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PART I

HIGHLIGHTS OF THIS ISSUE

This listing does not affect the legal status of any document published in this issue. Detailed table of contents appears inside.

(Continued inside)

November 20, 1973—Pages 31947–32113

REMINDERS

NOTE: There were no items published after October 1, 1972, that are eligible for inclusion in the list of RULES GOING INTO EFFECT TODAY.

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Contents

(Continued on next page)

List of CFR Parts Affected

The following numerical guide is a list of the parts of each title of the Code of Federal Regulations affected by documents published in today's issue. A cumulative list of parts affected, covering the current month to date, appears following the Notices section of each issue beginning with the second issue of the month. In the last issue of the month the cumulative list will appear at the end of the issue.

A cumulative guide is published separately at the end of each month. The guide lists the parts and sections affected by documents published since January 1, 1973, and specifies how they are affected.

Rules and Regulations

Title 7—Agriculture

CHAPTER I—AGRICULTURAL MARKETING SERVICE (STANDARDS, INSPECTIONS, MARKETING PRACTICES), DEPARTMENT OF AGRICULTURE

PART 46—REGULATIONS (OTHER THAN RULES OF PRACTICE) UNDER THE PERISHABLE AGRICULTURAL COMMODITIES ACT, 1930

License Fees

On September 19, 1973, a notice of proposed rulemaking was published in the FEDERAL REGISTER (38 FR 26207) regarding a proposed revision of regulations (other than rules of practice) (7 CFR 46.1–46.44), effective under the Perishable Agricultural Commodities Act, 1930 (46 Stat. 531, et seq., as amended; 7 U.S.C. 499a et seq.).

Interested persons were given until November 1, 1973, in which to submit written data, views or comments regarding the proposed revision of the regulations calling for an increase from $75 to $100 in the annual license fee under the Act. There were only two comments received concerning the proposed increase in license fee from a total of more than 16,878 licensed firms affected by the proposal. Both of the comments were opposed to the increase. This slight opposition is outweighed by the mandate of the statute that the program be carried out on a financially self-sustaining basis.

After due consideration of the comments presented concerning the proposed revision of the regulations, and pursuant to the authority contained in section 15, 46 Stat. 537, as amended (7 U.S.C. 499a), the regulations, other than the rules of practice (7 CFR Part 46) under the Perishable Agricultural Commodities Act, 1930, are hereby amended as follows:

Amend § 46.6 to read as follows:

§ 46.6 License fee.

The annual license fee is one hundred dollars ($100). The Director may require the fee be submitted in the form of a money order, bank draft, cashier's check, or certified check made payable to Agricultural Marketing Service. Authorized representatives of the Division may accept fees and issue receipts therefor.

This amendment shall become effective January 1, 1974.

Done at Washington, D.C., this 15th day of November, 1973.

JOHN C. BLUM,
Deputy Administrator,
Regulatory Programs.

[FR Doc.73-24711 Filed 11-19-73;8:45 am]

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

PART 354—OVERTIME SERVICES RELATING TO IMPORTS AND EXPORTS

Commuted Traveltime Allowances

The purpose of this amendment is to establish commuted traveltime periods as nearly as may be practicable to cover the time necessarily spent in reporting to and returning from the place at which an employee of the Plant Protection and Quarantine Programs performs overtime or holiday duty when such travel is performed solely on account of such overtime or holiday duty. Such establishment depends upon facts within the knowledge of the Animal and Plant Health Inspection Service.

Therefore, pursuant to the authority conferred upon the Deputy Administrator, Plant Protection and Quarantine Programs, by 7 CFR 354.1 of the regulations concerning overtime services relating to imports and exports, the administrative instructions appearing at 7 CFR 354.2, as amended, February 28, 1973 (38 FR 5340), April 9, 1973 (38 FR 9006), July 30, 1973 (38 FR 20233), and August 21, 1973 (38 FR 22466), prescribing the commuted traveltime that shall be included in each period of overtime or holiday duty are futher amended by adding (in appropriate alphabetical sequence) or deleting the information as shown below:

§ 354.2 **Administrative instructions prescribing commuted traveltime.**

* * * * *

COMMUTED TRAVELTIME ALLOWANCES
(In Hours)

Location covered	Served from	Metropolitan Area	
		Within	Outside
Delete:			
* * * * *			
California: March AFB	Los Angeles		3
Hawaii: Undesignated ports.	Hilo or Honolulu.		3
North Carolina: Cherry Point	Morehead City or New Bern.		2
Morehead City	New Bern		3
* * * * *			
Add:			
* * * * *			
California: March AFB	Los Angeles		4
Hawaii: Kealhole		1	
Keauhou	Kealhole		2
Undesignated ports.	Hilo, Honolulu, or Kealhole.		3
North Carolina: Cherry Point	New Bern		2
Morehead City	New Bern		2

(64 Stat. 561 (7 U.S.C. 2260))

Effective date. The foregoing amendment shall become effective on November 20, 1973.

It is to the benefit of the public that this instruction be made effective at the earliest practicable date. Accordingly, pursuant to 5 U.S.C. 553, it is found upon good cause that notice and public procedure on this instruction 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 15 day of November 1973.

LEO G. K. IVERSON,
Deputy Administrator, Plant Protection and Quarantine Programs.

[FR Doc.73-24703 Filed 11-19-73;8:45 am]

CHAPTER IV—FEDERAL CROP INSURANCE CORPORATION, DEPARTMENT OF AGRICULTURE

[Amdt. 48]

PART 401—FEDERAL CROP INSURANCE

Subpart—Regulations for the 1969 and Succeeding Crop Years

BURLEY TOBACCO POUNDAGE QUOTA ENDORSEMENT

Pursuant to the authority contained in the Federal Crop Insurance Act, as amended, the above-identified regulations are amended effective beginning with the 1974 crop year in the following respect:

1. The Burley Tobacco Poundage Quota Endorsement published in § 401.148 is amended effective beginning with the 1974 crop year to read as follows:

§ 401.148 **The Burley Tobacco Poundage Quota Endorsement with the amounts of insurance determined from poundage marketing quotas under the ASCS Burley Tobacco Marketing Quota Regulations.**

The provisions of the Burley Tobacco Poundage Quota Endorsement which shall be applicable for the 1974 and succeeding crop years in those burley tobacco counties where the actuarial table states that the table on file is applicable to insurance provided under the Burley Tobacco Poundage Quota Endorsement are as follows:

1. *Insured crop.* The crop insured shall be burley tobacco (Type 31).

2. *Insured acreage.* In lieu of the provisions of section 2(c) of the policy the following shall apply: The insured burley tobacco acreage for each crop year shall be all acreage planted to burley tobacco on the insurance unit (herein called unit) provided that no insurance shall be considered to have attached on any acreage the Corporation de-

termines was (1) destroyed and after such destruction it was practical to replant and such acreage was not replanted, (2) initially planted after the date fixed by the Corporation and placed on file in the office for the county, as being too late to initially plant and expect a normal crop to be produced, (3) designated as not insurable on the county actuarial table, (4) planted to tobacco of a discount variety under the provisions of the tobacco price support program, or (5) planted for experimental purposes.

