division in regard to the Service's audit program; participates in the development of tax return forms and instructions, and reviews pertinent portions of public-use forms and instructions; and participates in the Technical Field Conference Program. This Branch also performs the same functions with respect to determinations as to whether distribution, exchanges, or transfers referred to in IRC 306(b)(4), 355(a)(1)(D)(ii), 367, and 1492 are in pursuance of a plan having as one of its principal purposes the avoidance of Federal income taxes.

SEC. 1113.92 *Miscellaneous and Special Provisions Tax Division—Office of the Director.*

Has primary responsibility for providing basic principles and rules for uniform interpretation and application of the Federal tax laws in those areas involving Estate, gift, and certain excise taxes; organizations exempt from income tax under IRC 501; procedure and administration provisions of the Internal Revenue Code; matters requiring actuarial determinations; and the qualification of pension, annuity, profit-sharing, stock bonus, and bond purchase plans, and the tax treatment of employees and their beneficiaries and deductions for employer contributions under such plans. In carrying out these responsibilities, the Division: Issues rulings to taxpayers and technical advice and general technical information to District Directors and Regional Commissioners; advises the Appellate and Audit Divisions of the Service's position on particular issues; issues opinion letters to sponsoring organizations on master and prototype pension, annuity, and profit-sharing plans; drafts Revenue Rulings, Revenue Procedures, Announcements and Releases to be published for the guidance and information of taxpayers and Service personnel; drafts, or reviews, IR-Manual issuances to be published for the guidance of Service personnel; reviews or assists in preparing technical booklets, training materials, pamphlets and other materials, prepared for the guidance of taxpayers and Service personnel; conducts special studies of technical problem areas, including reappraisals of current rules and practices, with a view toward reducing controversy and promoting uniformity; reviews Actions on Decisions announcing the Commissioner's position on adverse decisions of the United States Tax Court, prior to publication in the Internal Revenue Bulletin; initiates recommendations and coordinates with the Research Division of Planning and Research in providing advice and assistance on legislative matters; initiates recommendations and coordinates with the Office of Chief Counsel and the Department of the Treasury in providing advice and assistance on regulatory matters; coordinates with the Office of the Chief Counsel and the Department of Justice in providing advice and assistance in connection with matters in litigation; reviews newly proposed and amendatory regulations for administrative feasibility and adequacy; analyzes and acts upon reports submitted by field offices under the Technical Coordination Program which disclose tax administrative problems, abuses, and inequities, as well as the views of field personnel as to the quality and effectiveness of regulations and tax return forms, the need for new or amendatory legislation or regulations, etc.; coordinates on matters of mutual concern with other Technical divisions, the Compliance organization, other offices of the Department of the Treasury, and other Government agencies; supplies the Audit Division with names or essential identifying characteristics of persons or organizations, and otherwise advises and assists the Audit Division in the selection of representative cases, involving issues on which Service position needs to be established, clarified, or otherwise developed; aids the Audit Division in developing the scope of and techniques needed in the examinations or investigations of such issues; supplies information for use by the Audit Division in programming, evaluating, and guiding audit operations throughout the Service; participates in the development of tax return forms and instructions and reviews pertinent portions of public-use forms and instructions; invites outside professional groups and industry and trade associates to participate in conferences and to submit comments, briefs, and suggestions in connection with tax problems and matters involving Revenue Rulings or Revenue Procedures proposed for the solution of tax problems; conducts conferences in the regional offices to discuss major programs of the Technical organization, to present papers on particular substantive technical areas, to discuss and explore possible solutions to technical areas of concern to field offices, and to discuss

other matters of mutual concern; and acts as competent authority in matters involving interpretation or application of tax treaties. This Division also performs the same functions with respect to determinations under IRC 170(b)(1)(A) in all situations involving a provision of Subchapter F of Chapter 1, Chapter 42, or section 6033 of the Code, and in any other situation bearing on the status of an organization as a private foundation. In tax matters dealing with actuarial questions: Provides or secures expert witnesses in support of the Government position in cases in litigation, and assists Government counsel in preparation and presentation of cases and in negotiations of settlements; and furnishes expert consulting assistance to other Service components, including the Office of the Chief Counsel, to the Department of the Treasury, and to other Federal and State Government agencies. This Division also: Post-reviews field determination letters relating to the status of organizations under IRC 501, and relating to qualification of pension, annuity, profit-sharing, stock bonus, and bond purchase plans under IRC 401 through 407; prepares and submits to the Audit Division special audit coordination digests calling attention to district determinations that do not conform to published Service positions on issues under IRC 401 through 407; on a certiorari basis, reviews and decides cases appealed by taxpayers to the National Office for reconsideration of determinations by District Directors under IRC 401 through 407; and provides the final level of appeal in the Service on proposals by District Directors to revoke the exempt status of organizations under IRC 501. The Director is responsible for and supervises the activities of six branches: Actuarial Branch; Administrative Provisions Branch; Estate and Gift Tax Branch; Excise Tax Branch; Exempt Organizations Branch; and Pension Trust Branch.

SEC. 1113.921 *Actuarial Branch.* In matters involving the application of Federal tax laws in the actuarial area, this Branch: Issues rulings, technical advice, and general technical information; drafts Revenue Rulings, Revenue Procedures, Announcements and Releases, and IR-Manual issuances; reviews or assists in preparing technical booklets, pamphlets, and other materials for the guidance of Service personnel and the public; conducts special studies directed toward resolving technical problem areas; reviews Actions on Decisions; reviews proposed regulations for administrative feasibility and adequacy; analyzes and acts upon reports submitted by field offices under the Technical Coordination Program; coordinates with other branches on matters of mutual concern; participates in the development of tax return forms and instructions, and reviews pertinent portions of public-use forms and instructions; participates in the Technical Field Conference Program; and provides, or secures, expert witnesses in support of the Government position in cases in litigation involving pension plans, insurance, and other tax matters dealing with actuarial questions, and assists Government counsel in preparation and presentation of cases and in negotiations of settlements. This Branch also furnishes expert consulting assistance to other Service components (including the Office of the Chief Counsel), to the Department of the Treasury, and to other Federal and State Government agencies on actuarial questions involved in: Valuation of life estates, remainder interests, contingent assurances, series of payments, and reversionary interests; tax treatment of pension, profit-sharing, stock bonus, annuity, life insurance, accident and health, and other benefit and compensation plans and contracts; deductions for amounts paid or accrued on indebtedness under insurance contracts; and taxation of life insurance companies.

SEC. 1113.922 *Administrative Provisions Branch.*

In matters involving the application of the procedure and administration provisions of the Internal Revenue Code, and similar provisions of related statutes, this Branch: Issues rulings, technical advice, and general technical information; drafts Revenue Rulings, Revenue Procedures, Announcements and Releases, and IR-Manual issuances; reviews or assists in preparing technical booklets, pamphlets, and other materials for the guidance of Service personnel and the public; conducts special studies directed toward resolving technical problem areas; reviews Actions on Decisions; provides advice and assistance to other offices of the Service (including the Office of the Chief Counsel), the Department of the Treasury, other Government agencies, and Congressional Committees; reviews proposed regulations for administrative feasibility and adequacy; analyzes and acts upon requests submitted by field offices under the Technical Coordination Program; coordinates with other Technical branches and other offices of the Service on matters of mutual concern; advises and assists the Audit Division in regard to the Service's Audit program; participates in the development of tax return forms and instructions, and reviews pertinent portions of public-use forms and instructions; and participates in the Technical Field Conference Program.

SEC. 1113.923 *Estate and Gift Tax Branch.*

In matters involving the application of Federal estate and gift laws, this Branch: Issues rulings, technical advice, and general technical information; drafts Revenue Rulings, Revenue Procedures, Announcements and Releases, and IR-Manual issuances; reviews or assists in preparing technical booklets, pamphlets, and other materials for the guidance of Service personnel and the public; conducts special studies directed toward resolving technical problem areas; reviews Actions on Decisions; provides advice and assistance to other offices of the Service (including the Office of the Chief Counsel), the Department of the Treasury, other Government agencies, and Congressional Committees; reviews proposed regulations for administrative feasibility and adequacy; analyzes and acts upon reports submitted by field offices under the Technical Coordination Program; coordinates with other Technical branches on matters of mutual concern; advises and assists the Audit Division in regard to the Service's audit program; participates in the development of tax return forms and instructions, and reviews pertinent portions of public-use forms and instructions; as requested, furnishes assistance in negotiations or renegotiations of estate and gift tax conventions with representatives of foreign countries; acts as competent authority in matters involving interpretation or application of tax treaties; and participates in the Technical Field Conference Program.

SEC. 1113.924 *Excise Tax Branch.*

In matters involving the application of Federal excise tax laws other than those involving excise taxes imposed by Chapter 42 on private foundations and certain related parties, and the alcohol, tobacco and firearms taxes (but including the manufacturer's excise tax on firearms under IRC 4181 and 4182), this Branch: Issues rulings, technical advice, and general technical information; drafts Revenue Rulings, Revenue Procedures, Announcements and Releases, and IR-Manual issuances; reviews or assists in preparing technical booklets, pamphlets, and other materials for the guidance of Service personnel and the public; conducts special studies directed toward resolving technical problem areas; reviews Actions on Decisions; provides advice and assistance to other offices of the Service (including the Office of the Chief Counsel), the Department of the Treasury, other Government agencies; and Congressional Committees; reviews proposed regulations for administrative feasibility and adequacy; analyzes and acts upon reports submitted by field offices under the Technical Coordination Program; coordinates with other Technical branches on matters of mutual concern; advises and assists the Audit Division in regard to the Service's audit program; participates in the development of tax return forms and instructions, and reviews pertinent portions of public-use forms and instructions; and participates in the Technical Field Conference Program.

SEC. 1113.925 *Exempt Organizations Branch.*

In matters involving the exemption of organizations under IRC 501, this Branch: Issues rulings, technical advice, and general technical information; drafts Revenue Rulings, Revenue Procedures, Announcements and Releases, and IR-Manual issuances; reviews or assists in preparing technical booklets, pamphlets, and other materials for the guidance of Service personnel and the public; maintains in current status a comprehensive Exempt Organizations Handbook; conducts special studies directed toward resolving technical problem

areas; reviews Actions on Decisions; provides advice and assistance to other offices of the Service (including the Office of the Chief Counsel), the Department of the Treasury, other Government agencies, and Congressional Committees; reviews proposed regulations for administrative feasibility and adequacy; analyzes and acts upon reports submitted by field offices under the Technical Coordination Program; post-reviews field determination letters; coordinates with other Technical branches on matters of mutual concern; advises and assists the Audit Division in regard to the Service's audit program; participates in the development of tax return forms and instructions, and reviews pertinent portions of public-use forms and instructions; participates in the Technical Field Conference Program; and provides the final level of appeal in the Service on proposals by District Directors to revoke the exempt status of organizations. This Branch also performs the same functions with respect to exempt organization matters involving: Feeder organizations; prohibited transactions; unreasonable accumulations, or misuse, of income; liability for tax on unrelated business taxable income; requirements for filing annual information returns and other reports; determination of status as a private foundation; determinations under IRC 170(b)(1)(A) in all situations involving a provision of Subchapter F of Chapter 1, Chapter 42, or section 6033 of the Code, and in any other situation bearing on the status of an organization as a private foundation; termination of private foundation status; special rules prescribed in IRC 508 with respect to IRC 501(c)(3) organizations; excise taxes imposed by Chapter 42 on private foundations and certain related parties, including questions arising under the savings provisions of section 101 (1) of the Tax Reform Act of 1969; assessable penalties relating to private foundations; restrictions on examination of churches; determinations of status required under IRC 1504(e) for qualification of certain exempt organizations to file consolidated corporate returns.

SEC. 1113.926 *Pension Trust Branch.*

In matters involving the qualification of pension, annuity, profit-sharing, stock bonus, and bond purchase plans and the tax treatment of employees and their beneficiaries and deductions for employer contributions under such plans, pursuant to IRC 401 through 407, this Branch: Issues rulings, technical advice, and general technical information; issues opinion letters to sponsoring organizations on master and prototype pension, annuity and profit-sharing plans; drafts Revenue Rulings, Revenue Procedures, Announcements and Releases, and IR-Manual issuances; reviews or assists in preparing technical booklets, pamplets, and other materials for the guidance of Service personnel and the public; conducts special studies directed toward resolving technical problem areas; reviews Actions on Decisions; provides advice and assistance to other offices of the Service (including the Office of the Chief Counsel), the Department of the Treasury, other Government agencies, and Congressional Committees; reviews proposed regulations for administrative feasibility and adequacy; analyzes and acts upon reports submitted by field offices under the Technical Coordination Program; coordinates with other Technical branches on matters of mutual concern; advises and assists the Audit Division in regard to the Service's audit program; participates in the development of tax return forms and instructions, and reviews pertinent portions of public-use forms and instructions; post-reviews field determination letters and, on a certiorari basis, reviews and decides cases appealed by taxpayers to the National Office for reconsideration of District Directors' determinations; prepares special audit coordination digests regarding conformance of field actions with established positions on stated issues; determines the applicability of the annuity treatment under IRC 72, the death benefit, exclusion under IRC 101(b), and the sick pay exclusion under IRC 105(d), to distributions under qualified plans and exempt employees' trusts; passes upon the tax treatment accorded deferred compensation under nonqualified plans; and participates in the Technical Field Conference Program. This Branch also performs the same functions with respect to pension trust matters involving: Exemption of employees' trusts under IRC 501; collateral matters involving the treatment of medical benefits for retired employees under qualified pension plans, the limitations and restrictions on self-employed persons participating in qualified plans, and the tax treatment of distributions to non-resident aliens; deductions by acquiring corporations for carryovers under IRC 381(c)(11) and (20); feeder organizations; prohibited transactions; liability for tax on unrelated business taxable income; and additional requirements and limitations under IRC 1379 with respect to plans that provide contributions or benefits for shareholder-employees of an electing small business corporation.

SEC. 1113.93 *Technical Publications and Services Division—Office of the Director.*

Has primary responsibility in Technical for functions related to: Tax return forms; other public-use forms and form letters; taxpayer publications; internal-use technical publications; field liaison programs; Part XI of the Manual; the "Freedom of Information Act"; technical and general correspondence; Congressional liaison; research facilities and reference services; and control and maintenance of correspondence files and exempt organization application files. In carrying out these responsibilities, the Division: Conducts a program for the development, annually or as needed, of all Federal tax return forms and instructions (other than those relating to alcohol, tobacco, and firearms taxes); coordinates and assists in the work of the National Office Tax Forms Coordinating Committee in planning, reviewing and approving tax return forms materials; assists the National Office Tax Forms Coordinating Committee by reviewing other public-use forms and form letters used by the Service; furnishes technical assistance to the Department of the Treasury and others on tax return matters; conducts a program for publication of the Internal Revenue Bulletin and related publications; conducts a program for preparation and publication of technical booklets, pamphlets, and other materials for the guidance of taxpayers, tax practitioners and Service personnel; reviews tax guide material prepared by other Government agencies; reviews or drafts tax guide material for dissemination through newspapers, other periodicals, radio, and television; reviews tax law training material for classroom and correspondence instruction of Service personnel; drafts expository papers on major technical developments for the instruction of Service personnel; drafts digests of significant developments to keep Service personnel abreast of changes; promotes and coordinates the Technical liaison program with regional and district offices; conducts special surveys of Service field offices; coordinates the Technical Field Conference Program; coordinates the development and publication of material for Part XI of the Internal Revenue Manual; coordinates the activities of the Technical organization under the Freedom of Information Act; coordinates Technical's correspondence program; provides research facilities and reference services; and maintains, and processes requests for inspection of, exempt organization application files. The Director is responsible for and supervises the activities of three branches: Tax Forms Development Branch; Technical Publications Branch; and Technical Services Branch.

SEC. 1113.931 *Tax Forms Development Branch.*

Assists in conducting the Service's public-use forms and instructions, and form letters programs. In carrying out these responsibilities, this Branch: On annual basis, or when otherwise necessary, initiates, develops, and revises the technical content of all Federal tax return forms, instructions, schedules, etc., relating to income, employment, estate, gift, and excise taxes (other than those relating to alcohol, tobacco, and firearms taxes); provides the principal support and assistance to the National Office Tax Forms Coordinating Committee in planning, reviewing and approving all tax return forms materials; provides the principal support and assistance to the National Office Tax Forms Coordinating Committee in its review and approval functions relating to other public-use forms and form letters; prepares replies to inquiries from Members of Congress, other Government agencies, professional groups, and the public on matters relating to the forms program; evaluates, and prepares replies to, suggestions on matters relating to tax return forms and other public-use forms; prepares Announcements and

Releases, and IR-Manual issuances, relating to tax return forms and other public-use forms; provides advice and assistance to other offices in the Service, the Department of the Treausry, and Congressional Committees in matters relating to tax return forms and instructions; and coordinates with other Technical branches on matters of mutual concern.

SEC. 1113.932 *Technical Publications Branch.*

Conducts the publications programs of the Technical organization. In carrying out this responsibility, this Branch: Compiles material for publication in the weekly Internal Revenue Bulletin, which is the Commissioner's authoritative instrument for announcing official rulings and procedures of the Service and for publishing Treasury Decisions, Executive Orders, tax conventions, legislation, court decisions, and other items of general interest; compiles all precedent material in the weekly Internal Revenue Bulletins for publication in semiannual Cumulative Bulletins; prepares digests of all substantive materials in the Bulletin for publication in the Index-Digest System, complete with topical indexes and finding lists, for research use by the public and Service personnel; compiles record retention requirements from regulations for publication in the Federal Register; drafts summaries of selected authoritative material for publication in Tax Briefs to keep Service personnel abreast of significant developments in Federal taxation; compiles the Service's Looseleaf Regulations System and drafts appropriate transmittals and filing instructions; compiles items to be published in the biennial Cumulative List of Exempt Organizations, its bimonthly supplements, and the announcements of current deletions in the Bulletin; initiates actions to preserve the standards and improve the effectiveness of the Bulletin system; drafts plain-language explanations of all Federal tax laws (other than those relating to alcohol, tobacco, and firearms taxes) for publication in booklets such as Your Federal Income Tax, Tax Guide for Small Business, Farmer's Tax Guide, and numerous pamphlets, to inform the public about the rights and duties of taxpayers; drafts plain-language instructional material for publication in the Teaching Taxes program; reviews material relating to Federal taxation in booklets and other issuances initiated by other Government agencies, and by others, when such cooperation is in the best interests of the Service; reviews for technical accuracy releases, articles, notices, and radio and television program materials, prepared for issuance by Public Affairs Division; drafts in-depth analyses and explanations of major developments in Federal taxation for publication in quarterly, annual, and special issues of the Review of Technical Developments, which are used to update the technical skills of Service personnel; participates in the drafting and reviewing of technical tax handbooks and guides for Service personnel and technical law text materials for use in Service training programs; drafts material for publication in Reports on Current Tax Literature to keep Service officials apprised about articles, comments, etc., published outside the Service regarding tax loopholes or inequities, and criticism of Service position; prepares Announcements and Releases, and IR-Manual issuances relating to the publications program; coordinates with other Technical branches, Chief Counsel, Audit Division, and others on matters of mutual concern; and coordinates with Publications Branch of Facilities Management Division and the Government Printing Office in the development of Production Control Schedules, format design, proof processing, and other matters of mutual interest.

SEC. 1113.933 *Technical Services Branch.*

Issues general technical information letters, coordinates the overall correspondence program of the Technical or for Technical. In carrying out these responsibilities, this Branch: Issues direct replies to all communications involving requests for information of a general technical or procedural nature, including a substantial portion of Congressional inquiries directed to Technical; serves as liaison office and point of contact on all Congressional office inquiries, oral or written, relating to matters under the jurisdiction of Technical; coordinates with other offices in Compliance, Chief Counsel, Accounts, Collection and Taxpayer Service, and administration on correspondence crossing jurisdictional lines; keeps the Assistant Commissioner (Technical) informed regarding incoming communications involving sensitive or controversial matters; promotes and coordinates the Technical liaison program with regional and district offices involving the submission of field reports on administrative problems, tax abuses, tax inequities, the quality and effectiveness of tax return forms and instructions, and the need for new or amendatory regulations; conducts special surveys to obtain factual information from Service field offices on particular tax areas at the request of the Department of the Treasury or National Office components; coordinates the Technical Field Conference program whereby teams of specialists in the various tax areas and representatives of the Chief Counsel's office and the Audit Division meet with field officials in district offices to discuss technical matters of mutual interest or concern; coordinates the preparation and clearance of material for Part XI of the Internal Revenue Manual; coordinates actions for the Technical organization on matters involving the Freedom of Information Act; maintains a technical reference library and provides research assistance and reference services for personnel of the Technical organization and other offices in the National Office, corresponds with field offices to supply or request needed information on current or prior matters; analyzes, acknowledges receipt, and directs the flow of all incoming correspondence, including requests for rulings and technical advice, general technical inquiries, reports submitted by Service field offices under the Technical Coordination Program, etc., to the appropriate Technical divisions or branches; and processes, maintains, and services all closed correspondence files and related records for the Technical organization. This Branch also maintains and services exempt organization application files that are open to public inspection, processes requests for indelete certain materials that are exempt from public inspection.

SEC. 1113.(10) *Office of Assistant Commissioner (Stabilization).*

The Assistant Commissioner (Stabilization) is the principal assistant to the Commissioner in administering the Stabilization Program of the Internal Revenue Service, which includes monitoring and enforcing the stabilization of prices, wages, and salaries pursuant to the coverage, classifications, and implementation procedures established by the Cost of Living Council. Such functions include, but are not limited to: advising the Cost of Living Council on matters concerning compliance with and implementation of decisions and regulations issued by the Council, and suggest changes which would lead to greater voluntary compliance or more effective use of resources; operation and maintenance of a nationwide network of Stabilization offices established in support of the Economic Stabilization Program; dissemination of information and guidance in response to inquiries from the public, to the extent authority has been delegated by the Cost of Living Council; planning for an effective enforcement program, including selecting industry targets, conducting investigations initiated locally or as directed by the Cost of Living Council; receiving, investigating, and resolving by obtaining compliance, where possible, complaints received with respect to alleged program violations, and taking enforcement action or recommending it to the Cost of Living Council, when necessary; receiving and processing price stabilization forms, reports, applications, and other information required to be submitted by firms covered under Phase IV regulations; making decisions and issuing orders with respect to notices of proposed price increases to the extent authority has been delegated by the Cost of Living Council; making decisions and issuing orders with respect to special filings, including applications for volatile pricing authority, loss or low profit pricing, merchandise pricing plans as delegated by the Cost of Living Council; making decisions and issuing orders with respect to individual requests for exceptions from the price regulations, and with respect to requests for reconsideration of initial decisions made and orders issued, to the extent authority has been delegated by the Cost of Living Council; and maintaining adequate records and making periodic reports to the Cost of Living Council. The Assistant Commissioner (Stabilization) is responsible for and supervises the activities of the Technical

Programs Division, the Compliance and Enforcement Division, the Planning and Program Staff, and the Administrative Office.

SEC. 1113.(10)1 *Planning and Program Staff.*

The Planning and Program Staff is the principal advisor to the Assistant Commissioner (Stabilization) for insuring maximum use of Stabilization resources through planning for and evaluating the utilization of these resources. Also coordinates matters affecting all Divisions of Stabilization, provides liaison with the Cost of Living Council, and consults with IRS functional officials in manpower or program issues which bear on Stabilization operations. In matters involving resources, this staff develops and monitors, in cooperation with other offices and the Cost of Living Council, long-range goals; estimates resource needs and prepares financial plans and recommends dollar and manpower resource allocations for all Stabilization activities based upon projected workload; monitors the execution of Stabilization manpower and financial resources; assesses the resource impact of current program and proposed program changes; and works with other National Office activities on manpower allocations. Develops organization, staffing, and position management control guidelines and coordinates all personnel management actions having Servicewide impact. Spearheads in-depth analyses of district and regional office operations, and effectiveness of stabilization areas, and provides the A/C (Stabilization) with data to meet his needs for NORP participation as well as for ongoing management appraisals and decisions. Assesses program accomplishments, trends, or developments of specific interest to the Assistant Commissioner. Coordinates with Internal Audit a program for obtaining additional data relevant to an evaluation of Stabilization program management. Provides recurring and other special reports to Deputy Commissioner, Commissioner, and the Cost of Living Council. Is the principal liaison with Stabilization field offices and provides assistance to the field on matters involving several divisions and represents the Assistant Commissioner at field conferences. Analyzes the biweekly field reports and coordinates for the Assistant Commissioner, division responses to field requests for corrective action and is responsible for identifying field problems and providing assistance when field problems arise as a result of unclear procedures, conflicting instructions, or lack of definitive policy interpretations. Coordinates with Public Affairs Division in developing an effective public information program for Stabilization.

SEC. 1113.(10)2 *Administrative Office.*

Plans, organizes, coordinates, and directs the administrative management activities of the Office of Assistant Commissioner (Stabilization) at the National level, assisting and collaborating with Division Directors in providing personnel, space management, duplication, supply, and other administrative services.

SEC. 1113.(10)3 *Technical Programs Division.*

Serves as the organization responsible for activities relating to the processing of price prenotifications, price increase reports, quarterly financial reports, merchandise pricing plans, exceptions, reconsiderations and other documents required to be filed in accordance with Economic Stabilization Regulations. It is also responsible for providing technical and interpretive advice and assistance to the IRS Stabilization Program and to the public.

Develops programs on and exercises functional supervision over Servicewide Economic Stabilization activities involving the processing of price prenotifications, price increase reports, quarterly financial reports, merchandise pricing plans, exceptions, reconsiderations and other documents required to be filed in accordance with Economic Stabilization Regulations. Develops procedures and assists field offices to assure uniformity and consistency of decisions; provides advice to field offices on case-related matters; reviews and approves proposed actions recommended by district offices in certain specific cases. For consistency of decisions, recommends appropriate action, and transmits decisions to district offices; reviews field office case processing to discern trends and precedents; identifies problem areas of nationwide concern, for consideration by the Cost of Living Council; identifies the need for, and recommends to the Cost of Living Council delegations of authority to the Internal Revenue Service; develops management information to be used to keep Internal Revenue Service management and the Cost of Living Council apprised of price prenotifications, merchandise pricing plans, exceptions and reconsiderations program execution. Provides technical and general information to the public; develops or reviews all Stabilization forms and publications; reviews proposed regulations and ruling; furnishes interpretive support to other organizational components of the Assistant Commissioner (Stabilization), serves as the liaison with other Federal, State, and local government agencies and with private or public interest groups. Provides technical assistance to the field and assures program uniformity.

The Director is responsible for and supervises the activities of three Branches: Interpretations Branch, Price Analysis Branch and Publications and Guidance Materials Branch. The Director also serves as Deputy Assistant Commissioner (Stabilization).

SEC. 1113.(10)31 *Interpretations Branch.*

Serves as the organization responsible for providing technical and interpretive advice and assistance to the IRS Stabilization Program.

Receives, comments on the reviews for administrative feasibility and adequacy Cost of Living Council drafts of regulations; reviews documents, questions and answer, news releases, forms and other publications to ensure technical accuracy; advises on Stabilization disclosure matters, testimony instructions, and release of Stabilization information as requested under the Freedom of Information Act; serves as contact point for all field technical problems; promotes and conducts institutes and conferences designed to foster voluntary compliance; exercises functional responsibility for programs concerning walk-in and telephone requests for public service or assistance, written inquiries, and other requests of a service nature performed in the field; provides assistance and guidance to the field in implementing, monitoring, and evaluating technical and service programs; coordinates activities of the Local Service and Compliance Centers with the Office of the Assistant Commissioner (ACTS).

SEC. 1113.(10)32 *Price Analysis Branch.*

Plans, directs and exercises functional supervision over field office activities relating to the processing of price prenotifications, price increase reports, quarterly financial reports, merchandise pricing plans, exceptions, reconsiderations and other documents required to be filed in accordance with Economic Stabilization Regulations. Develops procedures and assists field offices to assure uniformity and consistency of decisions; provides advice to field offices on case-related matters; reviews and approve proposed actions recommended by district offices in certain specific cases. For consistency of decisions, recommends appropriate action, and transmits decisions to district offices; reviews field office case processing to discern trends and precedents; identifies problem areas of nationwide concern, for consideration by the Cost of Living Council; identifies the need for, and recommends to the Cost of Living Council delegations of authority to the Internal Revenue Service; develops management information to be used to keep Internal Revenue Service management and the Cost of Living Council apprised of price prenotifications, merchandise pricing plans, exceptions and reconsiderations program execution.

SEC. 1113.(10)33. *Publications and Guidance Materials Branch.*

Develops publications and guidance material procedures for field and National Office use. Determines the content, directs the compilations, and reviews the Stabilization Program Guidelines (SPG) Service. Develops plain language publications and educational material used to inform Service employees and the public of substantive and procedural matters. Translates selected publications into Spanish for use in the Spanish-speaking communities. Identifies need for and develops publications independently and at the request of the Cost of Living Council; distributes publications throughout the country to appropriate business firms, associations, and other professional organizations. Plans, coordinates, and provides editorial support for publication of forms and form

letters; reviews, for administrative feasibility, consistency, and adequacy, all proposed Cost of Living Council public-use forms. Coordinates the presentation and clearance of Stabilization material for the IR Manual. Operates a correspondence unit that serves as the National Office clearing and routing center for all public and Congressional correspondence relating to Stabilization matters; maintains liaison with the Cost of Living Council concerning Congressional inquiries to the field; and maintains adequate records.

SEC. 1113.(10)4 *Compliance and Enforcement Division.*

In matters involving compliance and enforcement activities under the Phase IV Economic Stabilization regulations, this division: develops and exercises functional supervision of nationwide and local investigative and industry monitoring programs as directed by the Cost of Living Council or initiated by IRS; designs, implements, and reports on CLC-directed pay or price investigations of firms; designs, implements, and reports on CLC-directed pay or price factfinding surveys for industries, both in the controlled and uncontrolled sectors; designs, implements and reports on IRS locally initiated pay or price investigations for firms in controlled industries; develops and exercises functional supervision of nationwide and local enforcement activities as authorized and directed by CLC; designs, implements and reports analysis of economic developments and trends within broad industry groupings as received from field offices and nationally-gathered providing same to CLC as leads for enforcement and compliance action; engages in other special projects deemed appropriate by CLC and IRS; coordinates investigations involving several districts or regions; provides guidance to certain districts which have operational responsibility for conducting such investigations; informs and reports to CLC on investigation and analysis progress and status; designs and engages in a program of handling citizen complaints of violations of the ESP regulations; coordinates activities with other Stabilization organizational elements; and maintains adequate records. The Director is responsible for and supervises the activities of four branches: Compliance Investigations Branch, Case Control and Reports Branch, Industry Survey and Analysis Branch and Pay Branch.

SEC. 1113.(10)41 *Compliance Investigations Branch.*

In matters involving compliance administration, this branch: formulates policy and programs involving compliance with the Economic Stabilization Act; designs, initiates, and reports on nationwide and local Cost of Living Council directed price investigations; assists Cost of Living Council in formulating, implementing, monitoring and evaluating audit specifications and procedures, informs Cost of Living Council as to case progress and status; provides assistance and guidance to the field in implementing investigations; coordinates investigations involving several districts or regions; coordinates activities with other Stabilization organization elements and maintains adequate records.

SEC. 1113.(10)42 *Industry Survey and Analysis Branch.*

In matters involving the survey and analysis of industries, this branch: conducts Cost of Living Council directed price fact-finding surveys of industries; conducts CLC—and IRS-assigned special projects and analysis; engages in special economic analysis and targeting to monitor, analyze and present findings relating to on-going industry surveys where indicated with results and findings given to CLC for action and follow-up authority; maintains a program of nationwide information-gathering on economic developments and trends within broad industry groups by receiving, processing and analyzing information received from field offices, providing information to the CLC as leads for enforcement and compliance action; informs the CLC as to monitoring progress and status; provides assistance and guidance to the field in implementing and evaluating information-monitoring programs; drafts procedures for field information-monitoring programs; coordinates activities with other Stabilization organizational elements; coordinates monitoring operations which are of nationwide significance or involve several districts, and maintains adequate records.

SEC. 1113.(10)43 *Pay Branch.*

In matters of wage and pay investigations and surveys for both the controlled and uncontrolled industry sectors of the economy, this branch: designs, implements, monitors, evaluates and reports on CLC-directed nationwide pay investigations; designs, implements, evaluates and reports on CLC-directed pay factfinding surveys and monitoring of nationwide wage and pay matters in the uncontrolled sector; manages and controls wage and pay investigations, surveys and programs; informs the Cost of Living Council as to case progress and status; coordinates activities with other Stabilization organizational elements; coordinates investigations which are of nationwide significance or involve several districts, and maintains adequate records.

SEC. 1113.(10)44 *Case Control and Reports Branch.*

Designs, develops, installs, monitors, and evaluates reporting systems for the Office of Assistant Commissioner (Stabilization) in coordination with the Cost of Living Council. Consults and participates in the design and development of other Stabilization information systems. Develops statistical indicators to evaluate operations in a particular program area or element in order to identify significant trends. Provides an advisory service to the A/C Stabilization by identifying significant happenings, developing trends, identifying possible trouble areas and forecasting conditions within the Stabilization Program. Develops and monitors, in cooperation with CLC, an interactive computer/remove terminal management information system. Provides computer output reports to IRS/ESP. Provides CLC with manual reports not on the data base. Identifies and fulfills training needs for remote terminal operators in 29 key districts. Provides a nationwide net of telecommunications and facsimile transmission facilities for the ESP. Provides an automated Case Control system for monitoring directed investigations. Coordinates and develops specifications for Stabilization's IRS data processing requirements. Provides records management for Stabilization. Maintains adequate records and controls.

SEC. 1113.(11) *Office of the Chief Counsel.*

The Chief Counsel, and Assistant General Counsel of the Treasury Department, serves as a member of the Commissioner's executive staff and as counsel and legal officer to the Commissioner on all matters pertaining to the administration and enforcement of the internal revenue laws and related statutes, and on all legal matters pertaining to the Service's economic stabilization activities. The key officials under his supervision are: Deputy Chief Counsels, Associate Chief Counsel (Litigation), Associate Chief Counsel (Technical), Staff Assistants, Technical Advisors, Special Assistants, Director of the Operations and Planning Division, and Regional Counsel.

SEC. 1113.(11)1 *Deputy Chief Counsels.*

The two Deputy Chief Counsels act for and represent the Chief Counsel in the development of policies governing the Office of the Chief Counsel, and assist the Chief Counsel in the formulation of tax litigation policy and the interpretation and development of the internal revenue laws.

SEC. 1113.(11)2 *Associate Chief Counsel (Litigation).*

Plans, directs, coordinates and controls the policies and programs pertaining to Tax Court Litigation; Criminal Tax; General Litigation; and Refund Litigation work.

SEC. 1113.(11)21 *Tax Court Litigation Division.*

The Tax Court Ligitation Division develops policies, programs, and procedures relating to the disposition of tax cases pending in the United States Tax Court; supervises and coordinates the defense and settlement and the processing and handling of such cases, including preparation of pleadings, recomputations and other documents filed with the Tax Court together with hearings thereon to assure uniform treatment; coordinates and reviews Tax Court matters prepared in the Regional Offices; including the rendering of technical advice to the field offices, the approval of Chief Counsel's Decisions, the review of briefs to be filed with the Tax Court and recommendations of field offices for acquiescence or non-acquiescence in adverse Tax Court decisions; prepares recommendations to

the Department of Justice for the Commissioner's appeals to the Courts of Appeals and prepares petitions and records on review in such cases; makes recommendations to that Department regarding offers in compromise or settlement and prepares recommendations for or against filing petitions for writs of certiorari to the Supreme Court in such cases. It supervises the preparation and trial of cases assigned to, and handled by, attorneys in the Trial Branch.

SEC. 1113.(11)22 *Criminal Tax Division.*

The Criminal Tax Division handles and prepares for final decision those criminal tax cases referred to the Chief Counsel by Regional Counsel or by the National Office. It considers cases in which the Regional Commissioner and the Director of the Intelligence Division of the Office of the Assistant Commissioner (Compliance) do not concur in recommendations of Regional Counsel involving prosecution. The Division prepares acquiescence memorandums or protest letters on decisions by the Department of Justice or United States Attorneys against prosecution and recommendations to the Department of Justice respecting appeals of court decisions in criminal tax cases. It also prepares law opinions in cases involving penalties or other legal questions with respect to criminal cases or investigations or with respect to the disclosure of information. The Division coordinates with the Department of Justice or interested branches of the Service any questions involving investigations or actions respecting the civil aspects of pending criminal cases.

SEC. 1113.(11)23 *General Litigation Division.*

The General Litigation Division supervises and coordinates legal work or Regional Counsel on collection litigation matters. It reviews certain offers in compromise (except those concerning alcohol, tobacco, and firearms taxes). It prepares advisory opinions on collection litigation matters. The Division prepares and reviews recommendations to the Department of Justice concerning certiorari, appeal and petition for review in relation to all collection litigation cases. It handles certain legal work for the Director of General Operations. The General Litigation Division prepares and reviews recommendations to the Department of Justice concerning the defense of injunction actions to restrain the assessment or collection of federal taxes; offers in settlement; the waiver or release of a right to redeem under 28 U.S.C. 2410; and suits for the civil enforcement of summonses. Similarly, the Division considers recommendations that the Commissioner authorize or sanction affirmative action in insolvency cases (including decendents' estate proceedings), suits for foreclosure of mortgages or other liens and suits to quiet title where the United States is named as a party defendant, cases involving appointment of a receiver in aid of foreclosure of Federal tax liens, and suits for the collection of taxes.

SEC. 1113.(11)24 *Refund Litigation Division.*

The Refund Litigation Division performs all necessary legal service on behalf of the Internal Revenue Service in connection with taxpayers' suits for refund of taxes (except alcohol and tobacco taxes). It determines and coordinates the legal position of the Service in such suits and incorporates such determinations in recommendations to the Department of Justice with respect to the defense of such suits, the acceptance or rejection of settlement proposals and appeals and petitions for certiorari from adverse court decisions. The Division performs all necessary legal services on behalf of the Service in connection with all civil litigation affecting the Service and not within the responsibility of any other Division.

SEC. 1113.(11)3 *Associate Chief Counsel (Technical).*

Plans, directs, coordinates and controls the policies and programs pertaining to Legislation and Regulations, and Interpretative work.

SEC. 1113.(11)31 *Legislation and Regulations Division.*

The Legislation and Regulations Division has the basic responsibility for representing the Internal Revenue Service in connection with legislation affecting the various internal revenue taxes and for the preparation of regulations required to be issued in connection with those taxes, except for taxes relating to alcohol, tobacco, and certain firearms. In discharging this responsibility, the Division: participates in the development and drafting of new and amendatory internal revenue legislation and in connection therewith furnishes required technical assistance; prepares new and revised regulations; prepares reports on private and public bills; prepares news and information releases relating to regulations; prepares responses to correspondence concerning legislation and regulations from the Congress and the public; and, in developing regulations, arranges and conducts public hearings and meeting with taxpayers and their representatives and with professional and industry groups. The Division prepares Executive orders and related papers authorizing the inspection of tax returns, and reviews and prepares amendments to the Statement of Procedural Rules. The Division represents the Internal Revenue Service with respect to the negotiation and drafting of tax treaties with foreign countries and the preparation of the necessary implementing regulations.

SEC. 1113.(11)32 *Interpretative Division.*

The Interpretative Division reviews as to form and legality interpretations of internal revenue statutes and regulations and other law and legal materials bearing upon the administration of the Internal Revenue Service except those relating to alcohol, tobacco, and firearms matters; criminal tax investigations and prosecutions; lien and collection matters, including those involving bankruptcies, receiverships and other insolvencies; administrative matters; disclosure matters; and summons enforcement matters. The Division prepares formal opinions of the Chief Counsel in assisting him in carrying out his functions as legal advisor to the Commissioner in the technical area. The Division is also responsible for the legal review of closing agreements.

SEC. 1113.(11)4 *Operations and Planning Division.*

Operations and Planning Division is responsible for all law work in the Internal Revenue Service other than substantive tax law work; at the direction of the Chief Counsel performs special assignments of a technical nature in substantive tax law. The Division serves as the principal legal advisor to the Assistant Commissioner (Administration), the Assistant Commissioner (Accounts, Collection, and Taxpayer Service) and the Assistant Commissioner (Inspection). The Division is responsible for the supervision and coordination of all legal management work of the Chief Counsel's Office (National Office and all field offices); establishes and maintains appropriate standards of professional competence by members of the legal staff of the Office and evaluates their legal competence; analyzes the workload of the Office, and determines the distribution of personnel available to handle the workload. The Division is responsible for the general supervision of all matters relating to administration and management in the Office of the Chief Counsel. Reviews and prepares for action enrollee and disbarment cases referred to the Chief Counsel by the Director of Practice, and represents the latter in the trial of cases before Hearing Examiners.

SEC. 1114 *Office of Regional Commissioner.*

SEC. 1114.1 *Mission.*

The mission of the Office of Regional Commissioner is to execute the broad nationwide policies and programs for the administration of the internal revenue laws, to carry out appellate programs at the regional level, and direct and coordinate the functions and activities of the District Offices within the region.

SEC. 1114.2 *Basic organization.*

The principal organization components of the typical Office of the Regional Commissioner are the immediate Office of the Regional Commissioner, the Administration Division, the Appellate Division, the Audit Division, the Accounts, Collection, and Taxpayer Service Division, the Intelligence Division, and the Stabilization Division. An Assistant Regional Commissioner heads each division.

SEC. 1114.3 *Regional Commissioner.*

The Regional Commissioner administers within an assigned regional area the accounts, collection, and taxpayer service; audit; intelligence; appellate; economic stabilization; and administration programs of the Internal Revenue Service. He carries out Service policies and programs in conformity with delegations of authority and, in this connection, establishes regional standards and programs to assure proper and effective implementation of Service-wide policies

and programs within his region. The Regional Commissioner supervises and coordinates the work of the staff of the Regional Office and the District Directors within his region to assure that work is processed in an orderly and timely manner, and that proper and equable emphasis is placed and directed toward the accomplishment of current program objectives. As the principal field official, he evaluates the effectiveness of Service policies and programs, and advises the National Office as to the need for revising such policies and programs to bring about improved operations or service.

SEC. 1114.4 *Assistant Regional Commissioner (Administration).*

The Assistant Regional Commissioner (Administration) acts as the principal assistant to the Regional Commissioner in planning, coordinating and evaluating the administration activities of the Service under the jurisdiction of the Regional Commissioner to ensure that administration policies and programs are properly executed. In conformity with administration policies, and programs established by the National Office, he develops regional standards and other measures necessary to implement most effectively the administration program of the Service which includes budget and fiscal management, personnel administration, training, public information, property and records management, use of facilities, printing and reproduction, and reports management. He also coordinates organization planning and advises and makes recommendations to the Regional Commissioner thereon; and furnishes guidance for and coordinates management programs. He provides the Regional Commissioner with results of evaluations and other information upon which to base his administration of the regional administration programs and recommends improvements and adjustments therein needed to bring about and sustain a high level of performance in administration activities within the region. Under the Regional Commissioner he serves as the primary source of information to the National Office as to the effectiveness of administration policies, programs, procedures and standards in terms of regional and district requirements, provides reports and factual information upon which the National Office can base administration policy and program considerations, and recommends appropriate action with respect to problems encountered in observing and evaluating administration operations. Within the limits of his delegated authority, he provides the Regional Counsel and Regional Inspector with such administrative services as they may require in the performance of their duties. He is responsible for and supervises the activities of four branches: Facilities Management Branch, Fiscal Management Branch, Personnel Branch, and Training and Development Branch.

SEC. 1114.41 *Facilities Management Branch.*

The Facilities Management Branch coordinates, evaluates and carries out region-wide programs for providing essential support activities designed to increase the effectiveness of the region, reduce its operating costs and improve taxpayer relations. Develops, within the broad guidelines established by the National Office standards and procedures for such matters as the management of paperwork; space; property and supply; procurement and contracts; production, storage, and distribution of forms and publications initiated within the region and distribution and requirements of National Office forms and publications; emergency planning for civil defense; fire and safety, document and property security; and processes all claims arising within the region under the Federal Tort Claims Act.

SEC. 1114.42 *Fiscal Management Branch.*

The Fiscal Management Branch performs, coordinates and evaluates budgeting, administrative accounting and financial reporting (other than for revenue collections) for the region, including the preparation of the financial plan within over-all budget limitations, submission of budget data, allotment of funds, maintenance of accounts, and examination of vouchers. This Branch participates in long-range planning involving expenditures for personnel, equipment, administrative services, space and similar items.

SEC. 1114.43 *Personnel Branch.*

The Personnel Branch develops and evaluates the regional personnel program and standards relating to recruitment and selection, employee relations, disciplinary actions, performance, evaluation, promotions, in-service placements, incentive awards, records, reports and other aspects of a complete personnel program, within the frame work of Service policies, programs and procedures established by the National Office, and conducts the personnel program for the Regional Office. It conducts the position classification program for the region. The Branch represents the region in contacts with employee groups and the Regional Directors of the Civil Service Commission.

SEC. 1114.44 *Training and Development Branch.*

The Training and Development Branch is responsible for the administration, conduct, and evaluation of all the Region's Servicewide courses and for providing functional guidance, support, and coordination to local training. These programs include initial orientation, technical training, instructor training, supervisory and managerial training, career development programs, on-the-job and refresher training, and taxpayer education programs. The Branch is responsible for the Regional organizational development program, the planned, systematic approach to equipping Service managers to anticipate, identify, and, through the use of tested techniques such as "team building," overcome the obstacles to effective organizational operation. The Branch is also responsible for the operation of the Regional Training Center(s). Where the Center is not in the proximity of the Regional Office site, a Training Center Officer, under the direction of the Regional Training Officer, supervises its day-to-day operation. The Branch also provides training assistance to State and local government agencies.

SEC. 1114.5 *Assistant Regional Commissioner (Appellate).*

The Assistant Regional Commissioner (Appellate) acts as the principal assistant to the Regional Commissioner in planning, directing, coordinating and evaluating the appellate activities of the Service under the jurisdiction of the Regional Commissioner within the framework of Service policies and programs established by the National Office. He is responsible to the Regional Commissioner for a program of hearing and undertaking final settlement of taxpayers' appeals from determinations of tax liability made by District Directors within the region, involving income, profits, estate, gift, and employment taxes, and excise taxes except those imposed on alcohol, wagering, narcotics, firearms, and tobacco; and for a program of hearing and, with concurrence of Regional Counsel, undertaking final settlement of certain cases docketed in the United States Tax Court. His program includes preparing reports to the Joint Committee on Internal Revenue Taxation in Appellate cases involving overpayments in excess of $100,000, and hearing administrative appeals in offer in compromise cases. In the foregoing programs, he represents the Regional Commissioner and exercises authority under delegation of authority from the Commissioner of Internal Revenue. Under the Regional Commissioner he serves as the primary source of information to the National Office as to the effectiveness of appellate policies, programs, procedures, and standards in terms of regional requirements, provides reports and factual information upon which the National Office can base appellate policy and program considerations, and recommends action with respect to problems encountered in Appellate operations. He supervises the activities of all Appellate branch offices in the region.

SEC. 1114.51 *Appellate Branch Offices.*

The basic settlement work of the Appellate Division is performed in branch offices of the Division which are headed by Chiefs who report to the Assistant Regional Commissioner (Appellate). Chiefs, Appellate Branch Office, may also supervise sub-offices administered by an Assistant Chief or local representative of the Chief. The branch offices hold conferences and make final determinations, within the limits of their delegated authority, on cases involving income, profits, estate, gift, and employment taxes and excise taxes, except those imposed on alcohol, wagering, narcotics, firearms and tobacco, in which taxpayers have requested Appellate consideration. The branch offices prepare reports to the Joint Committee on Internal Revenue Taxation in protested and petitioned cases which involve overpayments in excess of $100,000, and also consider protested offers in compromise. Branch offices, under delegated authority, enter

into closing agreements under IRC 7121 in cases under their jurisdiction.

SEC. 1114.6 *Assistant Regional Commissioner (Audit).*

The Assistant Regional Commissioner (Audit) acts as the principal assistant to the Regional Commissioner in planning, coordinating and evaluating the audit activities of the Service under the jurisdiction of the Regional Commissioner to ensure that policies and programs are properly executed, that audit work is processed in an orderly and timely manner, that equal emphasis is placed and uniform effort directed toward the accomplishment of the current audit program objectives, and that required standards for audit uniformity are being maintained. In conformity with audit policies, and programs established by the National Office, he develops regional programs, standards, and other measures necessary to implement most effectively the audit program of the Service which includes the selection of returns for audit, their examination and investigation, the determination of tax liabilities and penalties where applicable, a regional review of selected district office cases and the administrative disposition of offers in compromise by district Audit Divisions. He provides the Regional Commissioner with results of evaluation and other information upon which to base his administration of the regional audit program and recommends improvements and adjustments in audit operations needed to bring about and sustain a high level of performance within the region. Under the Regional Commissioner he serves as the primary source of information to the National Office as to the effectiveness of policies, programs, procedures and standards in terms of regional and district requirements, provides reports and factual information upon which the National Office can base policy and program considerations, and recommends appropriate action with respect to problems encountered in observing and evaluating audit operations.

SEC. 1114.7 *Assistant Regional Commissioner (Accounts, Collection, and Taxpayer Service).*

The Assistant Regional Commissioner (Accounts, Collection, and Taxpayer Service) acts as the principal assistant to the Regional Commissioner in planning, coordinating and evaluating the returns processing (except wagering, alcohol and tobacco tax, firearms returns and applications), data processing, revenue accounting, collecting of delinquent accounts, securing delinquent returns, and taxpayer service activities under the jurisdiction of the Regional Commissioner to ensure that the policies and programs established by the National Office are timely and properly executed and that equal emphasis is placed and uniform effort directed toward the accomplishment of the accounts, collection and taxpayer service program objectives. He exercises line supervision over those activities at the Regional Office and functional supervision over related activities in the Service Center(s) and District Officers within the region. He provides the Regional Commissioner with results of evaluation and other information upon which to base his administration of these programs and recommends improvements and adjustments needed to bring about and sustain a high level of performance within the region. Under the Regional Commissioner, he serves as the primary source of information to the National Office as to the effectiveness of the accounts, collection and taxpayer service policies, programs, procedures and standards in terms of factual information upon which the National Office can base accounts, collection and taxpayer service policy and program considerations and recommends appropriate action with respect to problems encountered in observing and evaluating these activities.

SEC. 1114.8 *Assistant Regional Commissioner (intelligence).*

The Assistant Regional Commissioner (Intelligence) acts as the principal assistant to the Regional Commissioner in planning, coordinating and evaluating the intelligence activities of the Service under the jurisdiction of the Regional Commissioner to ensure that policies and programs are properly executed, and that the intelligence work is processed in an orderly and timely manner. In conformity with intelligence policies, and programs, established by the National Office, he develops regional programs, standards and other measures necessary to implement most effectively the intelligence program of the Service which includes the investigation of alleged tax fraud, certain other civil and alleged criminal violations of tax laws (except alcohol, tobacco and certain firearms tax cases), and such other special investigations as the Commissioner may direct. He provides the Regional Commissioner with results of evaluations and other information upon which to base his administration of the regional intelligence program and recommends improvements and adjustments in the intelligence operations needed to bring about and sustain a high level of performance within the region. Under the Regional Commissioner he serves as the primary source of information to the National Office as to the effectiveness of intelligence policies, programs, procedures and standards in terms of regional and district requirements, provides reports and factual information upon which the National Office can base intelligence policy and program considerations and recommends appropriate action with respect to problems encountered in observing and evaluating intelligence operations.

SEC. 1114.81 *Management and Evaluation Staff.*

Exercises primary responsibility for the adequacy of district program content and effectiveness of management of Service resources in each district; evaluates costs and benefits of achieving program objectives; develops and maintains statistical indicators of management effectiveness; identifies required changes in program operations through program reviews in districts and assists in redirecting needed emphases in program goals and operations; assists districts in evaluation of personnel; conducts workload analyses to determine proper balance of staffing and other resource requirements; evaluates case selection and management methods together with quality control practices; analyzes effectiveness of publicity concerning Intelligence matters; maintains mutually productive working relationships with members of the National Office, Service Center, and other offices regarding potential fraud situations; communicates information on all significant program and management developments; prepares narrative reports; and works on special projects and assignments.

SEC. 1114.82 *Operations and Technical Assistance Staff.*

Responsible for all general and special enforcement operational activities consisting of broad impact programs and objectives directed toward criminal violations of tax laws. Provides advice and assistance to district officials in the overall planning and execution of district Intelligence investigative programs, including determination of priorities and resource requirements; coordinates program operations with representatives of other IRS organizational segments and Department of Justice; evaluates and disseminates information and data to the districts, received from the National Office or other governmental agencies etc., relating to known or potential subjects of Intelligence enforcement efforts; identifies sensitive and significant situations; prepares reports on significant matters to be brought to the attention of the Regional Commissioner or National Office; coordinates special investigations, case development efforts and projects which involve two or more districts; assists districts in establishing and perfecting control practices and procedures with Service Centers and advising district officials regarding the application of data processing techniques to investigative problems. Provides technical guidance on case matters; conducts post review programs in each district; analyses supplemental requests and Criminal Action Memorandums; identifies technical training needs and participates in development of training programs; conducts refresher training programs and participates in fraud training programs; coordinates case matters with Counsel and Department of Justice; prepares protests on CAM actions; provides technical advice on complex case matters; develops new procedures and investigative approaches; makes annual evaluations of case inventories; reviews cases closed for insufficient resources; identifies indicators of potential case management selection weaknesses critiques investigations in terms of case selection standards and investigative quality; assists districts in evaluating fraud referral

program effectiveness and improving quality of investigations and reports.

SEC. 1114.9 *Assistant Regional Commissioner (Stabilization).*

The Assistant Regional Commissioner (Stabilization) acts as principal assistant to the Regional Commissioner in planning, directing, coordinating and evaluating the Stabilization activities under the jurisdiction of the Regional Commissioner within the framework of Service policies and programs established by the National Office. He is responsible to the Regional Commissioner for developing programs, standards and other measures necessary to implement most effectively the Stabilization Program of the Service which includes, but is not limited to, responding to inquiries from the public; disseminating information to the public; analyzing and issuing decisions upon application for exceptions and appeals; conducting investigations; resolving by obtaining compliance, where possible, complaints of violations of the Economic Stabilization Program, and recommending enforcement action when necessary; assuring proper allocation and utilization of manpower and resources; and maintaining adequate records and making periodic reports to the Assistant Commissioner (Stabilization).

SEC 1115 *Office of Regional Inspector.*

There are 7 Regional Inspectors, one in each internal revenue region. The Regional Inspector, who operates under the direct supervision of the Assistant Commissioner (Inspection), is responsible for the conduct throughout the region of both the internal audit and internal security programs.

SEC. 1115.1 *Assistant Regional Inspector (Internal Audit).*

Under the supervision of the Regional Inspector, the Assistant Regional Inspector (Internal Audit) is responsible for the conduct of the internal audit program throughout the region. The internal audit, which includes verification of financial transactions and analyses of operating practices and procedures, serves as the basis for informing appropriate officials of the manner in which operations are being carried out and responsibilities are being discharged as a basis for necessary changes in policies, practices and procedures.

SEC. 1115.2 *Assistant Regional Inspector (Internal Security).*

The Assistant Regional Inspector (Internal Security) is responsible for the conduct of the Internal Security program throughout the region. The program, which provides a factual basis for conclusions by management, the Department of Justice or other authority for making decisions, includes personnel background investigations, investigations of complaints and allegations of misconduct or irregularities concerning Service employees and actions of non-Service persons that may affect the integrity of the Service or safety of Service employees, including attempts to bribe or otherwise corrupt Service personnel; this authority includes investigation of attempts to interfere with administration of Internal Revenue laws through threats, assaults or forcible interference and also the unauthorized disclosure of Federal tax information. The program also includes background investigations of certain applicants for enrollment to practice before the Internal Revenue Service, investigations of charges against tax practitioners, formal investigations of accidents involving Service employees or property, and investigations of alleged discrimination because of race, creed, color, or national origin. In addition, he is responsible throughout the region for the conduct of special investigations as directed by higher authority, for the Office of the Secretary and other components of the Treasury Department.

SEC. 1116 *Office of Regional Counsel.*

(1) There are 7 Regional Counsels, one in each Internal Revenue region. The Regional Counsel, who operates under the Chief Counsel for the Internal Revenue Service, serves as the principal legal advisor to the Regional Commissioner, the Regional Inspector, and the District Directors of Internal Revenue and their staffs. The Regional Counsel, subject to the Chief Counsel's continuing general supervision and review where appropriate or necessary, directs and supervises a staff of attorneys engaged in processing and handling cases docketed in the United States Tax Court and in furnishing legal advice and performing legal services connected with the tax court, enforcement and general litigation functions.

(2) *Tax Court litigation matters.*—The Regional Counsel's office furnishes legal advice to the Assistant Regional Commissioner (Appellate); in the name of the Chief Counsel, represents the Commission in the trial of cases before the Tax Court and is responsible for the preparation of pleadings, stipulations, and other documents to be filed with the Tax Court on behalf of the Commissioner prior to the entry of a decision by the Court; makes recommendations to the Chief Counsel respecting adverse Tax Court decisions; considers and approves or disapproves the settlement of cases docketed in the Tax Court, subject to the concurrence of Appellate while such cases are in presession status; considers and concurs in, or disapproves, recommendations by Appellate to eliminate the ad valorem fraud penalties in cases not docketed in the Tax Court; and considers and reviews, prior to issuance, statutory notices of deficiency or liability proposed by Appellate, and certain of such notices proposed by the District Directors.

(3) Enforcement matters. The Regional Counsel's office is responsible for the performance of legal services in the field in connection with criminal cases arising under the internal revenue laws. The office reviews recommendations of prosecution in criminal cases received in the field, and prepares and refers such cases (other than alcohol and tobacco tax cases) to the Department of Justice or, where authorized by the Department of Justice, directly to United States Attorneys, or, where prosecution is not deemed warranted, prepares criminal action memoranda setting forth the reasons against the prosecution and closes such cases with the concurrence of the Assistant Regional Commissioner (Intelligence). On request, the office furnishes aid and assistance to United States Attorneys in criminal tax proceedings in the United States District Courts and Courts of Appeal.

(4) General litigation matters. The Regional Counsel's office is responsible for handling legal work with respect to cases under the Bankruptcy Act and other insolvency cases including decedents' estate proceedings; Federal tax liens in suits for foreclosure by mortgagees or other lienholders and in suits to quiet title; applications filed for the discharge of property from Federal tax liens or for the release of such liens; for review and handling of certain offers in compromise; recommendations as to the taking of affirmative action, whether by way of a separate suit or intervention in pending proceedings (with the exception of alcohol, tobacco and firearms matters not relating to proceedings under the Bankruptcy Act, liens, receiverships and other insolvencies); the defense of injunction suits to restrain the assessment or collection of Federal taxes (except with respect to alcohol, tobacco and firearms matters); the assessment and collection of taxes; and of the civil enforcement of summonses.

(5) Stabilization Matters. The Assistant Regional Counsel (Stabilization) is responsible for providing interpretative advice and guidance concerning the rulings and regulations issued by the Pay Board and the Price Commission to the Office of Assistant Regional Commissioner (Stabilization) and answering specific legal questions concerning stabilization matters that may be presented. Also, provides functional support to Regional Counsel's Branch Offices that may be requested to furnish legal advice at the Service's District Director level. In addition, this Office is responsible for the review of litigation cases, involving violations of Pay Board's or Price Commission's regulations or rulings, that are developed at the District Director level by Service personnel and Department of Justice attorneys, and after such review forwarding the cases with appropriate recommendations through the Regional Counsel to the General Counsel of either the Pay Board, or Price Commission for possible litigation action by the Department of Justice, and at the same time reports of potential litigation will be forwarded to the Chief Counsel's National Office Stabilization Division.

SEC. 1117 *Service Centers.*

SEC. 1117.1 *General.*

(1) There are 10 Internal Revenue Service Centers located at: Andover, Massachusetts, Austin, Texas; Brookhaven, New York; Chamblee, Georgia; Covington, Kentucky; Fresno, California; Kansas City, Missouri; Memphis,

Tennessee; Ogden, Utah; and Philadelphia, Pennsylvania. Each Service Center is under the line supervision of the Regional Commissioner having jurisdiction over the area of their location.

(2) Each Service Center is headed by a Director who operates under the general direction of a Regional Commissioner. The Service Center Director is responsible to the National Office, through the Regional Commissioner, for implementing the programs assigned to the Center. He is responsible for budget, fiscal, and personnel operations of the Center under directives of the Regional Commissioner. He also participates with the National Office, through the Regional Commissioner, in planning, coordinating, and evaluating experimental projects to develop improved techniques and methods for processing tax returns. The Regional Commissioner, in turn, is responsible to the National Office for supervising the execution of the Service Center's program and for recommending adjustments to or modifications of the program. The Regional Commissioner also exercises general supervision over the activities of the Service Center Director in coordinating and maintaining liaison with Regional Commissioners, District Directors, and the National Office in carrying out the programs prescribed for the Centers by the National Office.

SEC. 1117.2 *Service Center Organization.*

SEC. 1117.21 *General.*

(1) The principal organizational components of the typical Service Center are the immediate office of the Service Center Director, Management Staff, Administration Division, Audit Division, Data Conversion and Accounting Division, Processing Division, and Taxpayer Service Division.

(2) The organizational structure depicted is intended to prescribe the Service Center organization through the branch level. Regional Commissioners are authorized to establish the Service Center organization below branch level as they see fit.

SEC. 1117.22 *Office of the Director.*

Within the structure of the Internal Revenue Service, the Internal Revenue Service Center has organizational status comparable to that of the District Offices. It operates under the line supervision of the Service Center Director, who is responsible to the Regional Commissioner in the same manner as a District Director. The Director plans, directs, and administers functions of the Internal Revenue Service Center which provides services for the region(s). Its functions are to process tax returns and related documents through the use of automatic and manual data processing systems and high-speed processing devices and to maintain accountability records for internal revenue taxes collected within the region. Typical programs include the processing, analysis, and accounting control of income tax returns, estimated tax returns, wages and excise tax returns, corporation tax returns, income information documents, and mailing of income tax forms to individual taxpayers. The Director also plans, directs, and administers assigned Audit functions. Responsible for budget, fiscal and personnel operations of the Service Center. In addition, the Philadelphia Service Center assists the Assistant Commissioner (Compliance) in the exchange of authorized routine information with foreign countries having tax treaties with the United States.

SEC. 1117.221 *Management Staff.*

Provides staff assistance to the Director and line officials in the general management of Service Center operations. Assists by coordinating the preparation of work plans, work schedules, staffing and accession schedules. Monitors the Work Planning and Control System and maintains the daily production control system. As requested, provides assistance in analyzing day-to-day problems concerning systems and procedures. Monitors and coordinates various projects, particularly those in the implementation stage such as IDRS, RMF, and Returns Preparer Program. Coordinates the consolidation and referral of problems to the Regional or National Office. Monitors the Statistics of Income sampling and the Quality Review Program.

SEC. 1117.23 *Intelligence Staff.*

Advises the Service Center Director in matters relating to the Intelligence function; presents Intelligence objectives to Service Center personnel and assists in training them in characteristics of false and fraudulent returns and other potential criminal violations. Provides liaison between district and regional officials with the Service Center; devises procedures for the most expeditious manner of obtaining returns and transcripts for district officials and establishes guidelines and criteria for the selection of returns to be reviewed. Also provides assistance to district offices in locating addresses of taxpayers and/or witnesses. Evaluates informants' communications received by Service Center. Also advises district officials in the use of ADP facilities in their investigative processes.

SEC. 1117.24 *Audit Division.*

Administers the Audit activities centralized within service centers. These include: correspondence audit; classification of returns, claims and related documents; processing Audit/Appellate adjustments; technical and quality review; issuing claims disallowance notices, preliminary letters and statutory notices. Furnishes assistance and technical advice to other service center components, districts, regions and National Office. Provides assistance to taxpayers as requested.

SEC. 1117.241 *Classification Branch.*

Classifies and screen all types of Federal tax returns and claims for audit at district offices or service centers. Classifies various taxpayer initiated documents related to tax returns. Establishes and maintains a review system to ensure returns and claims with the greatest potential are selected for audit and to provide for the review of returns and claims audited at the service center. Prepares, controls and processes information reports related to the classification of returns. Furnishes technical and procedural advice and assistance to other service center components, districts, regions and National Office. Provides assistance to taxpayers as requested. Conducts a quality review of service center responses to written taxpayer inquiries.

SEC. 1117.242 *Correspondence Audit Branch.*

Conducts the Centralized Audit examination and verification of tax returns and claims through correspondence with taxpayers to determine correct liabilities for taxes and penalties. These include the less complex issues that do not require district office examination. Conducts tests to determine the feasibility of additional correspondence work. Issues notices of claims disallowance, preliminary letters and statutory notices. Reviews taxpayer protests, determines disposition and when applicable, refers protested returns to district offices.

SEC. 1117.243 *Audit Processing Branch.*

Performs necessary processing of Audit/Appellate Documents such as receipt and control, code and edit and error resolution.

SEC. 1117.25 *Offices of the Chief, All Operating Divisions.*

Receives, analyzes, and evaluates all new programs and procedures; prepares supplemental or clarifying instructions as necessary; and ensures full implementation. Determines resources needed in the Division through the preparation of work plans and schedules, personnel staffing and accession schedules, space requirements, formulation of training needs, and other logistical processes. Participates with other Division Chiefs and the Director in the final allocation of resources to accomplish the total Service Center work program. Coordinates with other Division Chiefs on interdivisional matters, as appropriate. Continuously reviews, analyzes, and evaluates the status of work programs with the aim of keeping the Director informed of operational problems on an exception basis. When appropriate, requests assistance from the Management Staff, or from the Office of the Assistant Regional Commissioner having functional responsibility.

SEC. 1117.26 *Administration Division.*

Directs and coordinates the personnel, facilities management, training, fiscal management, public information, and administrative management improvement programs. Serves as the principal administrative adviser to the Director, Assistant Director, and operating division chiefs. Provides functional leadership for the numerous and varied administrative programs designed to support and increase the effectiveness of Service Center operations. Executes the administrative management analysis program and coordinates the management improvement program for the Service Center. Conducts management studies

and provides staff assistance to Administration branch chiefs and operating officials as required. Prepares budget and financial plan estimates, maintains fiscal control, and recommends appropriate financial management actions. Develops and coordinates public information plans, techniques, guidelines, and informational materials. Establishes and maintains good relations with mass media in the vicinity of the Service Center; determines information needed, gathers and analyzes statistical and other data generated, and prepares information material for distribution to media outlets; and coordinates visit of media representatives, and others, from the entire region.

SEC. 1117.261 *Facilities Management Branch.*

Advises, informs, and assists Service Center management on operations relating to facilities management programs such as: space, property, communications, paperwork (including microfilm), records retention and disposal, distribution, emergency planning, safety, and security. Plans, develops, determines requirements, and evaluates these programs; provides additional, improved, or modified programs as required. Furnishes procurement, transportation, storage, supply, and messenger services; provides general building maintenance and maintenance of office, electronic, processing, and materials-handling equipment.

SEC. 1117.262 *Personnel Branch.*

Develops, executes and evaluates the Service Center personnel program and standards relating to recruitment, examination, and selection of employees, employee relations, union-management relationships, performance evaluation, promotions, in-Service placements, incentive awards, records, reports, and other aspects of a complete personnel program within the framework of policies, programs, and procedures established by the National and Regional Offices. Conducts the position classification program within delegated authority. Provides staff assistance to operating officials in all personnel areas.

SEC. 1117.263 *Training Branch.*

Provides leadership and coordination to the various Service Center training programs; promotes employee development programs and evaluates and reports on all such programs. Conducts studies and analyzes operating data to determine training needs; studies trends and developments in the employee development field and appraises new principles, concepts, methods, training devices, and materials for use in Service Center training programs. Develops or assists in the development of local and Service-wide course materials, audio-visual aids, and training devices. Assists Service Center management in developing a job environment which will enable trainees to maintain and improve their skills. At the request of the National or Regional Offices, provides data processing training for other than Service Center personnel. Prepares training program estimates for developing the Operating Financial Plan; prepares obligating documents for charges to the training portion of the Operating Financial Plan.

SEC. 1117.27 *Data Conversion and Accounting Division.*

Converts data from source documents to form processable by computers. Operates computer and peripheral equipment used to verify tax liability and service the accounts of all taxpayers within the Districts assigned to the Center and to convert input data to magnetic tape. Maintains tape files of rejected documents for reinput to Service Center Processing. Prepares computer printouts relating to outputs received from the National Computer Center for mailing to taxpayers, for internal reports and statistics, and for tax information authorized for external use. Programs projects as assigned from the National Office and provides the necessary liaison and programming for maintenance of National Office computer programs. Maintains an accounting system to provide subsidiary records and general ledger accounts that reflect the Director's accountability for the Master File and Non-Master File tax revenue collected within Districts assigned to the Center. Records assessments, collections, receivables, refunds, overassessments, and other elements of revenue accounting affecting accountability. Receives, verifies, balances and processes accounting outputs from the National Computer Center; and prepares special and periodic accounting reports. Determines the validity of taxpayer delinquent accounts and returns notices. Prepares various reports for the Service Center, Region, and National Office.

SEC. 1117.271 *Data Conversion Branch.*

Transcribes, verifies and corrects pertinent information of all tax returns, information documents and related documents associated with other miscellaneous programs. Processes documents related to all files (IMF, BMF, RMF, NMF, etc.), subsequent activity programs, and documents which have been previously transcribed for which error conditions have been detected in subsequent processing. Responsible for resolving error conditions identified by the Computer Branch. Enters corrections for each error condition into machine-generated listings. Responsible for resolving and reentering blocks out of balance or rejected blocks received from transcription control clerks.

SEC. 1117.272 *Computer Branch.*

Operates all computer systems used in processing, verifying, computing the tax liabilities, and servicing the accounts of all Master Files (IMF, BMF, RMF, NMF) taxpayers within Districts assigned to the Center, maintains tape library; processes tax information and documents for mailing to taxpayers and for internal use by the Service; generates computer reports; statistical information and other information for use by the National, Regional, District and Service Center offices, other program areas of the Service, and by various States. Processes other programs assigned by the National Office. Provides programming services as required for the maintenance of the system, as directed by the National Office. Performs quality review on computer generated output. Operates an EAM System for preconversion perfection of input data and processing of other Service Center card-oriented projects.

SEC. 1117.273 *Accounting Branch.*

Maintains general ledger accounts and subsidiary records covering revenue transactions for the recording of assessments, collections, receivables, refunds, over-assessments and other transactions affecting taxpayer's accounts. Controls accounting documents for entry to tax accounts. Establishes and maintains individual accounts for non-ADP (NMF) and pre-ADP tax returns and documents. Receives Master File accounting summaries for posted account transactions and accomplishes required journalization and general ledger postings. Initiates or processes account transfers, account adjustments, debit and credit transfers related to tax accounts. Reconciles National Computer Center accounting control records and refund appropriation accounts of Regional Disbursing Centers with general ledger balances. Prepares all accounting and ledger reports as required. Prepares various reports for the Service Center, Region, and National Office.

SEC. 1117.28 *Processing Division.*

Receives, blocks, sorts, and controls documents, both Master File and Non-Master File, received from taxpayers and District Offices; deposits and initiates accounting control of remittances. Ships processed documents to District Offices; and prepares a variety of forms, and other material for mailing to taxpayers, tax practitioners, District Offices, and other Government agencies. Examines, perfects, and codes returns and documents for all files (IMF, BMF, RMF, NMF, etc.) for subsequent processing; examines, edits, and codes returns for the Statistics of Income Program; prepares form and pattern paragraph letters to taxpayers requesting additional or clarifying information incidental to the initial processing of returns. Performs research, perfects and resolves processing errors detected during work cycles within the Service Center. Receives, processes and maintains control over applications for Employer Identification Numbers and Social Security Numbers.

SEC. 1117.281 *Receipt and Control Branch.*

Receives and categorically classifies all incoming returns, documents, remittances, and taxpayer correspondence. Sorts and establishes batch control prior to release of returns and documents into the initial work process, in accordance with work schedules. In coordination with the Management Staff, makes necessary adjustments in work schedules as dictated by actual work receipt patterns to maintain a steady balanced work flow. Numbers and blocks returns,

documents and related remittances; examines remittances and related documents, prepares appropriate registers and Certificates of Deposit prior to disposition of monies to local depository. Performs a variety of machine operations such as labeling, folding and inserting. Ships processed documents to District Offices; and prepares forms and other material for mailing to taxpayers, tax practitioners, District Offices and other Government Agencies.

SEC. 1117.282 *Examination Branch.*

Examines, edits, perfects and codes tax documents for all files (IMF, BMF, RMF, NMF, etc.) for transcription and other purposes: prepares form and pattern paragraph letter correspondence to District Offices and taxpayers to obtain missing or clarifying information necessary for the perfection of the return; and edits, codes, and extracts information from returns for audit and statistical programs.

SEC. 1117.283 *Input Perfection Branch.*

Perfects and resolves processing and taxpayer errors detected during work cycles within the Service Center. Prepares correspondence action sheets to obtain additional information from taxpayers and District Offices in order to make returns acceptable for processing. Responsible for control, examination, perfection and final disposition of all RMF rejected tax returns and documents. Perfects and resolves unpostable returns and documents. Resolves unpostable conditions arising from the attempt to input all documents and returns relating to the IMF, BMF, and RMF and prepares necessary input documents. Receives and processes applications for Employer Identification and Social Security Numbers. Maintains control over the assignment of Employer Identification Numbers. Performs all necessary actions concerning the control and maintenance of account numbers. Receives and processes applications from 941 filers to file magnetic tape returns; maintains case history file and control of 941, W2, 1099 and 1087 paper returns prior to approval of magnetic tape filing request.

SEC. 1117.29 *Taxpayer Service Division.*

Provides services to the taxpaying public by answering inquiries received by telephone, mail, or personal call. Controls, monitors, and takes necessary action on complaints and special cases requiring expedite action. Controls and makes adjustments to taxpayers' accounts on all files (IMF, BMF, RMF, NMF, etc.). Controls and processes statutory case adjustments. Performs microfilm research requested by all functional activities. Establishes, maintains and controls permanent and temporary returns files. Retires returns and documents in accordance with prescribed procedures. Performs output review and necessary correction. Performs payment tracing functions. Processing of all exempt organization returns has been centralized in the Philadelphia Service Center. In view of the scope and size of this function, the Philadelphia Service Center has been authorized an Exempt Organization Returns Branch which is: Responsible for processing, except for deposit and transcription operations, all exempt organization tax returns and other related change documents.

SEC. 1117.291 *Adjustment Branch.*

Receives taxpayer inquiries initiated by correspondence. Receives and controls requests for adjustments and determines appropriate action to be taken including adjustment to tax, penalty, and interest, and to the entity section of taxpayer accounts. Prepares written replies to taxpayer on contacts by telephone. Processes IMF and BMF Restricted Interest cases, combination overassessment and deficiency cases, Joint Committee cases, Appellate Division Overassessment and Deficiency cases, Justice Department cases, cases containing second agreements and partial agreements. Processes applications for Tentative Carryback Adjustments. Performs payment tracing functions.

SEC. 1117.292 *Research Branch.*

Performs research through microfilm, source documents, and other sources for entity and account information requested by all functional activities. Establishes, maintains, and controls permanent and temporary returns files. Retires returns and documents in accordance with prescribed procedures. Performs delinquency checks for Non-Master File returns. Reviews computer output, except that pertaining to taxpayer delinquent accounts and returns, for quality and accuracy and for validity of refunds; corrects any processing errors discovered.

SEC. 1117.293 *Taxpayer Relations Branch.*

Performs taxpayer service functions in connection with telephone inquiries or personal calls. When necessary, prepares replies to taxpayer inquiries which accompany returns and which indicate that complex issues need to be resolved before the return can be processed. Takes necessary action to process special or unusual cases and complaints. Maintains close liaison with Social Security Administration on unusual problems. Prepares and types replies to taxpayer correspondence and requests for correspondence from other activities which generally require individually tailored letters.

SEC. 1118 *Office of District Director.*

SEC. 1118.1 *Mission.*

The mission of the Office of the District Director is to administer the internal revenue laws within an internal revenue district in conformance with Service policies and programs of the National Office and Regional Offices.

SEC. 1118.2 *Basic Organization.*

The principal organizational components of the typical District Office are the immediate office of the District Director (including the Stabilization Staff), the Audit Division, Collection and Taxpayer Service Division, Intelligence Division and Administration Division.

SEC. 1118.3 *District Director.*

The District Director administers, within an internal revenue district, the collection, taxpayer service, audit, intelligence and administrative programs of the Internal Revenue Service. He is responsible for the determination of tax liability, the assessment of such liability, and scheduling and certification of refunds, and the investigation of certain criminal and civil violations of internal revenue tax laws (except those relating to alcohol, tobacco and firearms). He is also responsible for the collection and deposit of all internal revenue taxes.

SEC. 1118.4 *Audit Division.*

(1) Administers a district-wide audit program involving the selection and examination of all types of Federal tax returns (except those involving alcohol, tobacco, and firearms taxes), claims, offers in compromise based on doubt as to liability for taxes or for both taxes and statutory additions (except alcohol, tobacco, and firearms taxes), informants' claims for reward, and related activities, including the examination and approval of pension trust plans and the issuance of determination letters. The audit program involves the selective classification of returns for field and office audit, the conduct of district conferences in unagreed cases, participation with special agents of the Intelligence Division in the conduct of tax fraud investigations, and provision of technical support to the year-round taxpayer service program.

(2) Audit Divisions in the Atlanta, Chicago, Cincinnati, Dallas, Manhattan, Philadelphia and San Francisco districts on a region wide basis (Philadelphia reviews for the Office of International Operations), review all income and excess profits tax cases involving overpayments in excess of $100,000 and prepare reports for the Commissioner's signature to the Joint Committee on Internal Revenue Taxation in all nonpetitioned and nondocketed cases, including estate and gift tax cases.

(3) All district Audit Divisions are responsible for issuing determination letters on the qualification of pension, annuity, profit-sharing, stock bonus and bond purchase plans and for subsequent determinations on the status for exemption of trusts forming a part of such plans. Audit Divisions in the districts of Atlanta, Austin, Baltimore, Boston, Chicago, Cincinnati, Cleveland, Dallas, Detroit, Los Angeles, Manhattan, Philadelphia, St. Louis, St. Paul, San Francisco and Seattle are responsible for matters relating to the exemption of all other organizations. These sixteen key District Offices will be responsible for issuing determination letters, examining exempt organizations activities, issuing notices of revocation and reestablishment of exemption, performing technical review and holding district conferences.

(4) The Division structure conforms to one of three established patterns, depending upon size of the District Office. These patterns all recognize six distinct groups of functions which are known as: Returns Classification, District Conference, Review, Field Audit, Office Audit, and Service. In small District Offices the branch supervisory structure does not

exist, while in large offices there may be more than one Field Audit Branch. Some district Audit Divisions in Central Region have a Technical Branch in lieu of a separate Conference Staff and Review Staff.

(5) Each region has centralized the review of the following specialized tax areas to specific districts:

(a) Estate and Gift
(b) Excise Taxes
(c) Insurance
(d) International Issues

SEC. 1118.41 *Conference Staff.*

Directs and performs the district conference function. This includes holding conferences with taxpayers and their representatives, and preparing conference reports. Also screens taxpayer protests and acts as technical advisor to Chief, Audit Division.

SEC. 1118.42 *Review Staff.*

Reviews reports of examination of all types of tax returns to verify the determination of liability made by the examining officer. Directs the issuance of preliminary 30-day letters to taxpayers, reviews protests filed in response to such notices and prepares statutory notices of deficiency. Prepares closing letters and releases in estate and gift tax cases. Furnishes technical advice and assistance on pension trust plans, including examination thereof and issuance of determination letters, in those districts with three or less pension trust specialists where the District Director has assigned such responsibility to this Staff. Is responsible for the control, management and review of offers in compromise, informants' claims for reward and the special procedures applicable in cases involving renegotiation. Prepares Management Information Reports for both agreed and unagreed cases. Has primary responsibility within the district for maintaining quality standards in examinations and reports, and the technical accuracy of all matters subject to review. Issues correction memorandums in all cases or matters involving substantial errors.

SEC. 1118.43 *Returns Classifying Officer.*

Develops and administers district program for selecting all types of returns for examination. Conducts special studies to identify noncompliance problem areas and recommends audit programs to cope with them.

SEC. 1118.44 *Field Audit Branch.*

Conducts field examinations relative to all types of taxes (except alcohol, tobacco, and firearms) to determine correct liabilities of taxpayers for tax and penalties, including the examination of claims for refund, credit or abatement, or for redemption of stamps. Also conducts field examinations of offers in compromise based on doubt as to liability for taxes or for both taxes and statutory additions (except alcohol, tobacco, and firearms taxes), and special field examinations, as requested, including joint examinations with special agents of Intelligence Division where tax evasion may exist. Processes informants' claims for reward making any necessary investigations and prepares reports on such claims, together with recommendations as to the amount of rewards. Performs engineering and valuation work, prepares memorandums to accompany closing agreements, and recommends jeopardy assessments. Furnishes technical advice and assistance on pension trust plans and prepares determination letters except in those districts with less than three pension trust specialists where the District Director has assigned such responsibility to the Review Staff. Provides technical support to the year-round taxpayer service program.

SEC. 1118.45 *Office Audit Branch.*

Conducts examinations through correspondence or interviews with taxpayers in offices of the Service relative to all types of taxes (except alcohol, tobacco and firearms) to determine correct liability of taxpayers for tax and penalties, and the validity of claims for refund, credit, or abatement, or for redemption of stamps. Also, when necessary, conducts field examinations of all types of taxes (except alcohol, tobacco, and firearms) if such examinations do not require professional accounting skills of examiners assigned to Field Audit Branch. Recommends jeopardy assessments. Provides technical support to the year-round taxpayer service program.

SEC. 1118.46 *Service Branch.*

Performs clerical services for the Division necessary to the processing of returns, reports of examination, case files and correspondence. Maintains control of all returns and case files assigned to the Audit Division and of number assignments for Management Information Reports on audit cases. Types examining offices' reports, form letters, correspondence and other material as assigned and furnishes clerical, stenographic and typing assistance to all Division offices.

SEC. 1118.47 *Technical Branch.*

(1) The Technical Branch directs the issuance of preliminary 30-day letters to taxpayers, prepares letters to taxpayers covering deficiencies in bankruptcy and receivership cases which serve as a basis for assessment and filing of proof of claim by the Collection and Taxpayer Service Division; reviews protests filed in response to such notices of deficiency for proper form, compliance with existing requirements and for new issues or facts; and prepares statutory notices of deficiency.

(2) The Branch is responsible for the control, management and review of offers in compromise, informants' claims for reward, cases in which expiration of the statute of limitations is imminent and assessment, overassessment or statutory notice action is necessary prior to forwarding to the Assistant Regional Commissioner (Audit) for review, and the special procedures applicable in cases involving renegotiation. It maintains and controls the preliminary notice file, the statutory notice file, the file on cases suspended pending court or other decision (Form 1254), power of attorney file, fee statement file, and worthless stock and taxability of dividend file, taking appropriate action as required. The Branch is responsible for the district conference functions, which include assignment of conferees to handle the case, the holding of the conference, the manner in which conferences are conducted, the quality of the conference reports and the statistical reporting of the conferences. The Chief of the Technical Branch acts as Technical Advisor to the Chief of the Audit Division on cases under investigation or assigned for district conferences.

SEC. 1118.5 *Collection and Taxpayer Service Division.*

(1) The Collection and Taxpayer Service Division is responsible for the receipt, processing and retention of firearms and alcohol and tobacco tax returns and applications; the receipt and transmittal of other tax returns and documents received in the district; the deposit to the credit of the Service Center Director of tax remittances received in the district; the collection of delinquent accounts through distraint, seizure, levy and other means; the securing of delinquent returns; the conduct of a year-round taxpayer service program (including issuance of certificates of compliance to departing aliens); examination of offers in compromise based on doubt as to collectibility of taxes (except alcohol, tobacco and firearms taxes), offers in compromise of statutory additions based on doubt as to liability (except alcohol, tobacco, firearms, employment and withholding taxes and specific penalties), and all offers in compromise of 100 percent penalties. The Division receives, acts on, and processess information pertinent to bankruptcies, receiverships, assignments, reorganizations, probate proceedings, foreclosures and redemptions after civil foreclosure, bulk sales, gifts and prizes, and dissolutions and initiates investigations for securing delinquent returns where necessary. The Division maintains files or control records of payments received in insolvency, bankruptcy, and decedent cases and of surety bonds and other collateral posted as security for tax liability. It also maintains files and control records of property seized under distraint authority and takes appropriate action with respect to seized property to ensure that proper legal action may be timely taken.

(2) The organization of the Division below the branch level varies depending on the size of the Division.

SEC. 1118.51 *Special Procedures Staff.*

(1) The Special Procedures Staff is responsible for furnishing advisory assistance on technical delinquent collection and returns matters to the Chief, Collection and Taxpayer Service Division, Chief, Field Branch, Chief, Office Branch and Group Supervisors; providing liaison for the District Director with the Department of Justice, including the U.S. Attorneys, the Chief Counsel and Regional Counsel on all collection matters; ascertaining tax liability and filing of proof of claims in insolvency and decedent's estate proceedings; recommending civil suits to enforce collection or to protect the Government's interests; processing civil suits against the United States or

the District Director; examining, reviewing and processing seizure and sale reports; processing applications for discharge of property from the effect of Federal tax liens and for certificates of nonattachment of Federal tax liens and certificates of subordination of the Federal tax lien; processing filed notices of Federal tax liens and certificates of release; processing and maintaining executed collection waivers; analyzing and determining the sufficiency of various forms of collateral offered as security for release of lien or postponement of collection action; furnishing technical advice and assistance and recommendations for or against entry into suitable escrow agreements for the collection of delinquent accounts; reviewing recommendations for and holding conferences on 100% penalty and transferee assessments; post reviewing of accounts reported as uncollective; reviewing recommendations and holding conferences on offers in compromise cases based on inability to pay; and maintaining files and control records on all the above type cases to ensure that proper legal and other collection actions are taken timely.

(2) In the majority of District Offices this function is organized as a separate Special Procedures Staff. In small offices where the Special Procedures function is a one-position job, it is placed organizationally within the Office of the Division Chief.

SEC. 1118.52 *Office Branch.*

The Office Branch effects the collection of delinquent accounts and secures delinquent returns through demands made by correspondence, telephone or office interviews. It safeguards the Government's interest by causing the filing of notices of tax liens and serving or causing the service of notices of levies. It transfers to Revenue Officer groups those assignments which require field investigations or can be more efficiently completed by field Revenue Officers. The Branch carries out the Division's responsibility for district-wide execution of the year-round taxpayer service program. It provides taxpayer service within the Headquarters Office and surrounding metropolitan commuting area, including responses to correspondence requests of tax information, and provides functional supervision of taxpayer service at other posts of duty. The Branch screens and assigns cases and maintains assignment files. It prepares periodic reports of collection and taxpayer service activities. It receives and deposits to the credit of the Service Center Director remittances received in the District Office. It receives, processes and maintains files of wagering, alcohol and tobacco tax, firearms returns and applications. It also receives and transmits other returns and documents received in the District Office.

SEC. 1118.53 *Field Branch.*

The Field Branch is responsible for the management and control of five or more Revenue Officer groups (Type I Field Branch), or three or more Revenue Officer groups and an Office Group (Type II Field Branch). Within the assigned area, the Branch makes collections of delinquent accounts and conducts a continuing program for the securing of delinquent returns. It safeguards the Government's interest through the filing of notices of tax liens, and enforces collection by the serving of levies, and seizure and sale of real and personal property. It recommends jeopardy assessment when deemed necessary to protect revenue, civil actions to secure payment, suits to enforce penalty for failure to honor levies, and penalty assessments as a means of collection or as a method of obtaining compliance with existing laws and regulations. The Branch recommends the issuance of certificates of discharge of property from the effects of tax liens, recommends issuances of certificates of subordination of Federal tax liens, and conducts the investigations necessary to support such recommendations. The Branch examines offers in compromise based on doubt as to collectibility of taxes (except alcohol, tobacco and firearms taxes), offers in compromise of statutory additions based on doubt as to liability (except alcohol, tobacco, firearms, employment and withholding taxes and specific penalties), and all offers in compromise of 100% penalties. The Branch provides taxpayer service within the assigned area (except in the Headquarters Office location).

SEC. 1118.6 *Intelligence Division.*

The Intelligence Division enforces the criminal statutes applicable to income, estate, gift, employment, and excise tax laws (except those relating to alcohol, tobacco, narcotics and certain firearms), by developing information concerning alleged criminal violations thereof, evaluating allegations and indications of such violations to determine investigations to be undertaken, investigating suspected criminal violations of such laws, recommending prosecution when warranted, and measuring effectiveness of the investigation and prosecution processes. The Division assists other Intelligence offices in special inquiries, drives and compliance programs and in the normal enforcement programs, including those combating organized wagering, racketeering and other illegal activity, by providing investigative resources upon Regional or National Office request. It also assists U.S. Attorneys and Regional Counsel in the processing of Intelligence cases, including the preparation for and trial of cases.

SEC. 1118.61 *Branches A and B.*

In districts where a branch structure has been authorized for Intelligence Division, the branch functions are as follows: The Branch conducts investigations of criminal tax violations, except those relating to alcohol, tobacco, narcotics, and certain firearms tax cases. The Branch coordinates actions with the Office of the United States Attorney and with other Divisions in the District Office. The Branch assists the United States Attorney and the Chief Counsel in the trial of cases. The Branch evaluates allegations of tax law violations and initiates surveys, examinations and investigation to identify cases which may have prosecution potential. The Branch makes appropriate recommendations as to the disposition of matters coming to the attention of the Intelligence Division and as to the disposition of cases investigated. The Branch assists in the planning, organizing, coordinating and directing the local adoption of intelligence policies, programs and procedures of Regional and National Offices. The Branch keeps informed on investigations to ensure uniformity of actions, adherence to established policies and compliance with procedures; to ensure that evidence is adequate and sufficient and that the action taken is sound and proper; and to ensure that high standards of performance are maintained.

SEC. 1118.7 *Administration Division.*

(1) The Administration Division provides the personnel, training, budget, and fiscal, procurement and supply, records and communications services and other administrative services, within the limitations of the District Director's delegated authority, necessary to the effective operation and management of the District Office. It coordinates the District Office cost reduction and management improvement, Reports Management and Incentive Awards Programs and other special projects.

(2) The organization of the Administration Division varies according to the size of the district, its managerial staffing, and other local conditions, as follows:

(a) The Division is headed by a Chief in districts above 1,000 employees and in those with *no* Assistant District Director.

(b) In districts below 1,000 employees *with* an Assistant District Director, the District Director and the Regional Commissioner may decide whether to have a Chief, a Staff Assistant, or neither.

(c) The typical branch structure in districts above 1,000 employees is Facilities Management; Personnel; and Training. Districts below 1,000 employees are also structured into these branches if the District Director and Regional Commissioner decide they are necessary. However, in small districts (normally those below 400 employees) with a Chief, Administration, the branch structure is not authorized in the absence of compelling circumstances. (See also Administration Staffing Guides Handbook, IRM 1132.)

(3) For districts with a branch structure, the following functional descriptions refer to branches. For other districts, the functional descriptions indicate functions performed by staff personnel.

SEC. 1118.71 *Facilities Management Branch.*

The Facilities Management Branch provides essential facilities and services necessary to the efficient operation of the District Office. The Branch carries out the space programs of the District Director and conducts periodic surveys to ensure effective space utilization. It procures, requisitions, issues, and ensures

effective utilization of equipment, property and office supplies; maintains records on all equipment and property located within the district; and provides communications, duplicating paperwork management, and internal management document distribution services. The Branch also furnishes data necessary for the preparation of that portion of the District Office budget estimates and financial plans which is concerned with funds required for materials and facilities in the district. As required for district management control, it maintains blotter type records of fund commitments for materials and facilities (object classes 22, 23, 24, 25, 26 and 31 as defined in Bureau of the Budget Circular A–12). It administers document and property security, emergency planning for civil defense, and the safety programs in the district.

SEC. 1118.72 *Personnel Branch.*

The Personnel Branch furnishes professional advice to district officials responsible for manpower planning and management, to insure effective utilization of human resources in the accomplishment of the district mission. It plans and provides a comprehensive program of staff support, services, and technical advice for district personnel management activities. This includes program areas of recruitment, selection, placement, performance evaluation, promotion, management career programs, manpower utilization, position classification and position management, discipline, grievances, awards, employee benefits, and union relations. The branch serves as the primary point of contact in the day-to-day relationship between recognized labor organizations and district top management and advises managers on aspects of union relations bearing on their responsibilities. It performs necessary support activities of personnel action processing, records maintenance, and personnel reporting. In all programs, it emphasizes the fulfillment of Equal Employment Opportunity Program objectives, special emphasis and other personnel program priorities, and conformance to policies, regulations, and standards set by higher authority.

SEC. 1118.73 *Training Branch.*

The Training Branch provides leadership and coordination to the district training and taxpayer education programs. It assists district management in identifying training needs and developing local training programs, including the district organizational development program. The Branch coordinates the district execution of training programs and administers the selection and scheduling of employees for training conducted outside the district. It monitors and assists management in conducting OJT programs, and in idenitfying, developing, and utilizing instructors and OJT coaches. It assists in implementing the Management Careers Program. It manages the taxpayer education program by identifying taxpayer education needs, and developing and administering the program to meet these needs. It provides information and resources to employees regarding self-development opportunities. In addition, it evaluates and reports on all district training and taxpayer education programs.

SEC. 1118.8 *Stabilization Division.*

(1) Directs and administers the District Economic Stabilization Program involving planning, organizing, coordinating, and evaluating District Stabilization activities which include: responding to inquiries from the public; disseminating information to the public; analyzing and issuing decisions upon application for exceptions and appeals; conducting investigations; resolving complaints of violations by obtaining compliance, where possible, and recommending enforcement action when necessary.

(2) Program management of District Stabilization activities is accomplished through twenty-nine Key Districts which are responsible for technical and managerial guidance to and which exercise functional supervision for Stabilization work performed in the related Associate Districts. The Key District/Associate District relationship is:

Key districts	*Associate districts*
Boston	Augusta.
	Burlington.
	Portsmouth.
Brooklyn	None.
Buffalo	Albany.
Hartford	Providence.
Manhattan	None.
Baltimore	Do.
Richmond	Do.
Newark	Do.
Philadelphia	Wilmington.
Pittsburgh	None.
Atlanta	Birmingham.
Jacksonville	None.
Greensboro	Columbia.
Nashville	Jackson.
Cincinnati	Louisville.
Indianapolis	None.
Cleveland	Parkersburg.
Detroit	None.
Chicago	Do.
St. Louis	Springfield.
Des Moines	Omaha.
St. Paul	Aberdeen.
	Fargo.
Milwaukee	None.
Austin	New Orleans.
Dallas	Albuquerque.
Oklahoma City	Cheyenne.
	Denver.
	Little Rock.
	Wichita.
Los Angeles	Honolulu.
	Phoenix.
San Francisco	Reno.
	Salt Lake City.
Seattle	Anchorage.
	Boise.
	Helena.
	Portland.

(3) The Division structure conforms to one of three established organizational patterns which are:

(a) two branches: the Compliance and Enforcement Branch and the Technical Services Branch;

(b) a Compliance and Enforcement Branch and a Technical Staff; or

(c) no branch structure—the organization is directly under the Division Chief.

(4) The particular organizational pattern authorized depends upon: the size of the Key District Office and any related Associate Districts over which functional supervision is exercised; the geographic area encompassed; and the volume and complexity of the workload of the Key District and any related Associate Districts.

(5) In Districts where a two-branch structure has been authorized for the Stabilization Division, the branches will be the Compliance and Enforcement Branch, as defined in 1118.81 below; and the Technical and Services Branch, as defined in 1118.82 below. In Districts where one branch and a staff group have been authorized for the Stabilization Division, the organization structure will be a Compliance and Enforcement Branch, as defined in 1118.81 below; and a Technical Staff which will perform these duties under the Technical and Services Branch in 1118.82 below, without the Branch supervisory structure. In the small Key Districts and all Associate Districts, the functional description of branches in 1118.81 and 1118.82 below, are performed by staff personnel. Associate Districts may use the organizational title of "Stabilization Officer" for the person who will be the primary representative of the District for Stabilization matters.

SEC. 1118.81 *Compliance and Enforcement Branch.*

This branch is responsible for matters involving compliance and enforcement activities under the Economic Stabilization regulations. This branch has operational responsibility for local investigative and industry monitoring programs, and reports on National Office directed pay or price fact-finding investigations and surveys, local enforcement activities as authorized and directed by the National Office and other special projects deemed appropriate by the Regional and/or National Office.

SEC. 1118.82 *Technical and Services Branch.*

This branch has operational responsibility for providing technical and general information to the public; analyzing and issuing decisions upon applications for exceptions and appeals; furnishing interpretive support to other organizational components of Key and Associate Districts; assuring program uniformity; operating and maintaining the Stabilization reporting and information system; and other special projects deemed appropriate by the Regional and/or National Office.

SEC. 1118.9 *Offices Below the District Headquarters.*

(1) Offices below the district headquarters (Area, Zone, and Local offices as defined below) perform one or more of certain Collection, Taxpayer Service, Audit, and Intelligence functions such as: the collection of delinquent accounts and the securing of delinquent returns; the receiving and deposit of monies tendered in payment of taxes; conducting taxpayer service and related assistance activities to meet local taxpayer needs; the examination of returns to determine correct liability of taxpayers for

tax and penalties; the holding of conferences with taxpayers and their representatives regarding the determination of liability for tax and penalties; and the investigation of alleged criminal violation of the tax statutes. They also contain, to a limited extent, other functions such as administrative support.

(2) Offices below the district headquarters are classified according to these types:

(a) *Area office.* An Area office is a major subdivision of the District Office and usually contains all of its principal functional elements including one or more groups of Revenue Agents, one or more groups of Revenue Officers, an Office Group, and a Teller. Generally, it also contains one or more Special Agents.

(b) *Zone office.* A Zone office is an intermediate size office which includes one or more groups of Revenue Agents or one or more groups of Revenue Officers. Generally, it also contains one or more Special Agents. Usually it does not have a Teller and if it has Office Group personnel, they are supervised from some other office.

(c) *Local office.* All other offices below the district headquarters are classified as Local offices. Primarily, these are small posts of duty where the workload does not warrant the stationing of Revenue Agents and Revenue Officers in group strength.

(3) Program planning and functional supervision for personnel of an Area, Zone, or Local office are the responsibilities of the appropriate divisions of the District Office. However, administrative supervision of such an office may be assigned to an individual upon a determination by the District Director that such a position is needed in order to represent all IRS functions to the public, to coordinate functions, and to provide common administrative services. This position is to be assigned as an additional responsibility to one of the regular functional personnel of the office, usually the ranking or senior officer. Each person assigned this additional responsibility will be designated as the "(inserting name of city) representative" of the District Director.

(4) Generally, offices below the district headquarters do not contain Branch Chiefs in any of the functional activities. However, if the workload of an office (including nearby offices supervised by such office) is sufficient to justify five or more Audit groups, the District Director may determine that the needs for local supervision warrant the stationing of an Audit Branch Chief in the office. Similarly, if the workload justifies five or more Revenue Officer groups (counting less than ten Office Branch employees as the equivalent of a group; or ten or more Office Branch personnel as two groups), the District Director may establish a Field Branch Chief. Recommendations for establishing such positions shall be forwarded to the Regional Commissioner for approval in accordance with regular procedures for effecting changes in organization.

(5) When the personnel of an office below the district headquarters are supervised by Group Managers or Branch Chiefs, all of the functions in such offices will generally receive line supervision from the same city in order to foster functional coordination and efficient utilization of clerical and other manpower. However, when the District Director finds that the best interests of the Service require a different arrangement, he is authorized to make an exception. Exceptions may be particularly needed for those activities, such as Intelligence, which are more thinly represented than the Audit and Collection and Taxpayer Service functions; and for specialists, such as those trained in estate, gift, and excise tax work.

APPENDIX A

INTERNAL REVENUE REGIONAL OFFICES

San Francisco, CA, ZIP 94102, 870 Market Street.
Atlanta, GA, ZIP 30303, Federal Office Building, 275 Peachtree Street, NE.
Chicago, IL, ZIP 60601, 35 East Wacker Drive.
New York, NY, ZIP 10007, Federal Office Building, 90 Church Street.
Cincinnati, OH, ZIP 45202, Federal Office Building, 550 Main Street.
Philadelphia, PA, ZIP 19102, 2 Penn Center Plaza.
Dallas, TX, ZIP 75202, Federal Office Building, 1114 Commerce Street.

APPENDIX B

APPELLATE BRANCH OFFICES

Birmingham, AL, ZIP 35203, 2121 Eighth Avenue N.
Phoenix, AZ, ZIP 85004, 222 North Central Avenue.
Los Angeles, CA, ZIP 90012, 300 North Los Angeles Street.
San Francisco, CA, ZIP 94108, 447 Sutter Street, Room 301.
Denver, CO, ZIP 80202, 20th Floor, Prudential Building, 1050 17th Street.
New Haven, CT, ZIP 06511, 110 Washington Avenue, 4th Floor, North Haven.
Washington, DC, ZIP 20009, 432 Universal Building North, 1875 Connecticut Avenue, NW.
Jacksonville, FL, ZIP 32202, Federal Office Building, 400 West Bay Street.
Miami, FL, ZIP 33130, Federal Office Building, 51 Southwest First Avenue.
Atlanta, GA, ZIP 30303, 275 Peachtree Street NE.
Chicago, IL, ZIP 60601, 35 East Wacker Drive.
Indianapolis, IN, ZIP 46206, 510 Guaranty Building, 20 North Meridian Street.
Wichita, KS, ZIP 67202, 418 South Main Street (Suboffice, Oklahoma City Branch Office.)
Louisville, KY, ZIP 40202, 267 Federal Building, 600 Federal Place.
New Orleans, LA, ZIP 70130, 444 Federal Office Building, 600 South Street.
Baltimore, MD, ZIP 21201, Room 934, Federal Building, 31 Hopkins Plaza.
Boston, MA, ZIP 02203, John F. Kennedy Federal Building, Government Center.
Detroit, MI, ZIP 48226, 600 Griswold Bldg.
St. Paul, MN, ZIP 55101, 500 Federal Building and U.S. Courthouse, 316 North Robert Street.
Kansas City, MO, ZIP 64106, 1700 Federal Office Building, 911 Walnut Street. (Suboffice, St. Louis Branch Office.)
St. Louis, MO, ZIP 63101, 1114 Market Street, Room 919.
Omaha, NE, ZIP 68102, 3132 New Federal Building, 215 North 17th Street.
Newark, NJ, ZIP 07102, Room 701 Federal Building, 970 Broad Street.
Buffalo, NY, ZIP 14202, 300 U.S. Courthouse, 68 Court Street.
New York, NY, ZIP 10007, 90 Church Street.
Greensboro, NC, ZIP 27401, 320 Federal Place, Room 525.
Cincinnati, OH, ZIP 45201, Post Office Box 2026.
Cleveland, OH, ZIP 44199, 1653 Federal Office Building, 1240 East Ninth Street.
Oklahoma City, OK, ZIP 73102, 200 Northwest Fourth Street.
Portland, OR, ZIP 97201, 1500 Southwest First Avenue.
Philadelphia, PA, ZIP 19102, 2 Penn Center Plaza, Room 927.
Pittsburgh, PA, ZIP 15222, Room 1428 Federal Building, 1000 Liberty Avenue.
Nashville, TN, ZIP 37203, 801 Broadway, Room 654.
Dallas, TX, ZIP 75202, 1100 Commerce Street, Room 12B25:
Houston, TX, ZIP 77002, 8031 Federal Building, 515 Rusk Avenue.
Salt Lake City, UT, ZIP 84111, 125 South State Street, Room 3438.
Richmond, VA, ZIP 23240, 400 North Eighth Street, Room 11028.
Seattle, WA, ZIP 98121, Sixth and Lenora Building, Room 1112.
Huntington, WV, ZIP 25701, Ninth Street and Fifth Avenue (Suboffice, Cincinnati Branch Office).
Milwaukee, WI, ZIP 53233, 735 West Wisconsin Avenue, Room 700.

APPENDIX C

INTERNAL REVENUE SERVICE CENTERS

Fresno, CA, ZIP 93730, 5045 East Butler Avenue.
Chamblee, GA, ZIP 30005, 4800 Buford Highway.
Covington, KY, ZIP 41012, 200 West Fourth Street.
Andover, MA, ZIP 01812, 310 Lowell Street.
Kansas City, MO, ZIP 64170, Federal Building, 2306 East Bannister Road.
Holtsville, NY, ZIP 11799, 1040 Waverly Avenue.
Philadelphia, PA, ZIP 19154, 11601 Roosevelt Boulevard.
Memphis, TN, ZIP 38110, 3131 Democrat Road.
Austin, TX, ZIP 78740, 3651 South Interregional Highway.
Ogden, UT, ZIP 84405, 1160 West 1200 South Street.

APPENDIX D

INTERNAL REVENUE DISTRICT OFFICES

Birmingham, AL, ZIP 35203, 2121 Building, 2121 Eighth Avenue North.
Anchorage, AK, ZIP 99501, Alaska Mutual Savings Building, Fifth and F Streets.
Phoenix, AZ, ZIP 85025, Federal Building, U.S. Courthouse, 230 North First Avenue.
Little Rock, AR, ZIP 72201, Federal Office Building, 700 West Capitol Avenue.
Los Angeles, CA, ZIP 90012, Federal Building, 300 North Los Angeles Street.
San Francisco, CA, ZIP 94102, Federal Building and Courthouse, 450 Golden Gate Avenue.
Denver, CO, ZIP 80202, Prudential Tower Building, 1050 17th Street.
Hartford, CT, ZIP 06103, Federal Building, U.S. Courthouse, 450 Main Street.
Wilmington, DE, ZIP 19801, Federal Building, Courthouse and Custom House, 844 King Street.
Jacksonville, FL, ZIP 32202, Federal Building, 400 West Bay Street.
Atlanta, GA, ZIP 30303, Federal Building, 275 Peachtree Street NE.
Honolulu, HI, ZIP 96813, U.S. Post Office, Court & Custom House and Federal Building, 335 Merchant Street.

Boise, ID, ZIP 83702, Federal Building and U.S. Courthouse, 550 West Fort Street.
Chicago, IL, ZIP 60602, State-Madison Building, 17 North Dearborn Street.
Springfield, IL, ZIP 62704, Land of Lincoln Building, 325 West Adams Street.
Indianapolis, IN, ZIP 46204, Federal Building and Courthouse, 46 East Ohio Street.
Des Moines, IA, ZIP 50309, Federal Building, 210 Walnut Street.
Wichita, KS, ZIP 67202, Federal Office Building, 412–418 South Main.
Louisville, KY, ZIP 40202, Post Office, Courthouse, and Custom House, 601 West Broadway.
New Orleans, LA, ZIP 70130, Federal Office Building, 600 South Street.
Augusta, ME, ZIP 04330, Federal Office Building, 68 Sewall Street.
Baltimore, MD, ZIP 21201, Federal Building, 31 Hopkins Plaza.
Boston, MA, ZIP 02203, John Fitzgerald Kennedy Federal Building.
Detroit, MI, ZIP 48226, Cadillac Tower Building, 65 Cadillac Square.
St. Paul, MN, ZIP 55101, Federal Building and Courthouse, 316 North Robert Street.
Jackson, MS, ZIP 39202, 301 Building, 301 North Lamar Street.
St. Louis, MO, ZIP 63101, U.S. Court and Custom House, 1114 Market Street.
Helena, MT, ZIP 59601, Federal Office Building, U.S. Post Office and Court House, West Sixth Street and Park Avenue.
Omaha, NE, ZIP 68102, Federal Office Building, 106 South 15th Street.
Reno, NV, ZIP 89502, Federal Building, U.S. Courthouse, 300 Booth Street.
Portsmouth, NH, ZIP 03810, Federal Building, U.S. Post Office, 80 Daniel Street.
Newark, NJ, ZIP 07102, Federal Building, 970 Broad Street.
Albuquerque, NM, ZIP 87101, Federal Office Building, 517 Gold Avenue SW.
Albany, NY, ZIP 12206, 855 Central Avenue.
Brooklyn, NY, ZIP 11201, U.S. Courthouse and Federal Building, 35 Tillary Street.
Buffalo, NY, ZIP 14202, Federal Office Building, 111 West Huron Street.
New York, NY, ZIP 10007, Federal Office Building, 120 Church Street.
Greensboro, NC, ZIP 27401, Federal Building, 320 Federal Place.
Fargo, ND, ZIP 58102, Federal Building and Post Office, 653 Second Avenue, North.
Cincinnati, OH, ZIP 45202, Federal Office Building, 550 Main Street.
Cleveland, OH, ZIP 44199, Federal Building, 1240 East Ninth Street.
Oklahoma City, OK, ZIP 73102, Federal Office Building and Courthouse, 200 N.W. Fourth Street.
Portland, OR, ZIP 97204, Multnomah Building, 319 S.W. Pine Street.
Philadephia, PA, ZIP 19106, William J. Green Federal Building, 600 Arch Street.
Pittsburgh, PA, ZIP 15222, Federal Building, 1000 Liberty Avenue.
Providence, RI, ZIP 02903, 130 Broadway.
Columbia, SC, ZIP 29201, Federal Building, 901 Sumter Street.
Aberdeen, SD, ZIP 57401, Executive Building, 640 Ninth Avenue, S.W.
Nashville, TN, ZIP 37203, Federal Building, Eighth Avenue and Broadway.
Austin, TX, ZIP 78701, Federal Office Building, 300 East Eighth Street.
Dallas, TX, ZIP 75202, Federal Office Building and Courthouse, 1100 Commerce Street.
Salt Lake City, UT, ZIP 84110, U.S. Post Office and Courthouse, 350 South Main Street.
Burlington, VT, ZIP 05401, Federal Building, 11 Elmwood Avenue.
Richmond, VA, ZIP 23240, Federal Building, 400 North Eighth Street.
Seattle, WA, ZIP 98121, Sixth and Lenora Building, 2033 Sixth Avenue.
Parkersburg, WV, ZIP 26101, Federal Office Building, Juliana and Fifth Streets.
Milwaukee, WI, ZIP 53202, Federal Building and Courthouse, 517 East Wisconsin Avenue.
Cheyenne, WY, ZIP 82001, Federal Office Building, 21st and Carey Streets.

APPENDIX E

REGIONAL INSPECTORS' OFFICES

Cincinnati, OH, ZIP 45202, 8514 Federal Office Building, 550 Main Street.
Philadelphia, PA, ZIP 19106, Federal Building, 600 Arch Street, Room 4228.
Chicago, IL, ZIP 60601, 35 East Wacker Drive, Suite 646.
New York, NY, ZIP 10007, 26 Federal Plaza, 14th Floor.
Atlanta, GA, ZIP 30303, 221 Courtland Street N.E., 4th Floor.
Dallas, TX, ZIP 75202, U.S. Courthouse and Federal Office Building, 1100 Commerce Street, Room 3A5.
San Francisco, CA, ZIP 94111, 160 Pine Street, Suite 500.

APPENDIX F

REGIONAL COUNSEL OFFICES

Birmingham, AL, ZIP 35203, Room 1624, 2121 Eighth Avenue, North.
Phoenix, AZ, ZIP 85004, Suite 1214, Security Center Building, 222 North Central Avenue.
Los Angeles, CA, ZIP 90053, 2018 Federal Building, 300 North Los Angeles Street.
San Francisco, CA, ZIP 94108, Room 628, 447 Sutter Street.
Denver, CO, ZIP 80202, 20th Floor, 1050 17th Street.
Jacksonville, FL, ZIP 32202, Box 35027, Federal Building, 400 West Bay Street.
Miami, FL, ZIP 33130, Room 1502, Federal Office Building, 51 Southwest First Avenue.
Atlanta, GA, ZIP 30301, Federal Office Building, 275 Peachtree Street, NE.
Chicago, IL, ZIP 60601, Room 1622, 35 East Wacker Drive.
Indianapolis, IN, ZIP 46204, 632 Illinois Building, 17 West Market Street.
Louisville, KY, ZIP 40201, 579 Federal Office Building.
New Orleans, LA, ZIP 70130, Room 845, Federal Office Building, 600 South Street.
Boston, MA, ZIP 02203, John Fitzgerald Kennedy Building, Government Center.
Detroit, MI, ZIP 48226, 2300 Cadillac Tower Building.
St. Paul, MN, ZIP 55101, Room 572, Federal Building and U.S. Courthouse, 140 East Fourth Street.
Kansas City, MO, ZIP 64106, 2700 Federal Office Building, 911 Walnut Street.
St. Louis, MO, ZIP 63101, 935 U.S. Court and Custom House, 1114 Market Street.
Omaha, NE, ZIP 68101, Room 3101, U.S. Post Office and Court House, 215 North 17th Street.
Newark, N.J., ZIP 07102, Ninth Floor, 970 Broad Street.
Buffalo, NY, ZIP 14202, 304 U.S. Courthouse, Niagara Square.
New York, NY, ZIP 10007, 26 Federal Plaza, 12th Floor.
Greensboro, NC, ZIP 27420, Room 509, 320 Federal Place.
Cincinnati, OH, ZIP 45202, 7504 Federal Office Building, 550 Main Street.
Cleveland, OH, ZIP 44114, 1620 Williamson Building, 215 Euclid Avenue.
Oklahoma City, OK, ZIP 73101, Courthouse and Federal Office Building, 220 Northwest 4th Street.
Portland, OR, ZIP 97201, 810 Crown Plaza, 1500 Southwest First Avenue.
Philadelphia, PA, ZIP 19102, Room 464, 2 Penn Center Plaza.
Pittsburgh, PA, ZIP 15230, Room 726, Federal Building.
Nashville, TN, ZIP 37202, 703 U.S. Courthouse Building, 801 Broadway.
Dallas, TX, ZIP 75202, Room 12D27, Federal Office Building, 1100 Commerce Street.
Houston, TX, ZIP 77002, 515 Rusk Avenue, Room 8102.
Salt Lake City, UT, ZIP 84111, 3438 Federal Building, 125 South State Street.
Richmond, VA, ZIP 23240, 2018 Federal Building, 8th and Marshall Streets.
Washington, DC, ZIP 20009, Room 422, Universal Building, North, 1875 Connecticut Avenue, NW.
Milwaukee, WI, ZIP 53233, Sixth Floor, Continental Plaza, 735 West Wisconsin Avenue.
Seattle, WA, ZIP 98121, 1101 Sixth and Lenora Building.
Baltimore, MD, ZIP 21201, Room 1117, Federal Building, 31 Hopkins Plaza.

[FR Doc.74–7341 Filed 3–28–74;8:45 am]

Office of the Secretary

[Dept. Circular, Public Debt Series—No. 4–74, Supp.]

8 PERCENT TREASURY NOTES OF SERIES H–1976

Notice of Interest Rate

MARCH 27, 1974.

Pursuant to the provision in section I of Department Circular—Public Debt Series—No. 4–74, dated March 21, 1974, the Secretary of the Treasury announced on March 27, 1974, that the interest rate on the notes described in the circular will be 8 percent per annum. Accordingly, the notes are hereby redesignated 8 percent Treasury Notes of Series H–1976. Interest on the notes will be payable at the rate of 8 percent per annum.

[SEAL] JOHN K. CARLOCK,
Fiscal Assistant Secretary.

[FR Doc.74–7392 Filed 3–27–74;1:52 pm]

DEPARTMENT OF DEFENSE

Department of the Air Force

AIR FORCE ACADEMY BOARD OF VISITORS

Notice of Meeting

MARCH 25, 1974.

The Air Force Academy Board of Visitors will meet at the Air Force Academy, Colorado Springs, Colorado, during the period April 24–28, 1974.

The purpose of this meeting is to fulfill the requirements of 10 U.S.C. 9355d for the Board to meet at the Academy at least once annually to inquire into matters of morale, discipline, the curriculum, instruction, physical equipment, fiscal affairs, academic matters, and other matters relating to the Academy which the Board decides to consider.

Portions of this meeting will be open for public attendance on April 25, 1974, from 9:45 a.m. until 11:45 a.m., and from 3 p.m. until 4:15 p.m., in the Academy Superintendent's Conference Room, Harmon Hall.

Among the topics on the tentative agenda during the open portion of the meeting are: the Academic Program,

Cadet Honor System, Academy Fiscal Data, and the Air Force Academy Education Center.

The remainder of the meeting will pertain to internal Academy policies, procedures, and personnel matters and will be held in closed session.

If additional information is desired, contact HQ USAF (DPPA), Washington, D.C. 20330, telephone number 202–692–4635.

STANLEY L. ROBERTS,
Colonel, USAF, Chief, Legislative Division, Office of The Judge Advocate General.

[FR Doc.74–7244 Filed 3–28–74;8:45 am]

Office of the Secretary

ADVISORY GROUP ON ELECTRON DEVICES AND WORKING GROUPS THEREOF

Notice of Meetings

The Department of Defense Advisory Group on Electron Devices and various working groups thereof, will meet in closed sessions at 201 Varick Street, New York, New York, on dates indicated below:

a. Advisory Group on Electron Devices, April 11, 1974.
b. Working Group on Passive Devices, April 30, 1974.

The purpose of the DoD Advisory Group on Electron Devices, and various working groups thereof, is to provide the Director of Defense Research and Engineering and the Military Departments with advice and recommendations on the conduct of economical and effective research and development programs in the field of electron devices, e.g., lasers, radar tubes, transistors, infrared sensors, etc. The group is also the vehicle for interservice coordination of planned R&D efforts.

In accordance with Pub. L. 92–463, section 10, paragraph (d), it is hereby determined that the AGED meetings concern matters listed in section 552(b) of Title 5 of the United States Code, particularly subparagraph (1) thereof, and that the public interest requires such meetings to be closed insofar as the requirements of subsections (a)(1) and (a)(3) of section 10, Pub. L. 92–463 are concerned.

MAURICE W. ROCHE,
Director, Correspondence and Directives OASD (Comptroller).

MARCH 26, 1974.

[FR Doc.74–7252 Filed 3–28–74;8:45 am]

DEFENSE ADVISORY COMMITTEE ON WOMEN IN THE SERVICES

Rules Governing Public Participation

On March 13, 1974 notice was given in the FEDERAL REGISTER (39 FR 9702) of an open meeting of the Defense Advisory Committee on Women in the Services (DACOWITS) to be held April 21–25, 1974 in Washington, D.C. Pursuant to section 10(a)(3) of Pub. L. 92–463, the following rules will govern the participation by members of the public attending the meeting:

(1) Since the Pentagon is closed to the general public, persons desiring to attend the session on April 22, 1974, in the Pentagon must notify the DACOWITS Secretariat (202) OXford 5–5153, by April 17, 1974, so that proper escorts to and from the meeting room can be arranged.

(2) Interested persons may submit a written statement and/or make an oral presentation for consideration by the Committee during the meeting.

(3) Persons desiring to make an oral presentation or submit a written statement to the Committee must notify Lieutenant Colonel Martha A. Cox, DAC OWITZ Executive Secretary, OASD (Manpower and Reserve Affairs), Room 2B257, The Pentagon, Washington, D.C. 20301, by April 5, 1974.

(4) Length and number of oral presentations to be made will depend on the number of requests received. Maximum time permitted per presentation will be twenty (20) minutes.

(5) Oral presentations will be permitted only from 3:30 p.m. to 5:00 p.m. on April 22, 1974, in the Pentagon before the full committee.

(6) Each person desiring to make an oral presentation must provide the DACOWITS Secretariat with a copy of the presentation by April 15, 1974, to assist in the scheduling of speakers.

(7) Persons submitting a written statement for consideration by the Committee at the meeting must provide a minimum of forty (40) copies of such statement to the DACOWITS Secretariat by April 15, 1974, in order to provide each Committee member with a copy of the statement.

(8) Persons submitting a written statement only for inclusion in the minutes of the meeting must submit one (1) copy either before or during the meeting or within ten (10) days after the close of the meeting.

(9) Members of the public will not be permitted to enter into the oral discussion conducted by the Committee members at any of the sessions.

(10) Members of the public will not be permitted to orally question the speakers or members of the Committee during any session, but may submit written questions to the DACOWITS Chairman at the time she designates for this purpose. If time permits after members of the Committee have asked questions and/or made comments, the Chairman will present the written questions from members of the public to the speaker for response.

(11) Questions from members of the public will not be accepted during the new member orientation, the subcommittee sessions, the executive committee sessions or the final general session.

MAURICE W. ROCHE,
Director, Correspondence and Directives OASD (Comptroller)

MARCH 25, 1974.

[FR Doc.74–7254 Filed 3–28–74;8:45 am]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 74–3]

ALEXANDER ROBBINS

Notice of Hearing

Notice is hereby given that on February 5, 1974, the Drug Enforcement Administration, Department of Justice, issued to Alexander Robbins, M.D., Miami Beach, Florida, an Order to Show Cause as to why the Drug Enforcement Administration registration No. AR0148406 issued to him pursuant to section 303 of the Controlled Substances Act (21 U.S.C. 823) should not be revoked.

Thirty days having elapsed since said Order was received by Dr. Robbins, and written request for a hearing having been filed with the Drug Enforcement Administration, notice is hereby given that a hearing in this matter will be held commencing at 10:00 a.m. on April 8, 1974, in Room 208, Federal Office Building, 51 SW. First Avenue, Miami, Florida.

Dated: March 25, 1974.

ANDREW C. TARTAGLINO,
Acting Deputy Administrator, Drug Enforcement Administration.

[FR Doc.74–7274 Filed 3–28–74;8:45 am]

DEPARTMENT OF THE INTERIOR

Bonneville Power Administration

PUBLIC MEETING

Notice of Change of Date

Notice is hereby given of a change in the scheduled date of a public information meeting on Bonneville Power Administration's Fiscal Year 1975 Draft Environmental Statement.

Notification of the public meeting previously scheduled for Tuesday, April 2, 1974, at 7:30 p.m. appeared in the FEDERAL REGISTER on Friday, February 8, 1974 (39 FR 4934). This meeting has been postponed and as announced in the FEDERAL REGISTER on Thursday, March 21, 1974 (39 FR 10633), will be held instead on Tuesday, April 23, 1974. As previously arranged, the meeting is still to be conducted at the Islander Lopez Motel, Lopez Island, Washington, at 7:30 p.m.

Dated: March 27, 1974.

WILLIAM H. CLAGETT,
Assistant Administrator.

[FR Doc.74–7381 Filed 3–28–74;8:45 am]

Fish and Wildlife Service

GRIZZLY BEAR

Notice of Review of Status

On February 14, 1974, the Department of the Interior received a petition from the Fund for Animals of Washington, D.C. seeking, inter alia, a Departmental review of the status of the grizzly bear (*Ursus arctos horribilis*) for the purposes of determining whether that species should be listed, pursuant to section 4 of the Endangered Species Act of 1973, as

an endangered or threatened species within the lower 48 States of the United States.

As required by section 4(c)(2) of the Act, notice is hereby given of the Department's determination that substantial evidence has been presented by the petition to warrant a review of the status of the grizzly bear to determine whether the grizzly bear should be proposed for listing as either an endangered or threatened species. The Department is seeking the views of the Governors of the States of Montana, Wyoming, Idaho, Washington, and Colorado, on the issues presented by the petition, and has requested a report and recommendation of the National Academy of Sciences.

All other interested parties are hereby invited to submit any factual information which is germane to this review of the status of the grizzly bear within the lower 48 States of the United States. Such information should be sent to: Director, Bureau of Sport Fisheries and Wildlife, U.S. Department of the Interior, Washington, D.C. 20240. These views and recommendations together with the evidence presented and available to the Secretary and that provided with the petition of the Fund for Animals, will be reviewed to determine whether sufficient evidence is available to support the action requested by the petition.

LYNN A. GREENWALT,
Director, Bureau of Sport Fisheries and Wildlife.

MARCH 26, 1974.

[FR Doc.74-7298 Filed 3-28-74;8:45 am]

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

A. V. TISCHER AND SON, INC.

Iowa Grain Inspection Point

Notice is hereby given pursuant to section 26.101 of the regulations (7 CFR 26.101) under the U.S. Grain Standards Act (7 U.S.C. 71 et seq.) that the A. V. Tischer and Son, which is designated under section 7(f) of the U.S. Grain Standards Act (7 U.S.C. 79(f)) to operate as an official inspection agency at Ft. Dodge, Iowa, has changed its name to A. V. Tischer and Son, Inc. The change in name does not involve a change in management or ownership.

Done in Washington, D.C. on March 26, 1974.

E. L. PETERSON,
Administrator, Agricultural Marketing Service.

[FR Doc.74-7339 Filed 3-28-74;8:45 am]

Cooperative State Research Service

COMMITTEE OF NINE

Notice of Meeting

Pursuant to the Federal Advisory Committee Act, Pub. L. 92-463, notice is hereby given of a meeting of the Committee of Nine at 8:30 a.m. on April 17 and 8:30 a.m. on April 18, 1974, in room 509-A of the Administration Building, U.S. Department of Agriculture.

The purpose of the meeting is to evaluate and recommend proposals for cooperative research on problems that concern agriculture in two or more States and to prepare recommendations for allocation of research funds. The meeting is open to the public and written statements can be filed with the Committee before or after the meeting.

The names of the members of the Committee, the agenda, minutes, and other information pertaining to the meeting may be obtained from the Recording Secretary, Committee of Nine, Cooperative State Research Service, U.S. Department of Agriculture, Washington, D.C. 20250, telephone 202-447-5260.

Dated: March 18, 1974.

T. S. RONNINGEN,
Acting Administrator, Cooperative State Research Service.

[FR Doc.74-7340 Filed 3-28-74;8:45 am]

Forest Service

DESCHUTES NATIONAL FOREST MULTIPLE USE ADVISORY COMMITTEE

Notice of Meeting

The Deschutes National Forest Advisory Council will meet at 6:30 p.m. on April 11, 1974, at the Copper Room, 125 Oregon Avenue. Dinner will be at 7:00 p.m. at Original Joe's, 1033 Bond, Bend, Oregon, with the program to follow at 8:00 p.m.

The subject of this meeting is Solid Waste Disposal and Water Pollution Abatement Program for the Deschutes National Forest. This will be presented by Forest Engineer, Beryl Johnston.

The meeting will be open to the public.

EARL E. NICHOLS,
Forest Supervisor.

MARCH 21, 1974.

[FR Doc.74-7263 Filed 3-28-74;8:45 am]

BIGHORN NATIONAL FOREST MULTIPLE USE ADVISORY COMMITTEE

Notice of Meeting

The Bighorn National Forest Multiple Use Advisory Committee will meet at 9:00 a.m., May 22, 1974, at the Buffalo District Ranger's Office in Buffalo, Wyoming for their spring field trip. The purpose of this meeting is to discuss the Forest Interim Multiple Use Plan and view the cleanup and accomplishments of the Privy Timber Sale since last fall.

The meeting will be open to the public. Persons who wish to attend should notify the Forest Supervisor, P.O. Box 2046, Sheridan, Wyoming 82801 or call (307) 672-2457. Written statements may be filed with the committee before or after the meeting.

The committee has not established rules for public participation. Public members may speak up at any time.

ANTHONY K. QUINKERT,
Forest Supervisor.

MARCH 22, 1974.

[FR Doc.74-7242 Filed 3-28-74;8:45 am]

DEPARTMENT OF COMMERCE

Office of the Secretary

[Department Organization Order 25-5A; Amdt. 4]

NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION

Delegation of Authority

This order, effective March 13, 1974, further amends the material appearing at 37 FR 12245 of June 21, 1972; 37 FR 26745 of December 15, 1972; 38 FR 5277 of February 27, 1973; and 39 FR 6752 of February 22, 1974. National Oceanic and Atmospheric Administration.

Department Organization Order 25-5A, dated May 19, 1972, is hereby further amended as follows:

SEC. 3. *Delegation of Authority.* The following new subparagraph is added under paragraph .01.

z. The functions prescribed by Pub. L. 92-532, the Marine Protection, Research, and Sanctuaries Act of 1972 (86 Stat. 1052).

Effective date: March 13, 1974.

FREDERICK B. DENT,
Secretary of Commerce.

[FR Doc.74-7289 Filed 3-28-74;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

ADVISORY COMMITTEES

Notice of Meetings

Pursuant to the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463, 86 Stat. 770-776 (5 U.S.C. App.)), the Food and Drug Administration announces the following public advisory committee meetings and other required information in accordance with provisions set forth in section 10(a) (1) and (2) of the act:

Committee name	Date, time, place	Type of meeting and contact person
1. Panel on Review of Internal Analgesic including Anti-rheumatic Drugs.	April 10 and 11, 9 a.m., Conference Room A, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md.	Open April 10, 9 a.m. to 10 a.m., closed April 10 after 10 a.m., closed April 11. Lee Geismar, Room 10B-05, 5600 Fishers Lane, Rockville, Md. 20852, 301-443-4960.

Purpose. Reviews and evaluates available information concerning safety and effectiveness of active ingredients of currently marketed nonprescription drug

products containing internal analgesic agents.

Agenda. Open session: Comments and presentations by interested persons. Closed session: Continuing review of nonprescription internal analgesic drugs under investigation.

Committee name	Date, time, place	Type of meeting and contact person
2. Cardiovascular and Renal Advisory Committee.	April 19, 8:30 a.m., Conference Room A, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md.	Open 8:30 a.m. to 9:30 a.m., closed after 9:30 a.m. John B. MacGregor, M.D., Room 16B-20, 5600 Fishers Lane, Rockville, Md. 20852, 301-443-4731.

Purpose. Advises the Commissioner of Food and Drugs regarding the safety efficacy of drugs employed in cardiovascular and renal disorders:

Agenda. Open session: Finalization of prescription labeling for Digoxin and discussion of patient package insert for digitalis. Closed session: Discussion of safety and efficacy of diphenyl in treatment of cardiac arrhythmias.

Committee name	Date, time, place	Type of meeting and contact person
3. Panel on Review of Antiperspirant Drug Products.	April 25 and 26, 9 a.m., Room 12B-45, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md.	Open April 25, 9 a.m. to 10 a.m., closed April 25 after 10, a.m. closed April 26. Lee Geismar, Room 10B-05, 5600 Fishers Lane, Rockville, Md. 20852, 301-443-4960.

Purpose. Reviews and evaluates available data concerning the safety and effectiveness of active ingredients, and combinations thereof, of currently marketed nonprescription drug products for human use containing antiperspirant drug products, and adequacy of their labeling.

Agenda. Open session: Comments and presentations by interested persons. Closed session: Continued review of the safety and efficacy of antiperspirant drug products.

Agenda items are subject to change as priorities dictate.

During the open sessions shown above, interested persons may present relevant information or views orally to any committee for its consideration. Information or views submitted to any committee in writing before or during a meeting shall also be considered by the committee.

A list of committee members and summary minutes of meetings may be obtained from the contact person for the committee both for meetings open to the public and those meetings closed to the public in accordance with section 10(d) of the Federal Advisory Committee Act.

Most Food and Drug Administration advisory committees are created to advise the Commissioner of Food and Drugs on pending regulatory matters. Recommendations made by the committees on these matters are intended to result in action under the Federal Food, Drug, and Cosmetic Act, and these committees thus necessarily participate with the Commissioner in exercising his law enforcement responsibilities.

The Freedom of Information Act recognized that the premature disclousre of regulatory plans, or indeed internal discussions of alternative regulatory approaches to a specific problem, could have adverse effects upon both public and private interests. Congress recognized that such plans, even when finalized, may not be made fully available in advance of the effective date without damage to such interests, and therefore provide for this type of discussion to remain confidential. Thus, law enforcement activities have long been recognized as a legitimate subject for confidential consideration.

These committees often must consider trade secrets and other confidential information submitted by particular manufacturers which the Food and Drug Administration by law may not disclose, and which Congress has included within the exemptions from the Freedom of Information Act. Such information includes safety and effectiveness information, product formulation, and manufacturing methods and procedures, all of which are of substantial competitive importance.

In addition, to operate most effectively, the evaluation of specific drug or device products requires that members of committees considering such regulatory matters be free to engage in full and frank discussion. Members of committees have frequently agreed to serve and to provide their most candid advice on the understanding that the discussion would be private in nature. Many experts would be unwilling to engage in candid public discussion advocating regulatory action against a specific product. If the committees were not to engage in the deliberative portions of their work on a confidential basis, the consequent loss of frank and full discussion among committee members would severely hamper the value of these committees.

The Food and Drug Administration is relying heavily on the use of outside experts to assist in regulatory decisions. The Agency's regulatory actions uniquely affect the health and safety of every citizen, and it is imperative that the best advice be made available to it on a continuing basis in order that it may most effectively carry out its mission.

A determination to close part of an advisory committee meeting does not mean that the public should not have ready access to these advisory committees considering regulatory issues. A determination to close the meeting is subject to the following conditions: First, any interested person may submit written data or information to any committee, for its consideration. This information will be accepted and will be considered by the committee. Second, a portion of every committee meeting will be open to the public, so that interested persons may present any relevant information or views orally to the committee. The period for open discussion will be designated in any announcement of a committee meeting. Third, only the deliberative portion of a committee meeting, and the portion dealing with trade secret and confidential information, will be closed to the public. The portion of any meeting during which nonconfidential information is made available to the committee will be open for public participation. Fourth, after the committee makes its recommendations and the Commissioner either accepts or rejects them, the public and the individuals affected by the regulatory decision involved will have an opportunity to express their views on the decision. If the decision results in promulgation of a regulation, for example, the proposed regulation will be published for public comment. Closing a committee meeting for deliberations on regulatory matters will therefore in no way preclude public access to the committee itself or full public comment with respect to the decisions made based upon the committee's recommendation.

The Commissioner has been delegated the authority under section 10(d) of the Federal Advisory Committee Act to issue a determination in writing, containing the reasons therefor, that any advisory committee meeting is concerned with matters listed in 5 U.S.C. 552(b), which contains the exemptions from the public disclosure requirements of the Freedom of Information Act. Pursuant to this authority, the Commissioner hereby determines, for the reasons set out above, that the portions of the advisory committee meetings designated in this notice as closed to the public involve discussion of existing documents falling within one of the exemptions set forth in 5 U.S.C. 552(b), or matters that, if in writing, would fall within 5 U.S.C. 552(b), and that it is essential to close such portions of such meetings to protect the free exchange of internal views and to avoid undue interference with Agency and committee operations. This determination shall apply only to the designated portions of such meetings which relate to trade secrets and confidential information or to committee deliberations.

Dated: March 25, 1974.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

[FR Doc.74-7278 Filed 3-28-74;8:45 am]

Office of the Secretary

ASSISTANT SECRETARY FOR HUMAN DEVELOPMENT

Statement of Organization, Functions, and Delegations of Authority

Part 1 of the Statement of Organization, Functions, and Delegations of Authority is amended to include these changes: (1) Amendment to Chapter 1R (38 FR 17260-1, 6/29/73). This chapter is revised to include information on the newly-established Office for the Handicapped which replaces the Office of Mental Retardation Coordination, and on the Office of Native American Programs.

(2) Addition of a new Subchapter 1R55, Office for the Handicapped. This new subchapter describes in detail the mission, organization, and functions of the Office for the Handicapped. (3) Addition of a new Subchapter 1R60001, President's Committee on Mental Retardation. This new subchapter describes in detail the mission, organization, and functions of the President's Committee on Mental Retardation.

1R00. *Mission.* Serves as the principal staff adviser to the Secretary and the Under Secretary on matters dealing with special populations served by the Department, including the aging, children, youth, Native Americans, the mentally retarded, the handicapped, and those living in rural areas; recommends to the Secretary action for improving coordination and government-wide effectiveness in these areas; provides responsive and effective programs for groups of people and ensures that other Department programs also recognize and serve the needs of these people; directs, coordinates, and manages Human Development programs, ordering priorities within the Office of Human Development, approving strategies and ensuring that lines of communication to the Secretary, other HEW operating programs, and interest groups are open and responsive. Provides information for departmental policy-making.

1R10. *Organization.* The Office of the Assistant Secretary for Human Development, headed by the Assistant Secretary for Human Development who reports directly to the Secretary, consists of:

A. Immediate Office of the Assistant Secretary for Human Development.

B. Office of Administration and Management.

C. Office for the Handicapped.

D. President's Committee on Mental Retardation.

E. President's Council on Physical Fitness and Sports.

F. Office of Child Development.

G. Office of Youth Development.

H. Administration on Aging.

I. Office of Rural Development.

J. Office of Native American Programs.

1R20. *Functions.* Detailed functions of certain organizational elements of the Office of the Assistant Secretary for Human Development will be described in separate subchapters.

Functions. A. Immediate Office of the Assistant Secretary. Provides executive direction, leadership and guidance to all regional offices and ASHD components for the operation of Human Development programs. Determines the need for and approval of policy, basic systems, including handicapped program systems, and procedures, organization, program, budget plans, and Delegations of Authority which guide Human Development operations.

Directs planning development and coordinates all planning activities for ASHD, including OPS and long range planning. Tracks and reports progress on planning activities for the Assistant Secretary.

Functions. B. Office of Administration and Management. The Office of Administration and Management provides executive administrative management to ASHD offices; develops and recommends to the ASHD policy, systems, procedures, plans, organizational changes and management improvements; implements approved strategies throughout the various ASHD offices; focal point for budget activities of ASHD offices including budget development, justification, execution development of policies and procedures, and liaison with AS Comptroller for ASHD and its offices; liaison with appropriate OS offices for expenditure controls and responsible for expenditure controls within ASHD; develops, coordinates, and implements grants policy in conjunction with appropriate HEW policy and procedures; responsible for ASHD grants administration, including developing procedures and requirements for processing and review; recommends approval of certain grant actions; liaison with appropriate HEW contracting offices; responsible for provision of administrative and technical support for contracts, provides staff support to ASHD offices on all management issues.

The Office of Administration and Management is responsible for Management Analysis including: management studies of the ASHD organization, manpower utilization, methods analysis, cost reduction, and establishing standards; provides technical and staff assistance to ASHD; and provides unified Data Systems Management for ASHD organizations. The office serves as a focal point for studies and initiatives for ASHD organizations; responsible for administrative management functions, including personnel functions in conjunction with the Office of The Secretary Personnel Office, centralized support services, procurement, space allocation of ASHD office, processing travel requests and claims and other general administrative duties.

Functions. C. The Office for the Handicapped. Serves as the focal point for coordination and evaluation of Department-wide policies, programs, procedures, and activities related to the handicapped and mentally retarded; serves in an advisory capacity to the Secretary in regard to issues related to the administration of the Department's handicapped and mental retardation programs. Detailed description of the functions of the Office appear in Subchapter 1R55.

Functions. D. The President's Committee on Mental Retardation. Provides service and assistance in the areas of mental retardation as the President may require; evaluates the national effort to combat mental retardation and assists in the coordination of Federal, State, local, and private program review and planning activities in the mental retardation field; assists in the formulation of new program initiatives.

Functions. E. President's Council on Physical Fitness and Sports. The function of the President's Council on Physical Fitness and Sports is to carry out responsibilities stated in Executive Order 11562; these functions include establishing a program of Physical Fitness and Sports, advising the President and Secretary on Physical Fitness and Sports, coordinating the conference on Physical Fitness and Sports, and other duties as outlined in Executive Order 11562.

Functions. F. Office of Child Development. The function of the Office of Child Development is to advise the Secretary through the Assistant Secretary for Human Development and HEW agencies on Department plans and programs related to child development; to operate the Head Start and other related child service programs; and to provide leadership, advice, and services which affect the general well-being of children as mandated by the Act of April 9, 1912. Detailed functions of the Child Development will follow in Chapter 1R40.

Functions. G. Office of Youth Development. The function of the Office of Youth Development is to provide leadership in the planning, development, and coordination of those Federal programs that provide services to youth in danger of becoming delinquent. The Office coordinates its activities with other concerned Federal organizations to assure a unified approach to common target groups and to afford comprehensive services to the individual.

Within the authorities delegated to it, the Office of Youth Development administers, under the Juvenile Delinquency Prevention Act, Pub. L. 92–381, Federal grants and contracts designed to help State and local communities in providing community based preventive services including diagnosis and treatment, to youths who are in danger of becoming delinquent, to provide assistance in the training of personnel employed or preparing for employment in fields related to the provision of such services, and to provide technical assistance in such field. A detailed description will follow in Subchapter 1R20.

Functions. H. Administration on Aging. The Administration on Aging (AoA) is the Federal focal point for the needs, concerns, and interest of older persons and the principal agency for carrying out the programs of the Older Americans Act. It coordinates its activities with public and private organizations at the national, State, and local level to assure that the elderly are adequately considered in the planning and implementation of the programs of their organizations, and to promote the development of comprehensive and coordinated service systems to serve the elderly.

It develops program goals and objectives in terms of 5 year forward plans and current operational plans; conducts a research, development, and demonstration program to add to the basic knowledge about older persons' special capabilities and problems, and to develop and test new techniques designed to deal with the needs and problems of the elderly; assesses manpower requirements in the field of aging, makes reports and recommendations on meeting the manpower

needs, and designs and develops strategies for implementing the recommendations.

It analyzes the progress and problems of the programs of other agencies in serving the elderly; develops initiatives for improvements or innovations in these programs to better serve older persons; promotes coordination of the programs of the various agencies which affect the elderly.

It serves as a clearinghouse on information related to the problems of older persons and programs designed to deal with those problems; convenes conferences of public and private organizations concerned with the development and operation of programs for the elderly; analyzes and comments on budget and legislative proposals, program regulations, and program plans and initiatives from other agencies which would have impact on the elderly.

It administers a Federal-State-local grant program (Title III of the Older Americans Act) which provides support for: (a) State Agencies on Aging, which perform functions at the State level similar to those of the Administration on Aging at the Federal level; (b) Area Agencies on Aging, which provide leadership to public and private non-profit providers of services in their area in the development and implementation of a plan leading towards comprehensive and coordinated services for the elderly, and provide selective funding support to agencies to stimulate implementation of the plan; and (c) local community projects in areas not served by an Area Agency on Aging to provide needed services which are not furnished by other agencies.

It administers a grant program for training and research (Title IV of the Older Americans Act) which provides support for: A broad range of training responsive to the changing needs of programs in the field of aging; appraising personnel needs in the field of aging; attracting qualified persons to the field of aging; the study of current patterns of living conditions of older persons; developing and demonstrating approaches and methods for improving coordination of community services; evaluating these approaches; and grants for multidisciplinary centers of gerontology.

It administers a grant program (Title V of the Older Americans Act) for the acquisition, alteration or renovation of multipurpose senior centers including the provision of mortgage insurance for multipurpose senior centers, and initial staffing of such centers.

It develops regulations, policies and procedures for the Title III, IV, V and VII programs; provides technical assistance to the State agencies in program development and operation; and monitors progress.

It evaluates the administration of program operations in terms of progress toward goals and achievements of objectives; uses the results of evaluations to review plans and improve programs.

A detailed description will follow in Subchapter 1R10.

Functions. I. Office of Rural Development. The Office of Rural Development is concerned with the delivery of HEW services to non-metropolitan areas in concert with revenue sharing.

The Director of the Office reports to the Assistant Secretary for Human Development.

The Office will identify barriers to the delivery of services; design and recommend human services delivery systems in rural areas, coordinate efforts with other Federal agencies to select target areas for delivery of human services, and represent the Department in interdepartmental task forces concerned with rural development.

Functions. J. Office of Native American Programs (ONAP). The Office of Native American Programs is concerned with the social and economic well-being and progress of American Indians and Alaskan Natives. The Office has primary responsibility for developing national policies and legislative proposals and for providing leadership activities designed to assist American Indians and Alaskan Natives. The Office administers a Federal grants program to eligible Indian tribes and groups and provides liaison with other Federal agencies on Indian affairs. It explores new program concepts and new methods for increasing Indian self-determination, fosters opportunities for the exercise of Indian leadership and the operation of Indian businesses, and encourages increased involvement of the private sector in economic development programs on reservations. A detailed description of the functions of the Office appears in Subchapter 1R91.

1R30. *Delegations of Authority.* Except as provided in section 1A–30 of the DHEW Organization Manual and in this section, the Assistant Secretary for Human Development has been delegated the following functions by the Secretary:

1. The functions vested in the Secretary by the Older Americans Act of 1965, (42 U.S.C. 3001 et seq.).

2. The functions vested in the Secretary by the Juvenile Delinquency Prevention Act (42 U.S.C. 3801 et seq.).

3. The authority under section 222 (a) (1) of the Economic Opportunity Act of 1964, delegated by the Director of the Office of Economic Opportunity to the Secretary (42 U.S.C. 2809 et seq.).

4. Such functions with respect to research, demonstration and training projects under section 426 of the Social Security Act to the extent of the funds appropriated to the Office of Child Development for this purpose.