3. *Additional reporting requirement.* In addition to reporting the planted acreage (rounded to tenths of an acre) and share as provided in section 3 of the policy, the insured shall report the effective poundage marketing quota, or portion thereof, applicable to the unit on the final planting date (herein called poundage quota) for the current marketing year as provided under the ASCS Burley Tobacco Marketing Quota Regulations and the pounds, if any, by which in establishing the amount of insurance for the unit the poundage quota shall be reduced due to carryover tobacco to be marketed under the poundage quota applicable to the unit: *Provided*, That such poundage reduction shall not be allowed unless clearly specified in filing the acreage and quota report.

4. *Amount of insurance and premium for a unit.* (a) In lieu of the provisions of section 5 of the policy the following shall apply: The amount of insurance for a unit shall be the dollar amount determined by multiplying the applicable poundage for the unit as determined in (b) below by the applicable percentage of guarantee for the tobacco farm shown on the county actuarial table for this purpose and the result by the current year's burley tobacco price support per pound (rounded to the nearest cent) less 3 cents for warehouse charges.

(b) The poundage determined to be applicable to the unit shall be the effective burley poundage marketing quota for the crop year for the tobacco farm under the ASCS Burley Tobacco Marketing Quota Regulations, or portion thereof applicable to the unit, on the final planting date, as reported by the insured or as determined by the Corporation, whichever the Corporation shall elect, with such poundage for any unit reduced by the pounds of carryover tobacco to be marketed under the current crop year poundage quota if reported in accordance with section 3: *Provided, however*, If the result obtained by dividing the poundage as determined above by the farm yield per acre (see subsection 10(g)) exceeds the insured acreage on a unit, the poundage use in (a) above shall be reduced by the factor determined by dividing the insured acreage by such result.

Unless otherwise provided on the actuarial table, for any crop year in which burley tobacco poundage marketing quota regulations are not in effect, the poundage used in determining the applicable amount of insurance for a unit shall be obtained by multiplying the farm yield previously used by ASCS in establishing the basic poundage marketing quota for the tobacco farm by the percentage guarantee shown on the actuarial table and the result by the lower of the reported or insured acreage.

(c) The annual premium for the unit shall be determined by multiplying the amount of insurance, determined as provided above, by the applicable percentage premium rate shown on the actuarial table and this product by the insured's share at the time insurance attached, and, when applicable, applying the discounts shown in section 6(b) of the policy.

5. *Insurance period.* Insurance on any insured acreage shall attach at the time the tobacco is planted and, with respect to any portion of the crop, shall cease upon the earlier of February 28, weighing-in at the tobacco warehouse, transfer of interest in the tobacco after harvest, or removal of the tobacco from the insurance unit, except for curing, grading, packing, or immediate delivery to the tobacco warehouse.

6. *Notice of loss or substantial damage.* In lieu of the provisions of section 8(b) of the policy the following shall apply: If at the completion of selling or otherwise disposing of the insured tobacco an insured loss on a unit is probable, the insured shall give within 15 days written notice thereof to the Corporation at the office for the county, but in no event shall such notice be given later than February 28; *Provided, however*, That if any tobacco is destroyed or damaged by fire during the insurance period or any acreage will not be harvested, such notice shall be given immediately.

7. *Claims for loss.* (a) Any claim for loss on a unit shall be submitted to the Corporation on a form prescribed by the Corporation not later than 60 days after the amount of loss can be determined, but in no event shall such form be submitted later than the March 31 following the normal harvest period.

(b) It shall be a condition precedent to the payment of any loss that the insured establish the production of the insured crop on the unit and that such loss has been directly caused by one or more of the hazards insured against during the insurance period, and furnish any other information regarding the manner and extent of loss as may be required by the Corporation.

(c) The amount of loss with respect to any unit shall be determined by subtracting from the amount of insurance applicable to the unit the value (determined in accordance with subsection (d) of this section) of the total production to be counted for the unit and multiplying the remainder by the insured share.

The value of the total production to be counted for a unit shall be determined by the Corporation, and subject to the provisions hereinafter, shall include the value of all harvested production and the value of any appraisals made by the Corporation for unharvested or potential production, poor farming practices, uninsured causes of loss, or for acreage abandoned or put to another use without the consent of the Corporation: *Provided*, That the value of total production to be counted for any tobacco acreage not harvested nor considered as harvested within the meaning of the term "harvested" shall never be less than 20 percent of the average amount of insurance per insured acre for the unit, except that for acreage abandoned or put to another use without prior written release by the Corporation and acreage damaged solely by uninsured causes at least the average amount of insurance per insured acre for the unit shall be charged: *Provided, further*, That if the Corporation determines that the insured harvested tobacco with a value in excess of the amount of insurance from a unit, and such production is subsequently destroyed or damaged before the end of the insurance period by an insured cause, no appraisals shall be charged as production to count unless the Corporation determines that such production could have been harvested after the loss occurrence.

(d) In determining any loss under the contract, the production shall be valued as follows: (1) The gross returns (less 3 cents per pound for warehouse charges) from the tobacco sold on the warehouse floor, (2) the fair market value, as determined by the Corporation, of the tobacco sold other than on the warehouse floor, (3) the fair market value, as determined by the Corporation, of the tobacco harvested and not sold, and (4) the fair market value of any unharvested tobacco determined by the Corporation as if such tobacco were harvested and cured. Any appraisals of production for any crop year made for poor farming practices or uninsured causes of loss, shall be valued at the current support price per pound less 3 cents for warehouse charges.

(e) To enable the Corporation to determine the fair market value of tobacco not sold through auction warehouses, the Corporation shall be given the opportunity to inspect such tobacco before it is sold, contracted to be sold, or otherwise disposed of by the insured and, if the best offer received by the insured for any such tobacco is considered by the Corporation to be inadequate, to obtain additional offers therefor on behalf of the insured.

8. *Cancellation and debt termination dates.* (a) For each crop year of the contract the cancellation date (applicable to both the insured and the Corporation) shall be the January 31 immediately preceding the beginning of the crop year for which it is to become effective.

(b) The termination date for indebtedness for each crop year of the contract shall be the May 31 immediately preceding the beginning of the crop year for which the termination is to become effective.

9. *Sharecroppers.* Paragraph B of the Application Form FCI–12–Revised shall not be applicable under the Burley Tobacco Poundage Quota Endorsement.

10. *Meaning of terms.* For purposes of insurance on burley tobacco the terms:

(a) "Insurance Unit," notwithstanding the first sentence of section 19(e) of the policy, means all the insurable acreage in the county planted to burley tobacco on a farm for which a single farm poundage marketing quota for burley tobacco is established and at the time of planting (1) in which the insured has 100% interest, (2) which is owned by one person and operated by the insured as a tenant, or (3) which is owned by the insured and rented to one tenant: *Provided, however*, That if a burley tobacco price support program is not in effect for any crop year, the above words "planted on a farm for which a single poundage marketing quota for burley tobacco is established" shall be disregarded. Otherwise the provisions of section 19(e) of the policy apply to burley tobacco crop insurance, except that no other agreement shall be made which divides the insurable acreage into two or more units.

(b) "Market Price" for a crop year means the average auction price for burley tobacco (less 3 cents for warehouse charges) in the belt or area as determined by the Corporation. The market price when determined by the Corporation shall be filed in the office for the county with the actuarial table.

(c) "Support Price Per Pound" means the average price support level per pound for burley tobacco as announced by the United States Department of Agriculture under the tobacco price support program: *Provided, however*, That for any crop year in which a price support for burley tobacco is not in effect the market price for that crop year shall be used in lieu thereof.

(d) "Planting" means transplanting the tobacco plant from the bed to the field.

(e) "Harvest" or "Harvested" as to any acreage means cutting at least 20 percent of the number of pounds obtained by multiplying the applicable poundage for the unit by the applicable percentage of guarantee shown on the actuarial table for such acreage and dividing this result by the insured acres in the unit.

(f) "Effective Farm Marketing Quota" means the farm marketing quota as established and recorded by ASCS on the final planting date.

(g) "Farm Yield" means the yield per acre used by ASCS in establishing the basic farm marketing poundage quota for the tobacco farm.

(h) "Carryover Tobacco" means any tobacco on hand from a previous year's production.

(i) "ASCS" means the Agricultural Stabilization and Conservation Service of the United States Department of Agriculture.

(j) "Final Planting Date" means the date after which insurance does not attach on initial plantings (see item (2), section 2 of this endorsement).

(k) "Rounded" means rounding up for ½ and above and down for less than ½.

11. *Annual premium.* Section 6(b) of the policy shall not be applicable in those counties where variable percentage guarantees based on the insured's experience are provided on the actuarial table.

(Secs. 506, 516, 52 Stat. 73, as amended, 77, as amended (7 U.S.C. 1506, 1516).)

The Burley Tobacco Poundage Quota Endorsement proved to be a successful program in the seven experimental counties where it was first tried out in 1973. It is planned to expand coverage under this endorsement to 21 additional counties in 1974, which will require changes in the regulations. In addition there are a number of contractual and language changes necessary which will strengthen the contract. The proposed amendment is designed to accomplish this.

Since it will be necessary to start taking applications as soon as possible from new applicants for the 1974 crop year, the Board of Directors found that it would be impracticable and contrary to the public interest to follow the procedure for notice and public participation prescribed by (5 U.S.C. 553 (b) and (c)), as directed by the Secretary of Agriculture in a Statement of Policy, executed July 20, 1971 (36 FR 13804), prior to its adoption. Accordingly, said amendment was adopted by the Board of Directors on November 1, 1973.

[SEAL] LLOYD E. JONES,
Secretary,
Federal Crop Insurance Corporation.

Approved on November 15, 1973.

RICHARD E. BELL,
Deputy Assistant Secretary.

[FR Doc.73-24705 Filed 11-19-73;8:45 am]

[Amdt. 46]

PART 401—FEDERAL CROP INSURANCE

Subpart—Regulations for the 1969 and Succeeding Crop Years

CORN ENDORSEMENT (GRAIN AND SILAGE)

Pursuant to the authority contained in the Federal Crop Insurance Act, as amended, the above-identified regulations are amended effective beginning with the 1974 crop year in the following respects:

1. Subsection 4(e) of the corn endorsement (grain and silage) shown in § 401.-142 of this chapter is amended effective beginning with the 1974 crop year by changing the first sentence of the second paragraph thereof to read as follows:

The provisions of this paragraph shall be applicable only to corn crop insurance contracts in Minnesota (except Dakota, Douglas, Filmore, Goodhue, Grant, Houston, Olmsted, Pope, Scott, Wabasha, Washington, Winona, and Wright Counties), and in Wisconsin, except that it shall not apply in any county in either state in which a production guarantee in tons of silage per acre is shown in the actuarial table.

2. Subsection 4(e) of the corn endorsement (grain and silage) shown in § 401.-142 is amended effective beginning with the 1974 crop year by changing the first sentence of the third paragraph thereof to read as follows:

The provisions of this paragraph shall be applicable only to corn crop insurance contracts in Dakota, Douglas, Fillmore, Goodhue, Grant, Houston, Olmsted, Pope, Scott, Wabasha, Washington, Winona, and Wright Counties, Minnesota.

(Secs. 506, 516, 52 Stat. 73, as amended, 77, as amended; (7 U.S.C. 1506, 1516).)

The foregoing amendment deletes the reference to Stearns and Todd Counties, Minnesota, from the corn endorsement (grain and silage). This change is necessary inasmuch as corn insurance will be offered under the corn-silage endorsement beginning with the 1974 crop year. It is believed that the corn-silage endorsement will provide a more practical and attractive plan of corn insurance for these two counties where a large percentage of the corn is normally cut for silage and in poor years almost all of it is cut for silage. However, the contract provides that changes for the 1974 crop year must be placed on file in the office for the county by not later than December 15, 1973. It would, therefore, be impossible to follow both the procedure for notice and public participation prescribed by (5 U.S.C. 553(b) and (c)) prior to the adoption of the proposed amendment and to comply with contractual provisions with respect to filing such changes in time for them to be effective for the 1974 crop year.

Under the circumstances, the Board of Directors found that it would be impracticable and contrary to the public interest to follow the procedure for notice and public participation prescribed by 5 U.S.C. 553 (b) and (c), as directed by the Secretary of Agriculture in a Statement of Policy, executed July 20, 1971 (36 FR 13804), prior to its adoption. Accordingly, said amendment was adopted by the Board of Directors on November 1, 1973.

[SEAL] LLOYD E. JONES,
Secretary,
Federal Crop Insurance Corporation.

Approved on November 15, 1973.

RICHARD E. BELL,
Deputy Assistant Secretary.

[FR Doc.73-24709 Filed 11-19-73;8:45 am]

[Amdt. 47]

PART 401—FEDERAL CROP INSURANCE

Subpart—Regulations for the 1969 and Succeeding Crop Years

DRY BEANS

Pursuant to the authority contained in the Federal Crop Insurance Act, as amended, the above-identified regulations are amended effective beginning with the 1974 crop year in the following respects:

1. Section 2(b) of the dry bean endorsement shown in § 401.127 is amended effective beginning with the 1974 crop year to read as follows:

(b) Notwithstanding the provisions of section 5 of the policy, the price per pound at which indemnities shall be computed for bush varieties of garden seed beans shall be the applicable price per pound (i) shown on the actuarial table for this purpose or (ii) provided in the contract with the seed company, whichever is the lesser.