Office of Human Development

Office for the Handicapped; Statement of Organization and Functions

A new Subchapter 1R55 Office for the Handicapped reads as follows:

1R55.00 *Mission.* The Office for the Handicapped (OFH) implements the provisions of section 405 of the Rehabilitation Act of 1973, by providing a focal point within the Office of Human Development (OHD) for review, coordination, information and planning related to policies, programs, procedures and activities within HEW and other Federal agencies relevant to the physically and mentally handicapped.

1R55.10 *Organization.* The Office for the Handicapped is under the direction of the Director, OFH, who reports directly to the Assistant Secretary for Human Development. The Office includes a staff of specialists who are responsible for planning and evaluating programs, coordination, and the dissemination of information related to problems affecting the handicapped.

1R55.20 *Functions.* The Office for the Handicapped carries out its mission through the following functions:

1. Serves as the focal point in the Department for the consideration of issues and policies affecting the handicapped.

2. Prepares a long-range plan that includes projection for the provision of comprehensive services to handicapped individuals, and for programs of research, evaluation, and training related to such services and individuals.

3. Analyzes on a continuing basis: program operations to determine consistency with applicable provisions of law; progress towards meeting the goals and priorities set forth in the long-range plan; and the effectiveness of all programs providing services to all handicapped individuals. Seeks the elimination of unnecessary duplication and overlap in such programs under the jurisdiction of the Secretary.

4. Encourages coordinated and cooperative planning designed to produce maximum effectiveness, sensitivity, and continuity in the provision of services for handicapped individuals by all programs.

5. Develops means of promoting the prompt utilization of engineering and other scientific research to assist in solving problems in education, health, employment, rehabilitation, architectural, housing, and transportation barriers, and other areas so as to bring about full integration of all handicapped individuals into all aspects of society.

6. Provides a central clearinghouse for information and resource availability for handicapped individuals. This includes evaluation of information and data systems within the Department of Health, Education, and Welfare, other departments and agencies of the Federal government, public and private agencies and organizations of other sources.

Office of Assistant Secretary for Human Development, President's Committee on Mental Retardation

Statement of Organization and Functions

Part 1 of the Statement of Organization and Functions for the Department of Health, Education, and Welfare, Office of the Secretary, Assistant Secretary for Human Development is amended to add a new Subchapter 1R60001 which reads as follows:

1R60001.00 *Mission.* The President's Committee on Mental Retardation (PCMR), located in the Office of Human Development, DHEW, is responsible for advising and assisting the President on all matters pertaining to mental retardation.

The Committee, through the Assistant Secretary for Human Development, evaluates national, State and local mental retardation efforts, helps to coordinate relevant Federal activities, and facilitates communication between Federal, State and local agencies. In addition, the Committee informs the public about mental retardation and mobilizes support for related activities.

The Committee was established by Executive Order 11280 on May 11, 1966.

1R60001.10 *Organization.* The Committee consists of the Secretary of HEW, the Secretary of Labor, the Director of the Office of Economic Opportunity, and not more than twenty-one other members who shall be appointed by the President from public or private life. Staff support for the Committee is provided by an Executive Director and staff. The Executive Director reports to the Assistant Secretary for Human Development.

1R60001.20 *Functions.* A. The President's Committee on Mental Retardation shall provide such advice and assistance in the area of mental retardation as the President may from time to time request, including assistance with respect to:

(1) Evaluation of the national effort to combat mental retardation;

(2) Coordination of activities of Federal agencies in the mental retardation field;

(3) Provision of adequate liaison between such Federal activities and related activities of State and local governments, foundations, and other private organizations; and

(4) Development of such information, designed for dissemination to the general public, as will tend to reduce the incidence of mental retardation and ameliorate its effects.

B. The Committee shall make such reports or recommendations to the President concerning mental retardation as he may require or the Committee may deem appropriate. Such reports shall be made at least annually.

Dated: March 15, 1974.

S. H. CLARKE,
Acting Assistant Secretary for Administration and Management.

[FR Doc.74-7333 Filed 3-28-74;8:45 am]

SOCIAL SECURITY ADMINISTRATION

Statement of Organization, Functions, and Delegations of Authority

The Statement of Organization, Functions and Delegations of Authority for the central office of the Bureau of Hearings and Appeals (BHA) in the Social Security Administration (Part 4 of the Statement of Organization, Functions and Delegations of Authority for the Department of Health, Education, and Welfare), is hereby revised to reflect the establishment of the new position of Chief Administrative Law Judge in the Office of the Bureau Director, with responsibility for providing leadership to the nationwide corps of Administrative Law Judges and SSI Hearing Examiners within the Social Security Administration (SSA); to reflect the abolishment of the Office of the Assistant Bureau Director, Division of Field Operations; to reflect the establishment of the new position of Assistant Bureau Director, Division of Policy and Procedures, with responsibility for the review, development and implementation of policies and procedures pertaining to the hearings and appeals process in SSA; to reflect a change in the title of the Director, Division of Administration to Assistant Bureau Director, Division of Administration, and to update the functional statement for that office; to reflect the establishment of the new position of Assistant Bureau Director, Division of Appeals Operations, with responsibility for providing the Bureau's Appeals Council with analytical staff support; to reflect the establishment of the new position of Chief of the Appraisal Staff, with responsibility for conducting a program to assure a continuous appraisal of Bureau-wide efforts in meeting the Bureau's basic mission; and to reflect the functions assigned to components of BHA's central office. This material reads as follows:

MISSION

The Bureau of Hearings and Appeals (BHA) directs and administers the hearings and appeals process for the Social Security Administration (SSA). It directs a nationwide field hearings organization staffed with Administrative Law Judges and SSI Hearing Examiners who conduct impartial hearings and make decisions on appealed determinations involving retirement, survivors, disability, health insurance, black lung and supplemental security income benefits. It performs regional and central reviews of appealed Administrative Law Judge and SSI Hearing Examiner decisions and renders the Secretary's final decision on such cases.

ORGANIZATION

The central office of BHA, under the supervision of a Bureau Director, consists of:

1. The Bureau Director
2. The Immediate Office of the Bureau Director
3. Functional components within BHA

The Bureau Director. A. The Director of BHA is directly responsible to the Commissioner of Social Security and provides general supervision to each component in BHA.

B. In the event of the absence or disability of the Bureau Director, or in the event of a vacancy in this position, the Deputy Bureau Director acts for him.

C. In the event of the absence or disability of both the Bureau Director and the Deputy Bureau Director, or in the event of vacancies in both positions, a designated BHA executive acts for them.

Immediate Office of the Bureau Director. The Immediate Office of the Bureau Director consists of:

1. The Director of BHA
2. The Deputy Director of BHA
3. The Chief Administrative Law Judge

Functional Components Within BHA. The Bureau consists of the following functional components:

1. Appeals Council
2. Medical Advisory Staff
3. Office of the Assistant Bureau Director, Division of Policy and Procedures
4. Office of the Assistant Bureau Director, Division of Administration
5. Office of the Assistant Bureau Director, Division of Appeals Operations
6. Appraisal Staff

FUNCTIONS

The central office of BHA is responsible for:

1. Planning, directing, coordinating, administering and appraising the nationwide SSA hearings and appeals process.

2. Reviewing appeals filed in Federal courts on appealed actions or decisions, and recommending whether to defend or to request remand for further action.

3. Providing medical and vocational specialist services to Administrative Law Judges, SSI Hearing Examiners and Appeals Council members.

4. Developing substantive and administrative operating instructions to assure uniform and fair appellate review.

5. Conducting liaison with other components of SSA, DHEW, and other governmental, professional and private organizations.

Immediate Office of the Bureau Director. A. The Director of BHA:

1. Is responsible to the Commissioner of Social Security for providing overall executive leadership in implementing a fair and impartial hearings and appeals process within SSA.

2. Plans and directs the overall management of BHA to assure that the Bureau's mission is efficiently and effectively accomplished.

B. The Deputy Director of BHA assists the Bureau Director in carrying out his responsibilities, performs such duties as he requires and acts in his behalf when he is absent.

C. The Chief Administrative Law Judge:

1. Provides professional leadership to the nationwide corps of Administrative Law Judges and SSI Hearing Examiners.

2. Serves as the focal point of communication between the Office of the Bureau Director and Administrative Law Judges and SSI Hearing Examiners.

3. Directs a small professional staff engaged in maintaining close contact with the field hearings organization to obtain and assess the views of Administrative Law Judges and SSI Hearing Examiners on hearings operations.

Functional Components Within BHA. The functional components within BHA, and their responsibilities are as follows:

1. The Appeals Council, which is responsible for:

a. Reviewing decisions of Administrative Law Judges and SSI Hearing Examiners involving retirement, survivors disability, health insurance and supplemental security income benefits under the provisions of titles II, XVI and XVIII of the Social Security Act, as amended, and disability and survivors benefits under Part B of title IV and related provisions of the Federal Coal Mine Health motion of appellants or on its own motion.

b. Examining case records, obtaining additional evidence and rendering written decisions or orders which are the Secretary's final decisions or orders, or remanding cases to Administrative Law Judges and SSI Hearing Examiners.

c. Determining and recommending action in relation to decisions appealed to the courts.

d. Obtaining additional evidence and preparing supplemental decisions on remanded cases, and recommending whether appeals should be taken to higher courts on judicial reversals of the Secretary's decisions.

2. The Medical Advisory Staff which is responsible for:

a. Providing medical advisory services to the Appeals Council and other BHA components in the evaluation of disability, health insurance and supplemental security income cases under the provisions of titles II, XVI, and XVIII of the Social Security Act, as amended, and disability and survivors cases under Part B of title IV and related provisions of the Federal Coal Mine Health and Safety Act of 1969, as amended.

b. Assisting in medical training of Bureau staff.

c. Negotiating for the services of medical specialists to serve as special consultants to the Appeals Council, and as advisors to Administrative Law Judges, SSI Hearing Examiners, Regional Appeals Panels and Regional Chief Administrative Law Judges.

d. Providing guidance in the effective utilization of medical advisors throughout BHA.

e. Participating in the formulation of medical policies used in the evaluation of disability, health insurance, supplemental security income and black lung benefits cases.

f. Maintaining liaison with medical groups to promote program understanding, and to keep abreast of disability evaluation developments and changes in health insurance regulations.

3. The Office of the Assistant Bureau Director, Division of Policy and Procedures, which is responsible for:

a. Planning, analyzing and developing Bureau-wide policy and procedural guidelines pertaining to the hearing process as performed in regional development centers and hearing offices.

b. Planning, analyzing and developing policy and procedural guidelines pertaining to Appeals Council/Regional Appeals Panel review processes and civil actions processes, and the Appeals Council/Regional Appeals Panel support staffs.

c. Providing an effective system for communicating hearings and appeals policies and procedures, through the issuance of manuals and directives that assure consistent and efficient operations in the best interest of service to the public; and developing and maintaining substantive publications, informational material, references and forms relative to the hearings and appeals process.

d. Reviewing current and developing trends in administrative law, analyzing policy recommendations, and developing long-range and short-range hearings and appeals policy plans.

e. Providing advice and guidance throughout BHA on matters involving program policies and procedures.

f. Coordinating policy and procedural matters within BHA, and with other SSA components, the Office of the General Counsel, other DHEW components, other Federal agencies and, where appropriate, with private organizations.

4. The Office of the Assistant Bureau Director, Division of Administration, which is responsible for:

a. Planning, developing and administering BHA's personnel management program, including: recruitment and placement, position classification, incentive awards, employee services, and employee-management relations.

b. Planning, developing, coordinating and conducting BHA employee development and training programs.

c. Planning and directing BHA administrative support activities, such as: space, forms and records, property management, procurement and supply, safety, equipment control and maintenance, preparation of visual aids, and mail/messenger services.

d. Planning and directing BHA's management analysis program, which includes the design, development, implementation, and appraisal of management policies and programs; and researching management techniques and technological developments having possible utility for BHA.

e. Directing BHA's operational and management information systems planning programs; assuring effective coordination of the BHA management information system with the SSA system; and maintaining a case control and statistical reporting system on the adjudication process.

f. Planning, developing and coordinating BHA's financial management program; and providing financial guidance and control in the areas of budget formulation and execution, work measurement and workload forecasting, pay and travel, position control, contract services, and fiscal operations.

g. Controlling and preparing replies to correspondence; developing standards and procedures for correspondence; receiving records and indexes; and maintaining claims and hearings materials.

5. The Office of the Assistant Bureau Director, Division of Appeals Operations which is responsible for:

a. Providing advice and assistance to the Appeals Council on the adjudication of cases.

b. Reviewing Administrative Law Judge and SSI Hearing Examiner decisions to assist the Appeals Council in deciding whether to assume jurisdiction.

c. Analyzing cases and recommending action to the Appeals Council on appealed claims and litigated cases, and preparing necessary documents to implement the action decided upon by the Appeals Council.

d. Identifying and analyzing problem areas and recommending improvements in the appeals process.

e. Reviewing and analyzing fee petitions from attorneys and representatives of claimants for the provision of services at the hearing level, and authorizing payments of appropriate fees, in all cases where fees recommended by Administrative Law Judges and SSI Hearing Examiners exceed their delegated authority, and in all cases at the Appeals Council level.

f. Providing BHA-wide leadership and guidance on all matters pertaining to psychological, vocational, educational and related factors having a bearing on claimants' capacity to work.

6. The Appraisal Staff, which is responsible for:

a. Performing a continuing appraisal on the progress being achieved throughout BHA in meeting basic objectives.

b. Conducting a BHA-wide program of appraisals and studies necessary for maintaining an ongoing assessment of overall BHA performance.

c. Recommending actions for implementation or further study by other BHA components.

Dated: March 25, 1974.

S. H. CLARKE,
Acting Assistant Secretary for Administration and Management.

[FR Doc.74-7332 Filed 3-28-74;8:45 am]

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

NATIONAL MOTOR VEHICLE SAFETY ADVISORY COUNCIL

Notice of Public Meeting

On April 10 and 11, 1974, the National Motor Vehicle Safety Advisory Council will hold open meetings in the DOT Headquarters Building, 400 Seventh Street, SW., Washington, D.C. The Advisory Council is composed of 22 members, a majority of whom are representatives of the general public, including representatives of State and local governments, with the remainder including representatives of motor vehicle manufacturers, motor vehicle equipment manufacturers, and motor vehicle dealers. The Advisory Council makes recommendations to the Secretary of Transportation on motor vehicle safety and property loss reduction programs carried out by the National Highway Traffic Safety Administration.

The following meetings are subject to the approval of the Secretary of Transportation.

On April 10 at 9:30 a.m. in room 10234 the Subcommittee on Motorcycle Safety will meet with the following agenda:

Discussion of Recommendations on Motorcycle Safety Resulting from Second International Congress—July 1972.
Proposed Technical Meeting—Neck and Head Protection for Motorcyclists.

At 11:30 a.m. on April 10 in room 10234 the Accident Avoidance and Operating Systems Committee will meet with the following agenda:

Briefing—Standardizing Maximum Speedometer Readings.
Briefing—Daytime Running Lights.
Briefing—Rear-end Lighting Systems Red/Green/Amber.
New Business:
Discussion of Department Replies to Resolutions.
Future Committee Meetings.

On April 10 at 2:00 p.m. in room 4238 the Crashworthiness Committee will meet with the following agenda:

Review of FMVSS 208—Occupant Protection.
Review of School Bus Crashworthiness Standards.
Report on Crash Recorder Program.
Discussion of Anthropomorphic Dummy Design—Human Injury Tolerance Research.
New Business:
Discussion of Department Replies to Resolutions.
Future Committee Meetings.

On April 11 at 9:00 a.m. in room 4238 the full Council will meet with the following agenda:

Report of Accident Avoidance and Operating Systems Committee.
Report of Crashworthiness Committee.
Report on Status of Third International Congress.
Treasurer's Report.
New Business.

For further information contact the NHTSA Executive Secretary, Room 5215, 400 Seventh Street, SW., Washington, D.C., telephone 202–426–2872.

This notice is given pursuant to section 10(a)(2) of Pub. L. 92–463, Federal Advisory Committee Act (FACA), effective January 5, 1973.

Issued on: March 25, 1974.

CALVIN BURKHART,
Executive Secretary.

[FR Doc.74–7294 Filed 3–28–74;8:45 am]

CIVIL AERONAUTICS BOARD

ALLEGHENY AIRLINES, INC.

[Docket No. 26113]

Deletion of Lima, Ohio; Notice of Prehearing Conference

Notice is hereby given that a prehearing conference in this proceeding is assigned to be held on April 30, 1974, at 10 a.m. (local time), in Room 503, Universal Building, 1825 Connecticut Avenue, NW., Washington, D.C., before Administrative Law Judge Frank M. Whiting.

In order to facilitate the conduct of the conference, parties are instructed to submit one copy to each party and four copies to the Judge of (1) proposed statements of issues; (2) proposed stipulations; (3) requests for information; (4) statement of positions of parties; and (5) proposed procedural dates. The Bureau of Operating Rights will circulate its material on or before April 16, 1974, and the other parties on or before April 24, 1974. The submissions of the other parties shall be limited to points on which they differ with the Bureau of Operating Rights, and shall follow the numbering and lettering used by the Bureau to facilitate cross-referencing.

Dated at Washington, D.C., March 26, 1974.

[SEAL] RALPH L. WISER,
Chief Administrative Law Judge.

[FR Doc.74–7319 Filed 3–28–74;8:45 am]

[Docket No. 25280; Order 74–3–109]

INTERNATIONAL AIR TRANSPORT ASSOCIATION

Free and Reduced Transportation for Cargo Sales Agents

An agreement has been filed with the Board pursuant to section 412(a) of the Federal Aviation Act of 1958 (the Act) and Part 261 of the Board's Economic Regulations between various air carriers, foreign air carriers and other carriers, embodied in the resolutions of the Traffic Conferences of the International Air Transport Association and resulting from the Fifth Cargo Agency Committee Meeting, held at Geneva, November 27–29, 1973. The agreement has been assigned the above C.A.B. agreement number.

The agreement would adopt a new resolution expanding provisions for the instruction and training of employees of IATA cargo agents, currently regulated by paragraph (1)(e) of Resolution 811b. Under the new resolution, carriers would be permitted to arrange for and absorb, within certain limits, transportation costs as well as housing and other associated expenses for those employees participating in training programs scheduled to a maximum of five days for minimum size groups of eight. Additionally, the agreement revalidates to December 31, 1976, by means of a standard revalidation resolution (002), certain portions of a previously Board-approved resolution governing reduced fares for foreign-based cargo agents presently due to expire December 31, 1974. This resolution allocates each agent registered for a specific country two 75 percent discount tickets per carrier per year; a maximum of 40 75 percent discount tickets under a productivity feature based on commissionable sales; and 20 additional 50 percent discount tickets.

In line with Board policy, we will approve the agreement insofar as it applies to foreign-based cargo agents and their employees. Historically, the Board's position has been that foreign-based agents operate under differing laws which make their activities more the concern of their respective governments. The Board has also noted, to a lesser degree, the practical difficulties of enforcement of any differing scheme affecting these agents.

We will disapprove the agreement insofar as it would apply to U.S.-based agents and their employees consistent with our past policy of strictly limiting free or reduced-rate transportation for U.S.-based agents to the extent which has been permitted under the resolution governing such reduced-fare concessions for U.S.-based cargo agents. The Board has conditioned that resolution to specifically exclude any travel under the entertainment or instruction provisions of any other agency resolution. This reflects the Board's long held opinion that the provisions for travel by U.S.-based agents under that resolution provide ample travel opportunity for any educational or training purpose.[1]

The Board, acting pursuant to sections 102, 204(a), 404(b) and 412 of the Act, makes the following findings:

1. It is not found that the following resolution, incorporated in the agreement as indicated, is adverse to the public interest or in violation of the Act, provided that approval is subject to conditions previously imposed by the Board:

[1] See Orders 69–7–77 and 71–4–126 of July 16, 1969 and April 19, 1971, respectively.

Agreement CAB	IATA No.	Title	Application
24221: R–1	002	Standard Revalidation Resolution	1; 2; 3; 1/2; 2/3; 3/1; 1/2/3.

2. It is not found that the following resolution, incorporated in the agreement as indicated, is adverse to the public interest or in violation of the Act insofar as it would apply to the employees of foreign-based IATA cargo sales agents provided that approval is subject to the conditions stated herein:

Agreement CAB	IATA No.	Title	Application
24221: R–2	203e	Training Courses for Cargo Agents (New)	1; 2; 3; 1/2; 2/3; 3/1; 1/2/3.

Provided that with respect to Resolution 203e:

Approval of the provisions embodied in said resolution, insofar as it is applicable in air transportation as defined by the Federal Aviation Act of 1958, shall not be construed as:

(a) An exemption from the requirements of filing tariff provisions as a condition precedent under section 403 of the Federal Aviation Act of 1958 to the issuance of passes to any person described in said resolution;

(b) A determination as to whether a violation of section 404 of the Federal Aviation Act of 1958 would result from the issuance of passes pursuant to such resolution whether or not tariff provisions applicable thereto have previously been filed with the Board; and

(c) An exemption from the provisions of the Board's Economic Regulations relating to tariffs for free or reduced-rate transportation.

3. It is found that the following resolution, incorporated in the agreement as indicated, is adverse to the public interest and in violation of the Act insofar as it would apply to the employees of United States-based IATA cargo sales agents:

Agreement CAB	IATA No.	Title	Application
24221: R-2	203e	Training Courses for Cargo Agents (New)	1; 2; 3; 1/2; 2/3; 3/1; 1/2/3.

Accordingly, it is ordered, That:

1. That portion of Agreement C.A.B. 24221 set forth in finding paragraph 1 above be and hereby is approved, subject to conditions previously imposed by the Board;

2. That portion of Agreement C.A.B. 24221 set forth in finding paragraph 2 above be and hereby is approved subject to the conditions stated therein, insofar as it would apply to the employees of foreign-based IATA cargo sales agents; and

3. That portion of Agreement C.A.B. 24221 set forth in finding paragraph 3 above be and hereby is disapproved insofar as it would apply to the employees of United States-based IATA cargo sales agents.

This order will be published in the FEDERAL REGISTER.

By the Civil Aeronautics Board:

[SEAL] EDWIN Z. HOLLAND,
Secretary.

[FR Doc.74-7322 Filed 3-28-74;8:45 am]

[Docket 25280; Order 74-3-90]

INTERNATIONAL AIR TRANSPORT ASSOCIATION

Order Relating to Specific Commodity Rates

Issued under delegated authority March 20, 1974.

Agreements have been filed with the Board pursuant to section 412(a) of the Federal Aviation Act of 1958 (the Act) and Part 261 of the Board's Economic Regulations between various air carriers, foreign air carriers, and other carriers embodied in the resolutions of the Joint Traffic Conferences of the International Air Transport Association (IATA), and adopted pursuant to the provisions of Resolution 590 dealing with specific commodity rates.

The agreements name additional specific commodity rates, as set forth below, reflecting reductions from general cargo rates; and were adopted pursuant to unprotested notices to the carriers and promulgated in IATA letters dated February 26, 1974 and March 13, 1974, respectively.

Agreement CAB	Specific Commodity Item No.	Description and Rate
24243:	7046	Photographic Sensitized Paper 220 cents per kg., minimum weight 200 kgs. From New York/Montreal to Nairobi.
24278: R-1	7448	Rubber Seals [1] 99 cents per kg., minimum weight 500 kgs. From Malta to New York/Montreal.
R-2	6806	Gums and Resins and Manufactures (Plastic) Sheets, Slabs, Rods, Tubes and other unfinished forms [1] 92 cents per kg., minimum 500 kgs. From New York/Montreal to London.

[1] Area of application changed to include the North Atlantic.

Pursuant to authority duly delegated by the Board in the Board's regulations, 14 CFR 385.14, it is not found that the subject agreements are adverse to the public interest or in violation of the Act, provided that approval is subject to the conditions hereinafter ordered.

Accordingly, it is ordered, That:

1. Agreements C.A.B. 24243 and C.A.B. 24278, R-1 and R-2, be and hereby are approved, provided that approval shall not constitute approval of the specific commodity descriptions contained therein for purposes of tariff publications; provided further that tariff filings shall be marked to become effective on not less than 30 days' notice from the date of filing.

2. The findings and approval herein shall not be deemed to modify the findings and Order of the Board in its decision in Agreements Adopted by IATA Relating to North Atlantic Cargo Rates, Order 73-2-24 of February 6, 1973, Order 73-7-9 of July 5, 1973, and Order 73-9-109 of September 28, 1973, and are subject to all the provisions of such orders.

Persons entitled to petition the Board for review of this order, pursuant to the Board's Regulations, 14 CFR 385.50, may file such petitions within ten days after the date of service of this order.

This order shall be effective and become the action of the Civil Aeronautics Board upon expiration of the above period, unless within such period a petition for review thereof is filed or the Board gives notice that it will review this order on its own motion.

This order will be published in the FEDERAL REGISTER.

[SEAL] EDWIN Z. HOLLAND,
Secretary.

[FR Doc.74-7321 Filed 3-28-74;8:45 am]

[Docket Nos. 22670 and 22500; Order 74-3-112]

LOS ANGELES AIRWAYS, INC.

Order To Show Cause

By Order 73-7-20, July 6, 1973, the Board denied the application of Los Angeles Airways, Inc. (LAA) for renewal, for an indefinite period, of its temporary suspension authority on route 84 and ordered the carrier to resume service in conformance with the terms and conditions of its certificate within ninety days from the effective date of the order.[1]

LAA failed to resume service within the 90-day period provided for in Order 73-7-20, and we have been informed by counsel for the receiver in bankruptcy that all of LAA's tangible assets have now been sold. We have, therefore, decided to issue an order to show cause which proposes to render LAA's certificate for route 84 ineffective, rather than to conduct unnecessary hearings. Accordingly, we tentatively find and conclude that the public convenience and necessity require that, pursuant to section 401(f) of the Act and section 205.1 of the Board's Economic Regulations, the Board direct that LAA's certificate for route 84 cease to be effective.[2]

In support of our ultimate conclusion, we make the following tentative findings and conclusions. LAA filed a petition under Chapter XI of the Bankruptcy Act

[1] We also instituted an investigation, to be set for hearing at a time and place to be designated at a future date, to determine whether, in the event that LAA did not resume service within 90-days from the date of the order, the Board should (a) grant temporary suspension of LAA's authority on route 84; or (b) direct that LAA's certificate of public convenience and necessity for route 84 shall cease to be effective under section 401(f) of the Act or shall be revoked under section 401(g).

We further ordered that the investigation should determine whether the application of LAA, in Docket 22500, for renewal of the "area" exemption authority granted in Order E-22798, October 25, 1965, and amended in Order 69-4-82, April 17, 1969, should be granted and, to that end, consolidated Docket 22500 with Docket 22670.

[2] Section 401(f) of the Federal Aviation Act and section 205.10 of the Board's Economic Regulations provide, in part, that if, for a period of 90 days, any service authorized by a certificate is not operated, the Board may, by order entered after notice and hearing, direct that such certificate shall thereupon cease to be effective to the extent of such service.

on October 6, 1970, and its court-appointed receiver determined the following day that its operations should be suspended. No scheduled route service has been provided by LAA since that time. Although directed by the Board under section 401(f) to resume service, the carrier has failed to do so. All the carrier's tangible assets have been sold.

In the above circumstances, it appears unlikely in the extreme that LAA will be able to or intends to resume operations. Therefore, we tentatively find that it is required by the public convenience and necessity and would be in the public interest for the Board to order that LAA's certificate for route 84 cease to be effective.[3]

Interested persons will be given twenty days following the date of this order to show cause why the tentative findings and conclusions set forth herein should not be made final. We expect such persons to support their objections, if any, with detailed answers, specifically setting forth the tentative findings and conclusions to which objection is taken. Such objections should be accompanied by arguments of fact or law and should be supported by legal precedent or detailed economic analysis. If any evidentiary hearing is requested, the objector should state in detail why such a hearing is considered necessary and what relevant and material facts he would expect to establish through such a hearing that cannot be established in written pleadings. General, vague, or unsupported objections will not be entertained.

Accordingly, it is ordered, That:

1. All interested persons are directed to show cause why the Board should not issue an order making final the tentative findings and conclusions stated herein, and directing that the certificate of Los Angeles Airways, Inc. for route 84 cease to be effective;

2. Any interested person having objections to the issuance of an order making final any of the proposed findings or conclusions set forth herein shall, within 20 days after the date of this order, file with the Board and serve upon all persons listed in paragraph 5 a statement of objections together with a summary of testimony, and other evidence expected to be relied upon to support the stated objections;[4]

3. If timely and properly supported objections are filed, full consideration will be accorded the matters and issues raised by the objections before further action is taken by the Board;

4. In the event no objections are filed, all further procedural steps will be deemed to have been waived and the Board may proceed to enter an order in accordance with the tentative findings and conclusions set forth herein; and

5. A copy of the order shall be served upon Los Angeles Airways, Inc., its receiver in bankruptcy, and the mayors of the cities of Newport Beach and Riverside, California.

This order shall be published in the FEDERAL REGISTER.

By the Civil Aeronautics Board:

[SEAL] EDWIN Z. HOLLAND,
Secretary.

[FR Doc.74-7323 Filed 3-28-74;8:45 am]

[Docket No. 2636; Order 74-3-114]

UNION DE TRANSPORTS AERIENS (U.T.A.)

Statement of Tentative Findings and Conclusions

Union de Transports Aeriens (U.T.A.) holds a foreign air carrier permit reissued pursuant to Order E-21178, 41 CAB 662, (1964) authorizing the carrier to engage in foreign air transportation of persons, property, and mail between New Caledonia, Tahiti, and Bora Bora, the intermediate point Honolulu, Hawaii, and the terminal point Los Angeles, California.

On January 29, 1974, U.T.A. filed an application for amendment of its permit so as to obtain authority to serve Pago Pago, American Samoa as a point on its route to Los Angeles, California. On February 5, 1974, U.T.A. revised its application to include a request for another point, Nandi, Fiji on its Los Angeles route.[1]

In granting U.T.A. a New Caledonia-Tahiti-Bora Bora-Honolulu-Los Angeles route, the Board found that the carrier met the fitness standards of the Act and that its services were in the public interest. U.T.A. has performed its presently authorized services successfully. It now serves the Papeete (Tahiti)-Los Angeles market four times a week (two DC-10 and two DC-8 frequencies) and the Noumea (New Caledonia)-Los Angeles market twice weekly (one DC-10 and one DC-8 frequency).

A New Caledonia-Los Angeles route, via Nandi, Pago Pago, and other points, is provided for in the United States-France bilateral Air Transport Services Agreement,[2] and U.T.A. has been designated by the Government of France to serve Nandi and Pago Pago as intermediate points on its route to the United States.

In view of the facts set forth, the Board tentatively finds and concludes that:

(a) It is in the public interest to amend the foreign air carrier permit held by Union de Transports Aeriens so as to authorize the carrier to engage in foreign air transportation of persons, property, and mail between a point or points in the islands of New Caledonia, Tahiti, and Bora Bora; the intermediate points Nandi, Fiji, Pago Pago, American Samoa; and Honolulu, Hawaii; and the terminal point Los Angeles, California;

(b) U.T.A. is fit, willing, and able to provide the above-described foreign air transportation and to conform to the provisions of the Act and the rules, regulations, and requirements of the Board thereunder;

(c) The public interest requires that the exercise of the privileges that would be granted in U.T.A.'s amended permit should be subject to the terms, conditions, and limitations contained in the attached proposed form of permit, and to such other reasonable terms, conditions, and limitations required by the public interest as may from time to time be prescribed by the Board.

Accordingly, it is ordered, That:

1. All interested persons be and they hereby are directed to show cause why the Board should not make final the tentative findings and conclusions herein, and why, subject to the approval of the President pursuant to section 801 of the Federal Aviation Act, the Board should not issue an amended foreign air carrier permit to Union de Transports Aeriens (U.T.A.) in the form attached to this order;

2. Any interested person having objections to the tentative findings and conclusions set forth herein, or to the issuance of the proposed foreign air carrier permit, shall file such objections within 10 days after the date of service of this order, and file with the Board and serve on the persons named in paragraph 5 a memorandum of objection specifying the part or parts of the tentative findings and conclusions or permit objected to and stating the specific grounds of any such objections;[3]

3. If timely and properly supported objections are filed, full consideration will be accorded the matters and issues raised by the objections before further action is taken by the Board: Provided, That the Board may proceed to enter an order in accordance with the tentative findings and conclusions herein if it determines that there are no factual issues presented that warrant the holding of an evidentiary hearing;

4. In the event no objections are filed, all further procedural steps shall be deemed waived, and the Board may proceed to enter an order in accordance

[3] The carrier's request for renewal of its area exemption would be dismissed as moot.

[4] All motions and/or petitions for reconsideration shall be filed within the period allowed for filing objections and no further such motions, requests, or petitions for reconsideration of this order will be entertained.

[1] Copies of the applications have been transmitted to the President in accordance with section 801 of the Federal Aviation Act of 1958.

[2] The bilateral rights are set forth in two routes as follows:

"8. New Caledonia via the intermediate points Nandi, Pago Pago, Tahiti, and Bora Bora to Honolulu and the terminal point on the West Coast selected by France as the United States terminal of Route 4, in both directions. Note: Without rights to carry local, connecting, or stopover traffic between Nandi, and Pago Pago until such time as the United States of America receives such rights from the United Kingdom."

"8a. Tahiti and Bora Bora to Honolulu and the terminal point on the West Coast selected by France as the United States terminal of Route 4, in both directions."

On October 10, 1970, Fiji became independent. Accordingly, the right for U.S. carriers to transport local, connecting, or stopover traffic between Nandi, Fiji, and Pago Pago, American Samoa would be granted by the Government of Fiji, rather than the Government of the United Kingdom.

[3] Since provision is made for the filing of objections to this order, petitions for reconsideration of this order will not be entertained.

with the tentative findings and conclusions set forth herein; and

5. Copies of this order shall be served upon the following: Union de Transports Aeriens, Pan American World Airways, American Airlines.

This order will be published in the FEDERAL REGISTER.

By the Civil Aeronautics Board:

[SEAL] EDWIN Z. HOLLAND,
Secretary.

PERMIT TO FOREIGN AIR CARRIER
(AS AMENDED)

Union de Transports Aeriens (U.T.A.) is hereby authorized, subject to the provisions hereinafter set forth, the provisions of the Federal Aviation Act of 1958, and the orders, rules, and regulations issued thereunder, to engage in foreign air transportation with respect to persons, property, and mail, as follows:

Between a point or points in the islands of New Caledonia, Tahiti, and Bora-Bora; the intermediate points Nandi, Fiji; Pago Pago, American Samoa; and Honolulu, Hawaii; and the terminal point Los Angeles, California.

The holder hereof shall be authorized to engage in charter trips in foreign air transportation, subject to the terms, conditions, and limitations prescribed by Part 212 of the Board's Economic Regulations.

The holder shall not carry local, connecting, or stopover traffic between Nandi, Fiji and Pago Pago, American Samoa until such time as the United States of America receives such rights from the Government of Fiji.

The holder shall conform to the airworthiness and airman competency requirements prescribed by the Government of France for French international air service.

This permit shall be subject to all applicable provisions of any treaty, convention, or agreement affecting international air transportation now in effect, or that may become effective during the period this permit remains in effect, to which the United States and France shall be parties.

By accepting this permit, the holder waives any right it may possess to assert any defense of sovereign immunity from suit in any action or proceeding instituted against the holder in any court or other tribunal in the United States (or its territories or possessions) based upon any claim arising out of operations by the holder under this permit.

The holder shall keep on deposit with the Board a signed counterpart of CAB Agreement 18900, an agreement relating to liability limitations of the Warsaw Convention and the Hague Protocol approved by Board Order E-23680, May 13, 1966, and a signed counterpart of any amendment or amendments to such agreement which may be approved by the Board to which the holder becomes a party.

The holder (1) shall not provide foreign air transportation under this permit unless there is in effect third-party liability insurance in the amount of $1,000,000 or more to meet potential liability claims which may arise in connection with its operations under this permit, and unless there is on file with the Docket Section of the Board a statement showing the name and address of the insurance carrier and the amounts and liability limits of the third-party liability insurance provided, and (2) shall not provide foreign air transportation with respect to persons unless there is in effect liability insurance sufficient to cover the obligations assumed in CAB Agreement 18900, and unless there is on file with the Docket Section of the Board a statement showing the name and address of the insurance carrier and the amounts and liability limits of the passenger liability insurance provided. Upon request, the Board may authorize the holder to supply the name and address of an insurance syndicate in lieu of the names and addresses of the member insurers.

The exercise of the privileges granted hereby shall be subject to such other reasonable terms, conditions, and limitations required by the public interest as may from time to time be prescribed by the Board.

This permit shall be effective on ---------- Unless otherwise terminated at an earlier date pursuant to the terms of any applicable treaty, convention, or agreement, this permit shall terminate (1) upon the effective date of any treaty, convention, or agreement, or amendment thereto, which shall have the effect of eliminating the route hereby authorized from the routes which may be operated by airlines designated by the Government of France, or (2) upon the effective date of any permit granted by the Board to any other carrier designated by the Government of France in lieu of the holder hereof, or (3) upon the termination or expiration of the Air Transport Services Agreement between the Government of the United States and the Government of France, effective March 27, 1946, as amended by exchanges of notes, including that of May 29, 1969. *Provided, however,* That clause (3) of this paragraph shall not apply if prior to the occurrence of the event specified in clause (3), the operation of the foreign air transportation herein authorized becomes the subject of any treaty, convention, or agreement to which the United States and France are or shall become parties.

In Witness Whereof, the Civil Aeronautics Board has caused this permit to be executed by the Secretary of the Board, and the seal of the Board to be affixed hereto,

[SEAL] SIGNATURE
Secretary.

[FR Doc.74-7324 Filed 3-28-74;8:45 am]

[Docket No. 26509]

CHARTER REGULATIONS APPLICABLE TO FOREIGN ROUTE AIR CARRIERS

Order To Show Cause

Correction

In FR Doc. 74-6567, appearing at page 10645 for the issue for Thursday, March 21, 1974, the table in the first column of page 10646 should be transferred so that it appears under footnote number 7 at the bottom of the page.

CIVIL SERVICE COMMISSION

NATIONAL PROGRAM GRANTS

Notice of Requests for Proposals

The U.S. Civil Service Commission is now accepting proposals from qualified applicants for National IPA program grants to be made for Fiscal Year 1975 pursuant to Section 506(a) of the Intergovernmental Personnel Act (IPA). The Commission is interested in programs which address significant personnel management, manpower utilization, and training needs of State and local governments on a nationwide basis and intends to award national grants early in the Fiscal Year, consistent with its appropriations for Fiscal Year 1975. The deadline for receipt of official applications is August 5, 1974. All interested parties should contact: U.S. Civil Service Commission, Bureau of Intergovernmental Personnel Programs, Office of Grant Operations, 1900 E Street, NW., Washington, D.C. 20415, 202-632-6274. This notice pertains only to the award of Fiscal Year 1975 IPA grant funds for national programs. For information about IPA grant funds for specific State and local governments and combinations thereof, contact the appropriate Regional Office of the U.S. Civil Service Commission.

UNITED STATES CIVIL SERVICE COMMISSION,
[SEAL] JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc.74-7295 Filed 3-28-74;8:45 am]

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

CERTAIN WOOL AND MAN-MADE FIBER TEXTILE PRODUCTS PRODUCED OR MANUFACTURED IN THE REPUBLIC OF KOREA

Entry or Withdrawal From Warehouse for Consumption

MARCH 25, 1974.

On October 4, 1973, there was published in the FEDERAL REGISTER (38 FR 27547) a letter dated September 28, 1973 from the Chairman, Committee for the Implementation of Textile Agreements, to the Commissioner of Customs implementing those provisions of the Bilateral Wool and Man-Made Fiber Textile Agreement of January 4, 1972, as amended, between the Governments of the United States and the Republic of Korea which establish specific export limitations, among others, on wool textile products in Categories 104 and 120 and on man-made fiber textile products in Categories 216, 222 (part), 228 and 238, produced or manufactured in the Republic of Korea and exported to the United States during the 12-month period beginning October 1, 1973 and extending through September 30, 1974. As set forth in that letter, the levels of restraint are subject to adjustment pursuant to paragraph 4(a) of the Bilateral Wool and Man-Made Fiber Textile Agreement of January 4, 1972, as amended, which provides for the limited carryover of shortfalls in certain categories to the next agreement year.

Accordingly, at the request of the Government of the Republic of Korea and pursuant to the provisions of the bilateral agreement referred to above, there is published below a letter of March 25, 1974 from the Chairman of the Committee for the Implementation of Textile Agreements to the Commissioner of Customs amending the levels of restraint applicable to wool textile products in Categories 104 and 120 and to man-made fiber textile products in Categories 216,

222 (part), 228, and 238 for the 12-month period which began on October 1, 1973.

SETH M. BODNER,
Chairman, Committee for the Implementation of Textile Agreements, and Deputy Assistant Secretary for Resources and Trade Assistance.

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

COMMISSIONER OF CUSTOMS,
Department of the Treasury,
Washington, D.C. 20229.

MARCH 25, 1974.

DEAR MR. COMMISSIONER: On September 28, 1973, the Chairman, Committee for the Implementation of Textile Agreements, directed you to prohibit entry during the twelve-month period beginning October 1, 1973 of wool and man-made fiber textile products in certain specified categories, produced or manufactured in the Republic of Korea, in excess of designated levels of restraint. The Chairman further advised you that the levels of restraint are subject to adjustment.[1] The directive of September 28, 1973 was previously amended by directives of October 24, 1973 and February 6, 1974.

Pursuant to paragraph 4(a) of the Bilateral Wool and Man-Made Fiber Textile Agreement of January 4, 1972, as amended, between the Governments of the United States and the Republic of Korea, and in accordance with the procedures of Executive Order 11651 of March 3, 1972, you are directed further to amend, effective as soon as possible, the levels of restraint established in the aforesaid directive of September 28, 1973, for wool textile products in Categories 104 and 120 and for man-made fiber textile products in Categories 214/240 as a group, and individual Categories 216, 222 (part), 228 and 238 to the following:

Category	Amended Twelve-Month Levels of Restraint [1]
104 ----------square yards--	1,612,217
120 ----------numbers--	336,311
214/240---sq. yds. equivalent--	350,478,143
216 ----------dozen--	142,755
Part 222 (excluding T.S.U.S.A. Nos. 380.0428 and 380.8165) ----------dozen--	766,720
228 ----------do----	734,502
238 ----------do----	182,831

[1] These amended levels of restraint have not been adjusted to reflect any entries made on or after October 1, 1973.

The actions taken with respect to the Government of the Republic of Korea and with respect to imports of wool and man-made fiber textile products from the Republic of Korea have been determined by the Committee for the Implementation of Textile Agreements to involve foreign affairs functions of the United States. Therefore, the directions to the Commissioner of Customs, being necessary to the implementation of such actions, fall within the foreign affairs exception to the rule-making provisions of 5 U.S.C. 553. This letter will be published in the FEDERAL REGISTER.

Sincerely,

SETH M. BODNER,
Chairman, Committee for the Implementation of Textile Agreements, and Deputy Assistant Secretary for Resources and Trade Assistance.

[FR Doc.74-7255 Filed 3-28-74;8:45 am]

[1] The term "adjustment" refers to those provisions of the Bilateral Wool and Man-Made Fiber Textile Agreements of January 4, 1972, as amended, between the Governments of the United States and the Republic of Korea which provide in part that within the aggregate and applicable group limits, limits on certain categories may be exceeded by not more than 5 percent; for the limited carryover of shortfalls in certain categories to the next agreement year; for limited interfiber flexibility between cotton textiles and man-made fiber textile products of the comparable category; and for administrative arrangements.

CERTAIN COTTON TEXTILES AND COTTON TEXTILE PRODUCTS PRODUCED OR MANUFACTURED IN EL SALVADOR

Entry or Withdrawal From Warehouse for Consumption

MARCH 22, 1974.

On April 19, 1972, the United States Government concluded a bilateral cotton textile agreement with the Government of El Salvador concerning exports of cotton textiles and cotton textile products from El Salvador to the United States over a five-year period beginning on April 1, 1972. This agreement was amended by directive dated May 29, 1973 (38 FR 14437). Among the provisions of the agreement, as amended, are those establishing an aggregate limit for the 64 categories and within the aggregate limit specific limits on Categories 1/2/3/4, 9, 15, and 31 for the agreement year beginning April 1, 1974.

There is published below a letter of March 22, 1974, from the Chairman of the Committee for the Implementation of Textile Agreements to the Commissioner of Customs, directing that the amounts of cotton textiles and cotton textile products in Categories 1/2/3/4, 9, 15, and 31 produced or manufactured in El Salvador which may be entered or withdrawn from warehouse for consumption in the United States for the twelve-month period beginning April 1, 1974, be limited to the designated levels.

The letter published below and the actions pursuant thereto are not designed to implement all of the provisions of the bilateral agreement, as amended, but are designed to assist only in the implementation of certain of its provisions.

SETH M. BODNER,
Chairman, Committee for the Implementation of Textile Agreements, and Deputy Assistant Secretary for Resources and Trade Assistance.

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

COMMISSIONER OF CUSTOMS,
Department of the Treasury,
Washington, D.C. 20229.

MARCH 22, 1974.

DEAR MR. COMMISSIONER: Pursuant to the Bilateral Cotton Textile Agreement of April 19, 1972, as amended, between the Governments of the United States and El Salvador and in accordance with the procedures of Executive Order 11651 of March 3, 1972, you are directed to prohibit, effective as soon as possible, and for the twelve-month period beginning April 1, 1974, and extending through March 31, 1975, entry into the United States for consumption and withdrawal from warehouse for consumption of cotton textiles and cotton textile products in Categories 1/2/3/4, 9, 15 and 31, produced or manufactured in El Salvador, in excess of the following levels of restraint:

Category	12-month levels of restraint
1/2/3/4 ----------pounds--	388,043
9 ----------square yards--	1,575,000
15 ----------do----	1,050,000
31 ----------numbers--	1,058,620

In carrying out this directive, entries of cotton textiles and cotton textile products in Categories 1/2/3/4, 9, 15 and 31, produced or manufactured in El Salvador, which have been exported to the United States from El Salvador prior to April 1, 1974, shall, to the extent of any unfilled balances, be charged against the levels of restraint established for such goods for the twelve-month period beginning April 1, 1973 and extending through March 31, 1974.

In the event that the levels of restraint for that twelve-month period have been exhausted by previous entries, such goods shall be subject to the levels set forth in this letter.

The levels of restraint set forth above are subject to adjustment pursuant to the provisions of the bilateral agreement of April 19, 1972, as amended, between the Governments of the United States and El Salvador which provide, in part, that within the aggregate limit, the limits on certain categories may be exceeded by not more than 5 percent; for the limited carryover of shortfalls in certain categories to the next agreement year; and for administrative arrangements.

A detailed description of the categories in terms of T.S.U.S.A. numbers was published in the FEDERAL REGISTER on January 25, 1974 (39 FR 3430).

In carrying out the above directions, entry into the United States for consumption shall be construed to include entry for consumption into the Commonwealth of Puerto Rico.

The actions taken with respect to the Government of El Salvador and with respect to imports of cotton textiles and cotton textile products from El Salvador have been determined by the Committee for the Implementation of Textile Agreements to involve foreign affairs functions of the United States. Therefore, the directions to the Commissioner of Customs, being necessary to the implementation of such actions, fall within the foreign affairs exception to the rule-making provisions of 5 U.S.C. 553. This letter will be published in the FEDERAL REGISTER.

Sincerely,

SETH M. BODNER,
Chairman, Committee for the Implementation of Textile Agreements, and Deputy Assistant Secretary for Resources and Trade Assistance.

[FR Doc.74-7257 Filed 3-28-74;8:45 am]

CERTAIN COTTON TEXTILES AND COTTON TEXTILE PRODUCTS PRODUCED OR MANUFACTURED IN THAILAND

Entry or Withdrawal From Warehouse for Consumption

MARCH 25, 1974.

On March 16, 1972, the United States Government concluded a comprehensive bilateral cotton textile agreement with the Government of Thailand concerning exports of cotton textiles and

cotton textile products from Thailand to the United States over a five-year period beginning on April 1, 1972, and extending through March 31, 1977. Among the provisions of the agreement are those establishing an aggregate limit for the 64 categories and within the aggregate limit specific limits on Categories 9/10, 15/16, 18/19, 22/23, 26/27, 43, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 60, 62, 63, and 64 for the agreement year beginning on April 1, 1974.

Accordingly, there is published below a letter of March 25, 1974 from the Chairman of the Committee for the Implementation of Textile Agreements to the Commissioner of Customs, directing that the amounts of cotton textiles and cotton textile products in the above categories, produced or manufactured in Thailand, which may be entered or withdrawn from warehouse for consumption in the United States for the twelve-month period beginning April 1, 1974, and extending through March 31, 1975, be limited to the designated levels. The letter published below and the actions pursuant thereto are not designed to implement all of the provisions of the bilateral agreement, but are designed to assist only in the implementation of certain of its provisions.

SETH M. BODNER,
Chairman, Committee for the Implementation of Textile Agreements, and Deputy Assistant Secretary for Resources and Trade Assistance.

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

COMMISSIONER OF CUSTOMS,
Department of the Treasury,
Washington, D.C. 20229.

MARCH 25, 1974.

DEAR MR. COMMISSIONER: Pursuant to the Bilateral Cotton Textile Agreement of March 16, 1972, between the Governments of the United States and Thailand, and in accordance with Executive Order 11651 of March 3, 1972, you are directed to prohibit, effective April 1, 1974 and for the twelve-month period extending through March 31, 1975, entry into the United States for consumption and withdrawal from warehouse for consumption of cotton textiles and cotton textile products in Categories 9/10, 15/16, 18/19, 22/23, 26/27, 43, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 60, 62, 63, and 64, produced or manufactured in Thailand, in excess of the following levels of restraint:

Category		Twelve-Month Levels of Restraint
9/10	square yards	2,067,188
15/16	do	826,875
18/19	do	2,067,188
22/23	do	1,240,313
26/27	square yards (of which not more than 1,102,500 square yards shall be in duck fabric [1])	1,653,750
43	dozen	52,920
45	do	22,050
46	do	19,845
47	do	17,420
48	do	9,923
49	do	15,435
50	do	27,563
51	do	27,563
52	do	29,768
53	do	8,489
54	do	15,435
55	do	7,497
60	do	41,895
62	pounds	83,886
63	do	83,886
64	do	89,878

[1] The T.S.U.S.A. Nos. for duck fabric are:
320.—01 through 04, 06, 08
321.—01 through 04, 06, 08
322.—01 through 04, 06, 08
326.—01 through 04, 06, 08
327.—01 through 04, 06, 08
328.—01 through 04, 06, 08

In carrying out this directive, entries of cotton textiles and cotton textile products in the above categories, produced or manufactured in Thailand, which have been exported to the United States from Thailand prior to April 1, 1974, shall, to the extent of any unfilled balances, be charged against the levels of restraint established for such goods for the twelve-month period beginning April 1, 1973 and extending through March 31, 1974.

In the event that the levels of restraint for that twelve-month period have been exhausted by previous entries, such goods shall be subject to the levels set forth in this letter.

The levels of restraint set forth above are subject to adjustment pursuant to the provisions of the bilateral agreement of March 16, 1972, between the Governments of the United States and Thailand which provide, in part, that within the aggregate limit, the limits on certain categories may be exceeded by not more than 5 percent; for the limited carryover of shortfalls in certain categories to the next agreement year; and for administrative arrangements.

A detailed description of the categories in terms of T.S.U.S.A. numbers was published in the FEDERAL REGISTER on January 25, 1974 (39 FR 3430).

In carrying out the above directions, entry into the United States for consumption shall be construed to include entry for consumption into the Commonwealth of Puerto Rico.

The actions taken with respect to the Government of Thailand and with respect to imports of cotton textiles and cotton textile products from Thailand have been determined by the Implementation of Textile Agreements to involve foreign affairs functions of the United States.

Therefore, the directions to the Commissioner of Customs, being necessary to the implementation of such actions, fall within the foreign affairs exception to the rule-making provisions of 5 U.S.C. 553. This letter will be published in the FEDERAL REGISTER.

Sincerely,

SETH M. BODNER,
Chairman, Committee for the Implementation of Textile Agreements, and Deputy Assistant Secretary for Resources and Trade Assistance.

[FR Doc.74-7256 Filed 3-28-74;8:45 am]

COUNCIL ON ENVIRONMENTAL QUALITY

ENVIRONMENTAL IMPACT STATEMENTS

Notice of Receipt

Environmental impact statements received by the Council on Environmental Quality from March 18 through March 22, 1974. The date of receipt for each statement is noted in the statement summary. Under Council Guidelines, the minimum period for public review and comment on draft environmental impact statements is forty-five (45) days from this FEDERAL REGISTER notice of availability. (May 14, 1974)

Copies of individual statements are available for review from the originating agency. Back copies will also be available from a commercial source, the Environmental Law Institute, of Washington, D.C.

DEPARTMENT OF AGRICULTURE

Contact: Dr. Fred H. Tschirley, Acting Coordinator, Environmental Quality Activities, Office of the Secretary, U.S. Department of Agriculture, Room 331-F, Administration Building, Washington, D.C. 20250, 202-447-3965

FOREST SERVICE

Draft

Cedar Creek Unit, Clark National Forest, Mo., Boone and Callaway Counties, March 18: Proposed is a plan for the management direction of the Cedar Creek Purchase Unit, Clark National Forest. The Unit will be managed for recreational, wildlife, grazing, and timber values. The acquisition of land will require some displacement of people. There will be social, ecological, and economic impact from the proposal (28 pages). (ELR Order No. 40407.)

Cube Iron—Silcox Unit, Lolo National Forest, Mont., Sanders County, March 20: The statement refers to a proposed multiple use plan for the 16,927 acre Cube Iron-Silcox Planning Unit, Thompson Falls Ranger District, Lolo National Forest. Under the plan the Unit would be divided into six sub-units, to be managed for similar resource potentials and problems. Roadless conditions would be maintained upon 8,267 acres; roads and other activities will result in the development of 7,766 acres which are currently roadless. Management would be for recreation, aesthetics, fisheries, wildlife, watershed, timber, soil, water, vegetation, and wildlife (115 pages). (ELR Order No. 40424.)

Enterprise Planning Unit, Dixie National Forest, Utah, Iron and Washington Counties, March 18: The statement refers to a proposed land use plan for the 328,000 acre Enterprise Planning Unit of the Dixie National Forest. The plan sets forth the allocation of land to resource uses and activities, including watershed protection, recreation, livestock grazing, wildlife management, timber management, and road and trail maintenance. Of sixteen inventoried roadless areas within the unit, the plan recommends special management of only two. The activities of the plan will have impact upon vegetation, soils, aesthetics, wildlife, recreation, and water supply and quality. (ELR Order No. 40403.)

Final

Boulder-Grover Road, Dixie National Forest, Utah, Garfield and Wayne Counties, March 18: The statement refers to the proposed construction of a two lane, 28.5 mile road between Boulder and Grover. The road will traverse the east slope of the Boulder Mountains of Dixie National Forest; it is intended to increase ease in reaching marketing areas for the citizens of Boulder, and to increase tourist traffic at both communities. There will be short term adverse impact from construction activity. Comments made by: DOI, EPA, USDA, state and local agencies, and concerned citizens. (ELR Order No. 40414.)

Green Mountain National Forest, Vt., March 21: The statement refers to a proposed 2 year timber management plan for the Green Mountain National Forest. Under

the plan there will be an annual allowable cut of 10.8 million board feet of sawtimber and 7,000 cords of round wood products. There will be road construction as part of the plan. The plan will affect soil and water quality standards, aesthetic values, and wildlife habitat (46 pages). Comments made by: DOI, EPA, USDA, state and local agencies, and concerned citizens. (ELR Order No. 40431.)

RURAL ELECTRIFICATION ADMINISTRATION

Final

Transmisson Line, Ryceville to Lexington Park, Md., St. Marys and Charles Counties, March 18: The statement refers to the proposed lending of funds to Southern Maryland Electric Cooperative, Inc., for the construction of 22.3 miles of 230 kV transmission line from Ryceville to Lexington Park, a tap switching station, and a step-down substation. There will be some construction disruption and visual impact (135 pages). Comments made by: DOT, USDA, EPA, FPC, and DOI. (ELR Order No. 40416.)

SOIL CONSERVATION SERVICE

Draft

Chicot Watershed Project, Arkansas, Chicot County, March 18: Proposed is a watershed protection, flood prevention, and agricultural water management program on the Chicot Watershed. Project measures will include land treatment on 89,200 acres; the installation of 92.2 miles of channel work on existing channels and the installation of 30.8 miles of new channels; and the construction of 517 water control structures, 50 grade stabilization structures, and 5 low water weirs. Adverse impact will include the loss of some edge and wetlahd species, and the enhancement of the potential for future clearance of wooded areas and drainage of wetlands (47 pages). (ELR Order No. 40410.)

DEPARTMENT OF DEFENSE

ARMY CORPS

Contact: Mr. Francis X. Kelly, Director, Office of Public Affairs, Attn: DAEN–PAP, Office of the Chief of Engineers, U.S. Army Corps of Engineers, 1000 Independence Avenue SW., Washington, D.C. 20314, 202–693–7168.

Draft

Granada Local Protection Project, Colorado, March 18: The statement refers to the plan for improvement of flood protection at Granada. The project involves improving the existing Wolf Creek channel and levee system to protect the town from the Standard Project Flood of 41,000 cfs and the adjacent farmlands from floods up to and including the 15-year flood of 9,200 cfs. Adverse impacts are the use of 160 acres of land, alterations in the Arkansas River ecosystems, and potential increases in the levels of air, noise, and water pollution (Albuquerque District). (ELR Order No. 40418.)

Sycamore Creek Flood Protection, Kansas, Montgomery County, March 21: Proposed is the construction of a flood control dam on Sycamore Creek, north of the City of Coffeyville. Adverse impact would include the relocation of one family, and the rendering of two farm units are uneconomical due to loss of acreage. The project will result in the inundation of 147 acres of land and two miles of free flowing steam, (Tulsa District) (19 pages). (ELR Order No. 40433.)

Little Goose Lock and Dam, Wash.,-Whitman, Columbia, and Garfield Counties, March 22: The statement refers to the existing Little Goose Lock and Dam Project, a navigation-hydroelectric project on the Snake River. Project measures include a navigation lock, a 3 unit hydroelectric spillway dam, and a 10,025 acre lake. The proposed action is the addition of 3 power units, and the continued operation and management of the project. Inpacts discussed in the statement relate to recreational uses, navigation, wildlife habitat management, the operation of fish passage facilities, and the production of electric power (Walla Walla District) (Approximately 200 pages). (ELR Order No. 40436.)

Manitowac and Two Rivers Harbors, Wis., March 22: Proposed is the periodic maintenance dredging of the Manitowac and Two Rivers Harbors. A diked spoil containment structure with an incorporated effluent filter would be constructed adjacent to the existing breakwater at Manitowac. There would be adverse impact to local benthic organisms. Twenty-four acres of land would be formed at the disposal site: this land would be suitable for community development (Chicago District) (95 pages). (ELR Order No. 40437.)

Kaaawa Beach Erosion Control, Hawaii, March 21: Proposed is the construction of a protective beach by initial placement of 9,300 cu. yds. of sand at Kaaawa Beach and periodic nourishment, which will require an additional 2,700 cu. yds. of sand every four years. Adverse impact would include the destruction of some benthic organisms (Pacific Ocean Division) (13 pages). (ELR Order No. 40434.)

Final

McGee Creek Drainage and Levee District, March 18: The plan consists of the landside enlargement of approximately 59,100 linear feet of existing levee and construction of 16,-500 linear feet of new levee, along with the construction of 3 channel cutoffs, totaling 6,600 linear feet. Approximately 1,700 ft. of the left bank of McKee will be riprapped. The plan also provides for the replacement of an existing pumping station and construction of a new inlet ditch. Adverse impacts are the use of 475 acres of land for the project, loss of some aquatic habitat, and the loss of archeological sites (St. Louis District) (94 pages). Comments made by: USDA, DOC, EPA, HUD, DOI, DOT, and state agencies. (ELR Order No. 40402.)

DEPARTMENT OF DEFENSE

NAVY

Contact: Mr. Joseph A. Grimes, Jr., Special Civilian Assistant to the Secretary of the Navy, Washington, D.C. 20350, 202–697–0892.

Draft

Farallon de Medinilla Bombardment Range, Mariana I, March 18: Proposed is the continued use of Farallon de Medinilla, the smallest of the fourteen islands within the Mariana District of the U.S. Trust Territories of the Pacific Islands, as a Navy and Air Force bombardment range. The entire 224 acre island is used for air-to-ground weapons delivery and shore bombardment. Impact results primarily from explosion* and ordnance fragmentation, and includes water pollution, air pollution, and the destruction of vegetation and wildlife (50 pages). (ELR Order No. 40417.)

TRIDENT Support Site, Bangor, Wash., March 21: Proposed is the construction, operation, and maintenance of permanent support facilities of an advanced submarine-based missile defense system. The proposed site will include 6,929 acres of the Bangor Annex complex, on the Hood Canal, Puget Sound. The support site will directly employ 4,700 military and 3,500 civilian personnel; a gradual increase in population due to the project will reach an estimated 27,000 by 1983. The major impacts of the project will be the increased population, and its impacts upon the social and economic resources in the region. (ELR Order No. 40435.)

ENVIRONMENTAL PROTECTION AGENCY

Contact: Mr. Sheldon Meyers, Director, Office of Federal Activities, Room 3630 Waterside Mall, Washington, D.C. 20460, 202–755–0940.

Final

Monett Wastewater Treatment Facilities, Misosuri, March 19: Proposed is the construction of additional wastewater treatment facilites, interceptors, lift stations, and force mains for the City of Monett. The expansion will increase the capacity of present facilities to a level which would accomodate a population equivalent of 53,000 people. There will be adverse aesthetic impact from the project (528 p.). Comments made by: DOI, DOT, GSA, COE, HEW, USDA, state and local agencies, and concerned citizens. (ELR Order No. 40422.)

Trinity River Authority, Central Regional Facility, Texas, March 21: Proposed is federal grant assistance to the Trinity River Authority for aid in the construction of additional waste-water treatment facilities at its Central Regional Wastewater Facility site in Grand Prairie. The project involves construction of a 70 MGD activated sludge treatment facility to be operated in parallel to the existing 30 MGD trickling filter facility. The combined discharge will receive further treatment prior to discharge to the Trinity River 8 miles upstream from Dallas. Construction of the plant expansion and related work will involve local disruption. Comments made by: DOT, DOI, COE, USDA, state and local agencies, and concerned citizens. (ELR Order No. 40432.)

FEDERAL POWER COMMISSION

Contact: Dr. Richard F. Hill, Acting Advisor on Environmental Quality, 441 G Street NW., Washington, D.C. 20426, 202–386–6084.

Final

Skagit River Project No. 553, Washington, Whatcom County, March 18: The statement refers to the consideration of an application by the City of Seattle for an amendment to the license for the Skagit River Project No. 553. The amendment would allow the raising of the height of Ross Dam by 121 feet, the construction of a new spillway, the replacement of existing turbines, and related work. The new reservoir would affect lands in both the United States (the Ross Lake National Recreation Area) and Canada. Impact of the action will include the inundation of 8,300 acres and the elimination of fish spawning areas; and changes in recreational and scenic values from stream-type to reservoir type (2 volumes). Comments made by: AEC, DOC, COE, DOT, EPA, and state and local agencies. (ELR Order No. 40406.)

DEPARTMENT OF HUD

Contact: Mr. Richard H. Broun, Acting Director, Office of Community and Environmental Standards, Room 7206, 451 7th Street SW., Washington, D.C. 20410, 202–755–5980.

Draft

Yerba Buena Center Urban Renewal, San Francisco, Calif., March 22: The statement refers to a proposed urban renewal project in the 87.3 acre area southeast of San Francisco's financial and downtown retail districts. Planned development will include: a parking garage, a convention hall, a meeting room complex, a multi-purpose arena, a pedestrian concourse retail shops, a hotel, an office building, and related facilities. As of October, 1973, there were 499 individuals 26 families, and 130 business firms remaining to be displaced from the project area. A substantial number of the individuals involved

are low income, elderly persons (316 pages). (ELR Order No. 40438.)

DEPARTMENT OF INTERIOR

Contact: Mr. Bruce Blanchard, Director, Environmental Project Review, Room 7260, Department of the Interior, Washington, D.C. 20240, 202–343–3891.

BONNEVILLE POWER ADMINISTRATION

Draft

BPA Wholesale Power Rate Increase, March 18: The statement refers to an increase in BPA's wholesale power rates to a level which is intended to meet fiscal payout requirements covering costs and projected facilities for the Federal Columbia River Power System. The increase considered is in the 20–30 percent range, and is dated for December 20, 1974. There will be an estimated 2 percent reduction in demand as a result of the increase in rates, with a concomitant avoidance and/or delay in construction of new power plants. The statement discusses impacts upon transportation and transmission of electricity; increased use of fuel oil and utility gas; and social and economic impacts on the ultimate consumers (122 pages). (ELR Order No. 40405.)

Eastern Clark County Service, Washington, Clark County, March 18: The statement, which supplements the statement for BPA's Fiscal Year 1975 Program, refers to the construction of a 1.3 mile, 230 kV transmission line connecting the Sifton Substation with BPA's existing North Bonneville-Ross line. Impact of the action will include the removal of 4 acres of noncommercial forestland, siltation of nearby streams, and some degradation of AM reception immediately adjacent to the right-of-way (32 pages). (ELR Order No. 40404.)

Maple Valley Transmission, King County, Wash., March 21: The statement, which supplements an earlier statement on BPA's Fiscal Year 1975 Program, refers to the proposed construction of 16 miles of 500 kV double circuit transmission line and a new substation at Snoqualmie. The line will require approximately 134 acres of new right-of-way easement, including the removal of timber from 105 acres; the substation site will require an additional 25 acres. There will be siltation of nearby streams from construction activity, and some degradation of AM reception immediately adjacent to the right-of-way (51 pages). (ELR Order No. 40425.)

Richland Area Electrical Service, Washington, Benton and Franklin Counties, March 21: The document, which supplements BPA's statement on its Fiscal Year 1975 Program, refers to the proposed construction of 35.2 miles of 230kV transmission line and 3.6 miles of 115kV line, and the associated construction of three new substation facilities. A total of approximately 760 acres will be committed to transmission easements or construction sites; 697 acres of this would be entirely within AEC's Hanford Reservation (78 pages). (ELR Order No. 40426.)

BUREAU OF RECLAMATION

Draft

Fryingpan-Arkansas Project, Colorado, several counties, March 18: The statement refers to the Fryingpan-Arkansas Project, major features of which include 6 dams and reservoirs, 18 diversion structures, 10 tunnels, 2 canals, 2 powerplants, 52 miles of transmission line, and 2 municipal and industrial water delivery conduits, with a total length of 266 miles. Purposes of the project include: the development of the regional and national economy through irrigation; development of hydroelectric power; water supply and quality improvement; and development of recreation facilities. A total of 39,279 acres will be required to accommodate all project features. The project will deplete the Colorado Basin of 70,000 acre-ft of water, thus increasing salinity. (ELR Order No. 40401.)

BUREAU OF SPORT FISHERIES AND WILDLIFE

Draft

Proposed Lacassine National Wildlife Refuge, La., Cameron County, March 21: Proposed is the legislative designation of 3,296 acres of the Lacassine Wildlife Refuge as Wilderness within the National Wilderness Preservation System. The major impact of the proposal would be the removal of some future management options (31 pages). (ELR Order No. 40428.)

NATIONAL PARK SERVICE

Draft

Proposed Parker River Wilderness Area, Massachusetts, Essex County, March 21: Proposed is the legislative designation of 3,110 acres of the Parker River National Wildlife Refuge as wilderness within the National Wilderness Preservation System. Some future management options would be precluded by wilderness designation (55 pages). (ELR Order No. 40429.)

Proposed Assateague Island Wilderness Area, Virginia and Maryland, March 21: Proposed is the legislative designation of 1,300 acres of Assateague Island in Accomack County, Virginia, and 5,200 acres of Assateague in Worcester County, Maryland, as wilderness within the National Wilderness Preservation System. Some future management options would be removed by wilderness designation (64 pages). (ELR Order No. 40427.)

DEPARTMENT OF TRANSPORTATION

Contact: Mr. Martin Convisser, Director, Office of Environmental Quality, 400 7th Street SW., Washington, D.C. 20590, 202–426–4357.

FEDERAL AVIATION ADMINISTRATION

Draft

Andalusia-Opp Airport, Ala., Covington County, March 18: The statement refers to the proposed development of the Andalusia-Opp Airport in Covington County. The project involves construction of a runway, taxiways, and aircraft parking aprons; installation of lighting, wind cone, segmented circle, rotating beacon, and visual approach slope indicator; and acquisition of 100 acres of land for runway construction. There will be increased levels of air and noise pollution due to the expanded airport operations. There will also be temporary adverse effects normally associated with construction (44 pages). (ELR Order No. 40409.)

William P. Hobby Airport, Houston, Tex., March 18: The statement refers to the construction of two runways parallel to two existing runways at the William P. Hobby Airport for use by light aircraft. The new runways will be marked, and lighting will be installed. Adverse impact of the project is the increase in the levels of air and noise pollution (3 volumes). (ELR Order No. 40411.)

FEDERAL HIGHWAY ADMINISTRATION

Draft

I–15, San Diego County, Calif., March 18: The statement refers to the construction of I–15 for 6.7 miles from 0.8 mile north of Lake Hodges Bridge to 0.2 mile north of Country Club Lane in and near the city of Escondido. The proposed 8 lane freeway will be a bypass superseding the existing expressway through Escondido. Adverse impacts are increased levels of noise and air pollution and the use of approximately 400 acres of land (86 pages). (ELR Order No. 40419.)

U.S. 36, Brown and Doniphan Counties, Kans., March 18: The statement refers to approximately 13.5 miles of highway improvement to US 36 in Brown and Doniphan Counties. The project begins 1.5 miles west of Hiawatha and proceeds easterly to its terminus 1 mile east of the Brown-Doniphan County line. Adverse impact of the project include the loss of some natural growth and wildlife cover, and a slight increase in the noise level. (ELR Order No. 40415.)

US 69, Bourbon County, Kans., March 19: The project extends from the intersection of US–54 and US–69 at the north edge of Fort Scott in Bourbon County, north approximately 13.0 miles to the Bourbon-Linn County line. An alternative terminus may extend the improvement to K–239 at Prescott. Adverse impacts include the loss of 120 acres of land, and the displacement of an unspecified amount of people (122 pages). (ELR Order No. 40420.)

I–495 Rest Area, Bolton-Harvard Town Line, Mass., March 18: The project involves the construction of a rest area on the east side of Massachusetts I–495 at the Bolton-Harvard Town line adjacent to the northbound roadway. The area will also be accessible from the southbound lanes by means of a two-span bridge to be constructed over I–495. The area will require the use of 44 acres of land which is now in a rural undeveloped state (148 pages). (ELR Order No. 40413.)

State Trunk Highway 21, Juneau County, Wis., March 18: The statement refers to the proposed reconstruction and resurfacing of State Trunk Highway 21 in Juneau County. The project begins at the Juneau-Monroe County line and extends easterly 15.11 miles through the village of Necedah to the Wisconsin River. The westerly 9.56 miles involve reconstruction of the existing roadway and the easterly 5.55 miles involve resurfacing. The project will require acquisition of approximately 24 acres from private individuals and from the U.S. Government (26 pages). (ELR Order No. 40408.)

Final

I–19, Nogales-Tucson Highway, Supplement, Arizona, Santa Cruz County, March 19: The document is a final supplement to the environmental impact statement filed with the Council on August 11, 1971 (ELR Order No. 454; NTIS Order No. PB–201 785–F). Location changes for the project between Stations 890 and 900, and relocation of the Tumacacori Interchange are proposed (52 pages). Comments made by: DOI and state agencies. (ELR Order No. 40421.)

I–95, Center Leg of the Inner Loop Freeway, District of Columbia, March 18: The proposed action involves the construction of the final portion of the Center Leg of the Inner Loop Freeway. The project will initially consist of four lanes of depressed roadway which will connect the Southwest Freeway and New York Avenue. Project length is 2,100 feet of which 1,200 feet will be tunneled. One hundred ninety-two families and 36 businesses have been displaced since right-of-way acquisition began in 1966 (175 pages). Comments made by: EPA, DOT, HUD, DOI, USDA, local agencies. (ELR Order No. 40412.)

North Freeway, Omaha, Nebr., Douglas County, March 21: Proposed is the construction of a 0.7 mile extension to the present North Freeway in Omaha. Adverse effects of the project include acquisition of right of way, relocation impacts on wildlife, possible erosion and water pollution, and conflicts with present utilities (54 pages). Comments made by: DOT, COE, USDA, HUD, DOI, EPA. (ELR Order No. 40430.)

Draft

F.A.P. 408. Illinois, Pike and Adams Counties: The project involves the construction

of a section of Supplemental Freeway F.A.P. 408 between Barry and Quincy. The project length is 26 miles. Adverse impacts are the loss of agricultural land, the relocation of several farm residences, and revisions of local land access patterns in the rural areas. (ELR Order No. 40423.)

The following environmental impact statements were received during the week of March 11 to March 15, 1974. Notice of these statements appeared in the March 22, 1974 FEDERAL REGISTER, and the commenting period for them began on that date. Summaries of the statements were not available at that time, however, and therefore are provided below.

DEPARTMENT OF INTERIOR

Contact: Mr. Bruce Blanchard, Director, Environmental Project Review, Room 7260, Department of the Interior, Washington, D.C. 20240, 202–343–3891.

BONNEVILLE POWER ADMINISTRATION

Draft

San Juan Island Service, Washington, San Juan County, March 11: The statement, which supplements one for BPA's Fiscal 1975 Program, refers to the construction of a 1.7 mile 34.5kV double circuit transmission line across Decatur Island, and a substation on Lopez Island. From two to seven acres of land will be required for right-of-ways and the construction site. There will be some disturbance to wildlife, and some degradation of AM reception adjacent to the line (34 pages). (ELR Order No. 40376.)

DEPARTMENT OF AGRICULTURE

Contact: Dr. Fred H. Tschirley, Acting Coordinator, Environmental Quality Activities, Office of the Secretary, U.S. Department of Agriculture, Room 331–E, Administration Building, Washington, D.C. 20250, 202–447–3965.

FOREST SERVICE

Draft

Elk Summit Unit, Clearwater National Forest, Idaho, Idaho County, March 11: Proposed is a revised land use plan for the 82,627 acre Elk Summit Planning Unit, Powell Ranger District, Clearwater National Forest, under which the Unit would be divided into 11 sub-units for management. Under the plan, 41% of the Unit would be available for commercial timber harvest in the standard and marginal components; timber yields would be reduced in special management areas (32% of the Unit); and the remainder of the Unit would be non-commercial or unregulated timber. A total of 36,800 acres will remain roadless but with portions being available for commercial timber harvest by aerial or long line logging systems. A total of 46,200 acres will be available for development with roads. (ELR Order No. 40382.)

Aquatic Weed Control, Apache National Forest, N. Mex., March 14: Proposed is an aquatic weed control program for five lakes on the Apache National Forest. Mechanical and chemical (Diquat) methods, individually and in combination, would be used. The over-abundant aquatic vegetation is considered esthetically unpleasing, and interferes with the effective and proper harvest of fishery resources. The statement indicates that there will be no significant impact to the physical or biological environment (55 pages). (ELR Order No. 40398.)

Timber Management, Deschutes National Forest, Oreg., several counties, March 11: The statement refers to a revision of the 10 year timber management plan (July 1, 1974 through June 30, 1983) for the Deschutes National Forest. The recommended alternative for pine-associated species type has a biological potential yield of 1,882.0 MMBF. The potential yield for lodge-pole pine type is 282.0 MMBF, and the programmed harvest for mountain hemlock type is 28.0 MMBF. The management direction also provides a silvicultural prescription, reforestation plan, transportation development plan, timber sale schedule, and related measures. There will be impact upon air and water qualities, soil, wildlife, and beauty (184 pages). (ELR Order No. 40385.)

Laurel Fork, G. Washington, Monongahela National Forests, Virginia and West Virginia, March 11: The statement refers to proposed management directives for the Laurel Fork Planning Unit, George Washington and Monongahela National Forests. The Unit contains 14,752 acres of Forest land, with 8,310 acres proposed for Eastern Wilderness. Management directives will include timber sales and recreation development. Adverse effects will include the visual impact and soil disturbance from logging, and those resulting from increased recreational use (31 pages). (ELR Order No. 40381.)

Final

Skalkaho—Gird Unit, Bitterroot National Forest, Mont., Ravalli County, March 11: The proposed action is the implementation of a revised multiple use plan for the Skalkaho-Gird and Sleeping Child Planning Units of the Bitterroot National Forest. A total of 121,820 acres of National Forest land will be affected. The plan calls for unroaded management of 37,880 acres, roaded management of 83,940 acres, and timber harvesting. Impacts stemming from the project are: increased siltation and water pollution caused by logging and road construction; reduction of domestic livestock grazing on the unit; loss of or increased danger to fish and wildlife habitat (especially to deer and elk populations); and increased air pollution (83 pages). Comments made by: EPA, DOI, USDA, State and local agencies and concerned citizens. (ELR Order No. 40383.)

RURAL ELECTRIFICATION ADMINISTRATION

Draft

Purvis Generating Plant Units 1 and 2, Mississippi, Lamar County, March 11: The statement refers to a request by the South Mississippi Electric Power Association for a loan guarantee and insured loan funds totaling $165,000,000 in order to finance a new generating plant near Purvis. The plant will include two 207 MW (gross) steam generating units; coal fuel for the station will be mined in Bell, Clay, Harlan, and Leslie Counties, Kentucky; there will be 65 miles of new 161 kV transmission line. The station will release some oxides of sulfur and nitrogen, and particulate matter; coal mining operations will involve 5,600 acres of land during the life of the station (the area will be reclaimed as the mining operations proceed). Visual impact will occur (3 volumes). (ELR Order No. 40378.)

DEPARTMENT OF TRANSPORTATION

Contact: Mr. Martin Convisser, Director, Office of Environmental Quality, 400 7th Street SW., Washington, D.C. 20590, 202–426–4357.

FEDERAL HIGHWAY ADMINISTRATION

Draft

U.S. 14, Beadle County, S. Dak., Beadle County, March 12: The statement refers to the reconstruction of an existing section of U.S. 14 by building a 4 lane divided highway on the present alignment. The project begins approximately 1 mile east of Huron and follows existing U.S. 14 easterly 3.5 miles to the intersection of U.S. 14 and Bloomfield Road. Adverse impacts of the project include the use of 110 acres of land and the displacement of 6 families and 1 business (19 pages). (ELR Order No. 40394.)

GARY L. WIDMAN,
General Counsel.

[FR Doc.74–7389 Filed 3–28–74;8:45 am]

NOR-AM AGRICULTURAL PRODUCTS, INC.

Filing of Petition Regarding Pesticide Chemical

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 408 (d)(1), 68 Stat. 512; (21 U.S.C. 346a(d)(1))), notice is given that a petition (PP 4F1459) has been filed by NOR-AM Agricultural Products, Inc., Woodstock, IL 60098, proposing establishment of a tolerance (40 CFR Part 180) for negligible residues of the herbicide desmedipham (ethyl-*m*-hydroxycarbanilate carbanilate) in or on the raw agricultural commodity sugar beets (roots and tops) at 0.2 part per million.

The analytical method proposed in the petition for determining residues of the herbicide is a procedure in which the residues are hydrolyzed to aniline, which is extracted and reacted with bromine to form 2,4,6-tribromoaniline. The latter is determined by gas chromatography using electron-capture detection.

Dated: March 20, 1974.

JOHN B. RITCH, Jr.,
Director,
Registration Division.

[FR Doc.74–7287 Filed 3–28–74;8:45 am]

[OPP–32000/30]

RECEIPT OF APPLICATIONS FOR PESTICIDE REGISTRATION

Data To Be Considered in Support of Applications

On November 19, 1973, the Environmental Protection Agency published in the FEDERAL REGISTER (38 FR 31862) its interim policy with respect to the administration of section 3(c)(1)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 979), and its procedures for implementation. This policy provides that EPA will, upon receipt of every application, publish in the FEDERAL REGISTER a notice containing the information shown below. The labeling furnished by the applicant will be available for examination at the Environmental Protection Agency, Room EB–37, East Tower, 401 M Street, SW., Washington, D.C. 20460.

On or before May 28, 1974, any person who (a) is or has been an applicant, (b) desires to assert a claim for compensation under section 3(c)(1)(D) against another applicant proposing to use supportive data previously submitted and approved, and (c) wishes to preserve his opportunity for determination of reasonable compensation by the Administrator must notify the Administrator and

the applicant named in the FEDERAL REGISTER of his claim by certified mail. Every such claimant must include, at a minimum, the information listed in this interim policy published on November 19, 1973.

Applications submitted under 2(a) or 2(b) of the interim policy in regard to usage of existing supportive data for registration will be processed in accordance with existing procedures. Applications submitted under 2(c) will be held for the 60-day period before commencing processing. If claims are not received, the application will be processed in normal procedure. However, if claims are received within 60 days, the applicants against whom the particular claims are asserted will be advised of the alternatives available under the Act. No claims will be accepted for possible EPA adjudication which are received after May 28, 1974.

APPLICATIONS RECEIVED

EPA File Symbol 33484–E. Airwick Institutional, A Division of Airwick Industries, Inc., 380 North Street, Teterboro, New Jersey 07608. *Airwick Institutional Phenolic Detergent Disinfectant Concentrate.* Active Ingredients: o-phenylphenol 10.00 percent; o-benzyl-p-chlorophenol 7.50 percent; p-tertiary-amylphenol 2.00 percent; tetrasodium ethylene diamine tetraacetate 1.00 percent; sodium lauryl sulfate 0.51 percent; potassium ricinoleate 6.16 percent; sodium sulforicinoleate 3.27 percent. Method of Support: Application proceeds under 2(b) of interim policy.

EPA File Symbol 33484–G. Airwick Institutional, A Division of Airwck Industries, Inc.; 380 North Street, Teterboro, New Jersey 07608. *Airwick Institutional Heavy Duty Detergent Disinfectant.* Active Ingredients: n-Alkyl (60 percent C14, 30 percent C16, 5 percent C12, 5 percent C18) dimethyl benzyl ammonium chlorides 3.000 percent; Tetrasodium ethylene diamine tetraacetate 0.143 percent. Method of Support: Application proceeds under 2(b) of interim policy.

EPA File Symbol 33484–R. Airwick Institutional, A Division of Airwick Industries, Inc., 380 North Street, Teterboro, New Jersey 07608. *Airwick Institutional Detergent Disinfectant.* Active Ingredients: n-alkyl (60 percent C14, 30 percent C16, 5 percent C18, 5 percent C12) dimethyl benzyl ammonium chlorides 2.5 percent; Sodium Carbonate Anhydrous 0.2 percent; Tetrasodium ethylene diamine tetraacetate 0.1 percent. Method of Support: Application proceeds under 2(b) of interim policy.

EPA File Symbol 11329–I. Aladdin Chemical Co., 6460 Zane Avenue North, Minneapolis, Minnesota 55429. *Super Clearon Granular Chlorine.* Active Ingredients: Sodium dichloro-s-triazinetrione dihydrate 100 percent (available chlorine 56 percent). Method of Support: Application proceeds under 2(b) of interim policy.

EPA File Symbol 7124–GR. Alden Leeds, Inc., 55 Jacobus Avenue, South Kearny, New Jersey 07032. *Nuclo New Fire Resistant Concentrated Pool Chlorine.* Active Ingredients: Sodium dichloro-s-triazinetrione dihydrate 100 percent (available chlorine 56 percent). Method of Support: Application proceeds under 2(b) of interim policy.

EPA File Symbol 7151–L. Alexander Chemicals, Div. North American Car Corp., 222 S. Riverside Plaza, Chicago, Illinois 60606. *Hypo High Potency Chlorine for Swimming Pools.* Active Ingredients: Sodium dichloro-s-triazinetrione dihydrate 100 percent. Method of Support: Application proceeds under 2(b) of interim policy.

EPA File Symbol 8029–U. Dorex Inc., 121 Ontario Street, P.O. Box 418, Frankfort, Illinois 60423. *Superior Products Beverage Glass Sanitizer No. 263.* Active Ingredients: Monosodium phosphate anhydrous 46.0 percent; Sodium dichloro-s-triazinetrione 14.1 percent; Trichloromelamine 9.2 percent; Sodium dodecylbenzene sulfonate 9.2 percent; Citric Acid, Anhydrous 7.7 percent. Method of Support: Application proceeds under 2(b) of interim policy.

EPA Reg. No. 1677–44. Economics Laboratory, Inc., Osborn Bldg., St. Paul, Minnesota 55102. *Soilax Pool Sanitizer Concentrated Chlorine for all Swimming Pools.* Active Ingredients: Sodium dichloro-s-triazinetrione dihydrate 100 percent. Method of Support: Application proceeds under 2(b) of interim policy.

EPA File Symbol 8544–RG. General Pool Supply, 8700 Bellanca Avenue, Los Angeles 90045. *Sani-clor Dry Concentrate Pool Chlorine.* Active Ingredients: Sodium dichloro-s-triazinetrione dihydrate 100 percent (available chlorine 56 percent). Method of Support: Application proceeds under 2(b) of interim policy.

EPA File Symbol 259–LR. Missouri-Kansas Chemical Company, 1708 Campbell, Kansas City, Missouri 64108. *Minto-Cide II Bactericide and Disinfectant.* Active Ingredients: Isopropanol 20.0 percent; Soap 5.5 percent; o-benzyl p-chlorophenol 4.5 percent; o-phenylphenol 4.0 percent; Methyl Salicylate 2.0 percent; Para-tertiary-amylphenol 1.5 percent. Method of Support: Application proceeds under 2(b) of interim policy.

EPA File Symbol 8591–EE. The Mogul Corporation, Chagrin Falls, Ohio 44022. *Mogul S–493 A Flame-Resistant, Concentrated Pool Chlorine.* Active Ingredients: Sodium dichloro-s-triazinetrione dihydrate 100 percent (available chlorine 56 percent). Method of Support: Application proceeds under 2(b) of interim policy.

EPA File Symbol 8370–RU. Nyco Products Company, 3021 West 36th Street, Chicago, Illinois 60632. *Odorless-Sanitizer N–601.* Active Ingredients: n-Alkyl (60 percent C14, 30 percent C16, 5 percent C12, 5 percent C18) dimethyl benzyl ammonium chlorides 5 percent; n-Alkyl (68 percent C12, 32 percent C14) dimethyl ethylbenzyl ammonium chlorides 5 percent. Method of Support: Application proceeds under 2(b) of interim policy.

EPA File Symbol 266–GN. SwimChem Products, A Division of Hill Brothers Chemical Company, 15017 E. Clark Avenue, City of Industry, California 91745. *Hi-Chem New Fire Resistant Concentrated Pool Chlorine.* Active Ingredients: Sodium dichloro-s-triazinetrione dihydrate 100 percent (available chlorine 56 percent). Method of Support: Application proceeds under 2(b) of interim policy.

EPA File Symbol 1729–RNA. Tesco Chemicals, P.O. Box 6433, Marietta, Georgia 30062. *Tes-Chloron New Fire Resistant Concentrated Pool Chlorine.* Active Ingredients: Sodium dichloro-s-triazinetrione dihydrate 100 percent (available chlorine 56 percent). Method of Support: Application proceeds under 2(b) of interim policy.

EPA File Symbol 29443–E. Treat-Rite Water Laboratories, Inc., P.O. Box 226, Nowata, Oklahoma 74048. *Treat-Rite Best Value Bleach.* Active Ingredients: Sodium Hypochlorite 5.25 percent. Method of Support: Application proceeds under 2(c) of interim policy.

EPA File Symbol 1043–LE. Vestal Laboratories, Division of Chemed Corporation, 4963 Manchester Avenue, St. Louis, Missouri 63110. *Concentrated Vestal Staphene Hospital Germicide.* Active Ingredients: Sodium o-benzyl-p-chlorophenate 5.5 percent; sodium o-phenylphenate 5.2 percent; sodium p-tertiary amylphenate 5.1 percent; sodium 2,2' - methylenebis (3,4,6 - trichlorophenate) 0.4 percent. Method of Support: Application proceeds under 2(b) of interim policy.

EPA File Symbol 1043–LG. Vestal Laboratories, Division of Chemed Corporation, 4963 Manchester Avenue, St. Louis, Missouri 63110. *Vestal Environ-D Phenolic Disinfectant.* Active Ingredients: o-benzyl-p-chlorophenol 5.0 percent; o-phenylphenol 4.6 percent; p-tertiary amylphenol 4.5 percent; 2,2'-methylenebis (3,4,6-trichlorophenol) 0.4 percent. Method of Support: Application proceeds under 2(b) of interim policy.

EPA File Symbol 1043–LU. Vestal Laboratories, Division of Chemed Corporation, 4963 Manchester Avenue, St. Louis, Missouri 63110. *Vestal Eighty-Nine Germicidal Detergent.* Active Ingredients: Sodium o-phenylphenate 4.43 percent; sodium o-benzyl-p-chlorophenate 3.66 percent; sodium p-tertiary amylphenate 0.89 percent. Method of Support: Application proceeds under 2(b) of interim policy.

EPA File Symbol 1043–LL. Vestal Laboratories, Division of Chemed Corporation, 4963 Manchester Avenue, St. Louis, Missouri 63110. *T. B. Q. Germicidal Detergent.* Active Ingredients: Cocoamine ethoxylates (83 percent 1 mole; 17 percent 10 mole) 12 percent; Alkyl (50 percent C14, 40 percent C12, 10 percent C16) dimethyl benzyl ammonium chloride 8 percent. Method of Support: Application proceeds under 2(b) of interim policy.

EPA File Symbol 1043–LA. Vestal Laboratories, Division of Chemed Corporation, 4963 Manchester Avenue, St. Louis, Missouri 63110. *Vestal Ves-Phene Germicidal Detergent.* Active Ingredients: Sodium o-phenylphenate 4.43 percent; sodium o-benzyl-p-chlorophenate 3.66 percent; sodium p-tertiary amylphenate 0.89 percent. Method of Support: Application proceeds under 2(b) of interim policy.

EPA File Symbol 1043–LT. Vestal Laboratories, Division of Chemed Corporation, 4963 Manchester Avenue, St. Louis, Missouri 63110. *Concentrated Vestal 10 Hospital Disinfectant.* Active Ingredients: Sodium o-benzyl-p-chlorophenate 5.5 percent; sodium o-phenylphenate 5.2 percent; sodium p-tertiary amylphenate 5.1 percent; sodium 2,2'-methylenebis (3,4,6-trichlorophenate) 0.4 percent. Method of Support: Application proceeds under 2(b) of interim policy.

EPA File Symbol 1043–LI. Vestal Laboratories, Division of Chemed Corporation, 4963 Manchester Avenue, St. Louis, Missouri 63110. *Vestal Eight Hospital Germicidal Detergent.* Active Ingredients: Sodium o-phenylphenate 5.7 percent; sodium o-benzyl-p-chlorophenate 4.7 percent; sodium p-tertiary amylphenol 1.1 percent. Method of Support: Application proceeds under 2(b) of interim policy.

EPA File Symbol 1043–LO. Vestal Laboratories, Division of Chemed Corporation, 4963 Manchester Avenue, St. Louis, Missouri 63110. *Vestal Ecolocide Germicidal Detergent.* Active Ingredients: Citric Acid 10 percent; Pelargonic Acid 8.0 percent; Glycolic Acid 7.0 percent. Method of Support: Application proceeds under 2(b) of interim policy.

EPA File Symbol 15136–G. Wave Energy Systems Inc., Newtown Commons, Newtown, Pennsylvania 18940. *Agrocide Disinfecting or Sanitizing Solution.* Active Ingredients: Glutaraldehyde (1,5 Pentanedial) OHC (CH2)3 CHO 2 percent; Non ionic ethoxylates of isomeric linear alcohols (CH3)2 (CH2)n O(CH2—CH20) 12H 0.25 percent. Method of Support: Application proceeds under 2(b) of interim policy.

REPUBLISHED ITEMS

The following items represent corrections and/or changes in the list of Applications Received previously published in the FEDERAL REGISTER of March 19, 1974 (39 FR 10321).

EPA File Symbol 148–RRAI. Thompson-Hayward Chemical Company, 5200 Speaker Road, Kansas City, Kansas 66106. *Roach and Ant Spray.* Active Ingredients: O,O-diethyl O-(2-isopropyl-6-methyl-4-pyrimidinyl) phosphorothioate 0.500 percent; pyrethrins 0.052 percent; technical piperonyl butoxide (equivalent to .209 percent (butylcarbityl) (6-propylpiperonyl) ether and .052 percent other related compounds) 0.261 percent; petroleum distillate 98.400 percent. Correction: Originally published as Active Ingredients: O,O-diethyl O-(2-isopropyl-6-methyl-4-pyrimidmyl) phosphorothioate 0.500 percent; prethrins 0.052 percent. . . .

EPA File Symbol 635–ERI. Tide Products, Inc., P.O. Box 1020, Edinburg, Texas 78539. *Tide Expander.* Active Ingredients: O,O-dimethyl O-p-nitrophenyl thiophosphate 13.95 percent; toxaphene 55.80 percent. . . . Correction: Originally published as toyaphene 55.80 percent.

Dated: March 22, 1974.

JOHN R. RITCH, Jr.,
Director, Registration Division.

[FR Doc.74–7286 Filed 3–28–74;8:45 am]

PRESIDENT'S AIR QUALITY ADVISORY BOARD

Notice of Rescheduling

Notice is hereby given that the meeting of the President's Air Quality Advisory Board scheduled for April 1 and 2, 1974, in the Administrator's Conference Room (11th Floor), 401 M Street SW., Washington, D.C. 20460 has been rescheduled for April 18 and 19.

For further information on the agenda or public participation please call Robert F. Powell, Executive Secretary, 755–6906.

ROGER STRELOW,
Acting Assistant Administrator for Air and Water Programs.

[FR Doc.74–7415 Filed 3–28–74;8:45 am]

FEDERAL COMMUNICATIONS COMMISSION

[List No. 2]

CANADIAN TELEVISION STATIONS

Supplementary Listing

MARCH 22, 1974.

Supplementary list of changes, additions, deletions and corrections as of March 1, 1974, to the list of Canadian Television Stations within 250 miles of the border issued by the Commission, dated April 1, 1973.

Call sign	Licensee	Location	Radiated power (kW)	ANTENNA				Offset
				Directivity	Above ground	Above MSL	Above terrain	
		CHANNEL 4 (66–72 MHz)						
CHFD-TV		Thunder Bay, Ontario, N. 48°31'30", W. 89°06'50"	56.00 V 10.00 A	Om.	707	2,307	1,202	(–).
		CHANNEL 5 (76–82 MHz)						
CKX-TV		Brandon, Manitoba, N. 49°40'05", W. 100°00'40"	44.00 V 8.40 A	D.A.	1,332	2,882	1,363	(+).
		CHANNEL 6 (82–88 MHz)						
CKGN-TV-6		Ottawa, Ontario, N. 45°31'05", W. 75°44'48"	2.80 V 0.40 A	D.A.	249	649	149	No.
CKGN-TV		Paris, Ontario, N. 43°15'39", W. 80°26'39"	100.00 V 15.00 A	Om.	1,000	2,024	1,037	(+).
		CHANNEL 11 (198–204 MHz)						
CKSO-TV-3		Kearns, Ontario, N. 48°08'12", W. 79°33'12"	162.00 V 32.00 A	D.A.	445	1,795	734	No.
		CHANNEL 13 (210–216 MHz)						
CBST		Sept Iles, Quebec, N. 50°08'40", W. 66°28'05"	8.40 V	D.A.	227	962	903	(+).
CBKHT		Keno Hill, Yukon Territory, N. 63°54'55", W. 135°23'50"	0.248 V 0.025 A	D.A.	105	4,705	1,590	No.
		CHANNEL 22 (518–524 MHz)						
CKGN-TV-1		Cottam, Ontario, N. 42°08'00", W. 82°45'42"	218.00 V 33.00 A	Om.	398	1,048	396	(–).
CKGN-TV-22		Uxbridge, Ontario, N. 44°01'54", W. 79°08'13"	3,120.00 V 468.00 A	D.A.	472	1,577	598	(+).
		CHANNEL 55 (716–722 MHz)						
CBVT-4		Lac Etchemin, Quebec, N. 46°24'42", W. 70°35'37"	0.40 V 0.08 A	D.A.	120	2,160	800	(+).

[SEAL]

FEDERAL COMMUNICATIONS COMMISSION,
WALLACE E. JOHNSON,
Chief Broadcast Bureau.

[FR Doc.74–7180 Filed 3–28–74;8:45 am]

FEDERAL HOME LOAN BANK BOARD

[H.C. 171]

GENERAL OHIO S&L CORP.

Notice of Receipt of Application for Permission To Acquire Control of Union Savings and Loan Co.

MARCH 25, 1974.

Notice is hereby given that the Federal Savings and Loan Insurance Corporation has received an application from the General Ohio S&L Corporation, Findlay, Ohio, a multiple savings and loan holding company, for approval of acquisition of control of the Union Savings and Loan Company, St. Marys, Ohio, an insured institution, under the provisions of section 408(e) of the National Housing Act, as amended (12 U.S.C. 1730a(e)), and § 584.4 of the regulations for savings and loan holding companies, said acquisition to be effected by a purchase for cash of the stock of the Union Savings and Loan Company. Following the proposed acquisition it is proposed that the Union Savings and Loan Company be merged into The Mutual Savings and Loan Association, an insured subsidiary of the applicant. Comments on the proposed acquisition should be submitted to the Director, Holding Companies Section, Office of Examinations and Supervision, Federal Home Loan Bank Board, Washington, D.C. 20552, on or before April 29, 1974.

[SEAL] GRENVILLE L. MILLARD, Jr.,
Assistant Secretary, Federal Home Loan Bank Board.

[FR Doc.74–7292 Filed 3–28–74;8:45 am]

FEDERAL POWER COMMISSION

[Docket No. E-8664]

ALABAMA POWER CO.

Notice of Filing of Initial Rate Schedule

MARCH 22, 1974.

Take notice that on March 15, 1974, Alabama Power Company (Alabama) tendered for filing an Agreement with Baldwin County Electric Membership Corporation intended as an initial rate schedule. Alabama states that it is unable to estimate the amount of revenues involved under this contract.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's rules of practice and procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before April 2, 1974. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.74-7305 Filed 3-28-74;8:45 am]

[Docket No. E-8665]

ALABAMA POWER CO.

Notice of Filing of Initial Rate Schedule

MARCH 22, 1974.

Take notice that on March 15, 1974, Alabama Power Company (Alabama) tendered for filing an Agreement with the Utilities Board of the City of Sylacauga intended as an initial rate schedule. Alabama states that it is unable to estimate the amount of revenue involved under the contract.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's rules of practice and procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before April 2, 1974. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.74-7306 Filed 3-28-74;8:45 am]

[Docket No. CI73-784]

BLAKE HAMMAN

Order Providing for Hearing, Granting Intervention, and Prescribing Procedures

MARCH 25, 1974.

On May 16, 1973, Blake Hamman (Hamman) filed an Application for Abandonment and Cancellation of FPC jurisdiction involving a gas well in the Campsey Area in Jack County, Texas. Sales from this well have been made to Natural Gas Pipe Line Company of America (Natural), pursuant to a contract dated August 10, 1971, containing a 20-year sale term. Hamman requests abandonment of the sale from the instant acreage because of a current lack of production therefrom. For this reason, Hamman decided to cancel the above contract with Natural on May 1, 1973, and to file the instant application.

On January 24, 1974, Natural filed a late petition to intervene in opposition to Hamman's application alleging sufficient interest in the proceeding as the buyer of gas from the well in question. Because Natural's participation in this proceeding may be in the public interest we will grant their intervention since no other party can adequately represent their interest.

The application and petition to intervene raise factual and legal questions which should be resolved in an evidentiary proceeding.

The Commission finds. (1) Good cause exists for setting for formal hearing the issues involved in the aforementioned pleadings and for establishing the procedures for that hearing all as hereinafter ordered.

(2) The participation of Natural may be in the public interest.

The Commission orders. (A) Pursuant to the authority of the Natural Gas Act, particularly sections 7 and 15 thereof, the Commission's rules of practice and procedure, and the regulations under the Natural Gas Act (18 CFR, Chapter 1), a public hearing shall be held commencing May 14, 1974, at 10:00 a.m. (e.d.t.), in a hearing room of the Federal Power Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, concerning the propriety of permitting the proposed abandonment requested by the application herein of May 16, 1973.

(B) On or before April 30, 1974, applicant shall file and serve its testimony and exhibits comprising its case-in-chief in support of its application upon all parties to this proceeding including Commission Staff.

(C) An Administrative Law Judge, to be designated by the Chief Administrative Law Judge for that purpose, [see Delegation of Authority (18 CFR 3.5 (d))], shall preside at the hearing and shall prescribe relevant procedural matters not herein provided.

(D) The petitioner hereinabove set forth is permitted to intervene in those proceedings subject to the rules and regulations of the Commission; Provided, however, that the participation of such intervenors shall be limited to matters affecting asserted rights and interests specifically set forth in the petition to intervene, and, Provided, further, that the admission of said intervenor shall not be construed as recognition by Commission that it might be aggrieved because of any order of the Commission entered in this proceeding.

By the Commission.

[SEAL] KENNETH F. PLUMB,
Secretary.

[FR Doc.74-7314 Filed 3-28-74;8:45]

[Docket No. CP74-186]

CITIES SERVICE GAS CO.

Order Granting Interventions, Setting Hearing Date and Prescribing Procedures

MARCH 25, 1974.

On January 14, 1974, Cities Service Gas Company (Cities) filed in Docket No. CP74-186 an application pursuant to section 7(b) of the Natural Gas Act for permission and approval to abandon certain facilities and service on its transmission system in Montgomery County, Kansas.

More specifically, Cities proposes to (1) abandon by reclaiming measuring and regulating facilities and approximately 4.6 miles of its so-called State Line 16-inch pipeline, and (2) abandon by reclaiming measuring and regulating facilities and approximately 12.69 miles of 18-inch pipeline in its Cotton Valley-Grabham 18-inch pipeline. Cities also requests authorization to discontinue gas deliveries and sales to Union Gas System, Inc. (Union) for resale to fifteen rural domestic consumers along the State Line pipeline facilities proposed to be abandoned and to one direct sale customer. The service to the rural consumers originated through provisions of right of way agreements between Cities and the landowners. Cities states that Union will file an appropriate application with the State Corporation Commission of Kansas for authority to discontinue service to such customers if the application is approved. Cities proposes, if the application is granted, to reimburse the rural domestic customers for the costs of converting to alternate fuel since it appears no alternate natural gas service appears to be available. A like payment would be made, if the application were granted, to the direct sale customer to assist its conversion to an alternate fuel.

Cities states, as reasons for the abandonment as proposed, that it is presently experiencing excessive leakage and losses on the State Line and Cotton Valley-Grabham pipelines and, that due to their age and deteriorated condition, such pipelines are no longer economical to operate or maintain and are operationally obsolete. Cities further states that, due to the relocation of certain facilities, the capacity of such pipelines proposed to be abandoned herein is no

longer needed to meet its transmission system demands.

On February 15, 1974, the State Corporation Commission of the State of Kansas (Kansas) filed a timely petition to intervene and has requested that a formal hearing be granted. On February 25, 1974, Union filed an untimely petition to intervene in the proceeding. Union states that if the application by Cities were approved it would be required to obtain authority from the State Corporation Commission of Kansas to abandon the service to the fifteen rural domestic consumers affected and is unable to state whether such authority would be granted.

We shall set this matter for formal hearing to determine whether the present or future public convenience and necessity requires abandonment of both service and facilities as requested by Cities.

The Commission finds. (1) The Intervention of Kansas and Union in this proceeding may be in the public interest.

(2) It is necessary and proper in the public interest and to aid in the enforcement of the provisions of the Natural Gas Act that the issues in this proceeding be scheduled for hearing in accordance with the procedures set forth below.

The Commission orders. (A) Kansas and Union are hereby permitted to intervene in this proceeding subject to the rules and regulations of the Commission; Provided, however, that the participation of such intervenors shall be limited to matters affecting asserted rights and interests as specifically set forth in said petitions for leave to intervene, and provided, further, that the admission of such intervenors shall not be construed as recognition by the Commission that they might be aggrieved because of any order or orders of the Commission entered in this proceeding.

(B) Pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by the Natural Gas Act (particularly sections 4, 5, and 15 thereof), and the Commission's rules of practice and procedure, a hearing will be held in a hearing room of the Federal Power Commission, 825 North Capitol Street, NE., Washington, D.C. 20426 on April 30, 1974 (e.d.t.) concerning the issue of whether the present or future public convenience and necessity permit such abandonment.

(C) On or before April 15, 1974, Cities, Kansas and Union shall file with the Commission and serve upon all parties, including Commission Staff, their direct testimony and exhibits in support of their respective positions.

(D) An Administrative Law Judge to be designated by the Chief Administrative Law Judge—See Delegation of Authority, 18 CFR 3.5(d)—shall preside at, and control, this proceeding in accordance with the policies expressed in the Commission's rules of practice and procedure and the purposes expressed in this order.

By the Commission.

[SEAL] KENNETH F. PLUMB, *Secretary.*

[FR Doc.74-7312 Filed 3-28-74;8:45 am]

[Dockets Nos. E-8661 and E-8662]

CONNECTICUT LIGHT AND POWER CO., ET AL.

Notice of Termination of Contracts

MARCH 22, 1974.

Take notice that on March 13 and 14, 1974, Connecticut Light and Power Company (CL&P), Hartford Electric Light Company (HELCO), and Western Massachusetts Electric Company (WMECO) tendered for filing two notices of Termination of Rate Schedules. The March 13, 1974 filing relates to a Transmission Agreement, dated November 1, 1971, between CL&P, HELCO, WMECO, and the Vermont Electric Power Company, Inc. The March 14, 1974 filing relates to a Transmission Agreement, dated November 1, 1971, and an Extension and Amendment of that agreement, dated April 1, 1972, between CL&P, HELCO, WMECO and the Bangor Hydro-Electric Company.

CL&P, HELCO and WMECO allege that the filing is in accordance with Part 35 of the Commission's regulations. They further assert that both contracts terminated according to their terms.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's rules of practice and procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before April 9, 1974. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB, *Secretary.*

[FR Doc.74-7311 Filed 3-28-74;8:45 am]

[Docket No. E-8659]

KANSAS GAS AND ELECTRIC CO.

Notice of Change in Rate Schedule

MARCH 25, 1974.

Take notice that Kansas Gas and Electric Company (Kansas) on March 5, 1974, tendered for filing Service Schedule E, Capacity Participation Service, dated February 20, 1974, Supplementing the Power Interchange Agreement between Kansas and Missouri Public Service Company (Missouri). Kansas proposes an effective date of February 20, 1974 for Service Schedule E.

Kansas states Service Schedule E provides for the sale of 30 MV of capacity by Kansas to Missouri during the twelve month period beginning June 1, 1974. According to Kansas, Service Schedule E is an initial filing which has the following rate: $1.50 per Kw for each Kw of capacity available, and 4.5 mills per Kwh, or cost of production plus 10 percent, whichever is higher, for energy actually delivered.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protests with the Federal Power Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's rules of practice and procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before April 9, 1974. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB, *Secretary.*

[FR Doc.74-7307 Filed 3-28-74;8:45 am]

[Docket No. E-8494]

MINNESOTA POWER & LIGHT CO.

Notice of Extension of Time

MARCH 25, 1974.

On March 20, 1974, Minnesota Power & Light Company (MP&L) filed a motion for an extension of time to and including April 1, 1974, within which to answer the motion for rejection filed by the Village of Hibbing, City of Two Harbors and City of Virginia (Cities) on March 8, 1974, in the above-designated matter.

Upon consideration, notice is hereby given that the time is extended to and including April 1, 1974, within which MP&L may file an answer to the motion filed by Cities on March 8, 1974.

KENNETH F. PLUMB, *Secretary.*

[FR Doc.74-7303 Filed 3-28-74;8:45 am]

[Docket No. E-8595]

MISSOURI POWER AND LIGHT CO.

Notice of Cancellation of Filing

MARCH 22, 1974.

Take notice that on February 28, 1974, Missouri Power and Light Company (Company) filed a letter cancelling the Company's filing (in which a deficiency letter was sent out on February 14, 1974) of an Electric Service Agreement made on January 24, 1974. Company states that due to a substantial increase in wholesale power costs the proposed wholesale power contract with the City of Centralia, Missouri, may need to be renegotiated and therefore a new filing will be made in the near future.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's rules of practice and procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before April 5, 1974. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.74-7304 Filed 3-28-74;8:45 am]

[Docket No. E-8578]

PUBLIC SERVICE CO. OF OKLAHOMA

Notice of Withdrawal of Cancellation of Rate Schedule

MARCH 22, 1974.

Take notice that on February 28, 1974, Public Service Company of Oklahoma (Company) filed a withdrawal of its notice of cancellation of Supplement No. 9 to Rate Schedule FPC No. 180. Company states that it has been notified that Associated Electric Cooperative, Inc., wishes to extend this purchase agreement to May 31, 1974, and therefore filing of an Extension Agreement will be made in the near future.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's rules of practice and procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before April 5, 1974. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.74-7308 Filed 3-28-74;8:45 am]

[Docket Nos. RP71-29 and RP71-120]

UNITED GAS PIPE LINE CO.

Notice of Further Extension of Time and Postponement of Hearing

MARCH 22, 1974.

On March 21, 1974, Mississippi River Transmission Corporation filed a motion for a further extension of the procedural dates fixed by notice issued March 6, 1974, in the above-designated matter.

Upon consideration, notice is hereby given that the procedural dates in the above matter are further modified as follows:

Service of simultaneous rebuttal testimony by all parties, April 3, 1974.
Commencement of hearing, April 23, 1974 (10:00 a.m. e.d.t.).

KENNETH F. PLUMB,
Secretary.

[FR Doc.74-7309 Filed 3-28-74;8:45 am]

[Project No. 1744]

UTAH POWER & LIGHT CO.

Order Granting Request To File Late and Setting Time Period for Filing

MARCH 22, 1974.

Bountiful (Utah) City Light and Power, a municipality under section 3(7) of the Federal Power Act (16 U.S.C. 791a-825r), petitioned the Commission on February 15, 1974, for leave to file a major license application in the pending relicensing proceeding for Utah Power and Light Company's (UP&L) constructed Project No. 1744.

UP&L held the original license, 5 F.P.C. 865, modified, 6 F.P.C. 783, which expired June 30, 1970. Since that time the project has been operated under annual license.

After the original filing and several supplements thereto, public notice of application by UP&L for new license for Project No. 1744 was published in the FEDERAL REGISTER, July 29, 1972, 37 FR 15344 (1972), and Bountiful's Davis County Clipper, August 11, 1972. According to the Commission's rules and regulations, 18 CFR 16.3(b), Bountiful should have filed the instant request no later than January 1, 1968, unless later filing was authorized by the Commission.

In conjunction with 18 CFR 16.3(c), we herein grant Bountiful's request to file late, subject to the requirement that its application be filed no later than 120 days after the issuance date of this order. We consider it in the public interest to allow this municipality to present its case in the relicensing proceeding. Bountiful's delay in filing its request appears to have been in good faith, and same should not be denied.

The Commission finds. Good cause exists and the public interest may be served by granting the request of Bountiful City Lights and Power to file late a major license application for Project No. 1744.

The Commission orders. (A) Bountiful City Light and Power's request to file late a new license application for Project No. 1744 is hereby granted.

(B) Said license application must be filed no later than 120 days after the issuance date of this order.

By the Commission.

[SEAL] KENNETH F. PLUMB,
Secretary.

[FR Doc.74-7313 Filed 3-28-74;8:45 am]

NATIONAL POWER SURVEY TECHNICAL ADVISORY COMMITTEE ON CONSERVATION OF ENERGY

Order Designating an Additional Member

MARCH 25, 1974.

The Federal Power Commission, by order issued September 28, 1972, established the National Power Survey Technical Advisory Committees.

2. *Membership.* An additional member of the Technical Advisory Committee on Conservation of Energy, as selected by the Chairman of the Commission, with the approval of the Commission, is as follows:

Mr. Paul C. Greiner, Vice President, Electric Energy Association.

By the Commission.

[SEAL] KENNETH F. PLUMB,
Secretary.

[FR Doc.74-7316 Filed 3-28-74;8:45 am]

NATIONAL POWER SURVEY TECHNICAL ADVISORY COMMITTEE ON CONSERVATION OF ENERGY

Order Designating an Additional Member

MARCH 25, 1974.

The Federal Power Commission, by order issued September 28, 1972, established the National Power Survey Technical Advisory Committee on Conservation of Energy.

2. *Membership.* An additional member to the Technical Advisory Committee on Conservation of Energy, as selected by the Chairman of the Commission, with the approval of the Commission, is as follows:

Mr. Roderick R. Kirkwood, President, American Society of Heating, Refrigerating, and Air-Conditioning Engineers.

By the Commission.

[SEAL] KENNETH F. PLUMB,
Secretary.

[FR Doc.74-7317 Filed 3-28-74;8:45 am]

NATIONAL POWER SURVEY TECHNICAL ADVISORY COMMITTEE ON THE IMPACT OF INADEQUATE ELECTRIC POWER SUPPLY

Order Designating an Additional Member

MARCH 25, 1974.

The Federal Power Commission, by order issued February 28, 1974, established the National Power Survey Technical Advisory Committee on the Impact of Inadequate Electric Power Supply.

2. *Membership.* An additional member of the Technical Advisory Committee on the Impact of Inadequate Electric Power Supply, as selected by the Chairman of the Commission, with the approval of the Commission, is as follows:

Mr. W. P. Schmechel, Vice President and General Manager, Western Energy Company.

By the Commission.

[SEAL] KENNETH F. PLUMB,
Secretary.

[FR Doc.74-7315 Filed 3-28-74;8:45 am]

[Docket Nos. RI74-182, etc.]

SHELL OIL CO., ET AL.

Order Providing for Hearing on and Suspension of Proposed Changes in Rates, and Allowing Rate Changes To Become Effective Subject to Refund [1]

MARCH 22, 1974.

Respondents have filed proposed changes in rates and charges for jurisdictional sales of natural gas, as set forth in Appendix A hereof.

The proposed changed rates and charges may be unjust, unreasonable, unduly discriminatory, or preferential, or otherwise unlawful.

The Commission finds: It is in the public interest and consistent with the Natural Gas Act that the Commission enter upon hearings regarding the lawfulness of the proposed changes, and that the supplements herein be suspended and their use be deferred as ordered below.

The Commission orders: (A) Under the Natural Gas Act, particularly sections 4 and 15, the Regulations pertaining thereto (18 CFR Ch. I), and the Commission's rules of practice and procedure, public hearings shall be held concerning the lawfulness of the proposed changes.

(B) Pending hearings and decisions thereon, the rate supplements herein are suspended and their use deferred until date shown in the "Date Suspended Until" column. Each of these supplements shall become effective, subject to refund, as of the expiration of the suspension period without any further action by the Respondent or by the Commission. Each Respondent shall comply with the refunding procedure required by the Natural Gas Act and § 154.102 of the regulations thereunder.

(C) Unless otherwise ordered by the Commission, neither the suspended supplements, nor the rate schedules sought to be altered, shall be changed until disposition of these proceedings or expiration of the suspension period, whichever is earlier.

By the Commission.

[SEAL] KENNETH F. PLUMB, *Secretary.*

[1] Does not consolidate for hearing or dispose of the several matters herein.

APPENDIX A

Docket No.	Respondent	Rate schedule No.	Supplement No.	Purchaser and producing area	Amount of annual increase	Date filing tendered	Effective date unless suspended	Date suspended until—	Cents per Mcf* Rate in effect	Cents per Mcf* Proposed increased rate	Rate in effect subject to refund in docket No.
RI74-182	Shell Oil Co	343	[2] 6	El Paso Natural Gas Co. (Gomez		3-1-74	4-1-74	[1]			
			[3] 7	Field, Pecos County, Tex.	$29,740	3-1-74	4-1-74	[1]	22.12	33.76	
			[3] 8	Permian Basin).	6,068	3-1-74		9-1-74	33.76	36.135	
RI74-183	The Superior Oil Co	138	9	Transwestern Pipeline Co. (Bell Lake Unit, Lea County, N. Mex. Permian Basin).	325	3-1-74		9-1-74	22.86	23.6343	
RI74-184	Atlantic Richfield	451	[4] 8	El Paso Natural Gas Co. (Eumont Field, Lea County, N.		3-1-74	4-1-74	[1]			
			[5] 9	Mex. Permian Basin).	43,011	3-1-74		9-1-74	17.852	[8] 36.0	
RI74-185	Mobil Oil Corp	17	[7] 32	Northern Natural Gas Co. (Eu-		2-1-74	3-4-74	[1]			
			33	nice Area, Lea County, N. Mex. Permian Basin).	620,487	3-7-74		9-7-74	35.0	[8] 55.0	

*Unless otherwise stated, the pressure base is 14.65 lb/in²a.
[1] Accepted effective as of the date set forth in the "Effective Date Unless Suspended" column.
[2] Amendatory agreement dated Oct. 5, 1973.
[3] Applicable only to production from the Price Estate No. 1 well.
[4] Amendatory agreement.
[5] Applicable only to sales made pursuant to Supplement No. 8.
[6] Subject to Btu adjustment.
[7] Interim agreement dated Jan. 15, 1974 extending term of expired contract until Mar. 31, 1974.
[8] Unilateral increase.

The proposed increased rates which exceed the applicable area just and reasonable ceiling prescribed in Opinion No. 662 are suspended for five months.

Mobil requests waiver of the 30 day statutory notice period and a suspension period of only one day for its proposed increased rate. Good cause has not been shown for granting such request, and the request is denied.

By the Commission.

[FR Doc.74-7193 Filed 3-28-74;8:45 am]

FEDERAL RESERVE SYSTEM

CHEMUNG CANAL TRUST CO.

Order Approving Application for Merger of Banks

Chemung Canal Trust Company, Elmira, New York ("Elmira Bank"), a member State bank of the Federal Reserve System, has applied for the Board's approval pursuant to the Bank Merger Act (12 U.S.C. 1828(c)) of the merger of that bank with Montour National Bank in Montour Falls, Montour Falls, New York ("Montour Bank") under the charter and title of Elmira Bank. As an incident to the merger, the present office of Montour Bank would become a branch of the resulting bank.

As required by the Act, notice of the proposed merger, in form approved by the Board, has been published, and the Board had requested reports on competitive factors from the Attorney General, the Comptroller of the Currency, and the Federal Deposit Insurance Corporation. The Board has considered the application and all comments and reports received in the light of the factors set forth in the Act, and finds that:

Elmira Bank ($82 million deposits) controls less than 1 per cent of the deposits of commercial banks in the State of New York and 23.2 percent of deposits in the Elmira-Corning banking market [1] as the second largest of nine banking organizations competing in that market. (All banking data are as of June 30, 1973.)

Montour Bank ($7 million deposits) is also located in the Elmira-Corning banking market and controls 2.2 percent of the total deposits therein as the market's eighth largest bank.

Approval of the transaction would result in the merged institution controlling 25.4 percent of market deposits. However, the largest banking organization in the Elmira-Corning market, Marine Midland Banks, Inc., controls 37 percent of total market deposits, representing the largest share of such deposits. Other large organizations represented in the market are Charter New York Corporation and Lincoln First Banks. Whereas this proposal represents a slight increase in the concentration of deposits in the area, it appears that deconcentration of the area's deposits through acquisition of Montour Bank by an organization outside the market is not a likely possibility in view of the market's poor economic prospects. In commenting on the proposed transaction, the Department of Justice concluded that it would "not have a substantial competitive impact" inasmuch as it did "not appear that concentration would be substantially increased in any relevant banking market."

The closest banking office of Elmira Bank to Montour Bank's office is 14 miles away, and the areas served by each are neither contiguous nor overlapping. There is no significant existing competition between the offices of the two banks and although each of the banks could branch into the other's service area, it is unlikely that such competition would

[1] The relevant banking market is comprised of Schuyler and Chemung Counties and the southern quarter of Steuben County.

arise in view of Montour Bank's limited resources and the poor economic conditions of the area. Accordingly, the Board concludes that consummation of the proposed merger would not have any significantly adverse effect on either existing or future competition in the relevant area.

The financial and managerial resources of Elmira Bank and Montour Bank are satisfactory, and the prospects for the resulting bank are favorable. Consequently, banking factors are consistent with approval of the application. Consummation of the proposed merger would improve the present banking services available to customers of Montour Bank by increasing lending capabilities and by offering new services which would include credit cards, fiduciary services and investment counseling. Considerations relating to the convenience and needs of the area to be served lend weight toward approval of the application. It is the Board's judgment that consummation of the proposed merger would be in the public interest and that the application should be approved.

On the basis of the record, the application is approved for the reasons summarized above. The transaction shall not be made (a) before the thirtieth calendar day following the date of this order or (b) later than three months after the date of this order, unless such period is extended for good cause by the Board, or by the Federal Reserve Bank of New York pursuant to delegated authority.

By order of the Board of Governors,[3] effective March 20, 1974.

[SEAL] THEODORE E. ALLISON,
Assistant Secretary of the Board.

[FR Doc.74-7243 Filed 3-28-74;8:45 am]

DOMINION BANKSHARES CORP.

Order Approving Acquisition of Bank

Before the Federal Reserve Bank of Richmond acting under delegated authority from the Board of Governors of the Federal Reserve System.

Dominion Bankshares Corporation, Roanoke, Virginia (Applicant), a bank holding company within the meaning of the Bank Holding Company Act (12 U.S.C. 1842), has applied for prior approval under section 3(a)(3) of the Act to acquire 100 percent of the voting shares of the successor by merger to Merchants and Farmers Bank, Portsmouth, Virginia (Merchants), a State member bank.

The bank into which Merchants is to be merged has no significance except as a means of acquiring the voting shares of Merchants. Accordingly, the proposed acquisition of the successor organization is treated herein as a proposed acquisition of the shares of Merchants. The application is to be acted upon by the Federal Reserve Bank of Richmond (Reserve Bank) under authority delegated by the Board of Governors (12 CFR Part 265). Notice of the receipt of the application has been given in accordance with section 3(b) of the Act, and the time for filing comments and views has expired. The Reserve Bank has considered the application and all comments received in the light of the factors set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Applicant controls eight banking subsidiaries operating 72 offices with aggregate deposits of approximately $840 million, representing 7.4 percent of the total commercial bank deposits in Virginia as of June 30, 1973. In terms of deposits, it is the State's fifth largest banking organization. Acquisition of Merchants (deposits of approximately $44.6 million as of June 30, 1973), would increase Applicant's share of deposits in Virginia by approximately .4 percent which would not represent a significant increase in the concentration of banking resources in the State.

Merchants operates five offices including its head office and two branches in the City of Portsmouth and two branches in the City of Chesapeake. The primary service areas of these offices are contiguous and encompass virtually all of Portsmouth and that part of Chesapeake along its southwestern boundary. The relevant market area for Merchants consists of the Norfolk-Virginia Beach-Portsmouth SMSA which is approximated by the Cities of Norfolk, Chesapeake, Portsmouth, Virginia Beach, Virginia, and Currituck County, North Carolina. Thirteen separate banking organizations operate within this area including one of the Applicant's present banking subsidiaries, First National Bank of Norfolk. This bank has seven offices in Norfolk and Virginia Beach and one in the eastern section of Chesapeake. There is, however, no significant overlap in the service area of these offices with the service area of Merchants. The largest bank in the relevant market area is a subsidiary of the State's second largest banking organization and controls 42.1 percent of the area deposits. The next five largest banks are subsidiaries of the first, eighth, fourth, sixth and third largest bank holding companies in Virginia, respectively. Merchants ranks seventh in the market with 4.0 percent of deposits while First National Bank of Norfolk, with a 3.3 percent of deposits, ranks ninth. Applicant's acquisition of Merchants would reduce the number of separate banking organizations in the market by one and result in the Applicant's becoming fourth in the market, controlling 7.3 percent of total deposits in commercial banks in the market. In view of the factors cited above, it is concluded that the consummation of the proposal would not eliminate any significant existing competition between Merchants and First National Bank of Norfolk, nor would it give Applicant a dominant position in the market. Consummation of the proposal would not have any significant adverse effect on future competition or the development of future competition between Merchants and First National Bank of Norfolk, particularly in view of the large number of banking organizations already competing in the market. Accordingly, this Bank is of the view that competitive considerations are consistent with approval of the application.

The financial and managerial resources of Applicant and Merchants are generally satisfactory and the future prospects appear favorable. The future of Merchants would be particularly enhanced through affiliation with Applicant since it faces keen competition from a number of much larger banking organizations in the area. Although there is nothing in the record to indicate that the banking needs of the area are not presently being served, Merchants' affiliation with Applicant would give Merchants access to Applicant's financial resources and expertise and would enable Merchants to increase its loan limit and provide its customers with services not presently offered by Merchants. Considerations relating to convenience and needs of the area lend some weight toward approval of the application. It is the Reserve Bank's judgment, therefore, that the proposed acquisition would be in the public interest and that the application should be approved.

On the basis of the record, the application is approved for the reasons summarized above. The transaction shall not be consummated (a) before the thirtieth calendar day following the effective date of this order, or (b) later than three months after the date of this order, unless such period is extended for good cause by the Board of Governors of the Federal Reserve System or by the Federal Reserve Bank of Richmond pursuant to delegated authority.

By order of the Federal Reserve Bank of Richmond, acting pursuant to delegated authority for the Board of Governors of the Federal Reserve System, effective March 19, 1974.

[SEAL] WELFORD S. FARMER,
Senior Vice President and Special Legal Adviser.

[FR Doc.74-7245 Filed 3-28-74;8:45 am]

FIRST CITY BANCORPORATION OF TEXAS, INC.

Acquisition of Bank

First City Bancorporation of Texas, Inc., Houston, Texas, has applied for the Board's approval under section 3(a)(3) of the Bank Holding Company Act (12 U.S.C. 1842(a)(3)) to acquire 100 percent of the voting shares (less directors' qualifying shares) of the successor by merger to the Meyerland Bank, Houston, Texas. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the office of the Board of Governors or at the Federal Reserve Bank of Dallas. Any person wishing to comment on the

[3] Voting for this action: Vice Chairman Mitchell and Governors Brimmer, Sheehan, Bucher, Holland and Wallich. Absent and not voting: Chairman Burns.

application should submit views in writing to the Reserve Bank, to be received not later than April 19, 1974.

Board of Governors of the Federal Reserve System, March 21, 1974.

[SEAL] THEODORE E. ALLISON,
Assistant Secretary of the Board.

[FR Doc.74-7247 Filed 3-28-74;8:45 am]

MANUFACTURERS NATIONAL CORP.

Order Approving Acquisition of Bank

Manufacturers National Corporation, Detroit, Michigan, a bank holding company within the meaning of the Bank Holding Company Act, has applied for the Board's approval under section 3(a)(3) of the Act (12 U.S.C. 1842(a)(3)) to acquire all of the voting shares of the successor by merger to Saline Savings Bank, Saline, Michigan ("Bank"). The bank into which Bank is to be merged has no significance except as a means to facilitate the acquisition of the voting shares of Bank. Accordingly, the proposed acquisition of shares of the successor organization is treated herein as the proposed acquisition of the shares of Bank.

Notice of the application, affording opportunity for interested persons to submit comments and views, has been given in accordance with section 3(b) of the Act. The time for filing comments and views has expired, and none has been timely received. The Board has considered the application in light of the factors set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Applicant controls two banks[1] with aggregate deposits of approximately $2.2 billion, representing 8.4 percent of the total deposits in commercial banks in the State, and is the fourth largest banking organization in Michigan.[2] The acquisition of Bank (deposits of $13.4 million) would increase Applicant's share of the total commercial bank deposits in the State by less than 0.1 percent, and would not result in a significant increase in the concentration of banking resources in Michigan.

Bank is the ninth largest of ten banks in the Washtenaw County banking market, which is approximated by the Ann Arbor SMSA, and controls only 2.4 percent of deposits in that market. Although Applicant is not presently represented in the market, Applicant's lead Bank, Manufacturers National Bank of Detroit ("MNB"), the fourth largest bank in the adjacent Detroit banking market,[3] has six branches located within 25 miles of Bank, the closest branch being about 21 miles from Bank. Due to the proximity of Bank to MNB in the adjacent market, each bank does draw a small amount of deposits from the service area of the other, and consequently some small amount of existing and potential competition would be eliminated by consummation of the proposal. While it appears that Applicant has the resources to enter the market de novo, such entry appears unlikely in view of the fact that the area served by Bank has experienced below average population growth and has a below average population per banking office when such figures are compared to the respective State averages. Accordingly, on the basis of these and other facts of record, the Board concludes that consummation of the proposal would not have a significant adverse effect on competition in any relevant area.

The financial and managerial resources, and future prospects of Applicant and its subsidiaries are regarded as satisfactory. The same general conclusion is applicable with respect to the financial and managerial resources of Bank. Thus, considerations relating to the banking factors are consistent with approval of the application. Applicant proposes to expand and improve the range of services offered by Bank in such areas as increasing agricultural loans and providing conventional residential mortgage loans for longer maturities with reduced down-payment requirements. Applicant has also indicated that interest rates paid by Bank on savings accounts would be raised to the maximum rates allowed by Regulation Q. Considerations related to the convenience and needs of the community to be served, therefore, lend weight to the approval of the application. It is the Board's judgment that the proposed acquisition would be in the public interest and that the application should be approved.

On the basis of the record, the application is approved for the reasons summarized above. The transaction shall not be made (a) before the thirtieth calendar day following the effective date of this order or (b) later than three months after the effective date of this order, unless such period is extended for good cause by the Board, or by the Federal Reserve Bank of Chicago pursuant to delegated authority.

By order of the Board of Governors,[4] effective March 20, 1974.

[SEAL] THEODORE E. ALLISON,
Assistant Secretary of the Board.

[FR Doc.74-7246 Filed 3-28-74;8:45 am]

[1] One of Applicant's subsidiary banks is a recently acquired de novo bank located in Livonia, Michigan. Applicant received approval of that acquisition from the Reserve Bank of Chicago, acting under delegated authority, on November 21, 1973, and the bank opened for business on January 2, 1974.

[2] All banking data are as of June 30, 1973, and reflect bank holding company formations and organizations approved by the Board through February 28, 1974.

[3] Approximated by Wayne, Oakland and Macomb Counties in Detroit.

[4] Voting for this action: Vice Chairman Mitchell and Governors Brimmer, Sheehan, Bucher, Holland, and Wallich. Absent and not voting: Chairman Burns.

PORTSMOUTH BANK

Order Approving Application for Merger of Banks

Before the Federal Reserve Bank of Richmond acting under delegated authority from the Board of Governors of the Federal Reserve System.

Portsmouth Bank, Portsmouth, Virginia (Portsmouth), an organizing State bank which has applied for membership in the Federal Reserve System, has applied to the Board of Governors of the Federal Reserve System for prior approval pursuant to the Bank Merger Act (12 U.S.C. 1828(c)) to merge with Merchants and Farmers Bank (Merchants), Portsmouth, Virginia, a State member bank of the Federal Reserve System, the resulting bank to operate under the charter of Portsmouth and with the name of Merchants and Farmers Bank. The application is to be acted upon by the Federal Reserve Bank of Richmond (Reserve Bank) under authority delegated by the Board of Governors of the Federal Reserve System (12 CFR Part 265).

As required by the Bank Merger Act, notice of the proposed merger, in form approved by the Board of Governors, has been published and reports on competitive factors have been requested from the Attorney General, the Comptroller of the Currency and the Federal Deposit Insurance Corporation. The Reserve Bank has considered the application and all comments and reports received in light of the factors set forth in the Act.

On the basis of the record in this case, the application is approved for the reasons summarized in the Reserve Bank's Order of this date relating to the application of Dominion Bankshares Corporation to acquire the successor by merger to Merchants and Farmers Bank. The transaction shall not be consummated (a) before the thirtieth calendar day following the date of this order, or (b) later than three months after the date of this order, unless such period is extended for good cause by the Board of Governors of the Federal Reserve System or by the Federal Reserve Bank of Richmond pursuant to delegated authority.

By order of the Federal Reserve Bank of Richmond, acting pursuant to delegated authority for the Board of Governors of the Federal Reserve System, effective March 19, 1974.

[SEAL] WELFORD S. FARMER,
Senior Vice President and Special Legal Adviser.

[FR Doc.74-7253 Filed 3-28-74;8:45 am]

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

VISUAL ARTS ADVISORY PANEL

Notice of Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given that a closed meeting of the Visual Arts Photography Exhibition Aid Advisory Panel to the National Council on the Arts will be held at 11:00 a.m. on April 1, 1974 in Room 1200 of the Shoreham Building, 806 15th Street NW., Washington, D.C.

This meeting is for the purpose of Panel review, discussion, evaluation, and

recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman published in the FEDERAL REGISTER of January 10, 1973, this meeting, which involves matters exempt from the requirements of public disclosure under the provisions of the Freedom of Information Act (5 U.S.C. 552(b) (4), (5) and (6)), will not be open to the public.

Further information with reference to this meeting can be obtained from Mrs. Luna Diamond, Advisory Committee Management Officer, National Endowment for the Arts, Washington, D.C. 20506, or call (202) 382–5871.

EDWARD M. WOLFE,
Administrative Officer, National Endowment for the Arts, National Foundation on the Arts and the Humanities.

[FR Doc.74–7337 Filed 3–28–74;8:45 am]

OFFICE OF MANAGEMENT AND BUDGET

REQUESTS FOR CLEARANCE OF REPORTS INTENDED FOR USE IN COLLECTING INFORMATION

Notice of List

The following is a list of requests for clearance of reports intended for use in collecting information from the public received by the Office of Management and Budget on March 26, 1974 (44 U.S.C. 3509). The purpose of publishing this list in the FEDERAL REGISTER is to inform the public.

The list includes the title of each request received; the name of the agency sponsoring the proposed collection of information; the agency form number, if applicable; the frequency with which the information is proposed to be collected; the name of the reviewer or reviewing division within OMB, and an indication of who will be the respondents to the proposed collection.

The symbol (x) identifies proposals which appear to raise no significant issues, and are to be approved after brief notice through this release.

Further information about the items on this Daily List may be obtained from the Clearance Office, Office of Management and Budget, Washington, D.C. 20503 (202–395–4529).

NEW FORMS

DEPARTMENT OF COMMERCE

Bureau of the Census, Franchising in the Economy, 1973–1975, Form DIB–910, Annual, Sunderhauf, Franchisors.

Refined Copper Shipments, Form DIB–973, Monthly, Lowry, Shippers of Refined Copper.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

National Institutes of Health, Request for Subscriber Interest Data, Form OS–NIH–OD–3, Annual, Caywood, Science Editors and Writers.

Office of Education, Upward Bound Study Data Collection Instruments, Form OE–351, –1 through –12, Single Time, HRD/Planchon, Students, principals, counsellors, teachers, etc.

REVISIONS

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of Education, Report on ESEA Title I Comparability Requirements—Pub. L. 89–10, as amended by Pub. L. 91–230, Form OE–4524, Annual, Planchon, Local Educational Agencies

EXTENSIONS

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Center for Disease Control, Joint Program for the Study of Abortion/CDC Form CDC 4.316, Occasional, Evinger(x), Medical Care Facilities

DEPARTMENT OF LABOR

Employment Standards Administration, Application for Industrial Homework Handbooks, Form WH–77, Occasional, Evinger (x), Individual Employers

DEPARTMENT OF STATE

Application for Employment in the Foreign Service of the United States, Form DSP–33, Occasional, Evinger (x), Job Applicants

PHILLIP D. LARSEN,
Budget & Management Officer.

[FR Doc.74–7386 Filed 3–28–74;8:45 am]

INTERSTATE COMMERCE COMMISSION

[Notice 475]

ASSIGNMENT OF HEARINGS

MARCH 26, 1974.

Cases assigned for hearing, postponement, cancellation or oral argument appear below and will be published only once. This list contains prospective assignments only and does not include cases previously assigned hearing dates. The hearings will be on the issues as presently reflected in the Official Docket of the Commission. An attempt will be made to publish notices of cancellation of hearings as promptly as possible, but interested parties should take appropriate steps to insure that they are notified of cancellation or postponements of hearings in which they are interested.

No amendments will be entertained after the date of this publication.

MC–C–8242, General Leaseways, Inc., Burk Distributing Co., Inc., Levi Distributing, Inc., Keith V. Knight, Dba Knight Distributing Co., and Joseph G. Bowers—Investigation of Operations, now assigned May 1, 1974, at Des Moines, Iowa, will be held in Room B, 7th Floor, Valley Bank Bldg., 4th and Walnut Street.

MC–134958 Sub 6, Hams Express, Inc., now assigned April 30, 1974, will be held in Room 1614 Court of Claims, Everett McKinley Dirksen Bldg., 219 South Dearborn St., Chicago, Ill.

MC–F–11915, Nussbaum Trucking, Inc.—Investigation of Control—Zone Motor Freight Inc., now assigned April 29, 1974 will be held in room 1614 Court of Claims, Everett McKinley Dirksen Bldg., 219 South Dearborn St., Chicago, Ill.

MC–136553 Sub 21, Art Pape Transfer, Inc., now assigned May 2, 1974, will be held in Room 1614 Court of Claims, Everett McKinley Dirksen Bldg., 219 South Dearborn St., Chicago, Ill.

MC–92692 Sub 6, Freeport Fast Freight, Inc., now assigned May 6, 1974, will be held in Room 1614 Court of Claims, Everett McKinley Dirksen Bldg., 219 South Dearborn St., Chicago, Ill.

MC 116073 Sub–31, Barrett Mobile Home Transport, Inc., Extension—Buildings (13 Western States); MC 116073 Sub–35, Barrett Mobile Home Transport, Inc., Extension—Buildings (Arizona), and MC 116073 Sub–85, Barrett Mobile Home Transport, Inc., Extension—Idaho (Moorhead, Minn.), now assigned April 29, 1974 at Phoenix, Arizona, will be held in Room 1, Arizona Corporation Commission, 1688 W. Adams Street; now assigned May 2, 1974 at Las Vegas, Nevada, will be held in Room 213 Tax Court, Federal Bldg. & Post Office, 301 Stewart Street; now assigned May 6, 1974 at Los Angeles, Calif., will be held in Courtroom 517, U.S. Courthouse, 312 N. Spring Street; now assigned May 9, 1974 at Seattle, Washington, will be held in Room 1057, Federal Office Bldg., 909 First Avenue; now assigned May 13, 1974 at Spokane, Washington, will be held in Room 695, U.S. Courthouse, W. 920 Riverside; now assigned May 15, 1974, at Boise, Idaho, will be held in Room 595, Federal Building & U.S. Courthouse, 550 W. Fort Street.

No. 35265, Anglo-Canadian Pulp and Paper Mills, Ltd., Aberdeen V. And Rockfish Rail-Road Company, et al., is continued to May 21, 1974, at the Offices of the Interstate Commerce Commission, Washington, D.C.

MC 2253 Sub 65, Carolina Freight Carriers Corp., now assigned May 20, 1974, at Atlanta, Ga., will be held in Room 305, 1252 West Peachtree St., NW.

[SEAL] JOSEPH M. HARRINGTON,
Acting Secretary.

[FR Doc.74–7329 Filed 3–28–74;8:45 am]

[AB–19 (Sub-No. 8)]

BALTIMORE & OHIO RAILROAD CO. AND BALTIMORE AND OHIO RAILROAD CO. IN PENNSYLVANIA

Abandonment of Certain Railroad Lines

Upon consideration of the record in the above-entitled proceeding and of a staff-prepared environmental threshold assessment survey which is available for public inspection upon request; and

It appearing, That no environmental impact statement need be issued in this proceeding because this proceeding does not represent a major Federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969, 42 U.S.C. 4321, et seq.; and good cause appearing therefore:

It is ordered, That applicant be, and is hereby, directed to publish the appended notice in a newspaper of general circulation in Allegheny County, Fla., within 15 days of the date of service of this order, and certify to this Commission that this has been accomplished.

And it is further ordered, That notice of this order shall be given to the general public by depositing a copy thereof in the Office of the Secretary of the Commission at Washington, D.C., and by forwarding a copy to the Director, Office of

the Federal Register, for publication in the FEDERAL REGISTER.

Dated at Washington, D.C., this 21st day of March, 1974.

By the Commission, Commissioner Tuggle.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[No. AB-19 (Sub-No. 8)]

BALTIMORE & OHIO RAILROAD COMPANY AND BALTIMORE AND OHIO RAILROAD COMPANY IN PENNSYLVANIA ABANDONMENT PORT PERRY BRANCH BETWEEN BESSEMER AND BESSEMER JUNCTION, ALLEGHENY COUNTY, PA.

The Interstate Commerce Commission hereby gives notice that by order dated March 21, 1974, it has been determined that the proposed abandonment of the line of The Baltimore and Ohio Railroad Company and The Baltimore and Ohio Railroad Company in Pennsylvania, between Bessemer and Bessemer Junction, Allegheny County, Pa., a distance of approximately 0.48 miles, if approved by the Commission, would not constitute a major Federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321, et seq., and that preparation of a detailed environmental impact statement will not be required under section 4332(2) (C) of the NEPA.

It was concluded, among other things, that no traffic has been moved over this line in over 2 years, that the involved traffic still moves by railroad but traverses an interchange point at Millvale, Pa., rather than Bessemer Junction, and that there has been no objection raised (environmental or otherwise) to this abandonment. The determination was based upon the staff preparation and consideration of an environmental threshold assessment survey, which is available for public inspection upon request at the Interstate Commerce Commission, Office of Proceedings, Washington, D.C. 20423; telephone 202-343-6989.

Interested parties may comment on this matter by the submission of representations to the Interstate Commerce Commission, Washington, D.C. 20423, on or before April 15, 1974.

[FR Doc.74-7326 Filed 3-28-74;8:45 am]

FOURTH SECTION APPLICATION FOR RELIEF

MARCH 26, 1974.

An application, as summarized below, has been filed requesting relief from the requirements of section 4 of the Interstate Commerce Act to permit common carriers named or described in the application to maintain higher rates and charges at intermediate points than those sought to be established at more distant points.

Protests to the granting of an application must be prepared in accordance with Rule 40 of the General Rules of Practice (49 CFR 1100.40) and filed on or before April 15, 1974.

FSA No. 42820—*Iron or Steel Scrap to Monongahela, Pennsylvania.* Filed by Traffic Executive Association-Eastern Railroads, Agent (E.R. No. 3042), for and on behalf of the Penn Central Transportation Company (George P. Baker, Richard C. Bond, and Jervis Langdon, Jr., Trustees). Rates on scrap iron or steel, in carloads, as described in the application, from Cincinnati, Ohio, to Monongahela, Pa.

Grounds for relief—Market competition and rate relationship.

Tariff—Supplement 112 to Traffic Executive Association-Eastern Railroads, Agent, tariff 789, I.C.C. No. C-689. Rates are published to become effective on April 25, 1974.

By the Commission.

[SEAL] JOSEPH M. HARRINGTON, *Acting Secretary.*

[FR Doc.74-7334 Filed 3-28-74;8:45 am]

[Notice 51]

MOTOR CARRIER BOARD TRANSFER PROCEEDINGS

Synopses of orders entered by the Motor Carrier Board of the Commission pursuant to sections 212(b), 206(a), 211, 312(b), and 410(g) of the Interstate Commerce Act, and rules and regulations prescribed thereunder (49 CFR Part 1132), appear below:

Each application (except as otherwise specifically noted) filed after March 27, 1972, contains a statement by applicants that there will be no significant effect on the quality of the human environment resulting from approval of the application. As provided in the Commission's special rules of practice any interested person may file a petition seeking reconsideration of the following numbered proceedings on or before April 18, 1974. Pursuant to section 17(8) of the Interstate Commerce Act, the filing of such a petition will postpone the effective date of the order in that proceeding pending its disposition. The matters relied upon by petitioners must be specified in their petitions with particularity.

No. MC-FC-75035. By order entered March 25, 1974, the Motor Carrier Board approved the transfer to A & A Transport, Inc., of Lisbon, Conn., of that portion of the operating rights set forth in Certificate of Registration No. MC-99227 (Sub-No. 1), issued October 28, 1964, to Laurel Van Lines, Inc., Norwich, Conn., evidencing a right to engage in operations in interstate or foreign commerce in the transportation of general commodities (other than household goods and office furniture and equipment and other than commodities which necessitate the use of dump trucks, tank trucks or special equipment), within Connecticut, between all points, upon call received at headquarters in Norwich. William J. Meuser, 86 Cherry St., Milford, Conn. 06460 and Paul J. Goldstein, 109 Church St., New Haven, Conn., attorneys for transferee and transferor, respectively.

[SEAL] JOSEPH M. HARRINGTON, *Acting Secretary.*

[FR Doc.74-7330 Filed 3-28-74;8:45 am]

[MC-730 (Sub-No. 342)]

PACIFIC INTERMOUNTAIN EXPRESS CO.

Extension—Alternate Routes

At a session of the Interstate Commerce Commission, Division 1, Acting as an Appellate Division, held at its office in Washington, D.C., on the 15th day of March, 1974.

It appearing, that by application filed November 13, 1972, Pacific Intermountain Express Co., a corporation, of Oakland, Calif., seeks a certificate of public convenience and necessity authorizing operation, in interstate or foreign commerce, as a common carrier by motor vehicle, over regular routes, of the commodities and between the points in the manner indicated in Appendix A;

It further appearing, that the Operating Rights Board, by order of September 13, 1973, granted applicant authority as indicated in Appendix B, and directed that notice of the authority actually granted be published in the FEDERAL REGISTER;

It further appearing, that on October 17, 1973, notice of the authority granted was published in the FEDERAL REGISTER to allow any proper party in interest to file an appropriate petition for leave to intervene in the proceeding; that on October 18, 1973, Werner Continental, Inc., a motor common carrier, filed a petition for leave to intervene and tendered verified statements in support of its position; that on November 23, 1973, applicant timely filed a petition for reconsideration embracing a reply to Werner's petition for leave to intervene; that Werner filed a reply to applicant's petition for reconsideration on December 14, 1973; and that by letter received January 8, 1974, Werner withdrew its opposition to the application; and good cause appearing therefor:

It is ordered, That the proceeding be, and it is hereby, reopened for reconsideration on the present record.

It further appearing, that the evidence of record, when considered in light of applicant's petition, shows the Operating Rights Board's statement of facts and its ultimate conclusion concerning the proposed routes in parts (1) and (3) of the application to be substantially correct; that as to the proposed routes in part (2) of the application the evidence of record fails to show that applicant now holds authority to serve Danville, Ill., which is merely identified as an intermediate nonservice point on another alternate route; that consequently alternate route authority from and to that point cannot properly be granted herein; and that in the circumstances, alternate route authority from Indianapolis through Danville to St. Paul should be granted;

It further appearing, that since it is possible that other parties who have relied upon the notice in the FEDERAL REGISTER of the application as originally published may have an interest in and would be prejudiced by the lack of notice of the grant of authority in part (2)

herein, a notice of the authority actually granted will be published in the FEDERAL REGISTER and issuance of the certificate in this proceeding will be withheld for a period of 30 days from the date of such publication, during which period any proper party in interest may file an appropriate petition for leave to intervene in the proceeding setting forth in detail the precise manner in which it has been prejudiced;

It further appearing, that inasmuch as the grant of authority described in this order duplicates to a certain extent existing authority held by applicant and applicant's commonly controlled affiliate, Ryder Truck Lines, Inc., in No. MC–2900 and sub-numbers thereunder, the grant of authority herein shall contain an appropriate nonserverability clause; and good cause appearing therefor:

It is further ordered, That the order entered in this proceeding on September 13, 1973, to the extent inconsistent herewith, be, and it is hereby, vacated and set aside.

We find on reconsideration, That the present and future public convenience and necessity require operation by applicant, in interstate or foreign commerce, as a common carrier by motor vehicle over regular routes, of the commodities and between the points indicated in Appendix C; that applicant is fit, willing, and able properly to perform such service and to conform to the requirements of the Interstate Commerce Act and the Commission's rules and regulations thereunder; that this decision is not a major Federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969; that an appropriate certificate should be issued, subject to publication in the FEDERAL REGISTER as stated above; and that the application in all other respects should be denied.

It is further ordered, That said application and said petition, except to the extent granted herein, be, and they are hereby, denied.

It is further ordered, That the grant of authority in this order shall not be severable, by sale or otherwise, from applicant's existing authority or from the authority held by applicant's commonly controlled affiliate, Ryder Truck Lines, Inc., in No. MC–2900 and sub-numbers thereunder.

It is further ordered, That upon compliance by applicant with the requirements of sections 215, 217, and 221(c) of the Interstate Commerce Act, and with the Commission's rules and regulations thereunder, within the time specified in the next succeeding paragraph, and subject to prior publication in the FEDERAL REGISTER of notice of the authority actually granted, an appropriate certificate will be issued.

It is further ordered, That unless compliance is made by applicant with the requirements of sections 215, 217, and 221(c) of the Act within 90 days after the date of service of this order, or within such additional time as may be authorized by the Commission, the grant of authority shall be considered as null and void, and the application shall stand denied in its entirety effective upon the expiration of the said compliance time.

It is further ordered, That notice of the authority granted herein be published in the FEDERAL REGISTER.

By the Commission, Division 1, Acting as an Appellate Division.

[SEAL] ROBERT L. OSWALD, *Secretary.*

APPENDIX A

Authority Sought. Operation as a common carrier by motor vehicle, over regular routes, of general commodities, (except those of unusual value, Classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment); (1) between Louisville, Ky., and St. Paul, Minn.: from Louisville over Interstate Highway 65 (also U.S. Highway 31) to Indianapolis, Ind., thence over Interstate Highway 65 (also U.S. Highway 52 to junction U.S. Highway 41, thence over U.S. Highway 41) to Chicago, Ill., thence over Interstate Highway 90 (also U.S. Highway 12) to Madison, Wis., thence over Interstate Highway 94 (also U.S. Highway 12) to St. Paul, and return over the same route. Applicant requests joinder of routes at junction Interstate Highway 65 and Interstate Highway 70; at junction Interstate Highway 65 and Interstate Highway 90; and at junction Interstate Highway 90 and U.S. Highway 18. (2) Between Danville, Ill., and St. Paul, Minn.: from Danville over Illinois Highway 1 to Chicago, Ill., (also from Danville over Illinois Highway 1 to junction Illinois Highway 17, thence over Illinois Highway 17 to Kankakee, Ill., thence over Interstate Highway 57 to Chicago), thence from Chicago to St. Paul as specified in Route (1) above, and return over the same routes. Applicant requests joinder of routes at Danville, Ill., at junction Illinois Highway 1 and U.S. Highway 20; and at junction Interstate Highway 57 and Interstate Highway 80. (3) Between Danville, Ill., and St. Paul, Minn.: from Danville over Interstate Highway 74 (also U.S. Highway 150) to Bloomington, Ill., thence over U.S. Highway 51 to Interstate 90 at or near South Beloit, Ill., thence over Interstate Highway 90 (also U.S. Highway 51) to Madison, Wis., thence from Chicago to St. Paul as specified in Route (1) above, and return over the same route. Applicant requests joinder of routes at junction Interstate Highway 74 and Interstate Highway 55; the junction of U.S. Highway 51 and U.S. Highway 30; the junction of U.S. Highway 51 and Illinois Highway 38 (formerly U.S. Highway 30 Alternate); the junction of U.S. Highway 51 and Interstate Highway 90; and at the junction of U.S. Highway 51 and U.S. Highway 12. (4) Between Chicago, Ill., and St. Paul, Minn.: from Chicago over Interstate Highway 90 to junction Interstate Highway 94, thence over Interstate Highway 94 to St. Paul, and return over the same route. The operations in (1), (2), (3), and (4) above are as alternate routes for operating convenience only, serving no intermediate points. RESTRICTION: Operations over Route (4) above is restricted against the transportation of traffic originating at points in the Chicago, Ill., Commercial Zone and destined to points in the Minneapolis-St. Paul, Minn., Commercial Zone; also against transportation of shipments originating at points in the Minneapolis-St. Paul, Minn., Commercial Zone and destined to points in the Chicago, Ill., Commercial Zone.

APPENDIX B

Authority Granted by Order Entered September 13, 1973. Operation by applicant, in interstate or foreign commerce, as a common carrier by motor vehicle, over regular routes, of general commodities, (except those of unusual value, Classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment) (1) between Louisville, Ky., and St. Paul, Minn., from Louisville over Interstate Highway 65 (also U.S. Highway 31) to Indianapolis, Ind., thence over Interstate Highway 65 to junction Interstate Highway 90 at or near Gary, Ind., thence over Interstate Highway 90 (also from Indianapolis over U.S. Highway 52 to junction U.S. Highway 41, thence over U.S. Highway 41) to Chicago, Ill., thence over Interstate Highway 90 (also U.S. Highway 12) to Madison, Wis., thence over Interstate Highway 94 (also U.S. Highway 12) to St. Paul, and return over the same route, as an alternate route for operating convenience only, serving no intermediate points, (2) between Danville, Ill., and St. Paul, Minn., (a) from Danville over Illinois Highway 1 to Chicago, (also from Danville over Illinois Highway 1 to junction Illinois Highway 17, thence over Illinois Highway 17 to Kankakee, Ill., thence over Interstate Highway 57 to Chicago), thence from Chicago to St. Paul as specified in Route (1) above, and return over the same routes, and (b) from Danville over Interstate Highway 74 (also U.S. Highway 150) to Bloomington, Ill., thence over U.S. Highway 51 to junction Interstate Highway 90 at or near South Beloit, Ill., thence over Interstate Highway 90 (also U.S. Highway 51) to Madison, Wis., thence from Madison to St. Paul as specified in Route (1) above, and return over the same route, serving no intermediate points, and restricted in both 2(a) and 2(b) to the transportation of traffic either received from or delivered to connecting carriers at Danville, Ill., and (3) between Chicago, Ill., and St. Paul, Minn.: from Chicago over Interstate Highway 90 to junction Interstate Highway 94, thence over Interstate Highway 94 to St. Paul, and return over the same route, as an alternate route for operating convenience only, serving no intermediate points, restricted in (3) above against the transportation of traffic originating at points in the Chicago, Ill., commercial zone and destined to points in the St. Paul, Minn., commercial zone and against transportation of traffic originating at points in the St. Paul, Minn., commercial zone and destined to points in the Chicago, Ill., commercial zone.

APPENDIX C

Authority granted herein. Operation by applicant, In interstate or foreign commerce, as a common carrier by motor vehicle, over regular routes, of general commodities (except those of unusual value, Class A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment) (1) between Louisville, Ky., and St. Paul, Minn., from Louisville over Interstate Highway 65 (also U.S. Highway 31) to Indianapolis, Ind., thence over Interstate Highway 65 to junction Interstate Highway 90 at or near Gary, Ind., thence over Interstate Highway 90 (also from Indianapolis over U.S. Highway 52 to junction U.S. Highway 41, thence over U.S. Highway 41) to Chicago, Ill., thence over Interstate Highway 90 (also U.S. Highway 12) to Madison, Wis., thence over Interstate Highway 94 (also U.S. Highway 12) to St. Paul, and return over the same route, as an alternate route for operating convenience only, serving no intermediate points, (2) between Indianapolis, Ind., and St. Paul,

Minn., (a) from Indianapolis over Interstate Highway 74 to Danville, Ill., thence over Illinois Highway 1 to Chicago, Ill. (also from Danville over Illinois Highway 1 to junction Illinois Highway 17, thence over Illinois Highway 17 to Kankakee, Ill., thence over Interstate Highway 57 to Chicago), thence from Chicago to St. Paul as specified in Route (1) above, and return over the same routes, as an alternate route for operating convenience only, serving no intermediate points, and (b) from Indianapolis over Interstate Highway 74 (also U.S. Highway 150) to Bloomington, Ill., thence over U.S. Highway 51 to junction Interstate Highway 90 at or near South Beloit, Ill., thence over Interstate Highway 90 (also U.S. Highway 51) to Madison, Wis., thence from Madison to St. Paul as specified in Route (1) above, and return over the same route, as an alternate route for operating convenience only, serving no intermediate points, and (3) between Chicago, Ill., and St. Paul, Minn., from Chicago over Interstate Highway 90 to junction Interstate Highway 94, thence over Interstate Highway 94 to St. Paul, and return over the same route, as an alternate route for operating conveniences only, serving no intermediate points, restricted in (3) above against the transportation of traffic originating at points in the Chicago, Ill., commercial zone and destined to points in the St. Paul, Minn., commercial zone and against transportation of traffic originating at points in the St. Paul, Minn., commercial zone and destined to points in the Chicago, Ill., commercial zone: The routes described in (1), (2)(a), (2)(b), and (3) above are restricted against joinder at any intermediate points.

[FR Doc.74-7328 Filed 3-28-74;8:45 am]

[Amdt. 6; I.C.C. Order No. 75; Rev. Service Order No. 994]

WESTERN MARYLAND RAILWAY CO.

Rerouting Traffic

To all Railroads. Upon further consideration of I.C.C. Order No. 75 (Western Maryland Railway Company) and good cause appearing therefor:

It is ordered, That I.C.C. Order No. 75 be, and it is hereby, amended by substituting the following paragraph (g) for paragraph (g) thereof:

(g) *Expiration date.* This order shall expire at 11:59 p.m., June 30, 1974, unless otherwise modified, changed, or suspended.

It is further ordered, That this amendment shall become effective at 11:59 p.m., March 31, 1974, and that this order shall be served upon the Association of American Railroads, Car Service Division, as agent of all railroads subscribing to the car service and car hire agreement under the terms of that agreement, and upon the American Short Line Railroad Association; and that it be filed with the Director, Office of the Federal Register.

Issued at Washington, D.C., March 25, 1974.

INTERSTATE COMMERCE COMMISSION,

[SEAL] R. D. PFAHLER, *Agent.*

[FR Doc.74-7325 Filed 3-28-74;8:45 am]

[No. AB-34 (Sub-No. 1)]

ST. JOSEPH & GRAND ISLAND RAILWAY CO. AND UNION PACIFIC RAILROAD CO.

Abandonment of Certain Railroad Lines

Upon consideration of the record in the above-entitled proceeding and of a staff-prepared environmental threshold assessment survey which is available for public inspection upon request; and

It appearing, That no environmental impact statement need be issued in this proceeding, because this proceeding does not represent a major Federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969, 42 U.S.C. 4321, et seq.; and good cause appearing therefore:

It is ordered, That applicant be, and is hereby directed to publish the appended notice in a newspaper of general circulation in Hall County, Nebr., within 15 days of service of this order, and certify to this Commission that this has been accomplished.

And it is further ordered, That notice of this order shall be given to the general public by depositing a copy thereof in the Office of the Secretary of the Commission at Washington, D.C. 20423, and by forwarding a copy to the Director, Office of the Federal Register, for publication in the FEDERAL REGISTER.

Dated at Washington, D.C., this 21st day of March 1974.

By the Commission, Commissioner Tuggle.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[AB-34 (Sub-No. 1)]

ST. JOSEPH & GRAND ISLAND RAILWAY COMPANY AND UNION PACIFIC RAILROAD COMPANY ABANDONMENT OF A PORTION OF THE ST. JOSEPH & GRAND ISLAND MAIN LINE AT GRAND ISLAND, HALL COUNTY, NEBR.

The Interstate Commerce Commission hereby gives notice that by order dated March 21, 1974, it has been determined that the proposed abandonment of a portion of the main line of St. Joseph & Grand Island Railway Company and Union Pacific Railroad Company (lessee) in Grand Island, Nebr., a distance of approximately 1.13 miles, if approved by the Commission, would not constitute a major Federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321, et seq.; and that preparation of a detailed environmental impact statement will not be required under section 4332(2)(C) of NEPA.

It was concluded, among other things, that traffic over the line has decreased substantially. This line is part of a three track main line system running through the city of Grand Island, Nebr., and the traffic presently being handled over the subject line will be diverted to the parallel tracks of the Union Pacific Railroad. Motor carrier service in the area is adequate. In addition, the abandonment will be consistent with local land use plans in Grand Island. There will, therefore, be a minimum impact on the area's total transportation scheme.

This determination was based upon the staff preparation and consideration of an environmental threshold assessment survey, which is available for public inspection upon request to the Interstate Commerce Commission, Office of Proceedings, Washington, D.C. 20423; telephone 202-343-6989.

Interested parties may comment on this matter by the submission of representations to the Interstate Commerce Commission, Washington, D.C. 20423, on or before April 15, 1974.

[FR Doc. 74-7327 Filed 3-28-74;8:45 am]

ATOMIC ENERGY COMMISSION

[Docket Nos. 50-400—50-403]

CAROLINA POWER AND LIGHT CO.

Notice of Availability of Revised Final Environmental Statement

Pursuant to the National Environmental Policy Act of 1969 and the United States Atomic Energy Commission's regulations in Appendix D to 10 CFR Part 50, notice is hereby given that the Revised Final Environmental Statement prepared by the Commission's Directorate of Licensing, related to the proposed Shearon Harris Nuclear Power Plant Units 1, 2, 3, & 4, to be constructed by Carolina Power and Light Company in Wake and Chatham Counties, North Carolina is available for inspection by the public in the Commission's Public Document Room at 1717 H Street, NW., Washington, D.C. and in the Wake County Public Library, 104 Fayetteville Street, Raleigh, North Carolina. The Revised Final Environmental Statement is also being made available at the Office of the Planning Coordinator, Clearinghouse and Information Center, 116 West Jones Street, Raleigh, North Carolina 27603.

The notice of availability of the Revised Draft Environmental Statement for the Shearon Harris Nuclear Power Plant Units 1, 2, 3, & 4, and requests for comments from interested persons was published in the FEDERAL REGISTER on January 18, 1974 (39 FR 2287). The comments received from Federal, State, local and interested members of the public have been included as appendices to the Revised Final Environmental Statement.

Single copies of the Revised Final Environmental Statement may be obtained by writing the U.S. Atomic Energy Commission, Washington, D.C. 20545, Attention: Deputy Director for Reactor Projects, Directorate of Licensing.

Dated at Bethesda, Md., this 25th day of March 1974.

For the Atomic Energy Commission.

GORDON K. DICKER, *Chief, Environmental Projects Branch 2, Directorate of Licensing.*

[FR Doc.74-7249 Filed 3-28-74;8:45 am]

[Docket Nos. 50-475, 50-476]

CONSUMERS POWER CO.

Notice of Receipt of Application for Construction Permits and Facility Licenses and Availability of Applicant's Environmental Report: Time for Submission of Views on Antitrust Matters

Consumers Power Company (the applicant), pursuant to section 103 of the Atomic Energy Act of 1954, as amended, has filed an application, which was docketed February 28, 1974, for authorization to construct and operate two generating units utilizing pressurized water nuclear reactors. The application was tendered on October 29, 1973. Following a preliminary review for completeness, the application was rejected on November 8, 1973, for lack of sufficient information. The applicant submitted additional information on February 11, 1974, and the application was found to be acceptable for docketing. Docket Nos. 50-475 and 50-476 have been assigned to the application and should be referenced in any correspondence relating to the application.

The proposed nuclear facility, designated by the applicant as the Quanicassee Plant, is located in Hampton Township, Bay County, Michigan, and each unit is designed for initial operation at aproximately 3425 megawatts (thermal), with a net electrical output of approximately 1150 megawatts.

A Notice of Hearing with opportunity for public participation is being published separately.

Any person who wishes to have his views on the antitrust matters of the application presented to the Attorney General for consideration should submit such views to the U.S. Atomic Energy Commission, Washington, D.C. 20545, Attention: Chief, Office of Antitrust and Indemnity, Directorate of Licensing, on or before May 29, 1974. The request should be filed in connection with Docket Nos. 50-475-A and 50-476-A.

A copy of the application is available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. 20545, and at the Bay City Public Library, 708 Center Avenue, Bay City, Michigan 48706.

The applicant has also filed, pursuant to the National Environmental Policy Act of 1969, and the regulations of the Commission in Appendix D to 10 CFR Part 50, an Environmental Report dated February 1974. The report, which discusses environmental considerations related to the construction and operation of the proposed facility is being made available for public inspection at the aforementioned locations and at the State Planning Division, Bureau of Programs and Budget, Executive Office of the Governor, Lewis Cass Building, Lansing, Michigan 48913, and the Bay Regional Planning Commission, County Building, Bay City, Michigan 48706.

After the Environmental Report has been analyzed by the Commission's Director of Regulation or his designee, a draft environmental statement will be prepared by the Commission's Regulatory staff. Upon preparation of the draft environmental statement, the Commission will, among other things, cause to be published in the FEDERAL REGISTER a summary notice of availability of the draft statement, with a request for comments from interested persons on the draft statement. The summary notice will also contain a statement to the effect that comments of Federal agencies and State and local officials will be made available when received. Upon consideration of comments submitted with respect to the draft environmental statement, the Regulatory staff will prepare a final environmental statement, the availability of which will be published in the FEDERAL REGISTER.

Dated at Bethesda, Md., this 14th day of March 1974.

For the Atomic Energy Commission.

KARL KNIEL,
Chief, Light Water Reactors Branch 2-2, Directorate of Licensing.

[FR Doc.74-7250 Filed 3-28-74;8:45 am]

[Docket Nos. 50-475, 50-476]

CONSUMERS POWER CO.

Notice of Hearing on Application for Construction Permits

Pursuant to the Atomic Energy Act of 1954, as amended (the Act), and the regulations in Title 10, Code of Federal Regulations, Part 50, "Licensing of Production and Utilization Facilities," and Part 2, rules of practice, notice is hereby given that a hearing will be held by an Atomic Safety and Licensing Board (Board), to consider the application filed under the Act by the Consumers Power Company (the applicant), for construction permits for two pressurized water nuclear reactors designated as the Quanicassee Plant, Units 1 and 2 (the facilities), each of which will be designed for operation at approximately 3425 thermal megawatts with a net electrical output of approximately 1150 megawatts. The proposed facilities are to be located in Hampton Township, Bay County, Michigan.

The hearing, which will be scheduled to begin in the vicinity of the site of the proposed facilities, will be conducted by an Atomic Safety and Licensing Board (Board) which has been designated by the Chairman of the Atomic Safety and Licensing Board Panel, consisting of Edward Luton, Esq., Chairman, Gustave A. Linenberger, and Dr. Ernest O. Salo.

Pursuant to 10 CFR 2.785, an Atomic Safety and Licensing Appeal Board will exercise the authority and the review function which would otherwise be exercised and performed by the Commission. Notice as to the membership of the Appeal Board will be published in the FEDERAL REGISTER at a later date.

Upon completion by the Commission's regulatory staff of a favorable safety evaluation of the application and an environmental review and upon receipt of a report by the Advisory Committee on Reactor Safeguards, the Director of Regulation will consider making affirmative findings on Items 1-3, a negative finding on Item 4, and an affirmative finding on Item 5 specified below as a basis for the issuance of construction permits to the applicant:

ISSUES PURSUANT TO THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

1. Whether in accordance with the provisions of 10 CFR 50.35(a):

(a) The applicant has described the proposed design of the facilities including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public;

(b) Such further technical or design information as may be required to complete the safety analysis and which can reasonably be left for later consideration, will be supplied in the final safety analysis report;

(c) Safety features or components, if any, which require research and development have been described by the applicant and the applicant has identified, and there will be conducted a research and development program reasonably designed to resolve any safety questions associated with such features or components; and

(d) On the basis of the foregoing, there is reasonable assurance that (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facilities, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100, the proposed facilities can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

2. Whether the applicant is technically qualified to design and construct the proposed facilities;

3. Whether the applicant is financially qualified to design and construct the proposed facilities; and

4. Whether the issuance of permits for construction of the facilities will be inimical to the common defense and security or to the health and safety of the public.

ISSUE PURSUANT TO NATIONAL ENVIRONMENTAL POLICY ACT OF 1969 (NEPA)

5. Whether, in accordance with the requirements of Appendix D of 10 CFR Part 50, the construction permits should be issued as proposed.

In the event that this proceeding is not a contested proceeding, as defined by 10 CFR 2.4(n), the Board will determine: (1) Without conducting a de novo evaluation of the application, whether the application and the record of the proceeding contain sufficient information, the review of the application by the Commission's regulatory staff has been

adequate to support the proposed findings to be made by the Director of Regulation on Items 1–4 above, and to support, insofar as the Commission's licensing requirements under the Act are concerned the issuance of the construction permits proposed by the Director of Regulation; and (2) whether the review conducted by the Commission pursuant to NEPA has been adequate.

In the event that this proceeding becomes a contested proceeding, the Board will consider and initially decide, as issues in this proceeding, Items 1–5 above as a basis for determining whether the construction permits should be issued to the applicant.

With respect to the Commission's responsibilities under NEPA, and regardless of whether the proceeding is contested or uncontested, the Board will, in accordance with section A.11 of Appendix D of 10 CFR Part 50: (1) Determine whether the requirements of section 102(2) (C) and (D) of NEPA and Appendix D of 10 CFR Part 50 have been complied with in this proceeding; (2) independently consider the final balance among conflicting factors contained in the record of the proceeding with a view to determining the appropriate action to be taken; and (3) determine whether the construction permits should be issued, denied, or appropriately conditioned to protect environmental values.

The Board will convene a special prehearing conference of the parties to the proceeding and persons who have filed petitions for leave to intervene, or their counsel, to be held within sixty (60) days after the notice of hearing is published or at such other time as the Board deems appropriate, for the purpose of dealing with the matters specified in 10 CFR 2.751a.

The Board will convene a prehearing conference of the parties, or their counsel, to be held subsequent to any required special prehearing conference, and within sixty (60) days after discovery has been completed or at such other time as the Board may specify, for the purpose of dealing with the matters specified in 10 CFR 2.752.

The Board will set the time and place for any special prehearing conference, prehearing conference and evidentiary hearing and the respective notices will be published in the FEDERAL REGISTER.

Any person who does not wish, or is not qualified, to become a party to this proceeding may request permission to make a limited appearance pursuant to the provisions of 10 CFR 2.715. A person making a limited appearance may make an oral or written statement on the record. He does not become a party, but may state his position and raise questions which he would like to have answered to the extent that the questions are within the scope of Items 1–5 above. Limited appearances will be permitted at the time of the hearing at the discretion of the Board, within such limits and on such conditions as may be fixed by the Board. Persons desiring to make a limited appearance are requested to inform the Secretary of the Commission and others in the manner specified below.

Any person whose interest may be affected by the proceeding, who wishes to participate as a party in the proceeding must file a written petition under oath or affirmation for leave to intervene in accordance with the provisions of 10 CFR 2.714. A petition for leave to intervene shall set forth the interest of the petitioner in the proceeding, how that interest may be affected by the results of the proceeding, and any other contentions of the petitioner including the facts and reasons why he should be permitted to intervene, with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. Any such petition shall be accompanied by a supporting affidavit identifying the specific aspect or aspects of the subject matter of the proceeding as to which the petitioner wishes to intervene and setting forth with particularity both the facts pertaining to his interest and the basis for his contentions with regard to each aspect on which he desires to intervene. A petition that sets forth contentions relating only to matters outside the jurisdiction of the Commission will be denied.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have all the rights of the applicant to participate fully in the conduct of the hearing, such as the examination and cross-examination of witnesses, with respect to their contentions related to the matters at issue in the proceeding.

A petition for leave to intervene must be filed with the Secretary of the Commission and others as specified below by April 29, 1974. A petition for leave to intervene which is not timely will not be granted unless the Board determines that the petitioner has made a substantial showing of good cause for failure to file on time and after the Board has considered those factors specified in 10 CFR 2.714(a)(1)–(4) and 2.714(d).

An answer to this notice, pursuant to the provisions of 10 CFR 2.705, must be filed by the applicant by April 29, 1974.

Papers required to be filed in this proceeding shall be filed by mail or telegram addressed to the Secretary of the Commission, United States Atomic Energy Commission, Washington, D.C. 20545, Attention: Chief, Public Proceedings Staff, or may be filed by delivery to the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. Pending further order of the Board, parties are required to file, pursuant to the provisions of 10 CFR 2.708, an original and twenty (20) conformed copies of each such paper with the Commission. A copy of the petition or request for limited appearance should also be sent to the Chief Hearing Counsel, Office of the General Counsel, Regulation, U.S. Atomic Energy Commission, Washington, D.C. 20545 and to Judd L. Bacon, Esq., Senior Attorney, Consumers Power Company, 212 W. Michigan Avenue, Jackson, Michigan 49201, attorney for the applicant.

For further details, see the application for construction permits dated February 28, 1974, and amendments thereto, and the applicant's environmental report dated February 1974, which are available for public inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, D.C., between the hours of 8:30 a.m. and 5:00 p.m. on weekdays. Copies of those documents are also available at the Bay City Public Library, 708 Center Avenue, Bay City, Michigan 48706 for inspection by members of the public between the hours of 9:30 a.m. and 9:00 p.m., Monday, Tuesday, Wednesday and Friday, and between 9:30 a.m. and 6:00 p.m., Thursday and Saturday. As they become available, a copy of the safety evaluation report by the Commission's Directorate of Licensing, the Commission's draft and final environmental statements, the report of the Advisory Committee on Reactor Safeguards (ACRS), the proposed construction permits, the transcripts of the prehearing conferences and of the hearing, and other relevant documents, will also be available at the above locations. Copies of the Directorate of Licensing's safety evaluation report and the Commission's final environmental statement, the proposed construction permits, and the ACRS report may be obtained, when available, by request to the Deputy Director for Reactor Projects, Directorate of Licensing, United States Atomic Energy Commission, Washington, D.C. 20545.

Dated at Germantown, Md., this 21 day of March 1974.

UNITED STATES ATOMIC ENERGY COMMISSION,
PAUL C. BENDER,
Secretary of the Commission.

[FR Doc.74-7300 Filed 3-28-74;8:45 am]

ADVISORY COMMITTEE ON REACTOR SAFEGUARDS ENVIRONMENTAL SUBCOMMITTEE

Notice of Meeting

MARCH 27, 1974.

In accordance with the purposes of sections 29 and 182b. of the Atomic Energy Act (42 U.S.C. 2039, 2232b.), the Advisory Committee on Reactor Safeguards' Environmental Subcommittee will hold a meeting on April 18 and 19, 1974 in Room 1046, 1717 H Street NW., Washington, D.C. The purpose of the meeting will be to consider a variety of subjects and programs pertaining to protection of the environment.

The following constitutes that portion of the Subcommittee's agenda for the above meeting which will be open to the public:

THURSDAY, APRIL 18, 1974, 9:00 A.M.–1:00 P.M.

Review of report by Marc Ross, Physics Departments, University of Michigan, entitled: "The Possibility of Release of Cesium in a Spent-Fuel Transportation Accident."

In connection with the above agenda item, the Subcommittee and its consultants will hold an executive session at 8:30 a.m. on April 18 which will involve a discussion of their preliminary views of the agenda item, and an executive session beginning at 2:00 p.m. on April 18 and continuing all day on April 19 to discuss and to formulate appropriate recommendations to the full ACRS regarding: Regulatory Guide 4.2, "Preparation of Environmental Reports for Nuclear Power Plants," March 1973, and Draft Regulatory Guides: "Calculation of Annual Average Doses to Man from Routine Releases of Reactor Effluents for the Purpose of Implementing Appendix I"; "Calculation of Releases of Radioactive Materials in Liquid and Gaseous Effluents from Pressurized Water Reactors (PWRs)"; "Calculation of Releases of Radioactive Materials in Liquid and Gaseous Effluents from Boiling Water Reactors (BWRs)"; "Methods for Estimating Atmospheric Dispersion of Gaseous Effluents from Routine Releases"; "Analytical Models for Estimating Radioisotope Concentration in Different Water Bodies"—all of which appear in Attachment to Concluding Statement of Position of the Regulatory Staff, Public Rulemaking Hearing On: Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion "As Low as Practicable" for Radioactive Material in Light-Water-Cooled Nuclear Power Reactors, Draft Regulatory Guides for Implementation, February 20, 1974, Docket No. RM–50–2, U.S. Atomic Energy Commission, Washington, D.C. 20545.

I have determined, in accordance with Subsection 10(d) of Pub. L. 92–463, that the executive sessions at the beginning and end of the meeting will consist of an exchange of opinions and formulation of recommendations, the discussion of which, if written, would fall within exemption (5) of (5 U.S.C. 552(b)). It is essential to close such portions of the meeting to protect the free interchange of internal views and to avoid undue interference with Agency or Committee operation.

Practical considerations may dictate alterations in the above agenda or schedule.

The Chairman of the Subcommittee is empowered to conduct the meeting in a manner that, in his judgment, will facilitate the orderly conduct of business, including provisions to carry over an incompleted open session from one day to the next.

With respect to public participation in the open portion of the meeting, the following requirements shall apply:

(a) Persons wishing to submit written statements regarding the agenda items may do so by mailing 25 copies thereof, postmarked no later than April 11, 1974, to the Executive Secretary, Advisory Committee on Reactor Safeguards, U.S. Atomic Energy Commission, Washington, D.C. 20545.

(b) Those persons submitting a written statement in accordance with paragraph (a) above may request an opportunity to make oral statements concerning the written statement. Such requests shall accompany the written statement and shall set forth reasons justifying the need for such oral statement and its usefulness to the Subcommittee. To the extent that the time available for the meeting permits, the Subcommittee will receive oral statements during a period of no more than 30 minutes at an appropriate time, chosen by the Chairman of the Subcommittee, between the hours of 10:00 a.m. and 12:30 p.m. on April 18, 1974.

(c) Requests for the opportunity to make oral statements shall be ruled on by the Chairman of the Subcommittee, who is empowered to apportion the time available among those selected by him to make oral statements.

(d) Information as to whether the meeting has been cancelled or rescheduled, and in regard to the Chairman's ruling on requests for the opportunity to present oral statements, and the time allotted, can be obtained by a prepaid telephone call on April 16, 1974, to the Office of the Executive Secretary of the Committee (telephone: 301–973–5651) between 8:30 a.m. and 5:15 p.m., e.d.t.

(e) Questions may be propounded only by members of the Subcommittee and its consultants.

(f) Seating for the public will be available on a first-come, first-served basis.

(g) The use of still, motion picture, and television cameras, the physical installation and presence of which will not interfere with the conduct of the meeting, will be permitted both before and after the meeting and during any recess. The use of such equipment will not, however, be allowed while the meeting is in session.

(h) A copy of the transcript of the open portions of the meeting will be available for inspection during the following workday at the Atomic Energy Commission's Public Document Room, 1717 H Street NW., Washington, D.C. 20545. Copies of the transcript may be reproduced in the Public Document Room or may be obtained from Ace Federal Reporters, Inc., 415 Second Street NE., Washington, D.C. 20002 (telephone 202–547–6222) upon payment of appropriate charges.

(i) On request, copies of the Minutes of the meeting will be made available for inspection at the Atomic Energy Commission Public Document Room, 1717 H Street NW., Washington, D.C. 20545 on or after June 19, 1974. Copies may be obtained upon payment of appropriate charges.

JOHN C. RYAN,
Advisory Committee
Management Officer.

[FR Doc.74–7481 Filed 3–28–74;10:55 am]

LIQUID METAL FAST BREEDER REACTOR (LMFBR) PROGRAM AND DRAFT ENVIRONMENTAL IMPACT STATEMENT

Notice of Public Hearing

On Wednesday, March 13, 1974, the Atomic Energy Commission published in the FEDERAL REGISTER (39 FR 9692) notice of the availability of a draft environmental impact statement, "Liquid Metal Fast Breeder Reactor Program," issued pursuant to 10 CFR Part 11—AEC regulations implementing the National Environmental Policy Act of 1969, and comments thereon were invited. Notice was also given in that document that copies of such statement are available for public inspection at the following locations:

1717 H Street, NW., Washington, D.C. 20545
P.O. Box 5400, Albuquerque, New Mexico 87115
9500 South Cass Avenue, Argonne, Illinois 60439
550 Second Street, Idaho Falls, Idaho 83401
Federal Building, Oak Ridge, Tennessee 37830
1333 Broadway, Oakland, California 94612
Savannah River Plant, Aiken, South Carolina 29801
Federal Building, Richland, Washington 99352

Single copies of the draft statement will be furnished free of charge upon request addressed to the Office of the Assistant General Manager for Biomedical and Environmental Research and Safety Programs, U.S. Atomic Energy Commission, Washington, D.C. 20545.

As comments are received, copies will be available for inspection at the AEC Public Document Room, 1717 H Street NW., Washington, D.C. 20545.

The March 13 FEDERAL REGISTER notice also stated that the AEC plans to conduct a legislative-type public hearing in connection with the Liquid Metal Fast Breeder Reactor (LMFBR) Program starting at 10 a.m. on April 24, 1974, in the AEC Auditorium, Germantown, Maryland. The hearing will be conducted by a Presiding Board which will be designated in a further notice in the FEDERAL REGISTER. Further notice of the procedures and other pertinent aspects of the public hearing is hereby supplied.

The purpose of the hearing is to afford further opportunity for public comments regarding the LMFBR program in general and the draft environmental impact statement in particular and for the furnishing of any additional information which will assist the Commission in determining whether to continue the LMF BR program. The Commission has decided as a matter of discretion to hold this hearing as there is no requirement for a hearing on the LMFBR program or draft environmental impact statement under the National Environmental Policy Act of 1969 or any other law.

Any person who wishes to become a participant in the proceeding must file with the Secretary of the Commission not later than the close of business on April 19, 1974, an original and five conformed copies of a request to become a participant. The request must set forth: (1) His name and address; (2) his organizational affiliation, if any; (3) his technical or other qualifications to make

a contribution to the hearing; (4) the text of any statements to be presented at the hearing, or a reasonably detailed summary thereof; (5) the names and addresses of all witnesses to be called at the hearing by the participant, the technical or other qualifications, if any, of such witnesses, and a statement of the substance of the proposed testimony, or a reasonably detailed summary thereof and (6) the amount of time desired to complete the presentation. The Presiding Board will endeavor to schedule participants for the full amount of time requested. However, it may not be able to accommodate requests in excess of one-half hour. Participants may, but need not be represented by counsel. The Presiding Board may, in its discretion, at the commencement of each session of the hearing, admit persons as participants on good cause shown as to why they did not seek advance qualification as participants.

Any person who wishes to present an oral or written statement at the hearing, but does not desire to become a participant as specified hereinabove, is encouraged to make a limited appearance. Such an appearance will be permitted in the discretion of the Presiding Board. Persons desiring to make a limited appearance are requested to inform the Secretary of the Commission not later than the close of business on April 19, 1974.

Participants and persons making limited appearances may submit written questions relevant to the purpose of the hearing to the Presiding Board, which will, in its discretion, make provision for the answering of such questions as appropriate.

Procedures that will be followed in the scheduled hearing are as follows:

1. Two members of the Presiding Board will constitute a quorum, if one of those members is the Chairman.

2. All persons admitted as participants will present their testimony under oath. Consistent with the full and true disclosure of the facts, duplicative, redundant or nonproductive testimony will not be permitted and the Presiding Board will impose suitable restrictions to that end.

3. The AEC will make available appropriate witnesses to explain the background and purpose of the LMFBR program and the contents of the draft environmental impact statement. Participants may request specified witnesses, and if such a request is made, the Presiding Board, upon determining that the request is relevant, nonduplicating and meritorius, will encourage such witness to testify. No subpoenas requiring the testimony of witnesses will be issued by the Presiding Board.

4. Participants will reference and produce on request the documents on which they rely. Requests for interrogatories, depositions or formal discovery will not be entertained.

5. The Presiding Board is authorized to take appropriate action to control the course of the hearing, including the authority to maintain order; administer oaths and affirmations; rule on offers of, and receive, evidence; regulate the course of the hearing and the conduct of the participants; provide for consolidation of presentations as appropriate; dispose of procedural requests or similar matters; examine witnesses; and hold conferences before or during the hearing.

The hearing will be conducted as expeditiously as practicable, consistent with affording participants and those making limited appearances a reasonable opportunity to present their positions, as determined by the Presiding Board. A transcript of the hearing will be made, and a copy of the transcript, together with copies of all documents presented at the hearing, will be placed in the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. 20545, and at the other locations specified in the first paragraph of this notice, where they will be available for inspection by members of the public.

After the conclusion of the hearing, the Presiding Board, without rendering any decision or making any recommendation, will forward the transcript of the hearing to the Commission together with its identification of issues raised at the hearing.

Dated at Germantown, Maryland, this 26th day of March 1974.

PAUL C. BENDER,
Secretary of the Commission.

[FR Doc.74–7406 Filed 3–29–74;8:45 am]

federal register

FRIDAY, MARCH 29, 1974

WASHINGTON, D.C.

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PART II



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

DRUGS FOR HUMAN USE

Reorganization and Republication

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER D—DRUGS FOR HUMAN USE

[Recodification Docket No. 5]

Reorganization and Republication

The Commissioner of Food and Drugs, for the purposes of establishing an orderly development of informative regulations for the Food and Drug Administration, furnishing ample room for expansion of such regulations in years ahead, and providing the public and affected industries with regulations that are easy to find, read, and understand, has initiated a recodification program for Chapter I of Title 21 of the Code of Federal Regulations.

This is the fifth document in a series of recodification documents that will eventually include all regulations administered by the Food and Drug Administration.

The volume of regulatory material for human drugs under Subchapter C—Drugs requires that these regulations be recodified in two documents. This, the fifth document, recodifies drug regulations in current Parts 130, 131, 164, 165, and 167. Another, a sixth document, pertaining to procedural regulations and individual drug monographs for antibiotic drugs for human use, will be published in the FEDERAL REGISTER prior to the revision of the annual volume of the Code of Federal Regulations relating to Parts 141 through 599, which is scheduled for May 1, 1974.

Regulations for human drugs formerly under Parts 130, 131, 164, 165, and 167 of Subchapter C—Drugs have been reorganized into a new Subchapter D—Drugs for Human Use in an effort to provide greater clarity and convenience to the user. The following table shows the relationship of the CFR section numbers under Subchapter C prior to this republication to their redesignation reflected in the new Parts 310, 312, 314, 328, 329, 330, 369, and 429 of Subchapter D:

Old section	*New section*
130.1	310.3
130.2	310.4
130.3	312.1
130.3a	312.9
130.3b	312.10
130.4	314.1
130.5	314.110
130.6	314.100
130.7	314.6
130.8	314.7
130.9	314.8
130.10	314.105
130.11	314.9
130.12	314.111
130.13	310.300
130.13a	310.301
130.13b	314.13
130.14	314.200
130.15	314.201
130.16	314.202
130.17	314.203
130.18	314.204
130.19	314.220
130.20	314.221
130.21	314.222
130.22	314.205
130.23	314.206
130.24	314.230
130.25	314.231
130.26	314.232
130.27	314.115
130.28	314.120
130.29	314.121
130.30	314.12
130.31	314.235
130.32	314.11
130.33	314.10
130.34	314.116
130.35	310.302
130.36	310.101
130.37	310.102
130.38	310.9
130.39	310.100
130.40	310.6
130.41	310.103
130.44	310.505
130.45	310.501
130.46	310.504
130.47	310.303
130.48	310.304
130.49	310.503
130.50	310.502
130.51	310.500
130.101	310.200
130.102	310.201
130.201	314.300
130.301(a) (1) through (12)	330.10
130.301(a) (13)	330.11
130.301(b)	330.5
130.302	330.1
130.303	330.12
131.1	369.1
131.2	369.2
131.3	369.3
131.4	369.4
131.5	369.5
131.6	369.6
131.7	369.7
131.8	369.8
131.9	369.9
131.10	369.10
131.15	369.20
131.16	369.21
131.17	369.22
131.25	369.30
164.1	429.3
164.2	429.40
164.3	429.41
164.4	429.45
164.5	429.10
164.6	429.11
164.7	429.12
164.8	429.60
164.9	429.47
164.10	429.55
164.11	429.25
164.12	429.26
164.15	429.30
164.16	429.50
165.1	329.1
165.2	329.10
165.5	329.20
167.1	328.3
167.2	328.10
167.3	328.30
167.4	328.4
167.5	328.34
167.6	328.35
167.7	328.20

The changes being made are nonsubstantive in nature and for this reason notice and public procedure are not prerequisites to this promulgation. For the convenience of the user, the entire text of Parts 310, 312, 314, 328, 329, 330, 369, and 429 of Subchapter D are set forth below.

Dated: March 27, 1974.

SAM D. FINE,
Associate Commissioner for Compliance.

Therefore, 21 CFR is amended by redesignating Parts 130, 131, 164, 165, and 167 of Subchapter C as Parts 310, 312, 314, 328, 329, 330, 369, and 429 of Subchapter D—Drugs for Human Use, and republished to read as follows:

Suchapter D—Drugs for Human Use

Part
310 New Drugs.
312 New Drugs for Investigational Use.
314 New Drug Applications.
328 In Vitro Diagnostic Products.
329 Habit Forming Drugs.
330 Over-the-Counter (OTC) Human Drugs Generally Recognized as Safe and Effective and Not Misbranded.
369 Interpretative Statements Re Warnings on Drugs and Devices for Over-the-Counter Sale.
429 Drugs Composed Wholly or Partly of Insulin.

PART 310—NEW DRUGS

Subpart A—General Provisions

Sec.
310.3 Definitions and interpretations.
310.4 Biologics; products subject to license control.
310.6 Applicability of Drug Efficacy Study Implementation Notices and Notices of Opportunity for Hearing to identical, related, and similar drug products.
310.9 Designated journals.

Subpart B—Specific Administrative Rulings and Decisions

310.100 New-drug status opinions; statement of policy.
310.101 FD&C Red No. 4; procedure for discontinuing use in new drugs for ingestion; statement of policy.
310.102 Consent for use of investigational new drugs (IND) on humans; statement of policy.
310.103 New-drug substances intended for hypersensitivity testing.

Subpart C—New Drugs Exempted From Prescription-Dispensing Requirements

310.200 Prescription-exemption procedure.
310.201 Exemption for certain drugs limited by new-drug applications to prescription sale.

Subpart D—Records and Reports

310.300 Records and reports concerning experience on drugs for which an approval is in effect.
310.301 Reporting of adverse drug experiences.
310.302 Records and reports on new drugs and antibiotics for use by man for which applications or certification forms 5 and 6 became effective or were approved prior to June 20, 1963.
310.303 Continuaton of long-term studies, records, and reports on certain drugs for which new-drug applications have been approved.
310.304 Drugs that are subjects of approved new-drug applications and that require special studies, records, and reports.

Subpart E—Requirements for Specific New Drugs or Devices

310.500 Digoxin products for oral use; conditions for marketing.
310.501 Oral contraceptive preparations; labeling directed to the patient.
310.502 Certain intrauterine devices for human use for the purpose of contraception.

Sec.
310.503 Requirements regarding certain radioactive drugs.
310.504 Amphetamines (amphetamine, dextroamphetamine, and their salts and levamfetamine and its salts) for human use.
310.505 Conditions for use of methadone.

AUTHORITY: Secs. 502, 503, 505, 701, 52 Stat. 1051, 1052, 1053, 1055, as amended (21 U.S.C. 352, 353, 355, 371) (5 U.S.C. 554), unless otherwise noted.

Subpart A—General Provisions

§ 310.3 Definitions and interpretations.

As used in this part:

(a) The term "act" means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201–902, 52 Stat. 1040 et seq., as amended; 21 U.S.C. 321–392).

(b) "Department" means the Department of Health, Education, and Welfare.

(c) "Secretary" means the Secretary of Health, Education, and Welfare.

(d) "Commissioner" means the Commissioner of Food and Drugs.

(e) The term "person" includes individuals, partnerships, corporations, and associations.

(f) The definitions and interpretations of terms contained in section 201 of the act shall be applicable to such terms when used in the regulations in this part.

(g) "New-drug substance" means any substance that when used in the manufacture, processing, or packing of a drug, causes that drug to be a new drug, but does not include intermediates used in the synthesis of such substance.

(h) The newness of a drug may arise by reason (among other reasons) of:

(1) The newness for drug use of any substance which composes such drug, in whole or in part, whether it be an active substance or a menstruum, excipient, carrier, coating, or other component.

(2) The newness for a drug use of a combination of two or more substances, none of which is a new drug.

(3) The newness for drug use of the proportion of a substance in a combination, even though such combination containing such substance in other proportion is not a new drug.

(4) The newness of use of such drug in diagnosing, curing, mitigating, treating, or preventing a disease, or to affect a structure or function of the body, even though such drug is not a new drug when used in another disease or to affect another structure or function of the body.

(5) The newness of a dosage, or method or duration of administration or application, or other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug when used in other dosage, or other method or duration of administration or application, or different condition, is not a new drug.

(i) "Animals used only for laboratory research" and "laboratory research animals" mean individual animals or groups of animals used solely for laboratory research purposes regardless of species and does not include animals intended to be used for any food purposes or animals intended to be kept as domestic pets or livestock.

(j) The term "sponsor" means the person or agency who assumes responsibility for an investigation of a new drug, including responsibility for compliance with applicable provisions of the act and regulations. The "sponsor" may be an individual, partnership, corporation, or Government agency and may be a manufacturer, scientific institution, or an investigator regularly and lawfully engaged in the investigation of new drugs.

(k) The phrase "related drug(s)" includes other brands, potencies, dosage forms, salts, and esters of the same drug moiety, including articles prepared or manufactured by other manufacturers; and any other drug containing a component so related by chemical structure or known pharmacological properties that, in the opinion of experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, it is prudent to assume or ascertain the liability of similar side effects and contraindications.

(l) [Reserved]

(m) "Designated journal(s)" means journals listed in § 310.9.

§ 310.4 Biologics; products subject to license control.

A new drug shall not be deemed to be subject to section 505 of the act if it is a drug licensed under the Public Health Service Act of July 1, 1944 (58 Stat. 682, as amended; 42 U.S.C. 201 et seq.) or under the animal virus, serum, and toxin law of March 4, 1913 (37 Stat. 832; 21 U.S.C. 151 et seq.).

§ 310.6 Applicability of Drug Efficacy Study Implementation notices and notices of opportunity for hearing to identical, related, and similar drug products.

(a) The Food and Drug Administration's conclusions on the effectiveness of drugs are currently being published in the FEDERAL REGISTER as Drug Efficacy Study Implementation (DESI) Notices and as Notices of Opportunity for Hearing. The specific products listed in these notices include only those that were introduced into the market through the new-drug procedures from 1938–62 and were submitted for review by the National Academy of Sciences-National Research Council (NAS–NRC), Drug Efficacy Study Group. Many products which are identical to, related to, or similar to the products listed in these notices have been marketed under different names or by different firms during this same period or since 1962 without going through the new-drug procedures or the Academy review. Even though these products are not listed in the notices, they are covered by the new drug applications reviewed and thus are subject to these notices. All persons with an interest in a product that is identical, related, or similar to a drug listed in a drug efficacy notice or a notice of opportunity for a hearing will be given the same opportunity as the applicant to submit data and information, to request a hearing, and to participate in any hearing. It is not feasible for the Food and Drug Administration to list all products which are covered by an NDA and thus subject to each notice. However, it is essential that the efficacy conclusions be applied to all identical, related, and similar drug products to which those conclusions are reasonably applicable. Any product not in compliance with an applicable drug efficacy notice is in violation of section 505 (new drugs) and/or section 502 (misbranding) of the act.

(b) An identical, related, or similar drug includes other brands, potencies, dosage forms, salts, and esters of the same drug moiety as well as of any drug moiety related in chemical structure or known pharmacological properties. Where experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs would conclude that the findings in a drug efficacy notice or notice of opportunity for hearing concerning effectiveness are applicable to an identical, related, or similar drug product, such product is affected by the notice. A combination drug product containing an identical, related, or similar drug is also subject to the conclusions contained in the notice. Any person may request an opinion on the applicability of such a notice to a specific product by writing to the Food and Drug Administration at the address shown in paragraph (e) of this section.

(c) Manufacturers and distributors of drugs should review their products as drug efficacy notices are published and assure that identical, related, or similar products comply with all the provisions of the notices.

(d) The published notices and summary lists of the conclusions are of particular interest to drug purchasing agents. These agents should take particular care to assure that the same purchasing policy applies to drug products that are identical, related, or similar to those named in the drug efficacy notices. The Food and Drug Administration applies the same regulatory policy to all such products. In many instances a determination can readily be made as to the applicability of a drug efficacy notice by an individual who is knowledgeable about drugs and their indications for use. Where the relationships are more subtle and not readily recognized, the purchasing agent may request an opinion by writing to the Food and Drug Administration at the address shown in paragraph (e) of this section.

(e) Interested parties may submit to the Food and Drug Administration, Bureau of Drugs, Office of Compliance, HFD–300, 5600 Fishers Lane, Rockville, MD 20852, the names of drug products, and of their manufacturers or distributors, that should be the subject of the same purchasing and regulatory policies as those reviewed by the Drug Efficacy Study Group. Appropriate action, including referral to purchasing officials of various government agencies, will be taken.

(f) This regulation does not apply to OTC drugs identical, similar, or related to a drug in the Drug Efficacy Study unless there has been or is notification in

the FEDERAL REGISTER that a drug will not be subject to an OTC panel review pursuant to §§ 330.10, 330.11, and 330.5 of this chapter.

§ 310.9 Designated journals.

The following journals are available to the Food and Drug Administration and thus permit waiving of the submission of reprints and summaries covering reports contained in these journals to the extent that such requirements are waived in the regulations in this part:

Acta Allergologica (Copenhagen).
Acta Endocrinologica (Copenhagen).
Acta Haematologica (Basel).
Acta Medica Scandinavica (Stockholm).
Acta Obstetricia et Gynecologica Scandinavica (Lund).
Acta Paediatrica Scandinavica (Stockholm).
Acta Pathologica et Microbiologica Scandinavica (Copenhagen).
Acta Pharmacologica et Toxicologica (Copenhagen).
Acta Physiologica et Pharmacologica Neerlandica (Amsterdam).
Acta Psychiatrica Scandinavica (Copenhagen).
Acta Psychiatrica Scandinavica Supplementum (Copenhagen).
Aerospace Medicine (St. Paul).
Alabama Journal of Medical Sciences (Birmingham).
Alaska Medicine (Anchorage).
American Heart Journal (St. Louis).
American Journal of Cardiology (New York).
American Journal of Clinical Nutrition (Bethesda).
American Journal of Clinical Pathology (Baltimore).
American Journal of Digestive Diseases (New York).
American Journal of Diseases of Children (Chicago).
American Journal of Gastroenterology (New York).
American Journal of Hospital Pharmacy (Ann Arbor).
American Journal of Medicine (New York).
American Journal of the Medical Sciences (Philadelphia).
American Journal of Obstetrics and Gynecology (St. Louis).
American Journal of Ophthalmology (Chicago).
American Journal of Pathology (New York).
American Journal of Pharmacy and the Sciences Supporting Public Health (Philadelphia).
American Journal of Physiology (Bethesda).
American Journal of Psychiatry (Hanover, N.H.).
American Journal of Psychotherapy (Lancaster, Pa.).
American Journal of Public Health and the Nation's Health (New York).
American Journal of Roetgenology, Radium Therapy and Nuclear Medicine (Springfield, Ill.).
American Journal of Surgery (New York).
American Journal of Tropical Medicine and Hygiene (Baltimore).
American Review of Respiratory Diseases (Baltimore).
Anaesthesia (London).
Anesthesia and Analgesia; Current Researches (Cleveland).
Anesthesiology (Philadelphia).
Angiology (Baltimore).
Annales de Pediatrie (Paris).
Annals of Allergy (St. Paul).
Annals of Internal Medicine (Philadelphia).
Annals of the New York Academy of Sciences (New York).
Annals of Otology, Rhinology and Laryngology (St. Louis).
Annals of the Rheumatic Diseases (London).
Annals of Surgery (Philadelphia).
Annals of Tropical Medicine and Parasitology (Liverpool).
Applied Microbiology (Baltimore).
Applied Therapeutics (Toronto).
Archives of Dermatology (Chicago).
Archives of Disease in Childhood (London).
Archives of General Psychiatry (Chicago).
Archives of Internal Medicine (Chicago).
Archives Internationales de Pharmacodynamie et de Therapie (Ghent).
Archives of Neurology (Chicago).
Archives of Ophthalmology (Chicago).
Archives of Otolaryngology (Chicago).
Archives of Pathology (Chicago).
Archives of Surgery (Chicago).
Arizona Medicine (Scottsdale).
Arthritis and Rheumatism (New York).
Arzneimittel-Forschung (Aulendorf).
Blood; Journal of Hematology (New York).
British Dental Journal (London).
British Heart Journal (London).
British Journal of Addiction (Shewsbury).
British Journal of Anaesthesia (Altrincham).
British Journal of Clinical Practice (London).
British Journal of Dermatology (London).
British Journal of Experimental Pathology (London).
British Journal of Diseases of the Chest (London).
British Journal of Haematology (Oxford).
British Journal of Industrial Medicine (London).
British Journal of Ophthalmology (London).
British Journal of Pharmacology and Chemotherapy (London).
British Journal of Psychiatry (London).
British Journal of Radiology (London).
British Journal of Surgery (Bristol).
British Journal of Venereal Diseases (London).
British Medical Bulletin (London).
British Medical Journal (London).
Bulletin of the Johns Hopkins Hospital (Baltimore).
Bulletin of Narcotic Drugs (New York).
Bulletin of the New York Academy of Medicine (New York).
Bulletin of the Parenteral Drug Association (Philadelphia).
Bulletin of the Sloane Hospital for Women (New York).
Bulletin of the Toilet Goods Association (New York).
Bulletin of the World Health Organization (Geneva).
Bulletin; University of Miami School of Medicine and Jackson Memorial Hospital (Miami).
California Medicine (San Francisco).
Canadian Anaesthetists' Society Journal (Toronto).
Canadian Medical Association Journal (Toronto).
Cancer (Philadelphia).
Cancer Chemotherapy Reports (Washington).
Cancer Research (Chicago).
Chemotherapia (Basel).
Chicago Medicine (Chicago).
Cincinnati Journal of Medicine (Cincinnati).
Circulation: Journal of the American Heart Association (New York).
Circulation Research (New York).
Clin Alert (Louisville).
Clinical Medicine (Winnetka, Ill.).
Clinical Obstetrics and Gynecology (New York).
Clinical Pediatrics (Philadelphia).
Clinical Pharmacology and Therapeutics (St. Louis).
Clinical Proceedings Children's Hospital (Washington).
Clinical Research (New York).
Clinical Science (London).
Comprehensive Psychiatry (New York).
Comptes Rendus des Seances de la Societe de Biologie et de Ses Filiales (Paris).
Connecticut Medicine (New Haven).
Current Psychiatric Therapies (New York).
Current Therapeutic Research (New York).
Dallas Medical Journal (Dallas, Texas).
Danish Medical Bulletin (Copenhagen).
Delaware Medical Journal (Wilmington).
Dental Clinics of North America (Philadelphia).
Deutsche Medizinische Wochenschrift (Stuttgart).
Diabetes (New York).
Diseases of the Chest (Chicago).
Diseases of the Colon and Rectum (Philadelphia).
Diseases of the Nervous System (Galveston).
DM; Disease-a-Month (Chicago).
Drug and Cosmetic Industry (New York).
Drug and Therapeutics Bulletin (London).
Drugs Made in Germany (Aulendorf).
Drug Research Reports ("Blue Sheet") (Washington).
Endocrinology (Springfield, Ill.).
European Journal of Cancer (Oxford).
Experientia (Basel).
Experimental Eye Research (London).
Eye, Ear, Nose and Throat Monthly (Chicago).
Farmakologiia i Toksikologiia (Moscow).
Federation Proceedings (Washington).
Fertility and Sterility (New York).
Gastroenterology (Baltimore).
General and Comparative Endocrinology (New York)
Geriatrics (Minneapolis).
German Medical Journal (Stuttgart).
Gerontologist (St. Louis).
GP (Kansas City, Mo.).
Gut (London).
Guthrie Clinic Bulletin (Sayre, Pa.).
Hawaii Medical Journal (Honolulu).
Headache (St. Louis).
Helvetica Medica Acta (Basel).
Helvetica Psysiologica et Pharmacologica Acta (Basel).
Illinois Medical Journal (Chicago).
Indian Journal of Medical Research (Calcutta).
Indian Journal of Medical Sciences (Bombay).
Industrial Medicine and Surgery (Miami).
International Archives of Allergy and Applied Immunology (Basel).
International Journal of Fertility (Springfield, Mass.).
International Journal of Neuropsychiatry (Chicago).
Internist (Berlin).
Investigative Ophthalmology (St. Louis).
Irish Journal of Medical Science (Dublin).
Japanese Journal of Medical Science and Biology (Tokyo).
Japanese Journal of Pharmacology (Kyoto).
Japan Medical News (Tokyo).
Journal of Allergy (St. Louis).
Journal of the American Dental Association (Chicago).
Journal of the American Dietetic Association (Chicago).
Journal of the American Geriatrics Society (Baltimore).
Journal of the American Medical Association (Chicago).
Journal of the American Medical Women's Association (Nashville).
Journal of the American Osteopathic Association (Chicago).
Journal of the American Pharmaceutical Association (Washington).
Journal of Antibiotics; Series A (Tokyo).
Journal of Applied Physiology (Washington).
Journal of the Arkansas Medical Society (Fort Smith).
Journal of Bone and Joint Surgery (American edition) (Boston).

Journal of the Canadian Dental Association (Toronto).
Journal of Chronic Diseases (St. Louis).
Journal of Clinical Endocrinology and Metabolism (Springfield, Ill.).
Journal of Clinical Investigation (Boston).
Journal of Clinical Pathology (London).
Journal of Comparative Pathology and Therapeutics (Croydon).
Journal of Endocrinology (London).
Journal of Experimental Medicine (New York).
Journal of the Florida Medical Association (Jacksonville).
Journal of Gerontology (St. Louis).
Journal of Helminthology (London).
Journal of the Indian Medical Association (Calcutta).
Journal of the Indiana State Medical Association (Indianapolis).
Journal of Infectious Diseases (Chicago).
Journal of the International College of Surgeons (Chicago).
Journal of Investigative Dermatology (Baltimore).
Journal of the Iowa Medical Society (Des Moines).
Journal of the Irish Medical Association (Dublin).
Journal of the Kansas Medical Society (Topeka).
Journal of the Kentucky State Medical Association (Louisville).
Journal of Laboratory and Clinical Medicine (St. Louis).
Journal-Lancet (Minneapolis).
Journal of the Louisiana State Medical Society (New Orleans).
Journal of the Maine Medical Association (Brunswick).
Journal of the Medical Association of the State of Alabama (Montgomery).
Journal of the Medical Association of Georgia (Atlanta).
Journal of the Medical Society of New Jersey (Trenton).
Journal of the Michigan State Medical Society (St. Paul, Minn.).
Journal of the Mississippi State Medical Association (Jackson).
Journal of the Mount Sinai Hospital (New York).
Journal of the National Cancer Institute (Washington).
Journal of the National Medical Association (New York).
Journal of Nervous and Mental Disease (Baltimore).
Journal of Neurology, Neurosurgery and Psychiatry (London).
Journal of Neuropathology and Experimental Neurology (Baltimore).
Journal of New Drugs (New York).
Journal of Nuclear Medicine (Chicago).
Journal of Nutrition (Philadelphia).
Journal of Obstetrics and Gynaecology of the British Commonwealth (London).
Journal of Occupational Medicine (Chicago).
Journal of the Oklahoma State Medical Association (Oklahoma City).
Journal of Oral Surgery (Chicago).
Journal of Oral Therapeutics and Pharmacology (Baltimore).
Journal of Parasitology (Colorado Springs).
Journal of Pathology and Bacteriology (London).
Journal of Pediatric Ophthalmology (Encino).
Journal of Pediatrics (St. Louis).
Journal of Periodontology (Indianapolis).
Journal of Pharmacy and Pharmacology (London).
Journal of Pharmaceutical Sciences (Washington).
Journal of the Pharmaceutical Society of Japan (Tokyo).
Journal of Pharmacology and Experimental Therapeutics (Baltimore).
Journal of Prosthetic Dentistry (St. Louis).
Journal of Reproduction and Fertility (Oxford).
Journal of the Society of Cosmetic Chemists (London).
Journal of the South Carolina Medical Association (Florence).
Journal of Surgical Research (Philadelphia).
Journal of the Tennessee Medical Association (Nashville).
Journal of Tropical Medicine and Hygiene (London).
Journal of Urology (Baltimore).
Kaiser Foundation Medical Bulletin (Oakland, Calif.).
Klinische Wochenschrift (Berlin).
Lancet (London).
Laryngoscope (St. Louis).
Letters of International Correspondence Society of Allergists (Columbus, Ohio).
Maryland State Medical Journal (Baltimore).
Mayo Clinic Proceedings (Rochester, Minn.).
Medical Annals of the District of Columbia (Washington).
Medical Bulletin (Veterans' Administration) (Washington).
Medical Clinics of North America (Philadelphia).
Medical Journal of Australia (Sydney).
Medical Letter—Drug and Therapeutics (New York).
Medical News (London).
Medical Science (Philadelphia).
Medical Times (Manhasset, N.Y.).
Medical Tribune (New York).
Medical World News (New York).
Medicina Pharmacologica Experimentalis (Basel).
Medicine (Baltimore).
Medicine, Science and the Law (London).
Medizinische Klinik (Munich).
Medizinische Monatsschrift (Stuttgart).
Metabolism, Clinical and Experimental (New York).
Michigan Medicine (East Lansing, Mich.).
Milbank Memorial Fund, Quarterly (New York).
Military Medicine (Washington).
Minerva Medica (Turin).
Minnesota Medicine (St. Paul).
Missouri Medicine (St. Louis).
Modern Concepts of Cardiovascular Disease (New York).
Modern Medicine (Minneapolis).
Munchener Medizinische Wochenschrift (Munich).
Nature (London).
Naunyn-Schmiedbergs Archiv fur Pharmakologie (Berlin).
Nebraska State Medical Journal (Lincoln).
Neurology (Minneapolis).
New England Journal of Medicine (Boston).
New York Physician and American Medicine (New York).
New York State Journal of Medicine (New York).
Nordisk Medicin (Stockholm).
North Carolina Medical Journal (Winston-Salem).
Northwest Medicine (Seattle).
Obstetrical and Gynecology Survey (Baltimore).
Obstetrics and Gynecology (New York).
Ohio State Medical Journal (Columbus).
Oral Surgery, Oral Medicine, and Oral Pathology (St. Louis).
Pacific Medicine and Surgery (Seattle).
Parasitology (London).
Pediatrics Clinics of North America (Philadelphia).
Pediatrics (Springfield, Ill.).
Pennsylvania Medical Journal (Harrisburg).
Pharmaceutical Journal (London).
Pharmacologist (Washington).
Physiology and Pharmacology for Physicians (American Physiological Society) (Washington).
Postgraduate Medical Journal (London).
Postgraduate Medicine (Minneapolis).
Practitioner (London).
Praxis (Bern).
Prescribers' Journal (London).
Presse Medicale (Paris).
Proceedings of the Royal Society of Medicine (London).
Proceedings of the Society for Experimental Biology and Medicine (New York).
Progress in Cardiovascular Diseases (New York).
Psychiatry (Washington).
Psychopharmacologia (Berlin).
Psychopharmacology Service Center Bulletin (NIH) (Bethesda, Md.).
Psychosomatic Medicine (New York).
Radiologic Clinics of North America (Philadelphia).
Radiology (Syracuse).
Revue Francaise d'Etudes Cliniques et Biologiques (Paris).
Rhode Island Medical Journal (Providence).
Rocky Mountain Medical Journal (Denver).
Scandinavian Journal of Clinical and Laboratory Investigation (Oslo).
Schweizerische Medizinische Wochenschrift (Basel).
Science (Washington).
Scottish Medical Journal (Glasgow).
Semaine des Hopitaux de Paris (Paris).
South African Medical Journal (Cape Town).
South Dakota Journal of Medicine and Pharmacy (Sioux Falls).
Southern Medical Journal (Birmingham).
Southwestern Medicine (El Paso, Texas).
Surgery (St. Louis).
Surgery, Gynecology and Obstetrics (Chicago).
Surgical Clinics of North America (Philadelphia).
Texas Reports on Biology and Medicine (Galveston).
Texas State Journal of Medicine (Austin).
Therapie (Paris).
Therapie der Gegenwart (Berlin).
Thrombosis et Diathesis Haemorrhagica (Stuttgart).
Toxicology and Applied Pharmacology (New York).
Transactions of the American Academy of Ophthalmology and Otolaryngology (Rochester, Minn.).
Transactions of the Royal Society of Tropical Medicine and Hygiene (London).
Ugeskrift for Laeger (Copenhagen).
Union Medicale du Canada (Montreal).
Virginia Medical Monthly (Richmond).
West Virginia Medical Journal (Charleston).
Western Medicine (Los Angeles).
Wiener Klinische Wochenschrift (Vienna).
Wiener Medizinische Wochenschrift (Vienna).
Wisconsin Medical Journal (Madison).
World Medical Journal (New York).
Yale Journal of Biology and Medicine (New Haven).

Subpart B—Specific Administrative Rulings and Decisions

§ 310.100 New-drug status opinions; statement of policy.

(a) Over the years since 1938 the Food and Drug Administration has given informal advice to inquirers as to the new-drug status of preparations. These drugs have sometimes been identified only by general statements of composition. Generally, such informal opinions were incorporated in letters that did not explicitly relate all of the necessary conditions and qualifications such as the quantitative formula for the drug and the conditions under which it was prescribed, recommended, or suggested. This has contributed to misunderstand-

ing and misinterpretation of such opinions.

(b) These informal opinions that an article is "not a new drug" or "no longer a new drug" require reexamination under the Kefauver-Harris Act (Public Law 87-781; 76 Stat. 788-89). In particular, when approval of a new-drug application is withdrawn under provisions of section 505(e) of the Federal Food, Drug, and Cosmetic Act, a drug generally recognized as safe may become a "new drug" within the meaning of section 201(p) of said act as amended by the Kefauver-Harris Act on October 10, 1962. This is of special importance by reason of proposed actions to withdraw approval of new-drug applications for lack of substantial evidence of effectiveness as a result of reports of the National Academy of Sciences—National Research Council on its review of drug effectiveness; for example, see the notice published in the FEDERAL REGISTER of January 23, 1968 (33 FR 818), regarding rutin, quercetin, et al.

(c) Any marketed drug is a "new drug" if any labeling change made after October 9, 1962, recommends or suggests new conditions of use under which the drug is not generally recognized as safe and effective by qualified experts. Undisclosed or unreported side effects as well as the emergence of new knowledge presenting questions with respect to the safety or effectiveness of a drug may result in its becoming a "new drug" even though it was previously considered "not a new drug." Any previously given informal advice that an article is "not a new drug" does not apply to such an article if it has been changed in formulation, manufacture control, or labeling in a way that may significantly affect the safety of the drug.

(d) For these reasons, all opinions previously given by the Food and Drug Administration to the effect that an article is "not a new drug" or is "no longer a new drug" are hereby revoked. This does not mean that all articles that were the subjects of such prior opinions will be regarded as new drugs. The prior opinions will be replaced by opinions of the Food and Drug Administration that are qualified and current on when an article is "not a new drug," as set forth in this subchapter.

§ 310.101 FD&C Red No. 4; procedure for discontinuing use in new drugs for ingestion; statement of policy.

(a) Section 8.502(d) of this chapter published December 11, 1964 (29 FR 16983), terminated the provisional listing of FD&C Red No. 4 for use in drugs that may be ingested and canceled the effectiveness of certificates for this color additive and mixtures containing it as of June 9, 1965 (§ 8.510(c) of this chapter), insofar as ingested drugs are concerned. On August 19, 1965 (30 FR 10289), FD&C Red No. 4 was restored to provisional listing by amendment to § 8.501(a) of this chapter, which restricted the use of the color to the terms of § 8.503 of this chapter. The use of FD&C Red No. 4 or mixtures containing it in the manufacture of ingested drugs (except for limited use as provided in § 8.503 of this chapter) will result in adulteration and may constitute grounds for withdrawing approval of drugs for which a new-drug approval is in effect.

(b) An approved supplemental new-drug application will not be required to provide for discontinuing the use of FD&C Red No. 4 in the manufacture of articles that are the subject of approved new-drug applications, provided that the applicant submits to the Food and Drug Administration a written notice of the date on which the change in formulation will be put into effect.

(c) It will be the policy of the Food and Drug Administration to take no action against a drug or applicant where a permitted color additive is substituted for FD&C Red No. 4 in the manufacture of a drug prior to receipt of a written notice of approval of a supplemental new-drug application, provided that the applicant submits a satisfactory supplemental application meeting all the following conditions:

(1) The applicant submits a full list of the components and a full statement of the composition of the drug.

(2) The date when the composition of the drug will be changed is stated.

(3) The applicant submits data showing that the change in composition does not interfere with any assay or other control procedures used in manufacturing the drug, or that the assay and other control procedures are revised to make them adequate.

(4) The data available to establish the stability of the revised formulation are included, and if the data are too limited to support a conclusion that the drug will retain its declared potency for a reasonable marketing period, a commitment from the applicant:

(i) To test the stability of marketed batches at reasonable intervals;

(ii) To submit the data as they become available; and

(iii) To recall from the market any batch found to fall below the approved specifications for the drug.

(d) When a supplemental application proposes the change prescribed in paragraph (c) of this section and the applicant informs the Food and Drug Administration that the changes have been put into effect, such notification will be regarded as an agreement by the applicant to an extension of the time for formal action on the supplemental application.

(e) Except as provided in paragraph (c) of this section, no provision of this statement of policy shall limit the authority of the Secretary of Health, Education, and Welfare or of the Commissioner of Food and Drugs to suspend or withdraw approval of a new-drug application as prescribed by section 505(e) of the act or to initiate any other regulatory proceedings with respect to a drug or applicant under the provisions of the act.

§ 310.102 Consent for use of investigational new drugs (IND) on humans; statement of policy.

(a) Section 505(i) of the act provides that regulations on use of investigational new drugs on humans shall impose the condition that investigators "obtain the consent of such human beings or their representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interests of such human beings."

(b) This means that the consent of such humans (or the consent of their representatives) to whom investigational drugs are administered primarily for the accumulation of scientific knowledge, for such purposes as studying drug behavior, body processes, or the course of a disease, must be obtained in all cases and, in all but exceptional cases, the consent of patients under treatment with investigational drugs or the consent of their representatives must be obtained.

(c) "Under treatment" applies when the administration of the investigational drug for diagnostic, therapeutic, or other purpose involves medical judgment, taking into account the individual circumstances pertaining to the patient to whom the investigational drug is to be administered.

(d) "Exceptional cases" as used in paragraph (b) of this section are those relatively rare cases in which it is not feasible to obtain the patient's consent or the consent of his representative, or in which as a matter of professional judgment exercised in the best interest of a particular patient under the investigator's care, it would be contrary to that patient's welfare to obtain his consent.

(e) "Patient" means the person under treatment.

(f) "Not feasible" is limited to cases where in the investigator is not capable of obtaining consent because of inability to communicate with the patient or his representative; for example, the patient is in a coma or is otherwise incapable of giving consent, his representative cannot be reached, and it is imperative to administer the drug without delay.

(g) "Contrary to the best interests of such human beings" applies when the communication of information to obtain consent would seriously affect the patient's well-being and the physician has exercised a professional judgment that under the particular circumstances of this patient's case, the patient's best interests would suffer if consent were sought.

(h) "Consent" means that the person involved has legal capacity to give consent, is so situated as to be able to exercise free power of choice, and is provided with a fair explanation of pertinent information concerning the investigational drug, and/or his possible use as a control, as to enable him to make a decision on his willingness to receive said investigational drug. This latter element means that before the acceptance of an affirmative decision by such person the investigator should carefully consider and make known to him (taking into

consideration such person's well-being and his ability to understand) the nature, expected duration, and purpose of the administration of said investigational drug; the method and means by which it is to be administered; the hazards involved; the existence of alternative forms of therapy, if any; and the beneficial effects upon his health or person that may possibly come from the administation of the investigational drug.

When consent is necessary under the rules set forth in this section, the consent of persons receiving an investigational new drug in Phase 1[1] and Phase 2[1] investigations (or their representatives) shall be in writing. When consent is necessary under such rules in Phase 3[1] investigations, it is the responsibility of investigators, taking into consideration the physical and mental state of the patient, to decide when it is necessary or preferable to obtain consent in other than written form. When such written consent is not obtained, the investigator must obtain oral consent and record that fact in the medical record of the person receiving the drug.

§ 310.103 New-drug substances intended for hypersensitivity testing.

(a) The Food and Drug Administration is aware of the need in the practice of medicine for the ingredients of a new drug to be available for tests of hypersensitivity to such ingredients and therefore will not object to the shipment of a new-drug substance, as defined in § 310.3(g), for such purpose if all of the following conditions are met:

(1) The shipment is made as a result of a specific request made to the manufacturer or distributor by a practitioner licensed by law to administer such drugs, and the use of such drugs for patch testing is not promoted by the manufacturer or distributor.

(2) The new-drug substance requested is an ingredient in a marketed new drug and is not one that is an ingredient solely in a new drug that is legally available only under the investigational drug provisions of this part.

(3) The label bears the following prominently placed statements in lieu of adequate directions for use and in addition to complying with the other labeling provisions of the act:

(i) "Caution: Federal law prohibits dispensing without a prescription"; and

(ii) "For use only in patch testing".

(4) The quantity shipped is limited to an amount reasonable for the purpose of patch testing in the normal course of the practice of medicine and is used solely for such patch testing.

(5) The new-drug substance is manufactured by the same procedures and meets the same specifications as the component used in the finished dosage form.

(6) The manufacturer or distributor maintains records of all shipments for this purpose for a period of 2 years after shipment and will make them available to the Food and Drug Administration on request.

(b) When the requested new-drug substance is intended for investigational use in humans or the substance is legally available only under the investigational drug provisions of Part 312 of this chapter, the submission of a "Notice of Claimed Investigational Exemption for a New Drug" (IND) is required. The Food and Drug Administration will offer assistance to any practitioner wishing an exemption (see § 312.1 of this chapter), and administrative procedures will be made as simple as possible.

(c) This section does not apply to drugs or their components that are subject to the licensing requirements of the Public Health Service Act of 1944, as amended. (See Subchapter F—Biologies, of this chapter.)

(Sec. 502, 52 Stat. 1053; 21 U.S.C. 352)

Subpart C—New Drugs Exempted From Prescription-Dispensing Requirements

§ 310.200 Prescription-exemption procedure.

(a) *Duration of prescription requirement.* Any drug limited to prescription use under section 503(b) (1) (C) of the act remains so limited until it is exempted as provided in paragraph (b) of this section.

(b) *Prescription-exemption procedure for drugs limited by a new-drug application.* Any drug limited to prescription use under section 503(b) (1) (C) of the act shall be exempted from prescription-dispensing requirements when the Commissioner finds such requirements are not necessary for the protection of the public health by reason of the drug's toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, and he finds that the drug is safe and effective for use in self-medication as directed in proposed labeling. A proposal to exempt a drug from the prescription-dispensing requirements of section 503(b) (1) (C) of the act may be initiated by the Commissioner or by any interested person. Any interested person may file a petition seeking such exemption, stating reasonable grounds therefor, which petition may be in the form of a supplement to an approved new-drug application. Upon receipt of such a petition, or on his own initiative at any time, the Commissioner will publish a notice of proposed rule making and invite written comments. After consideration of all available data, including any comments submitted, the Commissioner may issue a regulation granting or refusing the exemption, effective on a date specified therein. Whenever the Commissioner concludes, either at the time of publication of the notice of proposed rule making or after considering the written comments submitted, that granting or refusing the exemption requires a more thorough development of the facts than is possible in a written presentation, he may call a public hearing for that purpose. The notice of such hearing shall specify the questions to be considered. As soon as practicable after completion of the hearing, the final regulation granting or refusing the exemption shall be issued, effective on a date specified therein. If the Commissioner for good cause finds (and incorporates the finding and a brief statement of the reasons therefor in a regulation) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, he may issue the final regulation forthwith.

(c) *New-drug status of drugs exempted from the prescription requirement.* A drug exempted from the prescription requirement under the provisions of paragraph (b) of this section is a "new drug" within the meaning of section 201(p) of the act until it has been used to a material extent and for a material time under such conditions.

(d) *Prescription legend not allowed on exempted drugs.* The use of the prescription caution statement quoted in section 503(b) (4) of the act, in the labeling of a drug exempted under the provisions of this section, constitutes misbranding. Any other statement or suggestion in the labeling of a drug exempted under this section, that such drug is limited to prescription use, may constitute misbranding.

§ 310.201 Exemption for certain drugs limited by new-drug applications to prescription sale.

(a) The prescription-dispensing requirements of section 503(b) (1) (C) of the Federal Food, Drug, and Cosmetic Act are not necessary for the protection of the public health with respect to the following drugs subject to new-drug applications:

(1) *N*-Acetyl-*p*-aminophenol (acetaminophen, *p*-hydroxy-acetanilid) preparations meeting all the following conditions:

(i) The *N*-acetyl-*p*-aminophenol is prepared, with or without other drugs, in tablet or other dosage form suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The *N*-acetyl-*p*-aminophenol and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is approved for it.

(iv) The preparation contains not more than 0.325 gram (5 grains) of *N*-acetyl-*p*-aminophenol per dosage unit, or if it is in liquid form not more than 100 milligrams of *N*-acetyl-*p*-aminophenol per milliliter.

(v) The preparation is labeled with adequate directions for use in minor conditions as a simple analgesic.

(vi) The dosages of *N*-acetyl-*p*-aminophenol recommended or suggested in the labeling do not exceed: For adults, 0.65 gram (10 grains) per dose or 2.6 grams (40 grains) per 24-hour period; for children 6 to 12 years of age, one-half of the maximum adult dose or dosage; for children 3 to 6 years of age, one-fifth of the maximum adult dose or dosage.

[1] As discussed in item 10 of Form FD-1571, which Form is set forth in § 312.1(a) (2).

(vii) The labeling bears, in juxtaposition with the dosage recommendations, a clear warning statement against administration of the drug to children under 3 years of age and against use of the drug for more than 10 days, unless such uses are directed by a physician.

(viii) If the article is offered for use in arthritis or rheumatism, the labeling prominently bears a statement that the beneficial effects claimed are limited to the temporary relief of minor aches and pains of arthritis and rheumatism and, in juxtaposition with directions for use in such conditions, a conspicuous warning statement, such as "Caution: If pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age, consult a physician immediately".

(2) Sodium gentisate (sodium-2, 5-dihydroxybenzoate) preparations meeting all the following conditions:

(i) The sodium gentisate is prepared, with or without other drugs, in tablet or other dosage form suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The sodium gentisate and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is approved for it.

(iv) The preparation contains not more than 0.5 gram (7.7 grains) of anhydrous sodium gentisate per dosage unit.

(v) The preparation is labeled with adequate directions for use in minor conditions as a simple analgesic.

(vi) The dosages of sodium gentisate recommended or suggested in the labeling do not exceed: For adults, 0.5 gram (7.7 grains) per dose of 2.0 grams (31 grains) per 24-hour period; for children 6 to 12 years of age, one-half of the maximum adult dose or dosage.

(vii) The labeling bears, in juxtaposition with the dosage recommendations, a clear warning statement against administration of the drug to children under 6 years of age and against use of the drug for a prolonged period, except as such uses may be directed by a physician.

(3) Isoamylhydrocupreine and zolamine hydrochloride (N, N-dimethyl-N'-2-thiazolyl-N'-*p*-methoxybenzyl - ethylenediamine hydrochloride) preparations meeting all the following conditions:

(i) The isoamylhydrocupreine and zolamine hydrochloride are prepared in dosage form suitable for self-medication as rectal suppositories or as an ointment and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The isoamylhydrocupreine, zolamine hydrochloride, and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is approved for it.

(iv) The preparation contains not more than 0.25 percent of isoamylhydrocupreine and 1.0 percent of zolamine hydrochloride.

(v) If the preparation is in suppository form, it contains not more than 5.0 milligrams of isoamylhydrocupreine and not more than 20.0 milligrams of zolamine hydrochloride per suppository.

(vi) The preparation is labeled with adequate directions for use in the temporary relief of local pain and itching associated with hemorrhoids.

(vii) The directions provide for the use of not more than two suppositories or two applications of ointment in a 24-hour period.

(viii) The labeling bears, in juxtaposition with the dosage recommendations, a clear warning statement against use of the preparation in case of rectal bleeding, as this may indicate serious disease.

(4) Phenyltoloxamine dihydrogen citrate (*N,N*-dimethyl-(*α*-phenyl-*O*-toloxy) ethylamine dihydrogen citrate) preparations meeting all the following conditions:

(i) The phenyltoloxamine dihydrogen citrate is prepared, with or without other drugs, in tablet or other dosage form suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The phenyltoloxamine dihydrogen citrate and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is approved for it.

(iv) The preparation contains not more than 88 milligrams of phenyltoloxamine dihydrogen citrate (equivalent to 50 milligrams of phenyltoloxamine) per dosage unit.

(v) The preparation is labeled with adequate directions for use in the temporary relief of the symptoms of hay fever and/or the symptoms of other minor conditions in which it is indicated.

(vi) The dosages recommended or suggested in the labeling do not exceed: For adults, 88 milligrams of phenyltoloxamine dihydrogen citrate (equivalent to 50 milligrams of phenyltoloxamine) per dose or 264 milligrams of phenyltoloxamine dihydrogen citrate (equivalent to 150 milligrams of phenyltoloxamine) per 24-hour period; for children 6 to 12 years of age, one-half of the maximum adult dose or dosage.

(vii) The labeling bears, in juxtaposition with the dosage recommendations:

(*a*) Clear warning statements against administration of the drug to children under 6 years of age, except as directed by a physician, and against driving a car or operating machinery while using the drug, since it may cause drowsiness.

(*b*) If the article is offered for temporary relief of the symptoms of colds, a statement that continued administration for such use should not exceed 3 days, except as directed by a physician.

(5) [Reserved]

(6) Meclizine hydrochloride (1-*p*-chlorobenzhydryl - 4 - *m* - methylbenzylpiperazine dihydrochloride) preparations meeting all the following conditions:

(i) The meclizine hydrochloride is prepared with or without other drugs, in tablet or other dosage form suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The meclizine hydrochloride and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is approved for it.

(iv) The preparation contains not more than 25 milligrams of meclizine hydrochloride per dosage unit.

(v) The preparation is labeled with adequate directions for use in the prevention of motion sickness.

(vi) The dosages recommended or suggested in the labeling do not exceed: For adults, 50 milligrams of meclizine hydrochloride per 24-hour period; for children 6 to 12 years of age, 25 milligrams of meclizine hydrochloride per 24-hour period.

(vii) The labeling bears, in juxtaposition with the dosage recommendations, clear warning statements against:

(*a*) Exceeding the recommended dosage.

(*b*) Administration of the drug to children under 6 years of age, except as directed by a physician.

(*c*) Driving a car or operating machinery while using the drug, since it may cause drowsiness.

(*d*) Keeping the drug within reach of children, if it is in candy form.

(*e*) Administration of the drug to women who are pregnant or who may become pregnant, unless directed by a physician, since the drug may have the potentiality of injuring the unborn child.

(7) Diamthazole dihydrochloride (2-dimethylamino-6-(*β* - diethylamino ethoxy) - benzothiazole dihydrochloride) preparations meeting all the following conditions:

(i) The diamthazole dihydrochloride is prepared with or without other drugs, in a dosage form suitable for use in self-medication by external application to the skin, and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The diamthazole dihydrochloride and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is approved for it.

(iv) The preparation contains not more than 5 percent of diamthazole dihydrochloride.

(v) The preparation is labeled with adequate directions for use only for adults and children 12 years of age and over in those conditions for which it may be safely used without medical supervision.

(vi) The label bears a conspicuous warning to keep out of the reach of children, and the labeling bears, in juxtaposition with the directions for use, clear warning statements against:

(*a*) Application to infants or children under 6 years of age, because serious reactions may occur.

(*b*) Application to children 6 to 12 years of age, except as directed by a physician.

(*c*) Contact with mucous membranes.

(*d*) Use in the event of irritation or failure to obtain prompt relief.

(8) Dicyclomine hydrochloride (1-cyclohexylhexahydrobenzoic acid, β-diethylaminoethyl ester hydrochloride; diethylaminocarbethoxy-bicyclohexyl hydrochloride) preparations meeting all the following conditions:

(i) The dicyclomine hydrochloride is prepared with suitable antacid and other components, in tablet or other dosage form for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503(b) (1) of the act.

(ii) The dicyclomine hydrochloride and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is approved for it.

(iv) The preparation contains not more than 5 milligrams of dicyclomine hydrochloride per dosage unit, or if it is in liquid form not more than 0.5 milligram of dicyclomine hydrochloride per milliliter.

(v) The preparation is labeled with adequate directions for use only by adults and children over 12 years of age, in the temporary relief of gastric hyperacidity.

(vi) The dosages recommended or suggested in the directions for use do not exceed 10 milligrams of dicyclomine hydrochloride per dose or 30 milligrams in a 24-hour period.

(vii) The labeling bears, in juxtaposition with the dosage recommendations, clear warning statements against:

(*a*) Exceeding the recommended dosage.

(*b*) Prolonged use, except as directed by a physician, since persistent or recurring symptoms may indicate a serious disease requiring medical attention.

(*c*) Administration to children under 12 years of age except as directed by a physician.

(9) [Reserved]

(10) Sodium fluoride preparations meeting all the following conditions:

(i) The sodium fluoride is prepared, with other components, in a dosage form suitable for household use as a dentifrice powder, and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The sodium fluoride and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is approved for it.

(iv) The preparation contains not more than 5 milligrams of sodium fluoride per gram and is packaged to contain not more than 300 milligrams of sodium fluoride per retail package.

(v) The preparation is labeled with adequate directions for use only as a dentifrice by adults and children 6 years of age and over, and includes instructions to rinse the mouth thoroughly after brushing the teeth.

(vi) The labeling bears, in juxtaposition with the directions for use, a clear warning statement against use by children under 6 years of age.

(11) Hexadenol (a mixture of tetracosanes and their oxidation products) preparations meeting all the following conditions:

(i) The hexadenol is prepared and packaged, with or without other drugs, solvents, and propellants, in a form suitable for self-medication by external application to the skin as a spray, and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The hexadenol and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is approved for it.

(iv) The preparation contains not more than 5 percent by weight of hexadenol.

(v) The preparation is labeled with adequate directions for use by external application in the treatment of minor burns and minor skin irritations.

(vi) The labeling bears, in juxtaposition with the directions for use, clear warning statements against:

(*a*) Use on serious burns or skin conditions or prolonged use, except as directed by a physician.

(*b*) Spraying the preparation in the vicinity of eyes, mouth, nose, or ears.

(12) Sulfur dioxide preparations meeting all the following conditions:

(i) The sulfur dioxide is prepared with or without other drugs, in an aqueous solution packaged in a hermetic container suitable for use in self-medication by external application to the skin, and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The sulfur dioxide and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is approved for it.

(iv) The preparation contains not more than 5 grams of sulfur dioxide per 100 milliliters of solution.

(v) The preparation is labeled with adequate directions for use by external application to the smooth skin in the prevention or treatment of minor conditions in which it is indicated.

(vi) The directions for use recommend or suggest not more than two applications a day for not more than 1 week, except as directed by a physician.

(13) Doxylamine succinate preparations meeting all the following conditions:

(i) The doxylamine succinate is prepared, with or without other drugs, in tablet or other dosage form suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The doxylamine succinate and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is approved for it.

(iv) The preparation contains not more than 7.5 milligrams of doxylamine succinate per dosage unit, or if it is in liquid form not more than 1.5 milligrams of doxylamine succinate per milliliter.

(v) The preparation is labeled with adequate directions for use in the temporary relief of the symptoms of the minor conditions in which it is indicated.

(vi) The dosages recommended or suggested in the labeling do not exceed: For adults, 7.5 milligrams of doxylamine succinate per dose or 45 milligrams of doxylamine succinate per 24-hour period; for children 6 to 12 years of age, one-half of the maximum adult dose or dosage.

(vii) The labeling bears in juxtaposition with the dosage recommendations:

(*a*) Clear warning statements against administration of the drug to children under 6 years of age, except as directed by a physician, and against driving a car or operating machinery while using the drug, since it may cause drowsiness.

(*b*) If the article is offered for temporary relief of the symptoms of colds, a statement that continued administration for such use should not exceed 3 days, except as directed by a physician.

(14) Dextromethorphan hydrobromide (dextro-3-methoxy-*N*-methylmorphinan hydrobromide) preparations meeting all the following conditions:

(i) The dextromethorphan hydrobromide is prepared with or without other drugs, in tablet or other dosage form suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The dextromethorphan hydrobromide and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is approved for it.

(iv) The preparation contains not more than 30 milligrams of dextromethorphan hydrobromide per dosage unit, or if it is in liquid form not more than 6 milligrams of dextromethorphan hydrobromide per milliliter.

(v) The preparation is labeled with adequate directions for use in the temporary relief of cough due to minor conditions in which it is indicated.

(vi) The dosages recommended or suggested in the labeling do not exceed: For adults, 30 milligrams of dextromethor-

phan hydrobromide per dose or 120 milligrams of dextromethorphan hydrobromide per 24-hour period; for children 4 to 12 years of age, 15 milligrams per dose or 60 milligrams per 24-hour period; for children 2 to 4 years of age, 7.5 milligrams per dose or 30 milligrams per 24-hour period.

(vii) The label bears a conspicuous warning to keep the drug out of the reach of children and the labeling bears, in juxtaposition with the dosage recommendations:

(*a*) A clear warning statement against administration of the drug to children under 2 years of age, except as directed by a physician.

(*b*) Clear warning statements against use of the drug in the presence of high fever or if cough persists, since persistent cough as well as high fever may indicate the presence of a serious condition.

(15) Sodium monofluorophosphate (Na_2PO_3F) preparations meeting all the following conditions:

(i) The sodium monofluorophosphate is prepared with other components in an aqueous solution suitable for household use as a dentifrice, and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The sodium monofluorophosphate and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is approved for it.

(iv) The preparation contains not more than 60 milligrams of sodium monofluorophosphate per milliliter and is packaged to contain not more than 3.6 grams of sodium monofluorophosphate per retail package.

(v) The preparation is labeled with adequate directions for use only as a dentifrice by adults and children 6 years of age and over, and includes instructions to rinse the mouth thoroughly after brushing the teeth.

(vi) The labeling bears, in juxtaposition with the directions for use, a clear warning statement against use by children under 6 years of age.

(16) Tuaminoheptane sulfate (2-aminoheptane sulfate) preparations meeting all the following conditions:

(i) The tuaminoheptane sulfate is prepared, with or without other drugs, in an aqueous vehicle suitable for administration in self-medication as nose drops, and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The preparation is packaged with a style of container or assembly suited to self-medication by the recommended route of administration, and delivering not more than 0.1 milliliter of the preparation per drop.

(iii) The tuaminoheptane sulfate and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iv) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is approved for it.

(v) The tuaminoheptane sulfate content of the preparation does not exceed 10 milligrams per milliliter.

(vi) The preparation is labeled with adequate directions for use in the temporary relief of nasal congestion.

(vii) The dosages recommended or suggested in the directions for use do not exceed the equivalent: For adults, 5 drops of a 1 percent solution per nostril per dose, and 5 doses in a 24-hour period; for children 1 to 6 years of age, 3 drops of a 1 percent solution per nostril per dose, and 5 doses in a 24-hour period; for infants under 1 year of age, 2 drops of a 1 percent solution per nostril per dose, and 5 doses in a 24-hour period.

(viii) The labeling bears, in juxtaposition with the dosage recommendations:

(*a*) Clear warning statements against use of more than 5 doses daily, and against use longer than 4 days unless directed by a physician.

(*b*) A clear warning statement to the effect that frequent use may cause nervousness or sleeplessness, and that individuals with high blood pressure, heart disease, diabetes, or thyroid disease should not use the preparation unless directed by a physician.

(17) [Reserved]

(18) Vibesate (a mixture of copolymers of hydroxy-vinyl chlorideacetate, sebacic acid, and modified maleic rosin ester) preparations meeting all the following conditions.

(i) The vibesate is prepared and packaged, with or without other drugs, solvents, and propellants, in a form suitable for self-medication by external application to the skin as a spray, and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The vibesate and all other components of the preparation meet their professed standards of identity, strength quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is approved for it.

(iv) The preparation contains not more than 13 percent by weight of vibesate.

(v) The preparation is labeled with adequate directions for use by external application as a dressing for minor burns, minor cuts, or other minor skin irritations.

(vi) The labeling bears in juxtaposition with the directions for use clear warning statements against:

(*a*) Use on serious burns and on infected, deep, and puncture wounds unless directed by a physician.

(*b*) Spraying the preparation near the eyes or other mucous membranes.

(*c*) Inhaling the preparation.

(*d*) Use near open flames.

(*e*) Puncturing the container or throwing the container into fire.

(19) Pramoxine hydrochloride (4-*N*-butoxyphenyl γ-morpholinopropyl ether hydrochloride) preparations meeting all the following conditions:

(i) The pramoxine hydrochloride is prepared, with or without other drugs, in a dosage form suitable for use in self-medication by external application to the skin, and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The pramoxine hydrochloride and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is approved for it.

(iv) The preparation contains not more than 1.0 percent of pramoxine hydrochloride.

(v) The preparation is labeled with adequate directions for use by external application to the skin for the temporary relief of pain or itching due to minor burns and sunburn, nonpoisonous insect bites, and minor skin irritations.

(vi) The directions for use recommend or suggest not more than four applications of the preparation per day, unless directed by a physician.

(vii) The labeling bears, in juxtaposition with the directions for use, clear warning statements against:

(*a*) Prolonged use.

(*b*) Application to large areas of the body.

(*c*) Continued use if redness, irritation, swelling, or pain persists or increases, unless directed by a physician.

(*d*) Use in the eyes or nose.

(20) Carbetapentane citrate (2-(2-diethylaminoethoxy)-ethyl-1-phenylcyclopentyl-1-carboxylate citrate) preparations meeting all the following conditions:

(i) The carbetanentane citrate is prepared, with or without other drugs, in tablet or other dosage form suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The carbetapentane citrate and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, and application pursuant to section 505 (b) of the act is approved for it.

(iv) The preparation contains not more than 25 milligrams of carbetapentane citrate per dosage unit; or if it is in liquid form, not more than 1.5 milligrams of carbetapentane citrate per milliliter.

(v) The preparation is labeled with adequate directions for use in the temporary relief of cough due to minor conditions in which it is indicated.

(vi) The dosages recommended or suggested in the labeling do not exceed: For adults, 30 milligrams of carbetapentane citrate per dose or 120 milligrams of carbetapentane citrate per 24-hour period; for children 4 to 12 years of age, 7.5 milligrams per dose or 30 milligrams per 24-hour period; for children 2 to 4 years of age, 4.0 milligrams per dose or 16.0 milligrams per 24-hour period.

(vii) The label bears a conspicuous warning to keep the drug out of the reach of children, and the labeling bears, in juxtaposition with the dosage recommendations:

(*a*) A clear warning statement against administration of the drug to children

under 2 years of age, unless directed by a physician.

(b) Clear warning statements against use of the drug in the presence of high fever or if cough persists, since persistent cough as well as high fever may indicate the presence of a serious condition.

(21) Pamabrom (2-amino-2-methylpropanol - 1 - 8 - bromotheophyllinate) preparations meeting all the following conditions:

(i) The pamabrom is prepared with appropriate amounts of a suitable analgesic and with or without other drugs, in tablet or other dosage form suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The pamabrom and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is approved for it.

(iv) The preparation contains not more than 50 milligrams of pamabrom per dosage unit.

(v) The preparation is labeled with adequate directions for use in the temporary relief of the minor pains and discomforts that may occur a few days before and during the menstrual period.

(vi) The dosages recommended or suggested in the labeling do not exceed 50 milligrams of pamabrom per dose or 200 milligrams per 24-hour period.

(22) Diphemanil methylsulfate (4-diphenylmethylene - 1,1-dimethylpiperidinium methylsulfate) preparations meeting all the following conditions:

(i) The diphemanil methylsulfate is prepared, with or without other drugs, in a dosage form suitable for use in self-medication by external application to the skin, and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The diphemanil methylsulfate and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is approved for it.

(iv) The preparation contains not more than 2.0 percent of diphemanil methylsulfate.

(v) The preparation is labeled with adequate directions for use by external application to the skin for the relief of symptoms of mild poison ivy, oak, and sumac and other minor irritations and itching of the skin.

(vi) The directions for use recommend or suggest not more than four applications of the preparation per day, unless directed by a physician.

(vii) The labeling bears, in juxtaposition with the directions for use, a clear warning statement, such as: "Caution: If redness, irritation, swelling, or pain persists or increases, discontinue use and consult physician."

(23) Dyclonine hydrochloride (4-butoxy-3-piperidinopropiophenone hydrochloride; 4-*n*-butoxy-β-piperidonopropiophenone hydrochloride) preparations meeting all the following conditions:

(i) The dyclonine hydrochloride is prepared, with or without other drugs, in a dosage form suitable for use as a cream or ointment in self-medication by external application to the skin, or rectally, and contains no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The dyclonine hydrochloride and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is approved for it.

(iv) The preparation contains not more than 1.0 percent of dyclonine hydrochloride.

(v) The preparation is labeled with adequate directions for use:

(a) By external application to the skin for the temporary relief of pain and itching in sunburn, nonpoisonous insect bites, minor burns, cuts, abrasions, and other minor skin irritations.

(b) In the temporary relief of local itching and irritation associated with hemorrhoids.

(c) In the prevention or treatment of other minor conditions in which it is indicated.

(vi) The labeling bears, in juxtaposition with the directions for use, clear warning statements against:

(a) Continued use if redness, irritation, swelling, or pain persists or increases, unless directed by a physician.

(b) Use in case of rectal bleeding, as this may indicate serious disease.

(c) Use in the eyes.

(d) Prolonged use.

(e) Application to large areas of the body.

(f) Use for deep or puncture wounds or serious burns.

(24) Chlorothen citrate (chloromethapyrilene citrate; *N,N*-dimethyl-*N'*-(2-pyridyl)-*N'*-(5-chloro-2-thenyl) ethylenediamine citrate) preparations meeting all the following conditions:

(i) The chlorothen citrate is prepared, with or without other drugs, in tablet or other dosage form suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503(b) (1) of the act.

(ii) The chlorothen citrate and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505(b) of the act is approved for it.

(iv) The preparation contains not more than 25 milligrams of chlorothen citrate per dosage unit.

(v) The preparation is labeled with adequate directions for use in the temporary relief of the symptoms of hay fever and/or the symptoms of other minor conditions in which it is indicated.

(vi) The dosages recommended or suggested in the labeling do not exceed: For adults, 25 milligrams of chlorothen citrate per dose or 150 milligrams of chlorothen citrate per 24-hour period; for children 6 to 12 years of age, one-half of the maximum adult dose or dosage.

(vii) The labeling bears, in juxtaposition with the dosage recommendations:

(a) Clear warning statements against administration of the drug to children under 6 years of age or exceeding the recommended dosage, unless directed by a physician, and against driving a car or operating machinery while using the drug, since it may cause drowsiness.

(b) If the article is offered for the temporary relief of symptoms of colds, a statement that continued administration for such use should not exceed 3 days, unless directed by a physician.

(25) Chlorcyclizine hydrochloride (1-(p-chlorobenzhydryl) - 4 - methylpiperazine hydrochloride) preparations meeting all the following conditions:

(i) The chlorcyclizine hydrochloride is prepared, with or without other drugs, in tablet or other dosage form suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503(b) (1) of the act.

(ii) The chlorcyclizine hydrochloride and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505(b) of the act is approved for it.

(iv) The preparation contains not more than 25 milligrams of chlorcyclizine hydrochloride per dosage unit.

(v) The preparation is labeled with adequate directions for use in the temporary relief of the symptoms of hay fever and/or symptoms of other minor conditions in which it is indicated.

(vi) The dosages recommended or suggested in the labeling do not exceed: For adults, 25 milligrams of chlorcyclizine hydrochloride per dose or 75 milligrams of chlorcyclizine hydrochloride per 24-hour period; for children 6 to 12 years of age, one-half of the maximum adult dose or dosage.

(vii) The labeling bears, in juxtaposition with the dosage recommendations:

(a) Clear warning statements against administration of the drug to children under 6 years of age, or exceeding the recommended dosage unless directed by a physician, and against driving a car or operating machinery while taking the drug, since it may cause drowsiness.

(b) If the article is offered for the temporary relief of symptoms of colds, a statement that continued administration for such use should not exceed 3 days, unless directed by a physician.

(c) A clear warning statement against administration of the drug to women who are pregnant or who may become pregnant, unless directed by a physician, since this drug may have the potentiality of injuring the unborn child.

(26) Methoxyphenamine hydrochloride (β-(*o*-methoxyphenyl)-isopropylmethylamine hydrochloride; 1-(*o*-methoxyphenyl) - 2 - methylaminopropane hydrochloride) preparations meeting all the following conditions:

(i) The methoxyphenamine hydrochloride is prepared with appropriate amounts of a suitable antitussive, with or without other drugs, in a dosage form suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503(b)(1) of the act.

(ii) The methoxyphenamine hydrochloride and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505(b) of the act is approved for it.

(iv) The preparation contains not more than 3.5 milligrams of methoxyphenamine hydrochloride per milliliter.

(v) The preparation is labeled with adequate directions for use in the temporary relief of cough due to minor conditions in which it is indicated.

(vi) The dosages recommended or suggested in the labeling do not exceed: For adults, 35 milligrams of methoxyphenamine hydrochloride per dose or 140 milligrams of methoxyphenamine hydrochloride per 24-hour period; for children 6 to 12 years of age, one-half of the maximum adult dose or dosage.

(vii) The label bears a conspicuous warning to keep the drug out of the reach of children, and the labeling bears, in juxtaposition with the dosage recommendations:

(*a*) A clear warning statement against administration of the drug to children under 6 years of age, unless directed by a physician.

(*b*) A clear warning statement to the effect that frequent or prolonged use may cause nervousness, restlessness, or drowsiness, and that individuals with high blood pressure, heart disease, diabetes, or thyroid disease should not use the preparation unless directed by a physician.

(*c*) A clear warning statement against use of the drug in the presence of high fever or if cough persists, since persistent cough as well as high fever may indicate the presence of a serious condition.

(27) Biphenamine hydrochloride (*β*-diethylaminoethyl-3-phenyl-2-hydroxybenzoate hydrochloride) preparations meeting all the following conditions:

(i) The biphenamine hydrochloride is prepared in a form suitable for use as a shampoo and contains no drug limited to prescription sale under the provisions of section 503(b)(1) of the act.

(ii) The biphenamine hydrochloride meets its professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505(b) of the act is approved for it.

(iv) The preparation contains not more than 1 percent of biphenamine hydrochloride.

(v) The preparation is labeled with adequate directions for use for the temporary relief of itching and scaling due to dandruff.

(vi) The label bears a conspicuous warning to keep the drug out of the reach of children.

(28) Tyloxapol (an alkylarylpolyether alcohol) and benzalkonium chloride ophthalmic preparations meeting all the following conditions:

(i) The tyloxapol and benzalkonium chloride are prepared, with other appropriate ingredients which are not drugs limited to prescription sale under the provisions of section 503(b)(1) of the act, as a sterile, isotonic aqueous solution suitable for use in self-medication on eye prostheses.

(ii) The preparation is so packaged as to volume and type of container as to afford adequate protection and be suitable for self-medication with a minimum risk of contamination of the solution during use. Any dispensing unit is sterile and so packaged as to maintain sterility until the package is opened.

(iii) The tyloxapol, benzalkonium chloride, and other ingredients used to prepare the isotonic aqueous solution meet their professed standards of identity, strength, quality, and purity.

(iv) An application pursuant to section 505(b) of the act is approved for the drug.

(v) The preparation contains 0.25 percent of tyloxapol and 0.02 percent of benzalkonium chloride.

(vi) The label bears a conspicuous warning to keep the drug out of the reach of children and the labeling bears, in juxtaposition with the dosage recommendations, a clear warning that if irritation occurs, persists, or increases, use of the drug should be discontinued and a physician consulted. The labeling includes a statement that the dropper or other dispensing tip should not touch any surface, since this may contaminate the solution.

(29) Tolnaftate (*O*-2-naphthyl *m,N*-dimethylthiocarbanilate; $C_{19}H_{17}NOS$) preparations meeting all the following conditions:

(i) The tolnaftate is prepared, with or without other drugs, in a cream, solution, or powder dosage form suitable for use in self-medication by external application to the skin and containing no drug limited to prescription sale under the provisions of section 503(b)(1) of the act.

(ii) The tolnaftate and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505(b) of the act is approved for it.

(iv) The preparation contains not more than 1 percent of tolnaftate.

(v) (*a*) The preparation, if in cream or solution form, is labeled with adequate directions for use by external application to the skin for the relief of the burning and itching of athlete's foot and ringworm of the body.

(*b*) The preparation, if in powder dosage form, is labeled with adequate directions for use by external application to the skin to help prevent athlete's foot reinfection.

(vi) The label bears a conspicuous warning to keep the drug out of the reach of children, and the labeling bears in juxtaposition with the directions for use:

(*a*) If in a cream or solution dosage form, clear warnings that:

(*1*) If burning or itching do not improve within 10 days or if they become worse, use of the preparation should be discontinued and a physician consulted.

(*2*) The preparation is for external use only.

(*3*) The preparation should be kept out of the eyes.

(*4*) The preparation is not recommended for nail or scalp infections.

(*b*) If in a powder dosage form, clear warnings that:

(*1*) If irritation occurs, use of the preparation should be discontinued and a physician consulted.

(*2*) The preparation is for external use only.

(*3*) The preparation should not be used on scalp or hairy areas.

(*4*) The preparation should be kept out of the eyes.

Subpart D—Records and Reports

§ 310.300 Records and reports concerning experience on drugs for which an approval is in effect.

(a) On receiving notification that an application for a new drug is approved, the applicant shall establish and maintain records and make reports that are necessary to facilitate a determination whether there may be grounds for invoking section 505(e) of the act to suspend or withdraw approval of the application, including adequately organized and indexed files containing full reports of any of the following kinds of information, pertinent to the safety or effectiveness of the drug or the adequacy of the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug to assure and preserve its identity, strength, quality, and purity, that has not previously been submitted as part of his application for the drug and which is received or otherwise obtained by him from any source:

(1) Unpublished reports of clinical experience, studies, investigations, and tests conducted by the applicant or reported to him by any person involving the drug that is the subject of the application and related drugs, and reports in the scientific literature involving the drug that is the subject of the application. An adequate summary and bibliography of reports in the scientific literature will ordinarily suffice. (The applicant must identify at the time of each report submission each drug he considers related to the subject drug.)

(2) Unpublished reports of animal experience, studies, investigations, and tests conducted by the applicant or reported to him by any person involving the drug that is the subject of the application and related drugs, and reports in the scientific literature involving the drug that is the subject of the application. An adequate summary and bibliography of reports in the scientific literature will ordinarily suffice. (The applicant must identify at the time of each report submission each drug he considers related to the subject drug.)

(3) Experience, investigations, studies, or tests involving the chemical or physical properties or any other properties of the drug; such as, its behavior or properties in relation to microorganisms, including both the effects of the drug on microorganisms and the effects of microorganisms on the drug.

(4) The information required by this section shall include, when known, adequate identification of its source, including the name and post office address of the person who furnished such information.

(5) Copies of all mailing pieces and other labeling, and if it is a prescription drug all advertising, other than that contained in the application, used in promoting the drug; and copies of the currently used package labeling that gives full information for use of the drug, whether or not such labeling is contained in the application.

(6) Information concerning the quantity of the drug distributed, in a manner and form that facilitates estimates of the incidence of any adverse effects reported to be associated with the use of the drug. This does not require disclosure of financial or pricing data.

(7) Information concerning any previously unreported changes from the conditions described in an application, including changes conforming to the conditions of § 314.8(a)(5) of this chapter.

(b) The applicant shall submit to the Food and Drug Administration copies of the records and reports described in paragraph (a) of this section (except routine assay and control records) appropriately identified with the new-drug application(s) to which they relate, as follows. Such copies, including Form FD–1639, shall be submitted in duplicate, except that other individual patient case reports may be submitted in single copy. In lieu of Form FD–1639, a computer-generated report may be submitted if equivalent in all elements of information with the identical enumerated sequence of events and methods of completion and if forwarded with the same number of copies as specified for Form FD–1639; all formats proposed for such use will require initial review and approval by the Food and Drug Administration. Each report for human-use drugs that forwards an advertisement or promotional labeling pursuant to paragraph (b)(3) of this section or a periodic report pursuant to paragraph (b)(4) of this section shall be accompanied by a completed transmittal Form FD–2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) or FD–2252 (Transmittal of Periodic Reports for Drugs for Human Use), respectively. Forms are obtainable from the Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, DC 20204.

(1) Immediately upon receipt by the applicant, complete records or reports covering information of the following kinds:

(i) Information concerning any mixup in the drug or its labeling with another article.

(ii) Information concerning any bacteriological, or any significant chemical, physical, or other change or deterioration in the drug, or any failure of one or more distributed batches of the drug to meet the specifications established for it in the new-drug application.

(2) As soon as possible, and in any event within 15 working days of its receipt by the applicant, complete records or reports concerning any information of the following kinds:

(i) Information concerning any unexpected side effect, injury, toxicity, or sensitivity reaction or any unexpected incidence or severity thereof associated with clinical uses, studies, investigations, or tests, whether or not determined to be attributable to the drug, except that this requirement shall not apply to the submission of information described in a written communication to the applicant from the Food and Drug Administration as types of information that may be submitted at other designated intervals. "Unexpected" as used in this subdivision refers to conditions or developments not previously submitted as part of the new-drug application or not encountered during clinical trials of the drug, or conditions or developments occurring at a rate higher than shown by information previously submitted as part of the new-drug application, or than encountered during such clinical trials.

(ii) Information concerning any unusual failure of the drug to exhibit its expected pharmacological activity.

(3) When mailing pieces, any other labeling, and advertising are devised for promotion of the drug, specimens shall be submitted at the time of initial dissemination of such labeling and at the time of initial publication of any advertisement for a prescription drug. Mailing pieces and labeling that are designed to contain samples of a drug shall be complete except for omission of the drug.

(4) All the kinds of information described in paragraph (a) of this section, other than that submitted under the provisions of paragraph (b)(1), (2), and (3) of this section, shall be submitted at the following intervals, unless otherwise ordered in a written communication from the Commissioner:

(i) If the drug is intended for administration to man, within intervals of 3 months beginning with the date of approval of the application during the first year following such date; within intervals of 6 months during the second year following such date; and at yearly intervals thereafter.

(ii) [Reserved]

(iii) Whenever an applicant is required to submit reports under the provisions of paragraph (b)(4)(i) or (ii) of this section with respect to more than one approved application for preparations containing the same drug so that the same item(s) of information is (are) required to be reported for more than one application, he may elect to submit as part of the report for one such application all the information common to such applications in lieu of reporting separately and repetitively on each. The applicant shall state when this is done and identify all the applications for which the reports are submitted.

(iv) The submitted copies of records and reports shall include all the required information that was received or otherwise obtained by the applicant during the designated intervals.

(5) On written order of the Commissioner, within the time stated in such order or agreed to by the applicant and the Commissioner, any designated records or reports containing the kinds of information described in this section.

(c) The reports submitted under the provisions of this section are not required to furnish the names and addresses of individual patients unless the applicant is notified in writing by the Food and Drug Administration that individual patient identification is required with respect to designated reports in order to permit further investigation or because there is reason to believe that such reports do not represent actual results obtained.

(d) The applicant shall upon request of any properly authorized officer or employee of the Department, at reasonable times, permit such officers to have access to and copy and verify any records and reports established and maintained under the provisions of this section.

(e) If the Food and Drug Administration finds that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with the provisions of this section, or that the applicant has refused to permit access to, or copying or verification of such records or reports, the Commissioner shall give the applicant due notice and opportunity for a hearing on the question of whether to withdraw the approval of the application, as provided in §§ 314.200 and 314.115 of this chapter.

(f) Upon written request of the applicant, stating reasonable grounds therefor, the Commissioner will make available any information in possession of the Food and Drug Administration of the kinds the applicant is required to maintain under the provisions of this section, except information readily available to the applicant from other sources or information which the Commissioner concludes must be considered confidential.

(g) The "applicant" required to establish and maintain records and make reports required by this section and under the regulations in § 310.302 includes any person whose name appears on the labeling of the drug as its manufacturer, packer, or distributor under an approval or who is engaged in the manufacturing, processing, packing, or labeling of the drug under an approval of the application or any supplement to it: *Provided, however,* That in order to avoid unnecessary duplication in the submission of reports any such applicant's obligation to submit a report may be met by its

submission on his behalf, designated as such, by another person responsible for reporting.

§ 310.301 Reporting of adverse drug experiences.

(a)(1) All adverse experiences with drugs for human use reported as part of a new-drug application under § 314.1 of this chapter, as part of a supplemental new-drug application under § 314.8 of this chapter, or as part of the reporting requirements concerning experiences with drugs for which an approval is in effect prescribed by § 310.300 shall also be reported on Form FD–1639, Drug Experience Report, obtainable with instructions from the Food and Drug Administration, Department of Health, Education, and Welfare, Washington, DC 20204. If feasible, such forms may be used on a per patient basis, rather than on an adverse experience basis. In lieu of a Form FD–1639, a computer-generated report may be submitted if equivalent in all elements of information with the identical enumerated sequence of events and methods of completion and if forwarded with the same number of copies; all formats proposed for such use will require initial review and approval by the Food and Drug Administration.

(2) It is unnecessary, however, for Form FD–1639 to be:

(i) Used in reporting adverse experience information obtained in phase 1 and phase 2 of an investigation (phases 1 and 2 are described in paragraph 10a of Form FD–1571 set forth in § 312.1(a)(2) of this chapter).

(ii) Submitted for adverse reactions reported in the published scientific literature.

(iii) Submitted until July 1, 1968, for reporting adverse experiences described in new-drug applications, supplements, and in periodic reports of experience with marketed drugs if such experience occurred prior to August 5, 1967.

(3) For reports of the kinds required within 15 days, as prescribed by § 310.300 (b)(2), describing adverse reactions occurring after August 5, 1967, and for all such submissions received on or after July 1, 1968, adverse experiences shall be reported on Form FD–1639. Adverse experiences with marketed drugs as a result of an investigational use other than a phase 1 study shall be reported on Form FD–1639 under the conditions described in this paragraph. If desirable, such forms may be used on a per patient basis rather than on an adverse experience basis.

(b) For the purpose of such report, the terms "drug experience," "adverse drug experience," and "adverse reaction" mean any adverse experience associated with the use of the drug, whether or not considered drug-related, and include any side effect, injury, toxicity, or sensitivity reaction, or significant failure of expected pharmacological action.

§ 310.302 Records and reports on new drugs and antibiotics for use by man for which applications or certification forms 5 and 6 became effective or were approved prior to June 20, 1963.

(a) Each applicant for whom a new-drug application or supplement for a drug for human use became effective or was approved at any time prior to June 20, 1963, and each person holding an approved form 5 or 6 for an antibiotic drug for human use at any time prior to June 20, 1963, shall submit, in duplicate, the following information for each dosage form within 60 days from the effective date of this order:

(1) Identification of the dosage form of the drug by its established and proprietary names, if any, the formula showing quantitatively each ingredient of the drug to the extent disclosed on the label (a copy of the label will ordinarily fulfill this requirement), the route of administration, and the new-drug application number.

(2) Whether the drug was marketed and whether it is currently marketed.

(3) If the drug was marketed and marketing has been discontinued, the date and reason for discontinuing its marketing.

(b) Each applicant for whom a new-drug application or supplement for a drug for human use became effective or was approved at any time prior to June 20, 1963, and each person holding an approved form 5 or 6 for an antibiotic drug for human use at any time prior to June 20, 1963, shall submit the following information with respect to each drug currently marketed within 120 days from the effective date of this order:

(1) A copy of the label on the package of the drug and of the package insert or brochure bearing directions or information for use of the article.

(2) If the label, brochure, or package insert is not identical in content to the one in the effective or approved new-drug application and its supplements, if any, or in the approved form 5 or 6, the applicant shall also report what changes have been made (other than minor changes in arrangement or printing or changes of an editorial nature) and why they were made, and shall submit the data supporting such changes if it has not previously been submitted.

(3) The applicant shall review the label, brochure, and package insert and shall submit a statement, signed by a responsible officer or employee, whether the label, brochure, or package insert fairly reflects the clinical experience reported to or otherwise received by the applicant. The applicant shall submit full reports of any well-controlled clinical studies that have not previously been submitted and which are pertinent to an evaluation of the effectiveness of the drug.

(4) The applicant shall also review or cause to be reviewed in the promotional material currently in use, including labeling and advertising, and shall submit a statement, signed by a responsible officer or employee, whether all such promotional material fairly reflects the labeling in the approved or effective new-drug application and its supplements, if any, or in the approved antibiotic form 5 or 6. Copies of representative labeling and advertising shall be attached.

(5) If the promotional material does not fairly reflect the labeling in the approved or effective new-drug application and its supplements, if any, or in the approved form 5 or 6, the applicant shall report the differences, state why they exist, and shall submit the data supporting any differences.

(6) If clinical experience reported to or otherwise received by the applicant indicates the need for change in claims for effectiveness or in side effects, warnings, or contraindications in the labeling or advertising currently in use, the applicant shall submit a supplemental application proposing such changes in the labeling and a showing that any advertising will be appropriately revised.

(7) If the clinical or other experience reported to or otherwise obtained by the applicant has revealed any information concerning any side-effect, injury, toxicity, or sensitivity reaction, or any unexpected incidence or severity thereof, which by kind, or incidence or severity is not fully disclosed in the labeling, whether or not determined to be attributable to the drug, this information shall be submitted as soon as the review reveals such facts. Such information shall include full reports of all available information with respect to any deaths apparently related to drug administration whether or not determined to be attributable to the drug. Any such information previously submitted for inclusion in the new-drug application or antibiotic form 5 or 6 need not be resubmitted.

(8) If the clinical or other experience reported to or otherwise obtained by the applicant within the past 2 years has revealed any information with respect to a distributed batch concerning any mix-up in the drug or its labeling with another article; any bacteriological or any significant chemical, physical, or other change or deterioration of the drug; or any failure of one or more distributed batches to meet specifications established in the new-drug application or in the antibiotic regulations, this information shall be submitted as soon as the review reveals such facts. Any unresolved experience of the kinds listed in this paragraph shall be reported even though it occurred prior to the 2-year period.

(c) Such reports shall be addressed to the Secretary, Department of Health, Education, and Welfare, for the Commissioner of Food and Drugs, Washington, DC, 20204, and shall be distinctly marked "New Drug (or Antibiotic) Re-

port," together with the applicable new-drug application number or antibiotic account number on the envelope.

(d) Each such applicant shall maintain for inspection all records received or otherwise obtained by him containing any of the kinds of information described in § 310.300(a).

(e) After the submission of the initial reports required by paragraphs (a) and (b) of this section, each such applicant shall, after 1 year, submit for the reporting period reports of the kinds required by § 310.300(b)(4), not later than each anniversary date of the effectiveness of the new-drug application or initial antibiotic form 5 or 6 approval.

(f) Each applicant shall submit all information reported to or received by him of the kinds required by § 310.300(b)(1) and (2) as required in that section.

(g) Deliberate or repeated failure to make the reports required by paragraphs (a) and (b) of this section will be followed by written notice to the holder of the application and publication of such notice in the FEDERAL REGISTER, furnishing an opportunity for a hearing on a proposal to withdraw approval of the application. Any interested person who may be adversely affected by such an order may respond to such notice and avail himself of an opportunity to participate in such a hearing. This will allow any person distributing a drug that was covered by an application held by a person who did not make the required reports an opportunity to show cause why approval of the application should not be withdrawn and marketing of the drug discontinued.

(h) Reports showing that a new drug was not marketed or has been discontinued may be followed by publication in the FEDERAL REGISTER of a notice of a proposal to withdraw approval of such application, on any of the grounds specified in section 505(e) of the act, giving any interested person who would be adversely affected by such an order an opportunity to respond and avail himself of a hearing prior to the issuance of such order. This will allow any person distributing a new drug that was covered by an application held by a person who did not market the drug or who has abandoned marketing of the drug an opportunity to show cause why approval of the application should not be withdrawn and why marketing of the drug should not be discontinued.

(i) Exemptions from annual reporting will be considered on the basis of petitions therefor, giving reasons why annual reporting is not required to protect the public health. No exemption will be allowed from the reporting requirements of paragraph (f) of this section and of § 310.300(b)(1) and (2).

(Sec. 507, 59 Stat. 463, as amended; 21 U.S.C. 357)

§ 310.303 Continuation of long-term studies, records, and reports on certain drugs for which new-drug applications have been approved.

(a) A new drug may not be approved for marketing unless it has been shown to be safe and effective for its intended use(s). After approval, the applicant is required to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds under section 505(e) of the act for suspending or withdrawing approval of the application. Some drugs, because of the nature of the condition for which they are intended, must be used for long periods of time—even a lifetime. To acquire necessary data for determining the safety and effectiveness of long-term use of such drugs, extensive animal and clinical tests are required as a condition of approval. Nonetheless, the therapeutic or prophylactic usefulness of such drugs may make it inadvisable in the public interest to delay the availability of the drugs for widespread clinical use pending completion of such long-term studies. In such cases, the Food and Drug Administration may approve the new-drug application on condition that the necessary long-term studies will be conducted and the results recorded and reported in an organized fashion. The procedures required by paragraph (b) of this section will be followed in order to list such a drug in § 310.304.

(b) A proposal to require additional or continued studies with a drug for which a new-drug application has been approved may be made by the Commissioner on his own initiative or on behalf of any interested person. Prior to issuance of such a proposal, the applicant will be provided an opportunity for a conference with representatives of the Food and Drug Administration. When appropriate, investigators or other individuals may be invited to participate in the conference. Such proposal and a summary of the grounds upon which it is proposed will be published in the FEDERAL REGISTER and written comments thereon invited. After considering all available data, the Commissioner will publish an order in the FEDERAL REGISTER acting on the proposal. Proposals submitted by interested persons may be refused by written notice from the Commissioner if the proposal is not supported by reasonable grounds. Upon final determination that special studies, records, and reports are required for a drug, such requirements will be published in § 310.304.

§ 310.304 Drugs that are subjects of approved new-drug applications and that require special studies, records, and reports.

Listed below are the new drugs and requirements referred to in § 310.303:

(a) *Levodopa.* Levodopa has been shown to be of value for symptomatic relief in the treatment of Parkinson's disease. The nature of this disease requires that the drug be taken over a protracted period of time—even a lifetime. In view of the benefits attributable to levodopa, the Commissioner finds that it is not in the public interest to withhold the drug from the market until very long-term or lifetime studies have been completed for a determination of its long-term safety and effectiveness. The Food and Drug Administration has, by letters to applicants, approved new-drug applications for levodopa for use in the treatment of Parkinson's disease. In view of the known adverse effects associated with its use and considering its indicated long-term use, the Commissioner finds that holders of approved new-drug applications for levodopa should be required to continue studies with the drug as described below and to monitor such records and make such reports as are necessary with respect to the continuing studies. These studies are necessary for acquiring an organized body of information on the safety and effectiveness of levodopa in long-term use.

(1) The applicant is to carry to conclusion the 1-year chronic toxicity studies in dogs and 18-month chronic toxicity studies in rats, including the necessary histopathology.

(2) The clinical studies now being conducted under a standard protocol are to be extended in at least 600 of the patients now under treatment. This will include the blood chemistry and medical evaluation currently being done under the existing protocol.

(3) The applicant is to arrange for a central tissue registry to examine human autopsy material obtained from patients in the study who died while under treatment with levodopa.

(4) Reports on the studies will be submitted under § 310.300.

(5) At the end of each year after the date of approval of the application, representatives of the Food and Drug Administration, the applicant, and, if necessary, the investigators will meet to determine on the basis of available information whether or not clinical studies should be continued.

(b) *Methadone.* Methadone may be used as an analgesic in severe pain, for the detoxification of narcotic addicts, and as an oral substitute for heroin or other morphine-like drugs, in the maintenance treatment of narcotic addicts, pursuant to the conditions established in § 310.505. Further data and information are required to establish the safety and effectiveness of methadone under a variety of conditions during widespread and long-term use. In view of the tremendous public health and social problems associated with the use of heroin, the demonstrated usefulness of methadone in treatment, the lack of a safe and effective alternative drug or treatment modality, the need for additional safety and effectiveness data on methadone, and the danger to health that could be created by uncontrolled distribution and use of methadone, the Commissioner of Food and Drugs finds that it is not in the public interest either to withhold the drug from the market until it has been proved safe and effective under all conditions of use or to grant full approval for unrestricted distribution, prescription, dispensing, or administration of methadone. The Commissioner therefore concludes that it is essential to the public interest to prescribe detailed conditions for safe and effective use of methadone,

utilizing the IND and NDA control mechanisms and the authority granted under the Comprehensive Drug Abuse Prevention and Control Act of 1970, to assure that the required additional information for assessing the safety and effectiveness of methadone is obtained, to maintain close control over the safe distribution, administration, and dispensing of the drug, and to detail responsibilities for such control. The conditions established in § 310.505 constitute a determination of the appropriate methods of professional practice in the medical treatment of the narcotic addiction of various classes of narcotic addicts with respect to the use of methadone, pursuant to section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970.

Subpart E—Requirements for Specific New Drugs or Devices

§ 310.500 Digoxin products for oral use; conditions for marketing.

(a) Studies have shown evidence of clinically significant differences in bioavailability in different batches of certain marketed digoxin products for oral use from single manufacturers as well as in batches of these products produced by different manufacturers. These differences were observed despite the fact that the products met compendial specifications. Other studies have shown that there is a sufficient correlation between bioavailability in vivo and the dissolution rate of digoxin tablets in vitro to make the dissolution test an important addition to the compendial standards. Because of the potential for serious risk to cardiac patients using digoxin products which may vary in bioavailability, the Commissioner of Food and Drugs has determined that immediate action must be taken to assure the uniformity of all digoxin products for oral use. The Commissioner is of the opinion that digoxin products for oral use are new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act for which approved new drug applications are required. The Commissioner has determined that, because of questions raised regarding the bioavailability of digoxin products for oral use, there is sufficient evidence to invoke the authority under section 505(j) of the act to fully investigate this question and to facilitate a determination of whether there is a ground for withdrawal of approval of the drug product under section 505(e) of the act. Marketing of these products may be continued only under the following conditions:

(1) Digoxin products for oral use, other than tablets: Any person marketing digoxin products for oral use, other than tablets, shall submit to the Food and Drug Administration on or before February 21, 1974, an abbreviated new drug application for these products. Any such drug product then on the market which is not the subject of an application submitted for the drug product shall be subject to regulatory procedures under section 505 of the act. In addition to the information specified in § 314.1(f) of this chapter, the application shall contain:

(i) A full list of the articles used as components of the digoxin product, specifications for components, detailed identification and analytical procedures used to assure that the components meet established specifications of identity, strength, quality, and purity and a complete description of the manufacturing process.

(ii) The source of the digoxin used in the formulation including the name and address of the supplier.

(iii) A statement that stability studies will be conducted to establish a suitable expiration date for the digoxin product in the form in which it is distributed.

(iv) A statement that the product label will contain a suitable expiration date. In the absence of any stability test data, this expiration date shall be no longer than one year after the batch is manufactured. If the expiration date is greater than one year, supporting stability data shall be included in the application.

(v) Labeling that is in compliance with all requirements of the act and regulations promulgated thereunder, the pertinent parts of which are as indicated in paragraph (e) of this section.

(vi) A statement that the applicant will initiate recall of all stocks of the drug product outstanding when so requested by the Food and Drug Administration.

(vii) A statement that the applicant intends to conduct in vivo bioavailability tests and that the applicant, under the records and reports provisions of section 505(j) of the act, will:

(*a*) Within 30 days after the submission of the application, submit to the Food and Drug Administration the protocol which the applicant proposes to follow in conducting these in vivo bioavailability tests. The protocol shall contain all of the essential elements set forth in paragraph (d) of this section. The tests shall not be initiated prior to receiving notification from the Food and Drug Administration that the bioavailability protocol has been reviewed and either approved or its deficiencies delineated.

(*b*) Within 180 days after receiving notification from the Food and Drug Administration that the bioavailability protocol has been reviewed, submit to the Food and Drug Administration the results of the in vivo bioavailability tests.

(2) Digoxin tablets: Any person marketing digoxin tablets, in addition to complying with all of the requirements of paragraph (a)(1) of this section, shall include in their abbreviated new drug application:

(i) A statement that the applicant will establish procedures to test each lot of digoxin tablets prior to releasing the batch for distribution to assure that the batch meets all of The United States Pharmacopeia (USP XVIII) requirements for digoxin tablets including, but not limited to, potency, content uniformity, and dissolution and either (*a*) that the quantity of digoxin dissolved at one hour is not more than 95 percent of the assayed amount of digoxin or (*b*) that the quantity of digoxin dissolved at 15 minutes is not more than 90 percent of the assayed amount of digoxin.

(ii) A statement that finished product specifications shall be established to include provisions to assure that the range of average one-hour dissolution values among batches of digoxin tablets does not exceed 20 percent.

(3) Before releasing for distribution any batch of digoxin tablets manufactured after January 22, 1974, the manufacturer shall:

(i) Test a sample of the batch to assure that the batch meets all of the requirements of The United States Pharmacopeia (USP XVIII) including but not limited to, potency, content uniformity, and dissolution and either (*a*) that the quantity of digoxin dissolved at one hour is not more than 95 percent of the assayed amount of digoxin or (*b*) that the quantity of digoxin dissolved at 15 minutes is not more than 90 percent of the assayed amount of digoxin.

(ii) Submit a sample of the batch to the Food and Drug Administration according to the procedures set forth in paragraph (g) of this section. Results of tests conducted on the batch by or for the manufacturer and the batch production record shall accompany the sample.

(iii) Withhold the batch from distribution until he is notified by the Food and Drug Administration that the sample was tested and found to meet all of the requirements in The United States Pharmacopeia (USP XVIII) for potency, content uniformity, and dissolution and either (*a*) that the quantity of digoxin dissolved at one hour is not more than 95 percent of the assayed amount of digoxin or (*b*) that the quantity of digoxin dissolved at 15 minutes is not more than 90 percent of the assayed amount of digoxin.

(iv) Submit a sample of each batch of digoxin tablets as provided for in paragraph (a)(3)(ii) of this section until he is notified by the Food and Drug Administration that he is released from the certification program. This notification will be made on the basis of sample test results, inspectional findings regarding compliance with current good manufacturing practice, and compliance with all other requirements of this section and any other directives issued by the Food and Drug Administration as a condition for release from the certification program.

(4) Any manufacturer who has distributed any batch of digoxin tablets which does not meet the compendial requirement for dissolution, when tested by the method in The United States Pharmacopeia (USP XVIII), shall initiate recall of the subject batch when so requested by the Food and Drug Administration.

(b) Failure of an applicant to submit the protocol and/or the results of the in vivo bioavailability tests showing adequate evidence of the product's bioavail-

ability within the times specified in paragraph (a)(1)(vii) of this section and/or to comply with all of the certification requirements of paragraph (a)(3) of this section shall be justification for withdrawal of approval of the application under section 505(e) of the act.

(c) Any product reformulation or change in manufacturing process will require the submission of a supplement to the approved abbreviated new drug application containing adequate data to demonstrate the bioavailability of the reformulated product. Food and Drug Administration approval of the supplement is required before the reformulated product is marketed. The Food and Drug Administration recommends that, where digoxin tablets are reformulated, manufacturers reformulate their product to achieve dissolution of 70 to 90 percent at one hour when tested by all three methods (i.e., the USP method, and the "paddle-water" and "paddle-acid" methods) described in paragraph (h) of this section.

(d) The protocol for the in vivo bioavailability tests required in paragraphs (a) and (c) of this section shall employ a three-way crossover design using the digoxin test product; a reference digoxin tablet supplied, on request, by the Food and Drug Administration; and bulk digoxin USP in an oral solution. Appropriate venous blood and urinary samples are to be collected and analyzed. The method shall be capable of detecting the difference between the reference tablet and the reference oral solution. Bioavailability of the test product shall be demonstrated if a mean absorption of at least 75 percent of the combined mean of the two reference standards is observed. Assistance in developing a protocol for a particular dosage formulation may be obtained by contacting the Food and Drug Administration, Bureau of Drugs (HFD-220), 5600 Fishers Lane, Rockville, MD 20852.

(e) Parts of the digoxin product labeling indicated below shall be substantially as follows:

CARDIAC (DIGITALIS) GLYCOSIDES LABELING GUIDELINE (ADULT)

DESCRIPTION

The cardiac (or digitalis) glycosides are a closely related group of drugs having in common specific and powerful effects on the myocardium. These drugs are found in a number of plants. The term "digitalis" is used to designate the whole group. Typically, the glycosides are composed of three portions, a steroid nucleus, a lactone ring, and a sugar (hence "glycosides").

(This section should include a chemical and physical description of digoxin and the same quantitative ingredient information as that required on the label.)

ACTION

The digitalis glycosides have qualitatively the same therapeutic effect on the heart. They (1) increase the force of myocardial contraction, (2) increase the refractory period of the atrioventricular (A–V) node, and (3) to a lesser degree, affect the sinoatrial (S–A) node and conduction system via the parasympathetic and sympathetic nervous systems.

Gastrointestinal absorption of digoxin is a passive process. Absorption of digoxin from tablets is 50–75 percent. Digoxin is only 20–25 percent bound to plasma proteins and is predominantly excreted by the kidneys unmetabolized unless there is significant renal failure. Renal excretion of digoxin is proportional to glomerular filtration rate and is largely independent of urine flow. Digoxin is not effectively removed from the body by dialysis, exchange transfusions or during cardiopulmonary bypass presumably because of tissue binding. In subjects with normal renal function digoxin is excreted exponentially with an average half-life of 36 hours resulting in the loss of 35–40 percent of the body stores daily.

Serum levels and pharmacokinetics are essentially unchanged by massive weight loss suggesting that lean body mass should be used in dosage calculations. The peak blood level from oral dosing with tablets occurs 1–3 hours after administration. The onset of therapeutic action of digoxin after oral tablets is 1–2 hours with the peak therapeutic effect occurring 6–8 hours after dosing.

INDICATIONS

1. "Congestive heart failure," all degrees, is the primary indication. The increased cardiac output results in diuresis and general amelioration of the disturbances characteristic of right (venous congestion, edema) and left (dyspnea, orthopnea, cardiac asthma) heart failure.

Digitalis, generally, is most effective in "low output" failure and less effective in "high output" (bronchopulmonary insufficiency, infection, hyperthyroidism) heart failure.

Digitalis should be continued after failure is abolished unless some known precipitating factor is corrected.

2. "Atrial fibrillation"—especially when the ventricular rate is elevated. Digitalis rapidly reduces ventricular rates and eliminates the pulse deficit. Palpitation, precordial distress or weakness are relieved and any concommitant congestive failure ameliorated.

Digitalis is continued in doses necessary to maintain the desired ventricular rate and other clinical effects.

3. "Atrial flutter" digitalis slows the heart and regular sinus rhythm may appear. Frequently the flutter is converted to atrial fibrillation with a slow ventricular rate. Stopping digitalis at this point may be followed by restoration of sinus rhythm, especially if the flutter was of the paroxysmal type. It is preferable, however, to continue digitalis if failure ensues or if atrial flutter is a frequent occurrence.

4. "Paroxysmal atrial tachycardia" digitalis may be used, especially if it is resistant to lesser measures. Depending on the urgency, a more rapid acting parenteral preparation may be preferable to initiate digitalization, although if failure has ensued or paroxysms recur frequently, digitalis is maintained by oral administration.

Digitalis is not indicated in sinus tachycardia or premature systoles in the absence of heart failure.

"Cardiogenic shock"—the value of digitalis is not established, but the drug is often employed, especially when the condition is accompanied by pulmonary edema. Digitalis seems to adversely affect shock due to infections.

CONTRAINDICATIONS

The presence of toxic effects (See "Overdosage") induced by any digitalis preparation is an absolute contraindication to all of the glycosides.

Allergy, though rare, does occur. It may not extend to all preparations and another may be tried.

Ventricular Fibrillation.

Ventricular tachycardia, unless congestive failure supervenes after a protracted episode not itself due to digitalis.

WARNINGS

Many of the arrhythmias for which digitalis is advised are identical with those reflecting digitalis intoxication. If the possibility of digitalis intoxication cannot be excluded, cardiac glycosides should be temporarily withheld if permitted by the clinical situation.

The patient with congestive heart failure may complain of nausea and vomiting. These symptoms may also be indications of digitalis intoxication. A clinical determination of the cause of these symptoms must be attempted before further drug administration.

Patients with renal insufficiency are apt to be unusually sensitive to digoxin. See Action Section for mechanism.

PRECAUTIONS

"Potassium depletion" sensitizes the myocardium to digitalis and toxicity is apt to develop even with usual dosage. Hypokalemia also tends to reduce the positive inotropic effect of digitalis.

Potassium wastage may result from diuretic, corticosteroid, hemodialysis and other therapy. It is apt to accompany malnutrition, old age and long-standing congestive heart failure.

"Acute myocardial infarction," severe pulmonary disease, or far advanced heart failure are apt to be more sensitive to digitalis and more prone to disturbances of rhythm.

"Calcium" affects contractility and excitability of the heart in a manner similar to that of digitalis. Calcium may produce serious arrhythmias in digitalized patients.

"Myxedema"—Digitalis requirements are less because excretion rate is decreased and blood levels are significantly higher.

"Incomplete AV block," especially patients subject to Stokes Adams attacks, may develop advanced or complete heart block. Heart failure in these patients can usually be controlled by other measures and by increasing the heart rate.

"Chronic constrictive pericarditis," is apt to respond unfavorably.

"Idiopathic hypertrophic subaortic stenosis" must be managed extremely carefully. Unless cardiac failure is severe it is doubtful whether digitalis should be employed.

"Renal insufficiency" delays the excretion of digitalis and dosage must be adjusted accordingly in patients with renal disease.

NOTE: This applies also to potassium administration should it become necessary.

Electrical conversion of arrhythmias may require adjustment of digitalis dosage.

ADVERSE REACTIONS

Gynecomastia, uncommon.

Overdosage or toxic effects. Gastrointestinal—anorexia, nausea, vomiting, diarrhea are the most common early symptoms of overdosages in the adult (but rarely conspicuous in infants). Uncontrolled heart failure may also produce such symptons. Central Nervous System—headache, weakness, apathy, visual disturbances.

Cardiac Disturbances (Arrhythmias)—ventricular premature beats is the most common, except in infants and young children.

Paroxysmal and nonparoxysmal nodal rhythms, atrioventricular (inference) dissociation and paroxysmal atrial tachycardia (PAT) with block are also common arrhythmias due to digitalis overdosage.

Conduction Disturbances—excessive slowing of the pulse is a clinical sign of digitalis overdosage. Atrioventricular block of increasing degree, may proceed to complete heart block.

NOTE: The electrocardiogram is fundamental in determining the presence and nature of these toxic disturbances. Digitalis may also induce other changes (as of the ST seg-

ment), but these provide no measure of the degree of digitalization.

TREATMENT OF ARRHYTHMIAS PRODUCED BY OVERDOSAGES

Digitalis is discontinued until after all signs of toxicity are abolished. This may be all that is necessary if toxic manifestations are not severe and appear after the time for peak effect of the drug.

Potassium salts are commonly used. Potassium chloride in divided doses totaling 4 to 6 gm. for adults (See Pediatric Information for children) provided renal function is adequate.

When correction of the arrhythmia is urgent, potassium is administered intravenously in a solution of 5 percent dextrose in water, a total of 40–100 mEq. (40 mEq. per 500 ml.) at the rate of 40 mEq. per hour unless limited by pain due to local irritation.

Additional amounts may be given if the arrhythmia is uncontrolled and the potassium well tolerated.

Electrocardiographic monitoring is indicated to avoid potassium toxicity, e.g. peaking of T waves.

CAUTION

Potassium should not be used and may be dangerous for severe or complete heart block due to digitalis and not related to any tachycardia.

Chelating agents to bind calcium may also be used to counteract the arrhythmia effect of digitalis toxicity, hypokalemia and of elevated serum calcium which may also precipitate digitalis toxicity.

Four grams (0.8 percent solution) of the disodium salt of EDTA is dissolved in 500 ml. of 5 percent dextrose in water (50 mg. per ml.) and administered over a period of 2 hours unless the arrhythmia is controlled before the infusion is completed.

A continuous electrocardiogram should be observed so that the infusion may be promptly stopped when the desired effect is achieved.

Other counteracting agents are: Quinidine procainamide and beta adrenergic blocking agents.

DOSAGE AND ADMINISTRATION

Oral digitalis is administered slowly or rapidly as required until the desired therapeutic effect is obtained without symptoms of overdosage. The amount can be predicted approximately from the weight of the patient with allowances made for excretion during the time taken to induce digitalization.

Subsequent maintenance dosage is also determined tentatively by the amount necessary to sustain the desired therapeutic effect.

Recommended dosages are practical average figures which may require considerable modification as dictated by individual sensitivity or associated conditions. (See Warning Precautions.)

The average digitalizing dose with digoxin tablets is 1.25–1.5 milligrams. Digitalization may be accomplished by several approaches. A dose of 1.0 milligram orally usually produces a digitalis effect in 1–2 hours and becomes maximal in 6–8 hours. Additional doses of 0.25 or 0.5 milligram may be given at 6–8 hour intervals to full digitalization.

The usual daily oral maintenance dose is 0.25–0.5 milligram. For previously undigitalized patient, institution of daily maintenance therapy without a loading dose results in development of steady-state plateau concentrations in about seven days in patients with normal renal function. By giving 0.75 milligram digoxin daily in divided doses the desired therapeutic effect may be achieved in a previously undigitalized patient with normal renal function in 4–5 days.