2. Subsection 4(c) of the dry bean endorsement shown in § 401.127 of this chapter is amended effective beginning with the 1974 crop year by changing the first paragraph thereof to read as follows:

(c) Losses shall be determined separately for each unit. The amount of loss with respect to any unit shall be determined by (1) multiplying the insured acreage of beans on the unit by the applicable production guarantee per acre, which product shall be the production guarantee for the unit, (2) subtracting therefrom the total production to be counted for the unit, (3) multiplying the remainder by the applicable price for computing indemnities, and (4) multiplying the result obtained in (3) by the insured interest: *Provided, however,* That the amount of loss with respect to any unit on which the crop insured is bush varieties of garden seed beans shall be determined in the following manner: (1) for each insured variety of garden seed beans on the unit multiply the insured acreage by the applicable production guarantee per acre, and the result by the applicable price per pound at which indemnities shall be computed (i) as shown on the actuarial table or (ii) as provided in the contract with the seed company, whichever is the lesser, (2) for each insured variety of garden seed beans on the unit multiply the total production to be counted by the applicable price per pound at which indemnities shall be computed (i) as shown on the actuarial table, or (ii) as provided in the contract with the seed company, whichever is the lesser, (3) add the dollar amounts obtained in (1) above, (4) add the dollar amounts obtained in (2) above, and subtract this total from the total obtained in (3) above, and (5) multiply the result obtained in (4) by the insured interest: *Provided, however,* That if for the unit the insured fails to report all of his interest or insurable acreage the amount of loss shall be determined with respect to all of his interest and insurable acreage, but in such cases or otherwise, if the premium computed on the basis of the insurable acreage and interest exceeds the premium on the reported acreage

and interest, or the acreage and interest when determined by the Corporation under section 3 of the policy, the amount of loss shall be reduced proportionately.

3. The dry bean endorsement shown in § 401.127 is amended effective beginning with the 1974 crop year by adding a section 7 to read as follows:

7. *Annual premium.* Section 6(b) of the policy shall not be applicable in those counties where variable guarantees based on the insured's experience are provided on the actuarial table.

(Secs. 506, 516, 52 Stat. 73, as amended, 77, as amended; 7 U.S.C. 1506, 1516)

The current contract provides that the price per pound at which indemnities shall be computed for bush varieties of garden seed beans shall be the applicable contract price per pound provided in the contract with the seed company. However, present indications are that these contract prices will be more than doubled for 1974 as compared to 1973. This will result in the dollar amount of insurance doubling which would be greatly in excess of the cost of production.

The Federal Crop Insurance Act, as amended, provides that the amount of insurance per acre shall not be in excess of the cost of production. The foregoing amendment is designed to correct this situation by providing that indemnities for bush varieties of garden seed beans be computed on the basis of a price shown on the actuarial table for this purpose, or the applicable price per pound as provided in the contract with the seed company, whichever is the lesser.

Due to the necessity of complying with the Federal Crop Insurance Act, as amended, the Board of Directors found that it would be impracticable and contrary to the public interest to follow the procedure for notice and public participation prescribed by 5 U.S.C. 553 (b) and (c), as directed by the Secretary of Agriculture in a Statement of Policy, executed July 20, 1971 (36 FR 13804), prior to its adoption. Accordingly, said amendment was adopted by the Board of Directors on November 1, 1973.

[SEAL] LLOYD E. JONES,
Secretary, Federal Crop Insurance Corporation.

Approved on November 15, 1973.

RICHARD E. BELL,
Deputy Assistant Secretary.

[FR Doc.73-24704 Filed 11-19-73;8:45 am]

[Amdt. 49]

PART 401—FEDERAL CROP INSURANCE

Subpart—Regulations for the 1969 and Succeeding Crop Years

SUGAR BEET ENDORSEMENT (APPLICABLE IN ALL STATES EXCEPT CALIFORNIA)

Pursuant to the authority contained in the Federal Crop Insurance Act, as amended, the above-identified regulations are amended effective beginning with the 1974 crop year in the following respect:

1. The sugar beet endorsement published in § 401.140 is amended effective beginning with the 1974 crop year to read as follows:

§ 401.140 The Sugar Beet Endorsement (applicable in all States except California).

The provisions of the sugar beet endorsement (applicable in all states except California) for the 1974 and succeeding crop years are as follows:

1. *Insured crop.* The crop insured shall be sugar beets grown under a contract with a processor for processing as sugar. Item 1 of the second sentence of subsection 2(c) of the policy shall not be applicable to sugar beets.

Insurance shall not attach or be considered to have attached to any acreage (1) excluded from the processor contract for, or during, the crop year, and (2) unless otherwise provided on the county actuarial table, planted to sugar beets the preceding crop year in Michigan, Minnesota and Ohio, or the two preceding years in other states.

2. *Production guarantees.* (a) The production guarantee for a unit shall be the reported acreage or the actual planted acreage, whichever is less, multiplied by the applicable production guarantee per acre in hundredweight of commercially recoverable sugar. (Any underreporting of insurable acreage will have the effect of reducing the per acre guarantee proportionately.)

(b) The per acre production guarantees shall be the applicable percentages shown on th actuarial table of the normal yield (cwt. of commercially recoverable sugar) initially established for the acreage for the crop year in accordance with the regulations issued by the United States Department of Agriculture pursuant to the Sugar Act of 1948, as amended, except that, if the Corporation determines that such normal yield is not representative of the productivity of an insurance unit, the production guarantee shall be that established by the Corporation for such unit: *Provided*, That any redeterminations of the normal yield pursuant to the regulations issued under the Sugar Act of 1948, as amended, shall not apply for crop insurance purposes for such crop year, unless the Corporation so elects.

(c) The progressive per acre production guarantees provided on the actuarial table are as follows: (1) First Stage—From planting until July 1 or upon determination by the Corporation that the acreage was damaged prior to July 1 to the extent that growers in the area usually would not further care for the crop, (2) Second Stage—From July 1 until 15 percent of the production guarantee for the third stage has been delivered to and accepted by the processor, and (3) Third Stage—After 15 percent of the production guarantee for this stage has been delivered to and accepted by the processor.

3. *Insurance period.* Insurance on any insured acreage shall attach at the time the sugar beets are planted and shall cease upon harvesting, but in no event shall insurance remain in effect later than the applicable date set forth below of the calendar year in which the sugar beets are normally harvested.

Michigan, Minnesota, Montana, and North Dakota.	Nov. 10
Ohio	Nov. 25
All other States	Nov. 15

4. *Notice of possible loss.* To claim a loss, the insured must give notice of loss as provided in Section 8 of the policy even though bona fide abandonment is approved under the Sugar Act of 1948, as amended. Notice of probable loss, determined by applying the applicable rate of commercially recoverable sugar to the tonnage delivered, must be given to the Corporation office serving the county no later than the end of the insurance period (even if harvest on a unit has not been completed by that date) or within 15 days after harvest is completed on a unit, whichever occurs first.