It cannot be overemphasized that the values given are averages and substantial individual variation can be expected.

(If pediatric dosage is available the labeling sections above should be expanded to include the following information.)

PEDIATRIC INFORMATION

WARNINGS

Newborn infants during first month of life have a sharply defined tolerance to digitalis. Impaired renal function must also be carefully taken into consideration.

"Premature and immature infants" are particularly sensitive and further reduction of dosage may be necessary.

Congestive failure accompanying acute "glomerulonephritis" requires extreme care in digitalization. A relatively low total dose administered in divided doses and concomitant use of reserpine or other antihypertensive agents has been recommended. Constant ECG monitoring is essential and digitalis discontinued as soon as possible.

IDIOPATHIC HYPERTROPHIC SUBAORTIC STENOSIS

See Adult Precautions.

"Rheumatic carditis"—such cases, especially when severe, are unusually sensitive to digitalis and prone to disturbances of rhythm. If heart failure develops, digitalization may be tried with relatively low doses; then cautiously increased until a beneficial effect is obtained. If a therapeutic trial does not result in improvement, the drug should be considered ineffective and be discontinued.

NOTE: Digitalis glycosides are an important cause of accidential poisoning in children.

PRECAUTIONS

Dosage must be carefully titrated.

Electrocardiographic monitoring may be necessary to avoid intoxication.

Premonitory signs of toxicity in the newborn are undue slowing of the sinus rate, sinoatrial arrest, and prolongation of PR interval.

OVERDOSAGE EFFECTS

Toxic signs differ from the adult in a number of respects.

Cardiac arrhythmias are the more reliable and frequent signs of toxicity.

Vomiting and diarrhea, neurologic and ophthalmological disturbance are rare as initial signs.

Premature centricular systoles are rarely seen; nodal and atrial systoles are more frequent.

Atrial arrhythmias, atrial ectopic rhythms and paroxysmal atrial tachycardia with AV block particularly are more common manifestations of toxicity in children.

Ventricular arrhythmias are rare.

TREATMENT OF TOXIC ARRHYTHMIAS

(See section for adults.) Potassium preparations may be given orally in divided doses totaling 1–2 gm. daily in children. When correction of the arrhythmia is urgent, 5 to 10 mEq. of potassium per hour are given, this amount being dissolved in 100 ml. of 5 percent dextrose in water. Additional amounts of potassium may be given if necessary and well tolerated by the child.

A chelating agent may be tried if other measures fail. EDTA intravenously has been recommended in a dose of 15 mg./kg./hr. in 5 percent dextrose in water, the total not to exceed 60 mg./kg./day. A continuous electrocardiogram should be observed so that the infusion can be stopped promptly when the desired effect is achieved.

DOSAGE AND ADMINISTRATION

Digitalization must be individualized. Generally, premature and immature infants are particularly sensitive permitting reduced dosage which must be determined by careful titration.

Oral dosage. Newborn (normal), from birth to 1 month, require adult proportions by body weight.

Infants, 1 month to 2 years require approximately 50 percent more by body weight than adult proportions.

Children, 2 years and over require adult proportions by body weight.

(Complete by adding dosage for the specific preparation.)

Long term use of digitalis is indicated in almost all infants who have been digitalized for acute congestive failure unless the cause is transient. Many favor maintaining digitalis until at least 2 years of age in all infants with paroxysmal atrial tachycardia or who show either definite or latent failure.

Many children with severe inoperable congenital defects need digitalis throughout childhood and often for life.

(f) Abbreviated new drug applications shall be submitted to the Food and Drug Administration, Bureau of Drugs, Office of Scientific Evaluation, Generic Drug Staff (HFD–107), 5600 Fishers Lane, Rockville, MD 20852.

(g) All samples of digoxin tablets required by paragraph (a)(3) of this section to be submitted to the Food and Drug Administration shall be handled as follows:

(1) The sample shall consist of 6 subsamples of 1000 tablets each collected at random from throughout the manufacturing run. Each of the 6 subsamples shall be identified with the name of the product, the labeled potency, the date of manufacture, the batch number, and the name and address of the manufacturer.

(2) The sample together with the batch production record and results of all tests conducted by or for the manufacturer to determine the product's identity, strength, quality, and purity, content uniformity and dissolution shall be submitted to the Department of Health, Education, and Welfare, Public Health Service, FDA National Center for Drug Analysis, 1114 Market St., St. Louis, MO 63101. The outer wrapper shall be identified "SAMPLE—DIGOXIN CERTIFICATION."

(h) The Food and Drug Administration is aware of data with two in vitro methods, in addition to that described in The United States Pharmacopeia (USP XVIII), developed to measure digoxin tablets dissolution. These two methods, the so-called "paddle-water" and "paddle-acid" methods, are described below and are identical with the exception of the nature of the dissolution medium used in the procedures (i.e., distilled or deionized water vs. dilute hydrochloric acid (0.6 percent volume/volume)). The dissolution apparatus used in these two methods differs significantly from the apparatus described in the method in the compendium. The Food and Drug Administration is aware that the three methods (i.e., USP, "paddle-water," and "paddle-acid") show significant differences in dissolution in comparative tests on some formulations. Definitive bioavailability data to compare the relative value of each of these methods to predict bioavailability of the few formulations where the methods show significant differences in dissolution rate are not now available. Manufacturers who con-

duct research utilizing the "paddle-water" and "paddle-acid" methods, particularly in comparison with the method in The United States Pharmacopeia, shall submit any data obtained using these methods to the Food and Drug Administration pursuant to section 505(j) of the act.

(1) *Dissolution apparatus.*

(NOTE: Throughout this procedure use scrupulously clean glassware, which previously has been rinsed with dilute hydrochloric acid, distilled or deionized water, then with alcohol, and carefully dried. Take precautions to prevent contamination from airborne, fluorescent particles and from metal and rubber surfaces.) The apparatus consists of a suitable water bath, a 1000 milliliter glass vessel (Kimble Glass No. 26220 or equivalent), a motor, and a polytetrafluoroethylene stirring blade (Sargent S-76637, Size B, 3 inch length; or equivalent) on a glass stirring shaft (Sargent 5-76636, 14.5 inch length; or equivalent). The water bath may be of any convenient size that permits keeping the water temperature uniformly at 37° C. ±0.5° C. throughout the test. The vessel is spherical, and is provided with three ports at the top, one of which is centered. The lower half of the vessel is 65 millimeters in inside radius and the vessel's nominal capacity is 1000 milliliters. The glass stirring shaft from the motor is placed in the center port, and one of the outer ports may be used for insertion of a thermometer. Samples may be removed for analysis through the other port. The motor is fitted with a speed-regulating device that allows the motor speed to be held at 50 rpm ±2 rpm. The motor is suspended above the vessel in such a way that it may be raised or lowered to position the stirring blade. The glass stirring shaft is 10 millimeters in diameter and about 37 centimeters in length. It must run true on the motor axis without perceptible wobble. The polytetrafluoroethylene stirring blade is 4 millimeters thick and forms a section of a circle, whose diameter is 83 millimeters and which is subtended by parallel chords of 42 and 77 millimeters. The blade is positioned horizontally, with the 42-millimeter edge down, 2.5 centimeters ±0.2 centimeter above the lowest inner surface of the vessel.

(2) *Reagents*—(i) *Dissolution medium.* For "paddle-water," use distilled or deionized water. For "paddle-acid," use dilute hydrochloric acid (0.6 percent volume/volume). Use the same batch of dissolution medium throughout the test.

(ii) *Standard solutions.* Accurately weigh approximately 25 milligrams of The United States Pharmacopeia Digoxin Reference Standard, dissolve in a minimum amount of 95 percent ethanol in a 500 milliliter volumetric flask and add 95 percent ethanol to volume and mix. Dilute 10.0 milliliters of this first solution to 100.0 milliliters with 95 percent ethanol and mix for the second solution. Just prior to use, individually dilute 1.0, 2.0, 3.0, 4.0, and 5.0 milliliter aliquots of the second solution with dissolution medium to 50.0 milliliters. These solutions are equivalent to 20, 40, 60, 80, and 100 percent of dissolution, respectively, for a 0.25 milligram digoxin tablet.

(iii) *Extraction solvent.* Prepare a solvent containing 6 volumes of chloroform, analytical reagent grade, with 1 volume of n-propyl alcohol, analytical reagent grade.

(iv) *Ascorbic acid-methanol solution.* Prepare a solution containing 2 milligrams of ascorbic acid, analytical reagent grade, per 1 milliliter of methanol, absolute, analytical reagent grade.

(v) *Hydrochloric acid, concentrated reagent grade.*

(vi) *Hydrogen peroxide-methanol solution.* On the day of use, dilute 2.0 milliliters of recently assayed 30 percent hydrogen peroxide, reagent grade, with methanol, absolute, analytical reagent grade to 100.0 milliliters. Store in a refrigerator. Just prior to use, dilute 2.0 milliliters of this soluton with methanol to 100.0 milliliters.

(3) *Procedure*—(i) *Dissolution.* Place 500 milliliters of dissolution medium in the vessel, immerse it in the constant-temperature bath set at 37°C.±0.5°C., and allow the dissolution medium to assume the temperature of the bath. Position the shaft so that there is a distance of 2.5 centimeters ±0.2 centimeter between the midpoint of the bottom of the blade and the bottom of the vessel. With the stirrer operating at a speed of 50 rpm±2 rpm, place 1 tablet into the flask. After 60 minutes, accurately timed, withdraw 25 milliliters, using a glass syringe connected to a glass sampling tube, of solution from a point midway between the stirring shaft and the wall of the vessel, and approximately midway in depth. Filter the solution promptly after withdrawal, using a suitable membrane filter of not greater than 0.8 micron porosity (Millipore AAWP 025 00, or equivalent), mounted in a suitable holder (Millipore Swinnex SX00 025 00, or equivalent), discarding the first 100 milliliters of filtrate. This is the test solution. Repeat the dissolution procedure on 5 additional tablets.

(ii) *Extraction.* Transfer 10.0 milliliters of each of the six filtrates, 10.0 milliliters of each of the five standard solutions, and 10.0 milliliters of dissolution medium, to provide a blank, in separate 60-millliter separators. Extract each solution with two 10-milliliter portions of extraction solvent. Combine the extracts of each solution in separate, glass-stoppered, 50-milliliter conical flasks, and evaporate on a steam bath with the aid of a stream of nitrogen to dryness, rinsing the sides of the flasks with extraction solvent. Take care to ensure that all traces of solvent are removed, but avoid prolonged heating. For convenience the residues may be stored in a vacuum desiccator overnight.

(iii) *Measurement of fluorescence.* Begin with the standard solutions, and keep all flasks in the same sequence throughout, so that the elapsed time from addition of reagents to reading of fluorescence is the same for each. Carry the test solutions, standard solutions, and the blank through the determination in one group. Add the following three reagents in as rapid a sequence as possible, swirling after each addition, treating 1 flask at a time, in the order named: 1.0 milliliter of ascorbic acid-methanol solution, 3.0 milliliters of concentrated hydrochloric acid, and 1.0 milliliter of hydrogen peroxide-methanol solution. Insert the stoppers in the flasks, and after 2 hours, measure the fluorescence at about 485 millimicrons, using excitation at about 372 millimicrons. In order to provide a check on the stability of the fluorometer, reread one or more standard solutions. Correct each reading for the blank and plot a standard curve of fluorescence versus percentage dissolution. Determine the percentage dissolution of digoxin in the test solutions by reading from the standard graph.

(iv) Digoxin tablets formulated so that the quantity of digoxin dissolved at one hour, when tested by the method in The United States Pharmacopeia (USP XVIII), is greater than 95 percent of the assayed amount of digoxin and so that the quantity of digoxin dissolved at 15 minutes is greater than 90 percent of the assayed amount of digoxin are new drugs which may be marketed only with an approved full new drug application as provided for in § 314.1 of this chapter. The application shall include, but not be limited to, clinical studies establishing significantly greater bioavailability than digoxin tablets meeting compendial requirements and dosage recommendations based on clinical studies establishing the safe and effective use of the bioavailable digoxin product. Marketing of these digoxin products will be allowed only under a proprietary or trade name, established name, and labeling which differs from that used for digoxin tablets that meet all of the requirements in The United States Pharmacopeia (USP XVIII) and that are formulated so that either (a) the quantity of digoxin dissolved at one hour is not more than 95 percent of the assayed amount of digoxin or (b) the quantity of digoxin dissolved at 15 minutes is not more than 90 percent of the assayed amount of digoxin. New drug applications for these digoxin products shall be submitted to the Food and Drug Administration, Bureau of Drugs, Office of Scientific Evaluation (HFD-100), 5600 Fishers Lane, Rockville, MD 20852.

NOTE: The provisions of 21 CFR 310.500 (a)(1) as they apply to the submission of abbreviated new-drug applications are stayed until 30 days after such time as a decision is reached regarding revision of the product labeling set forth in § 310.500(e). See 39 FR 9184, Mar. 8, 1974.

§ 310.501 Oral contraceptive preparations; labeling directed to the patient.

(a) The Food and Drug Administration is charged with assuring both physicians and patients that drugs are safe and effective for their intended uses. The full disclosure of information to physicians concerning such things as the effectiveness, contraindications, warnings, precautions and adverse reactions is an important element in the discharge of this responsibility. In view of this, the Administration has reviewed the oral

contraceptive products, taking into account the following factors: The products contain potent steroid hormones which affect many organ systems; they are used for long periods of time by large numbers of women who, for the most part, are healthy and take them as a matter of choice for prophylaxis against pregnancy, in full knowledge of other means of contraception; and there is no present assurance that persons for whom the drugs are prescribed or dispensed are uniformly being provided the necessary information for safe and effective use of the drugs.

(b) In view of the foregoing, it is deemed in the public interest to present to users of the oral contraceptives a brief notice of the nature of the drugs, the fact that continued medical supervision is needed for safe and effective use, that the drugs may cause side effects and are contraindicated in some cases, that the most important complication is abnormal blood clotting which can have a fatal outcome, that the physician recognizes an obligation to discuss the potential hazards of taking the drugs with the patient, that he has available for the patient written material discussing the effectiveness and the hazards of the drugs, and that users of the oral contraceptives should notify their physicians if they notice any unusual physical disturbance or discomfort.

(c) The Commissioner agrees that the physician is the proper person for providing use information to his patients, and these regulations will provide him a balanced discussion of the effectiveness and the risks attendant upon the use of oral contraceptives for his use in discussing the drugs with his patients.

(d) (1) The oral contraceptives are restricted to prescription sale, and their labeling is required to bear information under which practitioners licensed to administer the drugs can use them safely and for the purpose for which they are intended. In addition, in the case of oral contraceptive drugs, the Commissioner concludes that it is necessary in the best interests of users that the following printed information for patients be included in or with the package dispensed to the patient:

(Patient Package Information)

ORAL CONTRACEPTIVES

(Birth Control Pills)

Do Not Take This Drug Without Your Doctor's Continued Supervision.

The oral contraceptives are powerful and effective drugs which can cause side effects in some users and should not be used at all by some women. The most serious known side effect is abnormal blood clotting which can be fatal.

Safe use of this drug requires a careful discussion with your doctor. To assist him in providing you with the necessary information, ---------- has prepared a booklet (or other form) written in a style understandable to you as the drug user. This provides information on the effectiveness and known hazards of the drug including warnings, side effects and who should not use it. Your doctor will give you this booklet (or other form) if you ask for it and he can answer any questions you may have about the use of this drug.

(Firm name)

Notify your doctor if you notice any unusual physical disturbance or discomfort.

(2) Providing the patient package information to users may be accomplished by including it in each package of the type intended for the user as follows:

(i) If such package includes additional printed materials for the patient (e.g., dosage schedules), the text of the information in paragraph (d) (1) of this section shall be an integral part of the printed material and be in boldface type set out in a box, preceding all other printed text.

(ii) If such package does not include printed material for the patient, the text of the information in paragraph (d) (1) of this section shall be provided as a printed leaflet in boldface type.

(iii) Include in each bulk package intended for multiple dispensing, a sufficient number of the patient package information leaflet, with instructions to the pharmacist to include one with each prescription dispensed.

(e) Written, printed, or graphic materials on the use of a drug that are disseminated by or on behalf of the manufacturer, packager, or distributor and are intended to be made available to the patient, are regarded as labeling. The Commissioner also concludes that it is necessary that information in lay language, concerning effectiveness, contraindications, warnings, precautions, and adverse reactions be incorporated prominently in the beginning of any such materials, and that such labeling must be made available to physicians for all patients who may request it. Such labeling shall be substantially as follows, based on the approved package insert for prescribers of the oral contraceptives, and shall included the following points:

(1) A statement that the drug should be taken only under continued supervision of physician.

(2) A statement regarding the effectiveness of the product.

(3) A warning regarding the serious side effects with special attention to thromboembolic disorders and stating the estimated morbidity and mortality in users vs. nonusers. Other serious side effects to be mentioned include mental depression, edema, rash, and jaundice. The possibility of infertility following discontinuation of the drug should be mentioned.

(4) A statement of contraindications.

(5) A statement of the need for special supervision of some patients including those with heart or kidney disease, asthma, high blood pressure, diabetes, epilepsy, fibroids of the uterus, migrane, mental depression or history thereof.

(6) A statement of the most frequently encountered side effects such as spotting, breast changes, weight changes, skin changes, and nausea and vomiting.

(7) A statement of the side effects frequently reported in association with the use of oral contraceptives, but not proved to be directly related such as nervousness, dizziness, changes in appetite, loss of scalp hair, increase in body hair, and increased or decreased libido.

(8) A statement regarding metabolic effects such as on blood sugar and cholesterol setting forth our current lack of knowledge regarding the long term significance of these effects.

(9) Instructions in the event of missed menstrual periods.

(10) A statement cautioning the patient to consult her physician before resuming the use of the drug after childbirth, especially if she intends to breastfeed the baby, pointing out that the hormones in the drug are known to appear in the milk and may decrease the flow.

(11) A statement regarding production of cancer in certain animals. This may be coupled with a statement that there is no proof of such effect in human beings.

(12) A reminder to the patient to report promptly to her physician any unusual change in her general physical condition and to have regular examinations.

Optionally, the booklet may also contain factual information on family planning, the usefulness and hazards of other available methods of contraception, and the hazards of pregnancy. This material shall be neither false nor misleading in any particular and shall follow the material presented above.

(f) The marketing of oral contraceptives may be continued if all the following conditions are met within 90 days of the date of publication of this section in the FEDERAL REGISTER.

(1) The labeling of such preparations shipped within the jurisdiction of the Act is in accord with paragraphs (d) (1) and (2), and (e) of this section.

(2) The holder of an approved new-drug application for such preparation submits a supplement to his new-drug application under the provisions of § 314.8(d) of this chapter to provide for labeling as described in paragraphs (d) and (e) of this section. Such labeling may be put into use without advance approval of the Food and Drug Administration.

(g) Existing stocks may be shipped without the package insert for a period of 90 days, provided the labeling booklet is prepared and disseminated as promptly as possible.

§ 310.502 Certain intrauterine devices for human use for the purpose of contraception.

(a) The Food and Drug Administration has become aware of the increased clinical use for the purpose of contraception of intrauterine devices that incorporate heavy metals, drugs, or other active substances. The amount of local irritation caused by such active materials has been reported as being correlated, in animal studies, to the efficacy of such devices in achieving their contraceptive effect. Several investigators have reported different pregnancy rates which appear to be dependent on the type of metal used and/or the amount of exposed surface of the metal. Drugs have been incorporated with otherwise inert intrauterine devices to increase the contraceptive ef-

fect, decrease adverse reactions, or provide increased medical acceptability.

(b) Intrauterine devices used for the purpose of contraception and incorporating heavy metals, drugs, or other active substances to increase the contraceptive effect, to decrease adverse reactions, or to provide increased medical acceptability, are not generally recognized as safe and effective for contraception and are new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act. A completed and signed "Notice of Claimed Investigational Exemption for a New Drug" (Form FD-1571 set forth in § 312.1(a)(2) of this chapter) must therefore be submitted to cover clinical investigations to obtain evidence that such preparations are safe and effective for this use. An approved new drug application is required for the marketing of such articles.

(c) Paragraphs (a) and (b) of this section do not apply to the following:

(1) Intrauterine devices fabricated solely from inactive materials (e.g., inactive plastics or metals).

(2) Intrauterine devices with substances added to improve the physical characteristics if such substances do not contribute to contraception through chemical action on or within the body and are not dependent upon being metabolized for the achievement of the contraceptive purpose.

(3) Intrauterine devices that contain a component, such as barium, added exclusively for the purpose of visualization by X-ray.

§ 310.503 Requirements regarding certain radioactive drugs.

(a) On January 8, 1963 (28 FR 183), the Commissioner of Food and Drugs exempted investigational radioactive new drugs from § 312.1 of this chapter provided they were shipped in complete conformity with the regulations issued by the Atomic Energy Commission. This exemption also applied to investigational radioactive biologics.

(b) It is the opinion of the Atomic Energy Commission, and the Food and Drug Administration that this exemption should not apply for certain specific drugs and that these drugs should be appropriately labeled for uses for which safety and effectiveness can be demonstrated by new-drug applications or through licensing by the Public Health Service in the case of biologics. Continued distribution under the investigational exemption when the drugs are intended for established uses will not be permitted.

(c) Based on its experience in regulating investigational radioactive pharmaceuticals, the Atomic Energy Commission has compiled a list of reactor-produced isotopes for which it considers that applicants may reasonably be expected to submit adequate evidence of safety and effectiveness for use as recommended in appropriate labeling; such use may include, among others, the uses in this tabulation:

Isotope	Chemical form	Use
Chromium 51	Chromate	Spleen scans.
Do	do	Placenta localization.
Do	do	Red blood cell labeling and survival studies.
Do	Labeled human serum albumin.	Gastrointestinal protein loss studies.
Do	do	Placenta localization.
Do	Labeled red blood cells.	Do.
Cobalt 58 or Cobalt 60.	Labeled cyanocobalamin.	Intestinal absorption studies.
Gold 198	Colloidal	Liver scans.
Do	do	Intracavitary treatment of pleural effusions and/or ascites.
Do	do	Interstitial treatment of cancer.
Iodine 131	Iodide	Diagnosis of thyroid functions.
Do	do	Thyroid scans.
Do	do	Treatment of hyperthyroidism and/or cardiac dysfunction.
Do	do	Treatment of thyroid carcinoma.
Do	Iodinated human serum albumin.	Blood volume determinations.
Do	do	Cisternography.
Do	do	Brain tumor localization.
Do	do	Placenta localization.
Do	do	Cardiac scans for determination of pericardial effusions.
Do	Rose Bengal	Liver function studies.
Do	do	Liver scans.
Do	Iodopyracet, sodium iodohippurate, sodium diatrizoate, diatrizoate methylglucamine, sodium diprotrizoate, sodium acetrizoate, or sodium iothalamate.	Kidney function studies and kidney scans.
Do	Labeled fats and/or fatty acids.	Fat absorption studies.
Do	Cholografin	Cardiac scans for determination of pericardial effusions.
Do	Macroaggregated iodinated human serum albumin.	Lung scans.
Do	Colloidal microaggregated human serum albumin.	Liver scans.
Iodine 125	Iodide	Diagnosis of thyroid function.
Do	Iodinated human serum albumin.	Blood volume determinations.
Do	Rose Bengal	Liver function studies.
Do	Iodopyracet, sodium iodohippurate, sodium diatrizoate, diatrizoate methylglucamine, sodium diprotrizoate, sodium acetrizoate, or sodium iothalamate.	Kidney function studies.
Do	Labeled fats and/or fatty acids.	Fat absorption studies.
Iron 59	Chloride, citrate and/or sulfate.	Iron turnover studies.
Krypton 85	Gas	Diagnosis of cardiac abnormalities.
Mercury 197	Chlormerodrin	Kidney scans.
Do	do	Brain scans.
Mercury 203 [1]	do	Kidney scans.
Do	do	Brain scans.
Phosphorus 32	Soluble phosphate.	Treatment of polycythemia vera.
Do	do	Treatment of leukemia and bone metastasis.
Do	Colloidal chromic phosphate.	Intracavitary treatment of pleural effusions and/or ascites.
Do	do	Interstitial treatment of cancer.
Potassium 42	Chloride	Potassium space studies.
Selenium 75	Labeled methionine.	Pancreas scans.
Strontium 85	Nitrate or chloride.	Bone scans on patients with diagnosed cancer.
Technetium 99m.	Pertechnetate	Brain scans.
Do	do	Thyroid scans.
Do	Sulfur colloid	Liver and spleen scans.
Do	Pertechnetate	Placenta localization.
Do	do	Blood pool scans.
Do	do	Salivary gland scans.
Do	Diethylenetriamine pentaacetic acid (DTPA).	Kidney scans.
Xenon 133	Gas	Diagnosis of cardiac abnormalities. Cerebral blood-flow studies. Pulmonary function studies. Muscle blood-flow studies.

[1] This item has been removed from the AEC list for kidney scans but is included as the requirements of this order are applicable.

(d) (1) In view of the extent of experience with the isotopes listed in paragraph (c) of this section, the Atomic Energy Commission, and the Food and Drug Administration conclude that they should not be distributed under investigational-use labeling when they are actually intended for use in medical practice.

(2) It is further concluded that manufacturers or distributors interested in continuing to ship in interstate commerce drugs containing the isotopes listed in paragraph (c) of this section for any of the indications listed should submit, within 90 days after the effective date of this section, to the Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, a new-drug application or a "Notice of Claimed Investigational Exemption for a New Drug" for each such drug for which the manufacturer or distributor does not have an approved new-drug application pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act. Any "Notice of Claimed Investigational Exemption for a New Drug" should be submitted in accordance with § 312.1 of this chapter, and any new-drug application should be submitted in accordance with § 314.1 of this chapter.

(3) If the drug is a biologic, a "Notice of Claimed Investigational Exemption for a New Drug" or an application for a license under section 351 of the Public

Health Service Act, should be submitted to the Bureau of Biologics, Food and Drug Administration. Any "Notice of Claimed Investigational Exemption for a New Drug" or a product license application for a biologic shall be submitted in accordance with 21 CFR 312.1 or 601.

(4) After such 90-day period, the isotopes listed in paragraph (c) of this section, in the "chemical form" and intended for the uses stated, will no longer be exempt from § 312.1 of this chapter.

(e) No exemption from section 505 of the act or from § 312.1 of this chapter is in effect or has been in effect for radioactive drugs prepared from accelerator-produced radioisotopes, naturally occurring isotopes, or nonradioactive substances used in conjunction with isotopes.

§ 310.504 Amphetamines (amphetamine, dextroamphetamine, and their salts and levamfetamine and its salts) for human use.

(a) Amphetamine and dextroamphetamine and their salts. (1) Pursuant to the drug efficacy requirements of the Federal Food, Drug, and Cosmetic Act, the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, has evaluated certain dosage forms of amphetamines and other sympathomimetic stimulant drugs intended for use in the treatment of obesity and for other uses. The Academy found that such drugs as a class have been shown to have a generally short-term anorectic action. They further commented that clinical opinion on the contribution of the sympathomimetic stimulants in a weight reduction program varies widely, the anorectic effect of these drugs often plateaus or diminishes after a few weeks, most studies of them are for short periods, no available evidence shows that use of anorectic alters the natural history of obesity, some evidence indicates that anorectic effects may be strongly influenced by the suggestibility of the patient, and reservations exist about the adequacy of the controls in some of the clinical studies. Their significant potential for drug abuse was also cited.

(2) In addition to those dosage forms that were reviewed for efficacy by the Academy, other dosage forms of amphetamine drugs are on the market that were not cleared through the new-drug procedures. While certain amphetamines were marketed prior to enactment of the Federal Food, Drug, and Cosmetic Act in 1938, some of the conditions of use subsequently prescribed, recommended, or suggested in their labeling (for example, for the treatment of obesity) differ from uses claimed for the amphetamines before said enactment. Such uses have not been cleared through the effectiveness provisions of the Drug Amendments of 1962 (Pub. L. 87-781 which amended the Federal Food, Drug, and Cosmetic Act). These drugs are very extensively used in the treatment of obesity. The extent of use for such purposes as narcolepsy and minimal brain dysfunction in children is believed to be minor as compared with the total usage of these drugs. Because of their stimulant effect on the central nervous system, they have a potential for misuse by those to whom they are available through a physician's prescription, and their abuse by those who obtain them through illicit channels is well documented. Production data indicate that amphetamines have been produced and prescribed in quantities greatly in excess of demonstrated medical needs.

(3) Pursuant to a notice published in the FEDERAL REGISTER of August 8, 1970 (35 FR 12652), which required the submission of new drug applications as a condition for continued marketing of amphetamines, 106 new drug applications for amphetamines or amphetamine-containing drug products were received. The data submitted in those applications, and data obtained from other sources concerning anorectic drugs, generally supported the efficacy of anorectic drugs.

(b) On the basis of currently available evidence derived from short-term studies, the Commissioner concludes that single drug entity oral dosage forms of amphetamine or dextroamphetamine are effective in the management of exogenous obesity as a short-term (a few weeks) adjunct in a regimen of weight reduction, based on caloric restrictions, for patients in whom obesity is refractory to other measures. For purposes of this regulation, a mixture of dextroamphetamine and amphetamine is ordinarily regarded as a single drug entity.

(c) The Food and Drug Administration is not aware of data providing substantial evidence of the effectiveness of levamfetamine and its salts and regards these preparations as new drugs requiring approval full new-drug applications.

(d) In view of the well-documented history of abuse of parenteral amphetamines the severe risk of drug dependence, and the availability of safer alternative parenteral drugs which are equally effective for recognized non-anorectic indications, the Food and Drug Administration regards parenteral amphetamines as lacking evidence of safety.

(e) Any combination drug containing amphetamine or dextroamphetamine is regarded as a new drug requiring an approved full new-drug application as a condition for marketing. Data in new-drug applications are required to fulfill the criteria set forth in § 3.86 of this chapter governing fixed combination prescription drugs for humans.

(f) New drug applications have been received from persons marketing orally administered single entity amphetamine or dextroamphetamine dosage forms. Any other person who intends to market such drug is required to submit to the Food and Drug Administration an abbreviated new drug application (§ 314.1 (f) of this chapter) except that in addition, the application shall contain full information required under items 7 and 8 (composition and methods, facilities, and controls) of the new drug application Form FD-356H (§ 314.1(c) of this chapter).

(g) The labeling conditions for single entity oral dosage forms of amphetamine and dextroamphetamine and their salts are as follows:

(1) The label shall bear the statement "Caution: Federal law prohibits dispensing without prescription".

(2) The drug shall be labeled to comply with all requirements of the act and regulations. The labeling shall bear adequate information for safe and effective use of the drug. The indications for use are:

Narcolepsy.

Minimal brain dysfunction in children (hyperkinetic behavior disorders), as an aid to general management.

Management of exogenous obesity as short-term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction, for patients in whom obesity is refractory to other measures.

(3) Complete labeling guidelines are available from the Food and Drug Administration.

(h) Regulatory proceedings will be initiated with regard to any such drug within the jurisdiction of the act which is not in accord with this regulation.

§ 310.505 Conditions for use of methadone.

(a) *Definitions.* (1) An individual is "drug dependent" when his addiction reaches a stage where a daily administration of heroin or other morphine-like drugs is required to avoid the onset of signs of withdrawal.

(2) "Detoxification treatment" using methadone is the administering or dispensing of methadone as a substitute narcotic drug in decreasing doses to reach a drug free state in a period not to exceed 21 days in order to withdraw an individual who is dependent on heroin or other morphine-like drugs from the use of these drugs.

(3) "Maintenance treatment" using methadone is the continued administering or dispensing of methadone, in conjunction with provision of appropriate social and medical services, at relatively stable dosage levels for a period in excess of 21 days as an oral substitute for heroin or other morphine-like drugs, for an individual dependent on heroin. An eventual drug free state is the treatment goal for patients but it is recognized that for some patients the drug may be needed for long periods of time.

(4) "State authority" means the State authority designated pursuant to section 409 of Public Law 92-255, the Drug Abuse Office and Treatment Act of 1972, or in lieu thereof any other State authority designated by the Governor for purposes of exercising the authority under this section. If no State authority is so designated, the provisions in this section relating to approval by the State authority shall be inapplicable with respect to that State.

(b) *Organizational structures and approval requirements*—(1) *Methadone treatment program*—(i) *Defined.* A methadone treatment program is defined as a person or organization furnishing a comprehensive range of services using methadone for the detoxification and/or maintenance treatment of narcotic addicts, conducting initial evaluation of patients and providing ongoing treatment at a specified location or locations. If there is a centralized organizational structure, consisting of a primary facility and other outpatient facilities, all of which conduct initial evaluation of patients and administer or dispense medication, both the primary facility and each outpatient facility shall be considered a separate program, even though some services may be shared (e.g. the same hospital or rehabilitative services).

(ii) *Services.* A methadone treatment program, in addition to providing medication and/or evaluation, shall provide, as a minimum, counseling, rehabilitative, and other social services (e.g. vocational and educational guidance, employment placement), which will help the patient become a well functioning member of society. These services should normally be made available at the primary outpatient facility, but the program sponsor is permitted to enter into a formal, documented agreement with private or public agencies, organizations or institutions for these services if they are available elsewhere. Evidence will be required to demonstrate that the services are fully available and are being utilized.

(iii) *Hospital affiliation.* If a program is not physically located within a hospital which has agreed to provide any needed medical care for drug related problems for the program's patients, there shall be a formal, documented agreement between the program sponsor and a responsible hospital official demonstrating that hospital care, both inpatient and outpatient, is fully available to any patient who may need it for such problems. It is suggested that the program sponsor enter into an agreement with the hospital official to provide general medical care for patients. Neither the program sponsor nor the hospital are required to assume financial responsibility for the patient's medical care.

(iv) *Private practitioners.* A private practitioner constitutes a separate program if he conducts initial evaluation of patients, administers and dispenses medication, provides a comprehensive range of services, and otherwise meets all of the requirements for a program established in this section. A private practitioner who qualifies and is approved as a program is permitted to serve as many patients as he desires, but will be required to meet all the requirements of this regulation, including staffing requirements, unless permission is granted by the Food and Drug Administration and the State authority for exemption from or revision of these requirements.

(v) *Program approval.* In order lawfully to operate a methadone treatment program, each separate program, whether an out-patient facility or a private practitioner, shall submit the applications specified in this section simultaneously to the Food and Drug Administration and the State authority and shall receive the approval of both, except as provided for in paragraph (h)(5) of this section. Before granting approval the Food and Drug Administration will first consult with the Drug Enforcement Administration, Department of Justice, to determine compliance with Federal controlled substances laws. Each physical location within any program shall be identified and listed in the approval application. At the time of application for approval the program sponsor shall indicate whether medication will be administered or dispensed at the facility. If medication is to be administered or dispensed at a location not previously used for this purpose, prior approval from both agencies shall be obtained. If a facility in which medication is administered or dispensed is deleted by a program the Food and Drug Administration and the State authority shall be notified within 3 weeks. Addition or deletion of facilities which provides services other than administering or dispensing medication is permitted with notification within 3 weeks to the Food and Drug Administration and the State authority.

(2) *Methadone treatment medication unit*—(i) *Defined.* A methadone treatment "medication unit" is a facility, established by a program sponsor as part of his program, from which licensed private practitioners and community pharmacists are permitted to administer and dispense methadone. These medication units may also collect urine for urine testing for narcotic drugs. Any such facility shall be geographically dispersed from the primary facility and other medication units that have been established. The enrollment in a medication unit shall be of reasonable size in relation to the space available for treatment and the size of the staff at the facility, and may not exceed 30 patients.

(ii) *Referral.* The patient shall be stabilized at his optimal dosage level before he may be referred to a medication unit. Since the medication unit will not provide a range of services, the program sponsor shall determine that the patient to be referred is not in need of frequent counseling, rehabilitative, and other services which are only available at the primary program facility. A patient may not be referred to a medication unit before he has demonstrated progress towards rehabilitation. The nature of this progress shall be entered in the patient's record.

(iii) *Responsibility for patient.* After a patient is referred to a medication unit, the program sponsor retains continuing responsibility for the patient's care. The program sponsor is responsible for assuring that the patient reports weekly for urinalysis at either the primary facility or the medication unit and receives needed medical and social services at least monthly at the primary facility.

(iv) *Services.* Medication units are limited to the administering or dispensing of medication and the collection of urine for urine testing, following the procedures outlined in paragraph (d)(6)(ii) of this section. If a private practitioner wishes to provide other services in addition to administering or dispensing medication and collecting urine samples, he shall be considered a program and shall be required to submit an application for separate approval.

(v) *Medication unit approval.* In order lawfully to operate a medication unit, the program shall obtain approval for each separate unit from both the Food and Drug Administration and the State authority, except as provided for in paragraph (h)(5) of this section. Approval will be based on the distribution of these units within a particular geographic area. Any new medication unit shall receive such approval before commencing operation.

(vi) *Revocation of approval.* If the primary program's approval is revoked by the Food and Drug Administration the approval for the medication unit is automatically revoked. If a particular medication unit's approval is revoked, the approval of the primary program will remain in effect unless it is also revoked.

(vii) *Methadone supply.* The medication unit will receive its supply of the drug directly from the stocks of the primary facility. Only persons permitted to administer or dispense the drug or security personnel licensed or otherwise authorized by State law may deliver the drug to a medication unit.

(3) *Organizational structure; central administration.* (i) The program sponsor shall submit to the Food and Drug Administration and the State authority a description of the organizational structure of the program applying for approval, listing the name of the person responsible for the particular program, the address, and the responsibilities of each facility or medication unit. The sources of funding for each program shall be listed and the name and address of each governmental agency providing funding shall be stated.

(ii) Where two or more programs share a central administration (e.g., a city or state-wide organization), the person responsible for the organization (Administrator) shall be listed as program sponsor for each separate program participating. An individual program shall indicate its participation in the central organization at the time of its application. The Administrator is permitted to fulfill all recordkeeping and reporting requirements for these programs, but it is emphasized that the programs will continue to receive separate approval.

(iii) One individual is permitted to assume primary medical responsibility for more than one program and be listed as medical director. If an individual assumes medical responsibility for more than one program, the feasibility of such an arrangement shall be documented and attached to the application.

(4) *Prohibition against unapproved use of methadone.* No individual, practitioner, organization, or legal entity, may prescribe, administer, or dispense methadone without prior approval by the Food

and Drug Administration and the State authority, except as provided for in paragraph (h)(5) of this section, unless specifically exempted by this section.

(c) *Conditions for approval of the use of methadone in a treatment program*—(1) *Applicants.* An individual listed as program sponsor for a treatment program using methadone need not personally be a licensed practitioner but shall employ a licensed physician for the position of medical director. Persons responsible for administering or dispensing the medication shall be practitioners as defined by section 102(20) of the Controlled Substances Act (21 U.S.C. 802 (20)) licensed to practice by the State in which the program is to be established.

(2) *Assent to regulation.* A person who sponsors a methadone treatment program, and any person responsible for a particular program, shall agree to adhere to all the rules, directives, and procedures, set forth in this regulation, and any regulation regarding the use of methadone which may be promulgated in the future. The program sponsor, and person responsible for a particular program, shall agree to assume responsibility for any practitioners, employees, agents, or other individuals providing services, who work in their programs at the primary facility or at other facilities or medication units. The responsible persons shall agree to inform these people of the provisions of this regulation and to monitor their activities to assure compliance with the provisions. The Food and Drug Administration and the State authority shall be notified within 3 weeks of any replacement of the program sponsor or medical director. Activities in violation of this regulation may give rise to the sanctions set forth in paragraph (i) of this section.

(3) *Facilities.* To obtain program approval, the applicant shall demonstrate that he will have access to adequate physical facilities to provide all necessary services. The physical facilities should be sufficiently spacious and well maintained to provide appropriate conditions for conducting individual and/or group counseling.

(4) *Submission of proper applications.* The following applications shall be filed simultaneously with both the Food and Drug Administration and the State authority.

(i) Form FD-2632 "Application for Approval of Use of Methadone in a Treatment Program." This form, set forth in paragraph (k)(1) of this section, shall be completed and signed by the program sponsor and submitted in triplicate to the Food and Drug Administration and the State authority.

(ii) Form FD-2633 "Medical Responsibility Statement for Use of Methadone in a Treatment Program." This form, set forth in paragraph (k)(2) of this section, shall be completed and signed by each licensed physician authorized to administer or dispense methadone and submitted in triplicate to the Food and Drug Administration and the State authority. The names of any other persons licensed by law to administer or dispense narcotic drugs working in the program shall be listed, even if they are not at present responsible for administering or dispensing the drug.

(iii) Form FD-2634 "Annual Report for Treatment Program Using Methadone." This form, set forth in paragraph (k)(3) of this section, shall be completed and signed by the program sponsor for every program over which he has responsibility for each calendar year of operation. It shall be submitted in triplicate to the Food and Drug Administration and the State authority on or before January 30 of each year.

(5) *State and Federal approval of treatment programs.* Treatment programs using methadone shall have been reviewed by the State authority and must conform to all State requirements for conducting a methadone treatment program. The Food and Drug Administration must have received notification of the program's approval by the State agency. Only after the State authority has given its approval will the Food and Drug Administration grant approval to a program. The Food and Drug Administration will also revoke approval when recommended by the State authority. If State approval of a program is denied or revoked the program shall have a right of appeal to the Commissioner, as provided for in paragraph (h)(5) of this section. Prior to granting or withholding approval, the Food and Drug Administration will consult with the Drug Enforcement Administration, Department of Justice, to determine the applicant's compliance with Federal controlled substances laws. No shipment of methadone may lawfully be made to any program which has not received approval from the Food and Drug Administration. The program sponsor will receive notification of approval or denial or a request for additional information, when necessary, within 60 days after receipt of the application by the Food and Drug Administration.

(d) *Requirements for operation of methadone treatment program*—(1) *Description of facilities.* A program shall have ready access to a comprehensive range of medical and rehabilitative services. The name, address, and description of each hospital, institution, clinical laboratory, or other facility available to provide the necessary services shall be given to the Food and Drug Administration and the State authority. This listing shall include the name and address of each medication unit.

(2) *Approximate number of patients to be treated.* The program sponsor shall submit to the Food and Drug Administration and the State authority an approximation of the number of patients who will be treated, based on past history, addict population in the area, treatment capacity, or other relevant information.

(3) *Minimum admission standards*—(i) *Voluntary participation; consent form.* Each patient shall be fully informed concerning the possible risk associated with the use of methadone. Participation in any program shall be voluntary. The person responsible for the program shall insure that all the relevant facts concerning the use of methadone are clearly and adequately explained to the patient and that all patients (including those under age 18) sign, with full knowledge and understanding of its contents, the first part of Form FD-2635 "Consent for Methadone Treatment" set forth in paragraph (k)(4) of this section and the parents or guardians of patients under age 18 sign the second part of that form.

(ii) *Physiologic addiction standards; records.* The mere use of a narcotic drug, even if periodic or intermittent, cannot be equated with narcotic addiction. Care shall be exercised in the selection of patients to prevent the possibility of admitting a person who was not first dependent upon heroin or other morphine-like drugs at least 2 years prior to admission to maintenance treatment. This drug history and evidence of current physiologic dependence on morphine-like drugs shall be documented. Evidence of physical dependence should be obtained by noting early signs of withdrawal (lacrimation, rhinorrhea, pupillary dilation, and piloerection) during the initial period of abstinence. Withdrawal signs may be observed during an initial period of hospitalization or while the individual is an outpatient undergoing diagnostic evaluation (e.g., medical and personal history, physical examination, and laboratory studies). Loss of appetite and increased body temperature, pulse rate, blood pressure, and respiratory rate are also signs of withdrawal, but their detection may require inpatient observation. It is unlikely that an individual would be currently dependent on narcotic drugs without having a positive urine test for one or more of these drugs. Additional evidence can be obtained by noting the presence of old and fresh needle marks, and by obtaining additional history from relatives and friends.

(iii) *Exceptions to physiologic addiction standards; justification.* An exception to the requirement for evidence of current physiologic dependence on narcotic drugs will be allowed only under exceptional circumstances. For example, maintenance treatment may be indicated prior to or within 1 week of release from a stay of 1 month or longer in a penal or chronic care institution, if an individual has a predetention history of dependence upon heroin or other morphine-like drugs at least 2 years prior to admission to the institution. Justification for any such exception shall be noted in the patient's record.

(iv) *Special limitations; treatment of patients under age 18.* (*a*) The safety and effectiveness of methadone when used in the treatment of adolescents has not been proven by adequate clinical study. Special procedures are therefore necessary to assure that patients under age 16 will not be admitted to a program and that patients between 16 and 18 years of age be admitted to maintenance treatment only under limited conditions.

(*b*) Patients between 16 and 18 years of age who are enrolled and under treatment in approved programs on the date of publication of this regulation may continue in maintenance treatment. No new

patients between 16 and 18 years of age may be admitted to a maintenance treatment program after the date of publication of this regulation unless a parent, legal guardian, or responsible adult designated by the State authority completes and signs Form FD–2635 "Consent to Methadone Treatment," set forth in paragraph (k)(4) of this section. Methadone treatment of new patients between the ages of 16 and 18 years will be permitted after December 15, 1972, only with a documented history of two or more unsuccessful attempts at detoxification and a documented history of dependence on heroin or other morphine-like drugs beginning 2 years or more prior to application for treatment. No patient under age 16 may be continued or started on methadone treatment after December 15, 1972, but these patients may be detoxified and retained in the program in a drug free state for follow-up and after care.

(c) Patients under age 18 who are not placed in maintenance treatment may be detoxified. Detoxification may not exceed 3 weeks. A repeat episode of detoxification may not be initiated until 4 weeks after the completion of the previous detoxification.

(v) *Denial of admission.* If in the professional judgment of the medical director a particular patient would not benefit from methadone treatment, he may be refused such treatment even if he meets the admission standards.

(vi) *Patient evaluation; admission record.* An admission evaluation and record shall be made and maintained for each patient upon admission to the program. This evaluation and record shall consist of a personal history, a medical history, a physical examination, and any laboratory or other special examinations indicated in the judgment of the attending physician. It is recommended that a complete blood count, liver function tests, and a serologic test for lues be part of the admission evaluation.

(a) *Personal history.* A personal history record will be completed for each patient accepted for admission and will include at least age, sex, educational level, employment history, criminal history, past history of drug abuse of all types and prior treatment for drug abuse.

(b) *Medical history.* A thorough medical history record will be completed for each patient accepted for admission.

(c) *Physical examination.* The findings of a comprehensive physical examination will be recorded.

(4) *Staffing requirements.* As a minimum standard for the staffing of a treatment program there shall be the equivalent of one full-time physician licensed by and registered by State or Federal law to order, dispense, and administer methadone, two nurses (registered nurse or licensed practical nurse), and four counselors, for every 300 patients receiving maintenance treatment. The staffing pattern may be varied to fit the operational pattern and population characteristics of the program, but there shall always be at least one medical or osteopathic physician available for initial medical evaluation and follow-up care and to supervise the patient medication schedules for each 300 patients. This staffing pattern is not the recommended pattern, but the minimum staffing pattern acceptable.

(5) *Access to a range of services.* A treatment program shall provide a comprehensive range of medical and rehabilitative services to its patients. These services normally should be provided at the primary facility, but the program sponsor may enter into formally documented agreements with other public or private agencies, institutions, or organizations to render these services. Such facilities must be located so as to provide ease of access to the patient. Any service not furnished at the primary facility shall be listed, and the agreements to furnish those services shall be documented, when application for approval is submitted to the Food and Drug Administration and the State authority. Modification of the services shall be submitted in triplicate to the Food and Drug Administration as services are added or deleted.

(6) *Minimum procedures for ongoing care*—(i) *Dosage and administration requirements*—(a) *Form; packaging.* The methadone shall be administered or dispensed in oral form only when used in a treatment program. Hospitalized patients under care for a medical or surgical condition are permitted to receive methadone in parenteral form, when in the attending physican's professional judgment it is deemed advisable. Although tablet, syrup concentrate, or other formulations are permitted to be distributed to the program, all oral medication shall be administered or dispensed in a liquid formulation. The dosage will be formulated in such a way as to reduce its potential for parenteral abuse and accidental ingestion and packaged for outpatient use in special packaging as required by 16 CFR 1700.14. Any take-out medication shall be labeled with the treatment center's name, address and telephone number. Exceptions may be granted when any of the provisions of this subsection are in conflict with State law with regard to the administering or dispensing of drugs.

(b) *Detoxification treatment.* In detoxification the patient may be placed on a substitutive methadone administration schedule when there are significant symptoms of withdrawal. The dosage schedules indicated below are recommended but could be varied depending upon clinical judgment. Initially, a single oral dose of 15–20 milligrams of methadone will often be sufficient to suppress withdrawal symptoms. Additional methadone may be provided if withdrawal symptoms are not suppressed or whenever symptoms reappear. When patients are physically dependent on high doses of methadone, it may be necessary to exceed these levels. Forty milligrams per day in single or divided doses will usually constitute an adequate stabilizing dose level. Stabilization can be continued 2 to 3 days and then the amount of methadone will normally be gradually decreased. The rate at which methadone is decreased will be determined separately for each patient. The dose of methadone can be decreased on a daily basis or in 2-day intervals, but the amount of intake shall always be sufficient to keep withdrawal symptoms at a tolerable level. In hospitalized patients a daily reduction of 20 percent of the total daily dose usually will be tolerated and will cause little discomfort. In ambulatory patients, a somewhat slower schedule may be needed. If methadone is administered for more than 3 weeks, the procedure is considered to have progressed from detoxification or treatment of the acute withdrawal syndrome to maintenance treatment, even though the goal and intent may be eventual total withdrawal.

(c) *Maintenance treatment; special considerations for a pregnant patient.* (1) In maintenance treatment the initial dosage of methadone should control the abstinence symptoms that follow withdrawal of narcotic drugs, but should not be so great as to cause sedation, respiratory depression, or other effects of acute intoxication. It is important that the initial dosage be adjusted on an individual basis to the narcotic tolerance of the new patient. If such a patient has been a heavy user of heroin up to the day of admission, he may be given 20 milligrams 4 to 8 hours later, or 40 milligrams in a single oral dose. If he enters treatment with little or no narcotic tolerance (e.g. if he has recently been released from jail or other confinement), the initial dosage may be one-half these quantities. When there is any doubt, the smaller dose should be used initially. The patient should then be kept under observation, and, if symptoms of abstinence are distressing, additional 10 milligram doses may be administered as needed. Subsequently, the dosage should be adjusted individually, as tolerated and required, up to a level of 120 milligrams daily. For daily dosages above 100 milligrams patients shall ingest medication under observation 6 days per week. These patients will be allowed take-home medication for 1 day per week only. Those patients in treatment on the date this regulation becomes effective who are receiving a take-home dose of more than 100 milligrams per day shall have their dosage level reduced to 100 milligrams per day or less by June 13, 1973. A daily dose of 120 milligrams or more shall be justified in the medical record. For daily dosages above 120 milligrams, prior approval from State authority and the Food and Drug Administration shall be obtained beginning on March 15, 1973. For take-home doses above 100 milligrams per day, prior approval from the State authority and the Food and Drug Administration shall be obtained beginning on June 13, 1973. A regular review of dosage level should be made by the responsible physician with careful consideration given for reduction of dosage as indicated on an individual basis. A new dosage level is only a test level until stability is achieved.

(2) Caution shall be taken in the maintenance treatment of pregnant patients. Dosage levels shall be maintained as low as possible if continued methadone treatment is deemed necessary. It is the responsibility of the program sponsor to assure that each female patient is fully informed concerning the possible risks to a pregnant woman or her unborn child from the use of methadone.

(d) *Authorized dispensers of methadone; responsibility.* Methadone will be administered or dispensed by a practitioner licensed or registered under appropriate State or Federal law to order narcotic drugs for patients or by an agent of the practitioner, supervised by and pursuant to the order of the practitioner. This agent may only be a pharmacist, registered nurse, or licensed practical nurse depending upon the State regulations regarding narcotic drug dispensing and administering. The licensed practitioner assumes responsibility for the amounts of methadone administered or dispensed and all changes in dosage schedule will be recorded and signed by the licensed practitioner.

(7) *Frequency of attendance; take-home medication*—(i) *For detoxification, the drug shall be administered daily under close observation.* In maintenance treatment the patient will initially ingest the drug under observation daily, or at least 6 days a week, for the first 3 months. It is recognized that diversion occurs primarily when patients take medication from the clinic for self-administration. It is also recognized, however, that daily attendance at a program facility may be incompatible with gainful employment, education, and responsible homemaking. After demonstrating satisfactory adherence to the program regulations for at least 3 months, and showing substantial progress in rehabilitation by participating actively in the program activities and/or by participation in educational, vocational, and homemaking activities, those patients whose employment, education, or homemaking responsibilities would be hindered by daily attendance may be permitted to reduce to three times weekly the times when they must ingest the drug under observation. They shall receive no more than a 2-day take-home supply. With continuing adherence to the program's requirements and progressive rehabilitation for at least 2 years after entrance into the program, such patients may be permitted twice weekly visits to the program for drug ingestion under observation with a 3-day take-home supply. Prior to reducing the frequency of visits, documentation of the patient's progress and the need for reducing the frequency of visits shall be recorded. The requirements and schedule for when the drug must be ingested under observation may be relaxed if the patient has a serious physical disability which would prevent frequent visits to the program facility. The Food and Drug Administration and the State authority shall be notified of such cases. Additional medication may also be provided in exceptional circumstances such as acute illness, family crises, or necessary travel when hardship would result from requiring the customary observed medication intake for the specific period. In these circumstances the reasons for providing additional medication will be recorded. In circumstances of severe illness, infirmity or physical disability, an authorized individual (e.g. a licensed practitioner) may deliver or obtain the medication.

(ii) *Urine testing*—(a) *Schedule of testing; substances tested for.* In maintenance treatment, a urinalysis will be performed randomly at least weekly for morphine and monthly for methadone, barbiturates, amphetamines and other drugs if indicated. Those patients receiving their doses of the drug from medication units will also adhere to this schedule. The urine shall be collected at the program's primary facility or at the medication unit.

(b) *Method of collection.* Urine shall be collected in a manner which minimizes falsification of the samples. The reliability of this collection procedure shall be demonstrated.

(c) *Laboratories.* Laboratories used for urine testing shall participate in and be approved by any proficiency testing program designated by the Food and Drug Administration. Any changes made in laboratories used for urine testing shall have prior approval of the Food and Drug Administration.

(iii) *Patient's clinical record.* An adequate clinical record will be maintained for each patient. The record will contain a copy of the signed consent form(s), the date of each visit, the amount of methadone administered or dispensed, the results of each urinalysis, a detailed account of any adverse reactions, which will also be reported within 2 weeks to the Food and Drug Administration on Form FD–1639, "Drug Experience Report," any significant physical or psychological disability, the type of rehabilitative and counseling efforts employed, an account of the patient's progress, and other relevant aspects of the treatment program. For recordkeeping purposes, if a patient misses appointments for 2 weeks or more without notifying the program, the episode of care is considered terminated and so noted in the clinical record. This does not mean that the patient cannot return for care. If the patient does return for care and is accepted into the program, this is considered a readmission and so noted in the clinical record. This method of recordkeeping helps assure the easy detection of sporadic attendance and decreases the possibility of administering inappropriate doses of methadone (e.g., the patient who has received no medication for several days or more and upon return receives the usual stabilization dose). An annual evaluation of the patient's progress will be recorded in the clinical record(s).

(8) *Discontinuation of methadone use.* All patients in treatment will be given careful consideration for discontinuation of methadone use, especially after reaching a 10–20 milligram dosage level. Social rehabilitation shall have been maintained for a reasonable period of time. Patients should be encouraged to pursue the goal of eventual withdrawal from methadone and becoming completely drug free. Upon successfully reaching a drug-free state the patient should be retained in the program for as long as necessary to assure stability in the drug-free state, with the frequency of his required visits adjusted at the discretion of the director. Maintenance treatment using methadone shall be discontinued within 2 years after such treatment is begun unless, based upon clinical judgment recorded in the clinical record for the patient, the patient's status indicates that such treatment should be continued for a longer period of time. Any patient continued on methadone for longer than 2 years shall be subject to periodic reconsideration for discontinuance of such treatment.

(9) *Record of drug dispensing.* Accurate records traceable to specific patients shall be maintained showing dates, quantity, and batch or code marks of the drug dispensed. These records shall be retained for a period of 3 years.

(10) *Security of drug stocks.* Adequate security shall be maintained over stocks of methadone, over the manner in which it is administered or dispensed, over the manner in which it is distributed to medication units, and over the manner in which it is stored to guard against theft and diversion of the drug. The security standards for the distribution and storage of controlled substances as required by the Drug Enforcement Administration, Department of Justice (§§ 1301.72–1301.76 of this title) shall be met by the program.

(11) *Inspections of programs; patient confidentiality.* Inspection of a program may be undertaken by the State authority, by the Food and Drug Administration and by the Drug Enforcement Administration, Department of Justice, in accordance with Federal controlled substances laws. The identity of patients will be kept confidential except (i) when it is necessary to make follow-up investigations on adverse effect information related to use of the drug, (ii) when the medical welfare of the patient would be threatened by a failure to reveal such information, or (iii) when it is necessary to verify records relating to approval of the program or any portion thereof. In all circumstances the provision of 21 CFR Part 1401 shall be followed.

(12) *Exemptions from specific program standards.* (i) A program is permitted, at the time of application or any time thereafter, to request exemption from or revision of specific program standards. The rationale for an exemption or revision shall be thoroughly documented in an appendix to be submitted with the application or at some later time. An example of a case in which an exemption might be granted would be for a private practitioner who wishes to treat a limited number of patients and requests exemption from some of the staffing and service standards in a non-

metropolitan area with few physicians and no rehabilitative services geographically accessible. The Food and Drug Administration will approve such exemptions or revisions of program standards at the time of application with the concurrence of the State authority.

(ii) The Food and Drug Administration has the right to withhold the granting of an exemption until such time as a program is in actual operation in order to assess if the exemption is necessary. If periodic inspections of the program reveal that discrepancies or adverse conditions exist, the Food and Drug Administration shall reserve the right to revoke any or all exemptions previously granted.

(13) *Additional reporting requirements*—(i) *Deaths.* The program sponsor shall report any patient death which is considered methadone related to the Food and Drug Administration within 2 weeks, using Form FD–1639 "Drug Experience Report."

(ii) *Newborns.* The program sponsor shall report to the Food and Drug Administration the birth of any child to a female patient, if the newborn is premature or shows any adverse reactions which, in the opinion of the attending physician, are due to methadone, within 1 month of the birth, using Form FD–1639 "Drug Experience Report."

(e) *Multiple enrollments*—(1) *Administering or dispensing to patients enrolled in other programs.* There is a danger of drug dependent persons attempting to enroll in more than one methadone treatment program to obtain quantities of methadone for the purpose of self-administration or illicit marketing. Therefore, except in an emergency situation, methadone shall not be provided to a patient who is known to be currently receiving the drug from another treatment program using methadone.

(2) *Patient attendance requirements.* The patient shall always report to the same treatment facility unless prior approval is obtained from the program sponsor for treatment at another program. Permission to report for treatment at the facility of another program shall be granted only in exceptional circumstances and shall be noted on the patient's clinical record.

(3) *Multiple enrollment prevention.* To prevent multiple enrollments, the program shall agree to participate in any patient identification system that exists or is designated and approved by the Food and Drug Administration. Information that would identify a patient shall be kept confidential in compliance with Part 1401 of this title.

(f) *Conditions for use of methadone in hospitals for analgesia in severe pain, for detoxification, and for temporary maintenance treatment*—(1) *Form.* The drug may be administered or dispensed in either oral or parenteral form.

(2) *Use of methadone in hospitals*—(i) *Approved uses.* Methadone is permitted to be administered or dispensed only for detoxification or temporary treatment of hospitalized patients, and for analgesia in severe pain for hospitalized patients and outpatients. If methadone is administered for treatment of heroin dependence for more than 3 weeks, the procedure passes from treatment of the acute withdrawal syndrome (detoxification) to maintenance treatment. Maintenance treatment is permitted to be undertaken only by approved methadone programs. This does not preclude the maintenance treatment of an addict who is hospitalized for treatment of medical conditions other than addiction and who requires temporary maintenance treatment during the critical period of his stay or whose enrollment in a program which has approval for maintenance treatment using methadone has been verified. Any hospital which already has received approval under this paragraph (f) may be permitted to serve as a temporary methadone treatment program when an approved methadone treatment program has been terminated and there is no other facility immediately available in the area to provide methadone treatment for the patients. The Food and Drug Administration may give this approval upon the request of the State authority or the hospital, when no State authority has been established.

(ii) *Individual responsible for supplies.* The name of the individual (pharmacist) responsible for receiving and securing supplies of methadone shall be submitted to the Food and Drug Administration and the State authority. Individuals not authorized by Federal or State law shall not receive supplies of methadone.

(iii) *General description.* A general description of the hospital including the number of beds, specialized treatment facilities for drug dependence, and nature of patient care undertaken shall be submitted.

(iv) *Anticipated quantity of drug needed.* The anticipated quantity of methadone needed per year shall be submitted.

(v) *Records.* The hospital shall maintain accurate records showing dates, quantity, and batch or code marks of the drug used for in patient and out patient treatment. The records shall be retained for a period of 3 years.

(vi) *Inspections.* The Food and Drug Administration and the State authority may inspect supplies of the drug and evaluate the uses to which the drug is being put. The identity of the patient will be kept confidential except (*a*) when it is necessary to make follow-up investigations on adverse effect information related to the drug, (*b*) when the medical welfare of the patient would be threatened by a failure to reveal such information, or (*c*) when it is necessary to verify records relating to approval of the hospital or any portion thereof. The confidentiality requirements of Part 1401 of this title shall be followed. Records relating to the receipt, storage, and distribution of narcotic medication shall also be subject to inspection as provided by Federal controlled substances laws; but use or disclosure of records identifying patients will, in any case, be limited to actions involving the program or its personnel.

(vii) *Approval of hospital pharmacy.* Application for a hospital pharmacy to provide methadone for analgesia, detoxification and temporary treatment will be submitted to the Food and Drug Administration and the State authority and shall receive approval from both, except as provided for in paragraph (h)(5) of this section. Within 60 days after receipt of the application by the Food and Drug Administration, the applicant will receive notification of approval or denial or a request for additional information, when necessary.

(viii) *Approval of shipments to hospital pharmacies.* Before a hospital pharmacy may lawfully receive shipments of methadone for use as an analgesic for severe pain and for detoxification or temporary maintenance treatment, a responsible hospital official shall complete, sign, and file in triplicate with the Food and Drug Administration and the State authority Form FD–2636, "Hospital Request for Methadone for Analgesia in Severe Pain and for Detoxification and Temporary Maintenance Treatment" set forth in paragraph (k)(5) of this section and shall receive a notice of approval thereof from the Food and Drug Administration.

(ix) *Sanctions.* Failure to abide by the requirements described in this section may result in revocation of approval to receive shipments of methadone, seizure of the drug supply on hand, injunction, and criminal prosecution.

(3) *Treatment of outpatients*—(i) If in a physician's professional judgment methadone would be the drug of choice as an analgesic for treating a patient in severe pain, the drug will be available for use on an out-patient basis from an approved hospital pharmacy, or in a remote area from an approved community pharmacy. Prior to filing a physician's prescription for methadone for outpatients, the pharmacy shall obtain from the physician a statement indicating that all such prescriptions written by him will be limited to use for analgesia in severe pain. The physician shall agree to maintain records to substantiate such use. These records will be available in the hospital or made available at the request of the hospital administrator. In remote areas the approved community pharmacy is permitted to maintain these records or they may be forwarded to the State authority. On January 30 of each year, the names and addresses of all physicians who prescribed methadone for analgesia on an outpatient basis during the previous year shall be reported to the Food and Drug Administration.

(ii) Prescriptions for analgesia may be filled only if they are written by a physician who has submitted the required statement to the approved hospital or community pharmacy.

(4) *Shipments to remote areas.* In remote areas or in certain exceptional circumstances where there are no approved hospitals, community pharmacies may be approved by the Food and Drug Admin-

istration to receive shipments of methadone for administering or dispensing for analgesia upon the recommendation of the State authority and after consultation with the Drug Enforcement Administration, Department of Justice.

(g) *Confidentiality of patient records.* (1) Except as provided in paragraph (g)(2) of this section, disclosure of patient records maintained by any program shall be governed by the provisions of Part 1401 of this title, and every program shall comply with the provisions of that part. Records relating to the receipt, storage, and distribution of narcotic medication shall also be subject to inspection as provided by Federal controlled substances laws; but use or disclosure of records identifying patients will, in any case, be limited to actions involving the program or its personnel.

(2) In addition to the restrictions upon disclosure in Part 1401 of this title, and in accordance with the authority conferred by section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a)), every program is hereby further authorized to protect the privacy of patients therein by withholding from all persons not employed by such program or otherwise connected with the conduct of its operations the names or other identifying characteristics of such patients under any circumstances under which such program has reasonable grounds to believe that such information may be used to conduct any criminal investigation or prosecution of a patient. Programs may not be compelled in any Federal, State, or local civil, criminal, administrative, or other proceedings to furnish such information, but this subparagraph does not authorize the withholding of information authorized to be furnished pursuant to § 1401.44 of this title nor does it invalidate any legal process to compel the furnishing of information in accordance with § 1401.44 of this title. Records relating to the receipt, storage, and distribution of narcotic medication shall also be subject to inspection as provided by Federal controlled substances laws; but use or disclosure of records identifying patients will, in any case, be limited to actions involving the program or its personnel.

(3) A treatment program or medication unit or any part thereof, including any facility or any individual, shall permit a duly authorized employee of the Food and Drug Administration to have access to and to copy all records relating to the use of methadone. Patient identities shall be revealed (i) when it is necessary to make follow-up investigations on adverse effect information related to the drug, (ii) when the medical welfare of the patient would be threatened by a failure to reveal such information, or (iii) when it is necessary to verify records relating to any approval or any portion thereof under this section. The Food and Drug Administration will retain such identities in confidence pursuant to § 1401.44 of this title and shall reveal them only when necessary in a related administrative or court proceeding.

(h) *Denial or revocation of approval.* (1) Complete or partial denial or revocation of approval of an application to receive shipments of methadone (Forms FD–2632 "Application for Approval of Use of Methadone in a Treatment Program" and FD–2636 "Hospital Request for Methadone for Analgesia in Severe Pain and for Detoxification and Maintenance Treatment") may be proposed to the Commissioner of Food and Drugs by the Director of the Food and Drug Administration's Bureau of Drugs, on his own initiative or at the request of representatives of the Drug Enforcement Administration, Department of Justice, National Institute of Mental Health, the State authority, or any other interested person.

(2) Before presenting such a proposal to the Commissioner, the Director of the Bureau of Drugs or his representative will notify the applicant in writing of the proposed action and the reasons therefor and will offer him an opportunity to explain the matters in question in an informal conference and/or in writing within 10 days after receipt of such notification. The applicant shall have the right to hear and to question the information on which the proposal to deny or revoke approval is based, and may present any oral or written information and views.

(3) If the explanation offered by the applicant is not accepted by the Bureau of Drugs as sufficient to justify approval of the application, and denial or revocation of approval is therefore proposed, the Commissioner will evaluate information obtained in the informal hearing before the Director of the Bureau of Drugs. If he finds that the applicant has failed to submit adequate assurance justifying approval of the application, he shall issue a notice of opportunity for hearing with respect to the matter pursuant to § 314.200 of this chapter and the matter shall thereafter be handled in accordance with established procedures for denial or revocation of approval of a new drug application. If the Secretary determines that there is an imminent hazard to health, revocation of approval will become effective immediately and any administrative procedures will be expedited. Upon revocation of approval of an application, the Commissioner will notify the applicant, the State authority, the Drug Enforcement Administration, Department of Justice, and all other appropriate persons that the applicant may no longer receive shipments of methadone, and will require the recall of all methadone from the applicant. Revocation of approval may also result in criminal prosecution.

(4) Denial or revocation of approval may be reversed when the Commissioner determines that the applicant has justified approval of the application.

(5) A treatment program or medication unit or any part thereof, including any facility or any individual, may appeal to the Food and Drug Administration a complete or partial denial or revocation of approval by the State authority unless the denial or revocation is based upon a State law or regulation. The appeal shall first be made to the Director of the Bureau of Drugs, who shall hold an informal conference on the matter in accordance with paragraph (h)(2) of this section. The State authority may participate in the conference. The appellant or the State authority may appeal the Director's decision to the Commissioner, who shall decide the matter in accordance with paragraph (h)(3) of this section. If the Commissioner denies or revokes approval, such action shall be handled in accordance with paragraph (h)(3) of this section. The Commissioner may not grant or retain Food and Drug Administration approval if he finds that the appellant is not in compliance with all applicable State laws and regulations and with this section.

(i) *Sanctions*—(1) *Program sponsor or individual responsible for a particular program.* If the program sponsor or the person responsible for a particular program fails to abide by all the requirements set forth in these regulations, or fails to adequately monitor the activities of those employed in the program, he may have the approval of his application revoked, his methadone supply seized, an injunction granted precluding operation of his program, and criminal prosecution instituted against him.

(2) *Persons responsible for administering or dispensing methadone.* If a person responsible for administering or dispensing methadone fails to abide by all the requirements set forth in these regulations, criminal prosecution may be instituted against him, his drug supply may be seized, the approval of the program may be revoked, and an injunction may be granted precluding operation of the program.

(j) *Requirements for distribution of methadone by manufacturers*—(1) *Distribution requirements.* Shipments of the drug are restricted to direct shipments by manufacturers of methadone to approved treatment programs using methadone, to approved hospital pharmacies, and to approved selected community pharmacies. If requested by a manufacturer or State authority, wholesale pharmacy outlets in some regions or States may be authorized to stock methadone for that area and then trans-ship the drug to approved methadone treatment programs and approved hospital and community pharmacies. Alternative methods of distribution will be permitted if they are approved by the Food and Drug Administration and the State authority. Prior to any approval of an alternative method of distribution there will be consultation with the Drug Enforcement Administration, Department of Justice, to assure compliance with its regulations regarding controlled substance distribution.

(2) *Information regarding approved programs, hospitals, and community pharmacies.* The Food and Drug Administration will provide methadone manufacturers and the public with the names and locations of programs, hospitals, and selected community pharmacies that have been approved to receive shipments

of the drug. All information contained in the forms set out in paragraph (k) of this section is available for public disclosure except for names or other identifying information with respect to patients.

(3) *Acceptance of delivery.* Delivery shall only be made to a licensed practitioner employed at the facility. At the time of delivery the licensed practitioner shall sign for the methadone and place his specific title and identification number on any invoice. Copies of these signed invoices shall be kept by the manufacturer.

(k) *Program forms*—(1) *Treatment Program Application.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

Form FD–2632 Application for Approval of Use of Methadone in a Treatment Program

Name or other identification of program_____
_____
Address _____
Name of program sponsor_____

Commissioner,
Food and Drug Administration,
Bureau of Drugs (HFD–106),
Rockville, MD 20852.

DEAR SIR: As the person responsible for this program, I submit this request for approval of a treatment program using methadone to provide detoxification and maintenance treatment for narcotic addicts in accordance with § 310.505 of the new drug regulations. I understand that failure to abide by the requirements described below may cause revocation of approval of my application, seizure of my drug supply, an injunction, and criminal prosecution.

I. Attached is the name, complete address, and a summary of the scientific training and experience of each physician and all other professional personnel having major responsibilities for the program and rehabilitative efforts, and a singed Form FD–2633 "Medical Responsibility Statement for Use of Methadone in a Treatment Program" for every licensed practitioner authorized to prescribe, dispense, or administer methadone under the program. (If the Medical Director of this program has been listed for a program in a previous application, the feasibility of serving as Medical Director for this program must be documented and this documentation attached to this application.)

II. Attached is a description of the organizational structure of this program and the name and complete address of any central administration or larger organizational structure to which this program is responsible.

III. Attached is a listing of the sources of funding for this program. (The name and address for each governmental agency providing funding must be provided.)

IV. The program shall have ready access to a comprehensive range of medical and rehabilitative services. Attached is the name, address, and description of each hospital, institution, clinical laboratory facility, or other facility available to provide the necessary services and a statement for each facility as to whether or not methadone will be administered or dispensed at that facility. These facilities shall comply with any guidelines established by Federal or State authorities. (This listing should include the address of each medication unit. If any medical or rehabilitative service is not available at the primary facility, there must be a formal, documented agreement with private or public agencies, organizations, or institutions for these services.)

V. Attached is a statement of the approximate number of addicts to be included in the program.

VI. The following minimal treatment standards shall be followed:

A. A statement shall be given to the addicts to inform them about the program. A voluntary request and consent Form FD–2636 "Consent to Methadone Treatment" shall be signed by each patient. Participation in the program shall be voluntary.

B. I concur that the mere use of a narcotic drug, even if periodic or intermittent, cannot be equated with narcotic addiction. Care shall be exercised in the selection of patients to prevent the possibility of admitting a person who was not first dependent upon heroin or other morphine-like drugs at least 2 years prior to admission to maintenance treatment. This drug history and evidence of current physiologic dependence on morphine-like drugs shall be documented. Evidence of physical dependence should be obtained by noting early signs of withdrawal (lacrimation, rhinorrhea, pupillary dilation, and piloerection) during the initial period of abstinence. (Withdrawal signs may be observed during an initial period of hospitalization or while the individual is an outpatient undergoing diagnostic evaluation—(medical and personal history, physical examination, and laboratory studies). Loss of appetite and increased body temperature, pulse rate, blood pressure, and respiratory rate are also signs of withdrawal, but their detection may require inpatient observation. It is unlikely that an individual would be currently dependent on narcotic drugs without having a positive urine test for one or more of these drugs. Additional evidence can be obtained by noting the presence of old and fresh needle marks, and by obtaining additional history from relatives and friends.)

C. An exception to the requirement for evidence of current physiologic dependence on narcotic drugs will be allowed under exceptional circumstances. For example, methadone treatment may be initiated prior to or within 1 week of release from a stay of 1 month or longer in a penal or chronic care institution if an individual has a pre-detention history of dependence upon heroin or other morphine-like drugs at least 2 years prior to admission to the institution. Justification for any such exception shall be noted on the patient's record.

D. Patients between 16 and 18 years of age who are enrolled and under treatment in approved programs on December 15, 1973 may continue in maintenance treatment. No new patients between 16 and 18 years of age may be admitted to a maintenance treatment program after such date unless a parent, legal guardian, or responsible adult designated by the State authority completes and signs consent form, Form FD–2635 "Consent to Methadone Treatment." Methadone treatment of new patients between the ages of 16 and 18 years of age will be permitted after such date only with a documented history of two or more unsuccessful attempts at detoxification and a documented history of dependence on heroin or other morphine-like drugs beginning 2 years or more prior to application for treatment. No patient under age 16 may be continued or started on methadone treatment after such date but these patients may be detoxified and retained in the program in a drug-free state for follow-up and aftercare. Patients under age 18 who are not placed in maintenance treatment may be detoxified. Detoxification may not exceed 3 weeks. A repeat episode of detoxification may not be initiated until 4 weeks after the completion of the previous detoxification.

VII. An admission evaluation and record shall be made and maintained for each patient upon admission to the program. This evaluation and record shall consist of a personal history, a medical history, a physical examination, and any laboratory or other special examinations as indicated in the judgment of the attending physician. (It is recommended that a complete blood count, liver function tests, and a serologic test for lues be part of the admission evaluation.)

A. A personal history record will include at least age, sex, educational level, employment history, criminal history, past history of drug abuse of all types, and prior treatment for drug abuse.

B. Medical history. A thorough medical history record will be completed for each patient accepted for admission.

C. Physical examination. The findings of a comprehensive physical examination will be recorded.

VIII. I understand that there is a danger of drug dependent persons attempting to enroll in more than one methadone treatment program to obtain quantities of methadone either for the purpose of self-administration or illicit marketing. To prevent such multiple enrollments, I will participate in whatever local, regional, or national patient identification system exists and I state my intention to participate in any system that may be developed and approved by the Food and Drug Administration unless I notify the Food and Drug Administration, in writing, to the contrary. I understand failure to participate may cause revocation of approval of my application. Except in an emergency situation, methadone will not be provided to a patient who is known to be currently receiving the drug from another treatment program using methadone. Except as provided in item XV of this form, information that could identify the patient will be kept confidential in compliance with 21 CFR Part 1401.

IX. The following minimal procedures will be used for ongoing care.

A. Dosage and administration for detoxification and maintenance treatment:

1. Methadone will be administered or dispensed in oral form only when used in a treatment program. Hospitalized patients under care for medical or surgical condition are permitted to receive methadone in parenteral form, when in the attending physician's professional judgment it is deemed advisable. Although tablet, sirup concentrate, or other formulations are permitted to be distributed to the program, all oral medication shall be administered or dispensed in a liquid formulation. The dosage shall be formulated in such a way as to reduce its potential for parenteral abuse and accidental ingestion, and packaged for outpatient use in special packaging as required by 16 CFR 1700.14. Any take-out medication shall be labeled with the treatment center's name, address, and telephone number. Exceptions may be granted when any of the provisions of this subsection are in conflict with State law with regard to the administering or dispensing of drugs.

2. In detoxification, the patient may be placed on a substitutive methadone administration schedule when there are significant symptoms of withdrawal. The dosage schedules indicated below are recommended but may be varied depending upon clinical judgment. Initially, a single oral dose of 15–20 milligrams of methadone will often be sufficient to suppress withdrawal symptoms. Additional methadone may be provided if withdrawal symptoms are not suppressed or whenever symptoms reappear. When patients are physically dependent on high doses of methadone, it may be necessary to exceed these levels. Forty milligrams per day in single or divided doses will usually constitute an adequate stabilizing dose level. Stabilization can be continued for 2 to 3 days and

then the amount of methadone will normally be gradually decreased. The rate at which methadone is decreased will be determined separately for each patient. The dose of methadone can be decreased on a daily basis or in 2-day intervals, but the amount of intake shall always be sufficient to keep withdrawal symptoms at a tolerable level. In hospitalized patients a daily reduction of 20 percent of the total daily dose usually will be tolerated and will cause little discomfort. In ambulatory patients, a somewhat slower schedule may be needed. If methadone is administered for more than 3 weeks, the procedure is considered to have progressed from detoxification or treatment of the acute withdrawal syndrome to maintenance treatment, even though the goal and intent may be eventual total withdrawal.

3. In maintenance treatment the initial dosage of methadone should control the abstinence symptoms that follow withdrawal of narcotic drugs but should not be so great as to cause sedation, respiratory depression, or other effects of acute intoxification. It is important that the initial dosage be adjusted on an individual basis to the narcotic tolerance of the new patient. If such a patient has been a heavy user of heroin up to the day of admission, he may be given 20 milligrams orally for the first dose and another 20 milligrams 4 to 8 hours later, or 40 milligrams in a single oral dose. If he enters treatment with little or no narcotic tolerance (e.g., if he has recently been released from jail or other confinement), the initial dosage may be one-half these quantities. When there is any doubt, the smaller dose should be used initially. The patient should then be kept under observation, and, if symptoms of abstinence are distressing, additional 10-milligram doses may be repeated as needed. Subsequently, the dosage should be adjusted individually, as tolerated and required, to a level of 120 milligrams daily. For daily dosages above 100 milligrams patients shall ingest medication under observation 6 days per week. These patients will be allowed take-home medication for 1 day per week only. Those patients in treatment on December 15, 1972 who are receiving a take-home dose of more than 100 milligrams per day shall have their dosage level reduced to 100 milligrams per day or less by June 13, 1973. A daily dose of 120 milligrams or more shall be justified in the medical record. For daily dosages above 120 milligrams or, beginning June 13, 1973, for take-home doses above 100 milligrams per day, prior approval shall be obtained from the Food and Drug Administration and the State authority. A regular review of dosage level should be made by the responsible physician with careful consideration given for reduction of dosage as indicated on an individual basis. A new dosage level is only a test level until stability is achieved.

4. Caution shall be taken in the maintenance treatment of pregnant patients. Dosage levels shall be maintained as low as possible if continued methadone treatment is deemed necessary. It is the responsibility of the program to assure that each female patient is fully informed concerning the possible risks to a pregnant woman or her unborn child from the use of methadone.

5. Methadone will be administered or dispensed by a practitioner licensed or registered under appropriate State or Federal law to order narcotic drugs for patients or by an agent of the practitioner, supervised by and pursuant to the order of the practitioner. This agent may be a pharmacist, registered nurse, or licensed practical nurse, depending upon the State regulations regarding narcotic drug dispensing and administering. The licensed practitioner assumes responsibility for the amounts of methadone administered or dispensed and all changes in dosage schedule shall be recorded and signed by the licensed practitioner.

6. For detoxification, the drug shall be administered daily under close observation. In maintenance treatment the patient initially will ingest the drug under observation daily, or at least 6 days a week, for the first 3 months. It is recognized that diversion occurs primarily when patients take medication from the clinic for self-administration. It is also recognized, however, that daily attendance at a program facility may be incompatible with gainful employment, education, and responsible homemaking. After demonstrating satisfactory adherence to the program regulations for at least 3 months and showing substantial progress in rehabilitation by participating actively in the program activities and/or by participation in educational, vocational, and homemaking activities, those patients whose employment, education, or homemaking responsibilities would be hindered by daily attendance may be permitted to reduce to 3 times weekly the times when they must ingest the drug under observation. They shall receive no more than a 2 day take-home supply. With continuing adherence to the program's requirements and progressive rehabilitation for at least 2 years after entrance into the program, such patients may be permitted twice weekly visits to the program for drug ingestion under observation with a 3 day take-home supply. Prior to reducing the frequency of visits, documentation of the patient's progress and the need for reducing the frequency of visits shall be recorded. The requirements and schedule for when the drug must be ingested under supervision may be relaxed if the patient has a serious physical disability which would prevent frequent visits to the program facility. The Food and Drug Administration and the State authority shall be notified of such cases. Additional medication may also be provided in exceptional circumstances such as acute illness, family crises, or necessary travel when hardship would result from requiring the customary observed medication intake for the specific period. In such circumstances the reasons for providing additional medication will be recorded in the clinical record. In circumstances of severe illness, infirmity or physical disability, an authorized individual (e.g., a licensed practitioner) may deliver or obtain the medication.

B. In maintenance treatment, a urinalysis will be performed randomly at least weekly for morphine and monthly for methadone, barbiturates, amphetamines, and other drugs if indicated. Those patients receiving their doses of the drug from medication units will also adhere to this schedule. The urine shall be collected in a manner which minimizes falsification of the samples. The reliability of this collection procedure shall be demonstrated. Laboratories used for urine testing shall participate in and be approved by any proficiency testing program designated by the Food and Drug Administration. Any changes in laboratories used for urine testing shall have prior approval of the Food and Drug Administration.

C. An adequate clinical record will be maintained for each patient. The record will contain a copy of the signed consent form(s), the date of each visit, the amount of methadone administered or dispensed, the results of each urinalysis, a detailed account of any adverse reactions, which will also be reported within 2 weeks to the Food and Drug Administration on Form FD-1639, "Drug Experience Report", any significant physical or psychologic disability, the type of rehabilitative and counseling efforts employed, an account of the patient's progress, and other relevant aspects of the treatment program. For recordkeeping purposes, if a patient misses appointments for 2 weeks or more without notifying the program, the episode of care is considered terminated and so noted in the clinical record. This does not mean that the patient cannot return for care. If the patient does return for care and is accepted into the program, this is considered a readmission and so noted in the clinical record. This method of recordkeeping helps assure the easy detection of sporadic attendance and decreases the possibility of administering inappropriate doses of methadone (e.g., the patient who has received no medication for several days or more and upon return receives the usual stabilization dose). An annual evaluation of the patient's progress will be recorded in the clinical record.

D. All patients in maintenance treatment will be given careful consideration for discontinuance of methadone, especially after reaching a 10–20 milligram dosage level. Social rehabilitation shall have been maintained for a reasonable period of time. Patients should be encouraged to pursue the goal of eventual withdrawal from methadone and becoming completely drug-free. Upon successfully reaching a drug-free state the patient should be retained in the program for as long as necessary to assure stability in the drug-free state, with the frequency of his required visits adjusted at the discretion of the director. Maintenance treatment using methadone shall be discontinued within 2 years after such treatment is begun unless, based upon clinical judgment recorded in the clinical record for the patient, the patient's status indicates that such treatment should be continued for a longer period of time. Any patient continued on methadone for longer than 2 years shall be subject to periodic reconsideration for discontinuance of such treatment.

X. To prevent diversion into illicit channels, adeqaute security shall be maintained over stocks of methadone and over the manner in which it is distributed, as required by the Drug Enforcement Administration, Department of Justice.

XI. Accurate records traceable to patients shall be maintained showing dates, quantity, and batch or code marks of the drug used. These records shall be retained for a period of 3 years.

XII. The program director may establish geographically dispersed medication units of reasonable size for administering and dispensing medication to patients stabilized at their optimal dosage level. The approval of such units for any geographic area shall be based upon the number and distribution of such units within the area. No more than 30 patients shall be under care at a medication unit at any one time. These units shall be responsible only for administering and dispensing medication. Private practitioners and community pharmacies may serve as medication units. Only after patients have been stabilized at their optimal initial dosage level may they be referred to a medication unit. Subsequent to such referral, the program director shall retain continuing responsibility for the patient's care and the patient shall be seen at the primary program facility at least monthly for medical evaluation and ancillary service. If a private practitioner wishes to provide other service in addition to administering and dispensing medication and collecting urine samples, the practitioner is considered a program component or a separate program, depending upon the type of services provided. In such case the restrictions on the number of patients served shall be determined by the staffing pattern and resources available.

XIII. All representations in this application are currently accurate, and no changes shall be made in the program until they have been approved by the Food and Drug Administration and the State authority.

XIV. If the program or any individual under the program is disapproved, the pro-

gram director shall recall the methadone from the disapproved sources and return the drug to the manufacturer in a manner prescribed by the Drug Enforcement Administration, Department of Justice.

XV. Inspections of this program may be undertaken by the State authority, by the Food and Drug Administration and by the Drug Enforcement Administration, Department of Justice, in accordance with Federal controlled substances laws. The identity of patients will be kept confidential except when it is necessary to make follow-up investigations on adverse effect information related to use of the drug, when the medical welfare of the patient would be threatened by a failure to reveal such information, or when it is necessary to verify records relating to approval of the program or any portion thereof. In all circumstances the provisions of 21 CFR Part 1401 shall be followed.

Signature _____
(Program sponsor)

(2) *Medical Responsibility Statement.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

Form FD-2633 Medical Responsibility Statement for Use of Methadone in a Treatment Program

(To be completed by each physician licensed to dispense or administer methadone under an approved program.)

Date _____
Name of program _____
Address _____
Telephone number _____
Medical Director for this facility (licensed by law to administer or dispense drugs and responsible for all medication administered or dispensed at this facility).

Address of this facility _____
Telephone number of this facility _____

I. The undersigned agrees to assume responsibility for the administration and dispensing of methadone under the above identified program and to abide by the required standards for methadone detoxification and maintenance treatment.

II. The name of each patient treated at a facility and the frequency of visits shall be registered with the medical director. An annual report Form FD-2634 "Annual Report for Treatment Program Using Methadone" shall be submitted to the program sponsor for submission to the Food and Drug Administration. The patient shall always report to the same facility unless prior approval is obtained from the medical director for treatment at another operation.

III. The following minimal treatment standards shall be followed.

A. A statement shall be given to the addicts to inform them about the program. A voluntary request and consent Form FD-2635 "Consent to Methadone Treatment" shall be signed by each patient. Participation in the program shall be voluntary.

B. The mere use of a narcotic drug, even if periodic or intermittent, cannot be equated with narcotic addiction. Care shall be exercised in the selection of patients to prevent the possibility of admitting a person who was not first dependent upon heroin or other morphine-like drugs at least 2 years prior to admission to maintenance treatment. This drug history and evidence of current physiologic dependence on morphine-like drugs shall be documented. Evidence of physical dependence should be obtained by noting early signs of withdrawal (lacrimation, rhinorrhea, pupillary dilation, and piloerection) during the initial period of abstinence. Withdrawal signs may be observed during an initial period of hospitalization or while the individual is an outpatient undergoing diagnostic evaluation (medical and personal history, physical examination, and laboratory studies). Loss of appetite and increased body temperature, pulse rate, blood pressure, and respiratory rate are also signs of withdrawal, but their detection may require inpatient observation. It is unlikely that an individual would be currently dependent on narcotic drugs without having a positive urine test for one or more of these drugs. Additional evidence can be obtained by noting the presence of old and fresh needle marks, and by obtaining additional history from relatives and friends.

C. An exception to the requirement for evidence of current physiologic dependence on narcotic drugs will be allowed under exceptional circumstances. For example, methadone treatment may be initiated prior to or within 1 week of release from a stay of 1 month or longer in in a penal or chronic care institution if an individual has a pre-detention history of dependence upon heroin or other morphine-like drugs at least 2 years prior to admission to the institute. Justification for any such exception should be noted on the patient's record.

D. Patients between 16 and 18 years of age who are enrolled and under treatment in approved programs on December 15, 1972 may continue in maintenance treatment. No new patients between 16 and 18 years of age may be admitted to a maintenance treatment after such date unless a parent, legal guardian, or responsible adult designated by the State authority completes and signs consent form. Form FD-2635, "Consent to Methadone Treatment". Methadone treatment of new patients between ages 16 and 18 years of age will be permitted after such date only with a documented history of two or more unsuccessful attempts at detoxification and a documented history of dependence on heroin or other morphine-like drugs beginning 2 years or more prior to application for treatment. No patient under age 16 may be continued or started on methadone treatment after such date, but these patients may be detoxified and retained in the program in a drug-free state for follow-up and aftercare. Patients under age 18 who are not placed in maintenance treatment may be detoxified. Detoxification may not exceed 3 weeks. A repeat episode of detoxification may not be initiated until 4 weeks after the completion of the previous detoxification.

IV. An admission evaluation and record shall be made and maintained for each patient upon admission to the program. This evaluation and record shall consist of a personal history, a medical history, and a physical examination, and any laboratory or other special examinations as indicated in the judgment of the attending physician. (It is recommended that a complete blood count, liver function tests, and a serologic test for lues be part of the admission evaluation.)

A. A personal history record will include at least age, sex, educational level, employment history, criminal history, past history of drug abuse of all types, and prior treatment for drug abuse.

B. Medical history. A thorough medical history record will be completed for each patient accepted for admission.

C. Physical examination. The findings of a comprehensive physical examination will be recorded.

V. I understand that there is a danger of drug dependent persons attempting to enroll in more than one methadone treatment program to obtain quantities of methadone either for the purpose of self-administration or illicit marketing. To prevent such multiple enrollments, I will participate in whatever local, regional, or national patient identification system that exists and I state my intention to participate in any system that may be developed and approved by the Food and Drug Administration unless I notify the Food and Drug Administration, in writing, to the contrary. I understand failure to participate may cause revocation of approval of my application. Except in an emergency situation, methadone will not be provided to a patient who is known to be currently receiving the drug from another treatment program using methadone. Except as provided in item XI of this form, information that could identify the patient will be kept confidential in compliance with 21 CFR Part 1401.

VI. The following minimal procedures will be used for ongoing care.

A. Dosage and administration for detoxification and maintenance treatment:

1. Methadone will be administered or dispensed in oral form only when used in a treatment program. Hospitalized patients under care for a medical or surgical condition are permitted to receive methadone in parenteral form, when in the attending physician's professional judgment it is deemed advisable. Although tablet, syrup concentrate, or other formulations are permitted to be distributed to the program, all oral medication shall be administered or dispensed in a liquid formulation. The dosage shall be formulated in such a way as to reduce its potential for parenteral abuse and accidental ingestion, and packaged for outpatient use in special packaging as required by 16 CFR 1700.14. Any take-out medication shall be labeled with the treatment center's name, address and telephone number. Exceptions may be granted when any of the provisions of this subsection are in conflict with State law with regard to the administering or dispensing of drugs.

2. In detoxification, the patient may be placed on a substitutive methadone administration schedule when there are significant symptoms of withdrawal. The dosage schedules indicated below are recommended but may be varied depending upon clinical judgment. Initially, a single oral dose of 15-20 milligrams of methadone will often be sufficient to suppress withdrawal symptoms. Additional methadone may be provided if withdrawal symptoms are not suppressed or whenever symptoms reappear. When patients are physically dependent on high doses of methadone, it may be necessary to exceed these levels. 40 milligrams per day in single or divided doses will usually constitute an adequate stabilizing dose level. Stabilization can be continued for 2 to 3 days and then the amount of methadone will normally be gradually decreased. The rate at which methadone is decreased will be determined separately for each patient. The dose of methadone can be decreased on a daily basis or in 2 day intervals, but the amount of intake shall always be sufficient to keep withdrawal symptoms at a tolerable level. In hospitalized patients a daily reduction of 20 percent of the total daily dose usually will be tolerated and will cause little discomfort. In ambulatory patients, a somewhat slower schedule may be needed. If methadone is administered for more than 3 weeks, the procedure is considered to have progressed from detoxification or treatment of the acute withdrawal syndrome to maintenance treatment, even though the goal and intent may be eventual total withdrawal.

3. In maintenance treatment the initial dosage of methadone should control the abstinence symptoms that follow withdrawal of narcotic drugs but should not be so great as to cause sedation, respiratory depression, or other effects of acute intoxification. It is important that the initial dosage be adjusted on an individual basis to the narcotic tolerance of the new patient. If such a patient

has been a heavy user of heroin up to the day of admission, he may be given 20 milligrams orally for the first dose and another 20 milligrams 4 to 8 hours later, or 40 milligrams in a single oral dose. If he enters treatment with little or no narcotic tolerance (e.g., if he has recently been released from jail or other confinement), the initial dosage may be one-half these quantities. When there is any doubt, the smaller dose should be used initially. The patient should then be kept under observation, and, if symptoms of abstinence are distressing, additional 10 milligram doses may be repeated as needed. Subsequently, the dosage should be adjusted individually, as tolerated and required, to a level of 120 milligrams daily. For daily dosages above 100 milligrams patients shall ingest medication under observation 6 days per week. These patients will be allowed take-home medication for 1 day per week only. Those patients in treatment on December 15, 1972 who are receiving a take-home dose of more than 100 milligrams per day shall have their dosage level reduced to 100 milligrams per day or less by June 13, 1973. A daily dose of 120 milligrams or more shall be justified in the medical record. For daily dosages above 120 milligrams or, beginning June 13, 1973, for take-home doses above 100 milligrams per day, prior approval shall be obtained from the Food and Drug Administration and the State authority. A regular review of dosage level should be made by the responsible physician with careful consideration given for reduction of dosage as indicated on an individual basis. A new dosage level is only a test level until stability is achieved.

4. Caution shall be taken in the maintenance treatment of pregnant patients. Dosage levels shall be maintained as low as possible if continued methadone treatment is deemed necessary. It is the responsibility of the program sponsor to assure that each female patient is fully informed concerning the possible risks to a pregnant woman or her unborn child from the use of methadone.

5. Methadone will be administered or dispensed by a practitioner licensed or registered under appropriate State or Federal law to order narcotic drugs for patients or by an agent of the practitioner, supervised by and pursuant to the order of the practitioner. This agent may only be a pharmacist, registered nurse, or licensed practical nurse depending upon the State regulations regarding narcotic drug dispensing and administering administration. The licensed practitioner assumes responsibility for the amounts of methadone administered or dispensed and all changes in dosage schedule shall be recorded and signed by the licensed practitioner.

6. For detoxification, the drug shall be administered daily under close observation. In maintenance treatment the patient initially will ingest the drug under the observation daily, or at least 6 days a week, for the first 3 months. It is recognized that diversion occurs primarily when patients take medication from the clinic for self-administraion. It is also recognized, however, that daily attendance at a program facility may be incompatible with gainful employment, education, and responsible homemaking. After demonstrating satisfactory adherence to the program regulations for at least 3 months and showing substantial progress in rehabilitation by participating actively in the program activities and/or by participation in educational, vocational, and homemaking activities, those patients whose employment, education or homemaking responsibilities would be hindered by daily attendance may be permitted to reduce to three times weekly the times when they must ingest the drug under observation. They shall receive no more than a 2-day take-home supply. With continuing adherence to the program's requirements and progressive rehabilitation for at least 2 years after entrance into the program, such patients may be permitted twice weekly visits to the program for drug ingestion under observation with a 3-day take-home supply. Prior to reducing the frequency of visits, documentation of the patient's progress and the need for reducing the frequency of visits shall be recorded. The requirements and schedule for when the drug must be ingested under supervision may be relaxed if the patient has a serious physical disability which would prevent frequent visits to the program facility. The Food and Drug Administration and the State authority shall be notified of such cases. Additional medication may also be provided in exceptional circumstances such as acute illness, family crises, or necessary travel when hardship would result from requiring the customary observed medication intake for the specific period. In such circumstances the reasons for providing additional medication will be recorded in the clinical record. In circumstances of severe illness, infirmity or physical disability, an authorized individual (e.g., a licensed practitioner) may deliver or obtain the medication.

B. In maintenance treatment, a urinalysis will be performed randomly at least weekly for morphine and monthly for methadone, barbiturates, amphetamines, and other drugs if indicated. Those patients receiving their doses of the drug from medication units will also adhere to this schedule. The urine shall be collected in a manner which minimizes falsification of the samples. The reliability of this collection procedure shall be demonstrated. Laboratories used for testing must participate in and be approved by any proficiency testing program designated by the Food and Drug Administration. Any changes made in laboratories used for urine testing shall have prior approval of the Food and Drug Administration.

C. An adequate clinical record will be maintained for each patient. The record will contain a copy of the signed consent form(s), the date of each visit, the amount of methadone administered or dispensed, the results of each urinalysis, a detailed account of any adverse reactions, which will also be reported within 2 weeks to the Food and Drug Administration on Form FD–1639, "Drug Experience Report," any significant physical or psychologic disability, the type of rehabilitative and counseling efforts employed, an account of the patient's progress, and other relevant aspects of the treatment program. For recordkeeping purposes, if a patient misses appointments for 2 weeks or more without notifying the program, the episode of care is considered terminated and so noted in the clinical record. This does not mean that the patient cannot return for care. If the patient does return for care and is accepted into the program, this is considered a readmission and so noted in the clinical record. This method of recordkeeping helps assure the easy detection of sporadic attendance and decreases the possibility of administering inappropriate doses of methadone (e.g., the patient who has received no medication for several days or more and upon return receives the usual stabilization dose). An annual evaluation of the patient's progress will be recorded in the clinical record.

D. All patients in maintenance treatment will be given careful consideration for discontinuance of methadone especially after reaching a 10 to 20 milligrams dosage level. Social rehabilitation shall have been maintained for a reasonable period of time. Patients should be encouraged to pursue the goal of eventual withdrawal from methadone and becoming completely drug-free. Upon successfully reaching a drug-free state the patient should be retained in the program for as long as necessary to assure stability in the drug-free state, with the frequency of his required visits adjusted at the discretion of the director. Maintenance treatment using methadone shall be discontinued within 2 years after such treatment is begun unless, based upon clinical judgment recorded in the clinical record for the patient, the patient's status indicates that such treatment should be continued for a longer period of time. Any patient continued on methadone for longer than 2 years shall be subject to periodic reconsideration for discontinuance of such treatment.

VII. To prevent diversion into illicit channels, adequate security shall be maintained over stocks of methadone and over the manner in which it is distributed, as required by the Drug Enforcement Administration, Department of Justice.

VIII. The program director may establish geographically dispersed medication units of reasonable size for administering and dispensing medication to patients stabilized at their optimal dosage level. The approval of such units for any geographic area shall be based upon the number and distribution of such units within the area. No more than 30 patients shall be under care at a medication unit at any one time. These units shall be responsible only for administering and dispensing medication. Private practitioners and community pharmacies may serve as medication units. Only after patients have been stabilized at their optimal initial dosage level may they be referred to a medication unit. Subsequent to such referral, the program director shall retain continuing responsibility for the patient's care and the patient shall be seen at the primary program facility at least monthly for medical evaluation and ancillary service. If a private practitioner wishes to provide other service in addition to administering and dispensing medication and collecting urine samples, the practitioner is considered a program component or a separate program, depending upon the type of services provided. In such case the restrictions on the number of patients served shall be determined by the staffing pattern and resources available.

IX. All representations in this application are currently accurate, and no changes shall be made in the program until they have been approved by the Food and Drug Administration and the State authority.

X. If the program or any individual under the program is disapproved, the program director shall recall the methadone from the disapproved sources and return the drug to the manufacturer in a manner prescribed by the Drug Enforcement Administration, Department of Justice.

XI. Inspections of this program may be undertaken by the State authority, by the Food and Drug Administration and by the Drug Enforcement Administration, Department of Justice, in accordance with Federal controlled substances laws. The identity of patients will be kept confidential except when it is necessary to make follow-up investigations on adverse effect information related to use of the drug, when the medical welfare of the patient would be threatened by a failure to reveal such information, or when it is necessary to verify records relating to approval of the program or any portion thereof. In all circumstances the provisions of 21 CFR Part 1401 shall be followed.

Signature:_____

(3) *Annual Report Form.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

Form FD–2634 Annual Report for Treatment Program Using Methadone

This form shall be completed in triplicate by the program sponsor for each calendar year.

One copy is to be sent to the Food and Drug Administration and one copy to the State authority on or before January 30.

I. Name or other identification of program _____

_____

Address _____

_____

II. Total Treatment Capacity _____

III. Amount of methadone dispensed (in grams) during the year: _____

IV. Number of individuals who applied to the program but were not admitted or given admission evaluation _____

V. Number of individuals who were provided only detoxification one or more times _____

VI. Census of patients provided methadone maintenance treatment _____

A. Number under care at the beginning of the year being reported _____

B. Of those in treatment at the beginning of the year:

1. Number continuously under care through the year being reported (still under care) _____.

2. Number discharged or transferred to other types of programs and not readmitted _____.

3. Number discharged or transferred to other types of programs and readmitted (still under care) _____.

4. Number discharged and readmitted (no longer under care) _____.

C. Number admitted to care during year ____, not previously treated in this program:

1. Number still under care at the end of the year _____.

2. Number discharged or transferred to other types of programs and not readmitted _____.

3. Number discharged or transferred to other types of programs and readmitted (still under care) _____.

4. Number discharged and readmitted (no longer under care) _____.

D. Number admitted to care during the year ____, previously treated in this program prior to the past year:

1. Number still under care at the end of the year _____.

2. Number discharged or transferred to other types of programs and not readmitted _____.

3. Number discharged and transferred to other types of programs and readmitted (still under care) _____.

4. Number discharged and readmitted (no longer under care) _____.

VII. Demographic and treatment characteristics of patients under care at the end of the year being reported:

A. By age and sex:

Age	Total	Male	Female
Under 14			
14-15			
16-17			
18-20			
21-25			
26-35			
36-45			
46+			

B. For the year being reported, give the number of patients who have been under continuous care for the following periods of time:

Under 3 months _____
3 months to 1 year _____
1 to 2 years _____
2 to 5 years _____
Over 5 years _____

C. Total number of individuals treated to date _____

D. For the year being reported, give the number of patients stabilized at each dosage level:

Daily dosage, mgm.	*Number of patients*
Under 20	
20-39	
40-59	
60-79	
80-99	
100-119	
Over 120	

E. For the year being reported, give the number of patients seen in the past 8 weeks who have fallen in the following categories:

No positive urinalysis for morphine for 2 months or more _____

Occasional positive urinalysis for morphine (monthly or less) _____

Frequent positive urinalysis for morphine (more than once per month) _____

In program for less than 2 months _____

For the year being reported, give the number of patients treated who were pregnant _____

VIII. Give the number of patients having significant adverse reactions, particularly reactions related to hematopoietic, cardiovascular, endocrine, neurologic, and immunological functions (attach a completed copy of Form FD-1639, "Drug Experience Report," for each incident not previously reported to the Food and Drug Administration):

Type of reaction	*Number of patients*

IX. Give the number of patients who have died while under methadone care (attach a completed copy of Form FD-1639, "Drug Experience Report", for each incident not previously reported to the Food and Drug Administation):

	Number of patients
A. Definitely methadone-related	
B. Not methadone-related	

Signature _____

(Program sponsor)

(4) *Patient Consent Form.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

Form FD-2635 Consent for Methadone Treatment

Patient _____ Date _____

Name of practitioner explaining procedures _____

(Provisions of this consent form may be modified to conform to any applicable State law.)

I hereby authorize and give my voluntary consent to Dr. _____

(Program medical director)

and/or any appropriately authorized assistants he may select, to administer or prescribe the drug methadone as an element in the treatment for my dependence on heroin or other narcotic drugs.

The procedures necessary to treat my condition have been explained to me and I understand that it will involve my taking daily dosages of methadone, or other drugs, which will help control my dependence on heroin or other narcotic drugs.

It has been explained to me that methadone is a narcotic drug which can be harmful if taken without medical supervision. I further understand that methadone is an addictive medication and may, like other drugs used in medical practice, produce adverse results. The alternative methods of treatment, the possible risks involved, and the possibilities of complications have been explained to me, but I still desire to receive methadone due to the risk of my return to the use of heroin or other drugs.

The goal of methadone treatment is total rehabilitation of the patient. Eventual withdrawal from the use of all drugs, including methadone, is an appropriate treatment goal. I realize that for some patients methadone treatment may continue for relatively long periods of time but that periodic consideration shall be given concerning my complete withdrawal from methadone use.

I understand that I may withdraw from this treatment program and discontinue the use of the drug at any time and I shall be afforded detoxification under medical supervision.

I agree that I shall inform any doctor who may treat me for any medical problem that I am enrolled in a methadone treatment program, since the use of other drugs in conjunction with methadone may cause me harm.

I also understand that during the course of treatment, certain conditions may make it necessary to use additional or different procedures than those explained to me. I understand that these alternate procedures shall be used when in the Program or Medical Director's professional judgment it is considered advisable.

_____

(For female patients of child-bearing age)

To the best of my knowledge, I (am/am not) pregnant at this time.

Besides the possible risks involved with the long-term use of methadone, I further understand that, like heroin and other narcotic drugs, information on its effects on pregnant women and on their unborn children is at present inadequate to guarantee that it may not produce significant or serious side effects.

It has been explained to me and I understand that methadone is transmitted to the unborn child and will cause physical dependence. Thus, if I am pregnant and suddenly stop taking methadone, I or the unborn child may show signs of withdrawal which may adversely affect my pregnancy or the child. I shall use no other drugs without the medical director or his assistants' approval, since these drugs, particularly as they might interact with methadone, may harm me or my unborn child. I shall inform any other doctor who sees me during my present or any future pregnancy or who sees the child after birth, of my current or past participation in a methadone treatment program in order that he may properly care for my child and me.

It has been explained to me that after the birth of my child I should not nurse the baby because methadone is transmitted through the milk to the baby and this may cause physical dependence on methadone in the child. I understand that for a brief period following birth, the child may show temporary irritability or other ill effects due to my use of methadone. It is essential for the child's physician to know of my participation in a methadone treatment program so that he may provide appropriate medical treatment for the child.

All the above possible effects of methadone have been fully explained to me and I understand that at present, there have not been enough studies conducted on the long term use of the drug to assure complete safety to my child. With full knowledge of this, I consent to its use and promise to inform the Medical Director or one of his

assistants immediately if I become pregnant in the future.

(For patients under 18 years of age)

The patient is a minor, _____ years of age, born, _____. The risks of the use of methadone have been explained to (me/us) and (I/we) understand that methadone is a drug on which long-term studies are still being conducted and that information on its effects in adolescents is incomplete. It has been explained to (me/us) that methadone is being used in the minor's treatment only because the risk of (his/her) return to the use of heroin is sufficiently great to justify this treatment. (I/We) declare that participation in the methadone treatment program is wholly voluntary on the part of both the (parent(s)/guardian(s)) and the patient and that methadone treatment may be stopped at any time on (my/our) request or that of the patient. With full knowledge of the potential benefits and possible risks involved with the use of methadone in the treatment of an adolescent, (I/we) consent to its use upon the minor, since (I/we) realize that otherwise (he/she) shall continue to be dependent upon heroin or other narcotic drugs.

I certify that no guarantee or assurance has been made as to the results that may be obtained from methadone treatment. With full knowledge of the potential benefits and possible risks involved, I consent to methadone treatment, since I realize that I would otherwise continue to be dependent on heroin or other narcotic drugs.

Patient _____
Date _____
Date of birth _____
Parent(s) or guardian(s) _____
Relationship _____
Witness _____

(5) *Hospital Application.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

Form FD-2636 Hospital Request for Methadone for Analgesia in Severe Pain and for Detoxification and Temporary Maintenance Treatment

Name of hospital _____
Address _____
Commissioner,
Food and Drug Administration,
Bureau of Drugs (HFD-106),
Rockville, MD 20852.

DEAR SIR: As hospital administrator, I submit this request for approval to receive supplies of methadone to be used for analgesia in severe pain and for detoxification and maintenance treatment in accord with § 310.505 of the new drug regulations. I understand that the failure to abide by the requirements described below may result in revocation of approval to receive shipments of methadone, seizure of the drug supply on hand, injunction, and criminal prosecution.

I. The name of the individual (pharmacist) responsible for receiving and securing supplies of methadone is _____.

II. There are a total of _____ beds in the hospital.

III. A general description of the hospital and nature of patient care undertaken is attached.

IV. The anticipated quantity of methadone needed per year is _____ (Gms.).

V. Methadone is permitted to be administered or dispensed only for detoxification or temporary treatment of hospitalized patients, and for analgesia in severe pain for hospitalized patients and outpatients. If methadone is administered for treatment of heroin dependence for more than 3 weeks, the procedure passes from treatment of the acute withdrawal syndrome (detoxification) to maintenance treatment. Maintenance treatment is permitted to be undertaken only by approved methadone programs. This does not preclude the maintenance treatment of an addict who is hospitalized for treatment of medical conditions other than addiction and who requires temporary maintenance treatment during the critical period of his stay whose enrollment in a program which has approval for maintenance treatment using methadone has been verified.

VI. Prior to filing a physician's prescription for methadone for outpatients, I shall obtain from the physician a statement indicating that all such prescriptions written by him shall be limited to use for analgesia in severe pain and his agreement to maintain records to substantiate such use. These records will be available in the hospital or made available at the request of the hospital administrator. On January 30 of each year, the hospital shall report to the Food and Drug Administration the names and addresses of all physicians who prescribed methadone for analgesia on an outpatient basis during the previous year.

VII. Prescriptions for analgesia may be filled only if they are written by a physician who has submitted the required statement to the hospital.

VIII. Accurate records shall be maintained showing dates, quantity, and batch or code marks of the drug for inpatient and outpatient treatment. The records shall be retained for a period of 3 years.

IX. The Food and Drug Administration and the State authority may inspect supplies of the drug and evaluate the uses to which the drug is being put. The identity of the patient will be kept confidential except when it is necessary to make follow-up investigations on adverse effect information related to the drug, when the medical welfare of the patient would be threatened by a failure to reveal such information, or when it is necessary to verify records relating to approval of the hospital or any portion thereof. The confidentiality requirements of 21 CFR Part 1401 shall be followed.

Signature _____
(Hospital official)

PART 312—NEW DRUGS FOR INVESTIGATIONAL USE

Subpart A—Exemptions From Section 505(a)

Sec.
312.1 Conditions for exemption of new drugs for investigational use.
312.9 New drugs for investigational use in laboratory research animals or in vitro tests.

Subpart B—Controlled Substances

312.10 Availability of records.

AUTHORITY: Secs. 502, 503, 505, 701, 52 Stat. 1051, 1052, 1053, 1055, as amended (21 U.S.C. 352, 353, 355, 371) (5 U.S.C. 554) unless otherwise noted.

Subpart A—Exemptions From Section 505(a)

§ 312.1 Conditions for exemption of new drugs for investigational use.

(a) A shipment or other delivery of a new drug shall be exempt from section 505(a) of the act if all the following conditions are met:

(1) The label of such drug bears the statement "Caution: New drug—Limited by Federal (or United States) law to investigational use."

(2) The person claiming the exemption has filed with the Food and Drug Administration a completed and signed "Notice of Claimed Investigational Exemption for a New Drug" in triplicate, with the information shown below in Form FD-1571; and not less than 30 days have elapsed following the date of receipt of the notice by the Food and Drug Administration; and the Food and Drug Administration has not, prior to expiration of such 30-day interval, requested that the sponsor continue to withhold or to restrict use of the drug in human subjects. The 30-day delay requirement may be waived by the Food and Drug Administration upon a showing of good reason for such waiver.

Form FD-1571

Department of Health, Education, and Welfare, Food and Drug Administration

Notice of Claimed Investigational Exemption for a New Drug

Name of sponsor _____
Address _____
_____
Name of investigational drug _____
To the Secretary of Health, Education, and Welfare,
For the Commissioner of Food and Drugs,
5600 Fishers Lane,
Rockville MD 20852

Dear Sir:

The sponsor, _____, submits this notice of claimed investigational exemption for a new drug under the provisions of section 505(i) of the Federal Food, Drug, and Cosmetic Act and § 312.1 of Title 21 of the Code of Federal Regulations.

Attached hereto are:

1. The best available descriptive name of the drug, including to the extent known the chemical name and structure of any new-drug substance, and a statement of how it is to be administered. (If the drug has only a code name, enough information should be supplied to identify the drug.)

2. Complete list of components of the drug, including any reasonable alternates for inactive components.

3. Complete statement of quantitative composition of drug, including reasonable variations that may be expected during the investigational stage.

4. Description of source and preparation of any new-drug substances used as components, including the name and address of each supplier or processor, other than the sponsor, of each new-drug substance.

5. A statement of the methods, facilities, and controls used for the manufacturing, processing, and packing of the new drug to establish and maintain appropriate standards of identity, strength, quality, and purity as needed for safety and to give significance to clinical investigations made with the drug.

6. A statement covering all information available to the sponsor derived from preclinical investigations and any clinical studies and experience with the drug as follows:

a. Adequate information about the preclinical investigations, including studies made on laboratory animals, on the basis of which the sponsor has concluded that it is reasonably safe to initiate clinical investigations with the drug: Such information should include identification of the person who conducted each investigation; identification and qualifications of the individuals who evaluated the results and concluded that it is reasonably safe to initiate clinical

investigations with the drug and a statement of where the investigations were conducted and where the records are available for inspection; and enough details about the investigations to permit scientific review. The preclinical investigations shall not be considered adequate to justify clinical testing unless they give proper attention to the conditions of the proposed clinical testing. When this information, the outline of the plan of clinical pharmacology, or any progress report on the clinical pharmacology, indicates a need for full review of the preclinical data before a clinical trial is undertaken, the Department will notify the sponsor to submit the complete preclinical data and to withhold clinical trials until the review is completed and the sponsor notified. The Food and Drug Administration will be prepared to confer with the sponsor concerning this action.

b. If the drug has been marketed commercially or investigated (e.g. outside the United States), complete information about such distribution or investigation shall be submitted, along with a complete bibliography of any publications about the drug.

c. If the drug is a combination of previously investigated or marketed drugs, an adequate summary of preexisting information from preclinical and clinical investigations and experience with its components, including all reports available to the sponsor suggesting side-effects, contraindications, and ineffectiveness in use of such components: Such summary should include an adequate bibliography of publications about the components and may incorporate by reference any information concerning such components previously submitted by the sponsor to the Food and Drug Administration. Include a statement of the expected pharmacological effects of the combination.

7. A copy (one in each of the three copies of the notice) of all informational material, including label and labeling, which is to be supplied to each investigator: This shall include an accurate description of the prior investigations and experience and their results pertinent to the safety and possible usefulness of the drug under the conditions of the investigation. It shall not represent that the safety or usefulness of the drug has been established for the purposes to be investigated. It shall describe all relevant hazards, contraindications, side effects, and precautions suggested by prior investigations and experience with the drug under investigation and related drugs for the information of clinical investigators.

8. The scientific training and experience considered appropriate by the sponsor to qualify the investigators as suitable experts to investigate the safety of the drug, bearing in mind what is known about the pharmacological action of the drug and the phase of the investigational program that is to be undertaken.

9. The names and a summary of the training and experience of each investigator and of the individual charged with monitoring the progress of the investigation and evaluating the evidence of safety and effectiveness of the drug as it is received from the investigators, together with a statement that the sponsor has obtained from each investigator a completed and signed form, as provided in subparagraph (12) or (13) of this paragraph, and that the investigator is qualified by scientific training and experience as an appropriate expert to undertake the phase of the investigation outlined in section 10 of the "Notice of claimed investigational exemption for a new drug." (In crucial situations, phase 3 investigators may be added and this form supplemented by rapid communication methods, and the signed Form FD–1573 shall be obtained promptly thereafter.)

10. An outline of any phase or phases of the planned investigations and a description of the institutional review committee, as follows:

a. *Clinical pharmacology.* This is ordinarily divided into two phases: Phase 1 starts when the new drug is first introduced into man—only animal and in vitro data are available—with the purpose of determining human toxicity, metabolism, absorption, elimination, and other pharmacological action, preferred route of administration, and safe dosage range; phase 2 covers the initial trials on a limited number of patients for specific disease control or prophylaxis purposes. A general outline of these phases shall be submitted, identifying the investigator or investigators, the hospitals or research facilities where the clinical pharmacology will be undertaken, any expert committees or panels to be utilized, the maximum number of subjects to be involved, and the estimated duration of these early phases of investigation. Modification of the experimental design on the basis of experience gained need be reported only in the progress reports on these early phases, or in the development of the plan for the clinical trial, phase 3. The first two phases may overlap and, when indicated, may require additional animal data before these phases can be completed or phase 3 can be undertaken. Such animal tests shall be designed to take into account the expected duration of administration of the drug to human beings, the age groups and physical status, as for example, infants, pregnant women, premenopausal women, of those human beings to whom the drug may be administered, unless this has already been done in the original animal studies.

b. *Clinical trial.* This phase 3 provides the assessment of the drug's safety and effectiveness and optimum dosage schedules in the diagnosis, treatment, or prophylaxis of groups of subjects involving a given disease or condition. A reasonable protocol is developed on the basis of the facts accumulated in the earlier phases, including completed and submitted animal studies. This phase is conducted by separate groups following the same protocol (with reasonable variations and alternatives permitted by the plan) to produce well-controlled clinical data. For this phase, the following data shall be submitted:

i. The names and addresses of the investigators. (Additional investigators may be added.)

ii. The specific nature of the investigations to be conducted, together with information or case report forms to show the scope and detail of the planned clinical observations and the clinical laboratory tests to be made and reported.

iii. The approximate number of subjects (a reasonable range of subjects is permissible and additions may be made), and criteria proposed for subject selection by age, sex, and condition.

iv. The estimated duration of the clinical trial and the intervals, not exceeding 1 year, at which progress reports showing the results of the investigations will be submitted to the Food and Drug Administration.

c. *Institutional review committee.* If the phases of clinical study as described under 10a and b above are conducted on institutionalized subjects or are conducted by an individual affiliated with an institution which agrees to assume responsibility for the study, assurance must be given that an institutional review committee is responsible for initial and continuing review and approval of the proposed clinical study. The membership must be comprised of sufficient members of varying background, that is, lawyers, clergymen, or laymen as well as scientists, to assure complete and adequate review of the research project. The membership must possess not only broad competence to comprehend the nature of the project, but also other competencies necessary to judge the acceptability of the project or activity in terms of institutional regulations, relevant law, standards of professional practice, and community acceptance. Assurance must be presented that neither the sponsor nor the investigator has participated in selection of committee members; that the review committee does not allow participation in its review and conclusions by any individual involved in the conduct of the research activity under review (except to provide information to the committee); that the investigator will report to the committee for review any emergent problems, serious adverse reactions, or proposed procedural changes which may affect the status of the investigation and that no such change will be made without committee approval except where necessary to eliminate apparent immediate hazards; that reviews of the study will be conducted by the review committee at intervals appropriate to the degree of risk, but not exceeding 1 year, to assure that the research project is being conducted in compliance with the committee's understanding and recommendations; that the review committee is provided all the information on the research project necessary for its complete review of the project; and that the review committee maintains adequate documentation of its activities and develops adequate procedures for reporting its findings to the institution. The documents maintained by the committee are to include the names and qualifications of committee members, records of information provided to subjects in obtaining informed consent, committee discussion on substantive issues and their resolution, committee recommendations, and dated reports of successive reviews as they are performed. Copies of all documents are to be retained for a period of 3 years past the completion or discontinuance of the study and are to be made available upon request to duly authorized representatives of the Food and Drug Administration. (Favorable recommendations by the committee are subject to further appropriate review and rejection by institution officials. Unfavorable recommendations, restrictions, or conditions may not be overruled by the institution officials.) Procedures for the organization and operation of institutional review committees are contained in guidelines issued pursuant to Chapter 1–40 of the Grants Administration Manual of the U.S. Department of Health, Education, and Welfare, available from the U.S. Government Printing Office. It is recommended that these guidelines be followed in establishing institutional review committees and that the committees function according to the procedures described therein. A signing of the Form FD–1571 will be regarded as providing the above necessary assurances. If the institution, however, has on file with the Department of Health, Education, and Welfare, Division of Research Grants, National Institutes of Health, an "accepted general assurance," and the same committee is to review the proposed study using the same procedures, this is acceptable in lieu of the above assurances and a statement to this effect should be provided with the signed FD–1571. (In addition to sponsor's continuing responsibility to monitor the study, the Food and Drug Administration will undertake investigations in institutions periodically to determine whether the committees are operating in accord with the assurances given by the sponsor.)

(The notice of claimed investigational exemption may be limited to any one or more phases, provided the outline of the additional phase or phases is submitted before

such additional phases begin. This does not preclude continuing a subject on the drug from phase 2 to phase 3 without interruption while the plan for phase 3 is being developed.)

Ordinarily, a plan for clinical trial will not be regarded as reasonable unless, among other things, it provides for more than one independent competent investigator to maintain adequate case histories of an adequate number of subjects, designed to record observations and permit evaluation of any and all discernible effects attributable to the drug in each individual treated, and comparable records on any individuals employed as controls. These records shall be individual records for each subject maintained to include adequate information pertaining to each, including age, sex, conditions treated, dosage, frequency of administration of the drug, results of all relevant clinical observations and laboratory examinations made, adequate information concerning any other treatment given and a full statement of any adverse effects and useful results observed, together with an opinion as to whether such effects or results are attributable to the drug under investigation.

11. A statement that the sponsor will notify the Food and Drug Administration if the investigation is discontinued, and the reason therefor.

12. A statement that the sponsor will notify each investigator if a new-drug application is approved, or if the investigation is discontinued.

13. If the drug is to be sold, a full explanation why sale is required and should not be regarded as the commercialization of a new drug for which an application is not approved.

14. A statement that the sponsor assures that clinical studies in humans will not be initiated prior to 30 days after the date of receipt of the notice by the Food and Drug Administration and that he will continue to withhold or to restrict clinical studies if requested to do so by the Food and Drug Administration prior to the expiration of such 30 days. If such request is made, the sponsor will be provided specific information as to the deficiencies and will be afforded a conference on request. The 30-day delay may be waived by the Food and Drug Administration upon a showing of good reason for such waiver; and for investigations subject to institutional review committee approval as described in item 10c. above, an additional statement assuring that the investigation will not be initiated prior to approval of the study by such committee.

Very truly yours,

(Sponsor)

Per ---

(Indicate authority)

15. When requested by the agency, an environmental impact analysis report pursuant to § 6.1 of this chapter.

(This notice may be amended or supplemented from time to time on the basis of the experience gained with the new drug. Progress reports may be used to update the notice.)

Provided, however, That where a new drug limited to investigational use is proposed for shipment to a foreign country for clinical investigation, in lieu of the filing of a "Notice of Claimed Investigational Exemption for a New Drug" (Form FD-1571), the Commissioner will authorize the shipment of the drug if he receives, through the Department of State, a formal request to allow such shipment, from the government of the country to which the drug is proposed to be shipped. This request shall specify that said government has adequate information about the drug and the proposed investigational use, and is satisfied that the drug may legally be used by the intended consignee in that country. This provisions is applicable only where the drug is to be used for purposes of clinical investigation and does not apply where it is intended for commercial marketing or use in routine medical practice.

(3) Each shipment or delivery is made in accordance with the commitments in the "Notice of claimed investigational exemption for a new drug."

(4) The sponsor maintains adequate records showing the investigator to whom shipped, date, quantity, and batch or code mark of each such shipment and delivery, until 2 years after a new-drug application is approved for the drug; or, if an application is not approved, until 2 years after shipment and delivery of the drug for investigational use is discontinued and the Food and Drug Administration has been so notified. Upon the request of a scientifically trained and properly authorized employee of the Department at reasonable times, the sponsor makes the records referred to in this subparagraph and in paragraph (a)(2) of this section available for inspection, **and upon written requests submits such records or copies of them to the Food and Drug Administration. If the investigational drug is subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970 adequate precautions are taken, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.**

(5) The sponsor monitors the progress of the investigations and currently evaluates the evidence relating to the safety and effectiveness of the drug as it is obtained from the investigators. Accurate progress reports of the investigations and significant findings, together with any significant changes in the informational material supplied to investigators, shall be submitted to the Food and Drug Administration at reasonable intervals, not exceeding 1 year. All reports of the investigation shall be retained until 2 years after a new-drug application is approved for the drug; or, if an application is not approved, until 2 years after shipment and delivery of the drug for investigational use is discontinued and the Food and Drug Administration so notified. Upon request of a scientifically trained and properly authorized employee of the Department at reasonable times, these reports shall be made available for inspection, and on written request copies of these reports shall be submitted to the Food and Drug Administration.

(6) The sponsor shall promptly investigate and report to the Food and Drug Administration and to all investigators any findings associated with use of the drug that may suggest significant hazards, contraindications, side-effects, and precautions pertinent to the safety of the drug. If the finding is alarming it shall be reported immediately and the clinical investigation discontinued until the finding is adequately evaluated and a decision reached that it is safe to proceed.

(7) If the investigations adduce facts showing that there is substantial doubt that they may be continued safely in relation to the drug's potential therapeutic effects, the sponsor shall promptly discontinue the investigation, notify all investigators and the Food and Drug Administration, recall all stocks of the drug outstanding, and furnish the Food and Drug Administration with a full report of the reason for discontinuing the investigation. The Food and Drug Administration will be prepared to confer with the sponsor on the need to discontinue the investigation.

(8) The sponsor shall discontinue shipments or deliveries of the new drug to any investigator who has repeatedly or deliberately failed to maintain or make available his records or reports of his investigations.

(9) The sponsor shall not unduly prolong distribution of the drug for investigational use but shall submit an application for the drug pursuant to section 505(b) of the act (or give reasons for not submitting such application, or a statement that the investigation has been discontinued and the reasons therefor):

(i) With reasonable promptness after finding that the results of such investigation appear to establish the safety and effectiveness of the drug; or

(ii) Within 60 days after receipt of a written request for such an application from the Commissioner.

(10) Neither the sponsor nor any person acting for or on behalf of the sponsor shall disseminate any promotional material representing that the drug being distributed interstate for investigational use is safe or useful for the purposes for which it is under investigation. This regulation is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay communications media; its sole intent is to restrict promotional claims of safety or effectiveness by the sponsor while the drug is under investigation to establish its safety or effectiveness.

(11) The sponsor shall not commercially distribute nor test-market the drug until a new-drug application is approved pursuant to section 505(b) of the act.

(12) The sponsor shall obtain from each investigator involved in clinical pharmacology a signed statement in the following form:

Form FD-1572

Department of Health, Education, and Welfare, Food and Drug Administration

Statement of Investigator (Clinical Pharmacology)

Name of investigator ---
Date ---

Name of drug _____
To supplier of the drug:
Name _____
Address _____

Dear Sir:

The undersigned, _____, submits this statement as required by section 505(i) of the Federal Food, Drug, and Cosmetic Act and § 312.1 of Title 21 of Code of Federal Regulations as a condition for receiving and conducting clinical pharmacology with a new drug limited by Federal (or United States) law to investigational use.

1. A statement of the education and training that qualifies me for clinical pharmacology.

2. The name and address of the medical school, hospital, or other research facility where the clinical pharmacology will be conducted.

3. If the experimental project is to be conducted on institutionalized subjects or is conducted by an individual affiliated with an institution which agrees to assume responsibility for the study, assurance must be given that an institutional review committee is responsible for initial and continuing review and approval of the proposed clinical study. The membership must be comprised of sufficient members of varying background, that is, lawyers, clergymen, or laymen as well as scientists, to assure complete and adequate review of the research project. The membership must possess not only broad competence to comprehend the nature of the project, but also other competencies necessary to judge the acceptability of the project or activity in terms of institutional regulations, relevant law, standards of professional practice, and community acceptance. Assurance must be presented that the investigator has not participated in the selection of committee members; that the review committee does not allow participation in its review and conclusions by any individual involved in the conduct of the research activity under review (except to provide information to the committee); that the investigator will report to the committee for review any emergent problems, serious adverse reactions, or proposed procedural changes which may affect the status of the investigation and that no such change will be made without committee approval except where necessary to eliminate apparent immediate hazards; that reviews of the study will be conducted by the review committee at intervals appropriate to the degree of risk, but not exceeding 1 year, to assure that the research project is being conducted in compliance with the committee's understanding and recommendations; that the review committee is provided all the information on the research project necessary for its complete review of the project; and that the review committee maintains adequate documentation of its activities and develops adequate procedures for reporting its findings to the institution The documents maintained by the committee are to include the names and qualifications of committee members, records of information provided to subjects in obtaining informed consent, committee discussion on substantive issues and their resolution, committee recommendations, and dated reports of successive reviews as they are performed. Copies of all documents are to be retained for a period of 3 years past the completion or discontinuance of the study and are to be made available upon request to duly authorized representatives of the Food and Drug Administration. (Favorable recommendations by the committee are subject to further appropriate review and rejection by institution officials. Unfavorable recommendations, restrictions, or conditions may not be overruled by the institution officials.) Procedures for the organization and operation of institutional review committees are contained in guidelines issued pursuant to Chapter 1–40 of the Grants Administration Manual of the U.S. Department of Health, Education, and Welfare, available from the U.S. Government Printing Office. It is recommended that these guidelines be followed in establishing institutional review committees and that the committees function according to the procedures described therein. A signing of the Form FD–1572 will be regarded as providing the above necessary assurance; however, if the institution has on file with the Department of Health, Education, and Welfare, Division of Research Grants, National Institutes of Health, an "accepted general assurance," and the same committee is to review the proposed study using the same procedures, this is acceptable in lieu of the above assurances and a statement to this effect should be provided with the signed FD–1572. (In addition to sponsor's continuing responsibility to monitor the study, the Food and Drug Administration will undertake investigations in institutions periodically to determine whether the committees are operating in accord with the assurances given by the sponsor.)

4. The estimated duration of the project, and the maximum number of subjects that will be involved.

5. A general outline of the project to be undertaken (modification is permitted on the basis of experience gained, without advance submission of amendments to the general outline, but with the approval of the review committee and upon notification of the sponsor).

6. The undersigned understands that the following conditions generally applicable to new drugs for investigational use govern his receipt and use of this investigational drug:

a. The sponsor is required to supply the investigator with full information concerning the preclinical investigation that justifies clinical pharmacology.

b. The investigator is required to maintain adequate records of the disposition of all receipts of the drug, including dates, quantity, and use by subjects, and if the clinical pharmacology is suspended, terminated, discontinued, or completed, to return to the sponsor any unused supply of the drug. If the investigational drug is subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970, adequate precautions must be taken, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.

c. The investigator is required to prepare and maintain adequate case histories designed to record all observations and other data pertinent to the clinical pharmacology.

d. The investigator is required to furnish his reports to the sponsor who is responsible for collecting and evaluating the results, and presenting progress reports to the Food and Drug Administration at appropriate intervals, not exceeding 1 year. Any adverse effect which may reasonably be regarded as caused by, or is probably caused by, the new drug shall be reported to the sponsor promptly; and if the adverse effect is alarming it shall be reported immediately. An adequate report of the clinical pharmacology should be furnished to the sponsor shortly after completion.

e. The investigator shall maintain the records of disposition of the drug and the case reports described above for a period of 2 years following the date the new-drug application is approved for the drug; or if no application is to be filed or is approved until 2 years after the investigation is discontinued and the Food and Drug Administration so notified. Upon the request of a scientifically trained and specifically authorized employee of the Department, at reasonable times, the investigator will make such records available for inspection and copying. The names of the subjects need not be divulged unless the records of the particular subjects require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual studies or do not represent actual results obtained.

f. The investigator certifies that the drug will be administered only to subjects under his personal supervision or under the supervision of the following investigators responsible to him, _____, and that the drug will not be supplied to any other investigator or to any clinic for administration to subjects.

g. The investigator certifies that he will inform any patients or any persons used as controls, or their representatives, that drugs are being used for investigational purposes, and will obtain the consent of the subjects, or their representatives, except where this is not feasible or, in the investigator's professional judgment, is contrary to the best interests of the subjects.

h. The investigator is required to assure the sponsor that for investigations involving institutionalized subjects the studies will not be initiated until the institutional review committee has reviewed and approved the study. (The organization and procedure requirements for such a committee should be explained to the investigator by the sponsor as set forth in Form FD–1571, division 10, unit c.)

Very truly yours,

_____
(Name of investigator)

_____
(Address)

_____

(13) The sponsor shall obtain from each investigator involved in clinical trials a signed statement in the following form:

Form FD–1573

Department of Health, Education, and Welfare, Food and Drug Administration

Statement of Investigator

Name of investigator _____
Date _____
Name of drug _____
To supplier of drug:
Name _____
Address _____

Dear Sir:

The undersigned, _____, submits this statement as required by section 505(i) of the Federal Food, Drug, and Cosmetic Act and § 312.1 of Title 21 of the Code of Federal Regulations as a condition for receiving and conducting clinical investigations with a new drug limited by Federal (or United States) law to investigational use.

1. The following is a statement of my education and experience:

a. Colleges, universities, and medical or other professional schools attended, with dates of attendance, degrees, and dates degrees were awarded.

b. Postgraduate medical or other professional training: Dates, names of institutions, and nature of training.

c. Teaching or research experience: Dates, institutions, brief description of experience.

d. Experience in medical practice or other professional experience: Dates, institutional affiliations, nature of practice, or other professional experience.

e. Representative list of pertinent medical or other scientific publications: Titles of articles, names of publications and volume, page, number, and date.

(If this information has previously been submitted to the sponsor, it may be referred to and any additions made to bring it up to date.)

2a. If the investigation is to be conducted on institutionalized subjects or is conducted by an individual affiliated with an institution which agrees to assume responsibility for the study, assurance must be given that an institutional review committee is responsible for initial and continuing review and approval of the proposed clinical study. The membership must be comprised of sufficient members of varying background, that is, lawyers, clergymen, or laymen as well as scientists, to assure complete and adequate review of the research project. The membership must possess not only broad competence to comprehend the nature of the project, but also other competencies necessary to judge the acceptability of the project or activity in terms of institutional regulations, relevant law, standards of professional practice and community acceptance. Assurance must be presented that the investigator has not participated in the selection of committee members; that the review committee does not allow participation in its review and conclusions by any individual involved in the conduct of the research activity under review (except to provide information to the committee) that the investigator will report to the committee for review any emergent problems, serious adverse reactions, or proposed procedural changes which may affect the status of the investigation and that no such change will be made without committee approval except where necessary to eliminate apparent immediate hazards; that reviews of the study will be conducted by the review committee at intervals appropriate to the degree of risk, but not exceeding 1 year, to assure that the research project is being conducted in compliance with the committee's understanding and recommendations; that the review committee is provided all the information on the research project necessary for its complete review of the project; and that the review committee maintains adequate documentation of its activities and develops adequate procedures for reporting its findings to the institution. The documents maintained by the committee are to include the names and qualifications of committee members, records of information provided to subjects in obtaining informed consent, committee discussion on substantive issues and their resolution, committee recommendations, and dated reports of successive reviews as they are performed. Copies of all documents are to be retained for a period of 3 years past the completion or discontinuance of the study and are to be made available upon request to duly authorized representatives of the Food and Drug Administration. (Favorable recommendations by the committee are subject to further appropriate review and rejection by institution officials. Unfavorable recommendations, restrictions, or conditions may not be overruled by the institution officials.) Procedures for the organization and operation of institutional review committees are contained in guidelines issued pursuant to Chapter 1-40 of the Grants Administration Manual of the U.S. Department of Health, Education, and Welfare, available from the U.S. Government Printing Office. It is recommended that these guidelines be followed in establishing institutional review committees and that the committees function according to the procedures described therein. A signing of the Form FD-1573 will be regarded as providing the above necessary assurances; however, if the institution has on file with the Department of Health, Education, and Welfare, Division of Research Grants, National Institutes of Health, and "accepted general assurance," and the same committee is to review the proposed study using the same procedures, this is acceptable in lieu of the above assurances and a statement to this effect should be provided with the signed FD-1573. (In addition to sponsor's continuing responsibility to monitor the study, the Food and Drug Administration will undertake investigations in institutions periodically to determine whether the committees are operating in accord with the assurances given by the sponsor.)

b. A description of any clinical laboratory facilities that will be used. (If this information has been submitted to the sponsor and reported by him on Form FD-1571, reference to the previous submission will be adequate).

3. The investigational drug will be used by the undersigned or under his supervision in accordance with the plan of investigation described, as follows: (Outline the plan of investigation, including approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be undertaken prior to, during, and after administration of the drug; the estimated duration of the investigation; and a description or copies of report forms to be used to maintain an adequate record of the observations and tests results obtained. This plan may include reasonable alternates and variations, and should be supplemented or amended when any significant change in direction or scope of the investigation is undertaken.)

4. The undersigned understands that the following conditions, generally applicable to new drugs for investigational use, govern his receipts and use of this investigational drug:

a. The sponsor is required to supply the investigator with full information concerning the preclinical investigations that justify clinical trials, together with fully informative material describing any prior investigations and experience and any possible hazards, contraindications, side-effects, and precautions to be taken into account in the course of the investigation.

b. The investigator is required to maintain adequate records of the disposition of all receipts of the drug, including dates, quantity, and use by subjects, and if the investigation is terminated, suspended, discontinued, or completed, to return to the sponsor any unused supply of the drug. If the investigational drug is subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970, adequate precautions must be taken, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.

c. The investigator is required to prepare and maintain adequate and accurate case histories designed to record all observations and other data pertinent to the investigation on each individual treated with the drug or employed as a control in the investigation.

d. The investigator is required to furnish his reports to the sponsor of the drug who is responsible for collecting and evaluating the results obtained by various investigators. The sponsor is required to present progress reports to the Food and Drug Administration at appropriate intervals not exceeding 1 year. Any adverse effects that may reasonably be regarded as caused by, or probably caused by, the new drug shall be reported to the sponsor promptly, and if the adverse effect is alarming, it shall be reported immediately. An adequate report of the investigation should be furnished to the sponsor shortly after completion of the investigation.

e. The investigator shall maintain the records of disposition of the drug and the case histories described above for a period of 2 years following the date a new-drug application is approved for the drug; or if the application is not approved, until 2 years after the investigation is discontinued. Upon the request of a scientifically trained and properly authorized employee of the Department, at reasonable times, the investigator will make such records available for inspection and copying. The subjects' names need not be divulged unless the records of particular individuals require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual cases studied, or do not represent actual results obtained.

f. The investigator certifies that the drug will be administered only to subjects under his personal supervision or under the supervision of the following investigators responsible to him, _____, and that the drug will not be supplied to any other investigator or to any clinic for administration to subjects.

g. The investigator certifies that he will inform any subjects, including subjects used as controls, or their representatives, that drugs are being used for investigational purposes, and will obtain the consent of the subjects, or their representatives, except where this is not feasible or, in the investigator's professional judgment, is contrary to the best interests of the subjects.

h. The investigator is required to assure the sponsor that for investigations involving institutionalized subjects, the studies will not be initiated until the institutional review committee has reviewed and approved the study. (The organization and procedure requirements for such a committee should be explained to the investigator by the sponsor as set forth in form FD-1571, division 10, unit c.)

Very truly yours,

_____
(Name of investigator)

_____
(Address)

_____

(This form should be supplemented or amended from time to time if new subjects are added or if significant changes are made in the plan of investigation.)

(b) A shipment or other delivery of a new drug that is being imported or is offered for importation into the United States shall be exempt from the requirements of section 505(a) of the act if the following conditions are complied with:

(1) The label of such drug bears the statement "Caution: New Drug—Limited by Federal (or United States) law to investigational use"; and

(2) The importer of all such shipments or deliveries is an agent of the foreign exporter residing in the United States or the ultimate consignee, which person has prior to such shipments and deliveries completed and submitted signed copies to the Food and Drug Administration of the "Notice of claimed investigational exemption for a new drug"; and acts as the sponsor of the clinical investigation to assure compli-

ance with the conditions prescribed by paragraph (a) of this section; or

(3) The drug is shipped directly to a scientific institution with adequate facilities and qualified personnel to conduct clinical pharmacology and is intended solely for such use in such institutions and a "Notice of claimed investigational exemption for a new drug" covering this activity has been filed.

(4) Not less than 30 days have elapsed following the date of receipt of the notice by the Food and Drug Administration; and the Food and Drug Administration has not prior, to expiration of such 30-day interval, requested that the sponsor continue to withhold or to restrict use of the drug in human subjects. The 30-day delay requirement may be waived by the Food and Drug Administration upon a showing of good reason for such waiver.

(c) (1) Whenever the Food and Drug Administration has information indicating that an investigator has repeatedly or deliberately failed to comply with the conditions of these exempting regulations outlined in Form FD–1572 or FD–1573 (set forth in paragraph (a) (12) and (13) of this section), or has submitted to the sponsor of the investigation false information in his Form FD–1572 or FD–1573 or in any required report, the Director of the Bureau of Drugs will furnish the investigator written notice of the matter complained of in general terms and offer him an opportunity to explain the matter in an informal conference and/or in writing. If an explanation is offered but not accepted by the Bureau of Drugs, the Commissioner will provide the investigator an opportunity for an informal hearing on the question of whether the investigator is entitled to receive investigational-use drugs, if the hearing is requested within 10 days after receipt of notification that the explanation is not acceptable.

(2) After evaluating all available information, including any explanation and assurance presented by the investigator, if the Commissioner determines that the investigator has repeatedly or deliberately failed to comply with the conditions of the exempting regulations in this section or has repeatedly or deliberately submitted false information to the sponsor of an investigation and has failed to furnish adequate assurance that the conditions of the exemption will be met, the Commissioner will notify the investigator and the sponsor of any investigation in which he has been named as a participant that the investigator is not entitled to receive investigational-use drugs with a statement of the basis for such determination.

(3) Each "Notice of Claimed Investigational Exemption for a New Drug" (Form FD–1571 set forth in paragraph (a) (2) of this section) and each approved new-drug application containing data reported by an investigator who has been determined to be ineligible to receive investigational-use drugs will be examined to determine whether he has submitted unreliable data that are essential to the continuation of the investigation or essential to the approval of any new-drug application.

(4) If the Commissioner determines after the unreliable data submitted by the investigator are eliminated from consideration that the data remaining are inadequate to support a conclusion that it is reasonably safe to continue the investigation, he will notify the sponsor and provide him with an opportunity for a conference and an informal hearing in accordance with paragraph (d) of this section. If an imminent hazard to the public health exists, however, he shall terminate the exemption forthwith and notify the sponsor of the termination. In such event the Commissioner, on request, will afford the sponsor an opportunity for an informal hearing on the question of whether the exemption should be reinstated.

(5) If the Commissioner determines after the unreliable data submitted by the investigator are eliminated from consideration that the data remaining are such that a new-drug application would not have been approved, he will proceed to withdraw approval of the application in accordance with section 505(e) of the act.

(6) An investigator who has been determined to be ineligible may be reinstated as eligible to receive investigational-use drugs when the Commissioner determines that he has presented adequate assurance that he will employ such drugs solely in compliance with the exempting regulations in this section for investigational-use drugs.

(d) If the Commissioner of Food and Drugs finds that:

(1) The submitted "Notice of claimed investigational exemption for a new drug" contains an untrue statement of a material fact or omits material information required by said notice; or

(2) The results of prior investigations made with the drug are inadequate to support a conclusion that it is reasonably safe to initiate or continue the intended clinical investigations with the drug; or

(3) There is substantial evidence to show that the drug is unsafe for the purposes and in the manner for which it is offered for investigational use; or

(4) There is convincing evidence that the drug is ineffective for the purposes for which it is offered for investigational use; or

(5) The methods, facilities, and controls used for the manufacturing, processing, and packing of the investigational drug are inadequate to establish and maintain appropriate standards of identity, strength, quality, and purity as needed for safety and to give significance to clinical investigations made with the drug; or

(6) The plan for clinical investigations of the drugs described under section 10 of the "Notice of claimed investigational exemption for a new drug" is not a reasonable plan in whole or in part, solely for a bona fide scientific investigation to determine whether or not the drug is safe and effective for use; or

(7) The clinical investigations are not being conducted in accordance with the plan submitted in the "Notice of claimed investigational exemption for a new drug"; or

(8) The drug is not intended solely for investigational use, since it is being or is to be sold or otherwise distributed for commercial purposes not justified by the requirements of the investigation; or

(9) The labeling or other informational material submitted for the drug as required by section 7 of the "Notice of claimed investigational exemption for a new drug" or any other labeling of the drug disseminated within the United States by or on behalf of the sponsor fails to contain an accurate description of prior investigations or experience and their results pertinent to the safety and possible usefulness of the drug, including all relevant hazards, contraindications, side-effects, and precautions; or any promotional materials disseminated within the United States by or on behalf of the sponsor contains any representation or suggestion that the drug is safe or that its usefulness has been established for the purposes for which it is offered for investigations; or

(10) The sponsor fails to submit accurate reports of the progress of the investigations with significant findings at intervals not exceeding 1 year; or

(11) The sponsor fails promptly to investigate and inform the Food and Drug Administration and all investigators of newly found serious or potentially serious hazards, contraindications, side-effects, and precautions pertinent to the safety of the new drug;

he shall notify the sponsor and invite his immediate correction or explanation. A conference will be arranged with the Bureau of Drugs if requested. If the Bureau of Drugs does not accept the explanation and/or the correction submitted by the sponsor, the Commissioner will provide the sponsor an opportunity for an informal hearing on the question of whether his exemption should be terminated, if the hearing is requested within 10 days after receipt of notification that the explanation or correction is not acceptable. After evaluating all the available information including any explanation and/or correction submitted by the sponsor, if the Commissioner determines that the exemption should be terminated he shall notify the sponsor of the termination of the exemption and the sponsor shall recall unused supplies of the drug. If at any time the Commissioner concludes that continuation of the investigation presents an imminent hazard to the public health, he shall terminate the exemption forthwith and notify the sponsor of the termination. The Commissioner will inform the sponsor that the exemption is subject to reinstatement on the basis of additional submissions that eliminate such hazard(s) and will afford the sponsor an opportunity for an informal hearing, on request, on the question of whether the exemption should be reinstated. The sponsor shall recall the unused supplies

of the drug upon notification of the termination.

(e) Where drugs were under clinical trial on man on or after August 10, 1962, the sponsor shall, within 30 days after these regulations become effective, submit a list of such investigational drugs, and within 120 days after such effective date shall submit to the Food and Drug Administration the completed "Notice of claimed investigational exemption for a new drug" or a new-drug application. Failure to do so shall automatically terminate the exemption. If any such clinical trials have been discontinued, the sponsor is requested to submit a statement of why the investigation was discontinued.

(f) [Reserved]

(g) A "Notice of Claimed Investigational Exemption for a New Drug" which pertains to a product subject to the licensing provisions of the Public Health Service Act of July 1, 1944 (58 Stat. 682, as amended; 42 U.S.C. 201 et seq.), should be submitted initially to the Director, Bureau of Biologies, 8800 Rockville Pike, Bethesda, MD 20014. Also, amendments of or supplements to such notice, and progress reports, consultations, or other communications with regard to the investigation, should be directed to the Bureau of Biologics, which monitors the development of biological products subject to license under section 351 of the Public Health Service Act. A sponsor for a "Notice of Claimed Investigational Exemption for a New Drug" pertaining to such biologic should substitute in reading this § 312.1 the unit "Bureau of Biologics" for "Food and Drug Administration" and the person "Director, Bureau of Biologics" for "Commissioner" or "Commissioner, Food and Drug Administration," wherever they appear.

(h) Any requirement by this section for the submission of information or data that has been submitted previously may be incorporated by reference.

(i) For requirements regarding certain radioactive drugs, see § 310.503 of this chapter.

NOTE: Order of the Commissioner of Food and Drugs published at 28 FR 183, Jan. 8, 1963, provides as follows:

"That, § 130.3 (28 FR 179) [now § 312.1] shall not apply to radioactive new drugs, until further notice, provided the radioactive new drugs for investigational use are being shipped in complete conformity with the regulations issued by the Atomic Energy Commission."

§ 312.9 New drugs for investigational use in laboratory research animals or in vitro tests.

(a) *New drugs for tests in vitro and in laboratory research animals.* (1) A shipment or other delivery of a new drug intended solely for tests in vitro or in animals used only for laboratory research purposes shall be exempt from section 505(a) of the act if it is labeled as follows:

Caution—Contains a new drug for investigational use only in laboratory research animals, or for tests in vitro. Not for use in humans.

(2) The person or firm shipping new drugs for tests in vitro or in anmials used only for laboratory research purposes under this exemption shall use due diligence to assure that the consignee is regularly engaged in conducting such tests and that the shipment of the new drug will actually be used for tests in vitro or in animals used only for laboratory research.

(3) The person who introduced such shipment or who delivered the drug for introduction into interstate commerce shall maintain adequate records showing the name and post office address of the expert to whom the drug is shipped, date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment and delivery. Upon the request of a properly authorized employee of the Department at reasonable times, he shall make such records available for inspection and copying.

(4) The exemption allowed in this paragraph shall not apply to any new drug intended for in vitro use in the regular course of diagnosing or treating disease, including antibacterial sensitivity discs impregnated with any new drug or drugs, which discs are intended for use in determining susceptibility of micro-organisms to the new drug or drugs.

(b) [Reserved]

(c) *Termination of exemption.* If the Commissioner of Food and Drugs finds that:

(1) The sponsor of the investigation has failed to comply with any of the conditions for the exemption established under this section; or

(2) The continuance of the investigation is unsafe or otherwise contrary to the public interest or the drug is used for purposes other than bona fide scientific investigation; He shall notify the sponsor and invite his immediate correction. A conference will be arranged if requested. If the conditions of the exemption are not immediately met, the Commissioner shall notify the sponsor of the termination of the exemption and the sponsor shall recall or have destroyed the unused supplies of the drug.

Subpart B—Controlled Substances

§ 312.10 Availability of records.

If an investigational drug is subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970, records concerning shipment, delivery, receipt, and disposition of the drug, which are required to be kept by §§ 312.1(a) (4), (12), and (13) and 312.9(a)(3) shall, upon the request of a properly authorized employee of the Drug Enforcement Administration of the U.S. Department of Justice, approved by the Secretary, be made available by the investigator or sponsor to whom the request is made, for inspection and copying.

PART 314—NEW DRUG APPLICATIONS

Subpart A—General Provisions

Sec.
314.1 Applications.
314.6 Amended applications.
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Subpart B—Administrative Actions on Applications

314.100 Comment on applications.
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Subpart D—Evidence

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314.230 Tentative order.
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Subpart F—Judicial Review of Order

314.235 Judicial review.

AUTHORITY: Secs. 502, 503, 505, 701, 52 Stat. 1051, 1052, 1053, 1055, as amended (21 U.S.C. 352, 353, 355, 371) (5 U.S.C. 554), unless otherwise noted.

EFFECTIVE DATE: This Part 314 effective March 29, 1974 except §§ 314.110(d), 314.121, 314.200, 314.235, the introductory text of § 314.115, and the revocation of § 314.201, which are effective April 12, 1974. See 39 FR 9749, March 13, 1974.

Subpart A—General Provisions

§ 314.1 Applications.

(a) Applications to be filed under the provisions of section 505(b) of the act shall be submitted in the form described in paragraph (c) of this section and, if for human use, optionally in the form described in paragraph (d) of this section and assembled as required by paragraph (e) of this section; if the drug is intended for human use and is one for which an abbreviated new application has been found by the Food and Drug Administration to be sufficient, the application may be limited to the information described in paragraph (f) of this section unless otherwise specified in such finding. If any part of the application is in a foreign language, an accurate and complete English translation shall be appended to such part. Translations of

literature printed in a foreign language shall be accompanied by copies of the original publication. The application must be signed by the applicant or by an authorized attorney, agent, or official. If the applicant or such authorized representative does not reside or have a place of business within the United States, the application must also furnish the name and post office address of, and must be countersigned by, an authorized attorney, agent, or official residing or maintaining a place of business within the United States.

(b) Pertinent information may be incorporated in, and will be considered as part of, an application on the basis of specific reference to such information, including information submitted under the provisions of § 312.1 of this chapter, in the files of the Food and Drug Administration; however, any reference to information furnished by a person other than the applicant may not be considered unless use of such information is authorized in a written statement signed by the person who submitted it.

(c) Applications for drugs for human use shall be assembled and submitted in the manner prescribed by paragraph (e) of this section.

(1) [Reserved]

(2) For drugs for human use:

FD-356H—Rev. 1974 : Drugs for Human Use.

Department of Health, Education, and Welfare.
Food and Drug Administration,
5600 Fishers Lane
Rockville, MD 20852

NEW DRUG APPLICATION (Title 21, Code of Federal Regulations, § 314.1)

Name of applicant _____
Address _____
Date _____
Name of drug _____

☐ Original application (regulation § 314.1).
☐ Amendment to original, unapproved application (regulation § 314.6).
☐ Abbreviated application (regulation § 314.1(f)).
☐ Amendment to abbreviated, unapproved application (regulation § 314.6).
☐ Supplement to an approved application (regulation § 314.8).
☐ Amendment to supplement to an approved application.

The undersigned submits this application for a new drug pursuant to section 505(b) of the Federal Food, Drug and Cosmetic Act. It is understood that when this application is approved, the labeling and advertising for the drug will prescribe, recommend, or suggest its use only under the conditions stated in the labeling which is part of this application; and if the article is a prescription drug, it is understood that any labeling which furnishes or purports to furnish information for use or which prescribes, recommends, or suggests a dosage for use of the drug will contain the same information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, any relevant warnings, hazards, contraindications, side effects, and precautions, as that contained in the labeling which is part of this application in accord with § 1.106(b) (21 CFR 1.106(b)). It is understood that all representations in this application apply to the drug produced until an approved supplement to the application provides for a change or the change is made in conformance with other provisions of § 314.8 of the new-drug regulations.

Attached hereto, submitted in the form described in § 314.1(e) of the new-drug regulations, and constituting a part of this application are the following:

1. *Table of contents.* The table of contents should specify the volume number and the page number in which the complete and detailed item is located and the volume number and the page number in which the summary of that item is located (if any).

2. *Summary.* A summary demonstrating that the application is well-organized, adequately tabulated, statistically analyzed (where appropriate), and coherent and that it presents a sound basis for the approval requested. The summary should include the following information: (In lieu of the outline described below and the evaluation described in Item 3, an expanded summary and elevation as outlined in § 314.1(d) of the new-drug regulations may be submitted to facilitate the review of this application.

a. Chemistry.

i. Chemical structural formula or description for any new-drug substance.

ii. Relationship to other chemically or pharmacologically related drugs.

iii. Description of dosage form and quantitative composition.

b. Scientific rationale and purpose the drug is to serve.

c. Reference number of the investigational drug notice(s) under which this drug was investigated and of any notice, new-drug application, or master file of which any contents are being incorporated by reference to support the application.

d. Preclinical studies. (Present all findings including all adverse experiences which may be interpreted as incidental or not drug-related. Refer to date and page number of the investigational drug notice(s) or the volume and page number of this application where complete data and reports appear.)

i. Pharmacology (pharmacodynamics, endocrinology, metabolism, etc.).

ii. Toxicology and pathology: Acute toxicity studies; subacute and chronic toxicity studies; reproduction and teratology studies; miscellaneous studies.

e. Clinical studies. (All material should refer specifically to each clinical investigator and to the volume and page number in the application and any documents incorporated by reference where the complete data and reports may be found.)

i. Special studies not described elsewhere.

ii. Dose-range studies.

iii. Controlled clinical studies.

iv. Other clinical studies (for example, uncontrolled or incompletely controlled studies).

v. Clinical laboratory studies related to effectiveness.

vi. Clinical laboratory studies related to safety.

vii. Summary of literature and unpublished reports available to the applicant.

3. *Evaluation of safety and effectiveness.*

a. Summarize separately the favorable and unfavorable evidence for each claim in the package labeling. Include references to the volume and page number in the application and in any documents incorporated by reference where the complete data and reports may be found.

b. Include tabulation of all side effects or adverse experience, by age, sex, and dosage formulation, whether or not considered to be significant, showing whether administration of the drug was stopped and showing the investigator's name with a reference to the volume and page number in the application and any documents incorporated by reference where the complete data and reports may be found. Indicate those side effects or adverse experiences considered to be drug-related.

4. *Copies of the label and all other labeling to be used for the drug* (a total of 12 copies if in final printed form, 4 copies if in draft form):

a. Each label, or other labeling, should be clearly identified to show its position on, or the manner in which it accompanies, the market package.

b. If the drug is to be offered over the counter, labeling on or within the retail package should include adequate directions for use by the layman under all the conditions for which the drug is intended for lay use or is to be prescribed, recommended, or suggested in any labeling or advertising sponsored by or on behalf of the applicant and directed to the layman. If the drug is intended or offered for uses under the professional supervision of a practitioner licensed by law to administer it, the application should also contain labeling that includes adequate information for all such uses, including all the purposes for which the over-the-counter drug is to be advertised to, or represented for use by, physicians.

c. If the drug is limited in its labeling to use under the professional supervision of a practitioner licensed by law to administer it, its labeling should bear information for use under which such practitioners can use the drug for the purposes for which it is intended, including all the purposes for which it is to be advertised or represented, in accord with § 1.106(b) (21 CFR 1.106(b)). The application should include any labeling for the drug intended to be made available to the layman.

d. If no established name exists for a new-drug substance, the application shall propose a nonproprietary name for use as the established name for the substance.

e. Typewritten or other draft labeling copy may be submitted for preliminary consideration of an application. An application will not ordinarily be approved prior to the submission of the final printed label and labeling of the drug.

f. No application may be approved if the labeling is false or misleading in any particular.

(When mailing pieces, any other labeling, or advertising copy are devised for promotion of the new drug, samples shall be submitted at the time of initial dissemination of such labeling and at the time of initial placement of any such advertising for a prescription drug (see § 310.300 of the new-drug regulations). Approval of a supplemental new-drug application is required prior to use of any promotional claims not covered by the approved application.)

5. *A statement as to whether the drug is (or is not) limited in its labeling and by this application to use under the professional supervision of a practitioner licensed by law to administer it.*

6. *A full list of the articles used as components of the drug.* This list should include all substances used in the synthesis, extraction, or other method of preparation of any new-drug substance, and in the preparation of the finished dosage form, regardless of whether they undergo chemical change or are removed in the process. Each substance should be identified by its established name, if any, or complete chemical name, using structural formulas when necessary for specific identification. If any proprietary preparation is used as a component, the proprietary name should be followed by a complete quantitative statement of composition. Reasonable alternatives for any listed substance may be specified.

7. *A full statement of the composition of the drug.* The statement shall set forth the

name and amount of each ingredient, whether active or not, contained in a stated quantity of the drug in the form in which it is to be distributed (for example, amount per tablet or per milliliter) and a batch formula representative of that to be employed for the manufacture of the finished dosage form. All components should be included in the batch formula regardless of whether they appear in the finished product. Any calculated excess of an ingredient over the label declaration should be designated as such and percent excess shown. Reasonable variations may be specified.

8. *A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drug.* Included in this description should be full information with respect to any new-drug substance and to the new-drug dosage form, as follows, in sufficient detail to permit evaluation of the adequacy of the described methods of manufacture, processing, and packing and the described facilities and controls to determine and preserve the identity, strength, quality, and purity of the drug:

a. A description of the physical facilities including building and equipment used in manufacturing, processing, packaging, labeling, storage, and control operations.

b. A description of the qualifications, including educational background and experience, of the technical and professional personnel who are responsible for assuring that the drug has the safety, identity, strength, quality, and purity it purports or is represented to possess, and a statement of their responsibilities.

c. The methods used in the synthesis, extraction, isolation, or purification of any new-drug substance. When the specifications and controls applied to such substance are inadequate in themselves to determine its identity, strength, quality, and purity, the methods should be described in sufficient detail, including quantities used, times, temperatures, pH, solvents, etc., to determine these characteristics. Alternative methods or variations in methods within reasonable limits that do not affect such characteristics of the substance may be specified.

d. Precautions to assure proper identity, strength, quality, and purity of the raw materials, whether active or not, including the specifications for acceptance and methods of testing for each lot of raw material.

e. Whether or not each lot of raw materials is given a serial number to identify it, and the use made of such numbers in subsequent plant operations.

f. If the applicant does not himself perform all the manufacturing, processing, packaging, labeling, and control operations for any new-drug substance or the new-drug dosage form, his statement identifying each person who will perform any part of such operations and designating the part; and a signed statement from each such person fully describing, directly or by reference, the methods, facilities, and controls in his part of the operation.

g. Method of preparation of the master formula records and individual batch records and manner in which these records are used.

h. The instructions used in the manufacturing, processing, packaging, and labeling of each dosage form of the new drug, including any special precautions observed in the operations.

i. Adequate information with respect to the characteristics of and the test methods employed for the container, closure, or other component parts of the drug package to assure their suitability for the intended use.

j. Number of individuals checking weight or volume of each individual ingredient entering into each batch of the drug.

k. Whether or not the total weight or volume of each batch is determined at any stage of the manufacturing process subsequent to making up a batch according to the formula card and, if so, at what stage and by whom it is done.

l. Precautions to check the actual package yield produced from a batch of the drug with the theoretical yield. This should include a description of the accounting for such items as discards, breakage, etc., and the criteria used in accepting or rejecting batches of drugs in the event of an unexplained discrepancy.

m. Precautions to assure that each lot of the drug is packaged with the proper label and labeling, including provisions for labeling storage and inventory control.

n. The analytical controls used during the various stages of the manufacturing processing, packaging, and labeling of the drug, including a detailed description of the collection of samples and the analytical procedures to which they are subjected. The analytical procedures should be capable of determining the active components within a reasonable degree of accuracy and of assuring the identity of such components. If the article is one that is represented to be sterile, the same information with regard to the manufacturing, processing, packaging, and the collection of samples of the drug should be given for sterility controls. Include the standards used for acceptance of each lot of the finished drug.

o. An explanation of the exact significance of the batch control numbers used in the manufacturing, processing, packaging, and labeling of the drug, including the control numbers that appear on the label of the finished article. State whether these numbers enable determination of the complete manufacturing history of the product. Describe any methods used to permit determination of the distribution of any batch if its recall is required.

p. A complete description of, and data derived from, studies of the stability of the drug, including information showing the suitability of the analytical methods used. Describe any additional stability studies underway or contemplated. Stability data should be submitted for any new-drug substance, for the finished dosage form of the drug in the container in which it is to be marketed, including any proposed multiple-dose container, and if it is to be put into solution at the time of dispensing, for the solution prepared as directed. State the expiration date(s) that will be used on the label to preserve the identity, strength, quality, and purity of the drug until it is used. (If no expiration date is proposed, the applicant must justify its absence.)

q. Additional procedures employed which are designed to prevent contamination and otherwise assure proper control of the product.

(An application may be refused unless it includes adequate information showing that the methods used in, and the facilities and controls used for, the manufacturing, processing, and packaging of the drug are adequate to preserve its identity, strength, quality, and purity in conformity with good manufacturing practice and identifies each establishment, showing the location of the plant conducting these operations.)

9. *Samples of the drug and articles used as components, as follows:* a. The following samples shall be submitted with the application or as soon thereafter as they become available. Each sample shall consist of four identical, separately packaged subdivisions, each containing at least three times the amount required to perform the laboratory test procedures described in the application to determine compliance with its control specifications for identity and assays:

i. A representative sample or samples of the finished dosage form(s) proposed in the application and employed in the clinical investigations and a representative sample or samples of each new-drug substance, as defined in § 310.3(g), of the new-drug regulations, from the batch(es) employed in the production of such dosage form(s).

ii. A representative sample or samples of finished market packages of each dosage form of the drug prepared for initial marketing and, if any such sample is not from a commercial-scale production batch, such a sample from a representative commercial-scale production batch; and a representative sample or samples of each new-drug substance as defined in § 310.3(g) of the new-drug regulations, from the batch(es) employed in the production of such dosage form(s).

iii. A sample or samples of any reference standard and blank used in the procedures described in the application for assaying each new-drug substance and other assayed components of the finished drug: *Provided, however,* That samples of reference standards recognized in the official U.S. Pharmacopeia or The National Formulary need not be submitted unless requested.

b. Additional samples shall be submitted on request.

c. Each of the samples submitted shall be appropriately packaged and labeled to preserve its characteristics, to identify the material and the quantity in each subdivision of the sample, and to identify each subdivision with the name of the applicant and the new-drug application to which it relates.

d. There shall be included a full list of the samples submitted pursuant to Item 9a; a statement of the additional samples that will be submitted as soon as available; and, with respect to each sample submitted, full information with respect to its identity, the origin of any new-drug substance contained therein (including in the case of new-drug substances, a statement whether it was produced on a laboratory, pilot-plant, or full-production scale) and detailed results of all laboratory tests made to determine the identity, strength, quality, and purity of the batch represented by the sample, including assays. Include for any reference standard a complete description of its preparation and the results of all laboratory tests on it. If the test methods used differed from those described in the application, full details of the methods employed in obtaining the reported results shall be submitted.

e. The requirements of Item 9a may be waived in whole or in part on request of the applicant or otherwise when any such samples are not necessary.

f. If samples of the drug are sent under separate cover, they should be addressed to the attention of the Bureau of Drugs and identified on the outside of the shipping carton with the name of the applicant and the name of the drug as shown on the application.

10. *Full reports of preclinical investigations that have been made to show whether or not the drug is safe for use and effective in use.* a. An application may be refused unless it contains full reports of adequate preclinical tests by all methods reasonably applicable to a determination of the safety and effectiveness of the drug under the conditions of use suggested in the proposed labeling.

b. Detailed reports of the preclinical investigations, including all studies made on laboratory animals, the methods used, and the results obtained, should be clearly set forth. Such information should include identification of the person who conducted each investigation, a statement of where the investigations were conducted and where the underlying data are available for inspection.

The animal studies may not be considered adequate unless they give proper attention to the conditions of use recommended in the proposed labeling for the drug such as, for example, whether the drug is for short- or long-term administration or whether it is to be used in infants, children, pregnant women, or women of child-bearing potential.

c. Detailed reports of any pertinent microbiological and in vitro studies.

d. Summarize and provide a list of literature references (if available) to all other preclinical information known to the applicant, whether published or unpublished, that is pertinent to an evaluation of the safety or effectiveness of the drug.

11. *List of investigators.* a. A complete list of all investigators supplied with the drug including the name and post office address of each investigator and, following each name, the volume and page references to the investigator's report(s) in this application and in any documents incorporated by reference, or the explanation of the omission of any reports.

b. The unexplained omission of any reports of investigations made with the new drug by the application, or submitted to him by an investigator, or the unexplained omission of any pertinent reports of investigations or clinical experience received or otherwise obtained by the application from published literature or other sources, whether or not it would bias an evaluation of the safety of the drug or its effectiveness in use, may constitute grounds for the refusal or withdrawal of the approval of an application.

12. *Full reports of clinical investigations that have been made to show whether or not the drug is safe for use and effective in use.* a. An application may be refused unless it contains full reports of adequate tests by all methods reasonably applicable to show whether or not the drug is safe and effective for use as suggested in the labeling.

b. An application may be refused unless it includes substantial evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling.

c. Reports of all clinical tests sponsored by the applicant or received or otherwise obtained by the applicant should be attached. These reports should include adequate information concerning each subject treated with the drug or employed as a control, including age, sex, conditions treated, dosage, frequency of administration of the drug, results of all relevant clinical observations and laboratory examinations made, full information concerning any other treatment given previously or concurrently, and a full statement of adverse effects and useful results observed, together with an opinion as to whether such effects or results are attributable to the drug under investigation and a statement of where the underlying data are available for inspection. Ordinarily, the reports of clinical studies will not be regarded as adequate unless they include reports from more than one independent, competent investigator who maintains adequate case histories of an adequate number of subjects, designed to record observations and permit evaluation of any and all discernible effects attributable to the drug in each individual treated and comparable records on any individuals employed as controls. An application for a combination drug may be refused unless there is substantial evidence that each ingredient designated as active makes a contribution to the total effect claimed for the drug combination. Except when the disease for which the drug is being tested occurs with such infrequency in the United States as to make testing impractical, some of the investigations should be performed by competent investigators within the United States.

d. Attach as a separate section a completed Form FD–1639, Drug Experience Report (obtainable with instructions, on request from the Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20852), for each adverse experience or, if feasible, for each subject or patient experiencing one or more adverse effects, described in item 12c, whether or not full information is available. Form FD–1639 should be prepared by the applicant if the adverse experience was not reported in such form by the investigator. The Drug Experience Report should be cross-referenced to any narrative description included in Item 12c. In lieu of a Form FD–1639, a computer-generated report may be submitted if equivalent in all elements of information with the identical enumerated sequence of events and methods of completion; all formats proposed for such use will require initial review and approval by the Food and Drug Administration.

e. All information pertinent to an evaluation of the safety and effectiveness of the drug received or otherwise obtained by the applicant from any source, including information derived from other investigations or commercial marketing (for example, outside the United States), or reports in the scientific literature, involving the drug that is the subject of the application and related drugs. An adequate summary may be acceptable in lieu of a reprint of a published report which only supports other data submitted. Reprints are not required of reports in designated journals listed in § 310.9 of the new-drug regulations about related drugs; a bibliography will suffice. Include the evaluation of the safety or effectiveness of the drug that has been made by the applicant's medical department, expert committee, or consultants.

f. If the drug is a combination of previously investigated or marketed drugs, an adequate summary of preexisting information from preclinical and clinical investigation and experience with its components, including all reports received or otherwise obtained by the applicant suggesting side effects, contraindications, and ineffectiveness in use of such components. Such summary should include an adequate bibliography of publications about the components and may incorporate by reference information concerning such components previously submitted by the applicant to the Food and Drug Administration.

g. The complete composition and/or method of manufacture of the new drug used in each submitted report of investigation should be shown to the extent necessary to establish its identity, strength, quality, and purity if it differs from the description in Item 6, 7, or 8 of the application.

13. *If this is a supplemental application, full information on each proposed change concerning any statement made in the approved application.*

Observe the provisions of § 314.8 of the new-drug regulations concerning supplemental applications.

(Applicant)

Per ---
(Responsible official or agent)

(Indicate authority)

(Warning: A willfully false statement is a criminal offense, 18 U.S.C. 1001.)

NOTE: This application must be signed by the applicant or by an authorized attorney, agent, or official. If the applicant or such authorized representative does not reside or have a place of business within the United States, the application must also furnish the name and post office address of and must be countersigned by an authorized attorney, agent, or official residing or maintaining a place of business within the United States.

15. The applicant is required to submit an environmental impact analysis report analyzing the environmental impact of the manufacturing process and the ultimate use or consumption of the drug pursuant to § 6.1 of this chapter.

(d) *Optional expanded summary and evaluation.* (1) A summary and evaluation prepared according to the guidelines described in paragraph (d)(2) of this section may be substituted for items 2 and 3 of the new-drug application Form FD–356H (drugs for human use).

(2) The following summary outline covers the elements that are pertinent to an evaluation of the safety and effectiveness of most drugs, but it is recognized that it may not be applicable in detail to all drugs and situations. It is not intended that all items listed must be dealt with irrespective of their applicability. If it is appropriate for other criteria to be covered, they should be included. An explanation of the reason for omission of an item should be given, if not self-evident. An accurate, complete, and concise summary should contribute materially to facilitate the evaluation of the application. When a supplemental application is proposed that requires the submission of substantial preclinical or clinical data, a summary and evaluation of those data are also invited.

SUMMARY AND EVALUATION

A. Chemistry:

1. Chemical structural formula or description for any new-drug substance.

2. Relationship to other chemically or pharmacologically related drugs.

3. Description of dosage form and quantitative composition.

B. Scientific rationale and purpose the drug is to serve.

1. Clinical purpose.

2. Highlights of preclinical studies. The reasons why certain types of studies were done or omitted as related to the proposed conditions of human use and to information already known about this class of compounds. Emphasize any unusual or particularly significant pharmacological effects or toxicological findings.

3. Highlights of clinical studies. The rationale of the clinical study plan showing why types of studies were done, amended, or omitted as related to preclinical studies and prior clinical experience.

4. Conclusions. A short statement of conclusions combining the major points of effectiveness and safety as they relate to the use of the drug.

C. Reference number of the investigational drug notice(s) under which this drug was investigated and of any notice, new-drug application, or master file, any contents of which are being incorporated by reference to support the application.

D. Preclinical studies: All findings should be presented including all adverse reactions which are interpreted as being incidental or

not drug-related. The summaries of the individual tests described hereinafter should include a brief statement of methodology with results and interpretation of the test. Each test should be referenced to the proper page number(s) and volume number of the detailed report or to the table of contents preceding the basic scientific data. Include a table of contents referring by volume and page number(s) to the summary and to the location of the complete data and reports in the application and any documents incorporated by reference.

1. Pharmacology. Studies on pharmacodynamics, endocrinology, etc., as appropriate.

a. Studies of activities related to the primary therapeutic activity.

b. Studies of activities related to secondary therapeutic activity.

c. Studies of miscellaneous pharmacologic activities of the compound that may be considered pertinent to the efficacy or safety of the drug.

d. Metabolism.

i. Absorption.

ii. Tissue distribution.

iii. Detoxification.

iv. Excretion.

2. Toxicology and pathology.

a. Acute toxicity. Summarize by species and route of administration. Give levels and number of animals per dose level with weights, sex, and maturity. In some unusual circumstances, a brief description of the method may be needed. Give LD_{50} values with standard deviation, signs of toxicity, times of deaths, and other pertinent information. It is desirable that species and/or sex differences be pointed out and that the ratio of the oral to parenteral LD_{50}'s be indicated.

b. Subacute and chronic toxicity studies (present by species).

i. Method. Give duration of study, route of administration, dose levels, and method of giving drug (diet, gavage). Include number of animals per dose level and range of weights at initiation. Indicate parameters studied, including pathology.

ii. Results. List pertinent observations, including pathology, with statement that other parameters were not affected. If necessary, indicate which alterations were related to pharmacodynamic activity and which were related to toxicity.

c. Reproduction and teratology studies (present by species).

i. Method. Give dose levels employed and time of drug administration relative to stage of pregnancy. List parameters examined. State method of examination of young.

ii. Results. Describe effect on mother and on the various parameters of pregnancy and the fetus. Discuss relationship of drug doses to the therapeutic and toxic doses.

d. Miscellaneous studies. Include studies designed to explore drug toxicity beyond the more routine acute, subacute, and chronic studies. Studies on tissue irritancy, ciliary motility, etc., and special tests of pharmaceutical formulations should be included.

e. Evaluation of effectiveness and safety. This section should be the final evaluation of effectiveness and safety based upon the known attributes of the new drug in animals.

E. *Clinical studies.* All material should be referenced to the investigator and to the volume and page number of the raw data. Include a table of contents referring by volume and page number(s) to the summary and to the location of the complete data and reports in the application and in any document incorporated by reference.

1. Special studies. Include all studies that do not clearly have applicability elsewhere. If anything is known about absorption, distribution, excretion, and fate of the drug, it should be included here. Correlations with similar animal data should be drawn. Drug studies on circulation, respiration, volunteer extraordinary safety studies, and overdosage effects are examples. Studies of dose findings are not to be included.

2. Dose-range studies (individual and collective analysis). Include for each study:

a. Investigator.

b. Plan.

c. Materials used.

d. Diagnosis.

e. Age and sex of patients and, if applicable:

i. Drug codes.

ii. Control agents.

iii. Statistical methods.

iv. Results, adverse reactions and experience, and other side effects.

3. Controlled clinical studies. A brief description of each giving:

a. Investigator.

b. Detailed design of study: Crossover, double crossover, stratified sample or matched groups, double-blind, single-blind, randomized, etc.

c. Control agents (placebo, reference compounds).

d. Drug codes.

e. Design for selection of control and drug groups.

f. Primary and secondary diagnoses, including severity and stage of disease, of patients in drug and control groups with numbers, sex, and age distribution.

g. Detailed criteria of effectiveness, objective and subjective.

h. A brief description of adverse experiences looked for by the subject or patient and by the investigator. Include laboratory tests and timing of observation.

i. Control and drug periods and kind and number of observations made in each.

j. Adverse reactions and all adverse experience by system and organ, general and local.

k. All results, positive, negative, or inconclusive.

l. Statistical analysis where possible, kind and applicability.

m. Conclusions. Overall conclusions of controlled clinical studies.

4. Other clinical reports. Depending on the nature of the investigation, this could be divided between incompletely controlled studies and reports of uncontrolled use. The presentation of the plan and method of analysis could be governed by the criteria in "3. Controlled clinical studies" and by the situation.

5. Clinical laboratory studies related to effectiveness. A description and summary of results. If applicable, use pre- and post-treatment tables and graphs.

6. Clinical laboratory studies related to safety.

a. The general plan giving the number of studies, duration of therapy, controls, number of control determinations, etc.

b. A description and summary of the results for each study, including all variations irrespective of the significance, the investigator's name (with reference to volume and page number of the raw data), the results of laboratory determinations, the number of patients, the range of normal values for each laboratory and what standardization procedures each laboratory employs. Discuss variations fully and make a judgment of the significance of variations with supporting reasons. Submit explanatory tables and graphs wherever useful.

7. Summary of clinical literature reviewed by applicant. All studies, including controlled studies, that yield data pertinent to safety and effectiveness of the drug and all reports of adverse experience should be abstracted, utilizing the criteria in "3. Controlled clinical studies" under "E. Clinical studies."

8. Overall results and conclusions. This category should combine findings from all categories in this item E (Clinical studies) and present composite, balanced conclusions.

a. Table of all investigators, academic affiliation, number of cases reported and nature of the study (special, controlled, double-blind, single-blind, randomized, or not, etc.). A statement should be made as to why the study was discontinued, if it was, or a statement that it is continuing, if such is the case. (If this information has been submitted elsewhere, it may be incorporated by reference.)

b. Table of age range for all studies giving totals in each age group and number of males and females in each age group.

c. Table of various dosage schedules by duration and number of patients.

d. Effectiveness.

i. Summarize evidence separately for each claim cited in the package circular. Give results by claim either by blending the results of equivalent types of studies done or by citing the results of the other well-done studies separately and then drawing a conclusion.

ii. Include summary tables containing the primary and secondary diagnoses, the number of patients and controls, the dosage schedule, duration, and responses.

e. Safety.

i. Includes tabulations listing all side effects or adverse experience, by age and sex, whether or not the applicant considers them to be significant, showing whether therapy was stopped and showing the investigator's name with a reference to the volume and page number in the application and any documents incorporated by reference where the complete data and reports may be found. Indicate which side effects and adverse experiences are regarded by the applicant as possibly drug-related.

ii. Append the investigator's and the applicant's discussion of the basis for deciding whether or not the adverse experience is drug-related and the significance of possibly drug-related experiences.

f. Overall conclusions about safety and effectiveness.

i. Concisely compare kind and incidence of beneficial experience with kind and incidence of adverse experience found in clinical studies. Tabulate adverse reactions and experiences with percentage of incidence that were derived from studies designed to seek such data, if possible. Concisely state effective and recommended clinical dosage range on a mg./kg. basis and state mg./kg. dosage levels which showed adverse effects in animals and adverse experience in clinical studies.

ii. To the extent known, or from studies by the applicant, concisely compare therapeutic index (effective vs. toxic dosage) and incidence of beneficial and significant adverse effects with related drugs.

iii. Summarize findings with regard to habit-forming or addiction potential, when applicable.

9. Annotated package circular.

a. For each claim or indication, give references supporting it in the summary, or give statements that are in turn referenced to the summary.

b. For each side effect and adverse experience contained in the submitted summaries and raw data, and for each contraindication, warning, and precaution suggested by such data, give references to it in the summary and cite the disclosure contained in the package circular, or explain its omission. Similarly, cite or explain the omission of such additional disclosures based on experience with related drugs.

(e)(1) For drugs for human use, assemble and bind three copies of the original application as follows:

(i) Obtain from the Food and Drug Administration, Bureau of Drugs, 5600 Fishers Lane, Rockville, MD 20852, sufficient folders for binding triplicate copies of the new-drug application. Approximately 2 inches of material may be bound in each folder.

(ii) Bind the original or ribbon copy of the application in a blue folder. This will be copy No. 1 and should be a complete copy.

(iii) Bind an identical copy in a red folder, copy No. 2, and an identical copy in a yellow folder, copy No. 3, except that the individual clinical case reports may be omitted from these copies and the forms FD–1639 may be omitted from copy No. 3.

(iv) Identify each front cover with the name of the applicant and the name of the drug.

(v) Use separate pages or sets of pages for each numbered heading, Items 1 through 12, of the new-drug application Form FD–356H. Arrange the parts as described under paragraph (e) (1) (vii) and (viii) of this section. Number the pages of the new-drug application and include a table of contents. Each copy should bear the same page numbering, except that copies No. 2 and No. 3 will not include the page numbers used for the individual clinical case reports and copy No. 3 will not include the page numbers used for the forms FD–1639.

(vi) The labeling should be distributed in three copies of the application as follows: Two sets of labeling in copy No. 1, one set in copy No. 2, and one set in copy No. 3; if the labeling is in printed form, the remaining eight sets should be submitted unbound.

(vii) Arrange the separate numbered items of a multivolume application (items 1 through 12 of Form FD–356H) in the following sequence. A new volume should be started for each of the following parts marked with an asterisk, and within each part as many volumes should be used as are needed to limit each volume to not more than 2 inches in thickness:

* Cover letter, if any; signed Form FD–356H; items 1 through 7 of the Form FD–356H.
* Manufacturing and sample information (items 8 and 9).
* Animal, toxicological, microbiological, and in vitro data (item 10).
* List of investigators; clinical information other than individual case reports (items 11 and 12).
* Forms FD–1639, Drug Experience Report, to be included in a separate volume in copy No. 1 and copy No. 2 only; cover of volume to be marked "FD–1639" (item 12d).
* Individual clinical case reports, to be included in copy No. 1 only (item 12).

(viii) Number each volume in the lower right-hand corner. Start with the number 1.1 and continue with 1.2, 1.3, 1.4, etc., as needed, until all volumes have been identified as 1.___. Copies No. 1, No. 2, and No. 3 should bear the identical volume numbers, except that the volumes of individual clinical case reports will be omitted from copies No. 2 and No. 3 and the volumes of forms FD–1639 will be omitted from copy No. 3.

(ix) Submit separate applications for each different dosage form of the drug proposed. It is not necessary to repeat in each application basic information pertinent to all dosage forms if reference is made to the application containing such information. Include in each application information applicable to the specific dosage form; such as labeling, composition, stability data, and method of manufacture.

(x) Forward amendments, supplements, reports, and other correspondence submitted after the original application in these folders and this format if they contain sufficient material.

The front cover of these submissions should be identified with the name of the applicant, the name of the drug, and the NDA number, if known. Number the volumes as described in paragraph (e) (1) (viii) of this section, using for each subsequent submission a higher number to the left of the decimal point; for example, a two-volume amendment submitted after the original application would be numbered 2.1 and 2.2, and if a one-volume supplement is then submitted, it would be 3.1. The next submission might be 4.1, 4.2, through 4.23. Submissions consisting of only a few pages will be added to the latest _____1 volume and need not be forwarded as a new volume number.

(2) An incomplete application, or one that has not been submitted in triplicate, will be retained but not filed as an application provided for in section 505(b) of the act. The applicant will be notified in what respects his application is incomplete.

(f) *Abbreviated new-drug applications.* Such applications shall contain:

(1) Satisfactory information of the kinds described in items 1 (table of contents), 4 (label and all other labeling), 5 (R_x or OTC statement), and 6 (components) of the new-drug application Form FD–356H, and in lieu of full information described under items 7 and 8 (composition and methods, facilities, and controls), brief statements that:

(i) Include the composition of the drug, stating the name and amount of each ingredient whether active or not, contained in a stated quantity of the drug in the form in which it is to be distributed.

(ii) Identify the place where the drug will be manufactured, processed, packaged, and labeled and the name of the supplier of the active ingredient(s).

(iii) Identify any person other than the applicant who performs a part of those operations and designate the part.

(iv) Include certifications from the applicant and from any person identified in paragraph (f) (1) (iii) of this section that the methods used in, and the facilities and controls used for, the manufacture, processing, packing, and holding of the drug are in conformity with current good manufacturing practice in accord with Part 133 of this chapter.

(v) Assure that the drug dosage form and components will comply with the specifications and tests described in an official compendium, if such article is recognized therein, or, if not listed or if the article differs from the compendium drug, that the specifications and tests applied to the drug and its components are adequate to assure their identity, strength, quality, and purity.

(vi) Outline the methods used in, and the facilities, and controls used for, the manufacture, processing, and packaging of the drug.

(2) Labeling that is in accord with the labeling conditions described in the finding that an abbreviated new-drug application is sufficient.

(3) If the drug finding so specifies for the formulation intended for marketing, data adequate to assure the biological availability of the drug. For preparations claiming sustained action, timed-release, or other delayed or prolonged effect, such data should show that the drug is available at a rate of release that will be safe and effective.

(4) Any information available to the applicant, including preclinical or clinical data developed by the applicant or by other persons on behalf of the applicant, on adverse effects of the drug that is not reflected in the labeling.

(5) Additional information that may be required for the approval of the application as specified in a written communication from the Food and Drug Administration.

(6) An environmental impact analysis report analyzing the environmental impact of the manufacturing process and ultimate use or consumption of the drug pursuant to § 6.1 of this chapter.

(7) The signature of the applicant or responsible official or agent on a completed form FD–356H.

§ 314.6 Amended applications.

The applicant may submit an amendment to an application that is pending, but in the case of a substantive amendment, the unamended application may be considered as withdrawn and the amended application may be considered resubmitted on the date on which the amendment is received by the Food and Drug Administration. The applicant will be notified of such date.

§ 314.7 Withdrawal of applications without prejudice.

The applicant may at any time withdraw his pending application from consideration as a new-drug application upon written notification to the Food and Drug Administration. Such withdrawal may be made without prejudice to a future filing. Upon resubmission, the time limitation will begin to run from the date the resubmission is received by the Food and Drug Administration. The application itself will be retained by the Food and Drug Administration although it is considered withdrawn, but the applicant shall be furnished a copy at cost, on request.

§ 314.8 Supplemental applications.

(a) (1) After an application is approved, a supplemental application may propose changes. A supplemental application may omit statements made in the approved application concerning which no change is proposed. Each supplemental application shall include up-to-date reports of any of the kinds of information required by § 310.300(a) of

this chapter that has not previously been submitted as part of the application, including such submission under the records and reports requirements of § 310.300 of this chapter or § 310.302 of this chapter. A supplemental application proposing substantial changes which may affect the quality of the human environment shall be accompanied by an environmental impact analysis report pursuant to § 6.1 of this chapter.

(2) A supplemental application should be submitted for any change beyond the variations provided for in the application (including changes in the scale of production, such as from pilot-plant to production batch), that may alter the conditions of use, the labeling, the safety, effectiveness, identity, strength, quality, or purity of the drug or the adequacy of the manufacturing methods, facilities, or controls to preserve them.

(3) Any mailing or promotional piece used after the drug is placed on the market is labeling requiring a supplemental application unless the parts of the labeling furnishing directions, warnings, and information for use of the drug are the same in language and emphasis as labeling approved or permitted, and any other parts of the labeling are consistent with and not contrary to such approved or permitted labeling.

(4) The supplemental application shall be submitted as follows: A communication proposing a change in a new-drug application should provide for no more than one of the following kinds of changes:

(i) Revision in labeling; such as, updating information pertaining to effects, dosages, and side effects and contraindications, which includes information headed side effects, warnings, precautions, and contraindications.

(ii) Addition of claim.

(iii) Revision in manufacturing or control procedures; for example, changes in components, composition, method of manufacture, analytical control procedures, package or tablet size, etc.

(iv) Change in manufacturing facilities.

(v) Provision for outside firm to participate in the preparation, distribution, or packaging of a new drug (new distributor, packer, supplier, manufacturer, etc.); one firm per submission.

Any number of changes may be submitted at any one time; but if they fall into different categories as listed in paragraph (a)(4) (i) through (v) of this section, the proposed changes should be covered by separate communications. Where, however, a change necessitates an overlap in categories, it should be submitted in a single communication. For example, a change in tablet potency would require other changes such as in components, composition, and labeling and should be submitted in a single communication.

(5) The following changes may be placed into effect without the approval of a supplemental application if such change is fully described in the next periodic report required under § 310.300 (b)(4) of this chapter or § 310.302(e) of this chapter or, when such a report is not required, in a written communication to the Food and Drug Administration within 60 days of the effective date of the change(s). This does not apply to a change proposed because of any mixup or any bacteriological or significant chemical, physical, or other change or deterioration in the drug or any failure of one or more distributed batches of the drug to meet its specifications.

(i) A different container size for solid oral dosage forms where container and closure are of the same materials as those provided for in the approved application.

(ii) Change in personnel not involving new facilities.

(iii) Change in equipment that does not alter the method of manufacture of a new drug substance or dosage form of a new drug.

(iv) Change from one commercial batch size to another without any change in manufacturing procedure.

(v) Change to more stringent specification without altering the method described in the approved application.

(vi) Inclusion of additional specifications and methods without deletion of those described in the approved application.

(vii) Alteration of specifications or methods for inactive ingredients to bring them into compliance with new or revised specifications or methods in an official compendium.

(viii) Initiation of a product identification coding system.

(ix) Addition to labeling of a reasonable expiration date, where none was previously used, with related conditions of drug storage when appropriate, except when there is evidence that there has been a significant deterioration of the drug under marketing conditions which necessitates the immediate submission of a report under the provisions of § 310.300(b)(1) of this chapter. The report or written communication describing such change in labeling should include stability data justifying the expiration date and recommended conditions of storage.

(x) Change from paper labels to direct printing on glass containers without a change in text.

(6) Approval of a supplemental application will not be required to provide for an additional distributor to distribute a drug which is the subject of an approved new-drug application if the conditions described below are met prior to putting such a change into effect. An order may issue refusing approval if any condition is not met or if any of the reasons for refusing or withdrawing approval, as stated in section 505 (d) and (e) of the act or § 314.110, applies. For the purposes of maintaining records and making reports under the requirements of §§ 310.300 and 310.302 of this chapter, a distributor provided for under this section shall be considered an "applicant" within the meaning of § 310.300(g) of this chapter.

(i) A supplemental application is furnished to the Food and Drug Administration to provide for a designated distributor.

(ii) There are no changes from the conditions of the approved application except for a different and suitable proprietary name of the drug (if one is used) and the name and address of the distributor as used on the label and labeling. The name of the distributor shall be accompanied by an appropriate qualifying phrase such as "manufactured for" or "distributed by."

(iii) A distributor's statement is furnished to the Food and Drug Administration identifying the category of his operations (for example, wholesaler, retailer) and stating: That he will distribute the drug only under the labeling provided for in the new drug application; that any other labeling or advertising for the drug will prescribe, recommend, or suggest its use only under the conditions stated in the labeling provided for in the application; and, if the drug is a prescription article, that he is regularly and lawfully engaged in the distribution or dispensing of prescription drugs.

(iv) Twelve copies of the printed labels and other labeling to be used by the distributor are submitted, identified with the new-drug application number.

(b) When necessary, for the safety or effectiveness of the drug, a supplemental application shall specify a period of time within which the proposed change will be made.

(c) If a material change is made in the components, composition, manufacturing methods, facilities or controls, or in the labeling or advertising from the representations in an approved application for a new drug (except changes conforming to the conditions set forth in paragraph (a) (5) and (6) and/or paragraphs (d), (e), (f), and (g) of this section) and the drug is marketed before a supplement is approved for such change, approval of the application may be suspended or withdrawn as provided in section 505(e) of the act.

(d) Changes of the following kinds proposed in supplemental new-drug applications should be placed into effect at the earliest possible time:

(1) The addition to package labeling, promotional labeling, and prescription drug advertising of additional warning, contraindication, side-effect, and precaution information.

(2) The deletion from package labeling, promotional labeling, and drug advertising of false, misleading, or unsupported indications for use or claims for effectiveness.

(3) Changes in the methods, facilities, or controls used for the manufacture, processing, packing, or holding of the drug (other than utilization of establishments not covered by the approval that is in effect) that give increased assurance that the drug will have the characteristics of identity, strength, quality, and purity which it purports or is represented to possess.

(4) The addition to the package labeling, promotional labeling, or prescription drug advertisements of information adequate to inform the prescriber of a drug of the findings of a panel of the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, with respect to any claim in the labeling evaluated other than "effective," in accordance with § 3.81 of this chapter.

(e) It will be the policy of the Food and Drug Administration to take no action against a drug or applicant solely because changes of the kinds described in paragraph (d) of this section are placed in effect by the applicant prior to his receipt of a written notice of approval of the supplemental new-drug application: *Provided*, That all the following conditions are met:

(1) The supplemental new-drug application providing a full explanation of the basis for the changes has been submitted, plainly marked on the mailing cover and on the supplement "Special new-drug application supplement—Changes being effected."

(2) The applicant specifically informs the Food and Drug Administration of the date on which such changes are being effected, and submits to the Administration 12 printed copies of any revised labeling to be placed in use, identified with the new-drug application number.

(3) All promotional labeling and all drug advertising are promptly revised consistent with the changes made in the labeling on or within the drug package.

(f) When a supplemental application proposes changes only of the kinds described in paragraph (d) of this section, and the applicant informs the Food and Drug Administration that the changes are being put into effect, such notification will be regarded as an agreement by the applicant to an extension of the time for formal action on the application.

(g) In addition to changes as permitted by paragraphs (d) and (e) of this section, an applicant may place into effect changes proposed in a supplement to a new-drug application that became effective prior to October 10, 1962, upon written notification from the Food and Drug Administration that such action is permitted, without approval of the supplemental application, pending the completion of the review of the effectiveness of such drug by the National Academy of Sciences—National Research Council and a determination as to whether there are grounds for refusing approval under section 505(d) of the act or for invoking section 505(e). It will be the policy of the Food and Drug Administration to take no action against a drug or an applicant solely because changes that have been permitted in a written communication are placed into effect by the applicant prior to his receipt of a written notice of approval of the supplemental new-drug application.

(h) Except as provided in paragraphs (e) and (g) of this section, no provision of this section shall limit the authority of the Secretary or of the Commissioner to suspend or withdraw approval of a new-drug application in accord with the provisions of section 505(e) of the act or to initiate any other regulatory proceedings with respect to a drug or applicant under provisions of the act.

(i) Changes from the conditions of an approved new-drug application in accord with the provisions of paragraphs (d), (e), and (g) of this section are permitted or the basis of a temporary deferral of final action on the supplemental application under the provisions of section 505 (c), (d), or (e) of the act.

(j) When an applicant receives written notification from the Food and Drug Administration, under the provisions of paragraph (g) of this section, that he may place into effect changes proposed in a supplemental application without approval of the supplemental application, he may within 30 days submit a written request that the Food and Drug Administration process the supplemental application. In such case, the change shall not be put into effect until approved. Within 180 days of the receipt of such written request, the Food and Drug Administration will approve the supplemental application or furnish notice of an opportunity for a hearing under the provisions of section 505 (d) or (e), or both, of the act on proposals to refuse the supplemental application or to withdraw approval of the application and supplements thereto.

(k) A supplement to an application that became effective prior to October 10, 1962, may include a written statement to the effect that a temporary deferral of final action under the provisions of paragraphs (d), (e), or (g) of this section is unacceptable to the applicant and that the applicant requests action as provided in section 505(c) of the act. Final action on such supplemental applications will be expedited in accord with applicable provisions of section 505 of the act and regulations in this part and Part 310 of this chapter. In such cases, if the applicant places into effect any of the proposed changes prior to his receipt of a written notice of approval of the supplemental new-drug application, such action may be regarded by the Food and Drug Administration as a basis for invoking the provisions of section 505(e) (4) of the act; that is, the applicant may be furnished notice of an opportunity for a hearing on a proposal to withdraw approval of the application on the grounds that the application contains an untrue statement of a material fact related to the changes from the conditions approved in the application.

§ 314.9 Insufficient information in application.

(a) The information contained in an application may be insufficient to determine whether a drug is safe or effective in use if it fails to include (among other things) a statement showing whether the drug is to be limited to prescription sale and exempt under section 502(f) (1) of the act from the requirement that its labeling bear adequate directions for use. If the drug is to be exempt, the information may also be insufficient if:

(1) The specimen labeling proposed fails to bear adequate information for use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to administer the drug can use the drug for the purposes for which it is intended, including all purposes for which it is to be advertised, or represented, in accordance with § 1.106 (b) or (c) of this chapter, and information concerning hazards, contraindications, side effects, and precautions, relevant with respect to any uses for which the drug is commonly prescribed.

(2) The application fails to show that the labeling and advertising of the drug will offer the drug for use only under those conditions for which it is offered in the labeling that is part of the application.

(3) The application fails to show that all labeling that furnishes or purports to furnish information for use of the drug will contain substantially the same information for use, including indications, effects, dosages, routes, methods, and frequency and duration of adminstration, and any relevant hazards, contraindications, side effects, and precautions, which is contained in the labeling that is part of the application, in accordance with § 1.106 (b) or (c) of this chapter.

(b) The information contained in an application will be considered insufficient to determine whether a drug is safe and effective for use when there is a refusal or failure upon written notice to furnish duly authorized inspectors of the Food and Drug Administration an adequate opportunity to inspect the facilities, controls, and any record pertinent to the application.

§ 314.10 New-drug application approvals; availability of information.

When a new-drug application or a supplement to an approved new-drug application is approved for a drug intended for humans, the approved labeling will be placed on file with the Food and Drug Administration, Office of Public Affairs, 5600 Fishers Lane, Rockville, MD 20852, for review by any person properly and directly concerned. The Press Relations Staff will make available weekly lists of such approved applications and supplements.

§ 314.11 Confidentiality of information contained in new-drug applications.

(a) The Federal Food, Drug, and Cosmetic Act provides. in section 505(b), that any person may file with the Secretary an application with respect to any new drug, which shall include, among other things, a full list of the articles used as components and a full statement of the composition of such drug. These requirements apply to all components or ingredients of a new drug, whether or not they are therapeutically active. Fulfillment of these requirements may be met by submitting a full statement of the chemical or common or usual name and of the quantity of each component or

ingredient of the drug. Such requirements may also be met through the inclusion in the new-drug application of a properly authorized reference to a previous application or other Food and Drug Administration file containing the relevant information.

(b) Section 301(j) of the act makes it an offense to divulge to unauthorized persons any information acquired from a new-drug application concerning any method or process that is a trade secret. Basic manufacturers sometimes submit data to the Food and Drug Administration in the form of so-called master files for the purpose of establishing the safety of ingredients that may be used in new drugs and authorize specified applicants to incorporate by reference such data in support of their applications. Such manufacturers may regard some of the data in such files as trade secrets and request the Food and Drug Administration to treat such information as confidential. The Food and Drug Administration will preserve the confidentiality of such data to the extent that it may properly do so. Because the applicant is legally responsible for the composition of the new drug and all its ingredients and may require information in the master file for judicial or administrative proceedings concerning the drug, the Food and Drug Administration will not withhold such information from the applicant when his need for it arises and he submits a written request for it. The Food and Drug Administration will inform the person who submitted the data of any such requests.

§ 314.12 Untrue statements in application.

Among the reasons why an application may contain an untrue statment of a material fact are:

(a) Differences in:

(1) Conditions of use prescribed, recommended, or suggested by the applicant for the drug from the conditions of such use stated in the application;

(2) Article used as components of the drug from those listed in the application;

(3) Composition of the drug from that stated in the application;

(4) Methods used in, or the facilities and controls used for, the manufacture, processing, or packing of the drug from such methods, facilities, and controls described in the application;

(5) Labeling from the specimens contained in the application;

or

(b) The unexplained omission in whole or in part, from the original application or any amendment or supplement to it, or from any record or report required under the provisions of section 505(j) of the act and § 310.300 of this chapter, of any information obtained from (1) investigations as to safety or effectiveness; or (2) investigations as to identity, strength, quality, or purity of the drug made by the applicant on the drug; or (3) investigations or experience with the drug that is the subject of the application, or any related drug, available to the applicant from any source, if such information is pertinent to an evaluation of the safety, effectiveness, identity, strength, quality, or purity of the drug, when such omission would bias an evaluation of the safety or effectiveness of the drug.

§ 314.13 New drugs with potential for abuse.

When a new-drug application is submitted for a drug which has a stimulant, depressant, or hallucinogenic effect on the central nervous system, if it appears that the drug has a potential for abuse, the Commissioner shall forward that information to the Attorney General of the United States.

Subpart B—Administrative Actions on Applications

§ 314.100 Comment on applications.

(a) After the application has been studied, the applicant will be furnished comment on any apparent deficiencies in the data submitted or on the need for any additional data or changes in the application to facilitate its consideration.

(b) When the description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug appears adequate on its face, but it is not feasible to reach a conclusion as to the safety and effectiveness of the drug solely from consideration of this description, the applicant may be notified that an inspection is required to verify their adequacy.

(c) Withdrawal of an application may be suggested when it is found that additional evidence is required to support a finding that the drug is safe or effective or that the methods, facilities, and controls used in manufacturing, processing, and packing the drug are adequate.

(d) On the basis of preliminary consideration of an application or supplemental application containing typewritten or other draft labeling in lieu of final printed labeling, an applicant may be informed that such application is approvable when satisfactory final printed labeling identical in content to such draft copy is submitted.

§ 314.105 Notification of applicant of approval of application.

If the Commissioner determines that none of the grounds for denying approval specified in section 505(d) of the act applies, the applicant shall be notified in writing that the application is approved and the application shall be approved on the date of the notification.

§ 314.110 Reasons for refusing to file applications.

(a) An application shall not be considered complete and will not be filed as a new-drug application within the meaning of section 505(b) of the act if one or more of the following is the case:

(1) It does not contain complete and accurate English translations of any pertinent part in a foreign language.

(2) Fewer than three copies are submitted.

(3) It is incomplete on its face in that it does not contain all the matter required by section 505(b) (1), (2), (3), (4), (5), and (6) of the act or by the new-drug application form set forth in § 314.1(c).

(4) On its face the information concerning required matter is so inadequate that the application is clearly not approvable.

(5) The drug is to be manufactured, prepared, propagated, compounded, or processed in whole or in part in any State in an establishment that has not been registered or exempted from registration under the provisions of section 510 of the act.

(6) The applicant does not reside or maintain a place of business within the United States and the application has not been countersigned by an attorney, agent, or other representative of the applicant, which representative resides in the United States and has been duly authorized to act on behalf of the applicant and to receive communications on all matters pertaining to the application.

(7) The new drug is a drug subject to licensing under the Public Health Service Act of July 1, 1944 (58 Stat. 682, as amended; 42 U.S.C. 201 et seq.).

(8) The applicant fails to submit an environmental impact analysis report analyzing the environmental impact of the manufacturing process and the ultimate use or consumption of the drug pursuant to § 6.1 of this chapter.

(b) An application that is not considered complete and is not filed will not be accepted as a basis for amendments if a review of the summary required for drugs for human use or other portion of the application shows that it is not a well-organized, coherent document and is so inadequate that it cannot be expeditiously reviewed on the basis of an amendment. In such circumstances, the applicant will be notified that he will be required to submit a new, complete new-drug application without reference to the previous submission.

(c) The applicant will be promptly notified of such nonacceptance and the reason therefor and, in case of incompleteness or inadequacy as to matter required by any clause of section 505(b) of the act or of the new-drug application form, such clause shall be specified. Otherwise, the date on which an application is received will be considered to be the date on which such application is filed, and the applicant will be notified of such date.

(d) If an applicant disputes the finding that his application is incomplete or inadequate, he may make written request to file the application over protest. In such case, the application shall be reevaluated, and within 60 days of the date of receipt of such written request, or such additional period as may be agreed upon by the parties, the application shall be approved, or the applicant shall be given written notice of an opportunity for a hearing on the question whether the application is approvable.

§ 314.111 Refusal to approve the application.

(a) If the Commissioner determines upon the basis of the application, or upon the basis of other information before him with respect to the new drug, that:

(1) The investigations, reports of which are required to be submitted pursuant to section 505(b) of the act, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; or

(2) The result of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; or

(3) The methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; or

(4) Upon the basis of the information submitted to the Food and Drug Administration as part of the application, or upon the basis of any other information before it with respect to such drug, it has insufficient information to determine whether such drug is safe for use under such conditions; or

(5) (i) Evaluated on the basis of information submitted as part of the application and any other information before the Food and Drug Administration with respect to such drug, there is lack of substantial evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling.

(ii) The following principles have been developed over a period of years and are recognized by the scientific community as the essentials of adequate and well-controlled clinical investigations. They provide the basis for the determination whether there is "substantial evidence" to support the claims of effectiveness for "new drugs" and antibiotic drugs.

(*a*) The plan or protocol for the study and the report of the results of the effectiveness study must include the following:

(*1*) A clear statement of the objectives of the study,

(2) A method of selection of the subjects that (*i*) Provides adequate assurance that they are suitable for the purposes of the study, diagnostic criteria of the condition to be treated or diagnosed, confirmatory laboratory tests where appropriate, and, in the case of prophylactic agents, evidence of susceptibility and exposure to the condition against which prophylaxis is desired.

(*ii*) Assigns the subjects to test groups in such a way as to minimize bias.

(*iii*) Assures comparability in test and control groups of pertinent variables, such as age, sex, severity, or duration of disease,, and use of drugs other than the test drug.

(*3*) Explains the methods of observation and recording of results, including the variables measured, quantitation, assessment of any subjects response, and steps taken to minimize bias on the part of the subject and observer.

(*4*) Provides a comparison of the results of treatment or diagnosis with a control in such a fashion as to permit quantitative evaluation. The precise nature of the control must be stated and an explanation given of the methods used to minimize bias on the part of the observers and the analysts of the data. Level and methods of "blinding," if used, are to be documented. Generally, four types of comparison are recognized:

(*i*) No treatment: Where objective measurements of effectiveness are available and placebo effect is negligible, comparison of the objective results in comparable groups of treated and untreated patients.

(*ii*) Placebo control: Comparison of the results of use of the new drug entity with an inactive preparation designed to resemble the test drug as far as possible.

(*iii*) Active treatment control: An effective regimen of therapy may be used for comparison, e.g., where the condition treated is such that no treatment or administration of a placebo would be contrary to the interest of the patient.

(*iv*) Historical control: In certain circumstances, such as those involving diseases with high and predictable mortality (acute leukemia of childhood), with signs and symptoms of predictable duration or severity (fever in certain infections), or in case of prophylaxis, where morbidity is predictable, the results of use of a new drug entity may be compared quantitatively with prior experience historically derived from the adequately documented natural history of the disease or condition in comparable patients or populations with no treatment or with a regimen (therapeutic, diagnostic, prophylactic) the effectiveness of which is established.

(*5*) A summary of the methods of analysis and an evaluation of data derived from the study, including any appropriate statistical methods.

Provided, however, That any of the above criteria may be waived in whole or in part, either prior to the investigation or in the evaluation of a completed study, by the Director of the Bureau of Drugs with respect to a specific clinical investigation; a petition for such a waiver may be filed by any person who would be adversely affected by the application of the criteria to a particular clinical investigation; the petition should show that some or all of the criteria are not reasonably applicable to the investigation and that alternative procedures can be, or have been, followed, the results of which will or have yielded data that can and should be accepted as substantial evidence of the drug's effectiveness. A petition for a waiver shall set forth clearly and concisely the specific provision or provisions in the criteria from which waiver is sought, why the criteria are not reasonably applicable to the particular clinical investigation, what alternative procedures, if any, are to be, or have been, employed, what results have been obtained, and the basis on which it can be, or has been, concluded that the clinical investigation will or has yielded substantial evidence of effectiveness, notwithstanding nonconformance with the criteria for which waiver is requested.

(*b*) For such an investigation to be considered adequate for approval of a new drug, it is required that the test drug be standardized as to identity, strength, quality, purity, and dosage form to give significance to the results of the investigation.

(*c*) Uncontrolled studies or partially controlled studies are not acceptable as the sole basis for the approval of claims of effectiveness. Such studies, carefully conducted and documented, may provide corroborative support of well-controlled studies regarding efficacy and may yield valuable data regarding safety of the test drug. Such studies will be considered on their merits in the light of the principles listed here, with the exception of the requirement for the comparison of the treated subjects with controls. Isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered.

(6) Based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; or

(7) The applicant fails to submit an environmental impact analysis report analyzing the environmental impact of the manufacturing process and the ultimate use or consumption of the drug pursuant to § 6.1 of this chapter.

the Commissioner shall within 180 days after the filing of the application inform the applicant in writing of his intention to issue a notice of hearing on a proposal to refuse to approve the application.

(b) Unless by the 30th day following the date of issuance of the letter informing the applicant of the intention to issue a notice of hearing, the applicant:

(1) Withdraws the application; or

(2) Waives the opportunity for a hearing; or

(3) Agrees with the Commissioner on an additional period to precede issuance of such notice of hearing;

the Commissioner shall expeditiously notify the applicant of an opportunity for a hearing on the question of whether such application is approvable as provided in § 314.200.

§ 314.115 Withdrawal of approval of an application.

The Commissioner shall notify the person holding an approved new drug application, and all other persons who manufacture or distribute identical, related, or similar drug products as defined in § 310.6 of this chapter, and afford an opportunity for a hearing on a proposal to withdraw approval of the application as provided in section 505(e) of the act and in accordance with the procedure in §§ 314.200 to 314.232, inclusive, if:

(a) The Secretary has suspended the approval of such application on a finding that there is an imminent hazard to the public health; or

(b) The Commissioner finds:

(1) That clinical or other experience, tests, or other scientific data show that the drug is unsafe for use under the conditions of use upon the basis of which the application was approved; or

(2) That new evidence of clinical experience, not contained in the application or not available to the Food and Drug Administration until after the application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when the application was approved, evaluated together with the evidence available when the application was approved, reveal that the drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or

(3) Upon the basis of new information before the Food and Drug Administration with respect to the drug, evaluated together with the evidence available when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof (the provisions of § 314.111(a)(5) apply to the meaning of "substantial evidence" as used in this subparagraph); or

(4) That the application contains any untrue statement of a material fact;

or

(c) The Commissioner finds:

(1) That the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under section 505(j) of the act and of § 310.300 of this chapter, or that the applicant has refused to permit access to, or copying or verification of, such records as required; or

(2) That on the basis of new information before the Food and Drug Administration, evaluated together with the evidence available when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity; or

(3) That on the basis of new information before the Food and Drug Administration, evaluated together with the evidence available when the application was approved, the labeling of the drug, based on a fair evaluation of all material facts, is false or misleading in any particular; and that the matter complained of was not corrected by the applicant within a reasonable time after his receipt of written notice from the Commissioner specifying the matter complained of.

(4) That the applicant has failed to comply with the notice requirements of section 510(j)(2) of the act.

(d) Any hearing following summary suspension on a finding of imminent hazard to health shall be afforded promptly and shall proceed on an expedited basis.

§ 314.116 Notice of withdrawal of approval of application.

Where approval of a new-drug application is withdrawn by the Commissioner, he will give appropriate public notice of such action by publication in the FEDERAL REGISTER.

§ 314.120 Revocation of order refusing to approve application, or suspending or withdrawing approval of an application.

The Commissioner, upon his own initiative or upon request of an applicant stating reasonable grounds therefor, may, if he finds that the facts so require, issue an order approving an application concerning which an approval has previously been refused, suspended, or withdrawn.

§ 314.121 Notices and orders.

Notices and orders under this part and section 505 of the act pertaining to new drug applications, including related, similar, and identical drug products as defined in § 310.6 of this chapter, old drug monographs, and related matters, shall be provided to applicants, parties to a hearing, and interested persons, as follows:

(a) To any person who has submitted a new drug application, by delivering the notice or order in person or by sending it by registered or certified mail to the last address shown in the new drug application.

(b) To any person who has not submitted a new drug application but who is subject to a notice or order pursuant to § 310.6 or § 330.10 or Part 328 of this chapter by publication of the notice or order in the FEDERAL REGISTER.

(c) To any person who is a party to or a participant in a hearing, by delivering the notice or order in person, or by sending it by registered or certified mail, to the last address shown in the records of the proceeding.

§ 314.200 Notice of opportunity for hearing; notice of appearance and request for hearing; grant or denial of hearing.

(a) The notice to the applicant, and to all other persons who manufacture or distribute identical, related, or similar drug products as defined in § 310.6 of this chapter, of an opportunity for a hearing on a proposal by the Director of the Bureau of Drugs to refuse to approve an application or to withdraw the approval of an application will state the reasons for his action and the grounds upon which he proposes to issue his order.

(1) Such notice may be general (i.e., simply summarizing in a general way the information resulting in the notice) or specific (i.e., either referring to specific requirements in the statute and regulations with which there is a lack of compliance, or providing a detailed description and analysis of the specific facts resulting in the notice).

(2) The notice will be published in the FEDERAL REGISTER and will state that the applicant, and other persons subject to the notice pursuant to § 310.6 of this chapter, has 30 days after the date of publication of the notice within which he is required to file a written notice of appearance and request for hearing if he elects to avail himself of the opportunity for a hearing. The failure to file such a written notice of appearance and request for hearing within that 30 days constitutes an election by the applicant, and other persons subject to the notice pursuant to § 310.6 of this chapter, not to avail himself of the opportunity for a hearing.

(3) It is the responsibility of every manufacturer or distributor of a drug product to review every notice of opportunity for hearing published in the FEDERAL REGISTER to determine whether it covers any drug product he manufactures or distributes. Any person may request an opinion of the applicability of such a notice to a specific product he manufactures or distributes that may be identical, related, or similar by writing to the Food and Drug Administration, Bureau of Drugs, Office of Compliance, HFD–300, 5600 Fishers Lane, Rockville, MD 20852. If such an opinion is requested, the time for filing an appearance and request for hearing and supporting studies and analyses shall begin as of the date or receipt of the opinion from the Food and Drug Administration.

(b) The notice of opportunity for hearing shall be provided to applicants and to other persons subject to the notice pursuant to § 310.6 of this chapter:

(1) To any person who has submitted a new drug application, by delivering the notice in person or by sending it by registered or certified mail to the last address shown in the new drug application.

(2) To any person who has not submitted a new drug application but who is subject to the notice pursuant to § 310.6 of this chapter, by publication of the notice in the FEDERAL REGISTER.

(c)(1) If the applicant, or any other person subject to the notice pursuant to § 310.6 of this chapter, elects to avail himself of the opportunity for a hearing, he shall file (i) within 30 days after the date of the publication of the notice (or of the date of receipt of an opinion requested pursuant to paragraph (a)(3) of this section) a written notice of appearance and request for hearing, and (ii) within 60 days after the date of publication of the notice, unless a dif-

ferent period of time is specified in the notice of opportunity for hearing, the studies on which he relies to justify a hearing as specified in paragraph (d) of this section.

(2) All data and information (including all protocols and underlying raw data) shall be included in full and may not be incorporated by reference, except that the raw data underlying a study submitted may be incorporated by reference from a prior submission as part of a new drug application or other report. A copy of any article cited shall be included. If any part of the submission is in a foreign language, an accurate and complete English translation shall be appended to such part. Translations of literature printed in a foreign language shall be accompanied by the original publication.

(3) All submissions required by paragraphs (c), (d), or (e) shall be in quintuplicate and filed with the Hearing Clerk, Food and Drug Administration, Room 6-86, 5600 Fishers Lane, Rockville, MD 20852.

(4) No data or analysis submitted after such 60 days will be considered in determining whether a hearing is warranted unless they are derived from well-controlled studies begun prior to the date of the notice of opportunity for hearing, the results of which were not in existence during that 60 days. Exceptions may be made on the basis of a showing of inadvertent omission and hardship. All studies in progress, the results of which the person requesting the hearing intends later to submit in support of the request for hearing, shall be listed. A copy of the complete protocol, a list of the participating investigators, and a brief status report of the studies shall be included in the submission made pursuant to paragraph (c) (1) (ii) of this section.

(5) Any other interested person who is not subject to the notice of opportunity for hearing may also submit comments on the proposal to withdraw approval of the new drug application. Such comments shall be submitted within the time and pursuant to the requirements specified in this section.

(d) A request for hearing shall be supported by a submission as specified in paragraph (c) (1) (ii) of this section containing the studies (including all protocols and underlying raw data) on which the person relies to justify a hearing with respect to his drug product.

(1) If effectiveness is at issue, a request for hearing shall be supported only by adequate and well-controlled clinical studies meeting all of the precise requirements of § 314.111(a) (5) and, for combination drug products, § 3.86 of this chapter, or by other studies not meeting those requirements for which a waiver has been previously granted by the Food and Drug Administration pursuant to the provisions of § 314.111(a) (5). All adequate and well-controlled clinical studies on the drug product known to the person requesting the hearing shall be submitted. Any unfavorable analyses, views, or judgments with respect to such studies known to such person shall also be submitted. No other data, information, or studies shall be submitted.

(2) Such submission shall include a factual analysis of all studies submitted. If effectiveness is at issue, such analysis shall specify how each such study accords, on a point-by-point basis, with each criterion required for an adequate well-controlled clinical investigation established in § 314.111(a) (5) and, if the product is a combination drug product, with each of the requirements for a combination drug established in § 3.86 of this chapter, or shall be accompanied by an appropriate waiver previously granted by the Food and Drug Administration. If a study deals with a drug entity or dosage form, or condition of use, or mode of administration other than the one(s) in question, such fact(s) shall be clearly stated. Any study conducted on the final marketed form of the drug product shall be so designated.

(3) Such analysis shall be submitted in the following format, except that the required information relating either to safety or to effectiveness shall be omitted if the notice of opportunity for hearing does not raise any issue with respect to that aspect of the drug; and information on compliance with § 3.86 shall be omitted if the drug product is not a combination drug product. Submissions not made in this format or not containing the required analyses will not be considered and will result in denial of a hearing, except that minor technical deficiencies may be excused if it is apparent that a good faith attempt has been made to comply with the requirements of this section and any deficiencies noted are immediately corrected upon request.

I. Safety data.
A. Animal safety data.
1. Individual active component(s).
a. Controlled studies.
b. Partially controlled or uncontrolled studies.
2. Combinations of the individual active components.
a. Controlled studies.
b. Partially controlled or uncontrolled studies.
B. Human safety data.
1. Individual active component(s).
a. Controlled studies.
b. Partially controlled or uncontrolled studies.
c. Documented case reports.
d. Pertinent marketing experiences that may influence a determination as to the safety of each individual active component.
2. Combinations of the individual active components.
a. Controlled studies.
b. Partially controlled or uncontrolled studies.
c. Documented case reports.
d. Pertinent marketing experiences that may influence a determination as to the safety of combinations of the individual active components.
II. Effectiveness data.
A. Individual active components: Controlled studies, with an analysis showing clearly how each such study satisfies, on a point-by-point basis, each of the criteria required by § 314.111(a) (5).
B. Combinations of individual active components.
1. Controlled studies, with an analysis showing clearly how such study satisfies, on a point-by-point basis, each of the criteria required by § 314.111(a) (5).
2. An analysis showing clearly how each requirement of § 3.86 of this chapter has been satisfied.
III. A summary of the data and views setting forth the medical rationale and purpose for the drug and its ingredients and the scientific basis for the conclusion that the drug and its ingredients have been proven safe and/or effective for the intended use. If there is an absence of controlled studies in the material submitted, or the requirements of any element of § 3.86 of this chapter or § 314.111 (a) (5) have not been fully met, such fact(s) shall be clearly stated, and a waiver obtained pursuant to § 314.111(a) (5) shall be enclosed.
IV. A statement signed by the person responsible for such submission, that it includes in full (or incorporates by reference as permitted in § 314.200(c) (2)) all studies and information specified in § 314.200(d). (Warning: A willfully false statement is a criminal offense, 18 U.S.C. 1001).

(e) A notice of opportunity for hearing encompasses all issues relating to the legal status of the drug product(s) subject to it, including identical, related, and similar drug products as defined in § 310.6 of this chapter. Any contention that any such product is not a new drug because it is generally recognized as safe and effective within the meaning of section 201(p) of the act, or because it is exempt from part or all of the new drug provisions of the act pursuant to the exemption for products marketed prior to June 25, 1938, contained in section 201 (p) of the act, or pursuant to section 107 (c) of the Drug Amendments of 1962, or for any other reason shall be stated in a notice of appearance and request for hearing pursuant to paragraph (c) (1) (i) of this section and supported by a submission pursuant to paragraph (c) (1) (ii) of this section and shall be the subject of an administrative determination by the Commissioner. The failure of any person subject to a notice of opportunity for a hearing, including any person who manufactures or distributes an identical, related, or similar drug product as defined in § 310.6 of this chapter, to submit a notice of appearance and request for hearing or to raise all such contentions on which he relies shall constitute a waiver of any such contentions not so raised.

(1) A contention that a drug product is generally recognized as safe and effective within the meaning of section 201 (p) of the act must be supported by submission of the same quantity and quality of scientific evidence as is required to obtain approval of a new drug application for the product, unless a waiver has been obtained from such requirement for effectiveness (as provided in § 314.111(a) (5)) and/or safety for good cause shown. Such submission shall be in the format and with the analyses required by paragraph (d) of this section. The failure to submit such scientific evidence or a submission that is not in the format or does not contain the analyses required by paragraph (d) of this section shall constitute a waiver of any such contention.

General recognition of safety and effectiveness shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data and information.

(2) A contention that a drug product is exempt from part or all of the new drug provisions of the act pursuant to the exemption for products marketed prior to June 25, 1938 contained in section 201 (p) of the act, or pursuant to section 107 (c) of the Drug Amendments of 1962, shall be supported by submission of evidence of past and present quantitative formulas, labeling, and evidence of marketing, on which reliance is made for such contention. The failure to submit such formulas, labeling, and evidence of marketing in the following format shall constitute a waiver of any such contention.

I. Formulation.

A. A copy of each pertinent document or record to establish the exact quantitative formulation of the drug (both active and inactive ingredients) on the date of initial marketing of the drug.

B. A statement whether such formulation has at any subsequent time been changed in any manner. If any such change has been made, the exact date, nature, and rationale for each change in formulation, including any deletion or change in the concentration of any active ingredient and/or inactive ingredient, shall be submitted, together with a copy of each pertinent document or record to establish the date and nature of each such change including but not limited to the formula which resulted from each such change. If no such change has been made, a copy of representative documents or records showing the formula at representative points in time shall be submitted to support the statement.

II. Labeling.

A. A copy of each pertinent document or record to establish the identity of each item of written, printed, or graphic matter used as labeling on the date the drug was initially marketed.

B. A statement whether such labeling has at any subsequent time been discontinued or changed in any manner. If such discontinuance or change has been made, the exact date, nature, and rationale for each discontinuance or change and a copy of each pertinent document or record to establish each such discontinuance or change shall be submitted, including but not limited to the labeling which resulted from each such discontinuance or change. If no such discontinuance or change has been made, a copy of representative documents or records showing labeling at representative points in time shall be submitted to support the statement.

III. Marketing.

A. A copy of each pertinent document or record to establish the exact date the drug was initially marketed.

B. A statement whether such marketing has at any subsequent time been discontinued. If such marketing has been discontinued, the exact date of each such discontinuance shall be submitted, together with a copy of each pertinent document or record to establish each such date.

IV. Verification.

A statement signed by the person responsible for such submission, that all appropriate records have been searched and to the best of his knowledge and belief it includes a true and accurate presentation of the facts (Warning: A willfully false statement is a criminal offense, 18 U.S.C. 1001).

(3) No drug product, including any active ingredient, which is identical, related, or similar, as defined in § 130.40, to a drug product, including any active ingredient, for which a new drug application is or at any time has been effective or deemed approved, or approved under section 505 of the act, will be determined to be exempt from part or all of the new drug provisions of the act.

(4) A contention that a drug product is not a new drug for any other reason must be supported by submission of such factual records, data, and information as is necessary and appropriate to support such contention.

(5) It is the responsibility of every person who manufactures or distributes a drug product in reliance upon a "grandfather" provision(s) of the act to maintain in his files, organized as required by this paragraph, the data and information necessary fully to document and support such status.

(f) Upon receipt of any request for hearing, the Director of the Bureau of Drugs shall prepare an analysis of the request and a proposed order ruling upon the matter. The analysis and proposed order, the request for hearing, and any proposed order denying a hearing and response pursuant to paragraph (g) (2) or (3) of this section, shall be submitted to the office of the Commissioner for independent review and decision. No representative of the Bureau of Drugs shall participate or advise in the review and decision by the Commissioner. The office of the General Counsel shall observe the same separation of functions.

(g) A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing with respect to the particular drug product(s) specified in the request for hearing.

(1) Where a specific notice of opportunity for hearing as defined in paragraph (a) (1) of this section) is used, it shall state that, if it conclusively appears from the face of the data, information, and factual analyses in the request for the hearing that there is no genuine and substantial issue of fact which precludes the refusal to approve the application or the withdrawal of approval of the application, e.g., no adequate and well-controlled clinical investigations meeting each of the precise elements of § 314.111(a)(5) and, for a combination drug product, § 3.86 of this chapter, showing effectiveness have been identified, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner will enter summary judgment against the person(s) who requests the hearing, making findings and conclusions, denying a hearing. Any such order entering summary judgment shall set forth the Commissioner's findings and conclusions in detail and shall specify why each study submitted fails to meet the requirements of the statute and regulations or why the request for hearing does not raise a genuine and substantial issue of fact or shall specify the requirements of this section with respect to format or analyses with which there is a lack of compliance.

(2) Where a general notice of opportunity for hearing (as defined in paragraph (a) (1) of this section) is used and the Director of the Bureau of Drugs concludes that summary judgment against the person(s) requesting a hearing should be considered, he shall serve upon such person(s) by registered mail a proposed order denying a hearing. Such person(s) shall have 60 days after receipt of such proposed order to respond with sufficient data, information, and analyses to demonstrate that there is a genuine and substantial issue of fact which justifies a hearing.

(3) Where a general or specific notice of opportunity for hearing is used and the person(s) requesting a hearing submits data or information of a type required by the statute and regulations, and the Director of the Bureau of Drugs concludes that summary judgment against such person(s) should be considered, he shall serve upon such person(s) by registered mail a proposed order denying a hearing. Such person(s) shall have 60 days after receipt of such proposed order to respond with sufficient data, information, and analyses to demonstrate that there is a genuine and substantial issue of fact which justifies a hearing.

(4) If review of the data, information, and analyses submitted warrants the conclusion that the ground(s) cited in the notice are not valid, e.g., that substantial evidence of effectiveness exists, the Commissioner shall deny the hearing, enter summary judgment for the person(s) requesting the hearing, and rescind the notice of opportunity for hearing.

(5) If a hearing is requested and is justified, the Commissioner will issue a written notice defining the issues, naming an administrative law judge, and specifying the time and place at which the hearing will commence, which shall be no more than 90 days after the expiration of such 30 days unless the parties otherwise agree in the case of denial of approval, and as soon as practicable in the case of withdrawal of approval.

(6) A hearing shall be granted if there exists a genuine and substantial issue of fact or if the Commissioner concludes, in his discretion, that a hearing would otherwise be in the public interest.

(7) If the manufacturer or distributor of a drug product that may be an identical, related, or similar drug product requests and is granted a hearing, the issue whether the product is in fact identical, related, or similar to the drug subject to new drug application is properly encompassed within the hearing.

(8) A request for hearing, and any subsequent grant or denial of a hearing, shall be applicable only to the particular drug product(s) named in such documents.

(h) Any hearing will be open to the public except that any portion of the

hearing concerning a method or process that the Commissioner finds is entitled to protection as a trade secret pursuant to section 301(j) of the act (21 U.S.C. 331(j)) or 18 U.S.C. 1905 will not be open to the public unless the respondent specifies otherwise in his appearance. All persons who have requested a hearing pursuant to paragraph (a) of this section and for whom a hearing has been granted pursuant to paragraph (g) of this section shall be parties to the hearing. Interested persons who are not parties may appear at and participate in a hearing and shall have the right to present evidence and file pleadings relevant to the issues. Such interested persons may otherwise participate, e.g., cross-examine witnesses, when in the judgement of the Administrative Law Judge their interests are not adequately protected otherwise or it is required for a full and true disclosure of the facts.

(i) Any drug product subject to a notice of opportunity for hearing, including any identical, related, or similar drug product as defined in § 310.6 of this chapter, for which an opportunity for a hearing is waived or for which a hearing is denied shall promptly be the subject of a notice withdrawing the new drug application approval and declaring all such products unlawful. The Commissioner may, in his discretion, defer or stay such action pending a ruling on any related request for a hearing or pending any related hearing or other administrative or judicial proceeding.

§ 314.201 [Revoked]

§ 314.202 Appearance of applicant.

If the applicant elects to avail himself of the opportunity for the hearing, he may appear in person or by counsel. If the applicant desires to be heard through counsel, the counsel will file with the Administrative Law Judge a written appearance.

§ 314.203 Administrative Law Judge.

The hearing will be conducted by an Administrative Law Judge appointed as provided in the Administrative Procedure Act (60 Stat. 235; 5 U.S.C. 551 et seq.) and designated for conducting the hearing. Any such designation may be made or revoked by the Commissioner at any time. Hearings will be conducted in an informal but orderly manner in accordance with these regulations and the requirements of the Administrative Procedure Act. The Administrative Law Judge will have the power to administer oaths and affirmations, to rule upon offers of proof and the admissibility of evidence, to receive relevant evidence, to examine witnesses, to regulate the course of the hearing, to hold conferences for the simplification of the issues, and to dispose of procedural requests, but will not have the power to decide any motion that involves final determination of the merits of the proceeding.

§ 314.204 Prehearing and other conferences.

The Administrative Law Judge, on his own motion or on the motion of the applicant or the Food and Drug Administration, may direct all parties or their representatives to appear at a specified time and place for a conference to consider:

(a) The simplification of the issues.

(b) The possibility of obtaining stipulations, admissions of facts, and documents.

(c) The limitation of the number of expert witnesses.

(d) The scheduling of witnesses to be called.

(e) The advance submission of all documentary evidence.

(f) Such other matters as may aid in the disposition of the proceeding.

The Administrative Law Judge will make an order reciting the action taken at the conference, the agreements made by the parties or their representatives, and the schedule of witnesses, and limiting the issues for hearing to those not disposed of by admissions or agreements. Such order will control the subsequent course of the proceeding unless modified for good cause by subsequent order. The Administrative Law Judge may also direct all parties and their representatives to appear at conferences at any time during the hearing with a view to simplification, clarification, or shortening the hearing.

§ 314.205 Transcript of the testimony.

Testimony given at a hearing shall be reported verbatim. All written statements, charts, tabulations, and similar data offered in evidence at the hearing shall be marked for identification and, upon a showing satisfactory to the Administrative Law Judge of their authenticity, relevancy, and materiality, shall be received in evidence subject to section 7(c) of the Administrative Procedure Act (5 U.S.C. 556(d)). Exhibits shall, if practicable, be submitted in quintuplicate. In case the required number of copies are not made available, the Administrative Law Judge shall exercise his discretion as to whether said exhibit shall be read in evidence or whether additional copies shall be required to be submitted within a time to be specified by the Administrative Law Judge. Where the testimony of a witness refers to a statute, or to a report or document, the Administrative Law Judge shall, after inquiry relating to the identification of such statute, report, or document, determine whether the same shall be produced at the hearing and physically be made a part of the evidence or shall be incorporated in the record by reference. Where relevant and material matter offered in evidence is embraced in a report or document containing immaterial and irrelevant matter, such immaterial and irrelevant matter shall be excluded and shall be segregated insofar as practicable, subject to the direction of the Administrative Law Judge.

§ 314.206 Oral and written arguments.

(a) Unless the Administrative Law Judge shall issue an announcement at the hearing authorizing oral argument before him, it shall not be permitted.

(b) The Administrative Law Judge shall announce at the hearing a reasonable period within which the parties or their representatives may file written arguments based solely upon the evidence received at the hearing, citing the pages of the transcript of the testimony or of properly identified exhibits where such evidence occurs.

Subpart D—Evidence

§ 314.220 Submission of documentary evidence in advance.

(a) All documentary evidence to be offered at the hearing shall be submitted to the Administrative Law Judge and to the parties sufficiently in advance of the offer of such documentary evidence for introduction into the record to permit study and preparation of cross-examination and rebuttal evidence.

(b) The Administrative Law Judge after consultation with the parties at a conference called in accordance with § 314.204 shall make an order specifying the time at which documentary evidence shall be submitted. He shall also specify in his order the time within which objections to the authenticity of such documents must be made to comply with paragraph (d) of this section.

(c) Documentary evidence not submitted in advance in accordance with the requirements of paragraphs (a) and (b) of this section shall not be received in evidence in the absence of a clear showing that the offering party had good cause for his failure to produce the evidence sooner.

(d) The authenticity of all documents submitted in advance shall be deemed admitted unless written objection thereto is filed with the Administrative Law Judge upon notice to the other parties within the time specified by the Administrative Law Judge in accordance with paragraph (b) of this section, except that a party will be permitted to challenge such authenticity at a later time upon a clear showing of good cause for failure to have filed such written objection.

§ 314.221 Excerpts from documentary evidence.

When portions only of a document are to be relied upon, the offering party shall prepare the pertinent excerpts, adequately identified, and shall supply copies of such excerpts, together with a statement indicating the purpose for which such materials will be offered, to the Administrative Law Judge and to the other parties. Only the excerpts, so prepared and submitted, shall be received in the record. However, the whole of the original document shall be made available for examination and for use by opposing counsel for purposes of cross-examination.

§ 314.222 Submission and receipt of evidence.

(a) Each witness shall, before proceeding to testify, be sworn or make affirmation.

(b) When necessary in order to prevent undue prolongation of the hearing, the Administrative Law Judge may limit the number of times any witness may testify, the repetitious examination and cross-examination of witnesses, or the

amount of corroborative or cumulative evidence.

(c) The Administrative Law Judge shall admit only evidence that is relevant, and not unduly repetitious.

(d) Opinion evidence shall be admitted when the Administrative Law Judge is satisfied that the witness is properly qualified.

(e) If any person objects to the admission or rejection of any evidence, or other limitation of the scope of any examination or cross-examination, he shall state briefly the grounds for such objection, and the transcript shall not include extended argument or debate thereon except as ordered by the Administrative Law Judge. A ruling on any such objection shall be a part of the transcript, together with such offer of proof as has been made.

Subpart E—Findings of Facts and Order

§ 314.230 Tentative order.

The Administrative Law Judge, within a reasonable time, shall prepare tentative findings of fact and a tentative order, which shall be served upon the applicant and the Food and Drug Administration or sent to them by certified mail. If not exceptions are taken to the tentative order within 20 days or such other time specified in such order, that order shall become final.

§ 314.231 Exceptions to the tentative order.

Within 20 days or such other time specified in the tentative order, the applicant or the Food and Drug Administration may transmit exceptions to the Administrative Law Judge, together with any briefs or argument in support thereof. If exception is taken to any tentative findings of fact, reference must be made to the pages or parts of the record relied upon, and a corrected finding of fact must be submitted. The applicant, if he files exceptions, shall state in writing whether he desires to make an oral argument.

§ 314.232 Issuance of final order.

Within a reasonable time after the filing of exceptions, or after oral argument (if such argument is requested), the Commissioner shall issue the final order in the proceeding. The order will include the findings of fact upon which it is based.

Subpart F—Judicial Review of Order

§ 314.235 Judicial review.

(a) The Assistant General Counsel for Food and Drugs of the Department of Health, Education, and Welfare is hereby designated as the officer upon whom copies of petitions for judicial review shall be served. Such officer shall be responsible for filing in the court a transcript of proceedings and the record on which the final orders were based. The transcript and record shall be certified by the Commissioner. In any case in which the Commissioner enters an order as provided in § 314.200(g), without a hearing, the request(s) for hearing together with the data and information submitted and the Commissioner's findings and conclusions shall be included in the record certified by the Commissioner.

(b) Judicial review of an order withdrawing approval of a new drug application, whether or not a hearing has been held, may be sought by a manufacturer or distributor of an identical, related, or similar drug product as defined in § 310.6 of this chapter in a United States court of appeals pursuant to section 505 (h) of the act.

(c) The record upon judicial review after denial of a hearing shall consist of the notice of opportunity for hearing, the request for hearing, any proposed denial of hearing served upon the person requesting a hearing and the response (where this procedure is applicable), and the final order denying a hearing.

PART 328—IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

Subpart A—General Provisions

Sec.
328.3 Definitions.
328.4 Confidentiality of submitted information.

Subpart B—Labeling

328.10 Labeling for in vitro diagnostic products.

Subpart C—Requirements for Manufacturers and Producers

328.20 General requirements for manufacturers and producers of in vitro diagnostic products.

Subpart D—Administrative Procedures

328.30 Procedure for establishing, amending or repealing standards.
328.34 Court appeal.
328.35 Regulatory action.

AUTHORITY: Secs. 201, 501, 502, 505, 508, 510, 701, 52 Stat. 1040–1042, as amended, 1049–1051, as amended, 1053, as amended, 1055, as amended, 1056, as amended; (21 U.S.C. 321, 351, 352, 355, 358, 360, 371).

Subpart A—General Provisions

§ 328.3 Definitions.

(a) "In vitro diagnostic products" are those reagents, instruments and systems intended for use in the diagnosis of disease or in the determination of the state of health in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation and examination of specimens taken from the human body. These products are drugs or devices as defined in section 201(g) and 201(h), respectively, of the Federal Food, Drug, and Cosmetic Act (the act) or are a combination of drugs and devices, and may also be a biological product subject to section 351 of the Public Health Service Act.

(b) A "product class" is all those products intended for use for a particular determination or for a related group of determinations or products with common or related characteristics or those intended for common or related uses. A class may be further divided into subclasses when appropriate.

(c) A "product class standard" is a statement describing performance requirements necessary to assure accuracy and reliability of results, specific labeling requirements necessary for the proper use of a particular class, and procedures for testing the product to assure its satisfactory performance.

(d) "Act" means the Federal Food, Drug, and Cosmetic Act.

§ 328.4 Confidentiality of submitted information.

(a) Data and information submitted pursuant to the provisions of § 328.30 or § 328.10(c) and falling within the confidentiality provisions of 18 U.S.C. 1905 or 21 U.S.C. 331(j) shall be treated as confidential by the Food and Drug Administration and any consultant to whom it is referred. Confidentiality of information will be determined in accordance with the provisions of Part 4 of this chapter.

(b) Data and information submitted pursuant to § 328.30 in connection with the establishment, amendment or repeal of a product class standard will be made publicly available at the office of the Hearing Clerk of the Food and Drug Administration 30 days after publication of a proposed product class standard, except for the identity of inactive ingredients, any quality control or other manufacturing data or information, or other data and information to the extent that the person submitting it has demonstrated that it falls within the confidentiality provisions of 18 U.S.C. 1905 or 21 U.S.C. 331(j).

Subpart B—Labeling

§ 328.10 Labeling for in vitro diagnostic products.

(a) The label for an in vitro diagnostic product shall state the following information, except where such information is not applicable, or as otherwise specified in a standard for a particular product class. Section 201(k) of the act provides that "a requirement made by or under authority of this act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper."

(1) The proprietary name and established name (common or usual name), if any.

(2) The intended use or uses of the product.

(3) For a reagent, a declaration of the established name (common or usual name), if any, and quantity, proportion or concentration of each reactive ingredient; and for a reagent derived from biological material, the source and a measure of its activity. The quantity, proportion, concentration or activity shall be stated in the system generally used and recognized by the intended user (e.g., metric, international units, etc.).

(4) A statement of warnings or precautions for users as established in the regulations contained in 16 CFR Part 1500 and any other warnings appropriate to the hazard presented by the product; and a statement "For In Vitro Diagnostic

Use" and any other limiting statements appropriate to the intended use of the product.

(5) For a reagent, appropriate storage instructions adequate to protect the stability of the product. When applicable, these instructions shall include such information as conditions of temperature, light, humidity, and other pertinent factors. For products requiring manipulation, such as reconstitution and/or mixing before use, appropriate storage instructions shall be provided for the reconstituted or mixed product which is to be stored in the original container. The basis for such instructions shall be determined by reliable, meaningful, and specific test methods such as those described in § 133.13 of this chapter.

(6) For a reagent, a means by which the user may be assured that the product meets appropriate standards of identity, strength, quality and purity at the time of use. This shall be provided, both for the product as provided and for any resultant reconstituted or mixed product, by including on the label one or more of the following:

(i) An expiration date based upon the stated storage instructions.

(ii) A statement of an observable indication of an alteration of the product (e.g., turbidity, color change, precipitate) beyond its appropriate standards.

(iii) Instructions for a simple method by which the user can reasonably determine that the product meets its appropriate standards.

(7) For a reagent, a declaration of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of these or other terms which accurately reflect the contents of the package. The use of metric designations is encouraged, wherever appropriate. If more than a single determination may be performed using the product, any statement of the number of tests shall be consistent with instructions for use and amount of material provided.

(8) Name and place of business of manufacturer, packer, or distributor.

(9) A lot or control number, identified as such, from which it is possible to determine the complete manufacturing history of the product.

(i) If it is a multiple unit product, the lot or control number shall permit tracing the identity of the individual units.

(ii) For an instrument, the lot or control number shall permit tracing the identity of all functional subassemblies.

(iii) For multiple unit products which require the use of included units together as a system, all units should bear the same lot or control number, if appropriate, or other suitable uniform identification should be used.

(10) Except that for items in paragraph (a) (1) through (9) of this section: (i) In the case of immediate containers too small or otherwise unable to accommodate a label with sufficient space to bear all such information and which are packaged within an outer container from which they are removed for use, the information required by paragraph (a) (2), (3), (4), (5), (6) (ii) (iii) and (7) of this section may appear in the outer container labeling only.

(ii) In any case in which the presence of this information on the immediate container will interfere with the test, the information may appear on the outside container or wrapper rather than on the immediate container label.

(b) Labeling accompanying each product (e.g., a package insert) shall state in one place the following information in the format and order specified below, except where such information is not applicable, or as specified in a standard for a particular product class. The labeling for a multiple-purpose instrument used for diagnostic purposes, and not committed to specific diagnostic procedures or systems, may bear only the information indicated in paragraph (b) (1), (2), (6), (14), and (15) of this section. The labeling for a reagent intended for use as a replacement in a diagnostic system may be limited to that information necessary to identify the reagent adequately and to describe its proper use in the system.

(1) The proprietary name and established name (common or usual name), if any.

(2) The intended use or uses of the product and the type of procedure (e.g., qualitative or quantitive).

(3) Summary and explanation of the test. Include a short history of the methodology, with pertinent references and a balanced statement of the special merits and limitations of this method or product. If the product labeling refers to any other procedure, appropriate literature citations shall be included and the labeling shall explain the nature of any differences from the original and their effect on the results.

(4) The chemical, physical, physiological, or biological principles of the procedure. Explain concisely, with chemical reactions and techniques involved, if applicable.

(5) Reagents. (i) A declaration of the established name (common or usual name), if any, and quantity, proportion or concentration or each reactive ingredient; and for biological material, the source and a measure of its activity. The quantity, proportion, concentration or activity shall be stated in the system generally used and recognized by the intended user (e.g., metric, international units, etc.). A statement indicating the presence of and characterizing any catalytic or nonreactive ingredients (e.g., buffers, preservatives, stabilizers).

(ii) A statement of warnings or precautions for users as established in the regulations contained in 16 CFR Part 1500 and any other warnings appropriate to the hazard presented by the product; and a statement "For In Vitro Diagnostic Use" and any other limiting statements appropriate to the intended use of the product.

(iii) Adequate instructions for reconstitution, mixing, dilution, etc.

(iv) Appropriate storage instructions adequate to protect the stability of the product. When applicable, these instructions shall include such information as conditions of temperature, light, humidity, and other pertinent factors. For products requiring manipulation, such as reconstitution and/or mixing before use, appropriate storage instructions shall be provided for the reconstituted or mixed product. The basis for such instructions shall be determined by reliable, meaningful, and specific test methods such as those described in § 133.13 of this chapter.

(v) A statement of any purification or treatment required for use.

(vi) Physical, biological, or chemical indications of instability or deterioration.

(6) Instruments: (i) Use or function.

(ii) Installation procedures and special requirements.

(iii) Principles of operation.

(iv) Performance characteristics and specifications.

(v) Operating instructions.

(vi) Calibration procedures including materials and/or equipment to be used.

(vii) Operational precautions and limitations.

(viii) Hazards.

(ix) Service and maintenance information.

(7) Specimen collection and preparation for analysis, including a description of: (i) Special precautions regarding specimen collection including special preparation of the patient as it bears on the validity of the test.

(ii) Additives, preservatives, etc., necessary to maintain the integrity of the specimen.

(iii) Known interfering substances.

(iv) Recommended storage, handling or shipping instructions for the protection and maintenance of stability of the specimen.

(8) Procedure: A step-by-step outline of recommended procedures from reception of the specimen to obtaining results. List any points that may be useful in improving precision and accuracy. (i) A list of all materials provided (e.g., reagents, instruments and equipment) with instructions for their use.

(ii) A list of all materials required but not provided: Include such details as sizes, numbers, types, and quality.

(iii) A description of the amounts of reagents necessary, times required for specific steps, proper temperatures, wavelengths, etc.

(iv) A statement describing the stability of the final reaction material to be measured and the time within which it shall be measured to assure accurate results.

(v) Details of calibration: Identify reference material. Describe preparation of reference sample(s), use of blanks, preparation of the standard curve, etc. The description of the range of calibration should include the highest and the lowest values measurable by the procedure.

(vi) Details of kinds of quality control procedures and materials required. If there is need for both positive and negative controls, this should be stated. State what are considered satisfactory limits of performance.

(9) Results: Explain the procedure for calculating the value of the unknown. Give an explanation for each component of the formula used for the calculation of the unknown. Include a sample calculation, step-by-step, explaining the answer. The values shall be expressed to the appropriate number of significant figures. If the test provides other than quantitative results, provide an adequate description of expected results.

(10) Limitation of the procedure: Include a statement of limitations of the procedure. State known extrinsic factors or interfering substances affecting results. If further testing, either more specific or more sensitive, is indicated in all cases where certain results are obtained, the need for the additional test shall be stated.

(11) Expected values: State the range(s) of expected values as obtained with the product from studies of various populations. Indicate how the range(s) was established and identify the population(s) on which it was established.

(12) Specific performance characteristics: Include, as appropriate, information describing such things as accuracy, precision, specificity, and sensitivity. These shall be related to a generally accepted method using biological specimens from normal and abnormal populations. Include a statement summarizing the data upon which the specific performance characteristics are based.

(13) Bibliography: Include pertinent references keyed to the text.

(14) Name and place of business of manufacturer, packer, or distributor.

(15) Date of issuance of the last revision of the labeling identified as such.

(c) A shipment or other delivery of an in vitro diagnostic product shall be exempt from the requirements of paragraphs (a) and (b) of this section and from a standard promulgated pursuant to this part provided the following conditions are met:

(1) For a product in the laboratory research phase of development, and not represented as an effective in vitro diagnostic product, all labeling bears the statement, prominently placed: "For Research Use Only. Not for use in diagnostic procedures."

(2) For a product being shipped or delivered for product testing prior to full commercial marketing (e.g., for use on specimens derived from humans to compare the usefulness of the product with other products or procedures which are in current use or recognized as useful), all labeling bears the statement, prominently placed: "For Investigational Use Only. The performance characteristics of this product have not been established."

(3) The person making a shipment or delivery under paragraph (c)(2) of this section shall submit to the FDA a notification that such shipments are being made.

(4) Within 30 days after the first commercial shipment of an in vitro diagnostic product, the person making such shipment shall submit the information required by the Drug Listing Act as provided in § 132.5 of this chapter.

(d) The labeling of general purpose laboratory reagents (e.g., hydrochloric acid) and equipment (e.g., test tubes and pipettes) whose uses are generally known by persons trained in their use need not bear the directions for use required by § 328.10 (a) and (b), if their labeling meets the requirements of this paragraph.

(1) The label of a reagent shall bear the following information:

(i) The proprietary name and established name (common or usual name), if any, of the reagent.

(ii) A declaration of the established name (common or usual name), if any, and quantity, proportion or concentration of the reagent ingredient (e.g., hydrochloric acid: Formula weight. 36.46, assay 37.9 percent, specific gravity 1.192 at 60° F.); and for a reagent derived from biological material, the source and where applicable a measure of its activity. The quantity, proportion, concentration or activity shall be stated in the system generally used and recognized by the intended user (e.g., metric, international units, etc.).

(iii) A statement of the purity and quality of the reagent, including a quantitative declaration of any impurities present. The requirement for this information may be met by a statement of conformity with a generally recognized and generally available standard which contains the same information (e.g., those established by the American Chemical Society, U.S. Pharmacopeia, National Formulary, National Research Council).

(iv) A statement of warnings or precautions for users as established in the regulations contained in 16 CFR Part 1500 and any other warnings appropriate to the hazard presented by the product; and a statement "For Laboratory Use."

(v) Appropriate storage instructions adequate to protect the stability of the product. When applicable, these instructions shall include such information as conditions of temperature, light, humidity, and other pertinent factors. The basis for such information shall be determined by reliable, meaningful, and specific test methods such as those described in § 133.13 of this chapter.

(vi) A declaration of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of these or other terms which accurately reflect the contents of the package. The use of metric designations is encouraged, wherever appropriate.

(vii) Name and place of business of manufacturer, packer, or distributor.

(viii) A lot or control number, identified as such, from which it is possible to determine the complete manufacturing history of the product.

(ix) In the case of immediate containers too small or otherwise unable to accommodate a label with sufficient space to bear all such information, and which are packaged within an outer container from which they are removed for use, the information required by paragraph (d)(1) (ii), (iii), (iv), (v), and (vi) of this section may appear in the outer container labeling only.

(2) The label of general purpose laboratory equipment (e.g., a beaker or a pipette) shall bear a statement adequately describing the product, its composition, and physical characteristics if necessary for its proper use.

EFFECTIVE DATE: § 328.10 (a), (b), and (d) become effective September 15, 1974; paragraph (c) became effective September 17, 1973. See 39 FR 8610, Mar. 6, 1974. The effective date for paragraphs (a) and (b) of this section, as applied to licensed blood grouping serum, was stayed. See 39 FR 2089, Jan. 17, 1974.

Subpart C—Requirements for Manufacturers and Producers

§ 328.20 General requirements for manufacturers and producers of in vitro diagnostic products.

(a) *Registration and product listing.* Any person who owns or operates any establishment engaged in the manufacture, preparation, compounding, or processing of an in vitro diagnostic product should register such establishment and list such product(s) in accordance with the procedures established under Part 132 of this chapter, except that registration and listing is not required or requested at this time for general purpose laboratory reagents and equipment for which labeling requirements are specified in § 328.10(d). Any such establishment not currently registered should register within 30 days of the effective date of this regulation. Any such establishment currently registered as a drug establishment shall at the next period for registration use the appropriate registration form indicating that it is a producer of in vitro diagnostic products. Registration forms may be obtained from the Department of Health, Education, and Welfare, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, or at any Food and Drug Administration district office. Registration and listing do not constitute an admission or agreement or determination that a product is a "drug" within the meaning of section 201(g) of the act.

(b) *Compliance with good manufacturing practices.* In vitro diagnostic products shall be manufactured in accordance with current good manufacturing practices. The principles established in Part 133 of this chapter, "Drugs; Current Good Manufacturing Practice in Manufacture, Processing, Packing, or Holding," should be followed as a guideline.

Subpart D—Administrative Procedures

§ 328.30 Procedure for establishing, amending or repealing standards.

(a) *Basis for standards and available approaches to developing standards.* Whenever in the judgment of the Commissioner the establishment of a product class standard is necessary to reduce or eliminate unreasonable risk of illness or injury associated with exposure to or use of an in vitro diagnostic product and there are no other more practicable means to protect the public from such risk, he may propose such a standard. In

proposing a product class standard he shall consider, and publish in the FEDERAL REGISTER findings on, the degree of risk or injury associated with the use of the product, the availability of information relating to the sciences upon which the products or their uses are based, the approximate number of products subject to the standard, the medical need for the products, and the probable effect of the standard upon the utility, cost, or availability of the product, and available means of achieving the objective of the standard with a minimal disruption of supply and of reasonable manufacturing and other commercial practices. Three procedures are available for developing product class standards and may be proposed on the initiative of the Commissioner or by petition of interested persons: (1) An existing standard may be utilized, (2) interested persons outside of the Food and Drug Administration may develop a proposed standard or (3) the Food and Drug Administration may develop the standard. If a petition is filed by an interested person, it shall be in the form prescribed in § 2.65 of this chapter with the number of copies specified therein.

(b) *Advisory committee.* An advisory committee of qualified experts shall be appointed to advise the Food and Drug Administration on the priorities for establishing product class standards, the scientific basis for in vitro diagnostic products, the selection of reference methodologies and reference materials, the adequacy and reasonableness of proposed standards and other related matters as determined by the Commissioner.

(c) *Request for information and comment.* Whenever a new standard is to be developed, the Commissioner will publish a notice in the FEDERAL REGISTER requesting the submission of all information, data, and views relevant to a specific product class for review and evaluation. Any interested person may submit comments and views on any matter relevant to the development of the standard, including the factors required by paragraph (a) of this section, to be considered by the Commissioner. The format for such submission may be determined by the nature of the information to be submitted. Any product performance information submitted shall relate to the performance of that product as marketed or intended for marketing. For information submitted by a manufacturer of a product which will be affected by the standard, the specific product information requested and the format for submission shall be as described below unless changed in the FEDERAL REGISTER notice. The time allotted for submission will ordinarily be 90 days. Four copies of the information and data on any product within the designated class shall be submitted, indexed, and bound.

(1) Name of product class and date of FEDERAL REGISTER statement.

(2) Proprietary name of product.

(3) Name of person responsible for submission.

(4) Intended use or uses of the product.

(5) A statement categorizing the procedure (e.g., qualitative or quantitative).

(6) Copies of label and all other labeling under which product is currently marketed or, for a proposed product, the label and all other labeling under which marketing is intended.

(7) Description of the product, as appropriate: For example, if the product is or includes a reagent, state the proprietary name and established name (common or usual name), if any, and quantity, proportion, or concentration of each reactive, catalytic, or inactive ingredient. If the product is a biological material, list the source and a measure of its activity. Include a statement of any purification or treatment required for use. If the product is or includes an instrument or equipment, describe as appropriate its use or functions, installation procedures and any special requirements, principle of operating instructions, calibration procedures including materials and/or equipment to be used, operation precautions and limitations, hazards, and service and maintenance instructions.

(8) Stability information: A description of, and data derived from, studies of the stability of the product. For any product that requires manipulation (e.g., reconstitution or mixing), stability data shall be described for the reconstituted or mixed product. Describe the means by which the information was developed. The data shall be for the product in the container in which it is marketed to assure, among other things, that the container is not reactive, additive, or absorptive to an extent that alters the product or its performance. Include any expiration period data which supports any expiration date which appears in the labeling of the product. Describe the storage conditions necessary for the product, such as temperature, light, humidity.

(9) Hazards to user: A statement of the principal hazards associated with the product. Include the result of tests conducted to determine the applicability of hazard warnings or cautions, including those established in the regulations contained in 16 CFR Part 1500.

(10) History of methodology: A brief history of the methodology, with pertinent references. All references to reports of adverse or unfavorable experience with the product or the procedure on which it is based shall be included. If the product procedure is the same as one which has been published, cite the reference. If the product is based on a modification of a published procedure, cite the reference, state the reason for and the nature of the modification and the effect such modification may have on the results of the procedure as compared to the original. Include data illustrating the comparison of the modified procedure to the original procedure.

(11) Principle of test: An explanation of the test procedure including the chemical, physical, physiological, or biological principle of the procedure with chemical reactions and techniques involved, if applicable.

(12) Specimen collection and preparation: A description of the specimen to be subjected to analysis: (i) Special precautions regarding specimen collections, including special preparation of the patient as it bears on the validity of the test.

(ii) Additives, preservatives, etc., necessary to maintain the integrity of the specimen.

(iii) Known interfering substances and their effect on the procedure and results.

(iv) Appropriate storage, handling or shipping instructions.

(13) Procedure: A detailed, step-by-step description of the test procedure from reception of the specimen to obtaining of results, including any points that may be useful in improving precision and accuracy. Give the exact details of calibration. Identify reference material. Describe preparation of reference sample, use of blanks, etc. Include a description of methods to be used in determining the standard curve.

(14) Results: Explain the procedure for calculating the value of the unknown. Give an explanation of each component of the formula used for the calculation of the unknown. Include a sample calculation, step-by-step, explaining the answer. Values should be expressed to the appropriate number of significant figures. Provide the basis for evaluation of nonquantitative test results.

(15) Limitation of the procedure: Include a statement of the limitations of the procedure and an explanation of extrinsic factors, if any, that may affect the results. Include statements regarding minimum training needed by the user, special precautions, interfering substances, likelihood of obtaining false positive or false negative results, etc. Positive data showing a lack of interference by commonly occurring substances shall be supplied. If a more specific or more sensitive laboratory test is indicated in certain instances, the indication for the additional test shall be stated and data submitted to support its value.

(16) Support of claims: Include all available data, published or unpublished, which supports or is critical of the product or its procedure. Include data for both normal and abnormal subjects and a description of the population or populations studies. State, for each claim: (i) Labeling claim.

(ii) Background documentation: Provide a bibliography and reprints of all pertinent references.

(iii) Procedure used for collecting evidence for claim.

(iv) Description of statistical protocol.

(v) Description of sampling procedure.

(vi) Summary of raw results in tabular form.

(vii) Analysis of results.

(viii) Statement of interpretation of results.

(17) Summary of scientific basis of procedure: A summary of the data and views setting forth the scientific rationale and purpose of the product, and the scientific basis for the conclusion that the product has or has not been proven accurate and reliable for its intended uses. If there is an absence of controlled studies in the material submitted, an ex-

planation as to why such studies are not considered necessary shall be included.

(18) If the submission is by a manufacturer, a statement signed by the person responsible for such submission, that to the best of his knowledge it includes unfavorable information as well as any favorable information, known to him pertinent to an evaluation of the performance of the product. Thus, if any type of scientific data is submitted, a balanced submission of favorable and unfavorable data must be submitted. The same would be true of any other pertinent data or information submitted, such as consumer surveys or marketing results.

(d) *Review and evaluation.* Any existing standard or petition for a product class standard, together with any information and comments submitted pursuant to a published notice, will be reviewed and evaluated by the Food and Drug Administration in consultation with its advisory committee and the Center for Disease Control.

(e) *Proposed product class standard.* When the Commissioner has concluded that the criteria in paragraph (a) of this section are met and the information available has been reviewed and found to justify the establishment of a product class standard, he shall publish in the FEDERAL REGISTER a proposed product class standard establishing conditions under which the products in the class are safe and effective and not adulterated or misbranded. The standard shall include a statement of the performance requirements necessary to assure accuracy and reliability of results, specific labeling requirements for the proper use of the products in the class, and procedures for testing the products to assure satisfactory performance at the time of marketing. The standard may include, where necessary to assure the accuracy and reliability of results, individual lot testing by or at the direction of the Food and Drug Administration, in addition to that normally required of the manufacturer; except that the Commissioner shall exempt any particular product from such a requirement upon a showing that the manufacturer has demonstrated such consistency in the production of that product, in compliance with the regulations, as is adequate to insure the accuracy and reliability of results, and the Commissioner shall revoke the requirement of individual lot testing under the standard when it is no longer necessary to the accuracy and reliability of the results of the product class covered by the standard. Any interested person may, within 60 days after publication of the proposed standard in the FEDERAL REGISTER, file written comments on the proposal, in quintuplicate, with the Hearing Clerk, Food and Drug Administration, Room 6–86, 5600 Fishers Lane, Rockville, MD 20852. Comments may be accompanied by a memorandum or brief in support thereof. All comments may be reviewed at the office of the Hearing Clerk during regular working hours, Monday through Friday.

(f) *Referral to an independent advisory committee.* The Commissioner may, in his discretion, refer a proposal under paragraph (e) of this section to an independent advisory committee of experts qualified in the subject matter at issue, for a report and recommendations with respect to any matter involved in such proposal which involves the exercise of scientific judgment. The Commissioner shall designate the chairman of each panel. The independent advisory committee may consult any person in connection with the matter referred to it. Any interested person may request, in writing, an opportunity to present oral views to the committee. Any interested person may present written data and views which shall be considered by the committee. The full report(s) of the committee and summary minutes of its meetings shall be made available upon request after submission of the report(s) to the Commissioner.

(g) *Final product class standard.* After reviewing all comments received in response to the proposal and considering all available relevant information, the Food and Drug Administration, in consultation with its advisory committee and the Center for Disease Control, and after consideration of any report of an independent advisory committee if the matter involved has been so referred, will publish in the FEDERAL REGISTER a final order containing a product class standard. This order shall state the reasons for promulgating the product class standard and the date the standard will become effective.

(h) *Petition to amend or repeal standards.* The Commissioner may propose to amend or repeal any standard established pursuant to this procedure or any interested person may petition the Commissioner for such action. A petition shall set forth the action requested and a detailed statement in support of the action. After review of the petition, the Commissioner may deny the petition if he finds a lack of reasonable support or he may publish a proposed amendment of or proposed repeal of the established standard in the FEDERAL REGISTER if adequate support has been presented. The petition shall be in the form specified in § 2.65 of this chapter with the number of copies and other information as specified therein. A new drug application submitted for an in vitro diagnostic product which does not comply with an applicable effective product class standard will be considered as a petition to amend the standard. Petitions for repeal or amendment for which reasonable support has been furnished will be handled pursuant to the procedures established in paragraphs (e) through (g) of this section.

§ 328.34 Court appeal.

The product class standard promulgated in the final order represents final agency action from which appeal lies to the courts. The Food and Drug Administration will request consolidation of all appeals in a single court. Upon court appeal, the Commissioner, at his discretion, may stay the effective date for part or all of the standard pending appeal and final court adjudication, and may establish a new effective date after final court adjudication.

§ 328.35 Regulatory action.

Any in vitro diagnostic product is subject to regulatory action if it fails to conform to an applicable product class standard or the general labeling requirements of § 328.10. If the product is a device, it is adulterated in violation of section 501 and it is misbranded in violation of section 502 of the act. If the product is a drug, it is in violation of section 505 as well as sections 501 and 502 of the act. If the product is a biologic, it is in violation of sections 501, 502, and 505 of the Federal Food, Drug, and Cosmetic Act and section 351 of the Public Health Service Act. Deviations from an established standard may be justified only by an amendment to the standard. Compliance with this part shall be deemed to constitute compliance with the labeling and new drug requirements of the act and with the labeling and licensing requirements of section 351 of the Public Health Service Act, unless the Commissioner otherwise informs the manufacturer or distributor of an in vitro diagnostic product of additional requirements imposed pursuant to either statute in order to protect the public health.

PART 329—HABIT-FORMING DRUGS

Subpart A—Derivatives Designated as Habit Forming

Sec.

329.1 Habit-forming drugs which are chemical derivatives of substances specified in section 502(d) of the Federal Food, Drug, and Cosmetic Act.

Subpart B—Labeling

329.10 Labeling requirements for habit-forming drugs.

Subpart C—Exemptions

329.20 Exemption of certain habit-forming drugs from prescription requirements.

AUTHORITY: Sec. 701, 52 Stat. 1055, as amended; (21 U.S.C. 371), unless otherwise noted.

Subpart A—Derivatives Designated as Habit Forming

§ 329.1 Habit-forming drugs which are chemical derivatives of substances specified in section 502(d) of the Federal Food, Drug, and Cosmetic Act.

Each of the following chemical derivatives of a substance named in section 502 (d) of the Federal Food, Drug, and Cosmetic Act is hereby designated as habit forming:

PARENT SUBSTANCE—BARBITURIC ACID

Chemical description of derivative	Common or official name of chemical derivative or its salts	Some trade or other names of chemical derivative or its salts[1]
5-Allyl-5-*sec*-butylbarbituric acid.[2]	Talbutal	Lotusate.
5-Allyl-5-cyclopentenylbarbituric acid		Cyclopal. Cyclopen.
5-Allyl-5-isobutylbarbituric acid	Allylbarbituric acid Allylisobutylbarbituric acid.	Sandoptal.
5-Allyl-5-isopropylbarbituric acid	Aprobarbital Allylisopropylbarbituric acid. Allylisopropylmalonylurea.	Alurate. Numal.
5-Allyl-5-isopropyl-1-methylbarbituric acid		Narconumal.
5-Allyl-5-(1-methylbutyl) barbituric acid	Secobarbital sodium Soluble secobarbital	Seconal Sodium. Evronal Sodium.
5-Allyl-5-(1-methylbutyl)-2-thiobarbituric acid	Sodium thiamylal	Surital Sodium.
5-Allyl-1-methyl-5-(1-methyl-2-pentynyl) barbituric acid.	Sodium methohexital	Brevital Sodium.
5-(2-Bromoallyl)-5-isopropyl-1-methylbarbituric acid.		Eunarcon.
5-(2-Bromoallyl)-5-(1-methylbutyl)-barbituric acid.	β-Bromoallyl *sec*-amylbarbituric acid.	Sigmodal. Rectidon. R239.
5-*sec*-Butyl-5-(2-bromoallyl)-barbituric acid	Butallylonal	Pernoston. Pernocton.
5-(1-Cyclohepten-1-yl)-5-ethylbarbituric acid	Heptabarbital	Medomin.
5,5-Diallylbarbituric acid	Diallyl barbituric acid	Dial. Allobarbital. Allobarbitone. Curral. Diadol.
5,5-Diethylbarbituric acid	Barbital Barbitone. Diethylbarbituric acid. Diethylmalonylurea.	Deba. Dormonal. Hypnogene. Malonal. Medinal. Sedeval. Veronal. Uronal.
5,5-Diethyl-1-methylbarbituric acid	Metharbital	Vesperal. Gemonil.

See footnote at end of table.

PARENT SUBSTANCE—BARBITURIC ACID—Continued

Chemical description of derivative	Common or official name of chemical derivative or its salts	Some trade or other names of chemical derivative or its salts[1]
1,5-Dimethyl-5-(1-cyclohexenyl)-barbituric acid.	Hexobarbital sodium	Cyclonal Sodium. Dorico Soluble. Evipal Sodium. Evipan Sodium. Hexanastab. Hexobarbitone Sodium; Methenexyl Sodium.
5,5-Dipropylbarbituric acid	Dipropylbarbituric acid	Proponal.
5-Ethyl-5-butylbarbituric acid	Butethal Butobarbital.	Etoval. Neonal Butobarbital; Soneryl.
5-Ethyl-5-*sec*-butylbarbituric acid	Butabarbital sodium	Butisol Sodium.
5-Ethyl-5-(1-cyclohexenyl)-barbituric acid	Cyclobarbital	Cyclobarbitone. Namuron. Palinum. Phanodorm. Phanodorn. Tetrahydrophenobarbital.
5-Ethyl-5-cyclopentenyl-barbituric acid		Pentenal.
5-Ethyl-5-hexylbarbituric acid	Hexethal sodium	Hebaral. Ortal Sodium;
5-Ethyl-5-isoamylbarbituric acid	Amobarbital	Amytal;
5-Ethyl-5-isopropylbarbituric acid	Probarbital	Ipral;
5-Ethyl-5-(1-methylbutyl)-barbituric acid	Pentobarbital sodium Soluble pentobarbital.	844. Embutal. Nembutal. Napethal. Pentyl.
5-Ethyl-5-(1-methylbutyl)-2-thiobarbituric acid.	Thiopental sodium Thiopentone sodium.	Intraval Sodium. Nesdonal Sodium. Pentothal Sodium Thiothal Sodium.
5-Ethyl-5-(1-methyl-1-butenyl)-barbituric acid	Vinbarbital	Delvinal Sodium.
5-Ethyl-5-phenylbarbituric acid	Phenobarbital Phenobarbitone. Phenylethylmalonylurea.	Barbenyl. Barbiphenyl. Dormiral. Euneryl. Gardenal. Luminal. Nunol. Neurobarb. Phenonyl. Somonal.
5-Ethyl-5-phenyl-1-methylbarbituric acid	Mephobarbital	Mebaral. Phemitone. Prominal.
5-Ethyl-5-(1-piperidyl)-barbituric acid		Eldoral.
5-Isopropyl-5-(2-bromoallyl)-barbituric acid	Propallylonal	Noctal. Nostal.
5-(1-Methylbutyl)-5-[2-(methylthio)ethyl]-2-thiobarbituric acid.	Methitural (sodium salt)	Methioturiate. Neraval. Thiogenal.
5-Methyl-5-phenylbarbituric acid	Phenylmethylbarbituric acid	Rutonal.
All lithium, sodium, potassium, magnesium, calcium, strontium, and ammonium salts of the foregoing chemical derivatives of barbituric acid.		

See footnote at end of table.

PARENT SUBSTANCE—BROMAL

Chemical description of derivative	Common or official name of chemical derivative or its salts	Some trade or other names of chemical derivative or its salts[1]
Tribromoacetaldehyde hydrate	Bromal hydrate	
Tribromomethane	Bromoform	
2-(Tribromomethyl)-2-propanol	Tribromo-*tert*-butyl alcohol	Acetone-Bromoform. Brometone.

PARENT SUBSTANCE—CANNABIS (MARIHUANA)

	Extract of cannabis. Fluid extract of cannabis. Tincture of cannabis.	

PARENT SUBSTANCE—CARBROMAL

α-Bromo-α-ethylbutyryl-acetyl urea	Acetylcarbromal	Abasin. Acetyl Adalin. *N* - Acetyl - *N* - bromodiethyl-acetylurea. *N* - Acetyl - *N'* - α - bromo - α-ethylbutyryl carbamide.
α-Bromoisovaleryl urea	Bromisovalum	Bromisoval. α - Bromo - β - dimethyl - propanoylurea. Bromural. Bromvaletone. Brovalurea. B. V. U. Dormigene. Isobromyl. 2-Monobromoisovalerylurea. Pivadorm. Uvaleral.
α-Bromo-α,α-diethylacetamide	Diethylbromo acetamide	Neuronal.
α-Allylisovaleryl-urea		Allyl - isopropyl - acetyl - carbamide. (2 - Isopropyl - 4 - pentenoyl)-urea. Sedormid.

PARENT SUBSTANCE—CHLORAL

Trichloroacetaldehyde hydrate	Chloral Chloral hydrate.	2,2,2-Trichloro-1,1-ethanediol. Trichloroethylidene glycol.
Trichloroethylidenäimine	Chloralimide	
N-(β-Trichloro-α-hydroxyethyl)-formamide	Chloralformamide	Chloralamide. Chloramide.
α-(β-trichloro-α-hydroxyethyl)-*D*-glucoside	α-Chloralose	A-D-Glucochloralose. Anhydro-Glucochloral. Glucochloral. Chloralosone.
2-(Trichloromethyl)-2-propanol	Chlorbutanol Chlorbutol. Chlorobutanol.	Acetone chloroform. Chloretone. Methaform. Sedaform. 1,1,1-trichloro-2-methyl-2-propanol. β,β,β-trichloro-*tert*-butyl alcohol

PARENT SUBSTANCE—COCAINE

All salts of cocaine obtained by combining cocaine with any acid.	Cocaine hydrochloride Cocainium chloride.	

See footnote at end of table.

PARENT SUBSTANCE—CODEINE

Chemical description of derivative	Common or official name of chemical derivative or its salts	Some trade or other names of chemical derivative of its salts.[1]
Codeine methylbromide	Eucodin	
Dihydrocodeinone		Dicodid.
Dihydrohydroxycodeinone	Eucodal	Oxycodone hydrochloride. 14-hydroxydihydrocodeinone.
All salts of the foregoing chemical derivatives of codeine obtained by combining any such derivative of codeine with any acid.		

PARENT SUBSTANCE—HEROIN

All salts of heroin obtained by combining heroin with any acid.		

PARENT SUBSTANCE—MORPHINE

Dihydromorphine	Paramorphan	
Dihydromorphinone	Dihydromorphinone hydrochloride. Dihydromorphinonium chloride	Dilaudid. Dimorphone. Hydromorphone hydrochloride.
Ethylmorphine	Ethylmorphine hydrochloride Ethylmorphinium chloride.	Dionin.
All salts of the foregoing chemical derivatives of morphine and all salts of morphine obtained by combining any such derivative or morphine with any acid.		

PARENT SUBSTANCE—OPIUM

	Extract of opium	
	Fluidextract of opium	
	Camphorated opium tincture Deodorized opium tincture. Laudanum. Opium tincture. Paregoric. Tincture of opium.	

PARENT SUBSTANCE—PARALDEHYDE

Metaldehyde		

PARENT SUBSTANCE—SULFONMETHANE

2,2-Diethylsulfonylbutane	Sulfonethylmethane	Diethylsulfonmethylethylmethane. Ethylsulfonal. 2,2-*bis*-(Ethylsulfonyl)-butane. Methylsufonal. Sulfonethylmethanum. Trional.
3,3-Diethylsulfonylpentane	Sulfondiethylmethane	

[1] This list of trade or other names is not a complete list of the many proprietary names under which the designated habit-forming chemical derivatives are distributed.

[2] The name "butalbital" is obsolete for this compound; "butalbital" is the nonproprietary name assigned by the United States Adopted Name Council and the World Health Organization for 5-allyl-5-isobutylbarbituric acid.

(Sec. 502, 52 Stat. 1050, as amended; (21 U.S.C. 352)

Subpart B—Labeling

§ 329.10 Labeling requirements for habit-forming drugs.

(a) (1) The name of a substance or derivative required to be borne on the label of a drug by section 502(d) of the act shall be the common or usual name of such substance or derivative, unless it is designated solely by a name recognized in an official compendium and such designation complies with the provisions of section 502(e).

(2) A statement on the label of a drug of the name of a constituent, which constituent is a chemical derivative of a substance named in section 502(d) of the act, shall show the substance from which such constituent is derived and that such constituent is a derivative thereof.

(b) If the drug is in tablet, capsule, ampul, or other unit form, the statement of the quantity or proportion of such substance or derivative contained therein shall express the weight or measure of such substance or derivative in each such unit. If the drug is not in such unit form the statement shall express the weight or measure of such substance or derivative in a specified unit of weight or measure of the drug. Such statement shall be in terms which are informative to the ordinary consumer and user of the drug.

(c) The names and quantities or proportions of all such substances and derivatives, and the statement "Warning—May be habit forming", shall immediately follow (without intervening written, printed, or graphic matter) the name by which such drug is titled in the part or panel of the label thereof which is presented or displayed under customary conditions of purchase.

(d) A drug shall not be considered to be misbranded by reason of failure of its label to bear the statement "Warning—May be habit forming":

(1) If such drug is not suitable for internal use, and is distributed and sold exclusively for such external use as involves no possibility of habit formation; or

(2) If the only substance or derivative subject to section 502(d) of the act contained in such drug is chlorobutanol, which is present solely as a preservative and in a quantity not more than 0.5 percent by weight, and such drug is for parenteral use only; or

(3) If the only substance or derivative subject to section 502(d) of the act contained in such drug is chlorobutanol which is present as an analgesic or as an analgesic and a preservative in a quantity not more than 3.0 percent, and such drug contains one or more other active ingredients and is for parenteral use only.

Cross Reference: For the Spanish-language version of the required labeling statement, see § 1.106 of this chapter.

Subpart C—Exemptions

§ 329.20 Exemption of certain habit-forming drugs from prescription requirements.

The prescription-dispensing requirements of section 503(b)(1)(A) of the act are not necessary for the protection of the public health with respect to the following drugs subject to section 502(d):

(a) The following exempt narcotic preparations:

(1) Pharmaceutical preparations containing not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

(2) Pharmaceutical preparations containing not more than 16.2 milligrams (¼ grain) morphine, or any of its salts, per 29.5729 cubic centimeters (1 fluid ounce) or per 28.3 grams (1 avoirdupois ounce);

(3) Pharmaceutical preparations containing not more than 64.8 milligrams (1 grain) codeine, or any of its salts, per 29.5729 cubic centimeters (1 fluid ounce) or per 28.3 grams (1 avoirdupois ounce);

(4) Pharmaceutical preparations containing not more than 32.4 milligrams (½ grain) dihydrocodeine, or any of its salts, per 29.5729 cubic centimeters (1 fluid ounce) or per 28.3 grams (1 avoirdupois ounce);

(5) Pharmaceutical preparations containing not more than 16.2 milligrams (¼ grain) ethylmorphine, or any of its salts, per 29.5729 cubic centimeters (1 fluid ounce) or per 28.3 grams (1 avoirdupois ounce);

Provided, That the preparations described in this paragraph contain one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the preparation valuable medicinal qualities other than those possessed by the narcotic drug alone.

(b) Drugs containing chlorobutanol, intended for external use only.

(c) Epinephrine solution, 1 percent, preserved with chlorobutanol and intended for use solely as a spray.

(d) Combination drugs listed in § 166.8(a) of this chapter as exempted from section 511 of the act.

PART 330—OVER-THE-COUNTER (OTC) HUMAN DRUGS WHICH ARE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED

Subpart A—General Provisions

Sec.
330.1 General conditions for general recognition as safe, effective and not misbranded.
330.5 Drug categories.

Subpart B—Administrative Procedures

330.10 Procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing monographs.
330.11 NDA deviations from applicable monograph.
330.12 Status of over-the-counter (OTC) drugs previously reviewed under the Drug Efficacy Study (DESI).

Authority: Secs. 502, 503, 505, 601, 52 Stat. 1051, 1052, 1053, 1055, as amended (21 U.S.C. 35, 353, 355, 371) (5 U.S.C. 554), unless otherwise noted.

Subpart A—General Provisions

§ 330.1 General conditions for general recognition as safe, effective and not misbranded.

An over-the-counter (OTC) drug listed in this subchapter is generally recognized as safe and effective and is not misbranded if it meets each of the conditions contained in this part and each of the conditions contained in any applicable monograph. Any product which fails to conform to each of the conditions contained in this part and in an applicable monograph is liable to regulatory action.

(a) The product is manufactured in compliance with current good manufacturing practices, as established by Part 133 of this chapter.

(b) The establishment(s) in which the drug product is manufactured is registered, and the drug product is listed, in compliance with Part 132 of this chapter. It is requested but not required that the number assigned to the product pursuant to Part 132 of this chapter appear on all drug labels and in all drug labeling. If this number is used, it shall be placed in the manner set forth in Part 132 of this chapter.

(c) The product is labeled in compliance with Chapter V of the act and § 1.100 et seq. of this chapter. For purposes of § 1.102a(b) of this chapter, the statement of identity of the product shall be the term or phrase used in the applicable monograph established in this part.

(d) The advertising for the product prescribes, recommends, or suggests its use only under the conditions stated in the labeling.

(e) The product contains only suitable inactive ingredients which are safe in the amounts administered and do not interfere with the effectiveness of the preparation or with suitable tests or assays to determine if the product meets its professed standards of identity, strength, quality, and purity. Color additives may be used only in accordance with section 706 of the act and Parts 8 and 9 of this chapter.

(f) The product container and container components meet the requirements of § 133.9 of this chapter.

(g) The labeling contains the general warning: "Keep this and all drugs out of the reach of children. In case of accidental overdose, contact a physician immediately." The Food and Drug Administration will grant an exemption from this general warning where appropriate upon petition.

(h) Where no maximum daily dosage limit for an active ingredient is established in this part, it is used in a product at a level that does not exceed the amount reasonably required to achieve its intended effect.

(i) The labeling for any drug for which an applicable monograph requires a drug interaction warning contains the following warning: "Warning: Do not take this product concurrently with a prescription drug except on the advice of a physician."

(j) It is recommended that the labeling of the product contain the quantitative amount of each active ingredient, expressed in terms of the dosage unit stated in the directions for use (e.g., tablet, teaspoonful).

§ 330.5 Drug categories.

Monographs promulgated pursuant to the provisions of this part shall be es-

tablished in this Part 330 and following parts and shall cover the following designated categories:

(a) Antacids.
(b) Laxatives.
(c) Antidiarrheal products.
(d) Emetics.
(e) Antiemetics.
(f) Antiperspirants.
(g) Sunburn prevention and treatment products.
(h) Vitamin-mineral products.
(i) Antimicrobial products.
(j) Dandruff products.
(k) Oral hygiene aids.
(l) Hemorrhoidal products.
(m) Hematinics.
(n) Bronchodilator and antiasthmatic products.
(o) Analgesics.
(p) Sedatives and sleep aids.
(q) Stimulants.
(r) Antitussives.
(s) Allergy treatment products.
(t) Cold remedies.
(u) Antirheumatic products.
(v) Ophthalmic products.
(w) Contraceptive products.
(x) Miscellaneous dermatologic products.
(y) Dentifrices and dental products such as analgesics, antiseptics, etc.
(z) Miscellaneous (all other OTC drugs not falling within one of the above therapeutic categories).

Subpart B—Administrative Procedures

§ 330.10 Procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing monographs.

For purposes of classifying over-the-counter (OTC) drugs as drugs generally recognized among qualified experts as safe and effective for use and as not misbranded drugs, the following regulations shall apply:

(a) *Procedure for establishing OTC drug monographs*—(1) *Advisory review panels.* The Commissioner shall appoint advisory review panels of qualified experts to evaluate the safety and effectiveness of OTC drugs, to review OTC drug labeling, and to advise him on the promulgation of monographs establishing conditions under which OTC drugs are generally recognized as safe and effective and not misbranded. A single advisory review panel shall be established for each designated category of OTC drugs and every OTC drug category will be considered by a panel. The members of a panel shall be qualified experts (appointed by the Commissioner) and may include persons from lists submitted by organizations representing professional, consumer, and industry interests. The Commissioner shall designate the chairman of each panel. Summary minutes of all meetings shall be made.

(2) *Request for data and views.* The Commissioner will publish a notice in the FEDERAL REGISTER requesting interested persons to submit, for review and evaluation by an advisory review panel, published and unpublished data and information pertinent to a designated category of OTC drugs. Data and information submitted pursuant to a published notice, and falling within the confidentiality provisions of 18 U.S.C. 1905, 5 U.S.C. 552(b), or 21 U.S.C. 331(j), shall be handled by the advisory review panel and the Food and Drug Administration as confidential until publication of a proposed monograph and the full report(s) of the panel. Thirty days thereafter such data and information shall be made publicly available and may be viewed at the office of the Hearing Clerk of the Food and Drug Administration, except to the extent that the person submitting it demonstrates that it still falls within the confidentiality provisions of one or more of those statutes. To be considered, eight copies of the data and/or views on any marketed drug within the class must be submitted, preferably bound, indexed, and on standard sized paper (approximately 8½ x 11 inches). When requested, abbreviated submissions should be sent. All submissions must be in the following format:

OTC DRUG REVIEW INFORMATION

I. Label(s) and all labeling (preferably mounted and filed with the other data—facsimile labeling is acceptable in lieu of actual container labeling).

II. A statement setting forth the quantities of active ingredients of the drug.

III. Animal safety data.
A. Individual active components.
1. Controlled studies.
2. Partially controlled or uncontrolled studies.
B. Combinations of the individual active components.
1. Controlled studies.
2. Partially controlled or uncontrolled studies.
C. Finished drug product.
1. Controlled studies.
2. Partially controlled or uncontrolled studies.

IV. Human safety data.
A. Individual active components.
1. Controlled studies.
2. Partially controlled or uncontrolled studies.
3. Documented case reports.
4. Pertinent marketing experiences that may influence a determination as to the safety of each individual active component.
5. Pertinent medical and scientific literature.
B. Combinations of the individual active components.
1. Controlled studies.
2. Partially controlled or uncontrolled studies.
3. Documented case reports.
4. Pertinent marketing experiences that may influence a determination as to the safety of combinations of the individual active components.
5. Pertinent medical and scientific literature.
C. Finished drug product.
1. Controlled studies.
2. Partially controlled or uncontrolled studies.
3. Documented case reports.
4. Pertinent marketing experiences that may influence a determination as to the safety of the finished drug product.
5. Pertinent medical and scientific literature.

V. Efficacy data.
A. Individual active components.
1. Controlled studies.
2. Partially controlled or uncontrolled studies.
3. Documented case reports.
4. Pertinent marketing experiences that may influence a determination on the efficacy of each individual active component.
5. Pertinent medical and scientific literature.
B. Combinations of the individual active components.
1. Controlled studies.
2. Partially controlled or uncontrolled studies.
3. Documented case reports.
4. Pertinent marketing experiences that may influence a determination on the efficacy of combinations of the individual active components.
5. Pertinent medical and scientific literature.
C. Finished drug product.
1. Controlled studies.
2. Partially controlled or uncontrolled studies.
3. Documented case reports.
4. Pertinent marketing experiences that may influence a determination on the efficacy of the finished drug product.
5. Pertinent medical and scientific literature.

VI. A summary of the data and views setting forth the medical rationale and purpose (or lack thereof) for the drug and its ingredients and the scientific basis (or lack thereof) for the conclusion that the drug and its ingredients have been proven safe and effective for the intended use. If there is an absence of controlled studies in the material submitted, an explanation as to why such studies are not considered necessary must be included.

(3) *Deliberations of an advisory review panel.* An advisory review panel will meet as often and for as long as is appropriate to review the data submitted to it and to prepare a report containing its conclusions and recommendations to the Commissioner with respect to the safety and effectiveness of the drugs in a designated category of OTC drugs. A panel may consult any individual or group. Any interested person may request an opportunity to present oral views to the panel; such request may be granted or denied by the panel. Such requests for oral presentations should be in written form including a summarization of the data to be presented to the panel. Any interested person may present written data and views which shall be considered by the panel. This information shall be presented to the panel in the format set forth in paragraph(a)(2) of this section and within the time period established for the drug category in the notice for review by a panel.

(4) *Standards for safety, effectiveness, and labeling.* The advisory review panel, in reviewing the data submitted to it and preparing its conclusions and recommendations, and the Commissioner, in reviewing the conclusions and recommendations of the panel and the published proposed, tentative, and final monographs, shall apply the following standards to determine general recognition that a category of OTC drugs is safe and effective and not misbranded:

(i) Safety means a low incidence of adverse reactions or significant side effects under adequate directions for use and warnings against unsafe use as well as low potential for harm which may result from abuse under conditions of

widespread availability. Proof of safety shall consist of adequate tests by methods reasonably applicable to show the drug is safe under the prescribed, recommended, or suggested conditions of use. This proof shall include results of significant human experience during marketing. General recognition of safety shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data.

(ii) Effectiveness means a reasonable expectation that, in a significant proportion of the target population, the pharmacological effect of the drug, when used under adequate directions for use and warnings against unsafe use, will provide clinically significant relief of the type claimed. Proof of effectiveness shall consist of controlled clinical investigations as defined in § 314.111(a)(5)(ii) of this chapter, unless this requirement is waived on the basis of a showing that it is not reasonably applicable to the drug or essential to the validity of the investigation and that an alternative method of investigation is adequate to substantiate effectiveness. Investigations may be corroborated by partially controlled or uncontrolled studies, documented clinical studies by qualified experts, and reports of significant human experience during marketing. Isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered. General recognition of effectiveness shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data.

(iii) The benefit-to-risk ratio of a drug shall be considered in determining safety and effectiveness.

(iv) An OTC drug may combine two or more safe and effective active ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s); when combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients; and when the combination, when used under adequate directions for use and warnings against unsafe use, provides rational concurrent therapy for a significant proportion of the target population.

(v) Labeling shall be clear and truthful in all respects and may not be false or misleading in any particular. It shall state the intended uses and results of the product; adequate directions for proper use; and warnings against unsafe use, side effects, and adverse reactions in such terms as to render them likely to be read and understood by the ordinary individual, including individuals of low comprehension, under customary conditions of purchase and use.

(vi) A drug shall be permitted for OTC sale and use by the laity unless, because of its toxicity or other potential for harmful effect or because of the method or collateral measures necessary to its use, it may safely be sold and used only under the supervision of a practitioner licensed by law to administer such drugs.

(5) *Advisory review panel report to the Commissioner.* An advisory review panel shall submit to the Commissioner a report containing its conclusions and recommendations with respect to the conditions under which OTC drugs falling within the category covered by the panel are generally recognized as safe and effective and not misbranded. Included within this report shall be:

(i) A recommended monograph or monographs covering the category of OTC drugs and establishing conditions under which the drugs involved are generally recognized as safe and effective and not misbranded. This monograph may include any conditions relating to active ingredients, labeling indications, warnings and adequate directions for use, prescription or OTC status, and any other conditions necessary and appropriate for the safety and effectiveness of drugs covered by the monograph.

(ii) A statement of all active ingredients, labeling claims or other statements, or other conditions reviewed and excluded from the monograph on the basis of the panel's determination that they would result in the drug's not being generally recognized as safe and effective or would result in misbranding.

(iii) A statement of all active ingredients, labeling claims or other statements, or other conditions reviewed and excluded from the monograph on the basis of the panel's determination that the available data are insufficient to classify such condition under either paragraph (a)(5)(i) or (ii) of this section and for which further testing is therefore required. The report may recommend the type of further testing required and the time period within which it might reasonably be concluded.

(6) *Proposed monograph.* After reviewing the conclusions and recommendations of the advisory review panel, the Commissioner shall publish in the FEDERAL REGISTER a proposed order containing:

(i) A monograph or monographs establishing conditions under which a category of OTC drugs is generally recognized as safe and effective and not misbranded.