5. *Claim for loss.* (a) Any claim for loss must be submitted to the Corporation no later than 30 days after the production records for that unit are available, but in no event later than the January 31, following the end of the insurance period. The Corporation reserves the right to provide additional time if it determines that circumstances beyond the control of either party prevent compliance with this provision.

(b) It is the responsibility of the insured to provide complete information of all production from the unit, to establish that the loss claimed was caused by one or more of the hazards insured against during the insurance period, and to furnish such other information about the loss as may be required by the Corporation.

(c) The amount of loss for a unit in hundredweight of commercially recoverable sugar shall be determined by subtracting from the production guarantee the total production to be counted as hereinafter provided. The indemnity due the insured shall be obtained by multiplying such amount of loss by the applicable price election for computing indemnities and the result by the insured interest.

The hundredweight of commercially recoverable sugar shall be determined by multiplying the net weight of sugar beets in tons at the time of delivery to the processor by the applicable rate of commercially recoverable sugar prescribed for the crop year under regulations issued by the United States Department of Agriculture pursuant to the Sugar Act of 1948, as amended. For appraised production the commercially recoverable sugar to be counted shall be 2.75 hundredweight per ton. The total production to be counted for a unit shall be determined by the Corporation from all insurable acreage in the unit (including any that was not reported for insurance) and, subject to the provisions hereinafter, shall include all harvested production and any appraisals made by the Corporation for unharvested or potential production, poor farming practices, uninsured causes of loss, or for acreage abandoned or put to another use without the consent of the Corporation: *Provided*, That for unharvested acreage or acreage not qualifying for the third stage production guarantee only the amount of appraised and harvested production in excess of the difference between the third stage production guarantee and the production guarantee applicable to such acreage shall be counted except that for acreage abandoned, put to another use without prior consent of the Corporation, or damaged solely by an uninsured cause not less than the applicable production guarantee shall be counted

6. *Cancellation and termination for indebtedness dates.* For each year of the contract the cancellation date is the December 31 and the termination date for indebtedness the April 15 immediately preceding the beginning of the crop year.

7. *Annual premium.* Section 6(b) of the policy shall not be applicable in those counties where variable guarantees based on the insured's experience are provided on the acturial table.

8. *Meaning of terms.* (a) "Harvest" means the lifting and topping of the sugar beets.

(Secs. 506, 516, 52 Stat. 73, as amended, 77, as amended; (7 U.S.C 1506, 1516).)

The current endorsement for sugar beets contains a number of provisions which experience has shown should be revised if the program is to function satisfactorily. The foregoing amendment contains these revisions and in addition

clarifies the language in a number of instances. It is desirable that the amendment become effective in 1974. Notice of changes must be given sugar beet insureds by December 15, 1973, and applications for insurance will be taken in the near future. It would therefore be impossible to follow both the procedures for notice and public participation prescribed by 5 U.S.C. 553(b) and (c) prior to the adoption of this amendment and to comply with the contractual provisions with respect to filing such changes in time to be effective for the 1974 crop year.

Under the circumstances, the Board of Directors found that it would be impracticable and contrary to the public interest to follow the procedure for notice and public participation prescribed by (5 U.S.C. 553(b) and (c)), as directed by the Secretary of Agriculture in a Statement of Policy, executed July 20, 1971 (36 FR 13804), prior to its adoption. Accordingly, said amendment was adopted by the Board of Directors on November 1, 1973.

[SEAL] LLOYD E. JONES,
Secretary,
Federal Crop Insurance Corporation.

Approved on November 15, 1973.

RICHARD E. BELL,
Deputy Assistant Secretary.

[FR Doc.73-24708 Filed 11-19-73;8:45 am]

[Amdt. 50]

PART 401—FEDERAL CROP INSURANCE

Subpart—Regulations for the 1969 and Succeeding Crop Years

SUGAR BEET ENDORSEMENT (APPLICABLE ONLY IN CALIFORNIA)

Pursuant to the authority contained in the Federal Crop Insurance Act, as amended, the above-identified regulations are amended effective beginning with the 1974 crop year in the following respect:

1. The portion of the table following paragraph (a) of § 401.103 of this chapter under the heading "Sugar Beets" is amended effective beginning with the 1974 crop year to read as follows:

§ 401.103 Application for insurance.

(a) * * *

(Closing Dates)	
SUGAR BEETS	
All States except California	Apr. 15

2. The following section is added:

§ 401.149 The Sugar Beet Endorsement (applicable only in California) for the 1974 and Succeeding Crop Years.

The provisions of the sugar beet endorsement (applicable only in California) for the 1974 and succeeding crop years are as follows:

1. *Insured crop.* The crop insured shall be sugar beets grown under a contract with a processor for processing as sugar. Item (1) of the second sentence of subsection 2(c) of the policy shall not be applicable to sugar beets.

Insurance shall not attach or be considered to have attached to any acreage (1) excluded from the processor contract for, or during, the crop year, and (2) unless otherwise provided on the county actuarial table, planted to sugar beets the two preceding crop years.

2. *Production guarantees.* (a) The production guarantee for a unit shall be the reported acreage or the actual planted acreage, whichever is less, multiplied by the applicable production guarantee per acre in hundredweight of commercially recoverable sugar. (Any underreporting of insurable acreage will have the effect of reducing the per acre guarantee proportionately.)

(b) The per acre production guarantees shall be based on a percentage of the normal yield (cwt. of commercially recoverable sugar) initially established for the acreage for the crop year in accordance with the regulations issued by the United States Department of Agriculture pursuant to the Sugar Act of 1948, as amended, or the normal yield that would have been established if only the acreage in the insurance unit had been used to establish the normal yield except that the Corporation may determine that such yield is not representative of the productivity of a unit and establish a production guarantee for the unit: *Provided*, That any redetermination of the normal yield pursuant to the regulations isued under the Sugar Act of 1948, as amended, shall not apply for crop insurance purposes for such crop years unless the Corporation so elects.

(c) The progressive per acre production guarantees are:

(1) The First Stage guarantee shown on the actuarial table applies until thinning or 90 days after planting, whichever occurs first, and to any acreage that the Corporation determines was damaged in this stage to the extent that growers in the area usually would not further care for the crop.

(2) The Second Stage guarantee applies from thinning or the 91st day after planting, whichever occurs first, until 15 percent of the production guarantee for the third stage has been delivered to and accepted by the processor.

(3) The Third Stage applies after delivery and acceptance by the processor of 15 percent of the guarantee for this stage.