(ii) A statement of the conditions excluded from the monograph on the basis of the Commissioner's determination that they would result in the drug's not being generally recognized as safe and effective or would result in misbranding.

(iii) A statement of the conditions excluded from the monograph on the basis of the Commissioner's determination that the available data are insufficient to classify such conditions under either paragraph (a)(6)(i) or (ii) of this section.

(iv) The full report(s) of the panel to the Commissioner.

The proposed order shall specify a reasonable period of time within which conditions falling within paragraph (a)(6)(iii) of this section may be continued in marketed products while the data necessary to support them are being obtained for evaluation by the Food and Drug Administration. The summary minutes of the panel meetings shall be made available to interested persons upon request. Any interested person may, within 60 days after publication of the proposed order in the FEDERAL REGISTER, file with the Hearing Clerk of the Food and Drug Administration written comments in quintuplicate. Comments may be accompanied by a memorandum or brief in support thereof. All comments may be reviewed at the office of the Hearing Clerk during regular working hours, Monday through Friday. Within 30 days after the final day for submission of comments, reply comments may be filed with the Hearing Clerk; these comments shall be utilized to reply to comments made by other interested persons and not to reiterate a position. The Commissioner may satisfy this requirement by publishing in the FEDERAL REGISTER a proposed order summarizing the full report of the advisory review panel, containing its conclusions and recommendations, to obtain full public comment before undertaking his own evaluation and decision on the matters involved.

(7) *Tentative final monograph.* After reviewing all comments and reply comments, the Commissioner shall publish in the FEDERAL REGISTER a tentative order containing a monograph establishing conditions under which a category of OTC drugs is generally recognized as safe and effective and not misbranded. Within 30 days, any interested party may file with the Hearing Clerk of the Food and Drug Administration written objections specifying with particularity the omissions or additions requested. These objections are to be supported by a brief statement of the grounds therefor. A request for an oral hearing may accompany such objections.

(8) *Oral hearing before the Commissioner.* After reviewing objections filed in response to the tentative final monograph, the Commissioner, if he finds reasonable grounds in support thereof, shall by notice in the FEDERAL REGISTER schedule an oral hearing. The notice scheduling an oral hearing shall specify the length of the hearing and how the time shall be divided among the parties requesting the hearing. The hearing shall be conducted by the Commissioner and may not be delegated.

(9) *Final monograph.* After reviewing the objections and considering the arguments made at any oral hearing, the Commissioner shall publish in the FEDERAL REGISTER a final order containing a monograph establishing conditions under which a category of OTC drugs is generally recognized as safe and effective and not misbranded. The monograph shall become effective as specified in the order.

(10) *Court appeal.* The monograph contained in the final order constitutes final agency action from which appeal lies to the courts. The Food and Drug Administration will request consolidation of all appeals in a single court. Upon court appeal, the Commissioner may, at

his discretion, stay the effective date for part or all of the monograph pending appeal and final court adjudication.

(11) *Amendment of monographs.* The Commissioner may propose on his own initiative to amend or repeal any monograph established pursuant to this section. Any interested person may petition the Commissioner for such proposal. A petition shall set forth the action requested and a detailed statement of the grounds in support of such action. After review of a petition, the Commissioner may deny the petition if he finds a lack of safety or effectiveness employing the standards in paragraph (a)(4) of this section (in which case the appeal provisions of paragraph (a)(10) of this section shall apply) or he may publish a proposed amendment or repeal in the FEDERAL REGISTER if he finds general recognition of safety and effectiveness employing the standards in paragraph (a)(4) of this section (in which case the provisions of paragraph (a) (6), (7), (8), and (9) of this section shall apply). A new-drug application may be submitted in lieu of or in addition to a petition under this paragraph.

(b) *Regulatory action.* Any product which fails to conform to an applicable monograph after its effective date is liable to regulatory action.

EFFECTIVE DATE: The final sentence of § 330.10(a)(6)(iv) becomes effective April 12, 1974. See 39 FR 9659, March 13, 1974.

§ 330.11 NDA deviations from applicable monographs.

A new-drug application requesting approval of an OTC drug deviating in any respect from a monograph that has become final shall be in the form required by § 314.1(a)(2) of this chapter, but shall include a statement that the product meets all conditions of the applicable monograph except for the deviation for which approval is requested and may omit all information except that pertinent to the deviation.

§ 330.12 Status of over-the-counter (OTC) drugs previously reviewed under the Drug Efficacy Study (DESI).

(a) There were 420 OTC drugs reviewed in the Drug Efficacy Study (a review of drugs introduced to the market through new drug procedures between 1938 and 1962). A careful review has been made of the reports on these drugs to determine those drugs for which implementation may be deferred without significant risk to the public health, pending review by appropriate OTC drug advisory review panels and promulgation of a monograph.

(b) On and after April 20, 1972, a number of notices were published in the FEDERAL REGISTER concerning previously unpublished OTC drugs reviewed by the National Academy of Sciences-National Research Council Drug Efficacy Study Group. Only the evaluations and comments of the panels were published, with no conclusions of the Commissioner of Food and Drugs. Those publications were for the purpose of giving interested persons the benefit of the Academy's opinions. For those products, and also for OTC drug products previously published with the Commissioner's conclusions (except for the products listed in paragraph (b)(1) and (2) of this section, all requests for data, revised labeling, requests for new drug applications, abbreviated new drug applications, updating supplements, data to support less than effective claims, if any, etc., are deferred, and such OTC drug products are instead subject to the OTC drug review in their appropriate classes pursuant to the procedures established in this subpart.

(1) The requirements of the following DESI announcements are not deferred (the reference document may also pertain to prescription drugs):

(i) Certain Surgical Sutures (DESI 4725), published in the FEDERAL REGISTER of November 11, 1971 (36 FR 21612).

(ii) Absorbable Dusting Powder (DESI 6264), published in the FEDERAL REGISTER of May 25, 1971 (36 FR 9475).

(iii) Certain Insulin Preparations (DESI 4286), published in the FEDERAL REGISTER of April 9, 1971 (36 FR 6842).

(iv) Sulfo-Van Ointment (DESI 2230), published in the FEDERAL REGISTER of October 8, 1970 (35 FR 15860).

(v) Antiperspirants and Deodorants Containing Neomycin Sulfate (DESI 11048) for which an order revoking provisions for certification or release was published in the FEDERAL REGISTER of December 5, 1972 (37 FR 25820) and has been stayed by the filing of objections.

(vi) Thorexin Cough Medicine (DESI 11160) for which a notice of opportunity for hearing was published in the FEDERAL REGISTER of February 2, 1973 (38 FR 3210).

(vii) Antibiotic susceptibility discs (DESI 90235) for which an order providing for certain discs to be certified and removing provisions for certification of other discs was published in the FEDERAL REGISTER of September 30, 1972 (37 FR 20525) and has been stayed by the filing of objections notice of which was published in the FEDERAL REGISTER of March 15, 1973 (38 FR 7007).

(2) Deferral of requirements is not appropriate when an announcement has been published and has been followed by a final order classifying a drug either as lacking substantial evidence of effectiveness or as not shown to be safe. These products will be removed from the market, if they have not already been removed. Regulatory action will also be undertaken against identical, similar and related products (21 CFR 310.6). Deferral of requirements is not appropriate for the following (the referenced document may also pertain to prescription drugs):

(i) Certain Sulfonamide-Decongestant Nasal Preparation (DESI 4850), for which notice of withdrawal of approval of new drug applications was published in the FEDERAL REGISTER of October 24, 1970 (35 FR 16605, 16606).

(ii) Eskay's Theranates, containing strychnine, sodium, and calcium glycerophosphates, thiamine hydrochloride, alcohol, and phosphoric acid (DESI 2220), for which notice of withdrawal of approval of the new drug application was published in the FEDERAL REGISTER of February 18, 1971 (36 FR 3152).

(iii) The following topical drugs (DESI 1726), for which notice of withdrawal of new drug applications was published in the FEDERAL REGISTER of August 28, 1971 (36 FR 17368):

(*a*) Rhulitol Solution, containing tannic acid, chlorobutanol, phenol, camphor, alum, and isopropyl alcohol.

(*b*) Zirnox Topical Lotion, containing phenyltoloxamine citrate and zirconium oxide.

(iv) Menacyl Tablets, containing aspirin, menadione, and ascorbic acid (DESI 6363), for which notice of withdrawal of approval of the new drug application was published in the FEDERAL REGISTER of July 23, 1970 (35 FR 11827).

(v) Curad Medicated Adhesive Bandage containing sulfathiazole (DESI 4964), for which notice of withdrawal of approval of the new drug application was published in the FEDERAL REGISTER of December 31, 1969 (34 FR 20441).

(vi) Drugs Containing Rutin, Quercetin, Hesperidin, or any Bioflavonoids (DESI 5960), for which notice of withdrawal of approval of new drug applications was published in the FEDERAL REGISTER of July 3, 1970 (35 FR 10872, 10873) and October 17, 1970 (35 FR 16332). A further notice of opportunity for hearing with respect to the drugs covered by the October 17, 1970 FEDERAL REGISTER notice will be published at a later date.

(vii) Antibiotics in Combination with Other Drugs for Nasal Use (DESI 7561), for which an order revoking provision for certification was published in the FEDERAL REGISTER of August 6, 1971 (36 FR 14469) and confirmed in the FEDERAL REGISTER of October 28, 1971 (36 FR 20686).

(viii) Antibiotic Troches (DESI 8328), for which an order revoking provision for certification was published in the FEDERAL REGISTER of July 14, 1971 (36 FR 13089) and confirmed in the FEDERAL REGISTER of October 9, 1971 (36 FR 19695).

(ix) Certain Drugs Containing Oxyphenisatin or Oxyphenisatin Acetate (DESI 10732), for which notices of withdrawal of approval of new drug applications were published in the FEDERAL REGISTER of February 1, 1972 (37 FR 2460), and March 9, 1973 (38 FR 6419).

(x) Curad Medicated Adhesive Bandage containing tyrothricin-nitrofurazone (DESI 6898), for which an order revoking provision for certification was published March 14, 1972 (37 FR 5294), and confirmed in the FEDERAL REGISTER of July 6, 1972 (37 FR 13254).

(xi) Candette Cough Gel (DESI 11562), for which notice of withdrawal of approval of the new drug application was published in the FEDERAL REGISTER of November 19, 1972 (37 FR 25249).

(xii) Certain OTC Multiple-Vitamin Preparations for Oral Use containing excessive amounts of vitamin D and/or vitamin A (DESI 97), for which notice of withdrawal of approval of the new drug applications was published in the FED-

ERAL REGISTER of November 29, 1972 (37 FR 25249).

(xiii) Certain Sulfonamide-Containing Preparations for Topical Ophthalmic or Otic Use (DESI 3684), for which a notice of withdrawal of approval was published in the FEDERAL REGISTER of February 2, 1973 (38 FR 3208).

(xiv) Those parts of the publication entitled "Certain Mouthwash and Gargle Preparations" (DESI 2855) pertaining to Tyrolaris Mouthwash, containing tyrothricin, panthenol, and alcohol, for which an order revoking provision for certification was published in the FEDERAL REGISTER of February 2, 1967 (32 FR 1172) prior to the drug efficacy study implementation.

(c) Manufacturers and distributors should take notice that the information on OTC drugs provided by the Drug Efficacy Study review is valuable information as to the deficiencies in the data available to support indications for use. They are encouraged to perform studies to obtain adequate evidence of effectiveness for the review of OTC drugs which is already in progress. In the interim it is in the public interest that manufacturers and distributors of all OTC drugs effect changes in their formulations and/or labeling to bring the products into conformity with current medical knowledge and experience.

(d) Manufacturers and distributors of OTC drugs may be reluctant to make appropriate formulation and/or labeling changes for fear of losing the protection of the so-called "grandfather" provisions of the 1938 Federal Food, Drug, and Cosmetic Act (sec. 201(p)(1)) and the 1962 amendments to the act (sec. 107(c) of those amendments). To encourage and facilitate prompt changes, the Food and Drug Administration will not take legal action against any OTC drug, other than those not deferred, based on a charge that the product is a new drug and not grandfathered under the act as a result of the changes if the changes in formulation and/or labeling are of the following kind:

(1) The addition to the labeling of warning, contraindications, side effects, and/or precaution information.

(2) The deletion from the labeling of false, misleading, or unsupported indications for use or claims of effectiveness.

(3) Changes in the components or composition of the drug that will give increased assurance that the drug will have its intended effect, yet not raise or contribute any added safety questions.

(4) Changes in the components or composition of the drug which may reasonably be concluded to improve the safety of the drug, without diminishing its effectiveness.

(e) The forbearance from legal action for lack of grandfather protection is an interim procedure designed to encourage appropriate change in formulation and/or labeling during the time period required to review the various classes of OTC drugs. At such time as an applicable OTC drug monograph becomes effective, the interim procedure will automatically be terminated and any appropriate regulatory action will be initiated.

PART 369—INTERPRETATIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE

Subpart A—Definitions and Interpretations

Sec.

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369.30 Devices; recommended warning and caution statements.

AUTHORITY: Secs. 502, 503, 506, 507, 701, 52 Stat. 1050, as amended, 1052, as amended, 53 Stat. 854, 55 Stat. 851, 59 Stat. 463, as amended, 52 Stat. 1055, as amended (21 U.S.C. 352, 353, 356, 357, 371).

Subpart A—Definitions and Interpretations

§ 369.1 Purpose of issuance.

The warning and caution statements suggested in Subparts B and C of this part, for inclusion in the label or labeling of drugs and devices subject to section 502 (d) and (f)(2) and other relevant provisions of the Federal Food, Drug, and Cosmetic Act are issued for the purpose of assisting industry in preparing proper labeling for these articles for over-the-counter sale and in meeting the legal requirements of the act that the label or labeling of drugs and devices bear adequate warnings, in such manner and form as are necessary for the protection of users. Only section 502(d) of the act requires use of the specific language included in these suggested warning and caution statements. These suggested warning or caution statements are illustrative of those that may be necessary or desirable. It is the responsibility of the manufacturer, packer, shipper, or distributor in interstate commerce to see that such statements are adequate for compliance with the provisions of the law. Omission of any article from this suggested list does not relieve drugs and devices subject to provisions of the act from bearing adequate warning or caution statements where such statements are necessary or desirable for the protection of the user.

§ 369.2 Definitions.

(a) As used in this part, the term "act" means the Federal Food, Drug, and Cosmetic Act.

(b) The terms "drugs" and "devices" are defined in section 201 (g) and (k) of the act.

(c) Official compendia are defined in section 201(j) of the act.

§ 369.3 Warnings required on drugs exempted from prescription-dispensing requirements of section 503(b)(1)(C).

Drugs exempted from prescription-dispensing requirements under section 503(b)(1)(C) of the act are subject to the labeling requirements prescribed in § 310.201(a) of this chapter. Although, for convenience, warning and caution statements for a number of the drugs named in § 310.201 of this chapter (cross-referenced in the text of this part) are included in Subpart B of this part, the inclusion of such drugs in §§ 369.20, 369.21, 369.22 in no way affects the requirements for compliance with § 310.201 (a) of this chapter, or the provisions of an effective application pursuant to section 505(b) of the act.

§ 369.4 Warnings suggested for drugs by formal or informal statements of policy.

The warning and caution statements included in Subpart B of this part in no way affect any warning statement suggested for such drugs or devices by any statement of policy or interpretation in Part 3 of this chapter.

§ 369.5 Warnings required on insulin intended for over-the-counter sale.

Warning and caution statements for insulin products sold over the counter must comply with the specific labeling provisions of the act and § 429.11 of this chapter.

§ 369.6 Warnings required on certifiable antibiotics exempted from prescription-dispensing requirements.

Certain certifiable antibiotic drugs are exempted from prescription-dispensing requirements under section 507 of the act, but are subject to the specific labeling requirements, including warning or caution statements, of the applicable section of the antibiotic regulations.

§ 369.7 Warnings required by official compendia.

Any drug included in the official compendia defined by the act shall bear such warning or caution statement as may be required by such compendia, and no statement in Subpart B or Subpart C of this part is intended to alter, modify, or permit the omission of any such statement required by such compendia.

§ 369.8 Warning statements in relation to conditions for use.

The mention in any warning or caution statement included in Subparts A, B, and C of this part, of a disease condition does not imply a finding on the part of the Food and Drug Administration that any drug or device is efficacious in such condition; nor is any drug or device

bearing labeling referring to such disease condition precluded from regulatory action under the applicable provisions of the act if such claim is considered to be misbranding.

§ 369.9 General warnings re accidental ingestion by children.

Section 369.20 includes under certain items, but not all medicines, the statement: "Warning—Keep this and all medicines out of children's reach. In case of accidental overdose, contact a physician immediately", or "Warning—Keep out of the reach of children". However, in view of the possibility of accidental ingestion of drugs, it is not only suggested but is recommended that one of these statements be used on the label of all drug products.

§ 369.10 Conspicuousness of warning statements.

Necessary warning statements should appear in the labeling prominently and conspicuously as compared to other words, statements, designs, and devices, and in bold type on clearly contrasting background, in order to comply with the provisions of section 502 (c) and (f)(2) of the act. The warning statements should be placed in the labeling in juxtaposition with the directions for use and, in any case, should appear on the label when there is sufficient label space in addition to mandatory label information.

Subpart B—Warning and Caution Statements for Drugs

§ 369.20 Drugs; recommended warning and caution statements.

ACETANILID.

Warning—Do not exceed recommended dosage. Overdosage or continued use may result in serious blood disturbances.

ACETOPHENETIDIN - CONTAINING PREPARATIONS. (See § 3.37 of this chapter.)

Warning—This medication may damage the kidneys when used in large amounts or for a long period of time. Do not take more than the recommended dosage, nor take regularly for longer than 10 days without consulting your physician.

ANESTHETICS FOR EXTERNAL USE (LOCAL ANESTHETICS). (See also § 310.201(a) (19) and (23) of this chapter.)

Caution—Do not use in the eyes. Not for prolonged use. If the condition for which this preparation is used persists or if a rash or irritation develops, discontinue use and consult physician.

ANTIBIOTICS FOR EXTERNAL USE FOR PREVENTION OF INFECTION. (See also §§ 310.201(a)(5), 146c.202, 146e.402, 146e.407, 146e.409, 146e.411, 146e.422 of this chapter.)

Caution—In case of deep or puncture wounds or serious burns consult physician. If redness, irritation, swelling, or pain persists or increases or if infection occurs, discontinue use and consult physician. Do not use in the eyes.

ANTIHISTAMINICS FOR EXTERNAL USE (EXCEPT PREPARATIONS FOR OPHTHALMIC USE).

Caution—Do not use in the eyes. If the condition for which this preparation is used persists or if a rash or irritation develops, discontinue use and consult physician.

ANTIHISTAMINICS, ORAL. (See also §§ 3.29 and 310.201(a) (4), (6), (13), (24), and (25) of this chapter.)

Caution—This preparation may cause drowsiness. Do not drive or operate machinery while taking this medication. Do not give to children under 6 years of age or exceed the recommended dosage unless directed by physician.

The reference to drowsiness is not required on preparations for the promotion or sleep or on preparations that are shown not to produce drowsiness.

Cyclizine - containing preparations should include the following:

Warning—Not for use by women who are pregnant or who may possibly become pregnant, unless directed by a physician, since this drug may have the potentiality of injuring the unborn child.

ANTIPERSPIRANTS.

Do not apply to broken skin. If a rash develops, discontinue use.

ANTIPYRINE.

Warning—Do not exceed recommended dosage. If skin rash appears, discontinue use and consult physician.

ANTISEPTICS FOR EXTERNAL USE.

Caution—In case of deep or puncture wounds or serious burns, consult physician. If redness, irritation, swelling, or pain persists or increases or if infection occurs discontinue use and consult physician.

The reference to wounds and burns is not required on preparations intended solely for diaper rash.

ARSENIC PREPARATIONS.

Warning—Frequent or prolonged use may cause serious injury. Do not exceed recommended dosage. Keep out of the reach of children.

BELLADONNA PREPARATIONS AND PREPARATIONS OF ITS ALKALOIDS (ATROPINE, HYOSCYAMINE, AND SCOPOLAMINE (HYOSCINE); HYOSCYAMUS, STRAMONIUM, THEIR DERIVATIVES, AND RELATED DRUG PREPARATIONS.

Warning—Not to be used by persons having glaucoma or excessive pressure within the eye, by elderly persons (where undiagnosed glaucoma or excessive pressure within the eye occurs most frequently), or by children under 6 years of age, unless directed by a physician. Discontinue use if blurring of vision, rapid pulse, or dizziness occurs. Do not exceed recommended dosage. Not for frequent or prolonged use. If dryness of the mouth occurs, decrease dosage. If eye pain occurs, discontinue use and see your physician immediately as this may indicate undiagnosed glaucoma.

See also Rectal Preparations for additional warnings.

In the case of scopolamine or scopolamine aminoxide preparations indicated for insomnia, the portion of the above warning that reads "children under 6 years of age" should read instead "children under 12 years of age".

BORIC ACID (POWDERED, CRYSTALLINE, OR GRANULAR).

Warning—Do not use as a dusting powder, especially on infants, or take internally. Use only as a solution. Do not apply to badly broken or raw skin, or to large areas of the body.

BROMIDES.

Caution—Use only as directed. Do not give to children or use in the presence of kidney disease. If skin rash appears or if nervous symptoms persist, recur frequently, or are unusual, discontinue use and consult physician.

CARBOLIC ACID (PHENOL) PREPARATIONS (MORE THAN 0.5 PERCENT) FOR EXTERNAL USE.

Warning—Use according to directions. Do not apply to large areas of the body. If applied to fingers or toes, do not bandage.

CATHARTICS AND LAXATIVES—IRRITANTS AND OTHER PERISTALTIC STIMULANTS.

Warning—Do not use when abdominal pain, nausea, or vomiting are present. Frequent or prolonged use of this preparation may result in dependence on laxatives.

Mercury preparations should have added to the "frequent use" statement, the words "and serious mercury poisoning".

Phenolphthalein preparations should bear, in addition to the general warning, the following statement:

Caution—If skin rash appears, do not use this or any other preparation containing phenolphthalein.

See also Mineral Oil Laxatives.

CHLORATES: MOUTH WASH OR GARGLE.

Avoid swallowing.

COBALT PREPARATIONS (See also § 3.48 of this chapter.)

Warning—Do not exceed the recommended dosage. Do not administer to children under 12 years of age unless directed by physician. Do not use for more than 2 months unless directed by physician.

This warning is not required on articles containing not more than 0.5 milligram of cobalt as a cobalt salt per dosage unit and which recommend administration of not more than 0.5 milligram per dose and not more than 2 milligrams per 24-hour period.

"COUGH-DUE-TO-COLD" PREPARATIONS. (See also § 310.201(a) (14) and (20) of this chapter.)

Warning—Persons with a high fever or persistent cough should not use this preparation unless directed by physician.

COUNTERIRRITANTS AND RUBEFACIENTS.

Caution—Do not apply to irritated skin or if excessive irritation develops. Avoid getting into the eyes or on mucous membranes.

If offered for use in arthritis or rheumatism, in juxtaposition therewith, the statement:

Caution—If pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age consult a physician immediately.

See also "Salicylates" in this section for additional warnings for preparations containing methyl salicylate.

CREOSOTE, CRESOLS, GUAIACOL, AND SIMILAR SUBSTANCES IN PREPARATIONS FOR EXTERNAL USE.

Caution—Do not apply to large areas of the body.

CREOSOTE, CRESOLS, GUAIACOL, AND SIMILAR SUBSTANCES IN DOUCHE PREPARATIONS.

Warning—The use of solutions stronger than those recommended may result in severe local irritation, burns, or serious poisoning. Mix as directed before pouring into douche bag. Do not use more often than twice weekly unless directed by physician.

DENTURE RELINERS, PADS, AND CUSHIONS.

Warning—For temporary use only. Long-term use of this product may lead to faster bone loss, continuing irritation, sores, and tumors. For Use Only Until a Dentist Can Be Seen.

DENTURE REPAIR KITS.

Warning—For emergency repairs only. Long-term use of home-repaired dentures may cause faster bone loss, continuing irritation, sores, and tumors. This kit for emergency use only. See Dentist Without Delay.

DIARRHEA PREPARATIONS.

Warning—Do not use for more than 2 days or in the presence of high fever or in infants or children under 3 years of age unless directed by a physician.

DISPENSERS PRESSURIZED BY GASEOUS PROPELLANTS FOR DRUGS FOR EXTERNAL USE. (See also § 310.201(a) (11) and (18) of this chapter.)

Warning—Keep away from eyes or other mucous membranes. Avoid inhaling.

This warning is not necessary for preparations specifically designed for use on mucous membranes.

Where indicated, in order to prevent chilling the tissues, a caution should be included against holding the dispenser too close to the body.

Warning—Contents under pressure. Do not puncture. Do not use or store near heat or open flame. Exposure to temperatures above 130° Fahrenheit may cause bursting. Never throw container into fire or incinerator.

DOUCHE PREPARATIONS.

Warning—Do not use more often than twice weekly unless directed by physician.

See also Creosote * * * Douche for additional warning.

DRESSINGS, PROTECTIVE SPRAY-ON TYPE. (See also § 310.201(a) (11) and (18) of this chapter.)

Warning—In case of deep or puncture wounds or serious burns consult physician. If redness, irritation, swelling or pain persists or increases or if infection occurs consult physician. Keep away from eyes or other mucous membranes. Avoid inhaling.

See also Dispensers Pressurized by Gaseous Propellants * * * for additional warnings to be included for products under pressure.

EPHEDRINE PREPARATIONS (ORAL)

Warning—Do not exceed the recommended dosage. Reduce dosage if nervousness, restlessness, or sleeplessness occurs. Do not use if high blood pressure, heart disease, diabetes, or thyroid disease is present unless directed by physician.

EPINEPHRINE INHALATION 1:100 (NOT FOR INJECTION).

Warning—For inhalation only. Reduce dosage if bronchial irritation, nervousness, restlessness, or sleeplessness occurs. Do not use if high blood pressure, heart disease, diabetes, or thyroid disease is present unless directed by physician. If prompt relief is not obtained consult physician. Do not use epinephrine inhalation if it is brown in color or contains a precipitate.

GENTIAN VIOLET (METHYLROSANILINE CHLORIDE) TABLETS.

Caution—Do not bite or chew tablets before swallowing. If nausea develops, discontinue for 1 or 2 days; then resume treatment with reduced dosage, increasing dose gradually to former level. This preparation should not be used by persons with heart, kidney, or liver disease or intestinal disorders. Abstinence from alcohol during treatment is advisable.

HEXYLRESORCINOL ANTHELMINTICS.

Warning—Do not chew or break in the mouth.

IODINE AND IODIDES (ORAL).

Caution—If a skin rash appears, discontinue use and consult physician.

MERCURY PREPARATIONS FOR EXTERNAL USE.

Warning—Discontinue use if rash or irritation develops or if condition for which used persists. Frequent or prolonged use, or application to large areas may cause serious mercury poisoning.

MINERAL OIL LAXATIVES. (See also § 3.4 of this chapter.)

Caution—Take only at bedtime. Avoid prolonged use. Do not administer to infants or young children, in pregnancy, or to bedridden or aged patients unless directed by physician.

NASAL PREPARATIONS: OIL BASE.

Warning—Do not exceed recommended dosage nor use for prolonged period. Do not administer to infants or children unless directed by physician. Do not use as a spray.

NASAL PREPARATIONS IN PLASTIC SPRAY CONTAINERS.

Avoid overdosage. Follow directions for use carefully.

NASAL PREPARATIONS: VASOCONSTRICTORS (AMPHETAMINE, EPHEDRINE, EPINEUHRINE, METHAMPHETAMINE, AND OTHERS OF SIMILAR ACTIVITY). (See also § 310.201(a) (16) of this chapter.)

Caution—Do not exceed recommended dosage. Overdosage may cause nervousness, restlessness, or sleeplessness. Do not use for more than 3 or 4 consecutive days unless directed by physician.

NASAL PREPARATIONS: VASOCONSTRICTORS (PHENYLEPHRINE HYDROCHLORIDE, HYDROXYAMPHETAMINE, PHENYLPROPANOLAMINE, AND OTHERS OF SIMILAR ACTIVITY).

Caution—Do not exceed recommended dosage.

NUX VOMICA AND STRYCHNINE PREPARATIONS.

Warning—Do not exceed the recommended dosage. Keep out of the reach of children.

OPHTHALMIC PREPARATIONS. (See also § 3.28 of this chapter.)

Warning—If irritation persists or increases, discontinue use and consult physician. Keep container tightly closed.

Solutions should include the statement: Do not touch dropper tip (or other dispensing tip) to any surface, since this may contaminate solution.

Boric acid offered for use in the preparation of ophthalmic solutions should bear the statement: Prepare solution by boiling in water. Store in a sterile container. Prepare sufficient for one day's use and discard unused portion.

PHENACETIN-CONTAINING PREPARATION. (See acetophenetidin.)

PHENYLEPHRINE HYDROCHLORIDE PREPARATIONS, ORAL.

Caution—Individuals with high blood pressure, heart disease, diabetes, or thyroid disease should use only as directed by physician.

PHENYLPROPANOLAMINE HYDROCHLORIDE PREPARATIONS, ORAL.

Caution—Individuals with high blood pressure, heart disease, diabetes, or thyroid disease should use only as directed by physician.

POTASSIUM PERMANGANATE AQUEOUS SOLUTIONS (CONTAINING NOT MORE THAN 0.04 PERCENT POTASSIUM PERMANGANATE). (See § 3.7 of this chapter.)

Warning—For external use on the skin only. Severe injury may result from use internally or as a douche. Avoid contact with mucous membranes.

QUININE AND OTHER CINCHONA DERIVATIVES (EXCEPT FOR USE IN MALARIA).

Caution—Discontinue use if ringing in the ears, deafness, skin rash, or visual disturbances occur.

RECTAL PREPARATIONS FOR EXTERNAL USE. (See also § 310.201(a) (3) of this chapter.)

Warning—In case of rectal bleeding, consult physician promptly.

See also Belladona Preparations * * * for additional warnings.

RESINS, OLEORESINS, AND VOLATILE OILS.

Caution—If nausea, vomiting, abdominal discomfort, diarrhea, or skin rash occurs, discontinue use and consult physician.

RESORCINOL (NOT THE MONOACETATE) HAIR PREPARATIONS.

Caution—Excessive use of this preparation may temporarily discolor blond, white, or red hair.

SALICYLATES, INCLUDING ASPIRIN AND SALICYLAMIDE (EXCEPT METHYL SALICYLATE, EFFERVESCENT SALICYLATE PREPARATIONS, AND PREPARATIONS OF AMINOSALICYLIC ACID AND ITS SALTS). (See also § 3.509 of this chapter.)

Warning—Keep this and all medicines out of children's reach. In case of accidental overdose, contact a physician immediately; or

Warning—Keep out of the reach of children.

If the article is an aspirin preparation, it should bear the first of the above two warning statements. In either case, the above information should appear on the label.

Caution—For children under 3 years of age, consult your physician; or

Caution—For younger children, consult your physician.

One of the two immediately preceding caution statements is required on the label of all aspirin tablets, but such a statement is not required on the labels of other salicylates clearly offered for administration to adults only.

If offered for use in arthritis or rheumatism, in juxtaposition therewith, the statement:

Caution — If pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age, consult a physician immediately.

SALICYLATES: METHYL SALICYLATE (WINTERGREEN OIL). See also §§ 3.35 and 3.509 of this chapter.

Warning — Do not use otherwise than as directed. Keep out of the reach of children to avoid accidental poisoning.

If the preparation is a counterirritant or rubefacient the statement:

Caution—Discontinue use if excessive irritation of the skin develops. Avoid getting into the eyes or on mucous membranes.

If offered for use in arthritis or rheumatism, in juxtaposition therewith, the statement:

Caution — If pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age consult a physician immediately.

SILVER.

Caution — Frequent or prolonged use of this preparation may result in permanent discoloration of skin and mucous membranes.

SODIUM PERBORATE MOUTH WASH AND GARGLE AND TOOTHPASTE.

Caution—Discontinue use if irritation or inflammation develops, or increases. Avoid swallowing.

SULFONAMIDE NOSE DROPS.

Caution — Do not use if a known allergy to sulfonamide drugs exists.

SULFUR PREPARATION FOR EXTERNAL USE.

Caution—If undue skin irritation develops or increases, discontinue use and consult physician.

THROAT PREPARATIONS FOR TEMPORARY RELIEF OF MINOR SORE THROAT: LOZENGES, TROCHES, WASHES, GARGLES, ETC. (See also § 3.510 of this chapter.)

Warning — Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult physician promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by physician.

TOOTHACHE PREPARATIONS.

For temporary use only until a dentist can be consulted.

ZINC STEARATE DUSTING POWDERS.

Warning — Keep out of the reach of infants and children; avoid inhaling.

§ 369.21 Drugs; warning and caution statements required by regulations.

ACETAMINOPHEN (N-ACETYL-*p*-AMINOPHENOL) (See § 310.201(a)(1) of this chapter.)

Warning—Do not give to children under 3 years of age or use for more than 10 days unless directed by a physician.

If offered for use in arthritis, or rheumatism, in juxtaposition therewith, the statement:

Caution — If pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age consult a physician immediately.

ALCOHOL RUBBING COMPOUND. (See 26 CFR 182.855(a) (5); The National Formulary, Tenth Edition 1955, pp. 27–28; and section 502(g) of the act).

Warning — For external use only. If taken internally serious gastric disturbances will result.

ANTIBIOTIC-CONTAINING DRUGS FOR EXTERNAL USE FOR PREVENTION OF INFECTION. (See § 310.201 (a) (5) of this chapter.)

Caution — If redness, irritation, swelling, or pain persists or increases or if infection occurs, discontinue use and consult physician. Do not use in the eyes.

ANTIHISTAMINICS, ORAL (PHENYLTOLOXAMINE DIHYDROGEN CITRATE, MECLIZINE HYDROCHLORIDE, DOXYLAMINE SUCCINATE, CHLOROTHEN CITRATE, CYCLIZINE HYDROCHLORIDE, AND CHLORCYCLIZINE HYDROCHLORIDE PREPARATIONS). (See §§ 3.29 and 310.201(a) (4), (6), (13), (24), and (25) of this chapter.)

Caution—This preparation may cause drowiness. Do not drive or operate machinery while taking this medication. Do not give to children under 6 years of age or exceed the recommended dosage unless directed by physician.

If offered for symptoms of colds, the statement:

Caution—If relief does not occur within 3 days, discontinue use and consult physician.

For chlorcyclizine-, cyclizine-, or meclizine-containing preparations, the statement:

Warning—Not for use by women who are pregnant or who may possibly become pregnant, unless directed by a physician, since this drug may have the potentiality of injuring the unborn child.

BACITRACIN-CONTAINING OINTMENTS. (See §§ 146e.402, 146e.407, 146e.411 of this chapter.)

For use only in the prevention of infection in minor cuts and abrasions.

Use of the drug should be discontinued and a physician consulted if signs of infection or irritation appear.

BACITRACIN (ZINC BACITRACIN)-POLYMYXIN OINTMENT; BACITRACIN-POLYMYXIN-NEOMYCIN OINTMENT. (See §§ 146e.409 and 146e.422 of this chapter.)

For use only in the prevention of infection in minor cuts and abrasions. Use of the drug should be discontinued

and a physician consulted if signs of infection or irritation appear.

If it is in liquid form, also the statement "Not for injection".

CARBETAPENTANE CITRATE PREPARATIONS. (See Cough-Due-to-Cold Preparations.)

"COUGH-DUE-TO-COLD" PREPARATIONS (DEXTROMETHORPHAN HYDROBROMIDE AND CARBETAPENTANE CITRATE). (See § 310.201(a) (14) and (20) of this chapter.)

Warning—Keep out of the reach of children. Do not administer to children under 2 years of age unless directed by physician. Persistent cough may indicate the presence of a serious condition. Persons with a high fever or persistent cough should not use this preparation unless directed by physician.

DEXTROMETHORPHAN HYDROBROMIDE PREPARATIONS. (See Cough-Due-to-Cold Preparations.)

DIAMTHAZOLE DIHYDROCHLORIDE FOR EXTERNAL USE. (See § 310.201 (a) (7) of this chapter.)

Warning—Do not apply to children under 6 years of age because serious reactions may occur. Do not apply to children 6 to 12 years of age unless directed by physician. Do not use on mucous membranes. Discontinue use and consult physician if irritation develops or relief is not obtained. Keep out of the reach of children.

DICYCLOMINE HYDROCHLORIDE WITH AN ANTACID. (See § 310.201(a) (8) of this chapter.)

Warning—Do not exceed the recommended dosage. Do not administer to children under 12 years of age or use for a prolonged period unless directed by physician, since persistent or recurring symptoms may indicate a serious disease requiring medical attention.

DIPHEMANIL METHYLSULFATE FOR EXTERNAL USE. (See § 310.201(a) (22) of this chapter.)

Caution—If redness, irritation, swelling, or pain persists or increases, discontinue use and consult physician.

DYCLONINE HYDROCHLORIDE. (See § 310.201(a) (23) of this chapter.)

Caution—Do not use in the eyes. Not for prolonged use. Do not apply to large areas of the body. If redness, irritation, swelling, or pain persists or increases, discontinue use unless directed by physician. Do not use, but consult physician for deep or puncture wounds or serious burns. Do not use in case of rectal bleeding, as this may indicate serious disease.

HEXADENOL. (See § 310.201(a) (11) of this chapter.)

Caution—Do not use for treatment of serious burns or skin conditions or for conditions which persist for prolonged periods. In such cases, consult your physician. Do not spray in vicinity of eyes, mouth, nose, or ears. Do not store above 120° F.

INSULIN. (See § 429.11(c) of this chapter.)

Insulin (40, 80, or 100 U.S.P. units per milliliter):

Caution—Do not remove stopper. Not for intravenous nor intramuscular use. Do not use after expiration date shown on outside wrapper or container. Do not use if drug has become viscous or it its color has become other than water clear.

In addition to the above warnings, the following statements should be included in the labeling: "Keep in a cold place, avoid freezing. Failure to follow directions for use may lead to infection." Potamine zinc insulin, isophane insulin, lente insulin, semilente insulin, or ultralente insulin:

Caution—Do not remove stopper. Not for intravenous nor intramuscular use. Do not use after expiration date shown on outside wrapper or container. Do not substitute for any other insulin-containing drug unless directed by physician. Do not use when precipitate has become lumped or granular in appearance or has formed a deposit of solid particles on the wall of the container.

In addition to the above warnings for protamine zinc insulin * * *, the following statements should be included in the labeling of these preparations: "Keep in a cold place, avoid freezing"; "Shake carefully" or "Shake well before using" or "Shake well" or "Shake carefully to suspend all particles"; "Failure to follow directions for use may lead to infection".

Globin zinc insulin:

Caution—Do not remove stopper. Not for intravenous nor intramuscular use. Do not use after expiration date shown on outside wrapper or container. Do not use if any turbidity or precipitate has developed in the solution. Do not substitute for any other insulin-containing drug unless directed by physician.

In addition to the above warnings for globin zinc insulin, the following statements should be included in the labeling: "Keep in a cold place, avoid freezing. Failure to follow directions for use may lead to infection".

IPECAC SYRUP IN ONE-FLUID OUNCE CONTAINERS FOR EMERGENCY TREATMENT OF POISONING, TO INDUCE VOMITING. (See § 3.30 of this chapter.)

Ipecac syrup packaged for over-the-counter sale must bear statements to the following effect, in a prominent and conspicuous manner:

The following statement (boxed and in red letters):

"For emergency use to cause vomiting in poisoning. Before using, call physician, the Poison Control Center, or hospital emergency room immediately for advice."

The following warning: Warning—Keep out of reach of children. Do not use in unconscious persons. Ordinarily, this drug should not be used if strychnine, corrosives such as alkalies (lye) and strong acids, or petroleum distillates such as kerosene, gasoline, coal oil, fuel oil, paint thinner, or cleaning fluid have been ingested.

ISOAMYLHYRDOCUPREINE AND ZOLAMINE HYDROCHLORIDE RECTAL PREPARATIONS FOR EXTERNAL USE. (See § 310.201(a) (3) of this chapter.)

Warning—Do not use this preparation in case of rectal bleeding, as this may indicate serious disease.

NEOMYCIN SULFATE WITH A VASOCONSTRICTOR, IN NASAL PREPARATIONS (SPRAY OR DROPS). (See § 310.201(a) (9) of this chapter.)

Caution—Do not exceed recommended dosage. Do not administer to children under 3 years of age unless directed by physician.

OXYTETRACYCLINE AND POLYMYXIN B SULFATE. (See Antibiotic-Containing Drugs for External Use * * *)

PRAMOXINE HYDROCHLORIDE FOR EXTERNAL USE. (See § 310.201(a) (19) of this chapter.)

Caution—Do not use in the eyes or nose. Not for prolonged use. Do not apply to large areas of the body. If redness, irritation, swelling, or pain persists or increases, discontinue use unless directed by a physician.

SODIUM FLUORIDE DENTIFRICE POWDER. (See § 310.201(a) (10) of this chapter.)

Caution—Children under 6 years of age should not use this drug.

SODIUM GENTISATE. (See §§ 3.509, 310.201(a) (2) of this chapter.)

Warning—Do not give to children under 6 years of age or use for prolonged period unless directed by physician.

Warning—Keep this and all medications out of the reach of children; or

Warning— Keep out of the reach of children.

If offered for use in arthritis or rheumatism, in juxtaposition therewith, the statement:

Caution—If pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age, consult a physician immediately.

SODIUM MONOFLUOROPHOSPHATE DENTIFRICE SOLUTION. (See § 310.-201(a) (15) of this chapter.)

Caution—Children under 6 years of age should not use this drug.

TUAMINOHEPTANE SULFATE NASAL PREPARATIONS. (See § 310.201(a) (16) of this chapter.)

Caution—Do not exceed recommended dosage. Overdosage may cause nervousness, restlessness, or sleeplessness. Individuals with high blood pressure, heart disease, diabetes, or thyroid disease should use only as directed by physician. Do not use for more than 3 or 4 consecutive days unless directed by physician.

VIBESATE PREPARATIONS. (See § 310.201(a) (18) of this chapter.)

Caution—Do not use but consult physician for deep or puncture wounds or serious burns. If redness, irritation, swelling, or pain persists or increases, discontinue use and consult physician.

Warning—Contents under pressure. Do not puncture. Do not use or store near heat or open flame. Exposure to temperatures above 130° Fahrenheit may cause bursting. Never throw container into fire or incinerator.

§ 369.22 Drugs; warning and caution statements specifically required by law.

PREPARATIONS CONTAINING HABIT-FORMING DERIVATIVES OF SUBSTANCES NAMED IN SECTION 502(d) OF THE ACT. (See §§ 329.1, 329.10, and 329.20 of this chapter.)

The statement "*Warning*—May be habit forming" is required to appear on the labels of all drugs containing derivatives designated in § 329.1 of this chapter as habit forming, including exempt narcotic preparations described in § 329.20 (a) of this chapter and preparations containing one or more derivatives of barbituric acid, unless such drug is not suitable for internal use and is distributed and sold exclusively for such external use as involves no possibility of habit formation.

Subpart C—Warning and Caution Statements for Devices

§ 369.30 Devices; recommended warning and caution statements.

DENTURE RELINERS, PADS, AND CUSHIONS.

Warning—For temporary use only. Long-term use of this product may lead to faster bone loss, continuing irritation, sores, and tumors. For Use Only Until A Dentist Can Be Seen.

DENTURE REPAIR KITS.

Warning—For emergency repairs only. Long-term use of home-repaired dentures may cause faster bone loss, continuing irritation, sores, and tumors. This kit for emergency use only. See Dentist Without Delay.

INFRARED GENERATORS (INCLUDING HEATING PADS).

Warning—Use carefully. May cause serious burns. Do not use over insensitive skin areas or in the presence of poor circulation. The unattended use of infrared heat by children or incapacitated persons may be dangerous.

MECHANICAL MASSAGERS AND VIBRATORS.

Warning—This device should not be used over swollen or inflamed areas or skin eruptions. Do not use in unexplained calf pain. Consult physician.

STEAM OR TURKISH BATH.

Warning—Elderly persons or those suffering from heart disease or high blood pressure should not use this device unless directed by physician.

ULTRAVIOLET GENERATORS.

Warning—Wear protective goggles during use to avoid eye injury. Serious burns may be caused by exposure in excess of recommended dosage. Do not use over skin eruptions unless directed by physician.

PART 429—DRUGS COMPOSED WHOLLY OR PARTLY OF INSULIN

Subpart A—General Provisions

Sec.
429.3 Definitions and interpretations.

Subpart B—Packaging and Labeling

429.10 Packaging.
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429.12 Distinguishing colors on packages.

Subpart C—Product Standards

429.25 Standards of quality and purity for protamine.
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Subpart D—Tests and Methods

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Subpart E—Certification

429.40 Requests for certification; samples; storage; approvals preliminary to certification.
429.41 Certifications.
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Subpart F—Administrative Procedures

429.50 Hearing procedure.
429.55 Fees.

Subpart G—Records

429.60 Records of distribution.

AUTHORITY: Sec. 701, 52 Stat. 1055, as amended, sec. 506, 55 Stat. 851 (21 U.S.C. 371, 356).

CROSS REFERENCES: For other regulations in this chapter concerning insulin drugs, see also §§ 1.115, 3.506, and 3.507.

Subpart A—General Provisions

§ 429.3 Definitions and interpretations.

For the purpose of the regulations in this part:

(a) The term "act" means the Federal Food, Drug, and Cosmetic Act, as amended.

(b) The term "Secretary" means the Secretary of Health, Education, and Welfare.

(c) The term "Commissioner" means the Commissioner of Food and Drugs.

(d) The term "U.S.P." means the official United States Pharmacopeia, including supplements thereto.

(e) The term "N.F." means the official National Formulary, including supplements thereto.

(f) The definitions and interpretations of terms contained in section 201 of the act shall be applicable to such terms when used in the regulations in this part.

(g) The term "insulin" means the active principle of pancreas which affects the metabolism of carbohydrate in the animal body and which is of value in the treatment of diabetes mellitus.

(h) The term "insulin injection" means the insulin injection recognized in the U.S.P.

(i) The term "protamine zinc insulin suspension" means the protamine zinc insulin suspension recognized in the U.S.P.

(j) The term "globin zinc insulin injection" means the globin zinc insulin injection recognized in the N.F.

(k) The term "isophane insulin suspension" means the isophane insulin suspension recognized in the U.S.P.

(l) The term "insulin zinc suspension" means the insulin zinc suspension recognized in the U.S.P.

(m) The term "prompt insulin zinc suspension" means the prompt insulin zinc suspension recognized in the U.S.P.

(n) The term "extended insulin zinc suspension" means the extended insulin zinc suspension recognized in the U.S.P.

(o) The term "master lot" means a quantity (which is purified and which has been mixed in one container so as to be homogeneous) of:

(1) A concentrated solution of insulin; or

(2) The insulin-containing solids, in amorphous or crystalline form, derived from one or more such solutions.

(p) Except as provided in § 429.41(c), the term "batch" means a quantity of a drug, in labeled packages, of uniform composition and intended for administration without further change, in which the sole insulin-containing ingredient is a single dilution (which has been mixed in one container so as to be homogeneous) of:

(1) A single master lot or part thereof; or

(2) A mixture of two or more master lots or parts thereof; except that such term means a portion of such quantity when certification of such portion is requested.

(q) The term "master lot mark" means an identifying mark or other identifying device assigned to a master lot by the manufacturer thereof.

(r) The term "batch mark" means an identifying mark or other identifying device assigned to a batch by the manufacturer thereof.

Subpart B—Packaging and Labeling

§ 429.10 Packaging.

Each batch shall be packaged in immediate containers of colorless transparent glass. Such containers shall be closed with a substance through which successive doses may be withdrawn by hypodermic needle without removing the closure or destroying its effectiveness. The containers and closures shall be sterile at the time the containers are filled and closed. The composition of the containers and closures shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor prescribed in applicable standards of strength, quality, and purity. The shape of the containers shall be cylindrical, except that the cross-section of the containers for isophane insulin suspension shall be a rounded square and the shoulder of the containers for insulin zinc suspension, prompt insulin zinc suspension,

or extended insulin zinc suspension shall be hexagonal.

§ 429.11 Labeling.

Each package from a batch that has been certified in accordance with the regulations in this part shall bear, on its label or labeling as hereinafter indicated, the following:

(a) On the outside wrapper or container and the immediate container of the retail package:

(1) The batch mark of such batch;

(2) The potency of the drug in terms of the U.S.P. Units of insulin per milliliter; and

(3) The statement "Expiration date _____," the blank being filled in with the date on which the certificate applicable to such batch expires with respect to such package, as provided in § 429.45(b)(1).

(b) On the outside container or wrapper of the retail package, the statement "Keep in a cold place, avoid freezing."

(c) If the batch contains 40, 80, or 100 U.S.P. Units of insulin per milliliter, on the circular or other labeling of the retail package:

(1) A statement that the treatment of diabetes mellitus is an individual problem and that the use of the drug, the time of its administration, and the number of daily doses and the quantity of each, as well as diet and exercise, are problems which require direct and continuous medical supervision;

(2) A statement explaining that the volume of the dose depends on the number of units of insulin per milliliter stated on the label, and that the patient should understand the meaning of the volume markings on the syringe;

(3) A description of a practicable method for sterilizing the needle and syringe before use;

(4) A description of the technique of withdrawal from the vial and the use of an antiseptic on the stopper, and a caution against the removal of the stopper;

(5) A description of the technique for cleansing, and the use of an antiseptic on the site of injection;

(6) A statement that failure to comply with the techniques described in paragraphs (c) (3), (4), and (5) of this section may lead to infection of the patient;

(7) A statement that injection should be subcutaneous, at a different site from that of the preceding injection, and a caution against intravenous or intramuscular use;

(8) An explanation of hypoglycemia and its relation to overdosage, omission of meals, illness, and infection;

(9) A statement of the significance of sugar in the urine and of the necessity of tests therefor; and

(10) A caution against use after the expiration date shown on the outside wrapper or container.

(d) On the circular or other labeling of the retail package, if the batch is insulin injection (in addition to the information required by paragraphs (a), (b), and (c) or (i) of this section), a caution against use if the drug has become viscous or if its color has become other than water clear.

(e) On the outside wrapper or container and immediate container of the retail package, if the batch is protamine zinc insulin suspension, isophane insulin suspension, insulin zinc suspension, prompt insulin zinc suspension, or extended insulin zinc suspension (in addition to the information required by paragraphs (a), (b), and (c) of this section), the statement "Shake carefully," or "Shake well before using," or "Shake well," or "Shake carefully to suspend all particles."

(f) On the circular or other labeling of the retail package, if the batch is protamine zinc insulin suspension, isophane insulin suspension, insulin zinc suspension, prompt insulin zinc suspension, or extended insulin zinc suspension (in addition to the information required by paragraphs (a), (b), (c), and (e) of this section):

(1) An explanation of the difference, as compared with other insulin-containing drugs, in onset of action, duration, and the time and frequency of administration;

(2) A caution that it is not to be substituted for any other insulin-containing drug except on the advice and direction of a physician;

(3) A statement that a uniform suspension of the preparation is necessary and is brought about by careful shaking before use; and

(4) A caution against use when the precipitate has become lumped or granular in appearance or has formed a deposit of solid particles on the wall of the container.

(g) On the circular or other labeling of the retail package, if the batch is globin zinc insulin injection (in addition to the information required by paragraphs (a), (b), and (c) of this section):

(1) An explanation of the difference, as compared with other insulin-containing drugs, in onset of action, duration, and the time and frequency of administration;

(2) A caution that it is not to be substituted for any other insulin-containing drug, except on the advice and direction of a physician; and

(3) A caution against use if any turbidity or precipitate has developed in the solution.

(h) If the batch contains 500 U.S.P. Units of insulin per milliliter, on the outside container or wrapper and the immediate container of the retail package:

(1) The statement "Caution: Federal law prohibits dispensing without prescription";[2] and

(2) The statement "Warning—High potency—Not for ordinary use".

(i) If the batch contains 500 U.S.P. Units of insulin per milliliter, on the circular or other labeling of the retail package:

(1) Information adequate for the safe and effective use of the drug, by practitioners licensed by law to administer it, in insulin shock therapy and for the treatment of diabetic patients with high insulin resistance (daily requirement more than 200 units);

(2) A prominently placed and conspicuous statement: "Warning—This insulin preparation contains 500 units of insulin in each milliliter. Extreme caution must be observed in measurement of dosage because inadvertent overdose may result in irreversible insulin shock. Serious consequences may result if it is used other than under constant medical supervision";

(3) A caution against intravenous use; and

(4) A caution against use after the expiration date shown on the outside wrapper or container.

§ 429.12 Distinguishing colors on packages.

(a) The outside containers or wrappers of the packages, and the labels on the immediate containers of each potency of insulin injection shall be distinguished by the following colors:

Red, if it contains 40 U.S.P. Units of insulin per milliliter.

Green, if it contains 80 U.S.P. Units of insulin per milliliter.

Orange, if it contains 100 U.S.P. Units of insulin per milliliter.

Narrow (at least 5 but not more than 20 to each inch) brown and white diagonal stripes, if it contains 500 U.S.P. Units of insulin per milliliter.

But if the master lot used was in crystalline form, the distinguishing colors, instead of those prescribed above, may be the following:

Red and gray, if it contains 40 U.S.P. Units of insulin per milliliter.

Green and gray, if it contains 80 U.S.P. Units of insulin per milliliter.

(b) The outside containers or wrappers of the packages, and the labels on the immediate containers of each potency of protamine zinc insulin suspension shall be distinguished by the following colors:

Red and white, if it contains 40 U.S.P. Units of insulin per milliliter.

Green and white, if it contains 80 U.S.P. Units of insulin per milliliter.

(c) The outside containers or wrappers of the packages, and the labels of the immediate containers of each potency of globin zinc insulin injection shall be distinguished by the following colors:

Red and brown, if it contains 40 U.S.P. Units of insulin per milliliter.

Green and brown, if it contains 80 U.S.P. Units of insulin per milliliter.

(d) The outside containers or wrappers of the packages, and the labels of the immediate containers of each potency of isophane insulin suspension shall be distinguished by the following colors:

Red and blue, if it contains 40 U.S.P. Units of insulin per milliliter.

Green and blue, if it contains 80 U.S.P. Units of insulin per milliliter.

(e) The outside containers or wrappers of the packages, and the labels of the immediate containers, of insulin zinc sus-

[2] For the Spanish-language version of the required labeling statement, see § 1.106 of this chapter.

pension, prompt insulin zinc suspension, and extended insulin zinc suspension shall bear a mark or design to distinguish each drug, and each potency of these drugs shall be distinguished by the following colors:

Red and lavender, if it contains 40 U.S.P. Units of insulin per milliliter.

Green and lavender, if it contains 80 U.S.P. Units of insulin per milliliter.

Subpart C—Product Standards

§ 429.25 Standards of quality and purity for protamine.

When protamine is dried to constant weight at 100° C., its total nitrogen content is not less than 22.5 percent and not more than 25.5 percent, and its sulfate content, calculated as SO_4, is not less than 16 percent and not more than 19 percent.

§ 429.26 Standards of quality and purity for globin hydrochloride.

The ash content of globin hydrochloride is not more than 0.3 percent; its nitrogen content, calculated to moisture, ash, and hydrochloric acid free basis, is not less than 16.0 percent and not more than 17.5 percent.

Subpart D—Tests and Methods

§ 429.30 Tests and methods of assay.

The following tests and methods of assay are prescribed for the purposes of the regulations in this Part 429. (All reagents specified in this section shall be of U.S.P. or N.F. quality or better.)

(a) *Tests and methods of assay for insulin injection, protamine zinc insulin suspension, globin zinc insulin injection, isophane insulin suspension, insulin zinc suspension, prompt insulin zinc suspension, and extended insulin zinc suspension.* The tests and methods of assay for insulin injection, protamine zinc insulin suspension, globin zinc insulin injection, isophane insulin suspension, insulin zinc suspension, prompt insulin zinc suspension, and extended insulin zinc suspension shall be those set forth therefor in the U.S.P. or N.F., except that alternative test procedures may be employed when such have been authorized by the Commissioner.

(b) [Reserved]

(c) *Isophane ratio.* The isophane ratio shall be expressed as milligrams of protamine per 100 U.S.P. Units of insulin.

(1) *Reagents*—(i) *The stock buffer solution.* Dissolve in water the quantities of metacresol, phenol, glycerin, and disodium phosphate required to make 10 liters of the batch of isophane insulin and dilute to 1,000 milliliters.

(ii) *The insulin solution.* From a sample of the zinc-insulin crystals to be used in making the batch weigh a quantity which contains 10,000 U.S.P. Units of insulin. Dissolve the crystals in 15 milliliters of 0.1 percent hydrochloric acid. The resulting solution must be clear. Add it to 25 milliliters of the stock buffer solution (subdivision (i) of this subparagraph). Dilute with water to approximately 200 milliliters. Adjust the pH to 7.2 using hydrochloric acid or sodium hydroxide. The solution must be clear at this stage. If sodium chloride is to be used in preparing the batch add 25 milliliters of 4.2 percent (w/v) sodium chloride solution. Dilute to 250 milliliters with water. The pH must be between 7.1 and 7.4.

(iii) *The protamine solution.* Weigh 500 milligrams of the protamine to be used in making the batch and dissolve in 10 milliliters of the stock buffer solution paragraph (c)(1)(i) of this section). If sodium chloride is to be used in preparing the batch add 10 milliliters of 4.2 percent (w/v) sodium chloride solution. Dilute with water to approximately 80 milliliters. Adjust the pH to 7.2 using hydrochloric acid or sodium hydroxide. Dilute with water to 100 milliliters. The pH must be between 7.2 and 7.4 and the solution must be clear.

(2) *Conduct of the test.* Measure six 25-milliliter samples of the insulin solution (paragraph (c)(1)(ii) of this section) into six tubes. To the first tube add 0.60 milliliter of the protamine solution (paragraph (c)(1)(iii) of this section), to the second add 0.72 milliliter, to the third add 0.84 milliliter, to the fourth add 0.96 milliliter, to the fifth add 1.08 milliliters, and to the sixth add 1.20 milliliters. Mix the contents of each tube and let stand for at least 30 minutes. Centrifuge. (Do not filter.) From each supernatant fluid remove two 10-milliliter samples, thus creating two series of samples. To each of one series add 1 milliliter of the insulin solution (paragraph (c)(1)(ii) of this section). To each of the other series add 1 milliliter of the protamine solution (paragraph (c)(1)(iii) of this section). Mix each sample and let stand 10 minutes. Measure the turbidity of each sample by means of a photometer or nephelometer. Plot the readings of the two series of samples, using the amount of protamine originally added in milligrams per 100 U.S.P. Units of insulin as abscissas, and the photometer or nephelometer readings as ordinates. The abscissa of the intersection of the two curves indicates the isophane ratio of the protamine to the zinc-insulin crystals. In order to increase the precision of the test, when the approximate isophane ratio is known, the quantities of protamine solution to be added to the six tubes may be so chosen that the range (0.60 to 1.20 milliliters) is reduced, and the approximate isophane ratio is near the middle of the range.

The isophane ratio found is not more than 100 percent nor less than 90 percent of the ratio of protamine to insulin used in the trial mixture referred to in § 429.40(d)(7).

(d)–(e) [Reserved]

(f) *Chloride in globin hydrochloride*—(1) *Conduct of the test.* Weigh accurately approximately 0.5 gram of globin hydrochloride into a small beaker and dissolve in 10-15 milliliters of distilled water. Add 10 milliliters of tenth-normal silver nitrate, 5 milliliters of nitricacid, and 5 milliliters of a saturated solution of potassium permanganate. Stir and place on a steam bath for approximately 1 hour. If any brown color remains, stir again, rinse the sides of the beaker with distilled water and place on the steam bath until the brown color disappears. Transfer quantitatively to a 50-milliliter volumetric flask and fill the flask to the mark with distilled water. Mix and filter through a dry filter paper into a dry vessel. Transfer exactly 40 milliliters of the filtrate to a flask, add 2 milliliters of ferric ammonium sulfate test solution and titrate with tenth-normal ammonium thiocyanate. To obtain the percent chloride as HCl, subtract 1.25 times the number of milliliters of ammonium thiocyanate used from 10; multiply this difference by 0.365 and divide by the weight of the sample in grams.

(2) *Reagents.* The reagents used are those described in the N.F.

(g) *Sulfate in protamine*—(1) *Conduct of the test.* Weigh accurately about 250 milligrams of protamine and dissolve it in about 100 milliliters of approximately tenth-normal hydrochloric acid. Heat to boiling and add 5 milliliters of barium chloride test solution. Digest on a steam bath for 1 hour; allow to cool. Filter through an ignited and weighed Gooch crucible; wash free of chlorides. Dry, ignite, and weigh. The weight of barium sulfate thus obtained multiplied by 41.15 and divided by the weight of sample is the percent sulfate (SO_4) in the sample. Calculate the results to a moisture-free basis.

(2) *Reagents.* The reagents used are those described in the U.S.P.

(h) *Nitrogen.* Determine total nitrogen by the method described in the U.S.P., for insulin U.S.P.

(i) *Zinc in insulin-containing solutions or suspensions.* Use the method described in the U.S.P. for insulin injection.

(j) *Zinc in insulin-containing solids.* Dissolve 10 to 20 milligrams, accurately weighed, of insulin-containing solids in 5 to 10 milliliters of distilled water containing one drop of 5*N* hydrochloric acid, and proceed as directed in the U.S.P. under the test for zinc in insulin injection.

Subpart E—Certification

§ 429.40 Requests for certification; samples; storage; approvals preliminary to certification.

(a) A request for certification of a batch shall be addressed to the Commissioner, Food and Drug Administration, Department of Health, Education, and Welfare, Washington, D.C., 20204. A request from a foreign manufacturer shall be signed by such manufacturer and by an agent of such manufacturer who resides in the United States.

(b) The initial request for certification submitted by any person shall be preceded or accompanied by a full statement of the facilities and controls used to maintain the identity, strength, quality, and purity of each batch, including a description of:

(1) The equipment, methods, and processes used in diluting master lots and parts thereof, and in maintaining

the identity, strength, quality, and purity of master lots and dilutions therefrom;

(2) The tests and assays made on master lots and mixtures thereof, on dilutions and batches therefrom, and on ingredients used in such dilutions and batches; and

(3) The laboratory facilities used in such controls.

Such initial request shall also be preceded or accompanied by the keys to the master lot marks and batch marks used by such person. When any change is made in any of such facilities or controls, or in any such key, the next request for certification thereafter shall be accompanied by a full statement of such change.

(c) A person who requests certification of a batch shall submit in connection with his request statements showing:

(1) The master lot mark of each master lot used or to be used wholly or partly as an ingredient or component of an ingredient of the batch;

(2) The quantity of each such master lot so used;

(3) The original quantity of each such master lot (unless such information has been previously submitted);

(4) The quantity of the batch; and

(5) The batch mark.

(d) Except as otherwise provided in paragraphs (g) and (h) of this section, a person who requests certification of a batch shall submit in connection with his request and in the quantities hereinafter indicated, accurately representative samples of the following:

(1) The single master lot or the mixture of two or more master lots or parts thereof, to be used as ingredients of the batch; in a quantity containing approximately 10,000 U.S.P. Units of insulin, except that, if the batch is to be isophane insulin suspension, the quantity shall contain not less than 20,000 U.S.P. Units of insulin.

(2) A trial dilution made from such master lot or mixture, glycerin, phenol or cresol, and hydrochloric acid, which dilution conforms to the standard of identity, strength, quality, and purity for insulin injection, except that it may contain not less than 35 U.S.P. Units nor more than 45 U.S.P. Units of insulin per milliliter; in a quantity containing approximately 2,000 U.S.P. Units of insulin.

(3) If the batch is to be protamine zinc insulin suspension, a trial mixture which is intended to be accurately representative of the mixture which will constitute the finished batch; in a quantity containing approximately 2,000 U.S.P. Units of insulin.

(4) If the batch is to be protamine zinc insulin suspension or isophane insulin suspension, the lot of protamine used as an ingredient of the trial mixture referred to in paragraph (d) (3) or (7) of this section; in a quantity of approximately 2 grams.

(5) If the batch is to be globin zinc insulin injection, a trial mixture made from the master lot or mixture referred to in paragraph (d)(1) of this section, globin, zinc chloride, hydrochloric acid, glycerin, and phenol or cresol, which mixture is intended to be accurately representative of the mixture which will constitute the finished batch; in a quantity containing approximately 2,000 U.S.P. Units of insulin.

(6) If the batch is to be globin zinc insulin injection, the lot of globin hydrochloride from which the globin is to be prepared for use as an ingredient of the trial mixture referred to in paragraph (d)(5) of this section; in a quantity of approximately 5 grams.

(7) If the batch is to be isophane insulin suspension, a trial mixture which is intended to be accurately representative of the finished batch; in a quantity of approximately 2,500 U.S.P. Units of insulin.

(8) If the batch is to be insulin zinc suspension, prompt insulin zinc suspension, or extended insulin zinc suspension, a trial mixture which is intended to be accurately representative of the finished batch; in a quantity of approximately 50 milliliters.

(9) The finished batch; for all tests except sterility, not less than 10 retail packages.

(10) The finished batch for sterility testing, 20 retail packages, collected at approximately equal intervals throughout each filling operation (as defined by the U.S.P.), except that if it is insulin injection containing 500 U.S.P. Units of insulin per milliliter, in lieu of the volume contained in the retail package each such container may contain an amount of drug that is less than that contained in the retail package but in no case less than 5 milliliters.

(e) Except as otherwise provided by paragraphs (g) and (h) of this section, a person who requests certification shall submit in connection with his request results of the tests and assays listed after each of the following materials, made by him on a sample of such material:

(1) The master lot or mixture, referred to in paragraph (d)(1) of this section: Ash, nitrogen, potency, pH, sterility, and zinc, if such master lot or mixture is a solution; ash, moisture, nitrogen, potency, and zinc, if such master lot or mixture is a solid.

(2) A trial dilution of such master lot or mixture, of the potency of the trial dilution referred to in paragraph (d)(2) of this section: Nitrogen, pH, and potency.

(3) If the batch is to be protamine zinc insulin suspension, the trial mixture referred to in paragraph (d)(3) of this section: Nitrogen, pH, zinc, and biological reaction (by the test prescribed in the U.S.P.).

(4) If the batch is to be protamine zinc insulin suspension or isophane insulin suspension, the protamine referred to in paragraph (d)(4) of this section: Moisture, nitrogen, and sulfate.

(5) If the batch is to be globin zinc insulin injection the trial mixture referred to in paragraph (d)(5) of this section: Nitrogen, pH, zinc, and biological reaction (by the test prescribed in the N.F.).

(6) If the batch is to be globin zinc insulin injection, the globin hydrochloride referred to in paragraph (d)(6) of this section: Moisture, nitrogen, chloride, and ash.

(7) If the batch is to be isophane insulin suspension, the trial mixture referred to in paragraph (d)(7) of this section: Nitrogen, pH, zinc, isophane ratio of the protamine to the master lot or mixture (by the test prescribed in § 429.30(c)), and biological activity of the supernatant liquid (by the test prescribed in the U.S.P.).

(8) If the batch is to be insulin zinc suspension, prompt insulin zinc suspension, or extended insulin zinc suspension, the trial mixture referred to in paragraph (d)(8) of this section: Nitrogen, pH, zinc, zinc in the supernatant liquid and insulin not extracted by buffered acetone solution.

(9) The finished batch: Nitrogen, pH, sterility; and if the batch is protamine zinc insulin suspension, globin zinc insulin injection, isophane insulin suspension, insulin zinc suspension, prompt insulin zinc suspension, or extended insulin zinc suspension, zinc.

(f) The results of tests and assays for the following shall be reported in the terms indicated:

(1) Ash (except globin hydrochloride)—milligrams per 1,000 U.S.P. Units of insulin.

(2) Ash in globin hydrochloride—percent by weight.

(3) Chloride—percent by weight as HCl.

(4) Insulin not extracted by buffered acetone solution—percent of total nitrogen of the preparation not extracted by buffered acetone solution.

(5) Isophane ratio—milligrams of protamine per 100 U.S.P. Units of insulin.

(6) Moisture—percent by weight.

(7) Nitrogen (except in globin hydrochloride and protamine)—milligrams per milliliter in the cases of solutions and suspensions, and percent by weight in the case of solids.

(8) Nitrogen in globin hydrochloride—percent by weight, calculated to a moisture-free, ash-free, chloride-free basis.

(9) Nitrogen in protamine—percent by weight, calculated to a moisture-free basis.

(10) Potency—U.S.P. Units of insulin per milliliter in the case of solutions, and U.S.P. Units of insulin per milligram in the case of solids.

(11) pH.

(12) Sulfate—percent by weight as SO_4, calculated to a moisture-free basis.

(13) Zinc—milligrams per milliliter in the cases of solutions and suspensions, and percent by weight in the case of solids.

(g)(1) No sample referred to in paragraph (d) (1) to (8), inclusive, of this section, and no result referred to in paragraph (e) (1) to (8), inclusive, of this section, is required if such sample or result has been submitted in connection with a previous request for certification.

No sample referred to in paragraph (d) (3) of this section, and no result referred to in paragraph (e) (3) of this section, is required if the batch is to be protamine zinc insulin suspension containing 80 U.S.P. Units of insulin per milliliter and the Commissioner has previously approved a trial mixture referred to in paragraph (d) (3) of this section containing 40 U.S.P. Units of insulin per milliliter, prepared from the same materials and in the same manner (except for adjustment of pH of the buffer solution) as such batch containing 80 U.S.P. Units of insulin per milliliter is to be made. No sample referred to in paragraph (d) (5) of this section and no result referred to in paragraph (e) (5) of this section, is required if the batch is to be globin zinc insulin injection containing 80 U.S.P. Units of insulin per milliliter and the Commissioner has previously approved a trial mixture referred to in paragraph (d) (5) of this section containing 40 U.S.P. Units of insulin per milliliter, prepared from the same materials and in the same manner as such batch containing 80 U.S.P. Units of insulin per milliliter is to be made. No sample referred to in paragraph (d) (7) of this section, and no result referred to in paragraph (e) (7) of this section, is required if the batch is to be isophane insulin suspension containing 80 U.S.P. Units of insulin per milliliter and the Commissioner has previously approved a trial mixture referred to in paragraph (d) (7) of this section containing 40 U.S.P. Units of insulin per milliliter, prepared from the same materials and in the same manner as such batch containing 80 U.S.P. Units of insulin per milliliter is to be made.

(2) Each sample submitted pursuant to this section shall be so packaged as to maintain its representative character, and in the case of any solution or suspension, shall be collected and packaged under aseptic conditions. Each package shall be clearly identified as to its contents and shall bear the name and post office address of the person submitting the request.

(3) The packages constituting the samples submitted pursuant to paragraph (d) (9) of this section shall be collected at such intervals that the quantities packaged between collections are approximately equal; in no case shall any such quantity be more than 10,000 packages. The collections shall cover the entire period of packaging.

(4) Each sample submitted pursuant to paragraph (d) (2), (3), (5), (7) and (8) of this section shall be accompanied by a statement showing the identity, quality, and quantity of each substance used as an ingredient or as a component of an ingredient in the material from which the sample was taken.

(5) If the tests and assays, results of which are submitted pursuant to paragraph (e) (2) of this section, were not made on the same trial dilution as that from which the sample submitted pursuant to paragraph (d) (2) of this section was taken, such sample shall be accompanied by a statement showing the identity, quality, and quantity of each substance used as an ingredient or as a component of an ingredient of the trial dilution on which such tests and assays were made.

(6) The value for nitrogen submitted pursuant to paragraph (e) (1) and (2) of this section may be calculated from the result of a test therefor submitted pursuant to either paragraph (e) (1) or (2) of this section. The result on potency required under paragraph (e) (1) of this section may be calculated from an assay therefor submitted pursuant to paragraph (e) (2) of this section. The value of each of the components nitrogen and zinc, to the extent required under paragraph (e) (9) of this section, may be calculated from the result of a test therefor submitted pursuant to paragraph (e) (3), or (5), or (7) or (8) of this section or from the result of a test of the bulk dilution from which the batch was prepared. The value for nitrogen required under paragraph (e) (9) of this section may, if the batch is insulin injection, insulin zinc suspension, prompt insulin zinc suspension, or extended insulin zinc suspension, be calculated from a test therefor submitted pursuant to either paragraph (e) (1) or (2) of this section. Each calculated value shall be indicated as such.

(7) The information required under paragraph (c) (1), (2), and (3) of this section, and the samples and results of tests and assays required under paragraphs (d) (1) and (2) and (e) (1) and (2) of this section, should be submitted before submission of the samples and results required in paragraphs (d) (3) to (8), inclusive, of this section and (e) (3) to (8), inclusive, of this section; and the samples and results required under paragraphs (d) (3) to (8), inclusive, and (e) (3) to (8), inclusive, should be submitted before submission of the information, samples, and results required under paragraphs (c) (4) and (5), (d) (9) and (10), and (e) (9) of this section. All information, including results of tests and assays (except results of tests for sterility), required under this section should be submitted at the same time as the samples to which they relate are submitted.

(h) The person who requests certifications shall submit such information additional to that submitted pursuant to paragraphs (b), (c), (e), and (g) of this section, such additional samples of any substance referred to in paragraph (d) of this section, and such samples of any other substance used or to be used as an ingredient or as a component of an ingredient in the batch, as the Commissioner may require for the purpose of investigations to determine whether or not such batch complies with the requirements set forth by § 429.41 for the issuance of a certificate.

(i) After a sample required by paragraph (d) of this section is taken from any master lot or mixture of parts of two or more master lots, such master lot or master lots and all parts thereof, and all dilutions and batches and all parts thereof in which any such master lot is used as an ingredient or as a component of an ingredient, shall be stored at the establishment where manufactured until used up or shipped or otherwise delivered, at a temperature above freezing but not above 15° C. (59° F.), and under such other conditions as prevent, so far as practicable, any change in composition; except that master lots and parts thereof which are solids may be stored at ordinary room temperatures.

(j) As promptly as practicable after the samples submitted pursuant to paragraph (d) (1) and (2) of this section, and any other material or information relative thereto that may be required under this section, are received by the Commissioner, he shall notify the person who submitted such samples of his approval or refusal to approve the use of the master lot or mixture for the making of bulk dilutions. In case of a refusal to approve, the Commissioner shall state his reasons therefor.

(k) In like manner, the Commissioner shall notify the person who submits samples pursuant to paragraph (d) (3) to (8), inclusive, of this section of his approval or refusal to approve the use of the materials represented by such samples in completing the manufacture of the batch. In case of a refusal to approve, the Commissioner shall state his reasons therefor.

(l) If, under the provisions of paragraph (j) or (k) of this section, the Commissioner has refused to approve any material for use in a subsequent operation, he shall examine no other sample required hereunder which includes such material as an ingredient or component of an ingredient, unless and until the person requesting certification makes an adequate showing that the cause for such refusal no longer exists.

§ 429.41 Certifications.

(a) If it appears to the Commissioner, after such investigation as he considers necessary, that:

(1) The information (including results of tests and assays) and the samples required by or pursuant to § 429.40 have been submitted, and such information contains no untrue statement of a material fact;

(2) The batch complies with the regulations in this Part 429 and conforms to the standards of identity, quality, strength, and purity for insulin injection, protamine zinc insulin suspension, globin zinc insulin injection, isophane insulin suspension, insulin zinc suspension, prompt insulin zinc suspension, or extended insulin zinc suspension;

the Commissioner shall certify that such batch is safe and efficacious for use, subject to such conditions on the effectiveness of such certifications as are set forth in § 429.45, and shall issue to the person who requested it a certificate to that effect.

(b) If the Commissioner determines, after such investigation as he considers

to be necessary, that the information submitted pursuant to § 429.40 or the batch covered by such request, does not comply with the requirements set forth in paragraph (a) of this section for the issuance of a certificate, the Commissioner shall refuse to certify such batch and shall give notice thereof to the person who requested certification, stating his reasons for refusal.

(c) Upon the request of the manufacturer, the Commissioner shall certify as a "batch" a master lot, which has been approved in accordance with § 429.40(j) as safe and efficacious for use in preparation of an insulin-containing drug, subject to the conditions on the effectiveness of such certifications as are set forth in § 429.45(a)(1) and (b)(4).

(d) For the purposes of his investigations under the authority of this section, the Commissioner may accept, when he is satisfied as to the completeness and accuracy thereof, the results of any tests or assays made by the control laboratory of the Insulin Committee of the University of Toronto.

§ 429.45 Conditions on the effectiveness of certificates.

(a) A certificate shall not become effective:

(1) If it is obtained through fraud, or through misrepresentation or concealment of a material fact.

(2) With respect to any package, unless its immediate container complies with the requirements of § 429.10 and such package or such immediate container has been so sealed that its contents cannot be used without destroying such package or seal.

(3) With respect to any package, unless its label and labeling bear all words, statements, and other information, and are distinguished by the color or colors, required by §§ 429.11 and 429.12.

(b) A certificate shall cease to be effective: (1) With respect to any package of insulin injection, protamine zinc insulin suspension, globlin zinc insulin injection, isophane insulin suspension, insulin zinc suspension, prompt insulin zinc suspension, or extended insulin zinc suspension on the expiration date specified in the U.S.P. or N.F.

(2) With respect to any package, when such package or the seal thereof or the immediate container therein or the seal of the immediate container is broken, or when its label or labeling ceases to conform to any requirement of § 429.11 or § 429.12.

(3) With respect to any package, when the drug therein so changes that it fails to meet the standards of identity, strength, quality, and purity upon the basis of which the batch was certified; except that those minor changes in potency (not exceeding 10 percent from the potency stated on the label, in the case of insulin injection) which occur before the expiration date, and which are normal and unavoidable in good storage and distribution practice, shall be disregarded.

(4) With respect to a master lot of insulin, 5 years after date of issue if the master lot is a solution, or 10 years after date of issue if the master lot is a solid.

§ 429.47 Authority to refuse certification service.

When the Commissioner finds, after giving notice and opportunity for hearing, that a person has:

(a) Obtained or attempted to obtain a certificate through fraud, or through misrepresentation or concealment of a material fact;

(b) Falsified the records required to be kept by § 429.60; or

(c) Failed to keep such records or to make them available, or to accord full opportunity to make an inventory of stocks on hand or otherwise to check the correctness of such records, as required by such section;

the Commissioner may immediately suspend service to such person under the regulations in this part, and may continue such suspension unless and until such person shows adequate cause why such suspension should be terminated.

Subpart F—Administrative Procedures

§ 429.50 Hearing procedure.

Hearings held pursuant to § 429.47 will be conducted in accordance with the rules provided in Part 314 of this chapter.

§ 429.55 Fees.

(a) (1) Fees for the services rendered under the regulations in this part shall be such as are necessary to provide, equip, and maintain an adequate certification service.

(2) Whenever in the judgment of the Commissioner the ratio between fees collected (which are based upon experience and the best estimate of costs and the best estimate of earnings) and the costs of providing the service during an elapsed period of time, in the light of all circumstances and contingencies, warrants a refund from the fund collected during such period, he shall make ratable refunds to those persons to whom the services were rendered and charged.

(b) Fees for the services rendered with respect to the samples submitted pursuant to § 429.40(d) shall be:

(1) For each master lot or mixture of two or more master lots or parts thereof, as follows:

(i) $50 if the master lot or mixture has not been previously approved by the Commissioner.

(ii) $25 if the master lot or mixture has been previously certified by the Commissioner in accordance with § 429.41(c).

(2) For each trial dilution, as follows:

(i) $120 if the results of an assay for potency of a trial dilution made by the laboratory referred to in § 429.41(d) are submitted or are to be submitted.

(ii) $1,320 if the results referred to in paragraph (b)(2)(i) of this section are not submitted and are not to be submitted.

(3) For each trial mixture of protamine zinc insulin suspension, as follows:

(i) $120 if the results of tests for biological reactions made by the laboratory referred to in § 429.41(d) are submitted or are to be submitted.

(ii) $1,320 if the results referred to in paragraph (b)(3)(i) of this section are not submitted and are not to be submitted.

(4) $140 for each lot of protamine.

(5) $350 for each trial mixture of isophane insulin suspension.

(6) For each trial mixture of globin zinc insulin injection, as follows:

(i) $120 if the results of tests for biological reactions made by the laboratory referred to in § 429.41(d) are submitted or are to be submitted.

(ii) $1,320 if the results referred to in paragraph (b)(6)(i) of this section are not submitted and are not to be submitted.

(7) $140 for each lot of globin hydrochloride.

(8) $210 for each trial mixture of insulin zinc suspension, prompt insulin zinc suspension, and extended insulin zinc suspension.

(9) Ten dollars for each package in the sample of the finished batch submitted for all tests except sterility; $58.80 for all the packages in the sample submitted for the initial sterility test in accordance with § 429.40(d)(10); and $117.60 for all packages in the sample submitted for any repeat sterility test, if necessary, in accordance with the U.S.P. or N.F.

Except as otherwise provided by paragraph (c) of this section, each request for certification submitted, or the initial sample or samples submitted in connection therewith pursuant to § 429.40(d), whichever is sent first to the Commissioner, shall be accompanied by such fees as are prescribed in specific amounts for the samples. If the Commissioner considers that investigations or additional samples are necessary to determine whether or not such batch complies with the requirements of § 429.41 for the issuance of a certificate, the fee shall include the cost of such investigations.

(c) A person requiring continuing certification services may maintain an advance deposit of the estimated costs of such services for a period of 2 months or more. Such deposits shall be debited with fees for services rendered, but shall not be debited for any fee the amount of which is not definitely specified in these regulations unless the depositor has previously requested the performance of the services to be covered by such fee. A monthly statement for each such advance deposit shall be rendered.

(d) The unearned portion of any advance deposit made pursuant to paragraph (b) or (c) of this section shall be refunded to the depositor upon his application.

(e) All advance deposits required by the regulations in this Part 429 shall be paid by money order, bank draft, or certified check drawn to the order of the Food and Drug Administration, collectible at par at Washington, D.C. All deposits shall be forwarded to the Food and Drug Administration, Department of Health, Education, and Welfare, Washington, DC 20204, whereupon after making appropriate record thereof they will be transmitted to the Chief Disbursing

Officer, Division of Disbursement, Treasurer of the United States, for deposit to the special account "Salaries and Expenses, Certification, Inspection and Other Services, Food and Drug Administration."

Subpart G—Records

§ 429.60 Records of distribution.

(a) The person to whom a certificate is issued shall keep complete records showing each shipment and other delivery (including exports) of each batch or part thereof, by the person requesting certification, and showing each such shipment and delivery into, or from any place in, any State or Territory, made by any person subject to his control, including records showing the date and quantity of each such shipment and delivery and the name and post office address of the person to whom such shipment or delivery was made.

(b) Upon the request of any officer or employee of the Food and Drug Administration or of any other officer or employee of the United States, acting on behalf of the Secretary, the person to whom a certificate is issued, at all reasonable hours within 2 years after disposal of all the batch covered by such certificate, shall make such records available to any such officer or employee, and shall accord to such officer or employee full opportunity to make inventory of stocks of such batch on hand and otherwise to check the correctness of such records.

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PART III

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Public Health Service

■

EMERGENCY MEDICAL SERVICES SYSTEMS

Proposed Grants

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Public Health Service

[42 CFR Part 56a]

EMERGENCY MEDICAL SERVICES SYSTEMS

Proposed Grants

Notice is hereby given that the Assistant Secretary for Health of the Department of Health, Education, and Welfare, proposes to add a new Part 56a, entitled "Grants for Emergency Medical Services Systems", to Title 42, Code of Federal Regulations. The purpose of the new Part 56a is to establish regulations governing grants for feasibility studies and planning, for establishment and operation, and for expansion and improvement of emergency medical service systems under Section 1202, 1203, and 1204, respectively of the Public Health Service Act (42 U.S.C. 300d–1, 300d–2, and 300d–3), as added by the Emergency Medical Services Systems Act of 1973. (Pub. L. 93–154).

Interested persons are invited to submit written comments, suggestions, or objections concerning the proposed regulations to the Health Services Administration, Room 14–05, 5600 Fishers Lane, Rockville, Maryland 20852, on or before April 15, 1974, in the above-named office on weekdays between the hours of 8:30 a.m. and 5:00 p.m.

It is therefore proposed to amend Title 42 by adding thereto a new Part 56a, as set forth below.

Dated: March 6, 1974.

CHARLES C. EDWARDS,
Assistant Secretary for Health.

Approved: March 25, 1974.

CASPAR W. WEINBERGER,
Secretary.

PART 56a—GRANTS FOR EMERGENCY MEDICAL SERVICES SYSTEMS

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AUTHORITY: Secs. 1202, 1203, and 1204 of the Public Health Service Act (42 U.S.C. 300d–1, 300d–2, and 300d–3).

Subpart A—General Provisions

§ 56a.101 Applicability.

The regulations of this subpart are applicable to grants (a) for projects which include both studying the feasibility of and planning for the establishment and operation of emergency medical services systems pursuant to section 1202 of the Public Health Service Act (42 U.S.C. 300d–1); (b) for the establishment and initial operation of such systems pursuant to section 1203 of the Public Health Service Act (42 U.S.C. 300d–2); and (c) for projects for the expansion and improvement of such systems pursuant to section 1204 of the Public Health Service Act.

(42 U.S.C. 300d–3).

§ 56a.102 Definitions.

As used in this part:

(a) "Act" means the Public Health Service Act.

(b) "State" means one of the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, or the Trust Territory of the Pacific Islands.

(c) "Unit of general local government" means (1) any city, county, township, town, borough, parish, village, or other general purpose political subdivision of a State; or (2) an Indian tribe.

(d) "Nonprofit," as applied to a private entity, means that no part of the net earnings of such entity inures or may lawfully inure to the benefit of any private shareholder or individual.

(e) "Secretary" means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department of Health, Education, and Welfare to whom the authority involved has been delegated.

(f) "Section 314(a) State health planning agency" means the agency of a State which administers or supervises the administration of a State's health planning functions under a State plan approved under section 314(a) of the Act.

(g) "Section 314(b) areawide health planning agency" means a public or nonprofit private agency or organization which has developed a comprehensive regional, metropolitan, or other local area plan or plans referred to in section 314(b) of the Act.

(h) "Section 314(b) plan" means a comprehensive regional, metropolitan, or other local area plan or plans referred to in section 314(b) of the Act.

(i) "Emergency medical services" means the services utilized in responding to the perceived individual need for immediate medical care in order to prevent loss of life or aggravation of physiological or psychological illness or injury.

(j) "Medical emergency" means an unforeseen event affecting an individual in such a manner that a need for immediate medical care (physiological or psychological) is created.

(k) "Rural area" means any area not classified as an urbanized area by the Bureau of the Census (1970 Census of Population, Number of Inhabitants, Bureau of the Census, U.S. Department of Commerce, Dec. 1971).

(l) "Modernization" means the alteration, major repair, remodeling, and renovation of existing buildings (including initial equipment thereof), and replacement of obsolete built-in equipment of existing buildings.

(m) "Major repair" means those repairs to an existing building excluding routine maintenance which restore the building to a sound state, the cost of which is no less than $100,000.

(n) "Equipment" means those items which are necessary for the functioning of the emergency medical services system, but does not include items of current operating expense or consumed in use such as glassware, chemicals, food, fuel, drugs, paper, printed forms, books, pamphlets, periodicals, and disposable housekeeping items.

(o) "Built-in equipment" means that equipment which is permanently affixed to the wall, floor, or ceiling or otherwise restricted in a like manner, including items which require (1) the modification of a facility for installation or removal, and (2) connection to utility services such as water, gas, steam, or the building ventilation system.

(p) "Grant period" means any period with respect to which assistance is granted under the Act for a particular project.

§ 56a.103 "Emergency medical services system"; definition and requirements.

For purposes of this part, an "emergency medical services system" means a system which provides for the arrangement of personnel, facilities, and equipment for the effective and co-ordinated delivery of health care services in an appropriate geographical area under emergency conditions (occurring either as a result of the patient's condition or of natural disasters or similar situations) and which is administered by a public or nonprofit private entity which has the authority and the resources to provide effective administration of the system.

(a) For purposes of this section, an "appropriate geographical area" shall be an area in which the Secretary determines, on the basis of information contained in an application for a grant under this part and such other information as he deems appropriate for purposes of such determination, efficient and economically feasible emergency medical services can be delivered, taking into consideration existing medical service areas and comprehensive health planning areas, including areas with respect to which applications have been approved by the Secretary under section 314(b) of the Act.

(b) An emergency medical services system shall:

(1) Include an adequate number of health professions, allied health professions, and other health personnel, including ambulance personnel, with appropriate training and experience.

(i) For purposes of this section, an "adequate number of health professions, allied health professions, and other health personnel" means sufficient numbers of such personnel to provide emergency medical services on a 24-hour basis within the service area of the system.

(ii) For purposes of this section, "appropriate training and experience" means

(A) As applied to physicians (doctors of medicine and doctors of osteopathy), those that meet appropriate State qualifications to practice medicine in the State in which they provide emergency medical services.

(B) As applied to nursing and allied health professions, licensure, certification, or registration as required by their respective professions and the State in which they provide emergency medical services.

(C) As applied to ambulance personnel, completion of training as an emergency medical technician in accordance with standards prescribed by the Department of Transportation (DHEW PHS Pub. No. 1071–C–4, April 1970); or an equivalent training program. In order that a program may be recognized as "equivalent," the Secretary must find that at least 75 percent of the graduates of such program either pass the National Emergency Technician Registry examination within 6 months after graduation or meet applicable State requirements which are determined by the Secretary to equal or exceed Department of Transportation requirements.

(2) Provide for its personnel appropriate training (including clinical training) and continuing education programs which are coordinated with other programs in the system's service area which provide similar training and education, and emphasize recruitment and necessary training of veterans of the Armed Forces with military training and experience in health care fields and of appropriate public safety personnel in such area.

(i) For the purposes of this section, "continuing education" means courses which improve job-specific skills and knowledge, such as refresher courses and seminars, and to which personnel devote more than 24 hours per year, whether or not a degree is awarded.

(ii) For the purposes of this section, the emergency medical services system shall use the "Military Experience Directed Into Health Careers" agency of the State or States in which it is located to recruit veterans of the Armed Forces with military training and experience in health care fields.

(iii) For purposes of this section "appropriate public safety personnel" includes police, firemen, and other public employees charged with maintaining public safety.

(3) Join the personnel, facilities, and equipment of the system by a central communications system so that requests for emergency health care services will be handled by a communications facility which utilizes emergency medical telephonic screening; utilizes (or, within such period as the Secretary may prescribe, will utilize) the universal emergency telephone number 911; and will have direct communication connections and interconnections with the personnel, facilities, and equipment of the system and with other appropriate emergency medical services systems.

(i) For the purposes of this section, a "central communications system" includes a system command and control center which is responsible for establishing those communication channels and providing those public resources essential to the most effective and efficient emergency medical services management of the immediate problem, and which has the necessary equipment and facilities to permit immediate interchange of information essential for the system's resource management and control. The essentials of such a communications center are that (A) all requests for system response are directed to the center; (B) all system resource response is directed from the center; and (C) all system liaison with other public safety and emergency response systems is coordinated from the center. Except to the extent provided in subdivision (ii) of this subparagraph, the center need not direct or control medical care or treatment.

(ii) For the purposes of this section, the term "emergency medical telephonic screening" means that the communications system has the capability of redirecting requests for assistance that appear to be non-emergent in nature.

(iii) For the purposes of this section, "other appropriate emergency medical services systems" are those in neighboring areas which might be involved in common disasters, those which are contiguous with the system, and those which have entered into agreements with the system.

(4) Include an adequate number of necessary ground, air, and water vehicles and other transportation facilities to meet the individual characteristics of the system's service area. Such vehicles and facilities must meet appropriate standards relating to location, design, performance, and equipment; and the operators and other personnel for such vehicles and facilities must meet appropriate training and experience requirements.

(i) For the purposes of this section "ground vehicles" include (A) ambulances which meet the requirements in the proposed Federal specifications for emergency medical care vehicles (Federal Specification, Ambulance, Emergency Care Vehicle, General Services Administration, KKK–A–1822, January 2, 1974); and (B) vehicles suitably equipped to transfer both ambulatory and nonambulatory patients who do not need emergency care to appropriate destinations including health care, extended care, and rehabilitation facilities.

(ii) For the purposes of this section "air vehicles" include helicopters, fixed wing, and other aircraft which meet all applicable Federal, State, and local certification and licensure requirements for the operation of such vehicles, and which are designed and equipped to provide the same resuscitative and life support measures and other emergency care procedures as ground vehicles.

(iii) For the purposes of this section "water vehicles" include boats and amphibian craft which meet all the applicable Federal, State, and local certification and licensure requirements for the operation of such vehicles, and which are designed and equipped to provide the same resuscitative and life support measures and other emergency care procedures as ground vehicles.

(iv) For the purposes of this section, an "adequate number of necessary ground, air, and water vehicles and other transportation facilities" means sufficient vehicles to respond to 95% of requests for assistance in the emergency medical services system area within 30 minutes.

(v) For the purposes of this section, the personnel of such vehicles and transportation facilities shall include during patient transport at least two attendants trained to the basic emergency medical technician level, one of whom may be the vehicle operator meeting State and local requirements for operating that type of vehicle.

(5) Include an adequate number of easily accessible emergency medical services facilities which are collectively capable of providing services on a continuous basis, which have appropriate standards relating to capacity, location, personnel, and equipment, and which are coordinated with other health care facilities of the system.

(i) For the purposes of this section the capabilities of accessible emergency medical services facilities must be categorized in accordance with a formulated method of classifying hospital emergency capabilities which is found by the Secretary to be acceptable for purposes of these regulations. Examples of acceptable methods of categorization are the guidelines developed by the American Medical Association (Recommendations of the Conference on the Guidelines for the Categorization of Hospital Emergency Capabilities, AMA, 1971) and systems of categorization having a similar

purpose developed pursuant to applicable State law.

(ii) For the purpose of this section "an adequate number of easily accessible emergency medical services facilities" means that in 95% of the cases, at least one facility which has the minimum capabilities required by the applicable method of categorization is within 60 minutes travel time from the scene of the emergency.

(iii) For the purposes of this section, the system's service area must contain at least one hospital which has the minimum capabilities required by the applicable method of categorization and which has a written working agreement with other hospitals offering greater emergency capabilities.

(6) Provide access (including appropriate transportation) to specialized critical medical care units in the system's service area, or, if there are no such units or an inadequate number of them in such area, provide access to such units in neighboring areas if access to such units is feasible in terms of time and distance.

(i) For the purposes of this section, "appropriate transportation" means a vehicle equipped to enable the emergency medical technician or more highly trained personnel to administer to the patient's intransit needs.

(ii) For the purposes of this section, "specialized critical medical care units" include intensive care units, burn centers, spinal cord centers, and detoxification centers.

(7) Provide for the effective utilization of the appropriate personnel, facilities, and equipment of each public safety agency providing emergency services in the system's service area. For the purposes of this section, "effective utilization" of personnel, facilities, and equipment of public safety agencies means the integration of public safety agencies into standard and disaster operating procedures of the areawide system, including the shared use of personnel and equipment particularly suited to use in medical emergencies, such as helicopters and rescue boats.

(8) Be organized in a manner that provides persons who reside in the system's service area and who have no professional training or financial interest in the provision of health care with an adequate opportunity to participate in the making of policy for the system.

(9) Provide, without prior inquiry as to ability to pay, necessary emergency medical services to all patients requiring such services.

(10) Provide for transfer of patients to facilities and programs which offer such followup care and rehabilitation as is necessary to effect the maximum recovery of the patient.

(i) For the purposes of this section, "followup care and rehabilitation" includes physical and psychiatric care and vocational rehabilitation.

(ii) For the purposes of this section the vehicle used in the transfer of patients to such facilities and programs shall be suitably equipped to meet the patient's intransit needs.

(11) Provide for a standardized patient recordkeeping system, which records shall cover the treatment of the patient from initial entry into the system through his discharge from it, and shall be consistent with ensuing patient records used in followup care and rehabilitation of the patient. For the purposes of this section, a "standardized patient recordkeeping system" means uniform records and forms throughout the emergency medical services system's service area, such as standard forms of ambulance and emergency department use which are integrated into the patient care record, discharge summary, and followup records. The standardized forms must provide such data as the Secretary may request, in such manner as the Secretary may prescribe, for the purpose of obtaining comparable national data upon which to evaluate the impact of the Emergency Medical Services Systems Act (Pub. L. 93–154).

(12) Provide programs of public education and information in the system's service area (taking into account the needs of visitors to, as well as residents of, that area to know or be able to learn immediately the means of obtaining emergency medical services) which programs stress the general dissemination of information regarding appropriate methods of medical self-help and first-aid and regarding the availability of first-aid training programs in the area.

(13) Provide for periodic, comprehensive, and independent review and evaluation of the extent and quality of the emergency health care services provided in the system's service area, and submission to the Secretary of the reports of each such review and evaluation. For the purposes of this section, "independent review" means review by persons not associated with the emergency medical services system and not residing or working within the service area of such system or within the State or States in which the service area of such system is located. Any such independent review and evaluation must address, at a minimum, any evaluative question which the Secretary may prescribe and in such manner as the Secretary may prescribe. The requirement of this subparagraph does not preclude interstate evaluation under the direction of the Department of Health, Education, and Welfare Regional Office.

(14) Have a plan to assure that the system will be capable of providing emergency medical services in the system's service area during mass casualties, natural disasters, or national emergencies. For the purposes of this section, a disaster plan must be tested at least once before completion of the grant period.

(15) Provide for the establishment of appropriate arrangements with emergency medical services systems or similar entities serving neighboring areas for the provision of emergency medical services on a reciprocal basis where access to such services would be more appropriate and effective in terms of the services available, time and distance. For the purposes of this section, any arrangements among emergency medical services systems or similar entities serving neighboring areas shall be written agreements, signed by individuals authorized to act for the respective parties with respect to such agreements, and reviewed and reevaluated at least once a year.

§ 56a.104 Eligible applicants.

The following are eligible to apply for a grant under this part:

(a) A State;

(b) A unit of general local government;

(c) A public entity administering a compact or other regional arrangement or consortium; or

(d) Any other public entity and any nonprofit private entity.

§ 56a.105 Priority.

In considering applications submitted under this part, the Secretary shall give priority to applications submitted by the eligible applicants described in paragraphs (a), (b), and (c) of § 56a.104.

§ 56a.106 Application.

(a) An application for a grant under this part shall be submitted to the Secretary at such time and in such form as the Secretary may prescribe.

(b) The application shall be executed by an individual authorized to act for the applicant and to assume in behalf of the applicant the obligations imposed by the statute, the applicable regulations of this part, and any additional conditions of the grant.

(c) The application shall contain a budget and narrative plan of the manner in which the applicant intends to conduct the project and carry out the requirements of this part. The application must describe the project in sufficient detail to identify clearly the nature, need, specific objectives, plan and methods of the project.

(d) The application shall contain a description of applicable provisions of law or regulations which restrict the full utilization of the training and skills of health personnel in the provision of emergency medical services.

(e) The application shall contain or be supported by a written statement from the applicant that it agrees to maintain such records and make such reports to the Secretary as the Secretary may require.

(f) The application shall contain or be supported by assurances satisfactory to the Secretary that the applicant will conduct the project in cooperation with (1) each section 314(b) areawide health planning agency (if any) whose section 314(b) plan covers (in whole or in part) the service area of the project, and (2) any emergency medical services council or other entity responsible for review and evaluation of the provision of emergency medical services in the service area of the project. For the purposes of this section such an emergency medical services council must be (i) a public agency, or (ii) a formally established advisory body of a public agency.

(g) The application shall indicate that (1) the section 314(a) State health plan-

ning agency of each State in which the service area of the emergency medical services system for which the application is submitted will be located, (2) each section 314(b) areawide health planning agency (if any) whose section 314(b) plan covers (in whole or in part) the service area of such system, and (3) any emergency medical services council or other entity responsible for review and evaluation of the provision of emergency medical services in the service area of the project, have had a reasonable opportunity of not less than 30 days (measured from the date a copy of the application was submitted to the agency or council by the applicant) to review and comment on the application. In addition, each such 314(a) and 314(b) agency shall be provided a copy of the final application at the time the application is submitted to the Secretary. Each such agency may submit comments on such application to the Secretary, with a copy of such comments to the applicant.

(h) In the case of an application submitted by a public entity administering a compact or other regional arrangement or consortium, the application shall contain or be supported by assurances satisfactory to the Secretary that the compact or other regional arrangement or consortium includes each unit of general local government of each standard metropolitan statistical area (as determined by the Office of Management and Budget) located (in whole or in part) in the service area of the emergency medical services system for which the application is submitted.

(i) In the case of an application submitted by an entity described in paragraph (d) of § 56a.104, the application shall contain or be supported by assurances satisfactory to the Secretary that such entity:

(1) Has provided a copy of its application to each entity described in paragraphs (a), (b), and (c) of § 56a.104 which is located (in whole or in part) in the service area of the emergency medical services system for which the application is submitted; and

(2) Has provided each such entity a reasonable opportunity of at least 30 days (measured from the date a copy of the application was submitted to the entity by the applicant) to submit to the Secretary comments on the application.

(j) The application shall contain or be supported by written statements which demonstrate to the satisfaction of the Secretary that there is adequate community support for carrying out the project, including support from representatives of concerned public agencies and of private groups or other organizations in the service area of the project.

§ 56a.107 Grant payments.

The Secretary shall from time to time make payments to a grantee of all or a portion of any grant award, either by advance or by way of reimbursement for expenses incurred or to be incurred to the extent he determines such payments necessary to promote prompt initiation and advancement of the approved project.

§ 56a.108 Nondiscrimination.

Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d et seq.) and in particular section 601 of such Act which provides that no person in the United States shall on the grounds of race, color or national origin be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such Title VI, which applies to grants made under this part, has been issued by the Secretary of Health, Education, and Welfare with the approval of the President (45 CFR Part 80). In addition no person shall, on the grounds of sex, or creed (unless otherwise medically indicated) be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. Nor shall any person be denied employment in or by such program or activity so receiving Federal financial assistance on the grounds of age, sex, creed, or marital status.

§ 56a.109 Confidentiality.

All information as to personal facts and circumstances obtained by the project staff shall be held confidential, and shall not be divulged without the individual's consent except as may be required by law or as may be necessary to provide service to the individual. Information may be disclosed in summary, statistical, or other form which does not identify particular individuals.

§ 56a.110 Inventions or discoveries.

A grant award is subject to the regulations of the Department of Health, Education, and Welfare as set forth in 45 CFR Parts 6 and 8, as amended. Such regulations shall apply to any activity for which grant funds are in fact used whether within the scope of the project as approved or otherwise. Appropriate measures shall be taken by the grantee and by the Secretary to assure that no contracts, assignments or other arrangements inconsistent with the grant obligation are continued or entered into and that all personnel involved in the supported activity are aware of and comply with such obligations. Laboratory notes, related technical data, and information pertaining to inventions and discoveries shall be maintained for such periods, and filed with or otherwise made available to the Secretary or those he may designate at such times and in such manner as he may determine necessary to carry out such Department regulations.

§ 56a.111 Publications and copyright.

(a) *State and local governments.* Where the grantee is a State or local government as defined in 45 CFR 74.3, the Department of Health, Education, and Welfare copyright requirement set forth in 45 CFR 74.140 shall apply with respect to any book or other copyrightable materials developed or resulting from a project supported by a grant under this part.

(b) *Grantees other than State and local governments.* Where the grantee is not a State or local government as so defined, except as may other be provided under the terms and conditions of the award, the grantee may copyright without prior approval any publications, films, or similar materials developed or resulting from a project supported by a grant under this part, subject, however, to a royalty-free, nonexclusive, and irrevocable license or right in the Government to reproduce, translate, publish, use, disseminate, and dispose of such materials and to authorize others to do so.

§ 56a.112 Royalties.

Royalties received by grantees from copyrights on publications or other works developed under the grant, or from patents or inventions conceived or first actually reduced to practice in the course of or under such grant, shall be accounted for as follows:

(a) *State and local governments.* Where the grantee is a State or local government as defined in 45 CFR 74.3, royalties shall be accounted for as provided in 45 CFR 74.44.

(b) *Grantees other than State and local governments.* Where the grantee is not a State or local government as so defined, royalties shall be accounted for as follows:

(1) Patent royalties, whether received during or after the grant period, shall be governed by agreements between the Assistant Secretary for Health, Department of Health, Education, and Welfare, and the grantee, pursuant to the Department's patent regulations (45 CFR Parts 6 and 8).

(2) Copyright royalties, whether received during or after the grant period, shall first be used to reduce the Federal share of the grant to cover the costs of publishing or producing the materials shall be distributed in accordance with Chapter 1–420 of the Department of Health, Education, and Welfare Grants Administration Manual.[1]

§ 56a.113 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other grant funds including funds derived from other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary

[1] The Department of Health, Education, and Welfare Grants Administration Manual is available for public inspection and copying at the Department's and Regional Offices' information centers listed in 45 CFR 5.31 and may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

of expenditures for direct and indirect costs meeting the requirements of this part: *Provided, however,* That when the amount awarded for indirect costs was based on a predetermined fixed percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total, or a selected element thereof, of the reimbursable direct costs incurred.

(b) *Accounting for interest earned on grant funds.* Pursuant to section 203 of the Intergovernmental Cooperation Act of 1968 (42 U.S.C. 4213), a State will not be held accountable for interest earned on grant funds, pending their disbursement for grant purposes. A State, as defined in section 102 of the Intergovernmental Cooperation Act, means any one of the several States, the District of Columbia, Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State, but does not include the governments of the political subdivisions of the State. All grantees other than a State, as defined in this section, must return all interest earned on grant funds to the Federal Government.

(c) *Grant closeout*—(1) *Date of final accounting.* A grantee shall render, with respect to each approved project, a full account, as provided herein, as of the date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) *Final settlement.* There shall be payable to the Federal Government as final settlement with respect to each approved project the total sum of:

(i) Any amount not accounted for pursuant to paragraph (a) of this section:

(ii) Any credits for earned interest pursuant to paragraph (b) of this section; and

(iii) Any other amounts due pursuant to Subparts F, M, and O of 45 CFR Part 74.

Such total sum shall constitute a debt owed by the grantee to the Federal Government and shall be recovered from the grantee or its successors or assignees by setoff or other action as provided by law.

§ 56a.114 Applicability of 45 CFR Part 74.

The provisions of 45 CFR Part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this part to States and local governments as those terms are defined in Subpart A of that Part 74. The provisions of the following subparts of Part 74 shall also apply to grants to all other grantee organizations under this part:

45 CFR PART 74

Subpart
- A General.
- B Cash Depositories.
- C Bonding and Insurance.
- D Retention and Custodial Requirements for Records.
- F Grant-related Income.
- G Matching and Cost Sharing.
- K Grant Payment Requirements.
- L Budget Revision Procedures.
- M Grant Closeout, Suspension, and Termination.
- O Property.
- Q Cost Principles.

§ 56a.115 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved project, the interests of public health, or the conservation of grant funds.

Subpart B—Grants for Feasibility Studies and Planning

§ 56a.201 Applicability.

The regulations of this subpart, in addition to the regulations of Subpart A of this part, are applicable to grants awarded pursuant to section 1202 of the Act for projects which include both (a) studying the feasibility of establishing (through expansion or improvement of existing services or otherwise) and operating emergency medical services systems, and (b) planning the establishment and operation of such systems.

§ 56a.202 Purpose.

The purpose of a project for which a grant is made pursuant to section 1202 of the Act shall be to study the feasibility of and plan for the establishment (through expansion or improvement of existing services or otherwise) and operation of an emergency medical services system which will meet the requirements of section 1206(b)(4)(C) of the Act and § 56a.103 of Subpart A of this part.

§ 56a.203 Content of application—supporting information.

In addition to meeting the applicable requirements of § 56a.106, an approvable application for a grant under section 1202 of the Act shall contain the following supporting information:

(a) Information as to the existence and extent of the need for an emergency medical services system in the project area. The needs of the area shall be described in detail with particular reference to the requirements for an emergency medical services system as described in section 1206(b)(4)(C) of the Act and § 56a.103 of Subpart A of this part;

(b) A narrative and graphic description of the area involved in the project, including geographical features, population, distribution of medical personnel, climate, epidemiological characteristics, socio-economic conditions, and any other relevant factors;

(c) A description of the staff of the project, including their qualifications, authority, functions, numbers, assignments, and the manner in which they are organized to carry out the proposed project;

(d) A description of the specific planning objectives which the project intends to accomplish, including specifically the development of an emergency medical services system which will meet each of the requirements of § 56a.103 of Subpart A of this part;

(e) Information as to how the project plans to attain its planning objectives, including a description of the methods, personnel, facilities, budget, responsible operational unit, and work schedule which will be utilized in order to accomplish each stated objective;

(f) The following budget and staffing information:

(1) Identification of all actual and potential staff positions and the compensation for such positions;

(2) Identification of those costs for which Federal assistance under this subpart is requested and the amount thereof; and

(3) The percentage of the budget which will be devoted to the needs of rural areas;

(g) Information which satisfies the Secretary that adequate facilities, equipment, and financial resources (in addition to the grant requested) will be available at the time of the grant award; and

(h) Any other statistical information which the Secretary may require, in such form as the Secretary may prescribe.

§ 56a.204 Grant evaluation and award.

(a) Within the limits of funds determined by the Secretary to be available for such purpose, the Secretary may award grants under this subpart to those applicants whose projects will, in his judgment, best promote the purposes of section 1202 of the Act and the regulations of this subpart, taking into account:

(1) The extent of the need for emergency medical services in the service area of the proposed project;

(2) The capability of the applicant to carry out the proposed project;

(3) The reasonableness of the budget and the soundness of the fiscal plan for assuring effective utilization of grant funds;

(4) The extent of coordination with existing health planning agencies and groups in the service area of the proposed project;

(5) The potential of the project for accomplishing its objectives and fulfilling the purposes of the emergency medical services systems grant program; and

(6) The degree to which the proposed project addresses the needs of rural areas.

(b) The amount of any award under this part will be determined by the Secretary on the basis of his estimate of the sum necessary for a designated portion of direct project costs plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either:

(1) On the basis of the estimate of the actual indirect costs reasonably related to the project; or

(2) On the basis of a percentage of all, or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs. Such award may include an estimated provisional amount for indirect costs or for designated direct costs (such as fringe benefit rates) subject to upward (within the limits of

available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary: *Provided, however*, That no grant will be made for an amount which exceeds $45,000 except where the Secretary determines that a larger amount is necessary to support a project of special regional or national significance which could not be accomplished without a grant under this subpart in such larger amount.

(c) All grant awards shall be in writing, shall set forth the amount of funds granted, and the period for which support is recommended.

(d) Neither the approval of any project nor any grant award shall commit or obligate the United States in any way to make additional, supplemental, continuation, or other award with respect to any approved project or portion thereof.

§ 56a.205 Use of project funds.

(a) Any funds granted pursuant to this subpart shall be expended solely for carrying out the approved project in accordance with section 1202 of the Act, the regulations of this part, the terms and conditions of the award, and the applicable cost principles prescribed by Subpart Q of 45 CFR Part 74.

(b) Project funds under this subpart may be used only for the following:

(1) Salaries and related benefits.

(2) Leasing or rental of office space, furniture, and equipment.

(3) Costs related to the conducting of surveys.

(4) Printing costs.

(5) Domestic travel related to feasibility studies and planning activities.

(6) Consultants' fees and related travel expenses in accordance with local compensation rates, or if none are available, with current Federal principles.

§ 56a.206 Reports.

Each grant awarded pursuant to section 1202 of the Act shall be subject to the condition that the grantee shall file with the Secretary such progress and other reports as the Secretary may require, including the following:

(a) *Report of feasibility study.* (1) Three months after the award of the grant, the grantee shall submit to the Secretary a report of the feasibility study which shall contain:

(i) A detailed statement indicating whether, in the judgment of the grantee, it is feasible to establish, expand, or improve an emergency medical services system in the service area of the project.

(ii) Information derived from studies as to the organizational structure, current resources, geographical area, and existing and contemplated standards of the proposed emergency medical services system.

If the Secretary determines, on the basis of the report of the feasibility study and other information relevant to such determination,

(2) That it is not feasible to establish, expand, or improve an emergency medical services system for the project area, the Secretary may, after reasonable notice to the grantee, terminate the grant.

(b) *Final report—planning outline.* Should the grantee determine that it is feasible to establish, expand, or improve an emergency medical services system for the service area of the project, the grantee shall, within 6 months after filing the feasibility study report, submit to the Secretary a final report, in the form of a planning outline, which contains the following information:

(1) A comprehensive description of the organizational structure which will manage the emergency medical services system;

(2) A detailed description of current emergency medical services resources and capability;

(3) A narative and graphic description of the project area, including geographic, demographic, climatological, epidemiological, and socio-economic characteristics;

(4) A description of actual and potential standards for emergency medical services, including methods and levels of performance;

(5) A description of the objectives of the project, identifying problems and needs and establishing priorities for achieving such objectives;

(6) A description of the projected emergency medical services capability that will exist at the completion of the plan, including types of services, status of subsystems, and nature of community involvement;

(7) A detailed description of the methodology which will be employed in order to achieve each of the objectives of the project;

(8) A schedule for the implementation of the plan;

(9) A fiscal schedule containing estimated expenditures and justification therefore; and

(10) A description of the methods which will be used to evaluate the operation of the planned emergency medical services system and the effect of such system on the patients involved.

Subpart C—Grants for Establishment and Initial Operation

§ 56a.301 Applicability.

The regulations of this subpart, in addition to the regulations of Subpart A of this part, are applicable to grants awarded pursuant to section 1203 of the Act for the establishment and initial operation of emergency medical services systems.

§ 56a.302 Project requirements.

(a) An application under this subpart will not be approved by the Secretary unless (1) the applicant demonstrates to the satisfaction of the Secretary that the emergency medical services system for which the application is submitted will meet each of the requirements specified in section 1206(b)(4)(C) of the Act and § 56a.103 of Subpart A of this part within the period of the grant for which application is made; except that if the applicant demonstrates to the satisfaction of the Secretary the inability of the applicant's emergency medical services system to meet one or more of such requirements within such period, the period (or periods) within which the system must meet such requirement (or requirements) is such period (or periods) as the Secretary may require; and

(2) The applicant provides in the application a plan satisfactory to the Secretary for the system to meet each of the requirements specified in section 1206(b)(4)(C) of the Act and § 56a.103 of Subpart A of this part within the period described in subparagraph (1) of this paragraph:

(b) *Provided*, That If an applicant submits an application for a grant under this subpart and demonstrates to the satisfaction of the Secretary the inability of the system for which the application is submitted to meet one or more of the requirements specified in section 1206(b)(4)(C) of the Act and § 56a.103 of Subpart A of this part within any specific period of time, the prerequisites prescribed in paragraph (a) of this section shall not apply with respect to such requirement (or requirements), and the applicant shall provide in the application a plan, satisfactory to the Secretary, for achieving appropriate alternatives to such requirement (or requirements).

§ 56a.303 Content of application—supporting information.

An approvable application for a grant under section 1203 of the Act shall contain the following information:

(a) A comprehensive description of the organizational structure which will manage the emergency medical services system;

(b) A detailed description of current emergency medical services resources and capability;

(c) A narrative and graphic description of the project area, including geographic, demographic, climatological, epidemiological, and socio-economic characteristics;

(d) A description of actual and potential standards for emergency medical services, including methods and levels of performance;

(e) A description of the objectives of the project, identifying problems and needs and establishing priorities for achieving such objectives;

(f) A description of the projected emergency medical services capability that will exist at the completion of the project, including types of services, status of subsystems, and nature of community involvement;

(g) A detailed description of the methodology which will be employed in order to achieve each of the objectives of the project;

(h) A schedule for the implementation of the project;

(i) A fiscal schedule containing estimated expenditures and justification therefor;

(j) A description of the methods which will be used to evaluate the operation of the planned emergency medical services system and the effect of such system on the patients involved; and

(k) Any other statistical information which the Secretary may require, in such form as the Secretary may prescribe.

§ 56a.304 Grant evaluation and award.

(a) Within the limits of funds determined by the Secretary to be available for such purpose, the Secretary may award grants under this subpart to those applicants whose projects will, in his judgment, best promote the purposes of section 1203 of the Act and the regulations of this subpart, taking into account:

(1) The extent of the need for emergency medical services in the service area of the proposed project;

(2) The capability of the applicant to carry out the proposed project;

(3) The reasonableness of the budget and the soundness of the fiscal plan for assuring effective utilization of grant funds;

(4) The extent of coordination with existing health planning agencies and groups in the service area of the proposed project;

(5) The potential of the project for accomplishing its objectives and fulfilling the purposes of the emergency medical services systems grant program;

(6) The potential of the project for becoming a self-supporting emergency medical services system; and

(7) The degree to which the proposed project addresses the needs of rural areas.

(b) The amount of any award under this part will be determined by the Secretary on the basis of his estimate of the sum necessary for a designated portion of direct project costs plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either:

(1) On the basis of the estimate of the actual indirect costs reasonably related to the project; or

(2) On the basis of a percentage of all, or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs. Such award may include an estimated provisional amount for indirect costs or for designated direct costs (such as fringe benefit rates) subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.

Provided, however, That such amount shall not represent a percentage of the total cost of the project as determined by the Secretary pursuant to these regulations which exceeds the applicable maximum percentage of Federal participation specified in section 1203(c)(4) of the Act. In determining the grantee's share of project costs, costs borne by Federal funds, or costs used to match other Federal grants may not be included except as otherwise provided by law.

(c) All grant awards shall be in writing, shall set forth the amount of funds granted, and the period for which support is recommended.

(d) Neither the approval of any project nor any grant award shall commit or obligate the United States in any way to make additional, supplemental, continuation, or other award with respect to any approved project or portion thereof. However, if a grant is made under this subpart for an emergency medical services system, the Secretary may make one additional grant for that system if he determines, after a review of the first nine months' activities of the applicant carried out under the first grant, that the applicant is satisfactorily progressing in the establishment and operation of the system in accordance with the plan contained in its application (pursuant to section 1206(b)(4) of the Act and § 56a.302) for the first grant.

§ 56a.305 Use of project funds.

(a) Any funds granted pursuant to this subpart, as well as other funds to be used in performance of the approved project, shall be expended solely for carrying out the approved project in accordance with section 1203 of the Act, the regulations of this part, the terms and conditions of the award, and the applicable cost principles set forth in 45 CFR Part 74.

(b) Project funds under this subpart may be used for, but need not be limited to, the following:

(1) Purchasing ambulances: *Provided,* That

(i) No other funds, Federal or non-Federal, are available for such purpose;

(ii) The cost will be no greater than the Federal share prescribed by the applicable Department of Transportation cost sharing requirements.

(iii) The ambulance meets the requirements for size and equipment prescribed by the Federal Specification, Ambulance, Emergency Care Vehicle, General Services Administration, (KKK–A–1822, January 2, 1974).

(iv) The ambulance is capable of responding to all medical emergencies in the service area of the system;

(v) The State allocation of Federal Highway Safety Funds for Department of Transportation Standard XI for the current year is not less than the allocation for 1973 or 1974 (whichever is greater), unless the total allocation for all Standards is less, and the reduction in the Standard XI allocation is proportionate to the overall reduction;

(vi) The ambulance, by the end of the grant period, will be manned by two certified emergency medical technicians when transporting patients; and

(vii) Existing ambulances cannot be improved economically to meet the system's standards, and additional ambulances are necessary for efficient operation of the system.

(2) Purchasing communications equipment: *Provided,* That

(i) There exists an overall public safety communications plan for the service area of the project that is consistent with the regulations of the Federal Communications Commission in 47 CFR Part 89, "Public Safety Radio Services," Subpart P, "Special Emergency Radio Service".

(ii) Existing equipment and facilities are utilized to the fullest possible extent; and

(iii) Evidence is presented that reasonable effort has been made to obtain funds from other sources for such purpose.

(3) Alterations to complete existing facilities: *Provided,* That

(i) The work is essential to the project and is limited to adapting space or utilities to accomplish the objectives of the grant-supported activities;

(ii) The facility has a usable life consistent with program purposes and is architecturally suitable for conversion; and

(iii) The space involved will actually be occupied by the project.

(4) Purchasing built-in equipment for existing ambulances, emergency departments, and communications centers.

(5) Training and continuing education for personnel, provided that the applicant demonstrates to the satisfaction of the Secretary that the applicant filed an application under Title VII or VIII of the Act for a grant or contract for a training program and such application was not approved or was approved but for which no or inadequate funds were made available under such title.

(6) Purchasing training aids, books, and materials, and related classroom expenses.

(7) Providing programs of public education and information regarding the emergency medical services system.

(8) Establishing use of the universal emergency telephone number 911, except for costs customarily borne by the telephone company or local government.

(c) Project funds may not be used for the following:

(1) Construction of new facilities.

(2) Acquisition of facilities.

(3) Purchasing built-in hospital equipment which will be used more than 25 percent of the time for non-emergency department purposes.

(4) Maintaining equipment or replacing supplies.

(5) Establishment, operation, or improvement of services or facilities involved in the care of patients in the normal hospital environs or in any other care facility, except for those which are customarily associated with the emergency department.

(6) Financial assistance to students for stipends, tuition and fees, per diem, or other reimbursement for food, lodging, etc. Domestic travel of trainees may be supported at the rate of eight cents per mile when justified as a necessary and integral part of an approved training program.

(7) Costs normally borne by the patient, such as hospitalization costs.

Subpart D—Grants for Expansion and Improvement

§ 56a.401 Applicability.

The regulations of this subpart, in addition to the regulations of Subpart A of this part, are applicable to grants awarded pursuant to section 1204 of the Act for the expansion and improvement of emergency medical services systems.

§ 56a.402 Purpose.

The purpose of a project for which a grant is made pursuant to section 1204 of the Act shall be (a) the expansion and improvement of an existing emergency medical services system's capabilities to meet the requirements of section 1206(b)(4)(C) of the Act and § 56a.103 of Subpart A of this part, or (2) the expansion of an existing system to cover geographical areas or population groups not previously served by such system.

§ 56a.403 Project requirements.

(a) An application under this subpart will not be approved by the Secretary unless (1) the applicant demonstrates to the satisfaction of the Secretary that the emergency medical services system for which the application is submitted will meet each of the requirements specified in section 1206(b)(4)(C) of the Act and § 56a.103 of Subpart A of this part within the period of the grant for which application is made; except that if the applicant demonstrates to the satisfaction of the Secretary the inability of the applicant's emergency medical services system to meet one or more of such requirements within such period, the period (or periods) within which the system must meet such requirement (or requirements) is such period (or periods) as the Secretary may require; and

(2) The applicant provides in the application a plan satisfactory to the Secretary for the system to meet each of the requirements specified in section 1206(b)(4)(C) of the Act, and § 56a.103 of Subpart A of this part within the period described in subparagraph (1) of this paragraph;

(b) *Provided*, That If an applicant submits an application for a grant under this subpart and demonstrates to the satisfaction of the Secretary the inability of the system for which the application is submitted to meet one or more of the requirements specified in section 1206(b)(4)(C) of the Act and § 56a.103 of Subpart A of this part within any specific period of time, the prerequisites prescribed in paragraph (a) of this section shall not apply with respect to such requirement (or requirements), and the applicant shall provide in the application a plan, satisfactory to the Secretary, for achieving appropriate alternatives to such requirement (or requirements).

§ 56a.404 Content of application—supporting information.

An approvable application for a grant under section 1204 of the Act shall contain the following information:

(a) A comprehensive description of the organizational structure which will manage the improved and expanded emergency medical services system;

(b) A detailed description of current emergency medical services resources and capability;

(c) A narrative and graphic description of the project area, including geographic, demographic, climatological, epidemiological, and socio-economic characteristics;

(d) A description of actual and potential standards for emergency medical services, including methods and levels of performance;

(e) A description of the objectives of the project, describing specifically which aspects of the emergency medical services system must be improved and expanded in order for the system to meet each of the requirements of section 1206(b)(4)(C) of the Act and § 56a.103 of Subpart A of this part;

(f) A description of the projected emergency medical services capability that will exist after improvement and expansion of the system, including types of services, status of subsystems, and nature of community involvement;

(g) A detailed description of the methodology which will be employed in order to achieve each of the objectives of the project;

(h) A schedule for the implementation of the project;

(i) A fiscal schedule containing estimated expenditures and justification therefor;

(j) A description of the methods which will be used to evaluate the operation of the improved and expanded emergency medical services system and the effect of such system on the patients involved; and

(k) Any other statistical information which the Secretary may require, in such form as the Secretary may prescribe.

§ 56a.405 Grant evaluation and award.

(a) Within the limits of funds determined by the Secretary to be available for such purpose, the Secretary may award grants under this subpart to those applicants whose projects will, in his judgment, best promote the purposes of section 1204 of the Act and the regulations of this subpart, taking into account;

(1) The extent of the need for improved and expanded emergency medical services in the service area of the system;

(2) The capability of the applicant to carry out the proposed project;

(3) The reasonableness of the budget and the soundness of the fiscal plan for assuring effective utilization of grant funds;

(4) The extent of coordination with existing health planning agencies and groups in the service area of the system;

(5) The potential of the project for accomplishing its objectives and fulfilling the purposes of the emergency medical services grant program;

(6) The potential of the project for becoming self-supporting; and

(7) The degree to which the proposed project addresses the needs of rural areas.

(b) The amount of any award under this Part will be determined by the Secretary on the basis of his estimate of the sum necessary for a designated portion of direct project costs plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either:

(1) On the basis of the estimate of the actual indirect costs reasonably related to the project; or

(2) On the basis of a percentage of all, or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs. Such award may include an estimated provisional amount for indirect costs or for designated direct costs (such as fringe benefit rates) subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.

Provided, however, That such amount shall not exceed 50 per centum of the total cost of the project, as determined by the Secretary pursuant to these regulations, or in the case of applications which demonstrate an exceptional need for financial assistance, 75 per centum of such cost. In determining the grantee's share of project costs, costs borne by Federal funds, or costs used to match other Federal grants may not be included except as otherwise provided by law.

(c) All grant awards shall be in writing, shall set forth the amount of funds granted, and the period for which support is recommended.

(d) Neither the approval of any project nor any grant award shall commit or obligate the United States in any way to make additional, supplemental, continuation, or other award with respect to any approved project or portion thereof. For continuation support, grantees must make separate application periodically at such times and in such form as the Secretary may direct.

§ 56a.406 Use of project funds.

(a) Any funds granted pursuant to this subpart, as well as other funds to be used in performance of the approved project, shall be expended solely for carrying out the approved project in accordance with section 1204 of the Act, the regulations of this part, the terms and conditions of the award, and the applicable cost principles set forth in 45 CFR Part 74.

(b) Project funds under this subpart may be used for, but need not be limited to, the following:

(1) The items enumerated in section 306(b) of Subpart C of this Part.

(2) Acquisition of equipment and existing facilities, exclusive of land and offsite improvements. Federal participation in mortgage amortization and similar loan payments in connection with such acquisition will be limited to a maximum of two years (See § 56a.407).

(3) Modernization of Facilities.

(c) Project funds may not be used for the following:

(1) Construction of new facilities.

(2) Purchasing built-in hospital equipment which will be used more than 25 percent of the time for non-emergency department purposes.

(3) Maintaining equipment or replacing supplies.

(4) Establishment, operation, or improvement of services or facilities involved in the care of patients in the normal hospital environs or in any other care facility, except for those which are customarily associated with the emergency department.

(5) Financial assistance to trainees for stipends, tuition and fees, per diem, or other reimbursement for food, lodging, etc. Domestic travel of trainees may be supported at the rate of eight cents per mile when justified as a necessary and integral part of an approved training program.

(6) Costs normally borne by the patient, such as hospitalization costs.

§ 56a.407 Acquisition of facilities.

The following provisions are applicable to the acquisition of existing facilities:

(a) *Estimated costs of acquisition and remodeling: Suitability of facility.* Each application for a project involving the acquisition of existing facilities shall include in the detailed estimates of the cost of the project the cost of acquiring such facilities to serve the purposes for which they are acquired. Such application shall demonstrate to the satisfaction of the Secretary that the architectural, structural and other pertinent features of the facility, as modified by any proposed expansion, remodeling, renovation, or alteration, will be clearly suitable for the purposes of the program, and, to the extent of the costs in which Federal participation is requested, are not in excess of what is necessary for the services proposed to be provided in such facilities.

(b) *Determination of necessary cost.* The necessary cost of acquisition of existing facilities shall be determined on the basis of such documentation submitted by the applicant as the Secretary may prescribe (including the reports of such real estate appraisers as the Secretary may approve) and other relevant factors.

(c) *Bona fide sale.* Federal participation in the acquisition of existing facilities is on condition that such acquisition constitutes a bona fide sale involving an actual cost to the applicant and will result in additional or improved facilities for purposes of the program.

(d) *Facility which has previously received Federal grant.* No grant for the acquisition of a facility which has previously received a Federal grant for construction, acquisition, or equipment shall serve either to reduce or restrict the liability of the applicant or any other transferor or transferee from any obligation of accountability imposed by the Federal Government by reason of such prior grant.

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PART IV

FEDERAL ENERGY OFFICE

■

CLARIFICATIONS AND REVISIONS TO PART 211

Proposed Rules

FEDERAL ENERGY OFFICE

[10 CFR Part 211]

CLARIFICATIONS AND REVISIONS TO PART 211

Notice of Proposed Rulemaking

The Federal Energy Office hereby gives notice of a proposal to amend Title 10 of the Code of Federal Regulations, Part 211.

This revision represents a restatement of the basic regulatory framework for the Mandatory Petroleum Allocation Program. It is intended to clarify and make more precise the regulatory scheme established in the January 15, 1974 Mandatory Allocation Regulations, as amended. The changes are largely technical in nature and are not intended to reflect fundamental policy changes except for new provisions dealing with the certification of current requirements for agricultural production and supplier-initiated adjustments to base period volumes of wholesale purchasers. Most of the changes in this proposed revision are intended to clarify areas of misunderstanding which have come to FEO's attention. To this end, it is anticipated that the reorganization of Subpart A, the new and revised definitions, and the expanded treatment of certain concepts would facilitate the uniform interpretation of Part 211 and compliance with the allocation program. This proposal does not represent an attempt to create or modify allocation programs in response to any anticipated increased supply of crude oil and petroleum products, but does provide a basis upon which to modify the various allocation programs when increased supplies are available.

Subpart C (Crude Oil) is not addressed in this proposal since it has already been the subject of a separate proposed rulemaking. In this proposal Subpart D (Propane) and Subpart E (Butane) have also not been conformed to the proposed changes in Subpart A. A proposed revision of Subpart D will be issued for public comment shortly, to become effective the first of May, 1974. At the same time it is anticipated that a proposed revision of Subpart E will be issued for public comment. No conforming changes have been found necessary in Subpart J (Petrochemical Feedstocks) at this time.

Interested persons commenting on the notice of proposed rulemaking concerning supplier/purchaser relationships for civil air carriers published in the FEDERAL REGISTER on March 26, 1974, should attempt to review those proposals in the light of these proposed revisions of Subparts A and B.

The general provisions of Subpart A would be reorganized so that the principles which form a common basis for the various allocation programs can be more easily understood in relation to one another. To this end, §211.24 would be revoked and a new § 211.9 issued which would contain a more comprehensive description of supplier/purchaser relationships. Similarly, the method of allocation contained in the existing § 211.11 would be found in a new § 211.10, and would set forth in detail the methods of allocation to be followed by suppliers. A new § 211.11 would provide the basis for a purchaser's entitlement to an allocation and would include such other subjects as the separate treatment of the parts of a firm when acting in certain capacities.

Proposed Subpart B would include new definitions and there would be changes made in the definition of certain terms. Basic concepts in Part 211 which have been the subject of misunderstanding would be clarified and more detail supplied to provide guidance in these problem areas. Subparts F through K and Subpart L would be revised to conform to the changes made in Subparts A and B.

Wholesale purchaser-resellers and wholesale purchaser-consumers. Proposed Subpart B would provide two new definitions in particular which should be noted. The term "wholesale purchaser" has been revised to mean either a wholesale purchaser-reseller or wholesale purchaser-consumer or both. A wholesale purchaser-reseller is defined as a

> "firm which purchases, receives through transfer, or otherwise obtains (as by consignment) an allocated product and resells or otherwise transfers it to other purchasers without substantially changing its form."

A wholesale purchaser-consumer is defined as a

> "firm that is an ultimate consumer which, as part of its normal business practices, purchases or obtains an allocated product from a supplier and receives delivery of that product into a storage tank substantially under the control of that firm at a fixed location and which either (1) purchased or obtained more than 20,000 gallons of that allocated product for its own use in agricultural production in any completed calendar year subsequent to 1971; (2) purchased or obtained more than 50,000 gallons of that allocated product in any completed year subsequent to 1971 for use in one or more multi-family residences; or (3) purchased or obtained more than 84,000 gallons of that allocated product in any completed calendar year subsequent to 1971."

Essentially, the definitions of wholesale purchaser-reseller and wholesale purchaser-consumer separate two concepts included within the definition of wholesale purchaser under the existing regulations. The two new definitions would make it easier to make distinctions between the two concepts.

Allocation levels not subject to an allocation fraction. The proposed revision would set forth in Subparts F through K for each allocated product those allocation levels not subject to an allocation fraction and those which are subject to an allocation fraction. Thus, in proposed Subpart F (Motor Gasoline), the allocation level not subject to an allocation fraction includes agricultural production and Department of Defense use while the allocation level subject to an allocation fraction includes such uses as emergency services and sanitation services.

Certification of end-user or wholesale purchaser-consumer requirements entitled to allocation levels not subject to an allocation fraction. Section 211.12(d) would provide a new procedure whereby the allocation requirements of end-users and wholesale purchaser-consumers whose allocation levels are not subject to an allocation fraction could be certified to each supplier in the distribution chain. Basically, such an end-user or wholesale purchaser-consumer would certify to its supplier on an annual basis its allocation requirements not subject to an allocation fraction. A supplier which received such a certification would in turn certify those requirements to its supplier.

Each supplier would then allocate its supply of an allocated product as provided in § 211.10(c). Wholesale purchaser-resellers would receive those amounts certified by the wholesale purchaser-reseller to its supplier as being for ultimate use under an allocation level not subject to an allocation fraction. The supplier would also allocate its supply to end-users and wholesale purchaser-consumers which it supplies directly and which have certified to the supplier that their use of the allocated product is for an allocation level not subject to an allocation fraction. The supplier would then allocate its remaining supply to wholesale purchaser-resellers, end-users, and wholesale purchaser-consumers whose allocation levels are subject to an allocation fraction. Wholesale purchaser-resellers which have thus been supplied by the supplier would then in turn allocate their supply in the same fashion.

Prior to receipt of a purchaser's certification of allocation requirements not subject to an allocation fraction, suppliers will supply such purchasers (other than agricultural production) at their allocation level but subject to an allocation fraction.

Agricultural production. In connection with the certification of requirements entitled to an allocation level not subject to an allocation fraction, it should be noted that the definition of agricultural production in proposed Subpart B has been revised to identify clearly those activities and services included within agricultural production. Agricultural production would be defined by reference to Standard Industrial Classification code numbers.

This revision is intended to identify more precisely those activities falling within the scope of agricultural production. The current definition is susceptible of varying interpretation. Special treatment for agricultural production, which would be enhanced in the proposed program, is designed to insure adequate availability of fuel for the production of foodstuffs and the principle processing activities related thereto. Use of the SIC code system for identifying the activities falling within this definition should assure greater uniformity and consistency in application. Activities which are related to the food industry but are not agricultural production fall into the category of "business activities" which are assigned allocation levels in the regulations. They are thereby treated in the same fashion as other industries in the

manufacturing and service sectors. FEO recognizes the difficulty of drawing the definitional line between what is agricultural production and what falls outside, and will be particularly receptive to comments on this issue.

End-users and wholesale purchaser-consumers as a single entity. Section 211.11 would define end-users and wholesale purchaser-consumers as including all parts of a parent and the consolidated and unconsolidated entities which the parent controls and which act as ultimate consumers. For the purpose of the allocation programs, suppliers would therefore allocate to such end-users and wholesale purchaser-consumers as a single entity.

Separate parts of firms as separate wholesale purchaser-resellers. Proposed § 211.11, however, provides that each part of a firm which operates an ongoing business at a retail sales outlet (as defined in Subpart B) will be considered a separate firm with respect to each retail sales outlet and therefore each retail sales outlet is a separate wholesale purchaser-reseller.

Suppliers would allocate their product separately for each wholesale purchaser-reseller. Suppliers are not permitted to reassign any portion of an allocation entitlement among wholesale purchaser-resellers including their own retail sales outlets.

Section 211.11 also provides that wholesale purchasers and end-users which go out of business lose their base period volumes. In this connection, a wholesale purchaser-reseller which operates a retail sales outlet would not be deemed to have gone out of business if it vacates a site but reestablishes within a reasonable time a retail sales outlet at another location serving substantially the same customers or market served at the former site.

Because proposed § 211.11 provides that each retail sales outlet of a firm is deemed a separate wholesale purchaser-reseller, § 211.11(d) provides rules governing the supplier/purchaser-relationships between a firm and its separate retail sales outlets. In addition, rules are set forth which reduce allocation requirements of the supplier of a retail sales outlet (often the operator of the outlet) so that the operator could not shift allocation requirements among its outlets by closing some outlets. Section 211.11 would require a supplier which supplies its own operated retail sales outlets to report to FEO reductions as to the number of retail sales outlets it operates.

Supplier's method of allocation. Section 211.10 would describe the method by which suppliers allocate their products. The allocation of product to purchasers whose allocation level is not subject to an allocation fraction has been previously described.

Allocations to purchasers whose allocation level is subject to an allocation fraction is also described in detail in proposed § 211.10. Allocation fractions are determined such that amounts to be supplied for certified uses not subject to an allocation fraction are excluded from allocable supply and supply obligation. Allocable supply and supply obligation are defined in proposed § 211.10.

Section 211.10 would provide that base period volume is either the historic volume purchased or obtained during a base period or is the volume assigned by FEO if the purchaser did not purchase or obtain a volume during a base period. The concepts of allocation requirements and allocation levels would be defined in § 211.10.

With respect to purchasers entitled to an allocation level, the allocation levels would not be arranged in order of priority except for allocation levels not subject to an allocation fraction which would be supplied as the first order of priority.

End-users not entitled to allocation levels. Section 211.10 would permit a state or local government to require or authorize suppliers (for example, a retail gasoline dealer) to grant priority among end-users which purchase an allocated product for uses listed in the FEO allocation levels for that product. Except as otherwise required by a state or local government, a supplier could also elect under § 211.10 to give the same priority to such end-users.

The provisions of proposed § 211.12(d) for certification by end-users and wholesale purchasers-consumers of allocation requirements not subject to an allocation fraction have been noted above.

New purchasers. Section 211.12(e) would provide the rules by which new wholesale purchasers may be supplied. It should be noted that wholesale purchasers without a base period supplier or without a new supplier as provided in § 211.10(e)(1) must be assigned to suppliers by FEO. Base period volumes also must be assigned by FEO. Assignments by FEO include arrangements between suppliers and new wholesale purchaser-resellers prior to May 1, 1974.

Section 211.12(f) provides for supply of new end-users.

New importers for end-use. New rules with respect to new end-user and wholesale purchaser-consumer importers which import for their own end-use are provided by § 211.12(g). Such imports may be allocated by FEO in certain circumstances. Reporting is required for such imports.

Adjustment to base period volume. Proposed § 211.13(b) provides an unusual growth adjustment which represents a significant change from the current method of adjusting wholesale purchasers' base period volumes for unusual growth. Supplier-initiated unusual growth adjustments would be mandatory if the supplier's records indicate unusual growth between the base period and December 31, 1973. The wholesale purchaser is only entitled to that growth over 10 percent for motor gasoline and 5 percent for other allocated products. There is no longer a requirement that FEO validate adjustments for growth in excess of twenty (20) percent. Suppliers also would not be required to absorb five percent growth before applying for an adjustment to their base period volumes.

There would be no requirement that the adjustment be initiated by the wholesale purchaser. The supplier is expected to make appropriate adjustments, notify the affected wholesale purchasers, commence deliveries based upon the adjustments and file the appropriate certified forms with FEO by May 1, 1974. These forms and the adjustments they reflect are subject to FEO audit. Deliveries reflecting the adjustments could be made before May 1, 1974 only if all wholesale purchasers eligible for the adjustment receive deliveries reflecting the unusual growth adjustment. Wholesale purchasers not entitled to an adjustment according to the supplier's records would be notified and advised of their right to apply for an unusual growth adjustment. No wholesale purchasers' base period volume would be decreased under this subsection.

Section 211.13(b)(2) would provide for an additional procedure whereby wholesale purchaser-resellers would apply to their suppliers to refine the supplier initiated unusual growth adjustments. This additional adjustment is intended to compensate wholesale purchaser-resellers whose base period volumes as adjusted by the supplier initiated procedure may be distorted to the extent that the 10 percent or 5 percent factor deducted in calculating unusual growth includes growth associated with allocation requirements not subject to an allocation fraction.

Wholesale purchasers which do not receive a supplier-initiated unusual growth adjustment or which disagree with the adjustment received, could apply to the supplier for an unusual growth adjustment based upon the supplier's records and the wholesale purchaser's records. In many cases it is anticipated that base period suppliers will not have complete information as to a base period wholesale purchaser's 1973 volumes to initiate an unusual growth adjustment that fully compensates a wholesale purchaser for 1973 unusual growth. Consequently, the wholesale purchaser must provide such data to the base period supplier so that the unusual growth adjustment can be fully made. Upon receipt of such an application, the supplier would be required to adjust the wholesale purchaser's base period supply within ten days. Suppliers would make an interim adjustment to the wholesale purchaser's base period volume pending FEO's resolution of any disputed application. If the adjustment were ultimately denied, FEO would require that the supplier adjust the wholesale purchaser's future allocation to compensate for excess product received.

Wholesale purchasers could also apply to the FEO for adjustments to their base period volumes for changed circumstances since January 1, 1973. These changed circumstances should indicate need for an adjustment to base period volumes due to such factors as plant expansions, changed traffic patterns, in-

creased population, and the like. A wholesale purchaser-reseller which was unable to increase sales to match increased demand in 1973 due solely to an allocation fraction imposed by its supplier under a voluntary petroleum allocation program could apply for an adjustment under this provision. End-users whose allocation level is a percentage of base period volumes could apply for adjustments based upon changed circumstances since January 1, 1974. The application is made to the State office, which forwards the application and its recommendation to FEO. FEO would only make adjustments for changed circumstances in compelling situations which are supported by detailed documentation.

End-users and wholesale purchaser-consumers entitled to an allocation level of 100 percent of current requirements which is subject to their supplier's allocation fraction would certify to these suppliers any increased requirements since January 1, 1974. If the supplier and the purchaser cannot agree, a request for validation would be forwarded to FEO. Pending this validation, the supplier would supply the requested increased requirement. The FEO could later require the supplier to adjust the purchaser's allocation requirements to compensate for excess product supplied during the period a validation is pending. Suppliers would in turn certify these increased requirements and have their base period volumes adjusted to cover the increase granted by suppliers under this paragraph.

No supplier may discriminate between or among its wholesale purchasers and end-users in adjusting base periods.

Complaints by wholesale purchasers concerning applications not approved or alleged discrimination between or among classes of wholesale purchasers supplied by the supplier would be filed with the FEO.

Redirection of product. Section 211.14 would be revised to define the term "area" as a state, a group of states within a region, or a subdivision of a state or states within a region. As revised, § 211.14 would specify that the FEO may order the redirection of products from one area or region to another or may order that different allocation fractions be used in different regions to meet imbalances in supplies of allocated products. In the case of refiners, importers and other suppliers which have significantly reduced marketing or distribution in an area, proposed § 211.14 provides that FEO may order the reassignment of wholesale purchasers or end-users from one supplier to another.

State set-aside. The provisions of § 211.17 would be reorganized and would specify determination of the State set-aside volume, action to be taken by the State in allocating from the state set-aside, the meaning of the authorizing document, suppliers' responsibilities and the role of prime suppliers. Section 211.17 would also be revised to specify that an authorizing document issued by a State office is effective when issued and represents a call on the prime suppliers' set-aside volumes for the month of issuance even when deliveries take place in a subsequent month. An authorizing document entitles a purchaser to receive product from a local distributor of the prime supplier. A local distributor may not delay deliveries required by the authorizing document while seeking confirmation from the prime supplier.

Supplier substitution. Section 211.25 would be revised to make it clear that when a supplier arranges to fulfill a supply obligation through a substituted supplier, the purchaser is entitled to the same amount of allocated product from the substituted supplier that the purchaser would receive if it were directly supplied by the obligated supplier using the obligated supplier's allocation fraction.

Base period volume for construction. Section 211.27 would include negotiated construction contracts in addition to competitive bid contracts.

Subparts F through L. Subparts F through I and Subpart K are revised to conform to changes in Subparts A and B. In addition, substantive changes are made in Subpart H (Aviation Fuels) and Subpart K (Other Products).

Subparts F through I and Subpart K (as previously noted) would specify whether particular allocation levels are subject to reduction by application of an allocation fraction. In each case the allocation level of 100 percent of current requirements, not subject to an allocation fraction, is assigned to agricultural production and Department of Defense uses except for housekeeping requirements. Space heating requirements are assigned the level of 100 percent of current requirements not subject to the allocation fraction under Subpart G (Middle Distillate) and Subpart I (Residual Fuel Oil). Aviation ground support vehicles and equipment are included at the allocation level of 100 percent of current requirements, subject to an allocation fraction, in Subpart F (Motor Gasoline) and Subpart G (Middle Distillate).

Subpart H (Aviation Fuels) would be revised to include telecommunications flying in the allocation level of 100 percent of current requirements subject to an allocation fraction and to clarify that the allocation levels specified for local air service carriers, other air carriers, domestic, supplemental and scheduled cargo air carriers, international air carriers, intra-state carriers, business flying and air travel club flying include fuel requirements for crew training and proficiency flying. The allocation level of 95 percent of base period volume for general aviation would be deleted. Wholesale purchaser-resellers which sell to wholesale purchaser-consumers and end-users engaged in general aviation are subject to the provisions of §§ 211.9–211.13.

Subpart K (Other Products) would be revised to include within its scope solvents, diluents, feedstocks for synthetic natural gas plants, refined lubricating oils and allocated products used in the blending and compounding of lubricating oils, as well as other refined petroleum products not subject to Subparts D through K. Any wholesale purchaser-consumer of crude oil or allocated products for use as a feedstock in synthetic natural gas production which has no base period volume or requirements which exceed base period volume would be required to apply to the FEO for approval of a base period volume or an adjusted base period volume.

Subpart L (General Reporting and Recordkeeping Requirements), requires that monthly prime suppliers' reports under § 211.222(b) be actually, rather than constructively, received by the National FEO, on the 10th day prior to the beginning of the month to which the report applies.

Section 211.223 would be added to Subpart L to set forth the recordkeeping requirements found in existing § 211.11 (d). Proposed § 211.225 sets forth the reporting requirements for new end-user and wholesale purchaser-consumer importers.

Subpart B. Subpart B would be revised to delete and amend a number of definitions. New definitions would also be added. The principal changes would include deletion of the definitions of "reseller", "retail supplier" and "wholesale supplier." Definitions of "wholesale purchaser-reseller", and "wholesale purchaser-consumer" and "agricultural production" would be added as previously noted. The definition of "bulk purchaser" is moved from Subpart B to Subpart F and would specify that the tank in which its product is stored must have a capacity of not less than 50 gallons.

The definition of "motor gasoline" would be revised to clarify that motor gasoline includes certain products when used as blending stock to form motor gasoline. The definitions of "energy production," "importer" and "total supply" would also be modified.

"Firm" would be defined to include "any association, company, corporation, estate, individual, joint-venture, partnership, or sole proprietorship or any other entity", including eleemosynary institutions and Federal, State and local government. This definition also specifies that the FEO may treat as a firm (1) a parent and any consolidated and unconsolidated entities which it controls; (2) a parent and its consolidated entities; (3) an unconsolidated entity; or (4) any part of a firm.

Interested persons are invited to participate in the rulemaking by submitting written data, views or arguments with respect to the proposed regulations set forth in this notice to the Executive Secretariat, Federal Energy Office, Box AF, Washington, D.C. 20461.

Comments should be identified on the outside envelope and on the documents submitted to the Federal Energy Office Executive Secretariat with the designation "Proposed Revision and Clarification of Part 211." Fifteen copies should be submitted. All comments received by April 8, 1974, and all other relevant information will be considered by the Federal Energy Office before final action is taken on the proposed regulations.

(Emergency Petroleum Allocation Act of 1973, Pub. L. 93–159, E.O. 11748; 38 FR 33575; Economic Stabilization Act of 1970, as amended, Pub. L. 92–210, 85 Stat. 743; Pub. L. 93–28, 87 Stat. 27; E.O. 11730, 38 FR 19345; Cost of Living Council Order No. 47, 39 FR 24.)

In consideration of the foregoing, it is proposed to amend Part 211, Chapter 2, Title 10 of the Code of Federal Regulations as set forth below.

Issued in Washington, D.C., March, 27, 1974.

WILLIAM E. SIMON,
Administrator,
Federal Energy Office.

1. Subpart A of Part 211 is revised to read as follows:

Subpart A—General Provisions

Sec.
211.1 Scope.
211.9 Supplier/purchaser relationships.
211.10 Supplier's method of allocation.
211.11 Basis for purchaser's entitlement to allocation.
211.12 Purchaser's allocation entitlement.
211.13 Adjustments to base period volume.
211.14 Redirection of products.
211.15 State offices of petroleum allocation.
211.17 State set-aside.
211.21 Energy conservation.
211.22 Administrative actions.
211.23 Normal business practices.
211.25 Supplier substitution.
211.26 Department of Defense allocations.
211.27 Construction industry.
211.28 Price.

AUTHORITY: Emergency Petroleum Allocation Act of 1973, Pub. L. 93–159; E.O. 11748, 38 FR 33575; Economic Stabilization Act of 1970, as amended, Pub. L. 92–210, 85 Stat. 743; Pub. L. 93–28, 87 Stat. 27; E.O. 11730, 38 FR 19345; Cost of Living Council Order Number 47, 39 FR 24.

Subpart A—General Provisions

§ 211.1 Scope.

(a) *General.* This part applies to the mandatory allocation of crude oil, residual fuel oil and refined petroleum products produced in or imported into the United States.

(b) *Exclusions.* (1) Exports of crude petroleum and petroleum products subject to Subchapter B of Chapter III of Title 15 of the Code of Federal Regulations are excluded from this part.

(2) The first sale of domestic crude petroleum and petroleum condensates, including natural gas liquids, produced from any stripper well lease as defined in § 210.32 of this chapter is excluded from this part.

(3) Petroleum refinery products such as petroleum wax, petroleum coke, asphalt, road oil, and refinery gases which are not crude oil, refined petroleum products, or residual fuel oils are excluded from this part.

(4) Natural gas is also excluded from this part.

(c) *State set-asides.* State set-asides are provided for middle distillates, residual fuel oil, motor gasoline and propane.

§ 211.9 Supplier/purchaser relationships.

(a) *Supplier/wholesale purchaser relationship.* (1) Each supplier of an allocated product shall supply all wholesale purchaser-resellers and all wholesale purchaser-consumers which purchased or obtained that allocated product from that supplier during the base period as specified in Subparts D through K of this part.

(2) Unless otherwise provided in this part or directed by FEO, the supplier/wholesale purchaser relationships defined by specific dates or base periods or otherwise imposed pursuant to this part shall be maintained for the duration of the Mandatory Petroleum Allocation Program and may not be waived or otherwise terminated without the express written approval of FEO.

(b) *Supplier/end-user relationship.* Each supplier of an allocated product shall, to the maximum extent practicable, supply all end-users which purchased that allocated product from that supplier as of January 15, 1974, and which are entitled to an allocation level under the provisions of Subpart D through K of this part.

(c) *Changes in ownership or brand.* The supplier/purchaser relationships required by this part shall not be altered by (1) changes in the ownership of the real property on which a wholesale purchaser or end user maintains its on-going business or end use; or (2) changes in the brand or franchise under which a wholesale purchaser-reseller maintains its on-going business.

(d) *New relationships.* (1) Suppliers shall not supply new wholesale purchasers except in accordance with § 211.12(f).

(2) Suppliers shall not supply new end-users except in accordance with § 211.12(e).

(3) New suppliers shall not supply wholesale purchasers or end users except in accordance with § 211.10(e).

(e) *Dual capacities.* A supplier may also act in the capacity of a wholesale purchaser and an end-user. A wholesale purchaser-consumer may also be a wholesale purchaser-reseller. A firm which is acting in one or more different capacities shall comply with the appropriate regulations governing each capacity in which it acts.

§ 211.10 Supplier's method of allocation.

(a) *General.* (1) Suppliers of allocated products shall allocate all of their allocable supply in accordance with the provisions of this section unless otherwise specified in Subparts D through K of this Part. Each supplier shall determine its allocation fraction pursuant to the provisions of paragraph (b) of this section. Suppliers shall then allocate to wholesale purchasers and end-users in accordance with the provisions of paragraph (c) of this section. End-users without allocation levels shall allocate their allocable supply in accordance with the provisions of paragraph (d) of this section. The method of allocation for new suppliers is specified in paragraph (e) of this section. Suppliers with allocation fractions less than one (1.0) must act in accordance with the provisions of paragraph (f) of this section, while suppliers with allocation fractions in excess of one (1.0) must act in accordance with the provisions of paragraph (g) of this section. Suppliers which sell products with different uses which are subject to allocation under more than one subpart shall determine the applicable subpart by reference to paragraph (h) of this section.

(2) For purposes of defining a supplier in this part, a firm shall mean the parent and the consolidated and unconsolidated entities (if any) which it directly or indirectly controls.

(b) *Allocation fraction.* Each supplier shall determine an allocation fraction prior to making any allocation. A supplier's allocation fraction for any particular month for an allocated product shall be equal to its allocable supply of that product, which is defined in subparagraph (1) of this paragraph, for that month, divided by its supply obligation for all levels of distribution, which is defined in subparagraph (2) of this paragraph. Suppliers shall adjust their allocation fractions for each base period to reflect adjustments in their supply obligation and in their allocable supply. Each supplier shall only have a single allocation fraction for all purchasers except to the extent permitted in § 211.14 or unless permitted or required by order of the FEO.

(1) *Allocable supply.* Each supplier's allocable supply of an allocated product for a particular period shall be equal to its total supply for that period, which is the sum of its estimated production, including amounts received under processing agreements, imports, purchases and any reduction in inventory of that allocated product made pursuant to § 211.22 except as otherwise ordered by FEO; less (i) any amounts designated as a state set-aside for a prime supplier pursuant to § 211.17, (ii) any amounts of allocation requirements supplied directly to end-users or wholesale purchaser-consumers under an allocation level not subject to an allocation fraction, and (iii) any amounts supplied to wholesale purchaser-resellers which have certified these amounts to be for ultimate use under an allocation level not subject to an allocation fraction. Any existing inventory, or production, importation or purchase of an allocated product used to increase that inventory consistent with the provisions of § 211.22 shall not be included in the allocable supply of that product.

(2) *Supply obligation*—(i) *General.* A supplier's supply obligation of a particular allocated product is the sum of (A) the amounts of its wholesale purchaser-resellers' base period volumes, as adjusted pursuant to § 211.13 for unusual growth and other allowable factors, which were supplied by the supplier during the appropriate base period provided that the wholesale purchaser is still in business; (B) the amounts of adjusted base period volumes of new wholesale purchasers and end-users which are assigned to or accepted by the supplier in accordance with the provisions of § 211.12; and (C) the amounts of allocation requirements of end-users and

wholesale purchaser-consumers supplied by the supplier; minus (D) any amounts of allocation requirements supplied directly to end-users or wholesale purchaser-consumers under an allocation level not subject to an allocation fraction and (E) any amounts supplied to wholesale purchaser-resellers which have certified those amounts to be for ultimate use under an allocation level not subject to an allocation fraction. A wholesale purchaser's base period volume, allocation requirements and allocation levels are defined below.

(ii) *Base period volume.* A wholesale purchaser's base period volume of a particular allocated product is the volume of that allocated product purchased or obtained during the appropriate base period as determined in accordance with § 211.12(c). In the case of a new wholesale purchaser, base period volume means the volume assigned pursuant to § 211.12(c). Base period volume, however, does not include any amounts of an allocated product obtained pursuant to in kind exchange agreements involving a single product which are normal business operating procedures. Suppliers do not have a base period volume except when acting in the capacity of a wholesale purchaser. Depending on the applicable allocation level, end-users may have a base period volume or may be treated on the basis of current requirements. Adjustments to base period volumes shall be made in accordance with the provisions of § 211.13.

(iii) *Allocation requirements.* The allocation requirement of an end-user or wholesale purchaser-consumer is the product of that purchaser's current requirements, base period volume or adjusted base period volume, as appropriate, multiplied by the applicable allocation level.

(iv) *Allocation levels.* An allocation level is the percentage of the current requirements, base period volume, or adjusted base period volume, as appropriate, of an end-user or wholesale purchaser-consumer that its supplier shall supply if sufficient volumes of the allocated product are available. Allocation levels are assigned on the basis of the use to be made of the product or the type of purchaser receiving the product.

(c) *Allocation by suppliers to wholesale purchasers and end-users.* There shall be two levels of priority in the allocation by suppliers to wholesale purchasers and end-users:

(1) *First priority.* The first priority shall be for each supplier at every distribution level (i) to allocate from its total supply to wholesale purchaser-resellers any amounts which those purchasers have certified pursuant to § 211.12(d)(2) to be for ultimate use under an allocation level not subject to an allocation fraction and (ii) to allocate from its total supply to end-users and wholesale purchaser-consumers supplied directly under an allocation level not subject to an allocation fraction sufficient volumes of the allocated product to supply one hundred percent of those purchasers' allocation requirements which those purchasers have certified pursuant to § 211.12(d)(1). The amounts allocated under this first priority shall not be subject to the supplier's allocation fraction.

(1) *Second priority.* The second priority for each supplier shall be (i) to allocate to each wholesale purchaser-reseller a volume of allocated product equal to the product of that supplier's allocation fraction multiplied by the amount equal to that wholesale purchaser-reseller's base period volume or adjusted base period volume minus any amounts which that purchaser has certified to be for ultimate use under an allocation level not subject to an allocation fraction and (ii) to allocate from its allocable supply to all end-users and wholesale purchaser-consumers supplied directly under an allocation level subject to an allocation fraction a volume of allocated product equal to the product of that supplier's allocation fraction multiplied by the allocation requirements of those purchasers.

(3) *Allocation level priority.* Allocation levels listed in Subparts D through K of this part are not arranged in sequence of priority except the allocation levels not subject to an allocation fraction which must be supplied as the first order of priority. Suppliers shall distribute their allocable supply to all classifications of purchasers listed within each particular percentage allocation level and among percentage allocation levels other than levels not subject to an allocation fraction without regard to the order of listing.

(d) *Purchasers without allocation levels.* Notwithstanding the provisions of paragraphs (c) and (g) of this section, suppliers such as retail gasoline dealers, which supply both end-users or wholesale purchaser-consumers which are not entitled to an allocation level and end-users or wholesale purchaser-consumers which are entitled to an allocation level shall allocate their allocable supply in the following manner:

(1) The first priority for each supplier shall be to allocate to all end-users and wholesale purchasers which are entitled to an allocation in accordance with the provisions of paragraph (c) of this section.

(2) The second priority for each supplier shall be to distribute equitably the remainder of the supplier's allocable supply among all end-users or wholesale purchaser-consumers which are not entitled to an allocation level. A state or local government may require or authorize priorities to or among such end-users or wholesale purchaser-consumers purchasing the allocated product for the uses listed in the allocation levels for that product in the subpart of this part applicable to the particular allocated product. Except to the extent that a state or local government requires otherwise, the supplier may also give priority to or among such end-users or wholesale purchaser-consumers purchasing the allocated product for the uses listed in the allocation levels for that product in the subpart of this part applicable to the particular allocated product. Priority treatment, per se, when granted in accordance with the provisions of this subparagraph, shall not be considered a form of discrimination among purchasers or any other prohibited conduct under § 210.62 of this chapter.

(e) *New supplier.* (1) A supplier which was not a base period supplier but was a supplier prior to January 15, 1974 shall supply, in accordance with the provisions of this section, (i) wholesale purchasers which it supplied as of January 15, 1974 and which have no base period supplier; (ii) any assigned purchasers; (iii) new wholesale purchasers acquired after January 15, 1974 in accordance with the provisions of § 211.12; and (iv) to the maximum extent possible, end-users.

(2) A supplier which was not a supplier prior to January 15, 1974 shall be considered to have no supply obligation and shall not allocate supplies to any purchaser without FEO approval.

(f) *Allocation fractions less than one.* When a supplier's allocation fraction is less than one (1.0), a supplier shall reduce, on a pro-rata basis, the amounts supplied to end-users and wholesale purchasers for uses subject to the allocation fraction. End-users and wholesale purchaser-consumers supplied under an allocation level not subject to an allocation fraction, shall, however, be supplied at a constant one hundred percent of allocation requirements. Wholesale purchaser-resellers which certify amounts of an allocated product to be for ultimate use under an allocation level not subject to an allocation fraction shall also be supplied at one hundred percent of these certified amounts. These purchasers shall not receive a pro-rata reduction unless the supplier's total supply is not sufficient to supply all such end-users and wholesale purchasers at one hundred percent of allocation requirements or certified amounts, as appropriate.

(g) *Allocation fractions greater than one.* (1) In allocating allocable supplies of any allocated product among wholesale purchasers, no supplier may use an allocation fraction greater than one (1.0) except as provided herein. If a supplier's allocable supply is of sufficient magnitude that the allocation fraction exceeds one (1.0), the supplier shall make allocations based on an allocation fraction of one (1.0), and shall separately report by certified mail to the National FEO and the appropriate Regional FEO the volume of surplus product available. The National FEO may direct that the product be distributed among other suppliers, sold to designated wholesale purchasers or end-users, or be accumulated in inventory. If the reporting supplier is not notified to the contrary by the National FEO within fifteen (15) days after filing with the National FEO, it shall distribute these volumes by applying the allocation fraction greater than one (1.0) until all the current requirements of all that supplier's purchasers have been supplied. If further supplies still remain after all the current requirements of that supplier's purchasers have been supplied, the supplier shall again separately report by

certified mail to the National FEO and the appropriate regional FEO the volume of surplus product available. No further distribution shall be made except at the direction of FEO.

(2) No supplier shall supply and no end-user or wholesale purchaser-consumer shall accept quantities of an allocated product which exceed one hundred (100) percent of that end-user or wholesale purchaser-consumer's current requirements, unless directed by FEO.

(h) *Products with different uses.* When an allocated product may be subject to allocation under more than one subpart of this part, a wholesale purchaser must certify to its supplier the use of the product during the base period for that use of the product. The supplier shall then supply that wholesale purchaser in accordance with the provisions of the subpart which applies to the certified use of that product unless the supplier and wholesale purchaser mutually agree that the product shall be supplied for a use other than the use during the base period. Suppliers shall supply end-users in accordance with the provisions of the subpart that applies to the end-users' present use of the product.

§ 211.11 Basis for purchaser's entitlement to allocation.

(a) *Basis of entitlement.* A wholesale purchaser or an end-user entitled to an allocation level shall receive an allocation based on its conduct of an on-going business or maintenance of an established end use.

(b) *End-users and wholesale purchasers as a firm.* (1) For purposes of defining an end-user or wholesale purchaser-consumer in this Part, a firm shall mean those parts of the parent and the consolidated and unconsolidated entities (if any) which it directly or indirectly controls which act as ultimate consumers including all sites, storage tanks and other facilities or entities of the end-user or wholesale purchaser-consumer that utilize or store an allocated product.

(2) Except as provided in subparagraph (3) of this paragraph, for purposes of defining a wholesale purchaser-reseller in this part, a firm shall mean all parts of the parent and the consolidated and unconsolidated entities (if any) which it directly or indirectly controls.

(3) (i) Each firm or part of a firm which operates an ongoing business at a retail sales outlet shall be considered a separate firm with respect to each such outlet for purposes of this subpart and, therefore, shall be a separate wholesale purchaser-reseller. The entity which merely holds a real property interest in a retail sales outlet on which another entity operates the on-going business shall not be considered the wholesale purchaser-reseller with respect to that outlet.

(ii) A supplier's obligation to provide an allocated product shall be determined separately for each wholesale purchaser-reseller, without distinguishing between wholesale purchaser-resellers operated by the supplier and wholesale purchaser-resellers not operated by the supplier. A supplier may not reassign all or part of an allocation entitlement from one wholesale purchaser-reseller to another, including reassignment among its own retail sales outlets, without the express written permission of FEO.

(c) *Loss of allocation entitlement for going out of business.* Wholesale purchasers and end-users which have gone out of business shall not be eligible for allocations based on volumes received or purchases made prior to going out of business. A wholesale purchaser-reseller which operates a retail sales outlet shall be deemed to have gone out of business if it vacates the site on which it conducts such business and does not, within a reasonable period of time, reestablish another retail sales outlet at another location serving substantially the same customers or market that was served by the former site.

(d) *Suppliers of retail sales outlets.* (1) The supplier of a retail sales outlet shall be that part of a firm which actually furnishes or physically delivers the allocated product to the retail sales outlet. The operator of one or more retail sales outlets shall not be considered the supplier of its own retail sales outlets unless it operates a terminal facility from which it furnishes product to each outlet or unless it otherwise physically delivers the allocated product to each outlet.

(2) Whenever an operator of a retail sales outlet goes out of business with respect to that retail sales outlet under paragraph (c) of this section, the supplier of that outlet (as wholesale purchaser-reseller) shall not be entitled to an allocation from its supplier for the part of the adjusted base period volume attributable to that retail sales outlet. The supplier of such retail sales outlet shall, in calculating its allocation fraction, remove the amount of such adjusted base period volume from its supply obligation, unless the right to such allocation has transferred to a successor wholesale purchaser-reseller under paragraph (e) (3) of this section.

(3) Any supplier which supplies its own operated retail sales outlets shall report to the National and appropriate regional FEO whenever, in any given month, the number of retail sales outlets it supplies currently (including independents) in any state is 10 percent below the number of retail outlets it supplied during the corresponding month of the base period in that state.

(e) *Transfer of entitlement*—(1) *General.* The right to receive an allocation shall not be assignable separately but shall be considered an integral part of the on-going business or established end use.

(2) *End-users and wholesale purchasers-consumers.* The right to an allocation for an end use shall be deemed to have been transferred only when the entire business or activity of the firm is transferred to a successor firm.

(3) *Wholesale purchaser-resellers.* Whenever a wholesale purchaser-reseller is deemed to have gone out of business in accordance with paragraph (c) of this section, the right to an allocation with respect to the retail sales outlet shall be deemed to have been transferred to its successor on the site, provided such successor establishes the same on-going business on the site within a reasonable period of time after its predecessor vacates the premises. Whenever a wholesale purchaser-reseller vacates a site on which it operated an on-going business, and within a reasonable period of time, re-establishes another retail sales outlet at another location serving substantially the same customers or market that was served by the former site, the right to the allocation with respect to the first site shall continue with that wholesale purchaser-reseller with respect to the second site.

§ 211.12 Purchaser's allocation entitlement.

(a) *Scope.* This section describes a purchaser's allocation entitlements. Paragraph (b) of this section specifies the volumes of an allocated product which wholesale purchasers and end-users are entitled to receive from suppliers. The method by which purchasers determine base period volumes is provided in paragraph (c) of this section and the method by which purchasers determine the amounts not subject to an allocation fraction is provided in paragraph (d) of this section. Paragraphs (e), (f) and (g) of this section set forth procedures by which new wholesale purchasers, new end-users and new importer-consumers, respectively, determine their entitlements and suppliers. Paragraph (h) of this section provides special relief for purchasers which are denied access to a fuel source by Federal or State order.

(b) *Entitlements*—(1) *Wholesale purchaser-reseller.* A wholesale purchaser-reseller shall be entitled to receive a volume of an allocated product equal to the sum of the volumes allocable to it from each of its suppliers. The volume supplied to a wholesale purchaser-reseller by each of its suppliers shall equal the sum of (i) any amounts which that purchaser has certified to a supplier to be for ultimate use and an allocation level not subject to an allocation fraction plus (ii) the product of that supplier's allocation fraction multiplied by an amount equal to that part of that wholesale purchaser's base period volume (or adjusted base period volume) purchased or obtained from that supplier minus any amounts which that purchaser has certified to be for ultimate use under an allocation level not subject to an allocation fraction.

(2) *Wholesale purchaser-consumers and end-users.* A wholesale purchaser-consumer or end-user shall be entitled to receive a volume of an allocated product equal to the sum of the volumes allocable to it from each of its suppliers. The volume supplied to a wholesale purchaser-consumer or end-user by each of its suppliers shall equal the sum of (i) that part of the wholesale-purchaser's or end-user's allocation requirements supplied directly by that supplier under an allo-

cation level not subject to an allocation fraction plus (ii) that part of the wholesale purchaser's or end-user's allocation requirements supplied by that supplier under an allocation level subject to an allocation fraction.

(c) *Base period volume determination.* (1) By February 1, 1974, each supplier which sells an allocated product to a wholesale purchaser or end-user entitled to an allocation level which is a percentage of a base period use shall report to each of those purchasers with respect to each allocated product, the volume of product which it sold to or transferred to that purchaser in each month of the base period year.

(2) If, after receipt of a supplier's report, a purchaser questions the accuracy of a supplier's report, it shall notify that supplier and attempt to resolve the disagreement as to base period purchases of the purchaser.

(3) If the supplier and purchaser are unable to resolve their differences, the supplier shall commence allocations based on the supplier's records, in accordance with the allocation provisions in this part, and the purchaser should make application to the appropriate FEO regional office for a corrected base period volume in accordance with FEO forms and instructions. Copies of the purchaser's records for base period purchases should be included with the application.

(4) If the FEO determines that the purchaser's application for a corrected base period volume is valid, it may order the supplier to adjust the purchaser's base period volume and to supply the purchaser with additional volumes of the allocated product equal to the adjusted amount the purchaser should have received if allocation had initially been based on the corrected base period volume.

(5) To the extent that retail sales outlets have not been considered separate firms and therefore separate wholesale purchaser-resellers as provided in § 211.-11(b)(3) in the base period volume determination required under subparagraph (1) of this paragraph, suppliers shall correct by May 1, 1974 any report made under this paragraph which did not treat such retail sales outlets separately. The corrected reports shall be delivered to such separate wholesale purchaser-reseller by May 1, 1974, and shall provide the information for each separate wholesale purchaser-reseller required under this paragraph.

(d) *Determination of amounts not subject to an allocation fraction.* (1) Any end-user or wholesale purchaser-consumer entitled to an allocation level of 100 percent of current requirements which is not subject to an allocation fraction shall certify those allocation requirements on an annual basis to its supplier (consistent with any energy conservation program such as the temperature reduction restrictions found in that end-user's allocation level). Any increase above the initial level of allocation requirements certified shall also be certified to the supplier. In the event that the end-user or wholesale purchaser-consumer and supplier cannot agree on the volume which the purchaser is entitled to receive, an application for validation may be referred by the end-user or wholesale purchaser-consumer to the office specified in § 205.13 of this chapter. During the period that a request for validation is pending, the supplier shall supply such requirements of the purchaser to the extent permitted by § 211.10(g)(2). The FEO may subsequently require the supplier to adjust such end-user's or wholesale purchaser-consumer's allocation requirements and to compensate for any excess product supplied during the period the validation is pending.

(2) All suppliers (as wholesale purchaser-resellers) which receive a certification of allocation requirements not subject to an allocation fraction pursuant to subparagraph (1) of this paragraph or which receive a certification from any other supplier of allocation requirements which have been certified to that other supplier, shall in turn certify to their suppliers these allocation requirements not subject to an allocation fraction.

(3) Prior to receipt of a certification of allocation requirements from an end-user or wholesale purchaser-consumer entitled to an allocation level of 100 percent of current requirements not subject to an allocation fraction, purchasers for uses other than agricultural production shall continue to be supplied as purchasers entitled to an allocation level of 100 percent of current requirements subject to an allocation fraction. Prior to receipt of a certification of allocation requirements, a purchaser for use in agricultural production shall be supplied at 100 percent of its current requirements not reduced by its supplier's allocation fraction. A supplier of such a purchaser for use in agricultural production may not, however, recertify these allocation requirements pursuant to subparagraph (2) of this paragraph prior to receipt of a certification of allocation requirements.

(4) End-users and wholesale purchaser-consumers which claim entitlement to allocation requirements under this paragraph must be prepared to establish their historic requirements and justify their allocation requirements. All such end-users and wholesale purchaser-consumers must also be in full compliance with § 211.10(g)(2).

(e) *New wholesale purchasers.* Wholesale purchasers which do not have base period suppliers and wholesale purchasers whose base period suppliers are unable to supply them with sufficient amounts of an allocated product shall be supplied as provided in this paragraph.

(1) *Mutual arrangements for wholesale purchaser-consumers.* Wholesale purchaser-consumers without a base period supplier or a new supplier as provided in § 211.10(e)(1) are encouraged to make mutually acceptable arrangements with suppliers. Suppliers are encouraged to continue any existing supplier/purchaser relationships with such wholesale purchaser-consumers and to accept wholesale purchaser-consumers as new purchasers.

(i) Wholesale purchaser-consumers without a base period supplier or a new supplier as provided in § 211.10(e)(1) and existing or prospective suppliers may agree upon a proposed base period volume for the wholesale purchaser-consumer.

(ii) The supplier shall within 10 days of making the mutual arrangement notify FEO by certified mail in accordance with FEO forms and instructions of the proposed base period volume and the basis upon which the proposed base period volume was determined. The proposed base period volume is subject to adjustment by FEO. FEO may also assign the wholesale purchaser-consumer to another supplier.

(iii) After FEO has been notified by the supplier and during the period that FEO has the proposed supplier/purchaser releationship (including the proposed base period volume) under consideration, the supplier may provide the wholesale purchaser-consumer with interim supplies in accordance with the proposed base period volume.

(2) *New wholesale purchaser-resellers.* (i) Suppliers which have accepted new wholesale purchaser-resellers prior to May 1, 1974 shall notify the FEO of the names of all such new purchasers, the proposed base period volume for each purchaser and the basis upon which the proposed base period volume was determined. The proposed base period volume is subject to adjustment by FEO. FEO may also assign the wholesale purchaser-reseller to another supplier.

(ii) Wholesale purchaser-resellers without a base period supplier or a new supplier as provided in § 211.10(e)(1) must apply to FEO for assignment to a supplier and for assignment of a base period volume.

(iii) Firms which intend to operate new retail sales outlets should advise FEO as soon as practicable (preferably before construction begins) of their intention and the anticipated base period volume requirements for such new retail sales outlets.

(iv) After FEO has been notified by the supplier pursuant to subparagraph (2) (ii) and (iii) of this paragraph, the supplier may not provide the wholesale purchaser-reseller with interim supplies.

(3) *Assignments.* Any wholesale purchaser which does not have a base period supplier or a new supplier as provided in § 211.10(e)(1) (including all wholesale purchaser-consumers which cannot locate a supplier under subparagraph (1)) or whose base period supplier(s) or new supplier as provided in § 211.10(e)(1) is unable to supply it with sufficient amounts of an allocated product may petition FEO as provided in § 205.13 of this chapter to be assigned a supplier and a base period volume on an interim or permanent basis.

(i) To the extent practicable, the FEO shall continue any existing supplier/purchaser relationships in making such assignments.

(ii) The wholesale purchaser shall certify to the FEO documented evidence justifying its proposed base period volume as normal and reasonable for the intended use.

(iii) FEO may assign the wholesale purchaser to one or more suppliers and will assign a base period volume to the wholesale purchaser when the assignment to a supplier(s) is made.

(4) Any assigned base period volume under the provisions of this paragraph will be deemed to have been adjusted for growth under § 211.13 through the date of the assignment and may be adjusted thereafter under the provisions of § 211.13. Base period volumes will not be assigned on any basis which gives a wholesale purchaser an unfair advantage over wholesale purchasers which have base period suppliers or new suppliers as provided in § 211.10(e).

(5) Any purchaser which is assigned to or accepted by a supplier under the provisions of this paragraph shall be accepted by the supplier for the duration of the program or until otherwise directed by the FEO.

(f) *New end-users.* (1) Suppliers to the maximum extent possible shall accept new end-users where such purchaser, under normal business practices, could logically have been served by the supplier in accordance with its base period business practices. Suppliers shall allocate to new end-users in a manner consistent with the allocation methods set forth in this chapter.

(2) If the supplier and new end-user cannot agree on an allocation requirement for the end-user or if the end-user cannot locate a supplier, the end-user may apply to the appropriate State office in accordance with the procedure specified in Subpart I of Part 205 of this chapter. In this event, the new end-user shall certify to the State office documented evidence justifying the proposed allocation requirement as normal and reasonable for the intended use.

(g) *New end-user and wholesale purchaser-consumer importers.* End-users and wholesale purchaser-consumers which have not previously imported an allocated product may import that product for their own use subject to § 211.10 (g)(2). Such imports will not otherwise affect their allocation entitlement except to the extent that FEO determines that such imports, without a reduction in domestic allocation entitlements, are inconsistent with the objectives of the Act. Should the circumstances warrant, FEO may require that such imports be allocated to other end-users or suppliers. New end-user and wholesale purchaser-consumer importers are required to report to both national and regional FEO's as provided in § 211.225.

(h) *Curtailment of certain energy sources by Federal or State rule or order.* Any end-user or wholesale purchaser-consumer which has been denied access to a source of energy other than an allocated product as a consequence of curtailment by, or pursuant to, a plan filed in compliance with a rule or order of a Federal or State agency, or where the end-user's or wholesale purchaser-consumer's supply of such fuel is unobtainable by reason of an abandonment of service permitted or ordered by a Federal or State agency may apply to a supplier, or the FEO, under the provisions of this section as a new purchaser for an allocated product. If such applications are approved, a base period volume shall be assigned on an equivalent BTU basis for the energy source denied and the amount of assigned allocated product shall be corrected for differences in use efficiency.

§ 211.13 Adjustments to base period volume.

(a) *Scope.* (1) The adjustment procedures under this section are applicable to the allocation of propane, butane, motor gasoline, middle distillates, aviation fuels and residual fuel oil (except allocations to utilities) and other products subject to Subpart K of this part. This section describes the means by which wholesale purchasers and end-users may receive adjustments to their base period volumes.

(2) Paragraph (b) of this section provides for supplier initiated and wholesale purchaser initiated adjustments of a wholesale-purchaser's base period volumes for each month of the appropriate base period year for unusual growth based upon actual sales volumes in 1972 and 1973. Paragraph (c) of this section provides for an adjustment of wholesale purchasers' and certain end-users' base period volumes to account for changed circumstances. Paragraph (d) of this section provides an adjustment to base period volumes when increased requirements are certified by end-users and wholesale purchaser-consumers entitled to receive an allocation level of 100 percent of current requirements subject to an allocation fraction.

(3) Paragraph (e) of this section requires non-discrimination between wholesale purchasers in granting adjustments. Paragraph (f) of this section requires purchasers to certify applications for adjustments while paragraph (g) of this section provides a complaint procedure for purchasers where application for adjustment is not approved by a supplier.

(b) *Adjustments for unusual growth—*(1) *Supplier initiated wholesale purchaser unusual growth adjustment.* Wholesale purchasers which purchased an allocated product (other than residual fuel oil which is assigned 1973 base periods) shall receive a supplier initiated adjustment to their base period volumes by their suppliers to compensate for unusual growth between the 1972 base periods and the corresponding months in 1973.

(i) For purposes of this paragraph, that part of any growth which exceeds 10 percent for the periods compared for motor gasoline or 5 percent for the periods compared for any other allocated product is defined as "unusual growth." Wholesale purchasers will be granted an adjustment only for the part of growth which was in excess of 10 percent for motor gasoline and 5 percent for other allocated products.

(ii) A supplier shall adjust the base period volume for unusual growth in each month of the base period year for each wholesale purchaser which purchased the allocated product from the supplier in 1972. There is no requirement that a wholesale purchaser apply to the supplier for this adjustment. A supplier shall make the adjustment without a request by the wholesale purchaser to the extent that the supplier's records indicate that any wholesale purchaser is eligible for the adjustment.

(iii) The adjustment made pursuant to this paragraph shall be based upon a comparison of the volume of the allocated product purchased from the supplier in 1972 and the volume purchased in 1973. If the supplier did not supply the wholesale purchaser for all of 1972 the adjustment shall be made by a comparison of the volume for the period in 1972 that the supplier did supply the wholesale purchaser and the volume purchased by the wholesale purchaser during the corresponding period of 1973. A wholesale purchaser's 1973 volume in excess of its 1972 volume shall be expressed as a percentage of the 1972 volume to determine growth rate. Unusual growth shall then be determined by subtracting from the growth rate the appropriate percentage figure set forth in subdivision (i) of this subparagraph. The resulting percentage shall be multiplied by the wholesale purchaser's base period volume for each base period in which the supplier is obligated to supply the wholesale purchaser to provide the amount by which each base period volume shall be increased for unusual growth.

Example. Firm A, a wholesale purchaser purchased 100,000 gallons of motor gasoline from Firm B in 1972 and 150,000 gallons in 1973. Firm A's 1973 growth rate is 50 percent (1973 volume minus 1972 volume divided by 1972 volume). Firm A's unusual growth is 40% (that growth in excess of first 10 percent). Firm B therefore will increase by 40 percent each of Firm A's base period volumes (the volumes sold in each month of 1972) to be supplied by Firm B.

(iv) Unusual growth adjustments under this paragraph shall be certified by the supplier in accordance with FEO forms and instructions and filed with FEO.

(v) The adjustments under this paragraph shall be made by, and the certified form required by subdivision (iv) of this subparagraph shall be filed with FEO on or before May 1, 1974. There is no requirement that FEO validate any adjustment made under this paragraph. Suppliers shall allocate products on the basis of adjustments to base period volumes which reflect unusual growth no later than May 1, 1974. A supplier may commence deliveries of an allocated product reflecting adjustments to base period volumes for unusual growth prior to May 1, 1974, provided that adjustments for all of its eligible wholesale purchasers of that allocated product have been made and such deliveries are commenced at the same time for all such wholesale purchasers.

(vi) Suppliers shall notify all wholesale purchasers for each base period of

the base period year of any adjustment for unusual growth made under this subparagraph. The notice shall be given on or before May 1, 1974.

(vii) Each supplier shall notify all of its wholesale purchasers which do not receive an adjustment under this subparagraph. The notice shall be given on or before the date the required certified form is filed with FEO. The notice shall advise each such wholesale purchaser that it may apply to the supplier for an adjustment to base period volume(s) for unusual growth under subparagraph (3) of this paragraph.

(viii) Although wholesale purchasers of propane have a base period that includes part of 1973, for the purpose of this paragraph, suppliers shall determine such wholesale purchasers' unusual growth by comparing the volume of propane purchased from the supplier in 1972 and the volume purchased in 1973. If the supplier did not supply the wholesale purchaser for all of 1972, the adjustment shall be made by a comparison of the volume for the period in 1972 that the supplier did supply the wholesale purchaser and the volume purchased by the wholesale purchaser during the corresponding period of 1973.

(ix) No wholesale purchaser which has received an adjustment for unusual growth in 1973 shall receive an additional adjustment under this paragraph except to the extent that such initial adjustment did not fully compensate the wholesale purchaser for unusual growth as allowed by this subparagraph. A supplier shall not decrease the base period volume (or adjusted base period volume) of a wholesale purchaser under this subparagraph if that purchaser's 1973 volume is less than that purchaser's 1972 volume.

(x) No wholesale purchaser shall accept an adjusted base period volume initiated by a supplier under this paragraph which, when combined with the adjusted base period volumes supplied to the wholesale purchaser by its other base period suppliers, would exceed the wholesale purchaser's actual unusual growth for a base period.

(2) *Additional unusual growth adjustment for wholesale purchaser-resellers.* This subparagraph provides an additional adjustment for wholesale purchaser-resellers following an adjustment of their base period volume under subparagraph (1) of this paragraph. If the base period volume of a wholesale purchaser-reseller as adjusted for unusual growth pursuant to subparagraph (1) of this paragraph minus the 1973 allocation requirements of its purchasers for use under an allocation level which is not now subject to an allocation fraction is less than the wholesale purchaser-resellers adjusted base period volume minus such allocation requirements as calculated under this paragraph, the wholesale purchaser-reseller may apply to its supplier for an adjustment to be calculated as follows:

(i) The wholesale purchaser-reseller will determine its 1972 volume less those volumes delivered to purchasers for use under an allocation level which is not now subject to an allocation fraction. A wholesale purchaser-reseller may calculate such volume by subtracting from its 1972 volume either:

(A) those actual volumes delivered in 1972 to purchasers for use under an allocation level which is not now subject to an allocation fraction and certificated as accurate by the wholesale purchaser-reseller, or

(B) that volume which as a percentage of its 1972 volume corresponds to the percentage of the total volume delivered in 1973 to purchasers for use under an allocation level which is not now subject to an allocation fraction.

(ii) The wholesale purchaser-reseller will determine its 1973 volume less those volumes delivered in 1973 to purchasers for use under an allocation level which is not now subject to an allocation fraction.

(iii) The wholesale purchaser-reseller may then calculate its unusual growth adjustment using its 1972 and 1973 volumes less the volume in both years delivered to purchasers for use under an allocation level which is not now subject to an allocation fraction as otherwise provided in subparagraph (1) of this paragraph.

(iv) If the aggregate adjusted base period volumes calculated under this subparagraph are greater than the aggregate adjusted base period volumes calculated under subparagraph (1) of this paragraph minus the 1973 allocation requirements of the wholesale purchaser-reseller's purchasers which are not subject to an allocation fraction, then the wholesale purchaser-reseller's aggregate adjusted base period volumes may be further adjusted to reflect the difference between those two amounts.

Example. Firm A, a wholesale purchaser, purchased 100,000 gallons of motor gasoline from Firm B in 1972 and 150,000 gallons in 1973. Firm B under subparagraph (b)(1) notified Firm A that the base period volumes supplied by Firm B to Firm A would be increased by 40 percent. See example following b(1)(iii). Since the aggregate of Firm A's base period volumes is 100,000 gallons, the aggregate of Firm A's base period volumes as adjusted under subparagraph (b)(1) will be 140,000 gallons (100,000 plus 40 percent of 100,000).

The 1973 requirements of Firm A's purchasers for use under an allocation level not now subject to an allocation fraction was 90,000 gallons. Firm A does not know the actual sales to such purchasers for such uses in 1972. To determine whether Firm A is entitled to an adjustment under § 211.13(b)(2), Firm A makes the following calculations:

(1) Under § 211.13(b)(2)(i)(B) Firm A assumes that 60 percent of its 1972 sales were to purchasers for use under an allocation level not now subject to an allocation fraction because 60 percent of its 1973 sales were in this category (90,000 divided by 150,000). Firm A then determines that it sold 40,000 gallons to purchasers for use under an allocation level now subject to the allocation fraction in 1972 by multiplying 60 percent times 100,000 and subtracting that product (60,000) from 100,000.

(2) Firm A's 1973 volume less those volumes delivered to purchasers for use under an allocation level not now subject to an allocation fraction is 60,000 (150,000—90,000).

(3) Firm A next calculates its unusual growth adjustment using its 1972 and 1973 volumes less the volume in both years delivered to purchasers for use under an allocation level not now subject to an allocation fraction. Firm A's 1973 growth rate using this method of calculation is 50 percent (60,000–40,000 divided by 40,000). Firm A's usual growth rate is 40 percent (that growth in excess of 10 percent). If Firm A increases its 1972 volume less the volume delivered to purchasers for use under an allocation level but not now subject to an allocation fraction, by 40 percent, the volume will be 56,000 (40,000 plus 40 percent of 40,000).

(4) Firm A then calculates its aggregate base period volumes adjusted for unusual growth pursuant to § 211.13(b)(1) which is 140,000 gallons. That volume minus the 1973 volume sold to purchasers for use under an allocation level not subject to an allocation fraction equals 50,000 gallons (140,000—90,000).

(5) Since the aggregate adjusted base period volumes calculated under paragraph (3) are greater than the aggregate adjusted base price volumes as calculated under paragraph (4), Firm A may apply to Firm B for an additional adjustment to its aggregate base period volumes of 6,000 gallons (56,000 minus 50,000). Firm A's newly aggregated adjusted base period volumes will then equal 146,000 gallons (140,000+6,000). If Firm B supplied Firm A in each month of 1972, Firm B will increase each base period as adjusted under b(1) by 500 gallons (6,000 divided by 12).

(3) *Wholesale purchaser initiated unusual growth application.* (i) Any wholesale purchaser which does not receive an adjustment under subparagraph (1) of this paragraph or which disputes the adjustment made thereunder by one of its suppliers may apply to that supplier for an adjustment of its base period volume to compensate for unusual growth in 1973 in accordance with FEO forms and instructions.

(ii) Any adjustment made under this subparagraph shall be based solely on actual volumes supplied or purchased in 1972 and 1973 as indicated by the records of the supplier and the wholesale purchaser. Unusual growth has the same meaning under this subparagraph as under subparagraph (1) of this paragraph. Adjustments to base period volumes for unusual growth under this subparagraph shall be calculated in the same manner as such adjustments under subparagraph (1) of this paragraph.

(iii) Base period suppliers of wholesale purchasers shall include in an adjustment for unusual growth their proportionate share of that part of a wholesale purchaser's 1973 volume which was not supplied to that wholesale purchaser by a base period supplier of the wholesale purchaser. Wholesale purchasers shall certify to their base period suppliers the 1973 volumes purchased by the wholesale purchaser from suppliers which were not base period suppliers of the wholesale purchaser. A base period supplier's share of such 1973 volumes shall be equal to that supplier's proportionate share of the 1972 volumes supplied to the wholesale purchaser by all suppliers which sup-

plied that purchaser during the base period.

(iv) Upon receipt of an application for unusual growth under this subparagraph, the supplier shall adjust the wholesale purchaser's base period volume within ten (10) days. If the supplier disagrees with the application, it may request validation from the appropriate regional FEO: *Provided, however,* That the supplier shall immediately make an interim adjustment to the applicant's base period volume for any base period which commences later than twenty (20) days after receipt of the application in the proposed adjusted amount during the pendency of any FEO validation proceeding. If the FEO validation proceeding results in an adjusted amount less than that supplied during the pendency of such proceeding, FEO may require the supplier to adjust the wholesale purchaser's future allocations to compensate for any excess product supplied during the interim period.

(v) No wholesale purchaser which has received an adjustment for unusual growth in 1973 shall receive an additional adjustment under this subparagraph except to the extent that such initial adjustment did not fully compensate the wholesale purchaser for unusual growth as allowed by this subparagraph.

(c) *Adjustments for changed circumstances*—(1) *Wholesale purchasers.* Wholesale purchasers may apply to the FEO pursuant to § 205.22 of this chapter for adjustments to their base period volumes (or adjusted base period volume) for changed circumstances since January 1, 1973, which have not been reflected in an adjustment under paragraph (b) of this section. In processing such applications, the FEO may consider situations that indicate a need for increased amounts over base period volumes including but not limited to plant expansions, changed traffic patterns, closed retail sales outlets which have increased demand upon remaining retail sales outlets, changes in the local economy, unusual seasonal fluctuations, new population, industrial growth, acceptance of new end-users or unusual growth problems such as could occur at truck stops on new highways. A wholesale purchaser-reseller which operated in a marketing area that experienced unusual growth or other changed circumstances during 1973 but which was unable to increase its sales to meet the increased demand because its supplier imposed an allocation fraction under the voluntary petroleum allocation program may apply for an adjustment under this paragraph.

(2) *End-users.* End-users whose allocation level is a percentage of base period volumes may apply to the appropriate State office to receive an adjustment to their base period volume for changed circumstances after January 1, 1974. The state office shall process the petition for adjustment and make recommendations to the FEO in accordance with the procedure specified in Subpart I of Part 205 of this chapter.

(3) *FEO action.* FEO shall only make adjustments for changed circumstances when there are compelling situations requiring relief. Such adjustments shall be based upon applications which are fully supported by detailed facts, figures and other relevant documentation.

(d) *Adjustments for increased current requirements.* (1) Any end-user or wholesale purchaser-consumer entitled to an allocation level of 100 percent of current requirements which is subject to an allocation fraction shall certify to its supplier any increased requirements (consistent with any energy conservation program such as the temperature reduction restrictions found in that end-user's allocation level) above the level of requirements on January 1, 1974. In the event that the end-user or wholesale purchaser-consumer and supplier cannot agree on a volume to be supplied, an application for validation may be referred by the end-user or wholesale purchaser-consumer to the office specified in § 205.13 of this chapter. During the period that a request for validation is pending, the supplier shall supply such increased requirement. The FEO may subsequently require the supplier to adjust such end-user's or wholesale purchaser-consumer's allocation requirements to compensate for any excess product supplied during the validation period.

(2) All suppliers (as wholesale purchaser-resellers) which receive a certification of increased requirements pursuant to subparagraph (1) of this paragraph or which receive a certification from any other supplier of increased requirements which have been certified to that other supplier, shall in turn certify to their suppliers these increased requirements and be assigned a proportionate adjustment to that part of their base period volume received from each supplier to cover the certified increases in volume granted under this paragraph.

(3) End-users and wholesale purchaser-consumers which claim increases under this paragraph must be prepared to establish their historic requirements and justify their increased requirements.

(e) *Non-discrimination among wholesale purchasers.* In granting adjustments to base period volumes under this section, the supplier shall not discriminate among branded independent marketers, non-branded independent marketers and wholesale purchaser-resellers operated by by the supplier.

(f) *Certifications and downward adjustments of base period volume.* The chief executive officer (or his authorized agent) of a purchaser applying to a supplier for an adjustment under this section shall certify such application for accuracy. Such applications shall contain a statement that increased allocations shall be used only for the purpose stated in the application, shall not be diverted for other uses; and that if the needs decline, the purchaser shall file an amended application for a downward adjustment to his base period volume.

(g) *Complaints.* Any wholesale purchaser may file a written complaint with the FEO if it appears that a valid application for an adjustment in base period volume has not been approved by a supplier within ten (10) days after the application has been received by the supplier, or if it appears that there is discrimination among branded independent marketers, non-branded independent marketers, or wholesale purchaser-resellers operated by the supplier.

§ 211.14 Redirection of products.

(a) To meet imbalances that may occur in the supplies of any allocated product, the regional or National FEO may order the transfer of specified amounts of any such product from one area to another or may order that different allocation fractions be used in different areas. An area, as used in this section, means a state, a group of states within a region, or any subdivision of a state or states within a region. The National FEO may also order the transfer of specified amounts of any allocated product from one region to another region or may order that different allocation fractions be used in different regions to meet such imbalances. Further, the FEO may transfer supplies of allocated products among suppliers in order to remedy supply imbalances.

(b) Refiners and importers are authorized to reduce the monthly allocable supply to purchasers of those allocated products covered under Subparts D, E, F, G, H (except Civil Air Carriers) and I (except utilities) for any region or area by up to five (5) percent and to increase the total quantity of any of these allocated products available in another region or area experiencing shortages significantly greater than are being experienced elsewhere in the nation to meet regional imbalances due to weather variation, seasonal demand, or other circumstances beyond their control. Such action may be accomplished without prior approval from the Administrator, FEO, but must be reported to the National FEO and the appropriate Regional FEO within immediately after the adjustment occurs. Redistribution involving reduction of product volumes greater than five (5) percent from any State shall require approval from the Administrator, FEO, prior to any action by any refiner or importer. The adjustment provided for in this section shall not be cumulative. Allocation fractions for a region or area which are reduced by such a reduction of an allocated product shall be returned to prereduction levels as soon as practicable.

(c) Shifts made pursuant to paragraph (b) of this section shall be employed solely to effect a better regional distribution of allocated products and shall not discriminate against branded or non-branded independent marketers, independent refiners, or small refiners.

(d) Any refiner, importer or other supplier which has significantly reduced marketing or distribution activities in any region and which is obligated to supply its base period purchasers in that region under the terms of this program may apply to the National FEO to seek a change in the method of supplying such purchasers. The FEO may order the reassignment of wholesale purchasers or end-users from one supplier to another.

§ 211.15 State offices of petroleum allocation.

(a) Any state may apply to the National Office of the FEO, to create a State Office of Petroleum Allocation within the State.

(b) Upon certification by the FEO, such State Office of Petroleum Allocation will be delegated authority to administer the State set-aside program, to provide assistance in obtaining adjustments specified in § 211.13 and such other authorities specified in this part, or in orders issued by the FEO.

§ 211.17 State set-aside.

(a) *Scope and purpose.* A state set-aside system shall be established for propane, middle distillates, motor gasoline, and residual fuel oil (except as used by utilities or as bunker fuel for maritime shipping). Authority may be delegated to a State office to administer the state set-aside for that State. The State set-aside shall be utilized by a State office to meet hardship and emergency requirements of all wholesale purchasers and end-users within that state from the state set-aside volumes, including wholesale purchasers and end-users which are part of any governmental organization.

(b) *State set-aside volume.* (1) A prime supplier shall inform each appropriate State office and each appropriate regional FEO office monthly, in accordance with § 211.222(b) by each product subject to State set-aside, of the estimated volume of each product to be sold into that State for consumption within that State.

(2) The FEO shall determine the State set-aside percentage level for each product. The initial percentage levels for the State set-aside system are specified in appropriate subparts of this part. The FEO will publish any changes in these percentages.

(3) The set-aside volume available to a State office for a particular month shall be the sum of the amounts calculated by multiplying the state set-aside percentage level by each prime supplier's estimated portion of its total supply for that month which will be sold into that state's distribution system for consumption within the state.

(4) The State set-aside for a particular month cannot be accumulated or deferred; it shall be made available from stocks of prime suppliers either directly or through their wholesale purchasers.

(c) *State action.* (1) All hardship and emergency petitions for assignment from the state set-aside and appeals shall be filed with and resolved by the appropriate State office in accordance with Subpart I of Part 205. Petitioners shall identify their existing supplier, or if they do not have a supplier, at least two suppliers which the petitioner has contacted and which could provide the allocated product. The final decision afforded by the State office on an appeal from a hardship or emergency petition shall be subject to judicial review in the manner prescribed by Section 211 of the Economic Stabilization Act of 1970.

(2) If a State office approves a hardship or emergency petition, it shall assign a prime supplier and amount from the State set-aside to the petitioner. To determine an appropriate prime supplier, the State office may coordinate with the regional distribution offices of the prime suppliers.

(d) *Authorizing document.* The State office shall issue to the purchaser granted an assignment a document authorizing the assignment. A copy of the authorizing document (or a summary) shall also be provided by the State office to the regional or local distribution offices of the prime supplier assigned to the purchaser. An authorizing document issued by the State office pursuant to this section is effective upon issuance and represents a call on the prime supplier's set-aside volumes for the month of issuance, irrespective of the fact that delivery of the product subject to the authorizing document cannot be made until a subsequent month.

(e) *Supplier's responsibilities.* Suppliers shall provide the assigned amount of an allocated product to a purchaser when presented with an authorizing document. The authorizing document shall entitle the purchaser to receive product from any convenient local distributor of the prime supplier from which the set-aside assignment has been made. Wholesale purchaser-resellers of prime suppliers shall, as non-prime suppliers, honor such authorizing documents upon presentation, and shall not delay deliveries required by the authorizing document while confirming such deliveries with the prime supplier. Any non-prime supplier which provides an allocated product pursuant to an authorizing document shall in turn receive from its supplier an equivalent volume of the allocated product which shall not be considered part of its allocation entitlement otherwise authorized by this part.

(f) *Prime suppliers.* All prime suppliers shall supply products from their State set-aside volume each month, as directed by the State office, not to exceed the total State set-aside volume for each product for that month. That portion of a prime supplier's State set-aside volume for a particular month which is not allocated by the State office during that month or which is not subject to an authorizing document issued no later than the last day of that month shall become a part of the prime supplier's total supply for the subsequent month and shall be distributed according to the allocation procedures set forth in this chapter.

§ 211.21 Energy conservation.

To promote the goal of increased energy conservation, every wholesale purchaser or end-user receiving an allocation pursuant to the operation of this part shall certify that it has an energy conservation program in effect. Every end-user or wholesale purchaser-consumer whose allocation level is one hundred (100) percent of current requirements for any allocated product shall make a similar certification to its supplier.

§ 211.22 Administrative actions.

(a) *Inventories of crude oil and allocated products.* No refiner, importer, wholesale purchaser or end-user shall accumulate inventories of any crude oil or allocated product which exceed customary inventories maintained by the refiner, importer, wholesale purchaser or end-user in the conduct of its normal business practices unless otherwise directed by the FEO. Normal inventory practices shall be observed in determining allocable supplies of crude oil or allocated products each month. The FEO may review inventory practices and direct an increase or decrease in inventories if:

(1) The inventory practices employed are inconsistent with the provisions of this part;

(2) The inventory practices circumvent or otherwise violate other provisions of this part; or

(3) The FEO determines that an adjustment is necessary in order to allocate crude oil or allocated product supplies consistent with the objectives of the Mandatory Petroleum Allocation Program.

(b) *Adjustment to calculations.* Upon a finding that incorrect or otherwise inaccurate data have been used in calculating the allocation of any crude oil or allocated product subject to this part, the FEO may take appropriate action to adjust any such figures or data and any allocations based thereon to account for the error.

§ 211.23 Normal business practices.

Nothing in this part is intended to exclude or supersede exchange or borrow/payback operations which are normal operating procedures provided these procedures are not used to circumvent the intent of this part.

§ 211.25 Supplier substitution.

(a) Any supplier may arrange to supply any purchaser which is entitled to receive an allocation from it through another supplier or suppliers in accordance with normal business practice. The purchaser shall, however, be entitled to receive the same amount of an allocated product from the substituted supplier that it would receive if it were directly supplied by the original supplier using that supplier's allocation fraction.

(b) In order to alleviate imbalances, suppliers may make normal business exchanges among themselves.

(c) To accommodate seasonal and other fluctuations in both supply and demand such as requirements for agricultural production, suppliers and wholesale purchasers may agree between and among themselves either to borrow on future allocations or to defer current allocations or both on a volume for volume basis within the total allocations for one calendar year as long as such arrangements do not result in an involuntary reduction in allocations to other wholesale purchasers.

§ 211.26 Department of Defense allocations.

Allocations of crude oil or any allocated product to the Department of Defense except for housekeeping requirements shall be supplied at an allocation level of one hundred (100) percent of current requirements without being subject to an allocation fraction. All such requirements shall be reported to the President on a quarterly basis and shall take effect only following his approval.

§ 211.27 Construction industry.

Any firm planning to award a construction contract to contractors (which may be wholesale purchasers) may apply as a new purchaser to a supplier or FEO as appropriate to be assigned a base period volume. The base period volume shall be estimated as the minimum amount sufficient to complete the proposed contract. Upon awarding the contract to a contractor, the assigned base period volume shall be transferred to the contractor by FEO unless the contractor or its subcontractors have a base period volume with suppliers in the area of the construction sufficient to perform the contract. If the contractor or its sub-contractors have a base period volume with suppliers in the area of the construction sufficient to perform the contract, or if construction plans are terminated, FEO shall be notified by the firm and the contractor and any base period volume assigned for the contruction shall terminate. To the extent that the base period volume established for the construction is found to exceed construction requirements or the contractor or its subcontractor has a base period volume with suppliers in the area of the construction partially sufficient to perform the contract, the firm and the contractor shall not accept any duplicating quantities and shall notify FEO immediately. Upon such notification, the FEO will adjust the base period volume accordingly. Contractors and suppliers are encouraged to arrange for exchange agreements between suppliers.

§ 211.28 Price.

The pricing provisions applicable to this part are provided in Part 212 of this chapter including provisions which allow any importer which imports an allocated product solely for his own end-use, and not for resale, to charge a margin for any volumes of that imported product it is required to sell under the provisions of this part.

2. Subpart B is revised to read as follows:

Subpart B—Definitions

§ 211.51 General definitions.

"Adjusted base period volume" means base period volume as adjusted pursuant to § 211.13.

"Agricultural production" means all the activities classified under the industry code numbers specified in paragraph (a) below as set forth in the Standard Industrial Classification Manual, 1972 edition, except those industry code numbers listed in paragraph (b) which are excluded:

(a) *Activities included.* (1) All industry code numbers included in Division A, Agriculture, Forestry and Fishing, except as specified in paragraph (b) of this section;

(2) All industry code numbers included in Major Group 20, Food and Kindred Products, of Division D, Manufacturing, except as specified in paragraph (b) below; and

(3) All the following other industry code numbers:

2141 Tobacco Stemming and Redrying;
2411 Logging Camps and Logging Contractors;
2421 Sawmills and Planing Mills;
2873 Nitrogenous Fertilizers;
2874 Phosphatic Fertilizers;
2875 Fertilizers, Mixing Only; and
4971 Irrigation Systems (for farm use).

(b) *Activities excluded.* (1) All the following industry code numbers, otherwise listed under Division A, Agriculture, Forestry and Fishing, are excluded from the definition:

0181 Ornamental Floriculture and Nursery Products, (except growing of fruit stocks and vegetable seeds which are included in the definition);
0189 Horticultural Specialties, Not Elsewhere Classified;
0271 Fur-Bearing Animals and Rabbits (except rabbit farms which are included in the definition);
0279 Animal Specialties, Not Elsewhere Classified, (except apiaries, honey production and bee, catfish, fish and frog farms which are included in the definition);
0742 Veterinary Services for Animal Specialties;
0752 Animal Specialty Services;
0781 Landscape Counseling and Planning;
0782 Lawn and Garden Services; and
0849 Gathering of Forest Products, Not Elsewhere Classified.

(2) All the following industry code numbers, otherwise listed under Major Group 20, Food and Kindred Products, of Division D, Manufacturing, are excluded from the definition:

2047 Dog, Cat and Other Pet Food;
2065 Candy and Other Confectionery Products;
2067 Chewing Gum;
2084 Wines, Brandy and Brandy Spirits;
2095 Roasted Coffee; and
2097 Manufactured Ice.

"Allocable supply" means allocable supply as defined in § 211.10(b)(1).

"Allocated products" means residual fuel oil and refined petroleum products.

"Allocation fraction" means allocation fraction as defined in § 211.10(b).

"Allocation level" means allocation level as defined in § 211.10(b)(2)(iv).

"Allocation requirement" means allocation requirement as defined in § 211.10(b)(2)(iii).

"API" means American Petroleum Institute.

"Asphalt" means asphalt as defined in ASTM standard D-288.

"ASTM" means American Society for Testing Materials.

"Assignment" means an action taken by the FEO, or an authorized State official, designating that an authorized purchaser be supplied at an allocation entitlement level determined by the FEO or authorized State official, by a specified supplier.

"Base period" means the historical period designated in Subparts C through K of this part.

"Base period use" means base period volume or adjusted base period volume.

"Base period volume" means base period volume as defined in § 211.10(b)(2)(ii).

"Bonded fuels" means those fuels produced outside the customs limits of the United States, held in bond under continuous United States customs custody in accordance with Treasury Department Regulations, and destined for use outside of the United States, its territories or possessions.

"Branded independent marketer" means a firm which is engaged in the marketing or distributing of refined petroleum products pursuant to—

(1) An agreement or contract with a refiner (or a firm which controls, is controlled by, or is under common control with such refiner) to use a trademark, trade name, service mark, or other identifying symbol or name owned by such refiner (or any such firm), or

(2) An agreement of contract under which any such firm engaged in the marketing or distributing of refined petroleum products is granted authority to occupy premises owned, leased, or in any way controlled by a refiner (or firm which controls, is controlled by, or is under common control with such refiner), but which is not affiliated with, controlled by, or under common control with any refiner (other than by means of a supply contract, or an agreement or contract described in paragraph (1) or (2) of this definition), and which does not control such refiner.

"Coker feedstock" means any crude oil or unfinished oil, as defined by Oil Import Regulation 1, Revision 5, which is used as a feedstock to any of the various types of process units in a refinery known as cokers.

"Commercial use" means usage by those purchasers engaged primarily in the sale of goods or services and for uses other than those involving industrial activities and electrical generation.

"Complaint" means an allegation, supported by relevant facts, of a violation of the regulations.

"Crude oil" means a mixture of liquid hydrocarbons including lease condensate that exist in natural underground reservoirs and remains liquid at atmospheric pressure after passing through surface separating facilities.

"Current requirements" means the supply of an allocated product needed by an end-user or wholesale purchaser-consumer to meet its present supply requirements for a particular use of that product, but does not include any amounts which the end-user or wholesale purchaser-consumer (1) purchases or obtains for resale, (2) accumulates as an inventory in excess of that purchaser's customary inventory maintained in the conduct of its normal business practices, or (3) uses in excess of the supply necessary to meet present supply requirements as constrained by the implementation of the energy conservation program required in § 211.21.

"Degree-day formula" means any one of the various systems in use by retailers to provide wholesale purchaser-consumers or end-users with automatic delivery service of an allocated product for space-heating.

"Degrees API" or "°API" is the hydrometer scale established by the American Petroleum Institute and used to measure the specific gravity of liquids.

"Emergency Services" means law enforcement, fire fighting, and emergency medical services.

"End-user" means any firm which is an ultimate consumer of an allocated product other than a wholesale purchaser-consumer.

"Energy production" means the exploration, drilling, mining, refining, processing, production and distribution of coal, natural gas, geothermal energy, petroleum or petroleum products, shale oil, nuclear fuels, and electrical energy. It also includes the construction of facilities and equipment used in energy production, such as pipelines, mining equipment and similar capital goods. Excluded from this definition are synthetic natural gas manufacturing and electrical generation whose power source is petroleum based.

"FEO" means the National Federal Energy Office, the appropriate regional Federal Energy Office or the delegate of either.

"Firm" means any association, company, corporation, estate, individual, joint-venture, partnership, or sole proprietorship or any other entity however organized including charitable, educational, or other eleemosynary institutions, and the Federal Government including corporations, departments, Federal agencies, and other instrumentalities, and State and local governments. The FEO may, in regulations and forms issued in this part, treat as a firm:

(1) A parent and the consolidated and unconsolidated entities (if any) which it directly or indirectly controls, (2) a parent and its consolidated entities, (3) an unconsolidated entity, or (4) any part of a firm.

"Gas processing plant" means a facility which recovers ethane, propane, butane, and/or other natural gas products by a process of absorption, adsorption, compression, refrigeration cycling, or a combination of such processes, from mixtures of hydrocarbons that existed in a reservoir.

"Importer" means any firm (excluding the Department of Defense) that owns at the first place of storage any allocated product or crude oil brought into the United States.

"Independent marketer" means either a branded independent marketer or a non-branded independent marketer.

"Independent refiner" means a refiner which (a) obtained, directly or indirectly, in the calendar quarter which ended immediately prior to November 27, 1973, more than 70 percent of its refinery input of domestic crude oil or 70 percent of its refinery input of domestic and imported crude oil from producers which do not control, are not controlled by, and are not under common control with such refiner, and (b) marketed or distributed in such quarter and continues to market or distribute a substantial volume of gasoline refined by it through branded independent marketers or non-branded independent marketers.

"Industry" means those firms primarily engaged in a process which creates or changes raw or unfinished materials into another form or product.

"Interruptible contracts" means those contracts between suppliers and purchasers which by their terms can be abrogated unilaterally by the supplier.

"LPG" means liquefied petroleum gas, and includes propane and butane, and propane/butane mixes, but not ethane.

"Local governmental unit" means any county, city, or other governmental subdivision of a State, and any special purpose district.

"Lubricants" means all grades of lubricating oils for industrial, commercial and automotive use, and lubricating greases which are solid to semifluid products consisting of a dispersion of a thickening agent in a liquid lubricant. This product includes all lubricants reported to the Bureau of Mines, United States Department of Interior as such, with the exception of a product controlled under Subparts other than Subpart K.

"Medical and nursing buildings" means buildings that house medical, dental and nursing practices including the use of clinics, hospitals, nursing homes and other facilities including but not limited to those listed in Appendix I of 6 CFR 300.18 and 300.19.

"Middle distillate" means any derivatives of petroleum including kerosene, home heating oil, range oil, stove oil, and diesel fuel, which have a fifty percent boiling point in the ASTM D86 standard distillation test falling between 371° and 700° F. Products specifically excluded from this definition are kerosene-base and naphtha-base jet fuel, heavy fuel oils as defined in VV–F–815C or ASTM D–396, grades #4, 5 and 6, intermediate fuel oils (which are blends containing #6 oil), and all specialty items such as solvents, lubricants, waxes, and process oil.

"Motor gasoline" means a mixture of volatile hydrocarbons, suitable for operation of an internal combustion engine, whose major components are hydrocarbons with boiling points ranging from 140° to 390° F and whose source is distillation of petroleum and cracking, polymerization, and other chemical reactions by which the naturally occurring petroleum hydrocarbons are converted to those that have superior fuel properties, and includes products such as natural gas liquids, alkylates, naphtha, toluene, and mixed xylenes when used as blending stock to form motor gasoline.

"Natural gas" means natural gas as defined by the Federal Power Commission.

"Nonbranded independent marketer" means a firm which is engaged in the marketing or distribution of refined petroleum products, but which (1) is not a refiner, (2) is not a firm which controls, is controlled by, is under common control with, or is affiliated with a refiner (other than by means of a supply contract), and (3) is not a branded independent marketer.

"PAD District" or "District" means any of the Petroleum Administration for Defense (PAD) Districts.

"Passenger transportation services" means (a) surface, including water and rail, facilities and services for carrying passengers whether publicly or privately owned, including tour and charter buses which serve the general public; and (b) bus transportation of pupils to and from school and school sponsored activities.

"Peak shaving" means the use of propane-air or butane-air mixtures to supplement supplies of pipeline gas for distribution by gas utilities during periods of high demand.

"Petrochemical precursors" means any hydrocarbon compounds which are produced in any facility through the chemical conversion of propane or butane, and which are further processed either directly or through intermediate steps into petrochemicals.

"Petroleum coke" means a solid residue, the final product of the condensation process in cracking, consisting mainly of highly polycyclic aromatic hydrocarbons very poor in hydrogen, including petroleum coke which when calcinated yields almost pure carbon or artificial graphite suitable for production of carbon or graphite electrodes, structural graphite, motor brushes, dry cells, etc. It includes both forms listed below:

(1) *Marketable.* Those grades of coke produced in delayed or fluid cokers which may be recovered as relatively pure carbon. This "green" coke may be further purified by calcinating or may be sold in the "green" state.

(2) *Catalyst.* In many catalytic operations (i.e., catalytic cracking) carbon is deposited on the catalyst, deactivating the catalyst. The catalyst is reactivated by burning off the carbon, using it as a fuel in the refinery process. This carbon or coke is not recoverable in a concentrated form. For statistical purposes, the amount of catalyst coke may be estimated by using an average weight percent (1.5%–8.5%) of charging stock.

"Petroleum wax" means petroleum wax as defined in ASTM standard D–288.

"Prime supplier" means the supplier which makes the first sale of any allocated product subject to the state set-aside into the state distribution system for consumption within the state.

"Purchaser" means a wholesale purchaser, an end-user, or both.

"Refined petroleum product" means gasoline, kerosene, middle distillates (including Number 2 fuel oil), LPG, refined lubricating oils, or diesel fuel.

"Refineries" means those industrial plants, regardless of capacity, processing crude oil feedstock and manufacturing refined petroleum products, except when such plant is a petrochemical plant.

"Refiners" means those firms that own, operate or control the operations of one of more refineries.

"Refinery gas" means a form of gas normally produced in the refining of crude oil which is predominately used for refinery fuel.

"Region" means one of the ten regions served by FEO's regional offices.

"Regional office" means a regional office of the FEO. The regional offices are located in Boston, Massachusetts; New York, New York; Philadelphia, Pennsylvania; Atlanta, Georgia; Chicago, Illinois; Dallas Texas; Kansas City, Missouri; Denver, Colorado; San Francisco, California; and Seattle, Washington.

"Residential use" means direct usage in a residential dwelling for space heating, refrigeration, cooking, water heating, and other residential uses.

"Residual fuel oil" means the fuel oils commonly known as: (1) No. 4, No. 5 and No. 6 fuel oils; (2) Bunker C; (3) Navy Special Fuel Oil; (4) crude oil when burned directly as a fuel; and all other fuel oils which have a fifty percent boiling point over 700° F in the ASTM D-86 standard distillation test.

"Retail sales outlet" means a site on which a supplier maintains an on-going business of selling any allocated product to end-users or wholesale purchaser-consumers.

"Road oil" means any heavy petroleum oil, including residual asphaltic oils, used as a dust palliative and surface treatment of roads and highways. It is generally produced in six grades from 0, the most liquid, to 5, the most viscous.

"Sanction" means the penalties as described in Subpart F of Part 202 of this Chapter.

"Sanitation services" means the collection and disposal for the general public of solid wastes, whether by public or private entities, and the maintenance, operation and repair of liquid purification and waste facilities during emergency conditions.

"School" means an educational institution up through the secondary level that maintains a regular facility and curriculum and has a regularly organized body of students, in attendance at the place where its educational activities are regularly carried on. It does not include post-secondary education facilities.

"Shortfall" means the difference between supply and demand for crude oil or an allocated product during any period.

"Small refiner" means a refiner whose total refinery capacity (including the refinery capacity of any firm which controls, is controlled by, or is under common control with such refiner) does not exceed 175,000 barrels per day.

"State" means each of the 50 States, the District of Columbia, Puerto Rico, possessions and territories of the United States, other than the Panama Canal Zone.

"State set-aside" means, with respect to a particular prime supplier, the amount of an allocated product which is made available from the total supply of a prime supplier pursuant to § 211.17 for utilization by a State to resolve emergencies and hardships due to fuel shortages. The state set-aside amount for a particular month and state is calculated by multiplying the state set-aside percentage level by the prime supplier's estimated portion of its total supply for that month which will be sold into that state's distribution system for consumption within the state. The initial state set-aside percentage level for an allocated product is specified in the appropriate subpart for that product but is subject to change by notice of the FEO.

"State office" means the State Petroleum Allocation Office certified by FEO pursuant to § 211.15.

"Supplier" means any firm other than the Department of Defense which supplies, sells, transfers or otherwise furnishes (as by consignment) any allocated product or crude oil to wholesale purchasers or end-users, including but not limited to refiners, importers, resellers, jobbers, and retailers.

"Supply obligation" means supply obligation as defined in § 211.10(b)(2).

"Telecommunications services" means the repair, operation, and maintenance of telephone, telegraph, and similar facilities, during periods of substantial disruption of normal service.

"Total supply" means the sum of a supplier's estimated production, including amounts received under processing agreements, imports, purchases and any reduction in inventory of an allocated product made pursuant to § 211.22 except as otherwise ordered by FEO. Any existing inventory, or production, importation or purchase of an allocated product used to increase that inventory consistent with the provisions of § 211.22 shall not be included in the total supply of that product.

"Utility" means a facility that generates electricity, by any means, and sells it to the public.

"Wholesale purchaser" means a wholesale purchaser-reseller or wholesale purchaser-consumer, or both.

"Wholesale purchaser - consumer" means any firm that is an ultimate consumer which, as part of its normal business practices, purchases or obtains an allocated product from a supplier and receives delivery of that product into a storage tank substantially under the control of that firm at a fixed location and which either (1) purchased or obtained more than 20,000 gallons of that allocated product for its own use in agricultural production in any completed calendar year subsequent to 1971; (2) purchased or obtained more than 50,000 gallons of that allocated product in any completed calendar year subsequent to 1971 for use in one or more multi-family residences; or (3) purchased or obtained more than 84,000 gallons of that allocated product in any completed calendar year subsequent to 1971.

"Wholesale purchaser-reseller" means any firm which purchases, receives through transfer, or otherwise obtains (as by consignment) an allocated product and resells or otherwise transfers it to other purchasers without substantially changing its form.

(Emergency Petroleum Allocation Act of 1973, Pub. L. 93-159; E.O. 11748, 38 FR 33575; Economic Stabilization Act of 1970, as amended, Pub. L. 92-210, 85 Stat. 743; Pub. L. 93-28, 87 Stat. 27; E.O. 11730, 38 FR 19345; Cost of Living Council Order Number 47, 39 FR 24.)

3. Subpart F is revised to read as follows:

Subpart F—Motor Gasoline

Sec.

211.101 Scope.
211.102 Definitions.
211.103 Allocation levels.
211.104 Supplier/purchaser relationships.
211.105 Method of allocation.
211.106 Procedures and reporting requirements.

AUTHORITY: Emergency Petroleum Allocation Act of 1973, Pub. L. 93-159; E.O. 11748, 38 FR 33575; Economic Stabilization Act of 1970, as amended, Pub. L. 92-210, 85 Stat. 743; Pub. L. 93-28, 87 Stat. 27; E.O. 11730, 38 FR 19345; Cost of Living Council Order Number 47, 39 FR 24.

Subpart F—Motor Gasoline

§ 211.101 Scope.

(a) This subpart applies to the mandatory allocation of all motor gasoline produced in or imported into the United States.

(b) This subpart provides for a State set-aside of motor gasoline.

§ 211.102 Definitions.

For purposes of this subpart—

"Base period" means the month of 1972 corresponding to the current month.

"Bulk purchaser" means any firm which is an ultimate consumer which, as part of its normal business practices, purchases or obtains an allocated product from a supplier and either (1) receives delivery of that product into a storage tank substantially under the control of that firm at a fixed location, (2) with respect to use in agricultural production, receives delivery into a storage tank with a capacity not less than 50 gallons substantially under the control of that firm, or (3) receives delivery of that product for use in cargo, freight and mail hauling by truck.

"Truck" means a motor vehicle with motive power designed primarily for the transportation of property or special purpose equipment and with a gross vehicle weight rating for a single vehicle (the value specified by the manufacturer as the loaded weight of the vehicle) or the equivalent thereof in excess of 20,000 pounds, or in the case of trucks designed primarily for drawing other vehicles and not so constructed as to carry a load other than part of the weight of the vehicle and the load so drawn, with a gross combination weight rating (the value specified by the manufacturer as the loaded weight of the combination vehicle) or the equivalent thereof in excess of 20,000 pounds.

§ 211.103 Allocation levels.

(a) *General.* The allocation levels listed in this section only apply to allocations made by suppliers to end-users which are bulk purchasers and to whole-

sale purchaser-consumers. Suppliers shall allocate to all purchasers to which the allocation levels apply in accordance with the provisions of § 211.10. End-users which are bulk purchasers and wholesale purchaser-consumers which are entitled to purchase motor gasoline under an allocation level not subject to an allocation fraction shall receive first priority and be supplied sufficient amounts to meet 100 percent of their allocation requirements. End-users which are bulk purchasers and wholesale purchaser-consumers which are entitled to purchase motor gasoline for all uses under an allocation level subject to reduction by application of an allocation fraction shall receive second priority.

(b) *Allocation levels not subject to an allocation fraction.* One hundred (100) percent of current requirements for the following uses:

(1) Agricultural production;

(2) Department of Defense use as specified in § 211.26.

(c) *Allocation levels subject to an allocation fraction.* (1) One hundred (100) percent of current requirements (as reduced by application of the allocation fraction) for the following uses:

(i) Emergency services;

(ii) Energy production;

(iii) Sanitation services;

(v) Passenger transportation services;

(vi) Cargo, freight and mail hauling by truck

(vii) Aviation ground support vehicles and equipment.

(2) One hundred (100) percent of base period use (as reduced by application of the allocation fraction) for all other business activities.

(d) *Purchasers without an allocation level.* There shall be no allocation levels for end-users which are not bulk purchasers or for purchasers which are not otherwise described in paragraph (b) and (c) of this section. Such end-users shall be supplied in accordance with the provisions of § 211.10(d)(2).

(e) *Wholesale purchaser-resellers.* Wholesale purchaser-resellers shall receive allocations on the basis of their base period volumes as determined by § 211.12(b) and adjusted in accordance with § 211.13.

§ 211.104 Supplier/purchaser relationships.

Supplier/purchaser relationships are set forth in § 211.9–211.13.

§ 211.105 Method of allocation.

(a) The initial State set-aside level for motor gasoline for a particular month and state is three (3) percent of a prime supplier's estimated portion of its total supply for that month which will be sold into the State's distribution system for consumption within the state. Subsequent adjustments to the percentage unit will be published by the FEO.

(b) Allocation of motor gasoline to retail gasoline dealers and all other purchasers shall be made as specified in § 211.10.

(c) Provisions to adjust a wholesale purchaser's base period volume are specified in § 211.13. New wholesale purchasers and end-users are subject to the requirements of § 211.12.

§ 211.106 Procedures and reporting requirements.

(a) All matters pertaining to the allocation of motor gasoline shall be addressed to the appropriate State office or regional FEO office as specified within this part.

(b) The general reporting and recordkeeping requirements contained in § 211.222 shall apply to this subpart.

(c) A hardship application may be submitted to the appropriate State office as provided in § 211.17 for undue hardship to any wholesale purchaser or end-user resulting from the provisions of this subpart.

4. Subpart G is revised to read as follows:

Subpart G—Middle Distillate

Sec.

211.121 Scope.
211.122 Definitions.
211.123 Allocation levels.
211.124 Supplier/purchaser relationships.
211.125 Method of allocation.
211.126 Procedures and reporting requirements.

AUTHORITY: Emergency Petroleum Allocation Act of 1973, Pub. L. 93–159; E.O. 11748, 38 FR 33575; Economic Stabilization Act of 1970, as amended, Pub. L. 92–210, 85 Stat. 743; Pub. L. 93–28, 87 Stat. 27; E.O. 11730, 38 FR 19345; Cost of Living Council Order Number 47, 39 FR 24.

Subpart G—Middle Distillate

§ 211.121 Scope.

(a) This subpart applies to all middle distillate fuels produced in or imported into the United States.

(b) This subpart provides for a State set-aside.

§ 211.122 Definitions.

For the purposes of this subpart—

"Base period" means the month of 1972 corresponding to the current month.

§ 211.123 Allocation levels.

(a) *General.* The allocation levels in this paragraph only apply to allocations made by suppliers to wholesale purchaser-consumers and end-users. Suppliers shall allocate to all purchasers to which the allocation levels apply in accordance with the provisions of § 211.10. End-users and wholesale purchaser-consumers which are entitled to purchase middle distillate fuels under an allocation level not subject to an allocation fraction shall receive first priority and be supplied sufficient amounts to meet 100 percent of their allocation requirements. End-users and wholesale purchaser-consumers which are entitled to purchase middle distillate fuels under an allocation level subject to reduction by application of an allocation fraction shall receive second priority.

(b) *Allocation levels not subject to an allocation fraction.* (1) One hundred (100) percent of current requirements for the following uses:

(i) Agricultural production;

(ii) Department of Defense use as specified in § 211.26;

(iii) Space heating requirements subject to the following specifications:

(A) No reduction for medical and nursing buildings for all uses;

(B) Six (6) degree F reduction for residences and schools; or

(C) Ten (10) degree F reduction for all others; or

(D) Reduction of the ambient indoor temperature by the appropriate amount, or other action which result in a fuel saving equivalent to that which would otherwise result under paragraph (b)(1)(iii)(A)–(C) of this section.

(c) *Allocation levels subject to an allocation fraction.* (1) One hundred (100) percent of current requirements (as reduced by the application of an allocation fraction) for the following uses:

(i) Emergency services;

(ii) Energy production;

(iii) Manufacture of ethical drugs and related research;

(iv) Sanitation services;

(v) Telecommunication services;

(vi) Passenger transportation services;

(vii) Cargo, freight, and mail hauling except as set forth elsewhere in this section;

(viii) Aviation ground support vehicles and equipment.

(2) One hundred ten (110) percent of base period use (as reduced by application of an allocation fraction) for industrial use except for space heating.

(3) *Electric utilities.* (i) One hundred (100) percent of base period use (as reduced by application of an allocation fraction) or as otherwise determined by the FEO upon recommendation by the Federal Power Commission (FPC), but not less than one hundred (100) percent of current requirements for nuclear plants, start-up, testing and flame stability of coal-fired plants (except for peaking uses).

(ii) In determining the middle distillate allocation for each utility, the FEO may take into account but is not limited to the following considerations:

(A) The fact that electric generating plants which now burn middle distillate fuel oil have been identified by the FEO as candidates for conversion to coal and the maximum possible extent to which such plants could be utilized after conversion;

(B) The extent to which any electric generating plants which burn coal may be utilized more fully than at present;

(C) The extent to which it is possible for electric utilities to obtain necessary supplies of coal;

(D) The extent to which certain minimal levels of middle distillate consumption are essential, as determined by the FEO upon recommendation of the FPC, to supply portions of a power system that cannot be supplied by non-middle distillate-fired generation, or for other special considerations. (Any volumes so identified shall be counted as part of the utility's total allocation.)

(E) The extent to which utilities currently utilizing natural gas supplied under interruptible contracts experience gas service interruptions.

(F) Available stocks of middle distillate held by each utility.

(4) One hundred (100) percent of base period use (as reduced by application of an allocation fraction) for all other non-space heating uses.

§ 211.124 Supplier/purchaser relationships.

Supplier/purchaser relationships are set forth in §§ 211.9–211.13.

§ 211.125 Method of allocation.

(a) The initial State set-aside level for middle distillate fuels for a particular month and state is (4) percent of a prime supplier's estimated portion of its total supply for that month which will be sold into the state's distribution system for consumption within the State. Subsequent adjustments to the percentage unit will be published by the FEO.

(b) Allocation of middle distillate shall be made as specified in § 211.10. Provisions to adjust a wholesale purchaser's base period volume are specified in § 211.13. New wholesale puchasers and end-users are subject to the requirements of § 211.12.

(c) Suppliers shall, to the extent practicable, make deliveries to all space-heating end-users and wholesale purchaser-consumers on the basis of certified need. Certified need for space-heating is the calculated quantity of fuel needed to maintain the ambient indoor temperature of a building at the reduced temperature required in § 211.123(b)(1)(iii).

(1) This calculation of certified need shall be done using historical usage factors for each building heated. Where suppliers do not have an historical usage factor for a building, this factor shall be calculated based on gallons of fuel consumed and actual degree-days exposure during the latest thirty (30) day period of normal heating usage before January 15, 1974. If no such period exists, a usage factor for that unit shall be established by an initial period of normal space-heating operations, subject to review by the State Office.

(i) Historical usage factors shall be associated with units and not with end-users or wholesale purchaser-consumers.

(ii) If this calculation of certified need results in undue hardship, the owners or occupants may apply to their State Office to obtain relief.

(2) To the extent practicable, the following procedure shall be followed by heating oil suppliers:

(i) Each space-heating end-user or wholesale purchaser-consumer shall be entitled to an initial fill-up at its first delivery after these regulations become effective, if sufficient supplies are available.

(ii) At the next delivery, the supplier shall again provide a full tank and determine, to the extent possible, compliance with this part. If the space-heating end-user or wholesale purchaser-consumer has clearly not complied, the supplier shall present a warning notice to the end-user or wholesale purchaser-consumer. The warning notice shall indicate that the end-user or wholesale purchaser-consumer faces the danger of running out of fuel if it does not reduce its ambient indoor temperature by the required amount or take equivalent actions to conserve fuel.

(iii) For each subsequent delivery, the supplier shall continue to deliver only the calculated certified need regardless of the quantity required to fill the tank, unless otherwise directed by the State Office.

§ 211.126 Procedures and reporting requirements.

(a) All matters pertaining to the allocation of middle distillate shall be addressed to the appropriate State Office or Regional FEO as specified within this part.

(b) The general reporting and recordkeeping requirements contained in Subpart L of this part apply to this subpart.

(c) Hardship applications may be submitted to the appropriate State Office for undue hardship resulting from the provisions of this subpart.

Subpart H—Aviation Fuels

5. Section 211.141 is amended in paragraph (b) to read as follows:

§ 211.141 Scope.

* * * * *

(b) Bonded aviation fuel is excluded from allocation; provision for bonded fuel shortfalls is addressed in § 211.145 (c).

* * * * *

6. Section 211.142 is amended by revising the following list of definitions and by adding the definition of telecommunications flying in the appropriate alphabetical order to read as follows:

§ 211.142 Definitions.

* * * * *

"Aircraft manufacturing uses" means the consumption of aviation fuels for aircraft production, major overhaul of aircraft, static and flight testing of aircraft and components, the ferrying of aircraft from the manufacturer, and initial type aircraft certification training provided by the manufacturer for the purchaser.

* * * * *

"Base period" means (i) the calendar month of 1972 corresponding to the current month; and (ii) after March 31, 1974, the calendar quarter of 1972 corresponding to the current quarter.

"Business flying" means any use of aircraft under 14 CFR Parts 91 and 133 by a firm for the purpose of transportation required by a business in which it is engaged and for the purpose of transporting its employees and/or property. Business flying includes such aerial uses as photography, advertising, survey and helicopter operations.

* * * * *

"General aviation" means (1) agricultural production flying; (2) air travel club flying; (3) business flying; (4) instructional flying; (5) personal non-business flying; (6) energy production flying; (7) aircraft manufacturing uses; (8) telecommunications flying.

"Instructional flying" means any use of aircraft operating under 14 CFR Parts 91, 127 and 141 for the purpose of formal instruction.

* * * * *

"Non-flying use of aviation fuels" means the consumption of aviation fuels associated with gas turbine engines in industry, utilities and passenger transportation services.

* * * * *

"Public aviation" means any aircraft operating under 14 CFR Parts 91, 133 or 137 used exclusively in the service of the Federal government or the government of the District of Columbia or of any state, territory or possession of the United States and any political subdivisions thereof, excluding military aircraft.

* * * * *

"Telecommunications flying" means the use of aircraft operating under 14 CFR Parts 91 and 133 in "telecommunications services" as defined in Subpart B of this part.

* * * * *

7. Section 211.143 is revised to read as follows:

§ 211.143 Allocation levels.

(a) *General.* The allocation levels listed in this section apply only to allocations made by suppliers to wholesale purchaser-consumers and end-users. Suppliers shall allocate to all purchasers to which allocation levels apply in accordance with the provisions of § 211.10. End-users and wholesale purchaser-consumers which are entitled to purchase aviation fuels under an allocation level not subject to an allocation fraction shall receive first priority and shall be supplied sufficient amounts to meet 100 percent of their allocation requirements. End-users and wholesale purchaser-consumers which are entitled to purchase aviation fuels for all uses under an allocation level subject to reduction by application of an allocation fraction shall receive second priority.

(b) *Allocation levels not subject to an allocation fraction.* (1) One hundred percent or current requirements for the following uses:

(i) Agricultural production flying;

(ii) Department of Defense use as specified in § 211.26.

(c) *Allocation levels subject to an allocation fraction.* (1) One hundred (100) percent of current requirements (as reduced by application of an allocation fraction) for the following uses:

(i) Emergency aviation services, safety and mercy missions;

(ii) Energy production flying;

(iii) Aircraft manufacturing but not to exceed one hundred thirty (130) percent of base period use;

(iv) Telecommunications flying;

(2) One hundred (100) percent of base period use (as reduced by application of an allocation fraction) for the following uses:

(i) Local service air carriers, including requirements for crew training and proficiency flying;

(ii) Other air carriers, including requirements for crew training and proficiency flying.

(iii) Non-flying use of aviation fuels;

(3) Ninety-five (95) percent of base period use (as reduced by application of an allocation fraction) for the following uses:

(i) Domestic, supplemental, and scheduled cargo air carriers, including requirements for crew training and proficiency flying;

(ii) International air carriers, including requirements for crew training and proficiency flying—the total of both bonded and non-bonded fuels;

(iii) Intra-state carriers, including requirements for crew training and proficiency flying.

(e) Ninety (90) percent of base period use (as reduced by application of an allocation fraction) for business flying, including requirements for crew training and proficiency flying.

(f) Eighty-five (85) percent of base period use (as reduced by application of an allocation fraction) for public aviation.

(g) Seventy-five (75) percent of base period use (as reduced by application of an allocation fraction) for the following uses:

(1) Personal non-business flying;

(2) Instructional flying;

(3) Air travel club flying including requirements for crew training and proficiency flying.

8. Section 211.144 is revised to read as follows:

§ 211.144 Supplier/purchaser/relationships.

Unless otherwise specified, the provisions of § 211.9–§ 211.13 apply to this subpart.

9. Section 211.145 is revised in paragraphs (a) and (e) to read as follows:

§ 211.145 Method of allocation.

(a) Suppliers of wholesale purchasers and end-users shall allocate aviation fuels in accordance with the provisions of § 211.10.

* * * * *

(e) Notwithstanding the provisions of § 211.143(c)(2)(iii), the use of aviation fuel for non-flying purposes by a utility may not exceed those volumes of aviation fuel contracted for or purchased during the base period. Aviation fuel shall not be used for peaking as long as the utility continues service during such peaking to interruptible non-priority industrial users (except where no suitable substitute fuel is available to the user) or to any purchaser which can use a fuel other than aviation fuel.

10. Section 211.146 is revised to read as follows:

§ 211.146 Procedures and reporting requirements.

(a) All matters pertaining to the allocation of aviation fuels to civil air carriers (except air taxi/commercial operators) shall be addressed to the Administrator, FEO, Washington, D.C. 20461, unless otherwise provided.

(b) All matters pertaining to the allocation of aviation fuels for general aviation, air taxi/commercial operators, public aviation and non-flying uses of aviation fuels shall be addressed to the appropriate supplier. Any matters unresolved at the supplier level may be referred directly to the appropriate Regional FEO office.

(c) The general reporting and recordkeeping requirements contained in § 211.222 shall apply to this subpart. In addition, civil air carriers (excluding air taxi/commercial operators) shall make a one time only report to the Administrator, FEO, of their base period volume, or adjusted base period volume, of aviation gasoline and of both naphtha-base and kerosene-base jet fuel broken down by month. At the option of the user, this may be modified to reflect one-twelfth (1/12) of the annual allocation volumes for each month or the estimated requirements by month, not to exceed total annual allocation volume. Use of this reporting option shall be applied for purposes of choosing the most realistic figures. The report required by this paragraph shall indicate the purchases of non-bonded fuel for domestic flights, non-bonded fuel for international flights, and bonded fuel for international flights, as applicable.

(d) For general aviation wholesale purchasers, the recordkeeping requirements specified in § 211.223 shall apply provided, however, that such reports need reflect only jet fuel and aviation gasoline usage for local purchasers and their uses and activities and total pumpage per month of jet fuel and aviation gasoline.

Subpart I—Residual Fuel Oil

11. Section 211.163 is revised to read as follows:

§ 211.163 Allocation levels.

(a) *General.* The allocation levels listed in this paragraph only apply to allocations made by suppliers to wholesale purchaser-consumers and end-users. Suppliers shall allocate to all purchasers to which allocation levels apply in accordance with the provisions of § 211.10. End-users and wholesale purchaser-consumers which are entitled to purchase residual fuel oil under an allocation level not subject to an allocation fraction shall receive first priority and be supplied sufficient amounts to meet 100 percent of their allocation requirements. Wholesale purchaser-consumers and end-users which are entitled to purchase residual fuel oil for all uses under an allocation level subject to reduction by application of an allocation fraction shall receive second priority.

(b) *Allocation levels not subject to an allocation fraction.* (1) One hundred (100) percent of current requirements for the following uses:

(i) Agricultural production;

(ii) Department of Defense for use as specified in § 211.26.

(iii) Space heating requirements subject to the following specifications:

(A) No reduction for medical and nursing building uses;

(B) Six (6) degree F reduction for residences and schools;

(C) Ten (10) degree F reduction for all others;

(D) Reduction of the ambient indoor temperature by the appropriate amount, or other actions which result in a fuel saving equivalent to that which would otherwise result under paragraph (b)(1)(iii)(A)–(C) of this section.

(2) The allocation level as specified each month by the FEO for utility use. In specifying the allocation levels for each utility the FEO may include but is not limited to the following considerations:

(i) Each utility within appropriate groupings shall absorb an equal percentage cut back in electricity generation, to the maximum extent possible.

(ii) The fact that electric generating plants which now burn residual fuel oil that have been identified by the FEO as candidates for conversion to coal, and the maximum possible extent to which such plants could be utilized after conversion.

(iii) The extent to which any electric generating plants which burn coal may be utilized more fully than at present.

(iv) The extent to which certain minimal levels of residual fuel oil consumption are essential, as determined by the FEO upon recommendation of the Federal Power Commission (FPC) to supply portions of a power system requirement that cannot be supplied by non-oil-fired generation, or for other special considerations. Any volumes so identified shall be counted as part of a utility's total allocation.

(v) The extent to which utilities currently utilize natural gas supplies under interruptible contracts and which have been interrupted.

(vi) Available stocks of residual fuel oil held by each utility.

(c) *Allocation levels subject to an allocation fraction.* (1) One hundred (100) percent of current requirements (as reduced by application of an allocation fraction) for the following uses:

(i) Emergency services;

(ii) Energy production;

(iii) Manufacture of ethical drugs and related research;

(iv) Non-military marine shipping, foreign and domestic (except cruise ships carrying passengers for recreational purposes). Sales to vessels engaged in the foreign trade of the United States shall be made on a non-discriminatory basis in regard to flag of registration, subject to modification by the FEO following consultation with appropriate Federal agencies on a case-by-case basis if required to encourage reciprocal non-discriminatory allocation of bunker fuels in foreign ports to vessels engaged primarily in the foreign trade of the United States;

(v) Sanitation services;

(vi) Telecommunications services;

(vii) Passenger transportation services.

(2) One hundred (100) percent of base period use for industrial users and all other users and uses of residual fuel oil not included in paragraph (b) or (c)(1) of this section.

12. Section 211.164 is revised in paragraph (b) to read as follows:

§ 211.164 Supplier/purchaser/relationships.

* * * * *

(b) Unless otherwise specified, supplier/purchaser relationships are set forth in § 211.9–13.

13. Section 211.165 is revised in paragraphs (a) and (c) to read as follows:

§ 211.165 Method of allocation.

(a) The initial State set-aside level for residual fuel oil for a particular month and State is one and one-half (1½) percent of a prime supplier's estimated portion of its total supply for that month which will be sold into that State's distribution system for consumption within the State. Subsequent adjustments to the percentage unit will be published by the FEO.

* * * * *

(c) *Non-utility.* The portion of each supplier's allocable supply not directed by the FEO to be distributed for utility use shall be allocated pursuant to § 211.10. With respect to space heating uses, suppliers must comply, to the fullest extent practicable, with the provisions of paragraph (e) of this section. Notwithstanding the provisions of § 211.164 or § 211.10, suppliers may not supply a utility in excess of the amounts established pursuant to paragraph (d) of this section until the non-utility allocations levels listed in § 211.163 have been filled, unless otherwise directed by the FEO.

14. Section 211.165 is revised in paragraphs (d)(1)(i) and (d)(2)(i) to read as follows:

§ 211.165 Method of allocation.

* * * * *

(d) *Utilities.* (1) * * *

(i) The FEO will determine the amount of residual fuel oil allocated to each utility for delivery during the month of February and publish that determination. The volume of residual fuel oil allocated to each utility shall be based upon the supply available for utilities, the considerations specified in § 211.163(b)(2) and other relevant considerations.

* * * * *

(2) * * *

(i) Each month, the FEO will determine the amount of residual fuel oil allocated to each utility for delivery in the following month. The volume of residual fuel oil allocated to each utility in a particular month shall be based upon the total supply available for utilities, the considerations specified in § 211.173(b)(2) and other relevant considerations.

§ 211.165 [Amended]

15. Section 211.165, is amended in paragraph (e) by deleting the reference to § 211.163(a)(2)(iv)" and inserting in lieu thereof "§ 211.163(b)(1)(iii)(D)."

16. Section 211.166 is revised in paragraph (f) to read as follows:

§ 211.166 Procedures and reporting requirements.

* * * * *

(f) Requests for adjusted base period volumes shall be submitted to suppliers or to the appropriate regional FEO specified in § 211.12 for purchasers (other than utilities) and in § 211.13 for suppliers, wholesale purchasers and end-users.

17. Subpart K is revised to read as follows.

Subpart K—Other Products

Sec.
211.201 Scope.
211.202 Definitions.
211.203 Allocation levels.
211.204 Supplier/purchaser relationships.
211.205 Method of allocation.
211.206 Procedures and reporting requirements.

AUTHORITY: Emergency Petroleum Allocation Act of 1973, Pub. L. 93–159; E.O. 11748, 38 FR 33575; Economic Stabilization Act of 1970, as amended, Pub. L. 92–210, 85 Stat. 743; Pub. L. 93–28, 87 Stat. 27; E.O. 11730, 38 FR 19345; Cost of Living Council Order Number 47, 39 FR 24.

Subpart K—Other Products

§ 211.201 Scope.

(a) This subpart applies to the mandatory allocation of solvents, diluents, feedstocks for synthetic natural gas plants, refined lubricating oils, allocated products used in the blending and compounding of lubricating oils, and any other allocated products not subject to Subparts D–J of this part, produced in or imported into the United States.

(b) This subpart does not provide for a State set-aside.

§ 211.202 Definitions.

For the purpose of this subpart—

"Base period" means the calendar quarter of 1973 which corresponds to the current quarter.

"Interruptible Customer" means any gas utility customer which has an alternative fuel source available on a regular basis or which has customers of its own who have such an alternative fuel source and who have not been curtailed.

"Other products" means solvents (including benzene, toluene xylene, and hexane when used for that purpose), diluents (including naphtha, special naphthas, kerosene, and other distillates when used for that purpose), feedstocks for synthetic natural gas plants, refined lubricating oils, allocated products used in the blending and compounding of lubricating oils and any other allocated products not subject to Subpart D–J of this part.

"Synthetic natural gas" means the gas which results from the manufacture, conversion or reforming of petroleum hydrocarbons which may be easily substituted for or interchanged with pipeline quality natural gas.

"Wholesale purchaser-consumer" means a wholesale purchaser-consumer as defined in § 211.51 or any firm which purchases other products at the wholesale level under a written contract.

§ 211.203 Allocation levels.

(a) General. The allocation levels listed in this section only apply to allocations made by suppliers to wholesale purchaser-consumers and end-users. Suppliers shall allocate to all purchasers to which the allocation levels apply in accordance with the provisions of § 211.10. End-users and wholesale purchaser-consumers which are entitled to purchase other products under an allocation level not subject to an allocation fraction shall receive first priority and be supplied sufficient amounts to meet 100 percent of their allocation requirements. End-users and wholesale purchaser-consumers which are entitled to purchase other products under a allocation level subject to reduction by application of an allocation fraction shall receive second priority.

(b) *Allocation levels not subject to an allocation fraction.* One hundred (100) percent of current requirements for the following uses:

(1) Agricultural production.

(2) Department of Defense for use as specified in § 211.26.

(c) *Allocation levels subject to the allocation fraction.* (1) One hundred (100) percent of current requirements (as reduced by the application of the allocation fraction) for the following uses:

(i) Emergency services;

(ii) Energy production;

(iii) Sanitation services;

(iv) Passenger transportation services;

(v) Telecommunications service;

(vi) Cargo, freight and mail hauling;

§ 211.204 Supplier/purchaser relationships.

(a) Each supplier of other products shall supply all wholesale purchasers which purchased other products during the base period.

(b) Supplier/purchaser relationships are as set forth in §§ 211.9–211.13.

§ 211.205 Method of allocation.

(a) Allocation of other products shall be made as specified in § 211.10 except that suppliers of allocated products used for blending and compounding of refined lubricating oils which have allocation fractions greater than one (1.0) shall not be required to report to FEO pursuant to § 211.10(g) the volume of surplus product available.

(b) Except as otherwise provided in this section, provisions to adjust a wholesale purchaser's base period volume are specified in § 211.13 and new wholesale purchasers and end-users are subject to the requirements of § 211.12.

(c) Notwithstanding the provisions of §§ 211.12 and 211.13, any wholesale purchaser-consumer of crude oil or allocated products for use as feedstock in synthetic natural gas production, which has requirements that exceed its base period volume or which had no base period volume may seek an adjustment of its base period volume or establishment of a base period volume only by notifying the FEO, in accordance with forms and instructions to be issued by the FEO, of the proposed base period volume or adjustment thereto and the basis upon which

the volume or adjustment was determined. The proposed base period volume or adjusted base period volume is subject to approval by FEO. The FEO shall, in granting or denying such assignment or adjustment, consider the following factors:

(1) The degree to which the wholesale purchaser has curtailed supplies of natural gas and synthetic natural gas to interruptible customers.

(2) Projected synthetic natural gas consumption and projected growth over the period of allocation.

(3) The source and volume of anticipated feedstocks.

(4) Attempts by the utility to obtain alternative gas and/or feedstock sources.

(5) Attempts by the utility to phase out natural gas service in areas that might be conveniently served by oil, coal, or electricity derived from nuclear power.

§ 211.206 Procedures and reporting requirements.

(a) All matters pertaining to the allocation of other products shall be addressed to the Administrator, Federal Energy Office, Washington, D.C. 20461.

(b) The general reporting and recordkeeping requirements contained in § 211.222 shall apply to this subpart.

18. Subpart L is revised to read as follows:

Subpart L—General Reporting and Recordkeeping Requirements

Sec.
211.221 Scope.
211.222 Monthly reports by refiners and importers.
211.223 Recordkeeping requirements.
211.224 Weekly petroleum reporting system.
211.225 Report of new end-user and wholesale purchaser-consumer importers.

AUTHORITY: Emergency Petroleum Allocation Act of 1973, Pub. L. 93-159; E.O. 11748, 38 FR 33575; Economic Stabilization Act of 1970, as amended, Pub. L. 92-210, 85 Stat. 743; Pub. L. 93-28, 87 Stat. 27; E.O. 11730, 38 FR 19345; Cost of Living Council Order Number 47, 39 FR 24.

Subpart L—General Reporting and Recordkeeping Requirements

§ 211.221 Scope.

This subpart provides the general reporting and recordkeeping requirements applicable to this part. Reporting and recordkeeping requirements that are limited in application to specific products or situations are contained in the other appropriate subparts of this part.

§ 211.222 Monthly reports by refiners and importers.

(a) Every refiner for each of its refineries; importer for each importing terminal; and gas processing plant operator for each of its processing plants shall report monthly to the National FEO the following information for each allocated product.

(1) The inventory at the beginning and end of the preceding month by allocated product.

(2) Deliveries received during the preceding month by allocated products; deliveries of domestic crude oil should be segmented into new and released domestic crude oil. All allocated products should be listed by source and by country of origin for imports.

(3) Inventory fluctuations which occurred during the preceding month and were caused by other than deliveries, receipts, and transfers.

(4) Total deliveries and supply redistribution in each State during the preceding month by allocated product.

(5) The estimated total supply for distribution in each State during the following month by product as described in § 211.10(b)(1) before adjustment for State set-aside and allocation requirements not subject to the supplier's allocation fraction.

(6) The estimated State set-aside volume for distribution in each State during the following month by product.

(7) The estimated volume by category for allocation requirements not subject to the supplier's allocation fraction to be supplied during the following month.

(8) Any existing inventory or production, importation, or purchase of an allocated product used to increase that inventory consistent with the provisions of § 211.22 by product.

(9) The allocable supply (i.e., subparagraph (5) minus subparagraphs (6), (7), and (8) of this paragraph), for distribution in each State during the following month, by product.

(10) The estimated supply obligation as described in § 211.10(b)(2) for the following month for purchasers to be supplied within each State, by product.

(11) The estimated average or shortfall, i.e., subparagraph (5) minus subparagraphs (7) and (10) of this paragraph.

(12) The estimated allocation fraction, i.e., subparagraph (9) divided by subparagraph (10) of this paragraph.

(13) The estimated total supply of allocated product which will be available in each of the following three (3) months.

(b) Beginning with the month of March 1974, and thereafter, prime suppliers shall report monthly to the National FEO, appropriate regional offices and appropriate State Offices subparagraphs (4) through (13) of paragraph (a) of this section by refiner (not refinery). This report will be the basis of the State set-aside program. Notwithstanding the provisions of § 205.4 of this chapter concerning constructive receipt of documents submitted by registered or certified mail, the prime supplier's monthly report must be delivered to the National FEO in Washington, D.C., on or before the tenth (10th) day prior to the commencement of the month described as "the following month" in § 211.222(a)(5).

§ 211.223 Recordkeeping requirements.

Suppliers which sell to wholesale purchaser-consumers and end-users shall maintain records on FEO forms, subject to FEO audit, which demonstrate the basis for distribution of allocable supplies among their various purchasers. These records shall contain the following information for each allocated product and for each purchaser, on a monthly basis:

(a) Purchaser identification.

(b) Base period volume, adjusted base period volume or current requirements, as appropriate.

(c) Allocation level.

(d) Allocation requirements (paragraph (c) multiplied by paragraph (b)) of this section.

(e) Purchaser's share of supplier's allocable supply (paragraph (d) of this section multiplied by the supplier's allocation fraction if the fraction applies).

(f) Actual volumes supplied.

§ 211.224 Weekly petroleum reporting system.

(a) This section establishes a weekly petroleum reporting system for each refiner or other firm which operates or controls a (1) refinery, (2) bulk terminal, (3) crude oil pipeline or (4) petroleum products pipeline, and for each importer which imports petroleum products by tanker, barge, or pipeline.

(b) *Definitions.* For the purposes of this section—

"Bulk terminal" means a facility which is primarily used for the marketing of gasoline, kerosene, and distillate and residual fuel oils and which (1) has total bulk storage capacity of 2,100,000 gallons or more, or (2) receives its petroleum products by tanker, barge or pipeline.

"Crude oil pipeline" means a common carrier pipeline, licensed by the Interstate Commerce Commission, which carries crude oil.

"Petroleum products pipeline" means a common carrier pipeline, licensed by the Interstate Commerce Commission, which carries petroleum products.

(c) *Initial report.* By February 15, 1974, every refiner or other firm, and every importer which receives petroleum products by tanker, barge or pipeline, shall prepare and file with FEO a report entitled "Petroleum Reporting Address Information," in accordance with forms and instructions issued by FEO.

(d) *Weekly report.* Every refiner or other firm, and every importer which receives petroleum products by tanker, barge or pipeline, shall prepare and file with FEO a weekly report in accordance with forms and instructions issued by FEO. The weekly petroleum reporting

system shall become effective, February 22, 1974. The first weekly report must be received by FEO by 5:00 p.m., March 4, 1974.

§ 211.225 Report of new end-user and wholesale purchaser-consumer importers.

Pursuant to § 211.12(g) new end-user and wholesale purchaser-consumer importers of an allocated product are required to report both to the National FEO and the appropriate regional FEO at least fifteen (15) days prior to commencing use of any allocated product which they import:

(a) The amounts and sources of these imports;

(b) Their intended use;

(c) Their projected monthly consumption; and

(d) A complete record of the domestic suppliers and amounts supplied of the allocated product which the purchaser intends to import, from January 1, 1972, to the date of the filing of the report.

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PART V



DEPARTMENT OF LABOR

Employment Standards Administration

■

Minimum Wages for Federal and Federally Assisted Construction

General Wage Determination Decisions

DEPARTMENT OF LABOR

Employment Standards Administration

MINIMUM WAGES FOR FEDERAL AND FEDERALLY ASSISTED CONSTRUCTION

General Wage Determination Decisions

General Wage Determination Decisions of the Secretary of Labor specify, in accordance with applicable law and on the basis of information available to the Department of Labor from its study of local wage conditions and from other sources, the basic hourly wage rates and fringe benefit payments which are determined to be prevailing for the described classes of laborers and mechanics employed in construction activity of the character and in the localities specified therein.

The determinations in these decisions of such prevailing rates and fringe benefits have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, (40 U.S.C. 276a)) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's Order No. 24–70) containing provisions for the payment of wages which are dependent upon determinations by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of Part 1 of Subtitle A of Title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates (37 FR 21138), and of Secretary of Labor's Orders 12–71 and 15–71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in effective date as prescribed in that section, because the necessity to issue construction industry wage determination frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General Wage Determination Decisions are effective from their date of publication in the FEDERAL REGISTER without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Accordingly, the applicable decision together with any modifications issued subsequent to its publication date shall be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR, Part 5. The wage rates contained therein shall be the minimum paid under such contract by contractors and subcontractors on the work.

Modifications and supersedeas decisions to general wage determination decisions. Modifications and Supersedeas Decisions to General Wage Determination Decisions are based upon information obtained concerning changes in prevailing hourly wage rates and fringe benefit payments since the decisions were issued.

The determinations of prevailing rates and fringe benefits made in the Modifications and Supersedeas Decisions have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's Order No. 24–70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of Part 1 of Subtitle A of Title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates (37 FR 21138), and of Secretary of Labor's Orders 13–71 and 15–71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in foregoing General Wage Determination Decisions, as hereby modified, and/or superseded shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged in contract work of the character and in the localities described therein.

Modifications and Supersedeas Decisions are effective from their date of publication in the FEDERAL REGISTER without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5.

Any person, organization, or governmental agency having an interest in the wages determined as prevailing is encouraged to submit wage rate information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Office of Special Wage Standards, Division of Wage Determinations, Washington, D.C. 20210. The cause for not utilizing the rule-making procedures prescribed in 5 U.S.C. 553 has been set forth in the original General Wage Determination Decision.

New General Wage Determination Decisions

Kansas	AQ–88
Louisiana	AQ–90
Pennsylvania	AQ–2078, AQ–2079, AQ–2081, AQ–2084

Modifications to General Wage Determination Decisions

The numbers of the decisions being modified and their dates of publication in the FEDERAL REGISTER are listed with each State:

Colorado:	
AQ–1012	Aug. 17, 1973
AQ–1061	Nov. 30, 1973
Georgia:	
AQ–4068	Feb. 15, 1974
Iowa:	
AQ–3	July 20, 1973
AQ–11; AQ–12; AQ–16	Aug. 3, 1973
Missouri:	
AQ–85	Mar. 8, 1974
Oklahoma:	
AQ–64	Dec. 7, 1973
Tennessee:	
AM–8623	June 16, 1972
AQ–4011	Sept. 21, 1973
AQ–4014; AQ–4015; AQ–4016	Oct. 5, 1973
Texas:	
AQ–70	Jan. 11, 1974

Supersedeas Decisions to General Wage Determination Decisions

The numbers of the decisions being superseded and their dates of publication in the FEDERAL REGISTER are listed with each State; Supersedeas Decision numbers are in parentheses following the number of the decisions being superseded:

Alabama:	
AQ–4027(AQ–4096)	Oct. 19, 1973
AQ–4034(AQ–4095)	Nov. 23, 1973
Arkansas:	
AP–701(AQ–89)	Feb. 9, 1973
New Jersey:	
AM–1719(AQ–2091)	Aug. 11, 1971
AP–828(AQ–2090)	May 18, 1973
West Virginia:	
AP–402(AQ–2088); AP–403 (AQ–2087)	July 21, 1972
AP–405(AQ–2089)	July 28, 1972
AP–801(AQ–2086)	Mar. 13, 1973

Signed at Washington, D.C., this 22d day of March 1974.

RAY J. DOLAN,
Assistant Administrator,
Wage and Hour Division.

NEW DECISION

STATE: Kansas COUNTIES: Geary and Riley
DECISION NO.: AQ-88 DATE: Date of Publication
DESCRIPTION OF WORK: Residential construction consisting of single family homes and garden type apartments up to and including 4 stories.

	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
Bricklayers	$6.75	.45	.25			
Carpenters	5.37					
Cement Masons	4.54					
Electricians	5.065					
Laborers	2.50					
Painters	5.00					
Plumbers (3 stories and under)	5.40	.425	.15		.05	
Plumbers (4 stories)	8.20	.425	.15		.05	
Roofers	5.50					
Sheet Metal Workers	5.21					
Sheet Rock Installers	5.69					
Sheet Rock Tapers	6.00					
Truck Drivers	3.00					
Power Equipment Operators:						
Backhoe	5.00					
Front End Loader	4.15					

NEW DECISION

STATE: Louisiana PARISH: Statewide
DECISION NO.: AQ-90 DATE: Date of Publication
DESCRIPTION OF WORK: Construction of Highways, Roads, Streets, Parking Areas (except those let with a building contract) and Erathen Dams.

	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
BRICKLAYERS & STONEMASONS 1						
ZONE 1	$7.09	.20	.15		.01	
ZONE 2	6.68					
ZONE 3	7.25	.30	.20		.02	
ZONE 4	7.90	.25	.15		.035	
ZONE 5	6.75					
ZONE 6	6.68					
ZONE 7	7.25	.20	.20			
ZONE 8	7.45		.20			
ZONE 9	7.50					
ZONE 10	7.65					
CARPENTERS 2						
ZONE 1	6.55					
ZONE 2	6.555	.25	.18		.05	
ZONE 3	5.80					
ZONE 4	6.60	.20	.20		.04	
ZONE 5	7.52	.20	.20		.04	
ZONE 6	7.355	.20	.20		.04	
ZONE 7	6.15					
ZONE 8	6.95		.25		.03	
ZONE 9	6.15					
ZONE 10	6.00	.35	.20		.05	
PILEDRIVERMEN 3						
ZONE 1	6.10					
ZONE 2	6.60	.20	.20		.04	
ZONE 3	7.62	.20	.20		.04	
ZONE 4	6.955				.05	
ZONE 5	6.55					
ZONE 6	7.20		.25		.03	
ZONE 7	6.65					
ZONE 8	6.50	.35	.20		.05	
CEMENT MASONS 4						
ZONE 1	5.70					
ZONE 2	5.20					

	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
ELECTRICIANS 5						
ZONE 1						
Electricians	$8.10	.25	1%+.30		3/10%	
Cable splicers	8.35	.25	1%+.30		3/10%	
ZONE 2						
Electricians	7.25		1%			
Cable splicers	7.75		1%			
ZONE 3						
Electricians	8.20	.35	1%+.10		1/10%	
Cable splicers	8.45	.35	1%+.10		1/10%	
ZONE 4						
Electricians	8.20	.25	1%			
Cable splicers	8.45	.25	1%			
ZONE 5						
Electricians	8.18	.30	1%+.20		.03	
Cable splicers	8.18	.30	1%+.20		.03	
ZONE 6						
Electricians	7.70	.30	1%		1/2%	
Cable splicers	8.20	.30	1%		1/2%	
ZONE 7						
Electricians	7.40	.40	1%		1%	
Cable splicers	7.90	.40	1%		1%	
ZONE 8						
Electricians	7.45	.35	1%		1/2%	
Cable splicers	7.70	.35	1%		1/2%	
IRONWORKERS 6						
ZONE 1	7.92					
ZONE 2	7.68					
ZONE 3	7.90					
ZONE 4	7.50					
ZONE 5	7.36					
ZONE 6	6.35					
ZONE 7	5.85					
ZONE 8	5.30					

LABORERS 7	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
GROUP 1						
ZONE 1	$4.40	.10	.10		.05	
ZONE 2	4.10	.10	.10		.05	
ZONE 3	3.70	.10	.10		.05	
ZONE 4	4.40	.10	.10		.05	
ZONE 5	3.40	.10	.10		.05	
GROUP 2						
ZONE 1	4.50	.10	.10		.05	
ZONE 2	4.20	.10	.10		.05	
ZONE 3	3.80	.10	.10		.05	
ZONE 4	4.50	.10	.10		.05	
ZONE 5	3.50	.10	.10		.05	
GROUP 3						
ZONE 1	4.95	.10	.10		.05	
ZONE 2	4.65	.10	.10		.05	
ZONE 3	4.25	.10	.10		.05	
ZONE 4	4.95	.10	.10		.05	
ZONE 5	3.95	.10	.10		.05	
GROUP 4						
ZONE 1	5.20	.10	.10		.05	
ZONE 2	4.90	.10	.10		.05	
ZONE 3	4.50	.10	.10		.05	
ZONE 4	5.20	.10	.10		.05	
ZONE 5	4.15	.10	.10		.05	

TRUCK DRIVERS 7	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
GROUP 1						
ZONE 1	$4.75					
ZONE 2	4.75					
ZONE 3	4.55					
ZONE 4	4.87					
ZONE 5	3.95					
GROUP 2						
ZONE 1	4.85					
ZONE 2	4.85					
ZONE 3	4.63					
ZONE 4	4.97					
ZONE 5	4.05					
GROUP 3						
ZONE 1	4.90					
ZONE 2	4.90					
ZONE 3	4.80					
ZONE 4	5.02					
ZONE 5	4.10					
GROUP 4						
ZONE 1	4.95					
ZONE 2	4.95					
ZONE 3	4.95					
ZONE 4	5.07					
ZONE 5	4.15					
GROUP 5						
ZONE 1	5.10					
ZONE 2	5.10					
ZONE 3	5.27					
ZONE 4	5.22					
ZONE 5	4.30					

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	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
PAINTERS 8						
ZONE 1						
Brush	$6.01					
Brush on steel	6.135					
ZONE 2						
Brush	6.15		.10			
Steel	6.76		.10			
ZONE 3						
Brush	5.875	.175	.20		.05	
Structural steel	6.25	.175	.20		.05	
ZONE 4						
Brush	5.85					
Steel	6.22					
ZONE 5						
Brush	4.25					
ZONE 6						
Brush	5.45					
ZONE 7						
Brush	6.25					
Structural steel	6.25					
ZONE 8						
Brush	5.60					
Structural steel, brush	6.10					

AQ-90 P. 6

	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
POWER EQUIPMENT OPERATORS 9						
GROUP 1						
ZONE 1	$7.53	.25	.15			
ZONE 2	7.41	.25	.15			
ZONE 3	7.21	.25	.15			
ZONE 4	7.36	.25	.15			
ZONE 5	6.20	.25	.15			
ZONE 6	5.70	.25	.15			
ZONE 7	5.15	.25	.15			
GROUP 2						
ZONE 1	7.78	.25	.15			
ZONE 2	7.66	.25	.15			
ZONE 3	7.46	.25	.15			
ZONE 4	7.61	.25	.15			
ZONE 5	6.45	.25	.15			
ZONE 6	5.95	.25	.15			
ZONE 7	5.40	.25	.15			
GROUP 3						
ZONE 1	7.28	.25	.15			
ZONE 2	7.16	.25	.15			
ZONE 3	6.96	.25	.15			
ZONE 4	7.11	.25	.15			
ZONE 5	5.95	.25	.15			
ZONE 6	5.45	.25	.15			
ZONE 7	4.90	.25	.15			
GROUP 4						
ZONE 1	6.42	.25	.15			
ZONE 2	6.35	.25	.15			
ZONE 3	6.15	.25	.15			
ZONE 4	6.16	.25	.15			
ZONE 5	5.17	.25	.15			
ZONE 6	4.67	.25	.15			
ZONE 7	4.15	.25	.15			

POWER EQUIPMENT OPERATORS (CONT'D)	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Yr.	Others
GROUP 5						
ZONE 1	$6.13	.25	.15			
ZONE 2	5.71	.25	.15			
ZONE 3	5.71	.25	.15			
ZONE 4	5.70	.25	.15			
ZONE 5	4.67	.25	.15			
ZONE 6	4.17	.25	.15			
ZONE 7	3.71	.25	.15			
GROUP 6						
ZONE 1	5.61	.25	.15			
ZONE 2	5.15	.25	.15			
ZONE 3	5.15	.25	.15			
ZONE 4	5.15	.25	.15			
ZONE 5	4.52	.25	.15			
ZONE 6	4.02	.25	.15			
ZONE 7	3.56	.25	.15			
GROUP 7						
ZONE 1	5.36	.25	.15			
ZONE 2	4.90	.25	.15			
ZONE 3	4.90	.25	.15			
ZONE 4	4.90	.25	.15			
ZONE 5	4.52	.25	.15			
ZONE 6	4.02	.25	.15			
ZONE 7	3.56	.25	.15			
GROUP 8						
ZONE 1	6.42	.25	.15			
ZONE 2	6.35	.25	.15			
ZONE 3	6.15	.25	.15			
ZONE 4	6.16	.25	.15			
ZONE 5	5.17	.25	.15			
ZONE 6	4.67	.25	.15			
ZONE 7	4.15	.25	.15			

POWER EQUIPMENT OPERATORS (CONT'D)	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Yr.	Others
GROUP 9						
ZONE 1	$6.67	.25	.15			
ZONE 2	6.60	.25	.15			
ZONE 3	6.40	.25	.15			
ZONE 4	6.41	.25	.15			
ZONE 5	5.42	.25	.15			
ZONE 6	4.92	.25	.15			
ZONE 7	4.40	.25	.15			
GROUP 10						
ZONE 1	5.61	.25	.15			
ZONE 2	5.15	.25	.15			
ZONE 3	5.15	.25	.15			
ZONE 4	5.15	.25	.15			
ZONE 5	4.77	.25	.15			
ZONE 6	4.27	.25	.15			
ZONE 7	3.81	.25	.15			
LINE CONSTRUCTION 10						
ZONE 1						
Linemen	8.18	.30	1%+.20		.03	
Operator hole digging equipment; operator, tractor with winch & derrick; operator line truck with winch & derrick working hot lines	75%JR	.30	1%+.20		.03	
Operator using hole truck & trailer, or pole hauling & setting truck (not in energized lines)	65%JR	.30	1%+.20		.03	
Operator using truck without winch	45%JR	.30	1%+.20		.03	
Groundmen (1½ yrs. service or over)	50%JR	.30	1%+.20		.03	
Groundmen (starting rate to 1½ yrs. service)	45%JR	.30	1%+.20		.03	
ZONE 2						
Linemen, line equipment & line truck operators	8.10	.25	1%+.30		3/10%	
Cable splicers	8.35	.25	1%+.30		3/10%	

	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Yr.	Others
LINE CONSTRUCTION (CONT'D)						
ZONE 3						
Linemen, equipment operators	$8.20	.35	1%+.10		1/10%	
Cable splicers	8.45	.35	1%+.10		1/10%	
Groundmen	6.20	.35	1%+.10		1/10%	
ZONE 4						
Linemen & equipment operators	8.20	.25	1%			
Cable splicers	8.45	.25	1%			
Groundmen	50%JR	.25	1%			
ZONE 5						
Linemen & equipment operators	7.45	.35	1%		1/2%	
Cable splicers	7.70	.35	1%		1/2%	
Groundmen	60%JR	.35	1%		1/2%	
ZONE 6						
Linemen & equipment operators	7.70	.30	1%		1/2%	
Cable splicers	8.20	.30	1%		1/2%	
ZONE 7						
Linemen & equipment operators	7.40	.40	1%		1%	
Cable splicers	7.90	.40	1%		1%	

CLASSIFICATION DEFINITIONS

LABORERS

GROUP 1: Laborers, including but not limited to signalman, foundation driller, and demolishing and dismantling man

GROUP 2: Raker, concrete spreader, carpenters helpers, distributor man, finishers helpers, formsetters helpers, jackhammer operator, jetting laborer, painters helpers, pit man, pipelayer or tile layer, powder monkey helper, tamper, tree pruner, stone masons helper, stoker, asphalt raker, concrete shovelers, power tool operator and motorized buggy operator

GROUP 3: Formsetter, head or master--high type pavement

GROUP 4: Powderman

TRUCK DRIVERS

GROUP 1: One ton and under: Warehouseman, material checker, receiving clerk, spotter and dumper

GROUP 2: One and one-half (1½) tons to and including two (2) tons (exclusive of dump trucks), truck mechanic helper

GROUP 3: Single axle dump trucks, single axle water trucks

GROUP 4: Heavy equipment, tandem axle dump and tandem axle water trucks, winch lift, transit mix, floats, pole trailer, four axle trailer and truck mechanic

GROUP 5: Special equipment, euclids and five axle moving equipment

POWER EQUIPMENT OPERATORS

GROUP 1: Over 60 ton crane; Crane with 125' boom

GROUP 2: Crane with 175' boom

GROUP 3: Heavy Duty Operators-Crane all types; deck winches (2); Hi-Ho and similar type equipment; three drum (or more) stabilizers; pulls all types; concrete mixer one yard and over; all pavers; ditching or trenching machines (track type); mechanics and equipment welders; well-point systems; hoist, two drums or more; hoist, one drum, forty vertical feet or more; scrapers; bulldozers, rubber-tired or track other than farm-type; scoopmobiles; motor patrol; gradall; rollers on hot mix; asphalt paving machines; front end loaders, other than farm-type, one cubic yard or over; shovels and backhoes, all types, and equivalent equipment; piledriver operator; sideboom cats; A-frame trucks when handling steel or pipe; work boats requiring licensed operators; tugboats; fork lifts over 10 ton capacity; and foundation drilling machines

GROUP 4: Medium Duty Operators-Two drum stabilizers; front end loaders under 1 cubic yard; A-frame truck except when handling steel or pipe; finishing machines (concrete); power subgraders; two tractors (crawler type); one drum hoist under 40 vertical feet; fireman; concrete spreader; pugmill operator; bituminous distributor on surface treatment and equivalent; bull floats and equivalent; job grease man on "Highway Construction"; unit operator (all Highway Zones); work boats not requiring licensed operators; inboard motored crew boats

GROUP 5: Light Duty Operators-Single drum stabilizer; concrete mixer under one yard; spray curing machines; rollers on subgrade; one air compressor over 125 cubic feet; form graders; asphalt finisher screed man; pump over 4 inches; scale operators; crusher operators; concrete jointing machines; concrete saw; tack machines and equivalent equipment; pump crete; electric elevator (inside); oiler driver; farm-type, rubber-tired tractor, with attachments, except backhoes; Kolum buff and similar equipment; fork lifts, ten ton capacity and under; outboard motored crew boats

GROUP 6: Mechanic Helper; Batch Plant Operator

GROUP 7: Oiler

GROUP 8: Fireman

GROUP 9: Fireman Operating Steam Valve

GROUP 10: Oiler on Crane Using Air to Drive Piles

AREA COVERED BY VARIOUS ZONES

1

BRICKLAYERS & STONEMASONS

ZONE 1 - Ascension, East Baton Rouge, East Feliciana, Iberville, Livingston, St. Helena, Tangipahoa, West Baton Rouge & West Feliciana Parishes
ZONE 2 - Evangeline, Pointe Coupee & St. Landry Parishes
ZONE 3 - Acadia, Allen, Beauregard, Calcasieu, Cameron, Jefferson Davis, Vermilion & Vernon Parishes
ZONE 4 - Assumption, Jefferson, Lafourche, Orleans, Plaquemines, St. Bernard, St. Charles, St. James, St. John the Baptist, St. Tammany (extending northward to that part of St. Tammany Parish from the Tangipahoa Parish line on the west, along U.S. Highway #190 through the lower limits of Covington, along State Highway #58, through the lower limits of Abita Springs & Talisheek & on a line due east from Talisheek to the Mississippi State Line) & Terrebonne Parishes
ZONE 5 - St. Tammany (north half including Covington north of Highway #190) & Washington Parishes
ZONE 6 - Avoyelles, Catahoula, Concordia, Grant, LaSalle & Rapides Parishes
ZONE 7 - Bienville, Bossier, Caddo, Claiborne, DeSoto, Red River & Webster Parishes
ZONE 8 - Natchitoches & Sabine Parishes
ZONE 9 - Caldwell, East Carroll, Franklin, Jackson, Lincoln, Madison, Morehouse, Ouachita, Richland, Tensas, Union, West Carroll & Winn Parishes
ZONE 10 - Iberia, Lafayette, St. Martin & St. Mary Parishes

2

CARPENTERS

ZONE 1 - Acadia, Evangeline, Iberia (west of the Atchafalaya River), Lafayette, St. Landry, St. Martin (west of the Atchafalaya River), St. Mary (west of the Atchafalaya River) & Vermilion Parishes
ZONE 2 - Allen, Beauregard, Calcasieu, Cameron, Jefferson Davis & Vernon Parishes
ZONE 3 - St. Tammany (to the overpass at Slidell, Louisiana, along State Highway #464 in St. Tammany Parish to the city limits of the town of Ponchatoula running north & south to Amite, Louisiana in Tangipahoa Parish including the town of Covington, Louisiana in St. Tammany Parish), Tangipahoa & Washington Parishes
ZONE 4 - Ascension (north of the Mississippi River), East Baton Rouge, East Feliciana, Iberville, Livingston, Pointe Coupee, St. Helena, St. James (north of the Mississippi River), West Baton Rouge & West Feliciana Parishes
ZONE 5 - Ascension (south of the Mississippi River), Assumption, Jefferson, Orleans, Plaquemines, St. Bernard, St. Charles, St. James (south of the Mississippi River) & St. John the Baptist Parishes
ZONE 6 - Iberia (northeast of the Atchafalaya River), Lafourche, St. Martin (southern segment), St. Mary (northeast of the Atchafalaya River), St. Tammany (southern portion) & Terrebonne Parishes
ZONE 7 - Avoyelles, Grant, LaSalle & Rapides Parishes
ZONE 8 - Bienville, Bossier, Caddo, Claiborne, DeSoto, Red River & Webster Parishes
ZONE 9 - Natchitoches & Sabine Parishes
ZONE 10 - Caldwell, Catahoula, Concordia, East Carroll, Franklin, Jackson, Lincoln, Madison, Morehouse, Ouachita, Richland, Tensas, Union, West Carroll & Winn Parishes

3

PILEDRIVERMEN

ZONE 1 - St. Tammany (to the overpass at Slidell, Louisiana, along State Highway #464 in St. Tammany Parish to the city limits of the town of Ponchatoula running north & south to Amite, Louisiana in Tangipahoa Parish, including the town of Covington, Louisiana in St. Tammany Parish), Tangipahoa & Washington Parishes
ZONE 2 - Ascension (north of the Mississippi River), East Baton Rouge, East Feliciana, Iberville, Livingston, Pointe Coupee, St. Helena, St. James (north of the Mississippi River), West Baton Rouge & West Feliciana Parishes
ZONE 3 - Ascension (south of the Mississippi River), Assumption, Jefferson, Lafourche, Orleans, Plaquemines, St. Bernard, St. Charles, St. James (south of the Mississippi River), St. John the Baptist, St. Martin (southern segment), St. Mary (northeast of the Atchafalaya River), St. Tammany (southern portion) & Terrebonne Parishes
ZONE 4 - Acadia, Allen, Beauregard, Calcasieu, Cameron, Evangeline, Iberia, Jefferson Davis, Lafayette, St. Landry, St. Martin (west of the Atchafalaya River), St. Mary (west of the Atchafalaya River), Vermilion & Vernon Parishes
ZONE 5 - Avoyelles, Grant, LaSalle & Rapides Parishes
ZONE 6 - Bienville, Bossier, Caddo, Claiborne, DeSoto, Red River & Webster Parishes
ZONE 7 - Natchitoches & Sabine Parishes
ZONE 8 - Caldwell, Catahoula, Concordia, East Carroll, Franklin, Jackson, Lincoln, Madison, Morehouse, Ouachita, Richland, Tensas, Union, West Carroll & Winn Parishes

4

CEMENT MASONS

ZONE 1 - Acadia, Allen, Ascension, Assumption, Avoyelles, Beauregard, Bienville, Bossier, Caddo, Calcasieu, Cameron, Claiborne, DeSoto, East Baton Rouge, East Feliciana, Evangeline, Iberia, Iberville, Jefferson, Jefferson Davis, Lafayette, Lafourche, Lincoln, Livingston, Madison, Natchitoches, Orleans, Ouachita, Pointe Coupee, Rapides, Red River, Richland, St. Bernard, St. Charles, St. Helena, St. James, St. John the Baptist, St. Landry, St. Martin, St. Mary, St. Tammany, Tangipahoa, Terrebonne, Vermilion, Vernon, Webster, West Baton Rouge & West Feliciana Parishes
ZONE 2 - Caldwell, Catahoula, Concordia, East Carroll, Franklin, Grant, Jackson, LaSalle, Morehouse, Plaquemines, Sabine, Tensas, Union, Washington, West Carroll & Winn Parishes

5

ELECTRICIANS

ZONE 1 - Ascension, East Baton Rouge, East Feliciana, Iberville, Livingston, Pointe Coupee, St. Helena, St. Landry, West Baton Rouge & West Feliciana Parishes
ZONE 2 - St. Tammany, Tangipahoa & Washington Parishes
ZONE 3 - Allen, Beauregard, Calcasieu, Cameron & Jefferson Davis Parishes
ZONE 4 - Acadia, Iberia, Lafayette, St. Martin (that portion north of Iberia Parish), St. Mary (that portion southwest of the Atchafalaya River) & Vermilion Parishes
ZONE 5 - Assumption, Jefferson, Lafourche, Orleans, Plaquemines, St. Bernard, St. Charles, St. James, St. John the Baptist, St. Martin (that portion south of Iberia Parish), St. Mary (that portion northeast of the Atchafalaya River) & Terrebonne Parishes

ELECTRICIANS CONTINUED
ZONE 6 - Avoyelles, Catahoula, Concordia, Evangeline, Grant, LaSalle, Natchitoches (that portion southwest of the Red River), Rapides, Sabine, Vernon & Winn Parishes
ZONE 7 - Bienville, Bossier, Caddo, Claiborne, DeSoto, Natchitoches (that portion northeast of the Red River), Red River & Webster Parishes
ZONE 8 - Caldwell, East Carroll, Franklin, Jackson, Lincoln, Madison, Morehouse, Ouachita, Richland, Tensas, Union & West Carroll Parishes

6
IRONWORKERS
ZONE 1 - Jefferson & Orleans Parishes
ZONE 2 - Plaquemines, St. Bernard & St. Charles Parishes
ZONE 3 - East Baton Rouge Parish
ZONE 4 - Calcasieu Parish
ZONE 5 - Bossier & Caddo Parishes
ZONE 6 - Lafayette, Ouachita & Rapides Parishes
ZONE 7 - Acadia, Ascension, Bienville, Cameron, DeSoto, Iberia, Iberville, Jefferson Davis, Livingston, Red River, Richland, St. James, St. John the Baptist, St. Landry, St. Martin (that portion north of Iberia Parish), St. Tammany, Tangipahoa, Vermilion, Washington, Webster & West Baton Rouge Parishes
ZONE 8 - Allen, Assumption, Avoyelles, Beauregard, Caldwell, Catahoula, Claiborne, Concordia, East Carroll, East Feliciana, Evangeline, Franklin, Grant, Jackson, Lafourche, LaSalle, Lincoln, Madison, Morehouse, Natchitoches, Pointe Coupee, Sabine, St. Helena, St. Martin (that portion south of Iberia Parish), St. Mary, Tensas, Terrebonne, Union, Vernon, West Carroll, West Feliciana & Winn Parishes

7
LABORERS & TRUCK DRIVERS
ZONE 1 - Jefferson, Orleans, Plaquemines, St. Bernard & St. Charles Parishes
ZONE 2 - East Baton Rouge Parish
ZONE 3 - Bossier & Caddo Parishes
ZONE 4 - Calcasieu Parish
ZONE 5 - Acadia, Allen, Ascension, Assumption, Avoyelles, Beauregard, Bienville, Caldwell, Cameron, Catahoula, Claiborne, Concordia, DeSoto, East Carroll, East Feliciana, Evangeline, Franklin, Grant, Iberia, Iberville, Jackson, Jefferson Davis, Lafayette, Lafourche, LaSalle, Lincoln, Livingston, Madison, Morehouse, Natchitoches, Ouachita, Pointe Coupee, Rapides, Red River, Richland, Sabine, St. Helena, St. James, St. John the Baptist, St. Landry, St. Martin, St. Mary, St. Tammany, Tangipahoa, Tensas, Terrebonne, Union, Vermilion, Vernon, Washington, Webster, West Baton Rouge, West Carroll, West Feliciana & Winn Parishes

8
PAINTERS
ZONE 1 - Allen (except Northeast Corner), Beauregard, Calcasieu, Cameron, Jefferson Davis & Vernon Parishes
ZONE 2 - Ascension (north & west of Highway #22), Assumption (north of Grand Bayou), East Baton Rouge, East Feliciana, Iberville, Livingston (north & west of Highway #22), Pointe Coupee, St. Helena, Tangipahoa (west of Highway #51), West Baton Rouge & West Feliciana Parishes
ZONE 3 - Ascension (east & south of Highway #22), Assumption (south of Grand Bayou), Lafourche, Livingston (east & south of Highway #22), Jefferson, Orleans, Plaquemines, St. Bernard, St. Charles, St. James, St. John the Baptist, St. Mary (Morgan City Area), St. Tammany (southern portion) & Terrebonne Parishes
ZONE 4 - Acadia, Iberia, Lafayette, St. Landry (south half), St. Martin, St. Mary (except Morgan City Area) & Vermilion Parishes
ZONE 5 - St. Tammany (northern portion), Tangipahoa (east of Highway #51) & Washington Parishes
ZONE 6 - Allen (northeast corner), Avoyelles, Catahoula, Evangeline, Grant, LaSalle, Natchitoches (south half), Rapides, St. Landry (north half) & Winn (south half) Parishes
ZONE 7 - Bienville, Bossier, Caddo, Claiborne, DeSoto, Natchitoches (to City of Natchitoches), Red River, Sabine & Webster Parishes
ZONE 8 - Caldwell, Concordia, East Carroll, Franklin, Jackson, Lincoln, Madison, Morehouse, Ouachita, Richland, Tensas, Union, West Carroll & Winn (north half) Parishes

9
POWER EQUIPMENT OPERATORS
ZONE 1 - Jefferson, Orleans, Plaquemines, St. Bernard & St. Charles Parishes
ZONE 2 - Ascension, East Baton Rouge, Iberville & West Baton Rouge Parishes
ZONE 3 - Bossier, Caddo & Red River Parishes
ZONE 4 - Calcasieu, Cameron & Jefferson Davis Parishes
ZONE 5 - Lafayette, Ouachita & Rapides Parishes
ZONE 6 - Acadia, Bienville, DeSoto, Iberia, Livingston, Richland, St. James, St. John the Baptist, St. Landry, St. Martin (north of Iberia Parish), St. Tammany, Tangipahoa, Vermilion, Washington & Webster Parishes
ZONE 7 - Allen, Assumption, Avoyelles, Beauregard, Caldwell, Catahoula, Claiborne, Concordia, East Carroll, East Feliciana, Evangeline, Franklin, Grant, Jackson, Lafourche, LaSalle, Lincoln, Madison, Morehouse, Natchitoches, Pointe Coupee, Sabine, St. Helena, St. Martin (south of Iberia Parish), St. Mary, Tensas, Terrebonne, Union, Vernon, West Carroll, West Feliciana & Winn Parishes

10

LINE CONSTRUCTION

ZONE 1 - Assumption, Jefferson, Lafourche, Orleans, Plaquemines, St. Bernard, St. Charles, St. James, St. John the Baptist, St. Martin (that portion south of Iberia Parish), St. Mary (that portion northeast of the Atchafalaya River) & Terrebonne Parishes

ZONE 2 - Ascension, East Baton Rouge, East Feliciana, Iberville, Livingston, Pointe Coupee, St. Helena, St. Landry, West Baton Rouge & West Feliciana Parishes

ZONE 3 - Allen, Beauregard, Calcasieu, Cameron & Jefferson Davis Parishes

ZONE 4 - Acadia, Iberia, Lafayette, St. Martin (that portion north of Iberia Parish), St. Mary (that portion southwest of the Atchafalaya River) & Vermilion Parishes

ZONE 5 - Caldwell, East Carroll, Franklin, Jackson, Lincoln, Madison, Morehouse, Ouachita, Richland, Tensas, Union & West Carroll Parishes

ZONE 6 - Avoyelles, Catahoula, Concordia, Evangeline, Grant, LaSalle, Natchitoches (that portion southwest of the Red River), Rapides, Sabine, Vernon & Winn Parishes

ZONE 7 - Bienville, Bossier, Caddo, Claiborne, DeSoto, Natchitoches (that portion northeast of the Red River), Red River & Webster Parishes

NEW DECISION

STATE: Pennsylvania COUNTY: Chester
DECISION NO.: AQ-2078 DATE: Date of Publication
DESCRIPTION OF WORK: Building Construction, (excluding single family homes and garden type apartments up to and including 4 stories)

15-PA-1-E 1 of 2

BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
Asbestos workers	$ 9.62	.50	.50		.01	
Boilermakers	9.12	.50	1.00	.25	.01	
Bricklayers	8.66	.77	.45	.45	½%	
Carpenters	8.77	1.23	.55		.07	
Cement masons:						
Oxford, Kenneth Square, Avondale & Longwood	8.70	.58	.42			
Remainder of County	8.00	.84	.50			
Electricians:						
Oxford, Kenneth Square, Avondale & Longwood	9.04	4%	4%		¼ of 1%	
Parkersburg, West Grove & West Chester	10.30	.45	1%+.17		½ of 1%	
West Clan, West Brandywine, Honey Brook, Wallace, West Natmeal, East Natmeal, Warwick, South Coventry, Valley Twps. & Coatesville	8.74	.28	1%		.03	
Remainder of County	10.25	.35	.22		1½%	
Elevator Constructors	9.25	.345	.23	2%+b+c	.015	
Elevator Constructors, helpers	6.475	.345	.23	2%+b+c	.015	
Elevator Constructors helpers (prob.)	4.625					
Glaziers:						
Warwick, S. Coventry, El Coventry, N. Coventry, Spring City & Royersford	7.32	.25	.10		.01	
Remainder of County	8.38	.35	.30		.01	
Ironworkers	8.95	.64	1.06		.05	
Lathers:						
Coatesville, & Lower part of County	8.35	.20	.15		.01	
Remainder of County	8.61	.225	.10			
Lead burners	8.75	.30		d	.01	
Line Construction:						
Linemen & Cable Splicers	10.74	.20	1%		1%	
Groundmen	6.44	.20	1%		1%	
Winch truck operator	7.52	.20	1%		1%	
Marble setters	7.35	.57	.55	.50		
Marble setters helpers	6.235	.50	.45			
Millwrights	9.27	1.23	.55		.07	
Painters:						
Commercial						
Brush	7.35	.35	.20			
Spray	7.60	.35	.20			
Piledrivermen	9.42	1.23	.55		.07	

AQ-2078 P. 2
15-PA-1-E 2 of 2

BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
Plasterers:						
Longwood, Kennett Square, Avondale & Oxford	$ 8.57	.45			.01	
Remainder of County	9.02	.53			.01	
Pointers, caulkers & cleaners	8.25	.35	.50			
Plasterers' tenders	5.16	.125	.10			
Plumbers & Steamfitters:						
Tedyffrin, E. Whiteland, W. Whiteland, Easttown, Willistown, E. Goshen, W. Goshen, W. Chester, E. Bradford, Westtown, Birmingham, Twps. & Thornbury City	9.52	.57	.92		.05	
Remainder of County	8.50	.485	.82		.035	
Roofers:						
(Parkersburg) Composition, Damp & Waterproofing	8.725	.375	.10	f		
Slate, tile & asbestos	9.175	.375	.10	f		
Precast slab	9.525	.375	.10	f		
Remainder of County:						
Composition	8.815	1.00	.55	e		
Helpers	4.70	.80	.55	e		
Sheet metal workers	10.00	.52	.50		.01	
Soft floor layers	7.53	.93	.55		.07	
Sprinkler fitters	9.70	.30	.50		.05	
Stone masons	8.66	.77	.45	.45	½%	
Terrazzo workers	7.58	.47	.45	.50		
Terrazzo workers' helpers	5.31	.15				
Tile setters	7.575	.70	.25			
Tile setters' helpers	5.125	.20				
Welders - receive rate prescribed for craft performing operation to which welding is incidental						

PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day; G-Election Day.