3. *Acreage insured.* Notwithstanding the provisions of Section 2 of the policy, upon acceptance by the Corporation of an application for sugar beet insurance the acreage insured shall be (a) all insurable acreage planted after the filing of the application and (b) any acreage planted before the filing of the application, or reinstatement request, that is inspected by the Corporation after a normal stand has been obtained and designated in writing as approved by the Corporation for insurance for the crop year.

4. *Insurance period.* Insurance on any insured acreage shall attach or be considered to have attached at the time the sugar beets are planted and shall cease upon the earlier of harvesting or July 15 for Imperial County or the last day of the 12th calendar month after planting of the acreage for all other counties, unless a written request from the insured for an extension of the insurance period is received prior to such date and is approved by the Corporation.

5. *Notice of possible loss.* To claim a loss, the insured must give notice of loss as provided in section 8 of the policy even though bona fide abandonment is approved under the Sugar Act of 1948, as amended. Notice of probable loss, determined by applying the applicable rate of commercially recoverable sugar to the tonnage delivered, must be given to the Corporation office serving the county no later than the end of the insurance period (even if harvest on a unit has not been completed by that date) or within 15 days after harvest is completed on a unit, whichever occurs first.

6. *Claim for loss.* (a) Any claim for loss must be submitted to the Corporation no later than 30 days after the production records for that unit are available but in no event later than 60 days after the applicable calendar date for the end of the insurance period (see section 4 above). The Corporation reserves the right to provide additional time if it determines that circumstances beyond the control of either party prevent compliance with this provision.

(b) It is the responsibility of the insured to provide complete information of all production from the unit, to establish that the loss claimed was caused during the insurance period by one or more of the hazards insured against, and to furnish such other information about the loss as may be required by the Corporation.

(c) The amount of loss for a unit in hundredweight of commercially recoverable sugar shall be determined by subtracting from the production guarantee the total production to be counted as hereinafter provided. The indemnity due the insured shall be obtained by multiplying such amount of loss by the applicable price election for computing indemnities and the result by the insured interest.

The hundredweight of commercially recoverable sugar shall be determined by multiplying the net weight of sugar beets in tons at the time of delivery to the processor by the applicable rate of commercially recoverable sugar prescribed for the crop year under regulations issued by the United States Department of Agriculture pursuant to the Sugar Act of 1948, as amended. For appraised production the commercially recoverable sugar to be counted shall be 2.75 hundredweight per ton.

The total production to be counted for a unit shall be determined by the Corporation from all insurable acreage in the unit (including any that was not reported for insurance) and, subject to provisions hereinafter, shall include all harvested production and any appraisals made by the Corporation for unharvested or potential production, poor farming practices, uninsured causes of loss, or for acreage abandoned or put to another use without the consent of the Corporation: *Provided*, That for unharvested acreage or acreage not qualifying for the third stage production guarantee only the amount of appraised and harvested production in excess of the difference between the third stage production guarantee and the production guarantee applicable to such acreage shall be counted except that for acreage abandoned, put to another use without prior written consent of the Corporation, or damaged solely by an uninsured cause not less than the applicable production guarantee shall be counted.

7. *Cancellation and termination for indebtedness dates.* That portion of item (1) in section 13(b) of the policy which reads, "other than the premium due on a crop normally harvested in the calendar year in which the termination date for indebtedness for that crop occurs," shall not be applicable with respect to sugar beet crop insurance in any county in California.

The cancellation date shall be the June 30 for Imperial County and the October 31 for all other counties preceding the beginning of the crop year for which such cancellation is to become effective.

The termination date for indebtedness shall be the August 31 preceding the beginning of the crop year for Imperial County and for all other counties shall be the date the insured begins planting for the next crop year unless prior to such date the insured has made arrangements satisfactory to the Corporation for payment of the premium owed the Corporation.

8. *Annual premium.* Section 6(b) of the policy shall not be applicable in those counties where variable guarantees based on the

insured's experience are provided on the actuarial table.

9. *Meaning of terms.* (a) "Harvest" means the lifting and topping of the sugar beets.

(b) "Crop Year", notwithstanding section 19(c) of the policy, shall be the period from planting until the applicable date for the end of the insurance period and shall be designated by reference to the calendar year designation applicable to such acreage under the Sugar Act of 1948, as amended.

(Secs. 506, 516, 52 Stat. 73, as amended, 77, as amended; (7 U.S.C. 1506, 1516).)

In revising the current sugar beet endorsement, it was decided that a special endorsement should be developed for California where sugar beets are planted and harvested the year around. In place of the current sugar beet endorsement which was applicable in all states, there will now be two endorsements, one of which will be applicable in all states except California (Amendment No. 49) and the endorsement contained in the foregoing amendment which will be applicable only in California.

Since it will be necessary to start taking applications as soon as possible for the 1974 crop year, the Board of Directors found that it would be impracticable and contrary to the public interest to follow the precedure for notice and public participation prescribed by 5 U.S.C. 553 (b) and (c), as directed by the Secretary of Agriculture in a Statement of Policy, executed July 20, 1971 (36 FR 13804), prior to its adoption. Accordingly, said amendment was adopted by the Board of Directors on November 1, 1973.

[SEAL] LLOYD E. JONES,
Secretary,
Federal Crop Insurance Corporation.

Approved on November 15, 1973.

RICHARD E. BELL,
Deputy Assistant Secretary.

[FR Doc.73-24707 Filed 11-19-73;8:45 am]

[Amdt. 3]

PART 404—APPLE CROP INSURANCE

Subpart—Regulations for the 1967 and Succeeding Crop Years

APPLES

Pursuant to the authority contained in the Federal Crop Insurance Act, as amended, the above-identified regulations are amended effective beginning with the 1974 crop year in the following respects:

1. Section 13 of the Application and Policy shown in § 404.25 is amended to read as follows:

13. *Notice of damage or loss.* (a) It shall be a condition precedent to payment of any indemnity on any unit that the insured give written notice to the Corporation office serving the county immediately after any insured damage occurs giving the date and cause. No insured damage shall be considered to have occurred unless the Corporation is given such notice and the applicable notices required in subsection (b) below so that a prompt inspection and determination of the extent of damage can be made.

(b) If a loss is to be claimed, the insured shall give notice to the Corporation at the office serving the county of the time of intended harvest at least seven days prior to the start of harvest and give immediate notice if damage occurs within this seven day period, or during harvest.

2. Subsection 14(c) of the Application and Policy shown in § 404.25 is amended to read as follows:

(c) The percent of insured damage shall be the ratio of the number of boxes the Corporation determines were lost from insured causes as provided hereinafter to the applicable of the following number of boxes: (1) If no spring freeze damage is determined by the Corporation, the total boxes obtained by adding all boxes harvested, remaining on the trees, lost due to windstorm or hail knocking them from the trees, lost due to uninsured causes and lost due to not following good cultural practices, or (2) if spring freeze damage is determined by the Corporation, the lower of (i) the expected production for the crop year determined by the Corporation based on the number, age, size, condition and care of the trees and the cultural practices followed or (ii) the highest number of boxes harvested from the acreage in any one of the previous four crop years as determined by the Corporation from warehouse and processor records provided by the insured. No freeze damage shall be deemed to have occurred, even though reported, if the determination made as provided in item (1) exceeds the determination as provided in item (2).

No insurance shall be considered to have attached to any acreage on which the Corporation determines the expected production as determined in item (1) or item (2) above was less than the expected production shown on the actuarial table as a prerequisite for insurability.

The boxes of production lost shall be the difference between the applicable of item (1) or item (2) above and the production to count which shall include all boxes harvested, remaining on the trees, lost due to uninsured causes and lost due to failure to follow good cultural practices: *Provided, however,* That for those apples determined by the Corporation to have been reduced below fancy grade (based on standards established by the duly authorized agency of the state) directly and solely by insured causes, only 30 percent of the number of boxes so reduced in grade shall be counted as production, except that in no event shall such reduction in production to be counted apply to any apple grading less than fancy due to shape or color.

2. Section 14 of the Application and Policy shown in § 404.25 is amended by deleting subsection 14(d) and by redesignating subsection 14(e) as subsection 14(d).

(Secs. 506, 516, 52 Stat. 73, as amended, 77, as amended; (7 U.S.C. 1506, 1516).)

Experience under the current apple crop insurance contract now in force in Oregon and Washington has been extremely adverse. It is imperative that immediate changes be made in the current provisions for adjusting and reporting losses. The foregoing amendment is designed to correct this situation by tightening the reporting requirements and limiting the amount of judgment required in determining the amount of loss. It is desirable that this change be made effective with the 1974 crop year. However, the contract provides that changes must be placed on file in the office for the county by not later than December 15, 1973. It would, therefore, be impossible to follow both the procedure for notice and public participation prescribed by (5 U.S.C. 553(b) and (c)) prior to the adoption of the proposed amendment and to comply with contractual provisions with respect to filing such changes in time for them to be effective for the 1974 crop year.

Under the circumstances mentioned above, and since applications from new applicants for the 1974 crop year will be taken in the near future, the Board of Directors found that it would be impracticable and contrary to the public interest to follow the procedure for notice and public participation prescribed by (5 U.S.C. 553(b) and (c)), as directed by the Secretary of Agriculture in a statement of policy, executed July 20, 1971 (36 FR 13804), prior to its adoption. Accordingly, said amendment was adopted by the Board of Directors on November 1, 1973.

[SEAL] LLOYD E. JONES,
Secretary,
Federal Crop Insurance Corporation.

Approved on November 15, 1973.

RICHARD E. BELL,
Deputy Assistant Secretary.

[FR Doc.73-24706 Filed 11-19-73;8:45 am]

Title 10—Atomic Energy

CHAPTER I—ATOMIC ENERGY COMMISSION

PART 170—FEES FOR FACILITIES AND MATERIALS LICENSES UNDER THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

Extension of Due Date for Payment

On July 11, 1973, the Atomic Energy Commission published in the FEDERAL REGISTER (38 FR 18443) a notice of rulemaking revising fees for Atomic Energy Commission facility and materials licenses and withdrawing the exemption from fees for certain licenses. The amendment to § 170.12(c) adopted therein required payment within 30 days after the effective date of the amendments of the prescribed fees for those licenses that were not subject to fees prior to the effective date of the amendments.

The Commission has received a number of applications for licensing actions which, if granted, would affect liability for or the amount of license fees.

To provide further opportunity for licensees to file applications for amendments or cancellation of their licenses, the Commission has amended § 170.12(c) to extend the due date for payment of license fees to 120 days after the effective date of the amendment of Part 170 published on July 11, 1973. When an application is filed on or before December 8, 1973, to cancel a license, the Commission will waive the applicable fee upon cancellation of the license. When an application is filed on or before December 8, 1973, to amend a license, and the Commission acts favorably upon the application, the fee will be assessed in the

amount applicable to the license as amended.

To provide greater equity in assessment of license fees, the Commission has established a new category for small quantities of special nuclear material contained in sealed sources when these sources are used in industrial gauges and similar measuring devices.

Since the 30-day period for payment of fees provided in the amendments which became effective August 10, 1973, has expired, the Commission has found that good cause exists for omitting notice of proposed rule making and public procedure as impracticable. Since the following amendments relieve from restrictions under regulations currently in effect, they will become effective without the customary 30-day notice.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 170, are published as a document subject to codification.

1. Paragraph (c) of § 170.12 is amended to read as follows:

§ 170.12 Payment of fees.

* * * * *

(c) *Annual fees.* All licenses outstanding on August 10, 1973, are subject to payment of the annual fee prescribed by this Part 170, as amended, on or before December 8, 1973, and annually on August 10 thereafter; *Provided, however,* That in the case of licenses which have been subject to license fees prior to August 10, 1973, the next annual fee will be payable 1 year from the due date of the last fee payment and annually thereafter. In the case of licenses issued on or after August 10, 1973, annual fees are payable 1 year following the date of issuance of the license and annually thereafter.

* * * * *

2. Section 170.31 is amended to redesignate the present fee Category 1E as fee Category 1F and to add a new fee Category 1E as follows:

§ 170.31 Schedule of fees for material licenses.

Applicants for materials licenses and holders of materials licenses shall pay the following fees:

SCHEDULE OF MATERIALS LICENSE FEES

Category of materials licenses [1]	Application fee [2]	Annual fee [2, 4]
1. Special nuclear material: [3]		
* * * * *	*	*
E. Licenses for possession and use of special nuclear material in sealed sources contained in devices used in industrial measuring systems.	$50.	$50.
F. All other specific special nuclear material licenses, except those licenses covered by Categories 4A, 4B, 5A, 6A, 7A, 7B, 7C, or 8A.	$200.	$200.

Effective date. This amendment shall become effective on November 20, 1973.

(Sec. 501, 65 Stat. 290; (31 U.S.C. 483a).)

Dated at Germantown, Md., this 14th day of November 1973.

For the Atomic Energy Commission.

PAUL C. BENDER,
Secretary of the Commission.

[FR Doc.73-24641 Filed 11-19-73;8:45 am]

Title 14—Aeronautics and Space

CHAPTER I—FEDERAL AVIATION ADMINISTRATION, DEPARTMENT OF TRANSPORTATION

[Airspace Docket No. 73-CE-24]

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

Designation of Transition Area

On pages 20347 and 20348 of the FEDERAL REGISTER dated July 31, 1973, the Federal Aviation Administration published a notice of proposed rulemaking which would amend § 71.181 of Part 71 of the Federal Aviation Regulations so as to designate a transition area at Ogallala, Nebraska.