FOOTNOTES

b. Employer contributes 4% of basic hourly rate for 5 years or more of service or 2% basic hourly rate for 6 months to 5 years of service as Vacation Pay Credit.

c. Six paid holidays: A through F.

d. Paid Holidays: A through F and Washington's Birthday and Good Friday and Christmas Eve provided the employee has worked 45 full days for the employer during the 120 days prior to the holiday, and is available for work the day preceding and following the holiday.

e. Paid Holiday: Election Day.

f. Paid Holiday: Labor Day and Election Day

PA-51-LAB - W

Building Construction	BASIC HOURLY RATES	FRINGE BENEFITS PAYMENTS H & W	PENSIONS	VACATION	APP. TR.	OTHERS
Laborers:						
Stripping & dismantling concrete form work, loading, unloading, carrying & handling of all reinforced steel & steel mesh, handling lumber and other building materials, operating jackhammers, paving breakers & all other pheumatic tools, building scaffolds, raking, shoveling & tamping of asphalt, spading & concrete pit work, grading, form pinning, shoring, demolition except burners, laying conduits and ducts, sheathing, lagging, laying non-metallic pipe & caulking, all other types of Laborers	$6.71	.44	.20			
Mason tender, power buggies, burners on demolition	6.81	.44	.20			
Wagon drill operator (single)	6.86	.44	.20			
Powdermen, wagon drill operator (multiple)	7.01	.44	.20			
Circular Caissons Excavation:						
Caisson groundmen	7.01	.44	.20			
Caisson bottom man	7.11	.44	.20			
Underpinning Excavation:						
Laborers, working at depth of 8 feet or under	7.01	.44	.20			
Yard workers	6.65	.44	.20			

POWER EQUIPMENT OPERATORS
BUILDING CONSTRUCTION

PA-51-PEO-1 - E 1 of 2

	Basic Hourly Rates	FRINGE BENEFITS PAYMENTS H & W	Pensions	Vacation	App. Tr.	Other
WAGE GROUP I						
Handling Steel and stone in connection with erection; Cranes doing hook work; Any machines handling machinery; Cable Spinning machine; Helicopters; Machines similar to the above	$9.75	4.6%	9.5%	a	1.2%	
WAGE GROUP II						
Engineers working with Dock Builders and Pile Drivers All types of cranes All types of backhoes; Cableways; Draglines; Keystones; All types of shovels; Derricks; Trench shovels; Trenching machines; Pippin type backhoes; Hoist with two towers; Pavers 21E and over; All types overhead cranes; Building Hoists - double drum (unless used as single drum); Mucking Machines in tunnel; Gradalls; Front-end loaders over 3 cu. yd., Boat Captain; Tandem scrapers; Tower type crane operation, erecting, dismantling, jumping or jacking; Drills self-contained (Drillmaster type); Fork Lift (20 ft. and over), Motor Patrols (Fine Grade), Batch Plant with Mixer; Machines similar to the above	9.49	4.6%	9.5%	a	1.2%	
WAGE GROUP III						
Conveyors (Except Building Conveyors), Building Hoists (single drum), Scrapers and Tournapulls, Asphalt plant engineers, Roller (High Grade finishing); Caterpillar-type tractors with front-end overhead loaders and Rubber-tired loaders 2 c.y. up to & including 3 c.y. Maintenance Engineers with tools; Spreaders, High or low pressure boilers, Concrete pumps, Well drillers, Forklift trucks of all types; Bulldozers D-7 or equivalent and over; Ditch witch type trencher, Motor patrol; Machines similar to the above	8.62	4.6%	9.5%	a	1.2%	

PA-51-PEO-1-E 2 of 2

BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
WAGE GROUP IV					
Concrete breaking machines Rollers Machines similar to the above	$8.40	4.6%	9.5%	a	1.2%
WAGE GROUP V					
All bulldozers under D-7 Tractors including rubber-tired type with front and overhead loaders under 2 c.y. Seaman pulverizing mixer Welders and Maintenance Engineers Tireman on Power Equipment Maintenance Engineer (Power Boat) Machines similar to the above	8.10	4.6%	9.5%	a	1.2%
WAGE GROUP VI					
Conveyors (Building) Welding Machines Heaters Wellpoints Compressors Farm Tractors Form line graders Road finishing machines Pumps Power Broom (Self contained) Seed Spreader Machines similar to the above	7.92	4.6%	9.5%	a	1.2%
WAGE GROUP VII					
Fireman	7.40	4.6%	9.5%	a	1.2%
WAGE GROUP VIII					
Oilers and Deck Hand (Personnel Boats)	6.66	4.6%	9.5%	a	1.2%

FOOTNOTE:

a. Paid Holidays: New Year's Day; Memorial Day; Independence Day; Labor Day Thanksgiving Day; and Christmas Day, providing the employee works the day before and after the holiday.

PA-51-TD-1 C

BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Truck Drivers:					
Class I Warehouseman, Checker, Fork Lift Driver, Stake Body Truck (single axle), 1-1/2 ton and under vehicles	$6.12	.3675	.35	a&b	
Class II Truck Driver over 1-1/2 tons, Dump Trucks, Tandem & Batch Trucks, Semi-Trailers, Agitator Mixer Trucks, and Dumpcrete Type Vehicles, Asphalt Distributors, Farm Tractor when used for transportation, Stake Body Truck (Tandem)	6.22	.3675	.35	a&b	
Class III Euclid Type, Off-Highway Equipment-Back or Belly Dump Trucks and Double-Hitched Equipment Staddle (Ross) Carrier, Low-Bed Trailers	6.42	.3675	.35	a&b	

FOOTNOTES:

a. Employee who have been on the employer's senority list for a period of one (1) year from date of hire and who shall have worked a minimum of one-hundred thirty (130) days in the year previous to his anniversary date, shall be eligible for one (1) week's vacation.

b. Paid Holidays: Memorial Day Independence Day & Labor Day for employee who have worked a minimum of thirty days and are on the employer's senority list, provided he works the schedule work days before and after the said holidays.

STATE: Pennsylvania
DECISION NO.: AQ-2079
COUNTY: Lycoming
DATE: Date of Publication
DESCRIPTION OF WORK: Building Construction, (excluding single family homes and garden type apartments up to and including 4 stories)

41-PA-1-X 1 of 2

	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
Asbestos workers	$8.49	.50	.35		.01	
Boilermakers	9.12	.50	1.00	.25	.01	
Bricklayers & Stonemasons	8.15	.25	.25		.05	
Carpenters	7.65	.25	.25		.02	
Cement masons	8.00					
Electricians	8.54	.28	.08	.30	.02	
Elevator constructors	8.07	.345	.23	2%+b+c	.015	
Elevator constructors' helpers	5.65	.345	.23	2%+b+c	.015	
Elevator constructors' helpers (prob.)	4.035					
Ironworkers	8.46	.64	1.06		.05	
Laborers:						
Unskilled laborers, scaffold builders, wrecking, window cleaners & demolition	5.85	.20	.25			
Mason tender	5.95	.20	.25			
Operators of jackhammers, paving breakers, vibrators & other pneumatic & mechanical tools coming under the jurisdiction of laborers, wagon drill operators, excavating for caisson, under pinning & pier holes (below 12'), non-metallic pipe layers, plaster tenders, mortar men (mixed by hand), handling & using cutting or burning torches in the wrecking of buildings	6.00	.20	.25			
Lathers	5.875		.10		.01	
Lead burners	8.75	.30		a	.01	
Line Construction:						
Line & Cable splicers	9.04	.20	1%			
Groundman - truck drivers	6.41	.20	1%			
Groundman	6.15	.20	1%			
Millwrights	8.21	.20	.25		.02	
Painters:						
Brush	6.70		.20			
Steel	7.00		.20			
Spray	7.40		.20			
Sandblasting	7.55		.20			
Plasterers	8.05					
Plumberers	7.95	.38	.30	.20	.02	
Roofers & Kettlemen	7.60	.50	.40			
Piledrivermen	9.42	1.23	.55		.07	
Sheet metal workers	8.37	.25	.30		.04	
Soft floor layers	7.39	.25	.25		.02	

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	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
Sprinkler fitters	$9.05	.40	.60		.07	
Steamfitters	7.95	.38	.30	.20	.02	
Tile setters	6.10					
Welders - rate for craft						
Glaziers:						
Inside	4.72			d	.01	
Outside	4.88			d	.01	

PAID HOLIDAYS: (Where Applicable)

A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

FOOTNOTES:

a. Nine paid holidays: A through F, Washington's Birthday, Good Friday and Christmas Eve, provided the employee has worked 45 full days for the employer.

b. Employer contributes 4% basic hourly rate for 5 years or more of service or 2% basic hourly rate for 6 months to 5 years of service as Vacation Pay Credit.

c. Six paid holidays: A through F.

d. Paid holidays: A through F plus 1st day of Buck Season and the employee's birthday provided such employees work the last scheduled day prior to and the next scheduled work day after the holiday unless permission for not working on such day is granted by the employer or unless a bonafide illness occurs.

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POWER EQUIPMENT OPERATORS
BUILDING CONSTRUCTION

PA-22-PEO-1-D 1 of 2

	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
WAGE GROUP I						
Machines doing hook work, any machine handling machinery, cable spinning machines, helicopters, machines similar to the above	$9.44	4.6%	9.5%	a	1.2%	
WAGE GROUP II						
All types of cranes, all types of backhoes, cableways, draglines, keystones, all types of shovels, derricks, trench shovels, trenching machines, hoist with two towers, pavers 21E and over, all types overhead cranes, building hoists (double drum) gradalls, mucking machines in tunnel, all front end loaders 3-½ c.y. and over, tandem scrapers, pippin type backhoes, boat Captains, batch plant operators (concrete) drills, self-contained rotary drills, fork lifts, 20 ft. lift and over machine to the above	9.15	4.6%	9.5%	a	1.2%	
WAGE GROUP III						
Conveyors, building hoists (single drum) scrapers and tournapulls, spreaders, high or low pressure boilers, concrete pumps, well drillers, bulldozers and tractors, asphalt plant engineers, roller (high grade finishing), ditch witch type trencher, all loaders under 3-½ cu. yds., mechanic-welders, motor patrols, drill helper-self contained rotary drills, core drill operator, forklift trucks under 20 ft. lift, machines similar to the above	8.27	4.6%	9.5%	a	1.2%	
WAGE GROUP IV						
Welding machines, well points, compressors, pumps, heaters, farm tractors, form line graders, fine grade machines, road finishing machines, concrete breaking machines, rollers, seaman pulverizing mixer, power broom, seeding spreader, tireman (for power equipment), machines similar to the above	7.50	4.6%	9.5%	a	1.2%	
WAGE GROUP V						
Fireman, grease truck	7.02	4.6%	9.5%	a	1.2%	
WAGE GROUP VI						
Oilers and deck hands (personnel boats), core drill helper	6.10	4.6%	9.5%	a	1.2%	

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POWER EQUIPMENT OPERATORS
BUILDING CONSTRUCTION
(CONTINUE)

PA-22-PEO-1-D 2 of 2

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
WAGE GROUP VII					
All machines with booms (including jib, masts, leads, etc.):					
100 ft. and over	$9.69	4.6%	9.5%	a	1.2%
150 ft. and over	9.94	4.6%	9.5%	a	1.2%
200 ft. and over	10.94	4.6%	9.5%	a	1.2%

FOOTNOTE:

a. Paid Holidays: New Year's Day; Memorial Day; Independence Day; Labor Day; Thanksgiving Day; and Christmas Day, provided the employee works the day before and after the holiday.

STATE: Pennsylvania
DECISION NO.: AQ-2081
DESCRIPTION OF WORK: Building Construction (excluding single family homes and garden type apartments up to and including 4 stories)

COUNTY: Cambria
DATE: Date of Publication

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BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
Asbestos workers	$ 9.47	.35	.70			
Boilermakers	9.07	7%	7%		.01	
Bricklayers & Stonemasons	8.38	.45	.60		.01	
Carpenters	8.04	5%	5%	5%	.015	
Cement mason	7.95	.50				
Electricians	9.60	.35	1% + .20	.60	.05	
Ironworkers, structural, ornamental & Reinforcing	8.775	.785	.775		.03	
Laborers:						
Laborers	5.93	.40	.40			
Plasterers tenders	5.98	.40	.40			
Blasters	6.53	.40	.40			
Lathers	7.72				.01	
Leadburners	8.75	.30	a		.01	
Line Construction:						
Linemen	10.33	.30	1%		3/8%	
Winch truck operator	7.23	.30	1%		3/8%	
Groundman	6.20	.30	1%		3/8%	
Millwrights	7.66	5%	2½%	.26	1%	
Painters:						
Commercial	7.04	.55	.35		.12	
Industrial	7.89	.55	.35		.12	
Piledrivermen	9.27	5%	7%		½ of 1%	
Plasterers	7.75				.01	
Plumbers	9.00	.54	.63		.18	
Roofers	8.59	4%	.95		.035	
Sheetmetal workers	8.83	.65	.85		.02	
Soft floor layers	8.04	5%	5%	5%	1%	
Sprinkler fitters	9.05	.40	.60		.07	
Steamfitters	9.00	.54	.63		.18	
Terrazzo workers, marble setters & tile setters	8.38	.45	.60		.015	
Truck Drivers:						
Service, dump, flat top, jeep, fuel and water	5.46	b	c			
Transit mix, dump trailer, winch truck	5.54	b	c			
Euclids, & tractor trailer	5.61	b	c			
Helper	5.36	b	c			
Welders - receive rate prescribed for craft performing operation to which welding is incidental.						

PAID HOLIDAYS:

A-New Year's Day; B-Memorial Day; C-Indpendence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

FOOTNOTES:

a. Holidays A through F, plus Washington's Birthday and Good Friday, providing the employee has worked 45 full days for the employer during the 120 days prior to the holiday, and is available for work the day preceding and following the holiday.

b. $37.61 per month.

c. $8.00 per week.

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BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
POWER EQUIPMENT OPERATORS:					
Austin-Western or similar type up to 25 ton, auto grader (CMI or similar), backhoe, batch plant, cableway, caisson drill, central mix plant, cranes (excluding overhead), cranes tower (mobile), crane tower (stationary), crane tower (climbing type), derrick traveler (self-propelled), derrick (all types), derrick boats, dragline, dredge, engineer-maintenance franki or similar type pile driver, gradall (remote control or otherwise), helicopter & helicopter hoist when used for erection purposes), hi-lift 4 yds. or over, hoist-hod (2 cages up to 10 floors), hoist-single cage with Chicago boom attached, hoist (50 ft. or over), hoist (slipform jobs), hop-to or similar type with 180 swing, hop-to or similar type with 360 swing, kocal, koehring scooper, metro chip harvester or similar type, mix mobile or similar type (with self-loading attachment), mix mobile or similar type, mucking machine (tunnel), multiple bowl machines, pile driver (sonic or similar type), post driver-guard rail (truck mounted), post driver-guard rail (skid type), pumpkrete-mobile or similar type, Quad Nine, shovels (all type), slip form paver (CMI or similar), tractors-boom mounted (all types), tractors (all types with hydraulic backhole attached), tug boat, Whirley	$9.175	.35	.50		.04
Austin-Western or similar type up to 25 ton with jib, Austin-Western or similar type 25 tons or over with jib, cranes (boom or mast 100 ft. or over up to & including 150 ft.), cranes-mobile (any type 15 ton or over placed on any building structure	9.425	.35	.50		.04
Cranes (boom or mast over 150 ft. up to & including 200 ft.) engineer-lead	9.675	.35	.50		.04
Cranes (boom or mast over 200 ft.)	9.925	.35	.50		.04

PA-42-PEO-1-E 2 of 3

BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
POWER EQUIPMENT OPERATORS (CONT'D):					
Asphalt plant op., athoy loader, auger-truck, truck or tractor mounted, back filling machine, boat-material or personnel carrying (powered), boat-job work (inboard or outboard), bulldozer, cable layer, compactor with blade, compressors-2, compressor and air pump, compressor and air tugger, compressor & gunnite machine (combination), compressor & sandblasting machine (combination), concrete bolt placer, crane-overhead, crushing and scrooning plants, drillcore (truck or skid mounted), drill-Davey or similar type, drill-well &core (truck mounted), elevator euclid loader, excavating equipment (all other), forklift-bull or similar, generators-2, grader, grader-elevating, greaser-equipment (hoad), hi-liftless than 4 yds., hoist-one drum (4 floors or over), hoist-hod (bldgs., 4 floors or more), hoist (2 drums or more in one unit), jumbo op., locomotive, lift slab machine (hydraulic), mixer-paving musking machine, pipe cleaning machine, refrigeration plant, ross carrier (or similar type), scoop (single bowl) self-powered & tractor drawn), spreader-concrete, asphalt and stone, tower mobile (hoisting or lowering material, trencher, welding machines (up to two small machines, grout pump (10 H.P. or over) paver op., asphalt (spreader), pumpkrete machine op., (stationary), tire repairman, welder (repairman)	$9.025	.35	.50		.04
Conveyors 4 units or more	8.55	.35	.50		.04
Oiler, compactor (ridden or self-propelled) concrete finishing machine & spreader, crane, carry, curb builder (self-propelled), drill well drill and horzontal (self-propelled and self-contained, elevator, forklifts (ridden or self-propelled, hoist one drum (regardless of power used), pavement breaker (self propelled or ridden), pipe dream, roller saw concrete, soil					

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BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
POWER EQUIPMENT OPERATORS (CONT'D):					
stabilizer (pump type), stone crusher, stone spreader self-propelled, tractors (when used for snaking and hauling), tube finisher C.M.I. or similar type, tugger, truck winch truck or hydraulic boom (when hoisting and placing), all other minor equipment	8.05	.35	.50		.04
Ballast regulator, boring machine, broom power (except push type), compressor-single (regardless of power used), conveyor-over 1 and up to 3 units (regardless of power used), form line machine, generator (over 5KW) hoists monorail (regardless of power used), hoist roof (regardless of power used), hunk machine or similar type, mixer concrete (regardless of power used), mixer mortar-over 10 c.f. (regardless of power used) pump (over 1-½" discharge, regardless of power (used) spray cure machine (power driven) steam Jenny (or similar type) syphon (steam or air) welding machine single (300 Amp or over) plant, private or industrial air or stream valve	7.80	.35	.50		.04
Compressor - 65 c.f. or under (regardless of power used) conveyor 1 unit (regardless of power used) heat-up to & including 6, jack motor, hydraulic (single type) power driven, ladavator, mixer mortar (10 c.f. or under, mulching machine, pin puller (powered), pulverizer, pump-1½" discharge or less, seeding machine, spreader side delivery shoulder (attachment tie tamper (multiple heads), tractor farm (when used on landscaping) water blaster, oilertruck crane 50 ton or over brake man, deck hand, helicopter, signalman, oiler, mechanic helper	7.05	.35	.50		.04
Crane truck oiler and fireman	7.15	.35	.50		.04
Oiler - truck crane 50 ton or over	7.30	.35	.50		.04

NEW DECISION

STATE: Pennsylvania
DECISION NO.: AQ-2084
COUNTY: Bedford
DATE: Date of Publication
DESCRIPTION OF WORK: Building Construction (excluding single family homes and garden type apartments up to and including 4 stories)

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BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
Asbestos workers	$ 9.47	.35	.70			
Boilermakers	9.07	7%	7%		.01	
Bricklayers	8.38	.45	.60		.01	
Carpenters	8.04	5%	5%	5%	1%	
Cement masons	7.95	.50				
Electricians	9.60	.35	.20 + 1%	.60	.05	
Elevator Constructors	7.73	.17	.185	1½%+c+d	.005	
Elevator Constructors' helpers	5.41	.17	.185	1½%+c+d	.005	
Elevator Constructors' helpers (prob.)	3.865					
Ironworkers	7.90	.35	.30			
Laborers:						
Laborers	5.78	.40	.40			
Ditch, trench or sumpwork exceeding 10' in depth including caissons	6.73	.40	.40			
Blasters	6.38	.40	.40			
Air track men, demolition of chimneys & erection of towers, antennas, cooling towers (on power plants) or other similar work in excess of 10' in height, suspension of workmen in swinging-cages, suspended scaffolds, swings, bosun's chair	6.28	.40	.40			
Plasterers tenders	5.83	.40	.40			
Lathers	7.72		.10		.01	
Line Construction:						
Lineman	10.33	.30	1%		3/8%	
Groundman	6.20	.30	1%		3/8%	
Winch truck operator	7.23	.30	1%		3/8%	
Marble, Tile & Terrazzo workers	8.38	.45	.60		.01	
Marble, setters helpers	6.45		.10			
Millwrights	7.66	5%	2½%	.26	1%	
Painters:						
Brush and Roller	6.07					
Structural steel	6.22					
Piledriverman	9.27	5%	7%		.50 of 1%	
Plasterers	7.75				.01	
Plumbers	7.50	.40	.35	.30	.04	
Roofers	8.59	4%	.95		.035	
Soft floor layers	8.04	5%	5%	5%	1%	
Sheet metal workers	8.43	.52	.50			
Sprinkler fitters	9.05	.40	.60		.07	
Steam fitters	7.50	.40	.35	.30	.04	
Stonemasons	8.38	.45	.60		.01	
Terrazzo workers helpers	6.855	.35	.10			
Tile setters helpers	6.79	.35				

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BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
Truck Drivers:						
Service, dump, flat top, jeep, fuel and water	$ 5.46	a	b			
Euclids	5.61	a	b			
Helper	5.36	a	b			
Welder - receive rate prescribed for craft performing operation to which welding is incidental						

PAID HOLIDAYS (Where Applicable):
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

FOOTNORES:
a. $37.61 per month.

b. $8.00 per week.

c. Employer contributes 4% of basic hourly rate for 5 years or more of service or 2% basic hourly rate for 6 months to 5 years of service as Vacation Pay Credit.

d. Paid Holidays: A through F.

Pa-42-PEO-1-E 1 of 3

BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
POWER EQUIPMENT OPERATORS:					
Austin-Western or similar type up to 25 ton, auto grader (CMI or similar), backhoe,, batch plant, cableway, caisson drill, central mix plant, cranes (excluding overhead), cranes tower (mobile), crane tower (stationary), crane tower (climbing type), derrick traveler (self-propelled), derrick (all types), derrick boats, dragline, dredge, engineer-maintenance franki or similar type pile driver, gradall (remote control or otherwise), helicopter & helicopter hoist when used for erection purposes), hi-lift 4 yds. or over, hoist-hod (2 cages up to 10 floors), hoist-single cage with Chicago boom attached, hoist (50 ft. or over), hoist (slipform jobs), hop-to or similar type with 180 swing, hop-to or similar type with 360 swing, kocal, koehring scooper, metro chip harvester or similar type, mix mobile or similar type (with self-loading attachment), mix mobile or similar type, mucking machine (tunnel), multiple bowl machines, pile driver (sonic or similar type), post driver-guard rail (truck mounted), post driver-guard rail (skid type), pumpkrete-mobile or similar type, Quad Nine, shovels (all type), slip form paver (CMI or similar), tractors-boom mounted (all types), tractors (all types with hydraulic backhole attached), tug boat, Whirley	$9.175	.35	.50		.04
Austin-Western or similar type up to 25 ton with jib, Austin-Western or similar type 25 tons or over with jib, cranes (boom or mast 100 ft. or over up to & including 150 ft.), cranes-mobile (any type 15 ton or over placed on any building structure	9.425	.35	.50		.04
Cranes (boom or mast over 150 ft. up to & including 200 ft.) engineer-lead	9.675	.35	.50		.04
Cranes (boom or mast over 200 ft.)	9.925	.35	.50		.04

PA-42-PEO-1-E 2 of 3

BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
POWER EQUIPMENT OPERATORS (CONT'D):					
Asphalt plant op., athoy loader, auger-truck, truck or tractor mounted, back filling machine, boat-material or personnel carrying (powered), boat-job work (inboard or outboard), bulldozer, cable layer, compactor with blade, compressors-2, compressor and air pump, compressor and air tugger, compressor & gunnite machine (combination), compressor & sandblasting machine (combination), concrete bolt placer, crane-overhead, crushing and scrooning plants, drillcore (truck or skid mounted), drill-Davey or similar type, drill-well &core (truck mounted), elevator euclid loader, excavating equipment (all other), forklift-bull or similar, generators-2, grader, grader-elevating, greaser-equipment (hoad), hi-liftless than 4 yds., hoist-one drum (4 floors or over), hoist-hod (bldgs., 4 floors or more), hoist (2 drums or more in one unit), jumbo op., locomotive, lift slab machine (hydraulic), mixer-paving musking machine, pipe cleaning machine, refrigeration plant, ross carrier (or similar type), scoop (single bowl) self-powered & tractor drawn), spreader-concrete, asphalt and stone, tower mobile (hoisting or lowering material, trencher, welding machines (up to two small machines, grout pump (10 H.P. or over) paver op., asphalt (spreader), pumpkrete machine op., (stationary), tire repairman, welder (repairman)	$9.025	.35	.50		.04
Conveyors 4 units or more	8.55	.35	.50		.04
Oiler, compactor (ridden or self-propelled) concrete finishing machine & spreader, crane, carry, curb builder (self-propelled), drill well drill and horzontal (self-propelled and self-contained, elevator, forklifts (ridden or self-propelled, hoist one drum (regardless of power used), pavement breaker (self propelled or ridden), pipe dream, roller saw concrete, soil					

BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
POWER EQUIPMENT OPERATORS (CONT'D):					
stabilizer (pump type), stone crusher, stone spreader self-propelled, tractors (when used for snaking and hauling), tube finisher C.M.I. or similar type, tugger, truck winch truck or hydraulic boom (when hoisting and placing), all other minor equipment	8.05	.35	.50		.04
Ballast regulator, boring machine, broom power (except push type), compressor-single (regardless of power used), conveyor-over 1 and up to 3 units (regardless of power used), form line machine, generator (over 5KW) hoists monorail (regardless of power used), hoist roof (regardless of power used), hunk machine or similar type, mixer concrete (regardless of power used), mixer mortar-over 10 c.f. (regardless of power used) pump (over 1-½" discharge, regardless of power (used) spray cure machine (power driven) steam Jenny (or similar type) syphon (steam or air) welding machine single (300 Amp or over) plant, private or industrial air or stream valve	7.80	.35	.50		.04
Compressor - 65 c.f. or under (regardless of power used) conveyor 1 unit (regardless of power used) heat-up to & including 6, jack motor, hydraulic (single type) power driven, ladavator, mixer mortar (10 c.f. or under, mulching machine, pin puller (powered), pulverizer, pump-1½" discharge or less, seeding machine, spreader side delivery shoulder (attachment tie tamper (multiple heads), tractor farm (when used on landscaping) water blaster, oilertruck crane 50 ton or over brake man, deck hand, helicopter, signalman, oiler, mechanic helper	7.05	.35	.50		.04
Crane truck oiler and fireman	7.15	.35	.50		.04
Oiler - truck crane 50 ton or over	7.30	.35	.50		.04

DECISION #AQ-1012 - Mod. #3
(38 FR 22322 - August 17, 1973)
El Paso County, Colorado

Change:
Bricklayers

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
	$8.12	.30	.50		.02

DECISION #AQ-1061 - Mod. #2
(38 FR 33242 - November 30, 1973)
Adams, Arapahoe, Boulder, Clear Creek, Denver, Douglas, Eagle, Elbert, Gilpin, Grand, Jefferson, Lake, Larimer Logan, Morgan, Park, Summit, and Weld Counties, Colorado

Change:
Bricklayers:
Boulder and Grand Counties

BUILDING CONSTRUCTION
Area A
LABORERS:
Adams, Arapahoe, Boulder, Denver, Lake, Larimer and Summit Counties. Douglas and Jefferson Counites lying North of the South line of Township 7 South; Elbert County lying West of the East line of Range 65 West and North of the South line of Township 7 South; Weld County lying south and west of the following described line: Beginning at the northwest corner or Township 4 North, Range 68 W. of the 6th p.m.; thence east along the north line of said Township six (6) miles, more or less, to the east line of said Township; thence south along the east line of said Township three (3) miles, more or less to the southeast corner of Section 13, Township 4 North, Range 68 West; thence east along the eastwest center line of Township 4 North, Range 67 West, six (6) miles, more or less to the east line of said Township; thence south along the east line of Range 67 West, being the east lines of Township 4 North, 3 North, 2 North and 1 North, Range67 west, sixteen (16) miles to the southeast corner of Section 1, Township 1 North, Range 67 West; thence east and parallel to the Base line, twelve (12) miles more or less to the southeast corner of Section 1 Township 1 North, Range 65 West; thence south along the east line of Range 65 West, five (5) miles more or less to the Base Line, being the south line of Weld County
ZONE 1 - 0 to 30 miles from nearest basing point located in the Cities of Boulder, Denver, Dillon, Engelwood, Fort Collins, Golden, Greeley and Leadville

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
	7.70	.45	.50		.05

DECISION #AQ-1061 - Mod. #2

AREA A - ZONE 1 (cont'd)	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
General laborers; Underpinning and shoring: 0 to 8' below working surface	$4.74	.37	.40		.05
Underpinning and shoring 8' below working surface to any depth below working surface; Power tool operators of all mechanical, air, gas and electric tools incl. self-propelled buggies and cement finisher tenders; Gunnite nozzlemen and sandblasters	5.03	.37	.40		.05
Laborers - preparing and placing of stone or any other aggregate in a sand bed to be used as exposed face of tiltup panels	5.05	.37	.40		.05
Pipelayers	5.25	.37	.40		.05
Jackhammer operator; Underpinning and shoring over 12' below working surface; Beller and stemmers on caisson work	5.30	.37	.40		.05
Mason tenders, brick and plaster	5.35	.37	.40		.05
ZONE 2 - 30 to 70 miles from nearest basing point located in the Cities of Boulder, Denver, Dillon, Englewood, Fort Collins, Golden, Greeley and Leadville					
General laborers; Underpinning and shoring 0' to 8' below working surface	5.20	.37	.40		.05
Underpinning and shoring 8' below working surface to any depth below working surface; Power tool operators of all mechanical, air, gas and electrical tools incl. self-propelled buggies and cement finisher tenders; Gunnite nozzlemen and sandblasters	5.48	.37	.40		.05

DECISION #AQ-1061 - Mod. #2

AREA A - ZONE 2 (cont'd)	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Laborers - preparing and placing of stone or any other aggregate in a sand bed to be used as exposed face of tiltup panels	$5.50	.37	.40		.05
Pipelayers	5.90	.37	.40		.05
Jackhammer operator; Underpinning and shoring over 12' below working surface; Bellers and stemmers on caisson work	5.75	.37	.40		.05
Mason tenders, brick and plaster	5.80	.37	.40		.05
ZONE 3 - 70 miles and over from nearest basing point located in the Cities of Boulder, Denver, Dillon, Englewood, Fort Collins, Golden, Greeley and Leadville					
General laborers; Underpinning and shoring 0' to 8' below working surface	5.65	.37	.40		.05
Underpinning and shoring 8' below working surface to any depth below working surface; Power tool operators of all mechanical, air, gas and electrical tools including self-propelled buggies and cement finisher tenders; Gunnite nozzlemen and sandblasters	5.93	.37	.40		.05
Laborers - preparing and placing of stone or any other aggregate in a sand bed to be used as exposed face of tiltup panels	6.95	.37	.40		.05
Pipelayers	6.15	.37	.40		.05
Jackhammer operator; Underpinning and shoring over 12' below working surface; Bellers and stemmers on caisson work	6.20	.37	.40		.05
Mason tenders, brick and plaster	6.25	.37	.40		.05

DECISION #AJ-1061 - Mod. #2

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Area B					
LABORERS:					
Douglas, Elbert, Jefferson and Weld Counties lying outside of the area as described in Area A and Clear Creek, Eagle, Gilpin, Grand, Logan, Park and Morgan Counties					
ZONE 1 - 0 to 30 miles from nearest basing point located in the Cities of Eagle, Fort Morgan, Golden, Grandby, Greeley, Sterling and Vail					
General laborers; Underpinning and shoring 0' to 8' below working surface	$4.55	.37	.40		.05
Power tool operators of all mechanical, air, gas and electrical tools including self-propelled buggies and cement finishers tenders; Gunnite nozzlemen and sandblasters	4.70	.37	.40		.05
Laborers - preparing and placing of stone or any other aggregate in a sand bed to be used as exposed face of tiltup panels	4.75	.37	.40		.05
Underpinning and shoring 8' below working surface to any depth below working surface	4.83	.37	.40		.05
Jackhammer operator; Underpinning and shoring over 12' below working surface; Bellers and stemmers on caisson work	4.87	.37	.40		.05
Pipelayers	5.03	.37	.40		.05
Mason tenders, brick and plaster	5.35	.37	.40		.05
ZONE 2 - 30 to 70 miles from nearest basing point located in the Cities of Eagle, Fort Morgan, Golden, Grandby, Greeley, Sterling, and Vail					
General laborers; Underpinning and shoring 0' to 8' below working surface	5.00	.37	.40		.05

DECISION #AJ-1061 - Mod. #2

AREA B - ZONE 2 (cont'd)	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Power tool operators of all mechanical, air, gas and electrical tools including self-propelled buggies and cement finisher tenders; Gunnite nozzlemen and sandblasters	$5.15	.37	.40		.05
Laborers - preparing and placing of stone or any other aggregate in a sand bed to be used as exposed face of tiltup panels	5.20	.37	.40		.05
Underpinning and shoring 8' below working surface to any depth below working surface	5.28	.37	.40		.05
Jackhammer operators; Underpinning and shoring over 12' below working surface; Bellers and stemmers on caisson work	5.32	.37	.40		.05
Pipelayers	5.48	.37	.40		.05
Mason tenders, brick and plaster	5.60	.37	.40		.05
ZONE 3 - 70 miles and over from nearest basing point located in the Cities of Eagle, Golden, Fort Morgan, Grandby, Greeley, Sterling and Vail					
General laborers; Underpinning and shoring 0' to 8' below working surface	5.45	.37	.40		.05
Power tool operators of all mechanical, air, gas and electrical tools including self-propelled buggies and cement finisher tenders; Gunnite nozzlemen and sandblasters	5.60	.37	.40		.05
Laborers - preparing and placing of stone or any other aggregate in a sand bed to be used as exposed face of tiltup panels	5.65	.37	.40		.05
Underpinning and shoring 8' below working surface to any depth below working surface	5.73	.37	.40		.05
Jackhammer operators; Underpinning and shoring over 12' below working surface; Bellers and stemmers on caisson work	5.77	.37	.40		.05
Pipelayers	5.93	.37	.40		.05
Mason tenders, brick and plaster	6.05	.37	.40		.05

MODIFICATIONS P. 7

	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
DECISION #AQ-4068 - Mod. #2						
(39 FR 5975 - February 15, 1974)						
Fulton, Cobb, & DeKalb Counties, Georgia						
Change:						
Carpenters:						
Carpenters and soft floor layers	$7.75	.35	.45		.02	
Piledrivermen	7.90	.35	.45		.02	
Painters:						
Brush	7.70	.45	.55		.04	
Spray and sandblasting	8.70	.45	.55		.04	
Paperhanging	7.95	.45	.55		.04	
Plasterers	7.52	.35	.55			
Power equipment operators - Mod. #1 (Building construction)						
Group G	4.91	.30	.15		.07	
Electricians (Heavy & Highway construction)	8.85	6%	7%+1%		4/10 of 1%	
Omit:						
Footnote - Mod. #1:						
a. $2.00 per week per apprentice employed.						
Add:						
County: Clayton						

MODIFICATIONS P 8

	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
DECISION #AQ-3 - Mod. #4						
(38 FR 19641 - July 20, 1973)						
Scott County, Iowa						
Change:						
Building Construction:						
Electricians:						
Electricians	$8.30	.32	5.5%		.03	
Cable splicers	8.55	.32	5.5%		.03	
DECISION #AQ-11 - Mod. #6						
(38 FR 21055 - August 3, 1973)						
Woodbury County (City of Sioux City & abutting municipalities), Iowa						
Change:						
Building Construction:						
Lathers	6.90				.01	
Plasterers	7.00					
Sheet metal workers	7.68	.35	.25			
DECISION #AQ-12 - Mod. #6						
(38 FR 21059 - August 3, 1973)						
Clinton County (City of Clinton & abutting municipalities), Iowa						
Change:						
Building Construction:						
Electricians:						
Electricians	8.30	.32	5.5%		.03	
Cable splicers	8.55	.32	5.5%		.03	
DECISION #AQ-16 - Mod. #5						
(38 FR 21074 - August 3, 1973)						
Des Moines County (City of Burlington & abutting municipalities & Burlington Ordnance Plant), Iowa						
Change:						
Building Construction:						
Carpenters:						
Carpenters & soft floor layers	6.75	.35	.40		.01	
Millwrights	7.40	.35	.40		.01	
Piledrivermen	7.25	.35	.40		.01	

DECISION #AQ-16 (CONT'D)	Basic Hourly Rates	Fringe Benefits Payments: H & W	Pensions	Vacation	App. Tr.	Others
Ironworkers: Ornamental; Reinforcing; Structural	$7.55	.40	.30			
Truck drivers: Warehouseman; Helpers; Teamsters; Mechanic helpers; Greasers; Single axle flat beds & dump trucks; Pulling air compressors & welding machines; batch trucks 2-34E batches or less; chip spreaders	5.63	10.50p/w				
Cheater axle; Tandems; 6 wheel trucks; semi-trailers; carryall; winch; mixers; batch over 2-34E batches; "A" Frame; Pole trailers	5.83	10.50p/w				
Track trucks; euclid type truck; oil distributors; front & rear; all types of dumpsters; pavement breakers	6.13	10.50p/w				
DECISION #AQ-85 - Mod. #1 (39 FR 9371 - March 8, 1974) Description of Work and Locations: Heavy and Highway Construction, Missouri						
Add To Description Of Work And Locations: Heavy Construction Scott County						
Change: Adair, Clark, Knox, Lewis, Macon, Marion, Monroe, Ralls, Schuyler, Scotland and Shelby Counties: Structural; ornamental; & reinforcing	$7.55	.40	.30			
DECISION #AQ-64 - Mod. #4 (38 FR 33904 - December 7, 1973) Tulsa County, Oklahoma						
Change: Sheet metal workers	$7.66	.38	.45		.06	

	Basic Hourly Rates	Fringe Benefits Payments: H & W	Pensions	Vacation	App. Tr.	Others
DECISION #AM-8523 - Mod. #2 (37 FR 12013 - June 16, 1972) Sullivan County, Tennessee						
Change: Bricklayers	$6.75					
DECISION #AQ-4011 - Mod. #3 (38 FR 26589 - September 21, 1973) Anderson and Roane Counties, Tennessee						
Change: Asbestos workers	$8.00	.35	.50		.03	
Ironworkers: Reinforcing	6.915	.125	.10		.02	
Fence erector	7.035	.125	.10		.02	
Plasterers	7.30					
Plumbers & Steamfitters	7.45	.35	.45	.30+e	.05	
Sheet metal workers	7.91	.30	.30		.02	
DECISION #AQ-4015 - Mod. #3 (38 FR 27734 - October 5, 1973) Hamilton County, Tennessee						
Change: Asbestos workers	8.00	.35	.50		.03	
DECISION #AQ-4014 - Mod. #3 (38 FR 27731 - October 5, 1973) Knox County, Tennessee						
Change: Asbestos workers	8.00	.35	.50		.03	
Lathers	6.20		.20		.02	
Plasterers	7.30					
Plumbers and Steamfitters	7.15	.35	.45	.30+e	.05	
DECISION #AQ-4016 - Mod. #3 (38 FR 27737 - October 5, 1973) Shelby County, Tennessee						
Change: Asbestos workers	8.00	.35	.50			
Lathers	7.15	.25			.01	
Marble setters	6.45	.25	.20			
Stonemasons	7.70	.35	.20		.14	
Terrazzo workers	6.45	.25	.20			
Tile setters	6.45	.25	.20			

MODIFICATIONS P.11

DECISION #AQ-70 - Mod. #3
(39 FR 1713 - January 11, 1974)
Travis County, Texas

Change:
Building Construction:

	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Yr.	Others
Electricians:						
Electricians	$7.90		1%		.8%	
Cable splicers	7.90		1%		.8%	

STATE: Alabama
COUNTY: Jefferson
DECISION NUMBER: AQ-4095
DATE: Date of Publication
Supersedes Decision No. AQ-4034 dated November 23, 1973 in 38 FR 32344
DESCRIPTION OF WORK: Building Construction, (excluding single family homes and garden type apartments up to and including 4 stories).

37 Alabama-1-M 1 of 2

BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
Asbestos workers	$6.79	.18	.15			
Boilermakers	7.13	.40	.70		.01	
Bricklayers, pointers, caulkers and stonemasons	7.25	.25	.25		.05	
Carpenters and soft floor layers	6.90	.35	.20		.06	
Millwrights	8.25				.06	
Piledrivermen	7.10	.35	.20		.06	
Cement masons	6.83	.40				
Electricians	7.80	.30	1%		1/2%	
Cable splicers	8.05	.30	1%		2%	
Elevator constructors	7.06	.345	.23	2%+a&b	.015	
Elevator constructors' helpers	4.94	.345	.23	2%+a&b	.015	
Elevator constructors' helpers (prob.)	3.53					
Glaziers	6.45	.40	.40		.01	
Ironworkers;						
Structural, ornamental and reinforcing	7.775	.42	.25		.04	
Lathers	6.90		.10		.01	
Linemen:						
Linemen	7.15	.20	1%		1/2%	
Groundmen under one year	3.44	.20	1%		1/2%	
Groundmen one year and over	4.04	.20	1%		2%	
Hole and ditch digging equipment, tractor with winch and derrick, truck with winch and derrick	6.08	.20	1%		1/2%	
Tractor with towing machine, truck with winch only	5.01	.20	1%		1/2%	
Truck with out winch	4.29	.20	1%		1/2%	
Marble setters	5.85					
Painters:						
Brush	6.70		.30			
Structural steel and spray	7.20		.30			
Paperhangers	6.85		.30			
Plasterers	6.87	.30				
Plumbers and pipefitters	8.50	.25	.25		.07	
Roofers	5.75		.20		.05	
Sheet metal workers	8.00	.40	.35		.02	
Sprinkler fitters	8.20	.40	.60		.07	
Tile setters and terrazzo workers	6.65					
Truck drivers:						
Up to but not including 1½ tons	5.05					
1½ to but not including 3 tons	5.25					
3 tons to but not including 5 tons	5.50					
5 tons and over including special equipment	5.65					
Welders, riggers, riveters - receive rate prescribed for craft performing operation to which welders, riggers and riveters are incidental.						

PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

FOOTNOTES:
a. Hodlidays: A through F.

b. Employer contributes 1% of regular hourly rate to Vacation Pay Credit for employee who has worked in business more than 5 years. Employer contributes 2% of regular hourly rate to Vacation Pay Credit for employee who has worked in business less than 5 years.

37-LAB-1-B

BUILDING CONSTRUCTION LABORERS:	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
Group A Air or electric tool operators and asphalt rakers	$5.05	.15	.20		.03	
Group B Vibrator operators, chain saw ops., of mechanical equipment which replaces (wheelbarrows or buggies), power mowers, mortar mixers, pipe layers, conc. & clay and muckers	5.00	.15	.20		.03	
Group C Plasterers' tenders & hod carriers	4.95	.15	.20		.03	
Group D Mason tenders, building laborers and wagon drill operators' helpers	4.90	.15	.20		.03	
Group E Burners on demolition, wagon drill operators and tunnel laborers	5.30	.15	.20		.03	
Group F Powderman	5.75	.15	.20		.03	
Group G Caisson-driller	5.65	.15	.20		.03	
Group H Tunnel miner	5.70	.15	.20		.03	
Group I Pneumatic concrete gun operator and nozzleman	5.60	.15	.20		.03	
Group J Chuck tender	5.45	.15	.20		.03	

ALA 2-PEO-1-G

BUILDING CONSTRUCTION POWER EQUIPMENT OPERATORS:	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
Group A Asphalt plant, boom tractor, bulldozer, cableways, core driller, compressors (2 or more), crane-derrick-dragline, dinky locomotive, dredges, fork lift, front end loader, gradall, heavy duty mechanic, hoist (1 drum or more), mixers push tractor, quarry master, scrapers, shovels, trenching machine (and all similar equipment), winch trucks	$7.31	.30	.20		.05	
Group B Air compressor (over 125), asphalt spreader, blade graders (pull type), boat operator, conveyor (2 or more up to 4), crawler tractor distributors (bituminous surface), farm tractors, finishing machine, pumps over 4 inches, rollers, welding machine (4 or more)	7.10	30	.20		.05	
Group C Air compressor (125 & under), apprentice engineer (oilers-firemen), conveyor (1) tended by oiler), mechanic helpers, pumps (under 4 in.), welding machines (3 or under)	6.41	.30	.20		.05	
Group D On Steel Erection: Crane, dragline, derrick, hoist operator, piledriver, winch truck, fork lift	7.94	.30	.20		.05	
Group E Tractors, welding machines, gasoline driven (4 or more), 1-welding machine no operator, Air compressors (1-125 or larger up to but not including 3)	7.57	.30	.20		.05	
Group F Gas or diesel welding machine (up to 4 tended by oiler), apprentice engineers (oilers-firemen)	6.52	.30	.20		.05	

STATE: Alabama COUNTY: Mobile
DECISION NUMBER: AQ-4096 DATE: Date of Publication
Supersedes Decision No. AQ-4027 dated October 19, 1973 in 38 FR 29155
DESCRIPTION OF WORK: Building Construction, (excluding single family homes and garden type apartments up to and including 4 stories).

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BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
Asbestos workers	$7.70	.395	.75	g	.02	
Boilermakers	7.13	.40	.70		.01	
Bricklayers, stonemasons, cleaners caulkers and pointers	7.39		.73			
Carpenters	6.80	.30	.30			
Carpenters on creosote material; power saw operator	7.20	.30	.30			
Millwright	7.24	.30	.30			
Piledriver	7.02	.30	.30			
Piledriver on creosote material	7.26	.30	.30			
Cement masons	6.62	.30	.30			
Electricians	8.05	.30	1%+.25	.125	.036%	
Elevator constructors	6.72	.145	.17	½% r+t+b	.005	
Elevator constructors' helpers	70%JR	.145	.17	½% r+t+b	.005	
Elevator constructors' helpers (prob.)	50%JR					
Glaziers	6.20	30				
Ironworkers: Structural, ornamental and reinforcing	7.13	.30	.30			
Lathers	7.13	.28	.25		.01	
Line Construction:						
Linemen	7.90	.20	1%	.125	.036%	
Cable splicers	8.15	.20	1%	.125	.036%	
Marble Setters	7.39		.73			
Painters:						
Brush	6.88	.28		e	.01	
Industrial	7.13	.28		e	.01	
Hazardous	7.38	.28		e	.01	
Spraying bituminous coatings	7.88	.28		e	.01	
Plasterers	7.20	.30	.30			
Plumbers and steamfitters	8.25	.30	.35	c	.02	
Roofers:						
Roofers	6.45		.15	f		
Kettleman	5.67		.15	f		
Sheet metal workers	7.29	.40	.40	d	.01	
Soft floor layers	7.20	.30	.30			
Sprinkler fitters	8.20	.40	.60		.07	
Terrazzo workers	7.39		.73			
Terrazzo; base grinder; machine op.	5.08	.28	.25			
Tile setters	7.39		.73			
Welders - Rate for Craft.						

PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

FOOTNOTES:

a. Holidays: A through F.

b. Employer contributes 4% basic hourly rate to Vacation Pay Credit for employee who has worked in business more than 5 years. Employer contributes 2% basic hourly rate to Vacation Pay Credit for employee who has worked in business less than 5 years.

c. Holidays: A, C, D, E, F, Christmas Eve and Mardi Gras.

d. Holidays: A,C, D, E and F.

f. 40 hours paid vacation after 1 year of employment.

g. Holidays: D and Mardis Gras Day, provided the employee works at least one day out of the 3 work days prior to the paid holidays, and the first work day of the paid holiday.

ALA - 49-LAB-R

	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
GROUP A						
General Building Construction Laborers	$4.40	.28	.25			
GROUP B						
Mortar makers (any method), hod carriers, paving breakers - breaking & chipping concrete (any method), air operating tools (elec. or gas), mason and plaster tenders, tile setter & terrazzo helpers, handling creosote or coppertox materials, glass wool and all types insulation, kettle man, asphalt raker & tamper, drills and vibrators, concrete dump bucketman, All concrete rollers, wheel barrows, Georgia buggies, pipe cleaners & pipe layers (of clay, terra cotta, ironstone, vitrified concrete or non-metallic pipe for main & side sewers and drainage only), pipe wipers (inside and out)	4.58	.28	.25			
GROUP C						
Gunnite or pressure concrete workers, nozzleman, gunman, rodman, power driven buggy mobiles, height: all work performed 40 ft. on scaffolds, inside and out (except where scaffolds are solid from wall to wall inside)	4.80	.28	.25			
GROUP D						
Cofferdam or tunnel workers (underground)	5.50	.28	.25			
GROUP E						
Blasting (powderman)	5.72	.28	.25			
GROUP F						
Concrete sawman	5.28	.28	.25			
GROUP G						
Form setters; roadways, runways, highways	5.09	.28	.25			
GROUP H						
Track laborer	4.74	.28	.25			
GROUP I						
Brick washers (laborers)	4.85	.28	.25			
GROUP J						
Burners on dismantling (anything not to be reused)	5.38	.28	.25			
GROUP K						
Stack laborers	4.87	.28	.25			
GROUP L						
Stack laborers (over 40 ft.)	5.28	.28	.25			
GROUP M						
Tank cleaners (caustic chemicals)	4.85	.28	.25			

ALA - 3-PEO-1-2-I

BUILDING CONSTRUCTION: POWER EQUIPMENT OPERATORS:	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
Group A						
HEAVY EQUIPMENT:						
Heavy duty mechanic, crane, shovel, derrick operator (2 or more drums), dragline pile driver operator, hoist operator (2 or more drums), trenching machines, cable ways, excavators, front end loader, backhoe, rubber tired backhoe, dredges, leverman, welders, mounted rotary drill machines, cherry pickers, side boom tractors, paving machines, motor patrol, pumpcrete machines, gradalls, johnson mixers, hydro-lift trucks, all batch plant and header house operators, panel board (ready-mix), hydro hammers on demolition work, concrete plants, asphalt plants, helicopter pilots and concrete paving trains	$7.16	.28	.25			
Group B						
MEDIUM EQUIPMENT:						
Dozer scraper, turnapull, one drum hoist, self-propelled rollers, construction elevators, locomotive engineer, elevating grader tractors with power control attachments, winch truck, tug boats, mixers, asphalt spreaders, drilling machines, form graders, asphalt distributors, forklift, well-point systems, subgraders, finishing machines, motorized compactors, wagmobiles and push carts	6.90	.28	.25			
Group C						
LIGHT EQUIPMENT:						
Light plants, generators, welding machines, air compressors, pumps, conveyors, motor boats under 30 feet, tow tractors, and pile driver hammers (diesel, ga, air or electric)	6.41	.28	.25			
Group D						
Fuel truck oilers, fireman, brakeman, outboard motor boats, truck grane oiler and mechanic helpers	5.76	.28	.25			
Group E						
Oilers (crawler), deck hand and oiler cherry picker	5.50	.28	.25			

BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
TRUCK DRIVERS:						
Group A Up to but not including 1½ tons such as station wagons, jeeps, autos, pick-up trucks, motor cycles, bicycles, truck spotters, teamsters, team drivers	$5.04	.28	.25			
Group B 1½ tons and up to but not including 5 tons such as dump trucks, flat beds, stake bodies, bus drivers, winch and "A" Frame trucks	5.51	.28	.25			
Group C 5 tons or 6 yards and over, including heavy equipment such as pole trucks, miss, or corning wagons, dumpsters, semi-drivers, agitators, ross carriers, dempsey dumps, euclid trucks, fork-lift truck in warehouse and similar equipment such as tractors, 10 wheelers, jeeps, or dump trucks or pickup trucks pulling 2 or 4 wheel trailers hauling equipment	6.55	.28	.25			
Group D Truck and auto mechanics	7.12	.28	.25			
Group E Truck drivers helpers, unloaders, unloading and handling creosote or coppertox material	5.04	.28	.25			
Group F Truck drivers helper	4.41	.28	.25			

SUPERSEDEAS DECISION

AQ-89 - P. 2 100 - ARK - 3J (2-2)

STATE: Arkansas COUNTY: Statewide
DECISION NO.: AQ-89 DATE: Date of Publication
Supersedes Decision No. AP-701, dated February 9, 1973 in 38 FR 4087
DESCRIPTION OF WORK: Construction, Alteration, and/or repair of streets, highways, runways, and water and sewer utilities.

	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
Bricklayers	$4.00					
Carpenters	4.00					
Concrete finisher	3.80					
Ironworkers:						
Structural	3.50					
Reinforcing	2.80					
Laborers:						
Air tool operator	2.80					
Asphalt heater operator	2.80					
Asphalt raker	3.40					
Carpenter helper	2.80					
Chain saw operator	2.80					
Checker grade	2.80					
Concrete finisher helper	2.80					
Concrete joint sealer	2.80					
Concrete saw operator	2.80					
Form setter (pavement)	3.00					
Laborer	2.24					
Pipelayer (concrete, clay)	3.00					
Powderman	3.34					
Vibratorman	2.80					
Painter	3.50					
Pile driver leadman	3.54					
Power Equipment Operators:						
Aggregate spreader operator	3.00					
Asphalt plant drier operator	2.50					
Asphalt plant fireman	2.50					
Batch plant operator	3.00					
Backhoe operator rubber tired (1 yard or less)	3.50					
Bulldozer Operator:						
Finish	3.86					
Rough	3.50					
Bull float operator	3.10					
Cherry picker operator	3.50					
Concrete curing machine operator	3.50					
Concrete mixer operator (less than 5 sacks)	2.80					
Concrete mixer operator (5 sacks or over)	4.00					
Concrete paver operator	4.00					
Concrete spreader operator	3.86					
Crane, Derrick, Dragline, Shovel, Backhoe Operator (1½ yd. or less)	4.00					
Crane, Derrick, Dragline, Shovel, Backhoe Operator (over 1½ yard)	4.20					
Crusher operator	3.00					
Distributor operator	3.00					
Drill operator (wagon or truck)	3.26					
Power Equipment Operators (Cont'd):						
Elevating grader operator	$3.86					
Euclid or like equipment operator (bottom or end dump)	3.00					
Finishing machine operator (concrete or asphalt)	3.50					
Forklift operator	2.80					
Form grader operator	2.80					
Front End Loader Operator:						
Finish	3.86					
Rough	3.50					
Hydro seeder operator	3.00					
Mechanic	3.86					
Mechanic helper	2.80					
Motor Patrol Operator:						
Finish	3.86					
Rough	3.50					
Mulching machine operator	3.00					
Oiler and greaser	2.80					
Pile driver operator	3.54					
Pub mill operator	2.80					
Roller operator (self-propelled)	2.80					
Scraper Operator:						
Finish	3.86					
Rough	3.50					
Sod slicing machine operator	2.80					
Stabilizer mixing machine operator	3.14					
Tractor operator (crawler type)	3.00					
Tractor operator (farm & wheel)	2.80					
Tractor operator wheel type (with attachments 1 yard or under)	3.00					
Trenching machine operator	3.00					
Stonemasons	4.00					
Truck Drivers:						
Distributor truck driver	3.00					
Semi-trailer	3.20					
Lowboy driver	3.50					
Transit mix truck driver	3.00					
Truck driver (heavy-maximum pay load in excess of 3000 lbs)	3.00					
Truck driver (light-maximum pay load 3000 lbs)	2.80					
Welder, finish	3.86					
Welder, rough	3.50					

STATE: NEW JERSEY COUNTY: HUDSON

DECISION NO.: AQ-2,090 DATE: DATE OF PUBLICATION

Supersedeas Decision No. AP-828 dated May 18, 1973 in 38 FR 13265
DESCRIPTION OF WORK: Building Construction, (excluding single family homes and garden type apartments up to and including 4 stories), heavy and highway construction.

9-New Jersey-1-2-3-U 1 of 4

BUILDING, HEAVY HIGHWAY CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Asbestos Workers	$ 9.202	.5803	.4974	11%	.02
Boilermakers	8.35	8%	9½%+3%	10%	.01
Boilermakers' helpers	7.82	8%	9½%+3%	10%	.01
Bricklayers, cement masons, plasterers and stone masons:					
W. of the Hackensack River	8.80	.35	.35		.02
Remainder of County:					
Bricklayers & stone masons	9.26	.75	.57		
Cement masons & plasterers	8.25	1.00	.50		.05
Carpenters:					
West of the Hackensack River:					
Carpenters	8.51	6%	6%		
Remainder of County:					
Carpenters and insulators	8.43	.896	8%+f	g	.02
Millwrights	8.43	.896	8%+f	g	.02
Electricians	10.23	3%+1%	5%+.58		1.5%
Elevator constructors	9.10	.395	.26 +a	b+c	.015
Elevator constructors' helpers	6.83	.395	.26 +a	b+c	.015
Elevator constuctors' helpers (prob.)	4.55				
Elevator constructor modernization	8.33	.395	.26 +a	b+c	.015
Elevator constructor modernization helpers	6.25	.395	.26 +a	b+c	.015
Elevator constructor repair	7.48	.395	.26 +a	b+c	.015
Elevator constructor repair helpers	5.61	.395	.26 +a	b+c	.015
Glaziers	8.30	.60	.65	d	.02
Ironworkers:					
Structural, ornamental & reinforcing	8.80	7%	11%+6%	10%	1%
Laborers, Building:					
Kearny, E. Newark and Harrison:					
Laborers	6.70	.40	.30		
Air tool op. (jackhammer, vibrator)	6.70	.40	.30		
Mortar mixers	6.70	.40	.30		
Mason tenders	6.70	.40	.30		
Plasterers' tenders	6.70	.40	.30		
Pipelayers (concrete & clay)	6.70	.40	.30		

BUILDING, HEAVY HIGHWAY CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Remainder of County:					
Laborers, air tool op., mason tenders, mortar mixers, concrete laborers, plasterers' tender & hod carrier	$ 6.65	.40	.40		
Laborers on structures 176' high or 22 stories from the ground level	6.75	.40	.40		
Lathers	6.65	.25	.25		.01
Lead Burners	8.75	.30		e	.01
Marble setters	7.40	.63	.66+h		
Marble setters' helpers	6.93	.63	.66+h		
Painters:					
Kearny and Harrison:					
Brush	7.20	.42	.50	.10	1
Structural steel & tanks under 3 stories	7.35	.42	.50	.10	1
Structural steel & tanks above 3 stories	7.80	.42	.50	.10	1
Bridges, TV-radio-water towers, stacks	7.80	.42	.50	.10	1
Remainder of County:					
Industrial and commercial	6.75	.70	1.15	.30	
Exterior scaffold work	7.25	.70	1.15	.30	
Structural steel, tanks, bridges, towers, smoke-stacks, radio towers, TV towers, flagpoles (steel or wood), & sandblasting	7.25	.70	1.15	.30	
Hazardous work	7.25	.70	1.15	.30	
Pipe type cable:					
Linemen, cable splicers	6.96	3%+1%	6%+.58		1.5%
Hole digging equipment	6.96	3%+1%	6%+.58		1.5%
Piledrivermen and dock builders	8.90	.80	1.45	.56	.02
Pipe fitters	9.50	.30	.75	1.00	.25
Plumbers:					
Jersey City Bayonne & Hoboken	9.50	.30	.75	1.00	.25
Kearny and Harrison	10.15	.70	.85		.10
Remainder of County	8.20	.61	.55	1.00	.02
Roofers:					
East of the Hackensack River:					
Composition, damp & waterproofing	7.55	6%	1.43	4%	

BUILDING, HEAVY HIGHWAY CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
West of the Hackensack River:					
Composition, damp & water-proofing	$ 6.82	.25	.20		
Slate, tile and asbestos	8.05	.30	.20		
Slate, tile and asbestos helpers	7.05	.30	.20		
Sheet metal workers	9.15	.5175	.4595	.4260	.02
Soft floor layers	8.53	6%	5%	4%	
Sprinkler fitters	9.82	.30	.50		.07
Terrazzo workers	7.95	.88	.43		
Terrazzo workers' helpers	6.98	.88	.43		
Terrazzo machine operators	7.13	.88	.43		
Tile setters	7.01	.45	.355+j	.15	
Welders - receive rate prescribed for craft performing operation to winch is incidental					

BUILDING, HEAVY HIGHWAY CONSTRUCTION

PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

FOOTNOTES:

a. Employer contributes $8.00 per day to Annuity Fund.

b. HOLIDAYS: A through F; Lincoln's Birthday, Washington's Birthday, Columbus Day, Election Day, and Armistice Day.

c. Employer contributes 6.4% basic hourly rate for 5 years or more of service or 4.2% basic hourly rate for 6 months to 5 years of service as Vacation Pay Credit.

d. One week vacation after 1 year's work; two weeks vacation after four year's work; 3 week vacation after 15 year's work.

e. Holidays A through F. Washington's Birthday, Good Friday, and Christmas Eve, providing employee has worked 45 full days during the 120 calendar days prior to the holiday, and the regular scheduled work days immediately preceding and following the holiday.

f. Employer contributes $.16 to an Annuity Fund.

g. Employer contributes $.30 to a Vacation Fund.

h. Employer contributes $.60 per hour to a Trust Fund and $.15 per hour to an Annuity Fund.

i. Employer contributes $.25 per hour to employees employed one year and $.30 per hour to employees employed two years.

j. Employer contributes $.75 per hour to an Annuity Fund.

N.J.-2-LAB-2-3-E

HEAVY AND HIGHWAY CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Laborers:					
Blasters	$7.60	.41	.64	a	
Finisher, rammer, paver, gunite nozzle man and stone cutter	7.45	.41	.64	a	
Timberman	7.20	.41	.64	a	
Form setter	7.15	.41	.64	a	
Sewer pipe, laser men, conduit and duct line layers	6.95	.41	.64	a	
Wagon drill op. and drill master	7.05	.41	.64	a	
Wagon drill op. helper, drill master helper, powder carrier and magazine tender	6.70	.41	.64	a	
Jackhammer, chipping hammer, pavement breaker, power buggy, concrete cutter, asphalt cutter, sheet hammer and tree cutter op. and such other power tools used to perform work usually done manually by laborers	7.05	.41	.64	a	
Signal man	6.75	.41	.64	a	
Wrapping and coating of all pipe	6.55	.41	.64	a	
Common laborers, landscape laborers, railroad track laborers, flagmen, traffic directors, salamander tenders, pitman and dumpmen	6.50	.41	.64	a	
Rakers and tampers on cold patch work	6.50	.41	.64	a	
FREE AIR TUNNEL WORK	Daily Rates				
Blasters	$63.77	.41	.59	a	
Skilled men (including miners, drill runners, iron men, maintenance men, conveyor men, safety miners, riggers, block layers, powder carriers, all other skilled men)	60.57	.41	.59	a	
Semi-skilled men (including miners' helpers, chuck tenders, track men, nippers, brake men, derail men, cable men, hose men, grout men, gravel men, form men, bell or signal men (top or bottom), form workers and movers, concrete workers, shaft men, tunnel laborers, caulkers' helpers, all other semi-skilled men)	59.28	.41	.59	a	
All others (including powder watchmen, change house attendants, top laborers)	55.22	.41	.59	a	

PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

FOOTNOTE:
a. Holidays: A through F; Washington's Birthday; Armistice Day; Presidential Election Day; (providing employee works 3 days for the same employer within a period of 10 working days consisting of 5 working days before and 5 working days after the day upon which the holiday falls).

N.J.-5-LAB-5-J

	BASIC HOURLY RATES	FRINGE BENEFITS PAYMENTS			
		H & W	PENSIONS	VACATION	APP. TR.
Laborers, Asphalt					
Streets:					
Head rakers	$6.40	.46	.39	a	
Rakers	6.25	.46	.39	a	
Tampers and smoothers, kettlemen, painters, top shovelers, and roller boys	6.00	.46	.39	a	
Plant:					
Scale mixer and burner men	6.25	.46	.39	a	
Feeders and dust men	6.00	.46	.39	a	

PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

FOOTNOTE:
a. Holidays: A through F, Washington's Birthday; Armistice Day; Presidential Election Day; providing an employee works or is available for work 3 days in the work week in which the holiday falls.

BUILDING & HEAVY CONSTRUCTION - POWER EQUIPMENT OPERATORS:

GROUP I: Autograde - combn. subgrader, base MTL spreader & base trimmer (CMI & similar types), autograde placer-trimmer-spreader-combn. (CMI & similar types), autograde slipform paver (CMI & similar types), backhoes (all types, including all combination hoe loaders), central power plants (all types), concrete paving machines, cranes (all types including overhead & straddle travelling type), cranes (gantry), derricks (land or floating), drillmaster, quarrymaster (down the hole drill), draglines, elevator graders, engines (large diesel 1620 HP and staging pump), front end loaders (5 yds. and over), gradalls, grader, rago, helicopters (co-pilot), jack (screw air hydraulic power operated unit or console type (not hand jack or pile load test type), locomotive (large), mucking machines, pavers (21-E and over), paver (resinous, broyhill), pavement & concrete breaker (super-hammer), pavement breaker truck mounted, piledriver, scooper (loader and shovel) koehring, shovels, tree chopper, trench machines

GROUP II: "A" frame, boring & drilling machines, brush chopper, chipper & shredder, cableways carryalls, cherry pickers (6 tons & under), concrete pump, concrete pumping system, pumpcrete, squeezecrete & similar types, conveyors (125' & over), econo-mobiles (hilo, lull, hyster similar type equipment), fork lifts, front end loaders (2 yds, but less than 5 yds.), grove cutting machine, heater planer, pans (letourneau, dw's ukes), pumpcrete (unit type), pumpcrete machines (squeezecrete & concrete pumping regardless of size), rollers (backtop), scrapers (letourneau, dw's ukes), side booms, squeezecrete, straddle carrier (ross & similar types), winch trucks (hoisting)

GROUP III: Aerial platform (used as hoist), hoist (all type hoists, gas, diesel, electric, air hydraulic, single and double drum, concrete, brick shaft caisson, conveyor, snorkel, roof, tugger, and house cars or any other similar type hoisting machines, portable or stationary, except Chicago boom type), elevators or house cars, roof hoist

GROUP IV: Asphalt curbing machine, asphalt plant engineer, asphalt spreaders, auto-grade tube finisher & texturing machine (CMI & similar), autograde curecrete machine (CMI & similar), autograde crub trimmer & sidewalk, shoulder slipform (CMI & similar types), bar bending machines (power), batchers, batching plant & crusher on site, belt conveyor systems, boilers and steam jennies (irrespective of their use), boom type skimmer machines, bridge deck finisher, car dumpers (railroad), compressor and blower type units (used independently or mounted on dual purpose trucks, on job site or in conjunction with hob site, in loading and unloading of concrete, cement, fly ash, instancrete, or similar type materials), concrete breaking machines, concrete finishing machines, concrete saws & cutters (ride on type), concrete spreaders hetzel, rexomatic and similar types, conveyors (under 125'), crushing machines, ditching machines (small, ditchwitch or similar), drill doctor (duties include dust collector, maintenance), dope pots (mechanical with or without pump), dumpsters, fine grade machine (large type), front end loaders (under 2 yds.), generators giraffe grinders, grader (finish only), graders and motor patrols, gunite machines (excluding nozzle), hammer vibrator (in conjunction with generator), hoppers, hopper doors (power operated), ladders (motorized), laddervator, lights (portable generating light plants), locomotive (dinky type), maintenance and repair of asphalt curbing machines, concrete finishing machines, concrete vibrators, gas buggies, leveling machines, portable generators, power saws, compressor equipment or compressor units used in connection with cement,

BUILDING & HEAVY CONSTRUCTION - POWER EQUIPMENT OPERATORS CONT'D.:

paint, insulating and acoustical sprays, plaster, curing and sandblasting (all and similar types), mechanic, mixers (excepting paving mixers), motor patrols and graders, pavers (under 21-E), pavement breakers (small, self propelled ride on type, also maintains compressor or hydraulic unit), pipe bending machine (power), pitch pump, plaster pump (regardless of size), post hole digger, rod bending machines (power), scales (power), seaman pulverizing mixer, silas, steam jennies and boilers (irrespective of theiruse), steel cutting machine (service & maintains), vibrating plants (used in conjunction with unloading, welder and repair mechanic.

GROUP V: Welding machines (gas or electric converters of any type 2 or 3 in battery), compressors (2 or 3 within a total distance of 100' constitutes a battery), welding system, mutiple (rectifier transformer type)

GROUP VI: Bulldozer, fireman, sprinkler and water pump trucks (used on job site or in conjunction with job site), stone, spreaders, sweepers & brooms, tractors (D-8 and over), water & sprinkler trucks (used on job site or in conjunction with job site)

GROUP VII: Compressor (single), heaters (nelson or other type including propane, natural gas or flow type units), pumps (4 inch suction & over including submersible pumps), temporary heating plant (nelson or other type including propane, natural gas or flow type units), welding machines (gas or electric converters of any type single), wellpoint system (including installation and maintenance)

GROUP VIII: Concrete spreaders (small type), fertilizing equipment and maintenance of), grease, gas, fuel and oil supply trucks, mulching equipment (operation and maintenance of), seeding equipment (operation and maintenance of), tamping machines (vibrating self propelled)

GROUP IX: Assistant engineer/oiler, mechanics helper, tire repair & maintenance

GROUP X: Water Operations: On all power boats used in conjunction with pipeline, river crossings and all types of construction: captain (power boats), tug master (power boats)

GROUP XI: Water Operations: Deckhand

GROUP XII: Pump (staging)

GROUP XIII: Rollers (grade fill or stone base)

GROUP XIV: Helicopters (pilot/engineer)

BUILDING AND HEAVY CONSTRUCTION

POWER EQUIPMENT OPERATORS	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
GROUP 1	$10.73	7%	10%+5%	a	3%	
GROUP 2	9.85	7%	10%+5%	a	3%	
GROUP 3	9.65	7%	10%+5%	a	3%	
GROUP 4	8.96	7%	10%+5%	a	3%	
GROUP 5	8.81	7%	10%+5%	a	3%	
GROUP 6	8.76	7%	10%+5%	a	3%	
GROUP 7	8.05	7%	10%+5%	a	3%	
GROUP 8	8.41	7%	10%+5%	a	3%	
GROUP 9	7.60	7%	10%+5%	a	3%	
GROUP 10	8.91	7%	10%+5%	a	3%	
GROUP 11	7.50	7%	10%+5%	a	3%	
GROUP 12	9.95	7%	10%+5%	a	3%	
GROUP 13	8.41	7%	10%+5%	a	3%	
GROUP 14	12.33	7%	10%+5%	a	3%	

PAID HOLIDAYS:

A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

FOOTNOTE

a. Holidays, A through F plus Washington's Birthday and Presidential Election Day provided the employee works any of the three days in the five work days preceding the holiday and the first work day after the recognized holiday.

POWER EQUIPMENT OPERATORS - HIGHWAY, ROAD, STREET & SEWER CONSTRUCTION:

GROUP I: Autograde-combn., subgrader, base MIL. spreader & base trimmer (CMI & similar types), autograde placer-trimmer-spreader-combn. (CMI & similar types), autograde slipform paver (CMI & similar types), backhoes (all types, including all combination hoe loaders), central power plants (all types), concrete paving machines, cranes (all types including overhead & straddle travelling type), cranes (gantry), drillmaster, quarrymaster (down the hole drill), draglines, elevator graders, engines (large diesel 1620 HP and staging pump), front end loader (5 yds. and over), gradalls, grader, rago, helicopters (co-pilot), jacks (screw air hydraulic power operated unit or console type (not hand jack or pile load test type), locomotive (large), mucking machine, pavers (21-E and over), paver (resinous, broyhill), pavement & concrete breaker (superhammer), pavement breaker truck mounted, piledriver, scooper (loader and shovel), koehring, shovels, tree chopper, trench machines

GROUP II: "A" frame, boring & drilling machines, brush chopper, chipper & shredder, cableways, carryalls, cherry pickers (6 tons and under), concrete pump, concrete pumping system, pumpcrete, squeezecrete and similar types, conveyors (125' and over), economobiles (hilo, lull, hyster and similar type equipment), fork lifts, front end loaders 2 yds. but less than 5 yds., groove cutting machine, heater planer, pans (letourneau, dw's ukes), pumpcrete (unit type), pumpcrete machines (squeezecrete & concrete pumping machines regardless of size), rollers (blacktop), scrapers (letourneau, dw's, ukes), side booms, squeezecrete, straddle carrier (ross & similar types), winch trucks (hoisting)

GROUP III: Asphalt curbing machine, asphalt plant engineer, asphalt spreaders, autograde tube finisher & texturing machine (CMI and similar), autograde curecrete machine (CMI and similar types), autograde curb trimmer & sidewalk, shoulder slip form (CMI and similar types), bar bending machines (power), batchers, batching plant and crusher on site, belt conveyor systems, bridge deck finisher, car dumpers (railroad), compressor and blower type units (used independently or mounted on dual purpose trucks, on the job site or in conjunction with job site in loading and unloading of concrete, cement, fly ash, instancrete or similar type materials, concrete breaking machines, concrete finishing machines, concrete saws & cutters (ride on type), concrete spreaders, hetzel, rexomatic & similar types, conveyors (under 125'), crushing machines, ditching machines (small ditchwitch or similar), drill doctor (duties include dust collector, maintenance), dope pots (mechanical with or without pump), dumpster, fine grade machine (large type), concrete vibrators, skimmer machines (boom type), generators, giraffe grinders, grader (finish only), graders & motor patrols, gunite machine (excluding nozzle), hammer vibratory (in conjunction with generator), hoppers, hopper doors (power operated), laddervator, lights (portable generating light plants), locomotive (dinky type), maintenance and repair of asphalt curbing machines, concrete finishing machines, concrete vibrators, gas buggies, leveling machines, portable generators, power saws, compressor equipment or compressor units used in connection with cement, paint, insulating and acoustical sprays, plaster, curing and sandblasting (all and similar types), mechanic, mixers (excepting paving mixers), motor patrols and graders, pavers (under 21-E), pavement breaker (small, selfpropelled ride on type, also maintains compressor or hydraulic unit), pipe bending machine (power), pitch pump, front end loaders (1 yd. and over, but less than 2 yds.), post hole digger, rod bending machine (power), scales (power), seaman pulverizing mixer, silas, steam jennies and boilers (irrespective of their use), steel cutting machine (services and maintains), vibrating plants (used in conjunction with unloading, welder and and repair mechanic

POWER EQUIPMENT OPERATORS - HIGHWAY, ROAD, STREET & SEWER CONSTRUCTION CONT'D. :

GROUP IV: Bulldozer, fireman, sprinkler and water pump trucks (used on job site or in conjunction with job site), stone spreaders, sweepers and brooms, tractors (D-8 and over), water and sprinkler trucks (used on job site in conjunction with job site

GROUP V: Compressors (single), heaters (nelson or other type including propane, natural gas or flowtype units), pumps (4 inch suction and over including submersible pumps), temporary heating plant (nelson or other type including propane, natural gas or flow type units), pumps (diesel engine and hydraulic immaterial of power), wellpoint systems (including installation and maintenance), welding machines (gas or electric converters of any type 2 or 3 in battery), pumps (2 of less than 4 inch suction including submersible pumps

GROUP VI: Front end loaders (under 1 yard)

GROUP VII: Helicopters (pilot/engineer)

GROUP VIII: Pump (staging)

GROUP IX: Rollers (grade fill or stone base), tractors (under D-8)

GROUP X: Tug master (power boats), captain (power boats)

GROUP XI: Compressors (2 or 3 within a total distance of 100' constitutes a battery

GROUP XII: Concrete spreaders (small type), fertilizing equipment, operation & maintenance of grease, gas, fuel and oil supply trucks, mulching equipment, operation and maintenance of seeding machines, tamping machines (vibrating, self propelled), farm tractors, conveyor loaders (not including elevator graders), fine grade machine (small type), concrete mixers (small), road finishing machines (small type), welding machines (gas or electric converters of any type-single), form line graders (small type)

HIGHWAY, ROAD, STREET & SEWER CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
GROUP I	$10.73	7%	5%+10%	a	3%	
GROUP II	9.85	7%	5%+10%	a	3%	
GROUP III	8.96	7%	5%+10%	a	3%	
GROUP IV	8.76	7%	5%+10%	a	3%	
GROUP V	8.05	7%	5%+10%	a	3%	
GROUP VI	8.61	7%	5%+10%	a	3%	
GROUP VII	12.33	7%	5%+10%	a	3%	
GROUP VIII	9.95	7%	5%+10%	a	3%	
GROUP IX	8.41	7%	5%+10%	a	3%	
GROUP X	8.91	7%	5%+10%	a	3%	
GROUP XI	8.66	7%	5%+10%	a	3%	
GROUP XII	7.90	7%	5%+10%	a	3%	

PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

FOOTNOTE:
a. Paid holidays; A through F, Washington's Birthday and Presidential Election Day; provided the employee works any three days in the five day work week preceding the holiday and the first work day following the holiday.

NJ-4-PEO-2-W

STEEL ERECTION	BASIC HOURLY RATES	FRINGE BENEFITS PAYMENTS H & W	PENSIONS	VACATION	APP. TR.
Power equipment Operators:					
Cranes and derricks (land or floating), with booms (including jib), less than 140'	$11.53	7%	15%	a	3%
Cranes and derricks (land or floating), with booms (including jib), 140' and over	12.33	7%	15%	a	3%
A-frames, cherry pickers, elevators, permanent or temporary or any other hoisting machine regardless of motor power, fork lifts, hoists house cars, side booms	10.88	7%	15%	a	3%
Air compressors (2 or 3 in battery), welding machines (gasoline or electric) converters of any type, 2 or 3 in battery multiple welders	9.31	7%	15%	a	3%
Air compressors single, welding machines (gasoline electric converter of any type, single)	8.50	7%	15%	a	3%
Fireman	8.83	7%	15%	a	3%
Oilers	8.00	7%	15%	a	3%
Water Operations:					
On all power boats used in conjunction with pipe line, river crossings and all types of construction work:					
Captain, tugmaster	9.25	7%	15%	a	3%
Deckhand	7.95	7%	15%	a	3%

Paid Holidays:
A-New Years' Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

Footnote:
a. Holidays: A through F; Washington's Birthday; Veteran's Day and Presidential Election Day.

NEW JERSEY-2-TD-1-2-3-0

BUILDING, HEAVY & HIGHWAY CONSTRUCTION	BASIC HOURLY RATES	FRINGE BENEFITS PAYMENTS H & W	PENSIONS	VACATION	APP. TR.	OTHERS
TRUCK DRIVERS						
Winch Trailer	5.68	.85		a+b		
Euclids, straight, bottom, rear and side dump, carryall and scrapers: (no self loading-loading over the top), water sprinkler trailers, water pulls, and similar types, flat, floats, I-Beam, low beds, transit-mix, road oil, fuel, asphalt, stringer, seeding fertilizing, bituminous distributor, and similar types of vehicles	5.58	.85		a+b		
Straight three-axle materials: trucks and floats	5.48	.85		a+b		
Straight dumps, flats, floats, pick-ups, container hauler, fuel, water sprinkler, road oil, winch, A-frame, scissor, nipper, "all dual purpose trucks", trucks with mechanical tail gates", any rubber tired tractor used in pulling and towing farm wagons and trailers of any description, mechanics	5.43	.85		a+b		
Mechanics helpers	5.20	.85		a+b		

PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

FOOTNOTES:
a. Holidays: A through F; Washington's Birthday; Lincoln's Birthday; Columbus Day; General Election Day; Veteran's Day; providing an employee works or shapes one day and is available during the Holiday calendar week.

b. Employees who have worked or have received pay for 85 days shall receive 48 hours vacation pay; 130 days - 96 hours vacation pay; 150 days - 120 hours vacation pay; an employee with 150 days credit and at least 15 years seniority shall receive an additional 40 hours vacation pay.

SUPERSEDEAS DECISION

STATE: NEW JERSEY

COUNTY: SOMERSET

DECISION NO.: AQ-2,091

DATE: DATE OF PUBLICATION

Supersedeas Decision No. AM-1,719 dated August 11,1971 in 36 FR 14892
DESCRIPTION OF WORK: Building Construction, (excluding single family homes and garden type apartments up to and including 4 stories), heavy and highway construction.

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BUILDING, HEAVY & HIGHWAY CONSTRUCTION	BASIC HOURLY RATES	FRINGE BENEFITS PAYMENTS				
		H & W	PENSIONS	VACATION	APP. TR.	OTHERS
Asbestos workers:						
Bedminster, Bernards, Bernardsville, Bound Brook, Bridgewater, Far Hills, Gladstone, Peapack, Raritan, Somerville & Warren	9.202	.5803	.4974		.02	
Remainder of County	9.30	.50	.50		.025	
Boilermakers	8.35	8%	9½+3%	10%	.01	
Boilermakers' helpers	7.82	8%	9½+3%	10%	.01	
Bricklayers, cement masons, plasterers, and stone masons:						
Franklin Park	9.55	.35	.25			
Bernardsville, Peapack, Gladstone, Far Hills, Bedminster, Liberty Corner and Basking Ridge	9.05	.45	.40		.02	
N. Plainfield and Watchung Twps.	9.45	.45	.40		.02	
Remainder of County	9.40	.40	.50			
Carpenters:						
Watchung & No. Plainfield:						
Carpenters	9.29	6%	6%		.02	
Millwrights	9.54	6%	6%		.02	
Skillman, and Blawenburg:						
Carpenters and insulators	9.35	.50	.55	.50	.02	
Millwrights	9.35	.50	.55	.50	.02	
Remainder of County:						
Carpenters & insulators	9.29	6%	6%	g	.02	
Millwrights	9.54	6%	6%	g	.02	
Dock builders and Piledrivermen	9.36	.90	1.53	.56	.02	
Electricians:						
Electricians, & cable splicers	10.11	.40	1%+.30		3/4 of 1%	
Elevator Constructors:						
Elevator constructors	9.10	.395	.26+a	b+c	.015	
Elevator constructors' helpers	6.83	.395	.26+a	b+c	.015	
Elevator constructors' helpers (prob.)	4.55					
Modernization	8.33	.395	.26+a	b+c	.015	
Modernization helper	6.25	.395	.26+a	b+c	.015	
Repair	7.48	.395	.26+a	b+c	.015	
Repair helpers	5.61	.395	.26+a	b+c	.015	
Glaziers	8.70	.70	.65	d	.02	
Ironworkers, structural, ornamental & reinforcing-nearest town listed below:						
Easton, Pennsylvania	8.78	h				
Trenton	8.63	.47	1.03	10%	.05	
Perth Amboy	9.15	.64	2.11	.90	.09	

18-N.J.-1-2-3-B 2 of 4

BUILDING, HEAVY & HIGHWAY CONSTRUCTION	BASIC HOURLY RATES	FRINGE BENEFITS PAYMENTS				
		H & W	PENSIONS	VACATION	APP. TR.	OTHERS
Laborers, Building:						
Bernardsville, Peapack, Gladstone, Far Hills, Basking Ridge, Liberty Corners, Lyons (VA Hospital)	$6.70	.45	.40			
N. Plainfield, Warren and Watchung:						
Laborers	6.65	.55	.50			
Air tool op., mason tenders, mortar mixers, plasterers' tenders	6.65	.55	.50			
E. Millstone and Franklin Twps:						
Laborers	7.00	.35	.35			
Mason tenders, mortar mixers, demolition and plasterers' tenders	7.00	.35	.35			
Scaffold builders	7.00	.35	.35			
Jackhammer and vibrator operator	7.25	.35	.35			
Remainder of County	6.80	.45	.45			
Lathers:						
Bridgewater, Branchburg, Bound Brook, Belle Mead, E. Millstone, Finderne, Flagtown, Franklin, Green Brook, Briggstown, Lamington, Martinsville, Millstone, Pluckermin, Raritan, Rocky Hill, Middlebush, Manville, N. Branch, Meshanic Station, S. Bound Brook Somerville, Watchung, Warren and Zarephath, Franklin Park	6.15	.25	.25		.01	
Remainder of County	6.15	.25	.25		.02	
Lead burners	8.75	.30		e	.01	
Marble setters	7.40	6-½%	7%			
Marble setters' helpers	6.83	6-½%	7%			
Painters:						
Skillman, Blawenburg, Rock Hill & Stoutsburg:						
Brush	4.70					
Steel	5.50					
Spray	5.80					
Roller	5.60					
Franklin Township:						
Commercial	7.15	.65	.50			
Steel, tanks, towers, steeples, stacks, and bridges	8.25	.65	.50			
Spray	8.25	.65	.50			
Remainder of County:						
Commercial	5.75	.35	.45			
Spray, steel, sandblast, tanks, power lines & stage work	6.70	.35	.45			
Plumbers and steamfitters	8.57	.40	.90		.15	

BUILDING, HEAVY & HIGHWAY CONSTRUCTION	BASIC HOURLY RATES	FRINGE BENEFITS PAYMENTS				
		H & W	PENSIONS	VACATION	APP. TR.	OTHERS
Roofers:						
Rocky Hill, Harlingen, Belle Meade, Neshanic, Montgomery, Zion, Skillman, Clover Hill, Stoutsburg, Blawenburg, Centerville, and Kingston	9.20	.40	.50			
Pottersville, Peapack, Gladstone, Bernardsville, Basking Ridge, Bedminster, Far Hills, Mine Brook, Lyons, Liberty Corner, Pluckamin, Mt. Bethel and Watchung:						
Composition, damp & waterproofing	6.82	.25	.20			
Slate and tile	8.05	.30	.20			
Slate and tile helpers	7.05	.30	.20			
Remainder of County:						
Roofers, composition, damp & waterproofing	8.50	.50	.325			
Slate and tile	8.625	.50	.325			
Slate and tile helper	7.55	.50	.325			
Sheet metal workers	9.30	5%	4%		.05	
Soft floor layers	5.80	6%	5%		4%	
Sprinkler fitters:						
Bernardsville, Basking Ridge, Mine Brook, Far Hills, Lyons, Mt. Bethel, Watchung, N. Plainfield, Martinville, and Somerville	10.12	.40	.60		.07	
Remainder of County	8.00	.25	.40		.05	
Terrazzo workers	7.95	.43+.45	.43			
Terrazzo workers' helpers	6.98	.43+.45	.43			
Terrazzo machine operator	7.13	.43+.45	.43			
Tile setters	6.16	4%	4%	2%		
Welders - rate prescribed for craft performing operation to which welding is incidental.						

PAID HOLIDAYS:

A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

FOOTNOTES:

a. Employer contributes $9.00 per day to Annuity Fund.

b. Holidays: A through F; Lincoln's Birthday, Washington's Birthday, Columbus Day, Election Day, Armistice Day.

c. Employer contributes 6.4% basic hourly rate for 5 years or more of service or 4.2% basic hourly rate for 6 months to 5 years of service as Vacation Pay Credit.

d. One week vacation after one year's work; 2 weeks' vacation after 4 years' work; 3 weeks' vacation after 15 years' work.

e. Holidays: A through F; Washington's Birthday, Good Friday and Christmas Eve, providing employee has worked 45 full days during the 120 calendar days prior to the holiday, and the regular scheduled work days immediately preceding and following the holiday.

f. Employer contributes 1% to Temporary Disability Fund.

g. Two hours off with pay on any general election day.

h. $1.50 per employer contribution to a combined health, welfare and pension fund.

N.J.-2-LAB-2-3-E

HEAVY AND HIGHWAY CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Laborers:					
Blasters	$7.60	.41	.64	a	
Finisher, rammer, paver, gunite nozzle man and stone cutter	7.45	.41	.64	a	
Timberman	7.20	.41	.64	a	
Form setter	7.15	.41	.64	a	
Sewer pipe, laser men, conduit and duct line layers	6.95	.41	.64	a	
Wagon drill op. and drill master	7.05	.41	.64	a	
Wagon drill op. helper, drill master helper, powder carrier and magazine tender	6.70	.41	.64	a	
Jackhammer, chipping hammer, pavement breaker, power buggy, concrete cutter, asphalt cutter, sheet hammer and tree cutter op. and such other power tools used to perform work usually done manually by laborers	7.05	.41	.64	a	
Signal man	6.75	.41	.64	a	
Wrapping and coating of all pipe	6.55	.41	.64	a	
Common laborers, landscape laborers, railroad track laborers, flagmen, traffic directors, salamander tenders, pitman and dumpmen	6.50	.41	.64	a	
Rakers and tampers on cold patch work	6.50	.41	.64	a	
FREE AIR TUNNEL WORK	Daily Rates				
Blasters	$63.77	.41	.59	a	
Skilled men (including miners, drill runners, iron men, maintenance men, conveyor men, safety miners, riggers, block layers, powder carriers, all other skilled men)	60.57	.41	.59	a	
Semi-skilled men (including miners' helpers, chuck tenders, track men, nippers, brake men, derail men, cable men, hose men, grout men, gravel men, form men, bell or signal men (top or bottom), form workers and movers, concrete workers, shaft men, tunnel laborers, caulkers' helpers, all other semi-skilled men)	59.28	.41	.59	a	
All others (including powder watchmen, change house attendants, top laborers)	55.22	.41	.59	a	

PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

FOOTNOTE:
a. Holidays: A through F; Washington's Birthday; Armistice Day; Presidential Election Day; (providing employee works 3 days for the same employer within a period of working days consisting of 5 working days before and 5 working days after the day upon which the holiday falls).

N.J.-5-LAB-5-J

	BASIC HOURLY RATES	FRINGE BENEFITS PAYMENTS				
		H & W	PENSIONS	VACATION	APP. TR.	OTHER
Laborers, Asphalt						
Streets:						
Head rakers	$6.40	.46	.39	a		
Rakers	6.25	.46	.39	a		
Tampers and smoothers, kettlemen, painters, top shovelers, and roller boys	6.00	.46	.39	a		
Plant:						
Scale mixer and burner men	6.25	.46	.39	a		
Feeders and dust men	6.00	.46	.39	a		

PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

FOOTNOTE:
a. Holidays: A through F, Washington's Birthday; Armistice Day; Presidential Election Day; providing an employee works or is available for work 3 days in the work week in which the holiday falls.

BUILDING & HEAVY CONSTRUCTION - POWER EQUIPMENT OPERATORS:

GROUP I: Autograde - combn. subgrader, base MIL spreader & base trimmer (CMI & similar types), autograde placer-trimmer-spreader-combn. (CMI & similar types), autograde slipform paver (CMI & similar types), backhoes (all types, including all combination hoe loaders), central power plants (all types), concrete paving machines, cranes (all types including overhead & straddle travelling type), cranes (gantry), derricks (land or floating), drillmaster, quarrymaster (down the hole drill), draglines, elevator graders, engines (large diesel 1620 HP and staging pump), front end loaders (5 yds. and over), gradalls, grader, rago, helicopters (co-pilot), jack (screw air hydraulic power operated unit or console type (not hand jack or pile load test type), locomotive (large), mucking machines, pavers (21-E and over), paver (resinous, broyhill), pavement & concrete breaker (super-hammer), pavement breaker truck mounted, piledriver, scooper (loader and shovel) koehring, shovels, tree chopper, trench machines

GROUP II: "A" frame, boring & drilling machines, brush chopper, chipper & shredder, cableways carryalls, cherry pickers (6 tons & under), concrete pump, concrete pumping system, pumperete, squeezecrete & similar types, conveyors (125' & over), econo-mobiles (hilo, lull, hyster similar type equipment), fork lifts, front end loaders (2 yds, but less than 5 yds.), grove cutting machine, heater planer, pans (letourneau, dw's ukes), pumperete (unit type), pumperete machines (squeezecrete & concrete pumping regardless of size), rollers (backtop), scrapers (letourneau, dw's ukes), side booms, squeezecrete, straddle carrier (ross & similar types), winch trucks (hoisting)

GROUP III: Aerial platform (used as hoist), hoist (all type hoists, gas, diesel, electric, air hydraulic, single and double drum, concrete, brick shaft caisson, conveyor, snorkel, roof, tugger, and house cars or any other similar type hoisting machines, portable or stationary, except Chicago boom type), elevators or house cars, roof hoist

GROUP IV: Asphalt curbing machine, asphalt plant engineer, asphalt spreaders, auto-grade tube finisher & texturing machine (CMI & similar), autograde curecrete machine (CMI & similar), autograde crub trimmer & sidewalk, shoulder slipform (CMI & similar types), bar bending machines (power), batchers, batching plant & crusher on site, belt conveyor systems, boilers and steam jennies (irrespective of their use), boom type skimmer machines, bridge deck finisher, car dumpers (railroad), compressor and blower type units (used independently or mounted on dual purpose trucks, on job site or in conjunction with hob site, in loading and unloading of concrete, cement, fly ash, instancrete, or similar type materials), concrete breaking machines, concrete finishing machines, concrete saws & cutters (ride on type), concrete spreaders hetzel, rexomatic and similar types, conveyors (under 125'), crushing machines, ditching machines (small, ditchwitch or similar), drill doctor (duties include dust collector, maintenance), dope pots (mechanical with or without pump), dumpsters, fine grade machine (large type), front end loaders (under 2 yds.), generators giraffe grinders, grader (finish only), graders and motor patrols, gunite machines (excluding nozzle), hammer vibrator (in conjunction with generator), hoppers, hopper doors (power operated), ladders (motorized), laddervator, lights (portable generating light plants), locomotive (dinky type), maintenance and repair of asphalt curbing machines, concrete finishing machines, concrete vibrators, gas buggies, leveling machines, portable generators, power saws, compressor equipment or compressor units used in connection with cement,

BUILDING & HEAVY CONSTRUCTION - POWER EQUIPMENT OPERATORS CONT'D.:

paint, insulating and acoustical sprays, plaster, curing and sandblasting (all and similar types), mechanic, mixers (excepting paving mixers), motor patrols and graders, pavers (under 21-E), pavement breakers (small, self propelled ride on type, also maintains compressor or hydraulic unit), pipe bending machine (power), pitch pump, plaster pump (regardless of size), post hole digger, rod bending machines (power), scales (power), seaman pulverizing mixer, silas, steam jennies and boilers (irrespective of theiruse), steel cutting machine (service & maintains), vibrating plants (used in conjunction with unloading, welder and repair mechanic.

GROUP V: Welding machines (gas or electric converters of any type 2 or 3 in battery), compressors (2 or 3 within a total distance of 100' constitutes a battery), welding system, mutiple (rectifier transformer type)

GROUP VI: Bulldozer, fireman, sprinkler and water pump trucks (used on job site or in conjunction with job site), stone, spreaders, sweepers & brooms, tractors (D-8 and over), water & sprinkler trucks (used on job site or in conjunction with job site)

GROUP VII: Compressor (single), heaters (nelson or other type including propane, natural gas or flow type units), pumps (4 inch suction & over including submersible pumps), temporary heating plant (nelson or other type including propane, natural gas or flow type units), welding machines (gas or electric converters of any type single), wellpoint system (including installation and maintenance)

GROUP VIII: Concrete spreaders (small type), fertilizing equipment and maintenance of), grease, gas, fuel and oil supply trucks, mulching equipment (operation and maintenance of), seeding equipment (operation and maintenance of), tamping machines (vibrating self propelled)

GROUP IX: Assistant engineer/oiler, mechanics helper, tire repair & maintenance

GROUP X: Water Operations: On all power boats used in conjunction with pipeline, river crossings and all types of construction: captain (power boats), tug master (power boats)

GROUP XI: Water Operations: Deckhand

GROUP XII: Pump (staging)

GROUP XIII: Rollers (grade fill or stone base)

GROUP XIV: Helicopters (pilot/engineer)

BUILDING AND HEAVY CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
POWER EQUIPMENT OPERATORS						
GROUP 1	$10.73	7%	10%+5%	a	3%	
GROUP 2	9.85	7%	10%+5%	a	3%	
GROUP 3	9.65	7%	10%+5%	a	3%	
GROUP 4	8.96	7%	10%+5%	a	3%	
GROUP 5	8.81	7%	10%+5%	a	3%	
GROUP 6	8.76	7%	10%+5%	a	3%	
GROUP 7	8.05	7%	10%+5%	a	3%	
GROUP 8	8.41	7%	10%+5%	a	3%	
GROUP 9	7.60	7%	10%+5%	a	3%	
GROUP 10	8.91	7%	10%+5%	a	3%	
GROUP 11	7.50	7%	10%+5%	a	3%	
GROUP 12	9.95	7%	10%+5%	a	3%	
GROUP 13	8.41	7%	10%+5%	a	3%	
GROUP 14	12.33	7%	10%+5%	a	3%	

PAID HOLIDAYS:

A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

FOOTNOTE

a. Holidays, A through F plus Washington's Birthday and Presidential Election Day provided the employee works any of the three days in the five work days preceeding the holiday and the first work day after the recognized holiday.

POWER EQUIPMENT OPERATORS - HIGHWAY, ROAD, STREET & SEWER CONSTRUCTION:

GROUP I: Autograde-combn., subgrader, base MTL. spreader & base trimmer (CMI & similar types), autograde placer-trimmer-spreader-combn. (CMI & similar types), autograde slipform paver (CMI & similar types), backhoes (all types, including all combination hoe loaders), central power plants (all types), concrete paving machines, cranes (all types including overhead & straddle travelling type), cranes (gantry), drillmaster, quarrymaster (down the hole drill), draglines, elevator graders, engines (large diesel 1620 HP and staging pump), front end loader (5 yds. and over), gradalls, grader, rago, helicopters (co-pilot), jacks (screw air hydraulic power operated unit or console type (not hand jack or pile load test type), locomotive (large), mucking machine, pavers (21-E and over), paver (resinous, broyhill), pavement & concrete breaker (superhammer), pavement breaker truck mounted, piledriver, scooper (loader and shovel), koehring, shovels, tree chopper, trench machines

GROUP II: "A" frame, boring & drilling machines, brush chopper, chipper & shredder, cableways, carryalls, cherry pickers (6 tons and under), concrete pump, concrete pumping system, pumpcrete, squeezecrete and similar types, conveyors (125' and over), economobiles (hilo, lull, hyster and similar type equipment), fork lifts, front end loaders 2 yds. but less than 5 yds., groove cutting machine, heater planer, pans (letourneau, dw's ukes), pumpcrete (unit type), pumpcrete machines (squeezecrete & concrete pumping machines regardless of size), rollers (blacktop), scrapers (letourneau, dw's, ukes), side booms, squeezecrete, straddle carrier (ross & similar types), winch trucks (hoisting)

GROUP III: Asphalt curbing machine, asphalt plant engineer, asphalt spreaders, autograde tube finisher & texturing machine (CMI and similar), autograde curbcrete machine (CMI and similar types), autograde curb trimmer & sidewalk, shoulder slip form (CMI and similar types), bar bending machines (power), batchers, batching plant and crusher on site, belt conveyor systems, bridge deck finisher, car dumpers (railroad), compressor and blower type units (used independently or mounted on dual purpose trucks, on the job site or in conjunction with job site in loading and unloading of concrete, cement, fly ash, instancrete or similar type materials, concrete breaking machines, concrete finishing machines, concrete saws & cutters (ride on type), concrete spreaders, hetzel, rexomatic & similar types, conveyors (under 125'), crushing machines, ditching machines (small ditchwitch or similar), drill doctor (duties include dust collector, maintenance), dope pots (mechanical with or without pump), dumpster, fine grade machine (large type), concrete vibrators, skimmer machines (boom type), generators, giraffe grinders, grader (finish only), graders & motor patrols, gunite machine (excluding nozzle), hammer vibratory (in conjunction with generator), hoppers, hopper doors (power operated), laddervator, lights (portable generating light plants), locomotive (dinky type), maintenance and repair of asphalt curbing machines, concrete finishing machines, concrete vibrators, gas buggies, leveling machines, portable generators, power saws, compressor equipment or compressor units used in connection with cement, paint, insulating and acoustical sprays, plaster, curing and sandblasting (all and similar types), mechanic, mixers (excepting paving mixers), motor patrols and graders, pavers (under 21-E), pavement breaker (small, selfpropelled ride on type, also maintains compressor or hydraulic unit), pipe bending machine (power), pitch pump, front end loaders (1 yd. and over, but less than 2 yds.), post hole digger, rod bending machine (power), scales (power), seaman pulverizing mixer, silas, steam jennies and boilers (irrespective of their use), steel cutting machine (services and maintains), vibrating plants (used in conjunction with unloading, welder and and repair mechanic

POWER EQUIPMENT OPERATORS - HIGHWAY, ROAD, STREET & SEWER CONSTRUCTION CONT'D. :

GROUP IV: Bulldozer, fireman, sprinkler and water pump trucks (used on job site or in conjunction with job site), stone spreaders, sweepers and brooms, tractors (D-8 and over), water and sprinkler trucks (used on job site in conjunction with job site

GROUP V: Compressors (single), heaters (nelson or other type including propane, natural gas or flowtype units), pumps (4 inch suction and over including submersible pumps), temporary heating plant (nelson or other type including propane, natural gas or flow type units), pumps (diesel engine and hydraulic immaterial of power), wellpoint systems (including installation and maintenance), welding machines (gas or electric converters of any type 2 or 3 in battery), pumps (2 of less than 4 inch suction including submersible pumps

GROUP VI: Front end loaders (under 1 yard)

GROUP VII: Helicopters (pilot/engineer)

GROUP VIII: Pump (staging)

GROUP IX: Rollers (grade fill or stone base), tractors (under D-8)

GROUP X: Tug master (power boats), captain (power boats)

GROUP XI: Compressors (2 or 3 within a total distance of 100' constitutes a battery

GROUP XII: Concrete spreaders (small type), fertilizing equipment, operation & maintenance of grease, gas, fuel and oil supply trucks, mulching equipment, operation and maintenance of seeding machines, tamping machines (vibrating, self propelled), farm tractors, conveyor loaders (not including elevator graders), fine grade machine (small type), concrete mixers (small), road finishing machines (small type), welding machines (gas or electric converters of any type-single), form line graders (small type)

HIGHWAY, ROAD, STREET & SEWER CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
GROUP I	$10.73	7%	5%+10%	a	3%	
GROUP II	9.85	7%	5%+10%	a	3%	
GROUP III	8.96	7%	5%+10%	a	3%	
GROUP IV	8.76	7%	5%+10%	a	3%	
GROUP V	8.05	7%	5%+10%	a	3%	
GROUP VI	8.61	7%	5%+10%	a	3%	
GROUP VII	12.33	7%	5%+10%	a	3%	
GROUP VIII	9.95	7%	5%+10%	a	3%	
GROUP IX	8.41	7%	5%+10%	a	3%	
GROUP X	8.91	7%	5%+10%	a	3%	
GROUP XI	8.66	7%	5%+10%	a	3%	
GROUP XII	7.90	7%	5%+10%	a	3%	

PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

FOOTNOTE:
a. Paid holidays; A through F, Washington's Birthday and Presidential Election Day provided the employee works any three days in the five day work week preceding the holiday and the first work day following the holiday.

STEEL ERECTION

	BASIC HOURLY RATES	FRINGE BENEFITS PAYMENTS				
		H & W	PENSIONS	VACATION	APP. TR.	OTHER
Power Equipment Operators:						
Cranes and derricks (land or floating), with booms (including jib), less than 140'	$11.53	7%	15%	a	3%	
Cranes and derricks (land or floating), with booms (including jib), 140' and over	12.33	7%	15%	a	3%	
A-frames, cherry pickers, elevators, permanent or temporary or any other hoisting machine regardless of motor power, fork lifts, hoists house cars, side booms	10.88	7%	15%	a	3%	
Air compressors (2 or 3 in battery), welding machines (gasoline or electric) converters of any type, 2 or 3 in battery multiple welders	9.31	7%	15%	a	3%	
Air compressors single, welding machines (gasoline electric converter of any type, single)	8.50	7%	15%	a	3%	
Firemen	8.83	7%	15%	a	3%	
Oilers	8.00	7%	15%	a	3%	
Water Operations:						
On all power boats used in conjunction with pipe line, river crossings and all types of construction work:						
Captain, tugmaster	9.25	7%	15%	a	3%	
Deckhand	7.95	7%	15%	a	3%	

Paid Holidays:
A-New Years' Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

Footnote:
a. Holidays: A through F; Washington's Birthday; Veteran's Day and Presidential Election Day.

New Jersey 1-TD-1-2-3-F 1 of 2

BUILDING, HEAVY & HIGHWAY CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
TRUCK DRIVERS:						
Winch Trailers	$6.28	a		b		
Euclid, International Haversters, Wabcos, caterpiller, koehring, tractors and wagons, dumptors, straight, bottom rear and side dump, carryalls and scrapers (not self-loading), over the top, water sprinkler, trailers, water pulls, and similar types of vehicles	6.18	a		b		
Tractor and trailer type vehicles, flat floats, I-Beam, low beds, water sprinkler, bituminous, transit-mix, road oil fuel, bottom dump hopper, rear dump, office shanty, epoxy, asphalt, agitator mix, mulching, stringer, seeding, fertilizing pole, spread, bituminous distributor, water pulls (entire unit) (tractor trailer), reel trailer, and similar types of vehicles	6.18	a		b		
Straight three-axle materials: Trucks and floats	6.08	a		b		
Straight dumps, flats, floats, pick-ups, container haulers, fuel, water sprinkler, road oil, stringer bead and hot pass, bus, dumpcrete, transit-mixers, agitator mix, half-track, winch truck, side-o-matic, dynamite, powder, X-ray, welding, skid, jeep, station wagon, stringer, A-Frame, all dual purpose trucks, mechanical tail gates, batch, seeding, mulching, fertilizer, air compressor trucks (in transit), escort scissor, hi-lift, telescope, concrete breaker, gin pole, stone, sand, asphalt-distributor and spreader, nipper, fuel trucks (driver on fuel truck including handling of hose and nozzle-entire unit), team drivers, vacuum or vac-all trucks, skid truck (debris container-entire unit), concrete mobile trucks (entire unit), beltcrete trucks, pumpcrete trucks, line trucks, reel, wreckers or tow trucks, utility, tack trucks, broyhill coal tar epoxy, littleford bituminous distributor, slurry seal truck or vehicle, thiokol track master pick-up (swamp cat pick-up), bucket loader dump, rubber tired tractor used in pulling and towing farm wagon and trailers of any discription	6.03	a		b		

New Jersey 1-TD-1-2-3-F 2 of 2

BUILDING, HEAVY & HIGHWAY CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
TRUCK DRIVERS (Cont'd):						
Teamster mechanic	$6.03	a		b		
Mechanic helper	5.80	a		b		

FOOTNOTES:

a. Employer contributes $.89 per hour to a combined Health, Welfare and Pension fund.

b. Employees worked or received pay: 80 days within a year receive one week's vacation, 125 days within a year receive two weeks' vacation, 145 days within a year receive 15 days' vacation, 15 years seniority and 145 days within a year receive four weeks' vacation.

SUPERSEDEAS DECISION

STATE: West Virginia
DECISION NO.: AQ-2036
COUNTY: Statewide
DATE: Date of Publication
Supersedes Decision No. AP 801, dated March 13, 1973 in 38 FR 9415.
DESCRIPTION OF WORK: Heavy and Highway Construction.

57-W.VA.-2-3- A

HEAVY & HIGHWAY CONSTRUCTION	BASIC HOURLY RATES	FRINGE BENEFITS PAYMENTS				
		H & W	PENSIONS	VACATION	APP. TR.	OTHERS
Ironworkers:						
Mineral, Pendelton & Tucker Counties:						
Structural and ornamental	8.10	.40	.40			
Reinforcing	8.10	.40	.40			
Barbour, Brooke, Harrison, Marion Marshall, Monongalia, Preston, Randolph, Taylor, Tyler, Wetzel & Ohio Counties:						
Ironworkers:	8.60	.60	.50	5%	.03	
Cabell, Mingo, & Wayne Counties:						
Ironworkers:	8.40	.50	.55		.01	
Wood, Calhoun, Doddridge, Gilmer, Jackson, Lewis, Mason, Pleasants, Ritchie, Roane, Upshur & Wirt Cos.:						
Ironworkers:	8.52	.55	.85		.01	
Kanawha, Putnman, Lincoln, Logan, Wyoming, McDowell, Raleigh, Fayette, Nicholas, Webster, Braxton, Clay and Boone Counties:						
Ironworkers:	8.10	.50	.75		.05	
Greenbrier, Mercer, Monroe, Pocahontas and Summers Counties:						
Structural and ornamental	8.10	.50	.75		.05	
Reinforcing	8.10	.50	.75		.05	

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HEAVY CONSTRUCTION	Basic Hourly Rates	FRINGE BENEFITS PAYMENTS				
		H & W	Pensions	Vacation	App. Tr.	Other
POWER EQUIPMENT OPERATORS						
EQUIPMENT with booms of one hundred and fifty (150) feet and/or capacity of three (3) yards and over, or (50) tons and over, front end loader with capacity of four (4) yards and over, capacity to be based on manufacturer's specifications	$8.04	.25	.35		.04	
Tunneling and underground	8.29	.25	.35		.04	
CABLEWAY, crane derrick (2 or more drums), derrick boat, dragline, dredge, gradall, hoist (2 or more drums), mechanic-heavy, mixer plant (2 or more mixers, including batch control), paver-dual drum, piledriver, shovel, sideboom tractor, trencher - 20" or over, truck crane, backhoe, hi-lift (1½ cy. or over), dozer with riiper (when dozer is D8 class or larger), double hitched equipment, bulldozer with roller, standard gauge locomotive, tug boat, concrete pump, controlled fine grade machine	7.28	.25	.35		.04	
Tunneling and underground	7.53	.25	.35		.04	
BULLDOZER, derrick (single drum), hi-lift (under 1½ cubic yards), hoist (single drum), single drum paver, trencher (under 20"), motor grader, air tugger, rubber-tired scraper, self-loading tractor pan, Ross Carrier "A" Frame, multiple concrete saw, asphalt paver, hydraulic post driver, base paver, rotary drill and greaser and greaser truck, snake or push tractor	6.58	.25	.35		.04	
Tunneling and underground	6.83	.25	.35		.04	
CONCRETE MIXER (single drum), one cubic yard or over, fork lift, asphalt batch plant, concrete batch plant, crushing plant, screening and washing plant, roller, and compactor, sub-grader, concrete finishing machine, self- propelled power concrete spreader, bull float, portable concrete saw, bar and joint installing machine, form grader	6.35	.25	.35		.04	
Tunneling and underground	6.60	.25	.35		.04	
HIGH PRESSURE FIREMEN	6.04	.25	.35		.04	
Tunneling and underground	6.29	.25	.35		.04	
AIR COMPRESSOR, Concrete mixer (under one cubic yard), conveyor-belt or bucket, light plant, narrow gauge locomotive, welding machine, low pressure fireman, mechanic's helper, oiler, screed man, spreader box man, farm tractor and joint sealer, pump	5.73	.25	.35		.04	
Tunneling and underground	5.98	.25	.35		.04	
When operating more than one piece of equipment	5.88	.25	.35		.04	
Tunneling and underground	7.13	.25	.35		.04	

HEAVY CONSTRUCTION

	Basic Hourly Rates	FRINGE BENEFITS PAYMENTS H & W	Pensions	Vacation	App. Tr.	Other
POWER EQUIPMENT OPERATORS (Cont'd)						
"A" Counties Only:						
Brooke, Cabell, Hancock, Harrison, Jackson, Kanawha, Marion, Marshall, Mason, Monongalia, Ohio, Pleasants, Putnam, Tyler, Wayne, Wetzel, Wood, Preston and Lewis.						
LABORERS "A" Counties only						
BLACKSMITH, tunnel driller, tunnel miner	$6.85	.25	.25		.03	
POWDERMEN, Mucker-Chucker	6.46	.25	.25		.03	
CAISON BOTTOM MAN, pipelayer, form setter (road), drill operator, inside laborer	6.16	.25	.25		.03	
AIR TOOL OPERATOR, vibrator man, whacker, chainsaw operator, mortarman, mason tender, blacksmith helper, cement finisher helper, waterproofer, sheeter & shorer, pipelayers helpers, bullfloat man, pavement reinforcing placer, drill helper, handyman, signal man, asphalt raker, greencutter, Georgia power buggies, burner, grade checker, cement blower man, and powderman helpers	5.87	.25	.25		.03	
LABORER, deckhand, mulcher & seeder (hand or machine), tree trimmer, flagman	5.63	.25	.25		.03	
WATCHMAN	5.16	.25	.25		.03	
TRUCK DRIVERS "A" Counties Only						
WAREHOUSE, yardman, truck helpers, pickups, station wagons, panel trucks, team 2-up	5.87	a	b			
FLATBODY MATERIAL TRUCKS (Straight jobs), dump trucks (up to 5 yards), material checkers, material receivers, team 4-up, greasers, tireman and mechanic helpers (truck)	6.01	a	b			
SEMI-DUMP TRUCKS, semi-trailers (flat, rack or pole), low boy trucks, distributor trucks, agitators or mixer trucks (up to and including 5 yards), dump trucks and dumpsters (5 yards to 12 yards)	5.26	a	b			
RUBBER-TIRED TRACTORS (towing or pushing)	6.59	a	b			
DUMP TRUCK, agitator or mixer trucks and other hauling equipment (12 yards to 20 yards), mucker trucker	6.66	a	b			
DUMP TRUCK, Agitator or mixer trucks and other hauling equipment (20 yards and over)	6.81	a	b			
"A" FRAME OPERATOR	6.98	a	b			
MECHANICS (truck)	7.04	a	b			

FOOTNOTES:

a. Employer contribution of $28.50 per month provided the employee has been employed for 30 days or more.

b. Employer contribution of $26.00 per month provided the employee has been employed for 30 days or more.

HEAVY CONSTRUCTION

	Basic Hourly Rates	FRINGE BENEFITS PAYMENTS H & W	Pensions	Vacation	App. Tr.	Other
CARPENTERS "A" Counties only	$7.32	.25	.25		.02	
PILEDRIVERS "A" Counties except for Brooke, Hancock, Marshall, Monongalia, Ohio and Wetzel Counties	7.63	.25	.25		.02	
CEMENT MASONS "A" Counties only	7.54	c				
PILEDRIVERS:						
Brooke, Hancock, Marshall, Monongalia, Ohio, and Wetzel Counties	8.79	5%	7%			
"B" Counties only:						
Berkeley, Fayette, Logan, McDowell, Mercer, Mingo, Raleigh, Taylor, Wyoming, Barbour, Boone, Braxton, Calhoun, Clay, Dodrige, Gilmer, Grant, Greenbrier, Hampshire, Hardy, Jefferson, Lincoln, Mineral, Monroe, Morgan, Nicholas, Pendleton, Pocahontas, Randolph, Ritchie, Roane, Summers, Tucker, Upsher, Webster, Wirt.						
LABORERS "B" Counties only						
BLACKSMITH, tunnel driller, tunnel miner	6.66	.25	.25		.03	
POWDERMAN, mucker-chucker	6.27	.25	.25		.03	
CAISON BOTTOM MAN, pipelayer, form setter (road), drill operator, inside laborer	5.98	.25	.25		.03	
AIR TOOL OPERATOR, vibrator man, whacker, chainsaw operator, mortarman, mason tender, blacksmith helper, cement finisher (helper), waterproofer, sheeter & shorer, pipelayer (helpers), bullfloats man, pavement reinforcing placer, drill helper, handyman, signal man, asphalt raker, greencutter, georgia power buggie, burner, grade checker, cement blower man and powderman helper	5.67	.25	.25		.03	
LABORER, deckhand, mulcher & seeder (hand or machine), tree trimmer, flagman	5.44	.25	.25		.03	
WATCHMAN	4.97	.25	.25		.03	
TRUCK DRIVERS "B" Counties only						
WAREHOUSE, yardman, truck helpers, pickups, station wagons, panel trucks, team 2-up	5.63	a	b			
FLATBODY MATERIAL TRUCKS (Straight jobs), dump trucks (up to 5 yds), material checkers, material receivers, team 4-up, greasers, tiremen and mechanic helpers (truck)	5.79	a	b			
SEMI-DUMP TRUCKS, semi-trailers (flat, rack or pole), low boy trucks, distributor trucks, agitators or mixer trucks (up to and including 5 yards), dump trucks and dumpsters (5 yards to 12 yards)	6.01	a	b			
RUBBER-TIRED TRACTORS (towing or pushing)	6.34	a	b			
DUMP TRUCKS, agitator or mixer trucks and other hauling equipment (12 yards to 20 yards), mucker trucker	6.40	a	b			

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HEAVY CONSTRUCTION

	Basic Hourly Rates	FRINGE BENEFITS PAYMENTS H & W	Pensions	Vacation	App. Tr.	Other
TRUCK DRIVERS (Cont'd)						
DUMP TRUCK, agitator or mixer trucks and other hauling equipment (20 yards and over)	$5.59	a	b			
"A" FRAME OPERATOR	6.81	a	b			
MECHANICS (truck)	6.81	a	b			
CARPENTERS - "B" Counties only	6.61	.25	.25		.02	
CEMENT MASONS - "B" Counties only	7.09	c				
PILEDRIVERS - "B" Counties only	6.92	.25	.25		.02	

FOOTNOTES:

a. Employer contribution of $41.16 per month provided the employee has been employed for 30 days or more.

b. Employer contribution of $34.67 per month provided the employee has been employed for 30 days or more.

c. Employer contributes $.25 per hour into the Health & Welfare or Pension Fund.

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HIGHWAY CONSTRUCTION

	Basic Hourly Rates	FRINGE BENEFITS PAYMENTS H & W	Pensions	Vacation	App. Tr.	Other
POWER EQUIPMENT OPERATORS-Statewide W.VA.						
Class I: Equipment with booms of one hundred and fifty (150) feet and /or capacity of three (3) yards and over, or 50 tons or over, frontend loader with capacity of four (4) yards and over, capacities to be based on manufacturer's specifications,						
Transloader.	$7.91	.25	.35		.04	
Tunneling and underground	8.16	.25	.35		.04	
Class II: Cable way, crane, derrick (two drums or more), derrick boat, dragline, dredge, gradall, hoist (two drums or more) mechanic (heavy) mixer plant (two or more mixers, including batch control), paver (dual drums), pile driver, shovel, side boom tractor cone drill operator, trencher (20"or over), truck crane, backhoe, hi-lift (1-½ cubic yards or over), dozer with ripper (when dozer is D-8 class or larger double hitched equipment, bulldozer with roller, standard guage locomotive, tug boat, concrete pump, controlled fine grade machine	7.12	.25	.35		.04	
Tunneling and underground	7.37	.25	.35		.04	
Class III: Bulldozer, derrick (single drum), hi-lift (under 1-½ cubic yards), hoist (single drum), single drum paver, trencher (under 20"), motor grader, air tugger, rubber-tired scraper, self-loading tractor pan, Ross Carrier,"A" Frame, multiple concrete saw, asphalt paver, hydraulic post driver, base paver, rotary drill and greaser and greaser truck, snake or push tractor	6.41	.25	.35		.04	
Tunneling and underground	6.66	.25	.35		.04	
Class IV: Concrete mixer (single drum), one cubic yard or over, fork lift, asphalt batch plant, concrete batch plant, crushing plant, screening and washing plant, self propelled power concrete spreader, sub-grader, power form handling equipment, burlap and curing machine, concrete finishing machine, form grader, bull float, portable concrete saw, bar and joint installing machine and compactor.	6.19	.25	.35		.04	
Tunneling and underground	6.44	.25	.35		.04	

HIGHWAY CONSTRUCTION POWER EQUIPMENT OPERATORS (CONT'D)	Basic Hourly	FRINGE BENEFITS PAYMENTS H & W	Pensions	Vacation	App. Tr.	Other
Class V: HIGHWAY PRESSURE FIREMAN	5.88	.25	.35		.04	
Tunneling and underground	6.13	.25	.35		.04	
Class VI: Air compressor, concrete mixer (under one cubic yard), conveyor-belt or bucket, light plant, narrow gauge locomotive, welding machine, low pressure fireman, mechanic's helper, oiler, screed man, spreader box man, farm tractor, joint sealer and pump.	5.57	.25	.35		.04	
Tunneling and underground	5.82	.25	.35		.04	
When operating more than 1 piece of equipment	5.73	.25	.35		.04	
Tunneling and underground	6.98	.25	.35		.04	
"A" Counties: Brooke, Cabell, Hancock, Harrison, Jackson, Kanawha, Lewis, Marion, Marshall, Mason, Monongalia, Ohio, Pleasants, Preston, Putman, Tyler, Wayne, Wetzel and Wood Counties, West Virginia.						
LABORERS-"A" Counties						
BLACKSMITH, Tunnel miner, tunnel driller	6.69	.25	.25		.03	
POWDERMAN, mucker-chucker	6.30	.25	.25		.03	
CAISSON BOTTOM MAN, Pipelayer, form setter, (road), drill operator, and inside laborer.	5.01	.25	.25		.03	
AIR TOOL OPERATOR, vibrator man, whacker chainsaw operator, mortarman, mason tender, blacksmith helper, cement finisher helper, waterproofer sheeter & shorer, pipelayers helpers, bullfloat man, pavement reinforcing placer, drill helper, handyman, signal man, asphalt raker, green-cutter, georgia power buggies, burner, grade checker, cement blower man, powderman helper	5.70	.25	.25		.03	
LABORER, deckhand, mulcher & seeder (hand or machine) tree trimmer, flagman	5.47	.25	.25		.03	
WATCHMAN	4.98	.25	.25		.03	
TRUCK DRIVERS-"A" Counties						
WAREHOUSES, yardmen, truck helpers, pick-ups, station wagons, panel trucks, team 2-up	5.64	a	b			
FLATBODY MATERIAL TRUCKS (straight jobs), dump trucks (up to 5 yards), material checkers, material receive team 4-up, greasers, tiremen and mechanic helpers (truck)	5.79	a	b			

HIGHWAY CONSTRUCTION	Basic Hourly Rates	FRINGE BENEFITS PAYMENTS H & W	Pensions	Vacation	App. Tr.	Other
TRUCK DRIVER "A" COUNTIES CONT'D						
SEMI-DUMP TRUCKS, semi-trailers (flat, rack or pole), low boy trucks, distributor trucks, agitators or mixer trucks (up to and including 5 yards), dump trucks and dumpsters (5 yards to 12 yards)	$6.01	a	b			
RUBBER-TIRED TRACTORS (towing or pushing)	6.36	a	b			
DUMP TRUCK, agitator or mixer trucks and other hauling equipment (12 yards to 20 yards), mucker trucker	6.41	a	b			
DUMP TRUCK, agitator or mixer trucks and hauling equipment (20 yards and over)	6.59	a	b			
"A" FRAME OPERATOR	6.66	a	b			
MECHANICS (trucks)	6.82	a	b			
CARPENTERS-"A" Counties	7.16	.25	.25		.02	
PILEDRIVERS-"A" Counties except Brooke, Hancock, Marshall, Monogalia, Ohio, and Wetzel Counties	7.47	.25	.25		.02	
PILEDRIVERS-Brooke, Hancock, Marshall, Monogalia, Ohio, and Wetzel Counties	3.79	5%	7%			
CEMENT MASONS-"A" Counties	7.39	c				
"B" Counties Barbour, Berkeley, Boone, Braxton, Calhoun, Caly, Dodridge, Fayette, Gilmer, Grant, Greenbrier, Hampshire, Hardy, Jefferson, Lincoln, Logan, McDowell, Mercer, Mineral, Mingo, Monroe, Morgan, Nicholas, Pendleton, Pocahontas, Raleigh, Randolph, Ritchie, Summers, Taylor, Tucker, Upshur, Webster, Wirt and Wyoming and Roane Counties.						
LABORERS-"B" Counties						
BLACKSMITH, Tunnel miner, tunnel driller	6.51	.25	.25		.03	
POWDERMAN, mucker-chucker	6.14	.25	.25		.03	
CAISSON BOTTOM MAN, pipe layer, form setter(road), drill operator, and inside laborer.	5.81	.25	.25		.03	
AIR TOOL OPERATOR, vibrator man, whacker chainsaw op., mortarman, mason tender, blacksmith helper, cement finisher helper, waterproofer, sheeter & shorer, pipelayers helpers, bullfloat man, pavement reinforcing placer, drill helper handyman, signal man, asphalt man, asphalt raker, greencutter, georgia power buggie, burner, grade checker, cement blower man, powderman helper	5.53	.25	.25		.03	

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57-W. VA.-3-A 4 of 4

HIGHWAY CONSTRUCTION	Basic Hourly Rates	FRINGE BENEFITS PAYMENTS H & W	Pensions	Vacation	Apr. Tr.	Other
LABORERS (CONT'D) "B" Counties only						
LABORERS, deckhand, mulcher & seeder (hand or machine) tree trimmer, flagman	$ 5.19	.25	.25		.03	
WATCHMAN	4.73	.25	.25		.03	
TRUCK DRIVERS-"B" Counties						
WAREHOUSE, yardmen, truck helpers, pick-ups, station wagons, panel trucks, team 2-up	5.46	a	b			
FLATBODY MATERIAL TRUCKS (straight jobs), dump trucks (up to 5 yards), material checkers, material receivers, team 4-up, greasers, tiremen and mechanic helpers (truck)	5.63	a	b			
SEMI-DUMP TRUCKS, semi-trailers (flat, rack or pole), low boy trucks, distributor trucks, agitators or miners trucks (up to and including 5 yards), dump trucks and dumpsters (5 yards to 12 yards)	5.86	a	b			
RUBBER-TIRED TRACTORS (towing or pushing)	6.18	a	b			
DUMP TRUCK, agitator or mixer trucks and other hauling equipment (12 yards to 20 yards), mucker truck	6.26	a	b			
DUMP TRUCK, agitator or mixer trucks and other hauling equipment (20 yards and over)	6.40	a	b			
"A" FRAME OPERATOR	6.64	a	b			
MECHANICS (trucks)	6.64	a	b			
CARPENTERS -"B" Counties	6.44	.25	.25		.02	
PILEDRIVERS -"B" Counties	6.76	.25	.25		.02	
CEMENT MASONS -"B" Counties	6.91	c				

FOOTNOTES:

a. Employer contribution of $41.16 per month provided employee has been employed 30 days or more.

b. Employer contribution of $34.67 per month provided employee has been employed 30 days or more.

c. Employer contributes $.25 per hour into the H&W Fund or Pension Fund.

STATE: West Virginia COUNTY: Cabell
DECISION NO.: AQ-2087 DATE: Date of Publication
Supersedes Decision No. AP-403, dated July 21, 1972, in 37 FR 14661.
DESCRIPTION OF WORK: Building construction,(excluding single family homes and garden type apartments up to and including 4 stories).

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BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
Asbestos workers	$9.45	.30	.25		.03	
Boilermakers	8.10	.30	.70		.01	
Boilermakers' helpers	7.85	.30	.70		.01	
Bricklayers	8.60				d	
Carpenters	7.60	.35	.50		.03	
Cement masons	7.40	.45	.70			
Electricians	8.10	.30	1% + .27	1.02	.04	
Elevator Constructors	7.74	.17	.185	½%+e&f	.005	
Elevator Constructors helpers	5.42	.17	.185	½%+e&f	.005	
Elevators Constructors helpers (Prob.)	3.87					
Ironworkers:						
Structural & Ornamental	8.10	.40	.55		.01	
Reinforcing	8.10	.40	.55		.01	
Lathers	7.865		.10			
Line Construction:						
Lineman	7.35	.20	1%+.17	1.02	.02	
Groundman	5.87	.20	1%+.17	1.02	.02	
Equipment Operators	7.35	.20	1%+.17	1.02	.02	
Marble setters	7.35				d	
Marble Setters' helpers	6.075				d	
Painters:						
Commercial, Brush	5.76	.20	.25		.02	
Industrial, Brush	6.71	.20	.25		.02	
Piledrivermen	7.85	.30	.50		.03	
Plasterers	7.40	.45	.70		.01	
Plumbers	8.62	.40	.60		.02	
Roofers	7.45		.10			
Sheet metal workers	8.69	.20	.25		.01	
Sprinkler Fitt ers	8.85	.40	.60		.07	
Steamfitters	8.62	.40	.60		.02	
Stonemasons	8.60				d	
Terrazzo workers	7.35				d	
Terrazzo workers' helpers	6.075				d	
Tile setters	7.75		.20		d	
Tile setters' helpers	6.075				d	
Truck Drivers:						
Pickups, stationwagons, panel trucks, flatbody material, dumps (to 5 cu. yds.)	6.60	a	c	b		
Tank trucks(straight)	6.70	a	c	b		
Dumps (5 cu. yds. & over) semi-dumps, semi-trailers; agitators or mixer truck (to 5 cu. yds.) tank trucks (semi)	6.85	a	c	b		

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BUILDING COSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
Truck Drivers (Cont'd)						
Low boy trailers; winch trucks; fork trucks; dostributor trucks(front end & back end); Truck crane driver & Monorial truck	$6.90	a	c	b		
Agitator or mixer truck (5 cu. yds. & over)	7.00	a	c	b		
Euclid; dumpster; turnarocker; ross carriers; athey wagon; a-frames hydro-lift; dual purpose trucks	7.25	a	c	b		
Welders - receive rate prescribed for craft performing operation to which welding in incidental.						

FOOTNOTES:

A. $28.50 per month for employees employed over 30 days.
b. Employees working a minimum of 480 hours receive one hour pay for each 40 hours worked with limit to 52 hours pay.
c. $26.00 per month for employees employed over 30 days.
d. Employer contributes $20.00 per year.
e. Employer contributes 4% basic hourly rate for 5 years or more of service or 2% of basic hourly rate for 6 months to 5 years of service as Vacation Pay Credit.
f. Paid Holidays: New Year's Day; Memorial Day; Independence Day; Labor Day; Thanksgiving Day and Christmas Day.

1-LAB-W.VA-1-A

BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Common laborers, flagmen, demolition worker, water boy, fire watch, landscape laborer	$5.70	.25	.25		.03
Mason tenders, plasterers' tender, cement finisher tenders, lathers tenders, tile setters tenders, mortar mixers, jackhammer, vibrator, tamper, pavement buster, air sipon & air pump, concrete saw, power saw, chain saw, motorized buggy ops., pipelayers' helpers, drill op. helpers, asphalt rakers, ride or walk roller tampers, signalmen, powderman helper, grade checker	6.00	.25	.25		.03
Burner & powdermen, air track op., pipelayer	6.35	.25	.25		.03

BUILDING CONSTRUCTION

4-W. VA-PEO-1-G 1 of 1

POWER EQUIPMENT OPERATORS	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
CLASS I Cranes, derricks, tower cranes, and similar equipment having a reach from the top of its boom to the ground of 175 feet or a lifting capacity of 70 tons. All shovels, draglines, clamshells, back hoes, endloaders, and concrete mixing plants of 4 cubic yard capacity or over. Hoist with 18, 000 pound line pull or over	$8.95	.25	.35		.04	
CLASS II All mechainos, cranes, derricks and similar equipment. Hydraulic cranes in excess of 15 tons capacity. All shovels, draglines clamshells, gradalls, tug or tow boats. Concrete mixing plants of 3 cubic yards capacity. Endloaders in excess of 2½ cubic yards capacity. Hoist in excess of 5,000 pound line pull. Side boom cat, standard gauge locomotive. Backhoe (over ½ cubic yard)	8.45	.25	.35		.04	
Class III Hydraulic cranes up to and including 15 tons capacity. Endloaders up to and including 2½ cu. yd. capacity. Two drum hoist. Well point system, concrete mixing plants, elevators, core drills, fork lift, ross carrier, air compressor (600 CFM or over), high compression equipment, concrete pumps double. Backhoe (½ cu. yd. & under)	8.05	.25	.35		.04	
Class IV Trencher, air tugger, concrete mixer, (2 bag) material hoist, (single cage) grick tote machine, concrete pump (single), "A" frame truck, rubber tired scraper, power grader, dozer tractor and pan, push cat, all tractors oiler's standard gauge locomotive, locomotive crane, truck cranes; over 15 tons, grease truck operator and greaser, fireman, deckhand, asphalt and concrete paving equipment operator	7.65	.25	.35		.04	
Class V Roller and compactor, concrete mixer (1 bag) Barber Greene loader, mechanic helper, oiler, air compressor, welding machine, (gasoline powered) light plant, generator, conveyor, mechanical heater, and pump operator	6.95	.25	.35		.04	

STATE: West Virginia COUNTIES: Clay, Boone, Fayette, Kanawha, Putnam
DECISION NO.: AQ-2088
Supersedes Decision No. AP-402, dated July 21, 1972, in 37 FR 14659. DATE: Date of Publication
DESCRIPTION OF WORK: Building construction,(excluding single family homes and garden type apartments up to and including 4 stories)

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BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
Asbestos workers	$9.45	.30	.25		.03	
Boilermakers	8.10	.30	.70	g	.01	
Boilermakers' helpers	7.85	.30	.70	g	.01	
Bricklayers	8.70	.35	.25		e	
Carpenters	8.35	.25	.25		.02	
Cement masons	7.85		.65			
Electricians	8.80	.30	1%+.07	.27	.04	
Elevator constructors	7.29	.17	.185	½%+a+b	.005	
Elevator constructors' helpers	5.10	.17	.185	½%+a+b	.005	
Elevator constructors' helpers (prob.)	3.645					
Glaziers	7.50					
Ironworkers, structural ornamental	8.10	.50	.75		.05	
Ironworkers, reinforcing	8.10	.50	.75		.05	
Lathers	7.85		.10		.01	
Line construction:						
Linemen	7.35	.20	1%+.17	1.02	.02	
Groundmen	5.87	.20	1%+.17	1.02	.02	
Mechanized equipment operators	7.35	.20	1%+.17	1.02	.02	
Painters:						
" Commercial, brush	6.43					
" Industrial, brush	6.90					
Piledrivermen	9.10	.25	.25		.02	
Plasterers	7.75					
Plumbers	8.82	.35	.30		.05	
Roofers	7.28	.20	.10		.02+f	
Sheet metal workers	8.48	.34	.40		.04	
Sprinkler fitters	8.85	.40	.60		.07	
Steamfitters	9.02	.30	.15		.03	
Stone masons	8.70	.35	.25		e	
Truck drivers:						
Pick-up, stationwagons, panel trucks, flatbody material truck (straight job), dump trucks (up to 5 cu. yds. greasers, washers, tiremen, gas pump attendants.	4.50	c	d			
Mechanic helpers, material checkers and receivers.	4.85	c	d			
Tank trucks (straight)	4.60	c	d			

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BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
Truck drivers: (cont'd)						
Dump trucks (5 cu. yds. & over), semi dump trucks, semi-trailers (whether flat, rack or pole and hauled or pushed by tractors), agitators or mixer trucks (up to 5 cu. yds.), farm type tractor, tank truck (semi).	$4.75	c	d			
Low boy trailers, winch trucks, fork truck, distributor trucks (front and back end), truck crane, mono-rail truck.	4.80	c	d			
Euclids, dumpsters, turnarockers, ross carriers, Athey wagons or semilar equipment, A-frame, hydro-lift, dual purpose trucks	5.15	c	d			
Welders - receive rates prescribed for craft performing operation to which welding is incidental.						

Paid Holidays:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

FOOTNOTES:
a. Employer contributes 4% of basic hourly rate for 5 years or more of service or 2% basic hourly rate for 6 months to 5 years of service as Vacation Pay Credit.
b. 6 paid holidays: A through F.
c. $20.15 per month for employees employed over 30 days.
d. $26.00 per month.
e. Employer contribution of $20.00 per year.
f. Employer contribution of $150.00 per year to the joint apprentice committee.
g. Employer contributes $.55 per hour to a saving fund.

1-LAB-W.VA-1-A

BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Common laborers, flagmem, demolition worker, water boy, fire watch, landscape laborer	$5.70	.25	.25		.03
Mason tenders, plasterers' tender, cement finisher tenders, lathers tenders, tile setters tenders, mortar mixers, jackhammer, vibrator, tamper, pavement buster, air sipon & air pump, concrete saw, power saw, chain saw, motorized buggy ops., pipelayers' helpers, drill op. helpers, asphalt rakers, ride or walk roller tampers, signalmen, powderman helper, grade checker	6.00	.25	.25		.03
Burner & powdermen, air track op., pipelayer	6.35	.25	.25		.03

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BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
POWER EQUIPMENT OPERATORS					
CLASS I					
Cranes, derricks, tower cranes, and similar equipment having a reach from the top of its boom to the ground of 175 feet or a lifting capacity of 70 tons. All shovels, draglines, clamshells, back hoes, endloaders, and concrete mixing plants of 4 cubic yard capacity or over. Hoist with 18, 000 pound line pull or over	$8.95	.25	.35		.04
CLASS II					
All mechaincs, cranes, derricks and similar equipment. Hydraulic cranes in excess of 15 tons capacity. All shovels, draglines clamshells, gradalls, tug or tow boats. Concrete mixing plants of 3 cubic yards capacity. Endloaders in excess of 2½ cubic yards capacity. Hoist in excess of 5,000 pound line pull. Side boom cat, standard gauge locomotive. Backhoe (over ½ cubic yard)	8.45	.25	.35		.04
Class III					
Hydraulic cranes up to and including 15 tons capacity. Endloaders up to and including 2½ cu. yd. capacity. Two drum hoist. Well point system, concrete mixing plants, elevators, core drills, fork lift, ross carrier, air compressor (600 CFM or over), high compression equipment, concrete pumps double. Backhoe (½ cu. yd. & under)	8.05	.25	.35		.04
Class IV					
Trencher, air tugger, concrete mixer, (2 bag) material hoist, (single cage) grick tote machine, concrete pump (single), "A" frame truck, rubber tired scraper, power grader, dozer tractor and pan, push cat, all tractors oiler's standard gauge locomotive, locomotive crane, truck cranes; over 15 tons, grease truck operator and greaser, fireman, deckhand, asphalt and concrete paving equipment operator	7.65	.25	.35		.04
Class V					
Roller and compactor, concrete mixer (1 bag) Barber Greene loader, mechanic helper, oiler, air compressor, welding machine, (gasoline powered) light plant, generator, conveyor, mechanical heater, and pump operator	6.95	.25	.35		.04

SUPERSEDEAS DECISION

STATE: West Virginia COUNTY: Kanawha County
DECISION NO.: AQ-2089 DATE: Date of Publication
Supersedes Decision No. AP-405, dated July 28, 1972, in 37 FR 15236.
DESCRIPTION OF WORK: Residential construction consisting of single family homes and garden type apartments up to and including 4 stories.

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BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
Asbestos workers	$9.45	.30	.25		.03	
Boilermakers	8.10	.30	.70	g	.01	
Boilermakers' helpers	7.85	.30	.70	g	.01	
Bricklayers	8.70	.35	.25		e	
Carpenters	8.35	.25	.25		.02	
Cement masons	7.85		.65			
Electricians	8.80	.30	1%+.07	.27	.04	
Elevator constructors	7.29	.17	.185	½%+a+b	.005	
Elevator constructors' helpers	5.10	.17	.185	½%+a+b	.005	
Elevator constructors' helpers (prob.)	3.645					
Glaziers	7.50					
Ironworkers, structural ornamental	8.10	.50	.75		.05	
Ironworkers, reinforcing	8.10	.50	.75		.05	
Lathers	7.85		.10		.01	
Line construction:						
Linemen	7.35	.20	1%+.17	1.02	.02	
Groundmen	5.87	.20	1%+.17	1.02	.02	
Mechanized equipment operators	7.35	.20	1%+.17	1.02	.02	
Painters:						
" Commercial, brush	6.43					
" Industrial, brush	6.90					
Piledrivermen	9.10	.25	.25		.02	
Plasterers	7.75					
Plumbers	8.82	.35	.30		.05	
Roofers	7.28	.20	.10		.02+f	
Sheet metal workers	8.48	.34	.40		.04	
Sprinkler fitters	8.85	.40	.60		.07	
Steamfitters	9.02	.30	.15		.03	
Stone masons	8.70	.35	.25		e	
Truck drivers:						
Pick-up, stationwagons, panel trucks, flatbody material truck (straight job), dump trucks (up to 5 cu. yds. greasers, washers, tiremen, gas pump attendants.	4.50	c	d			
Mechanic helpers, material checkers and receivers.	4.85	c	d			
Tank trucks (straight)	4.60	c	d			

20-W-VA - 1- A 2 of 2

BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
Truck drivers: (cont'd)						
Dump trucks (5 cu. yds. & over), semi dump trucks, semi-trailers (whether flat, rack or pole and hauled or pushed by tractors), agitators or mixer trucks (up to 5 cu. yds.), farm type tractor, tank truck (semi).	$4.75	c	d			
Low boy trailers, winch trucks, fork truck, distributor trucks (front and back end), truck crane, monorail truck.	4.80	c	d			
Euclids, dumpsters, turnarockers, ross carriers, Athey wagons or semilar equipment, A-frame, hydrolift, dual purpose trucks	5.15	c	d			
Welders - receive rates prescribed for craft performing operation to which welding is incidental.						

Paid Holidays:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

FOOTNOTES:
a. Employer contributes 4% of basic hourly rate for 5 years or more of service or 2% basic hourly rate for 6 months to 5 years of service as Vacation Pay Credit.
b. 6 paid holidays: A through F.
c. $20.15 per month for employees employed over 30 days.
d. $26.00 per month.
e. Employer contribution of $20.00 per year.
f. Employer contribution of $150.00 per year to the joint apprentice committee.
g. Employer contributes $.55 per hour to a saving fund.

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BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Common laborers, flagmen, demolition worker, water boy, fire watch, landscape laborer	$5.70	.25	.25		.03
Mason tenders, plasterers' tender, cement finisher tenders, lathers tenders, tile setters tenders, mortar mixers, jackhammer, vibrator, tamper, pavement buster, air sipon & air pump, concrete saw, power saw, chain saw, motorized buggy ops., pipelayers' helpers, drill op. helpers, asphalt rakers, ride or walk roller tampers, signalmen, powderman helper, grade checker	6.00	.25	.25		.03
Burner & powdermen, air track op., pipelayer	6.35	.25	.25		.03

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BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
POWER EQUIPMENT OPERATORS					
CLASS I					
Cranes, derricks, tower cranes, and similar equipment having a reach from the top of its boom to the ground of 175 feet or a lifting capacity of 70 tons. All shovels, draglines, clamshells, back hoes, endloaders, and concrete mixing plants of 4 cubic yard capacity or over. Hoist with 18, 000 pound line pull or over	$8.95	.25	.35		.04
CLASS II					
All mechaincs, cranes, derricks and similar equipment. Hydraulic cranes in excess of 15 tons capacity. All shovels, draglines clamshells, gradalls, tug or tow boats. Concrete mixing plants of 3 cubic yards capacity. Endloaders in excess of 2½ cubic yards capacity. Hoist in excess of 5,000 pound line pull. Side boom cat, standard gauge locomotive. Backhoe (over ½ cubic yard)	8.45	.25	.35		.04
Class III					
Hydraulic cranes up to and including 15 tons capacity. Endloaders up to and including 2½ cu. yd. capacity. Two drum hoist. Well point system, concrete mixing plants, elevators, core drills, fork lift, ross carrier, air compressor (600 CFM or over), high compression equipment, concrete pumps double. Backhoe (½ cu. yd. & under)	8.05	.25	.35		.04
Class IV					
Trencher, air tugger, concrete mixer, (2 bag) material hoist, (single cage) grick tote machine, concrete pump (single), "A" frame truck, rubber tired scraper, power grader, dozer tractor and pan, push cat, all tractors oiler's standard gauge locomotive, locomotive crane, truck cranes; over 15 tons, grease truck operator and greaser, fireman, deckhand, asphalt and concrete paving equipment operator	7.65	.25	.35		.04
Class V					
Roller and compactor, concrete mixer (1 bag) Barber Greene loader, mechanic helper, oiler, air compressor, welding machine, (gasoline powered) light plant, generator, conveyor, mechanical heater, and pump operator	6.95	.25	.35		.04

[FR Doc.74-7067 Filed 3-28-74;8:45 am]

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