Interested persons were given 30 days to submit written data, views or arguments concerning the proposed amendment. Two comments were received. The Air Transport Association offered no objection to the proposal. The Department of the Air Force objected to the proposal because it would conflict with olive branch route 82. Subsequent to the issuance of this proposal and after discussions with the Air Force, the Federal Aviation Administration has determined that Air Traffic Control can separate civil aircraft making instrument approach procedures to the Ogallala, Nebraska, Airport from olive branch flights so that no confliction will occur. In view of this determination the Air Force has withdrawn its objection. Accordingly, the proposed amendment is hereby adopted without change and is set forth below.

This amendment becomes effective 0901 G.m.t., January 31, 1974.

(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 Kansas City, Mo., on November 7, 1973.

A. L. COULTER,
Director, Central Region.

In § 71.181 (38 FR 435), the following transition area is added:

OGALLALA, NEBRASKA

That airspace extending upward from 700 feet above the surface within an 8.5 mile radius of the Searle Airport (latitude 41°07'00" N., longitude 101°46'00" W.); and that airspace extending upward from 1,200 feet above the surface within 9.5 miles north and 4.5 miles south of the 100° bearing from the Searle Airport, extending to 18.5 miles east; and within 9.5 miles south and 4.5 miles north of the 252° bearing from the airport extending to 18.5 miles west with the southern boundary extended eastward to intersect the eastern extension 12 miles southeast of the airport.

[FR Doc.73-24638 Filed 11-19-73;8:45 am]

[Airspace Docket No. 73-RM-25]

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

Alteration of Transition Area

On October 11, 1973, a notice of proposed rulemaking was published in the FEDERAL REGISTER (38 FR 28077) stating that the Federal Aviation Administration was considering an amendment to Part 71 of the Federal Aviation Regulations that would alter the transition area at Conrad, Mont.

Interested persons were given 30 days in which to submit written comments, suggestions, or objections. No objections have been received and the proposed amendment is hereby adopted without change.

Effective date. This amendment shall be effective 0901 G.m.t., January 31, 1974.

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

Issued in Aurora, Colo., on November 12, 1973.

M. M. MARTIN,
Director, Rocky Mountain Region.

In § 71.181 (38 FR 435) the description of the Conrad, Mont., transition area, as designated by (38 FR 18442) is further amended to read as follows:

CONRAD, MONT.

That airspace extending upward from 700 feet above the surface within a 9-mile radius of the Conrad Airport (latitude 48°10'10" N., longitude 111°58'30" W.); within 3.5 miles each side of the 060° bearing from the Conrad RBN (latitude 48°11'12" N., longitude 111°-55'31" W.) extending from the 9-mile radius area to 12 miles northeast of the RBN; and that airspace extending upward from 1,200' above the surface within 9.5 miles northwest and 4.5 miles southeast of the 060° bearing from the Conrad RBN extending from the RBN to 18.5 miles northeast of the RBN.

[FR Doc.73-24637 Filed 11-19-73;8:45 am]

CHAPTER II—CIVIL AERONAUTICS BOARD

SUBCHAPTER A—ECONOMIC REGULATIONS

[Reg. ER-832, Amdt. 19]

PART 298—AIR TAXI REGISTRATION FEE

Increase

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., on November 15, 1973.

By notice of proposed rulemaking EDR-253/ODR-7, September 4, 1973, the Board proposed, *inter alia*, to increase the air taxi registration fee to fifteen ($15) dollars. For reasons set forth in OR-80 (Part 389), published contemporaneously

herewith, the Board has decided to adopt that proposal.

Since the amended rule is one of agency procedure and practice, the Board finds that it may be made effective on less than thirty days' notice, and that the rule should be made effective on December 1, 1973.

In consideration of the foregoing, the Civil Aeronautics Board hereby amends Part 298 of the Economic Regulations (14 CFR Part 298), effective December 1, 1973, as set forth below:

1. Amend Part 298.50(c)(3) to read as follows:

§ 298.50 Filing for registration by air taxi operators.

* * * * *

(c) Registration and reregistration shall be * * *

(3) A fifteen ($15) dollar registration or reregistration fee, as the case may be. This shall be in the form of a check, draft, or postal money order, payable to the Civil Aeronautics Board.

(Sec. 204(a), Federal Aviation Act of 1958, as amended, 72 Stat. 743 (49 U.S.C. 1324(a); 31 U.S.C. 483(a)).)

By the Civil Aeronautics Board.

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

[FR Doc.73-24697 Filed 11-19-73;8:45 am]

SUBCHAPTER E—ORGANIZATION REGULATIONS

[Reg. OR-80, Amdt. 16]

PART 389—FEES AND CHARGES FOR SPECIAL SERVICES

Certain Filing and License Fees

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., on November 15, 1973.

By notice of proposed rulemaking EDR-253/ODR-7, dated September 4, 1973, the Board proposed to amend the above parts to provide for an increase in the current schedule of license and filing fees and to provide for additional filing fee items.

Comments in response to the notice were filed by American Airlines, Inc. (American), Capitol International Airways, Inc. (Capitol), and members of the National Air Carrier Association (NACA). The time for filing comments has expired, and no other person has filed a comment or has indicated its intention to do so.

Briefly summarized, objections have been made to the Board's filing fee proposals insofar as they would (1) charge a special fee for agreements filed for prior Board approval; (2) charge for the filing of certain motions; and (3) increase the fees for waivers of the Board's charter regulations. Certain objections have also been made to the Board's license fee proposals.

We have determined to adopt the amendments as proposed. All comments have been carefully considered, and all contentions not otherwise disposed of herein are rejected. There follows a discussion of the comments directed towards various aspects of the proposed amendments, and our conclusions with respect thereto.

1. *Agreements filed for prior Board approval.* The Board has proposed a filing fee of $200 for those contracts and agreements that require prior Board approval. As noted in EDR-253/ORD-7, these agreements are typically complex and controversial in nature and require a great deal of the staff's time for analytical review. Nevertheless, American claims that the fee would impose an undue financial burden on IATA and ATC carriers since both carrier groups, particularly IATA, file many routine agreements requiring prior Board approval. However, it appears that the proposed rule already satisfies American's complaint. Section 389.25(b)(2) specifies that the filing fee for agreements that the Board requires be filed for prior approval is the same as the fee for those not requiring prior approval i.e., only $50.00. Since the Board has such a requirement for all IATA Traffic Conference Resolutions, the $200 fee is inapplicable to those filings. The reference to hardship on ATC carriers is unsupported; indeed, we note that ATC does not file "routine" agreements for prior approval.

2. *Motions.* In proposing to charge a cost-related fee for motions to file unauthorized documents, to strike, and for expedited action, the Board noted that these motions should be subject to special charges because they confer special benefits. However, it is contended here that these proposed fees, particularly the fee for filing unauthorized documents, penalize parties who respond to improper statements or defective pleadings of others. We adhere to the view that persons filing these motions receive special benefits for which a reasonable processing fee is justified, and we are unable to conclude that the fee involved will have an inhibiting effect on filings which are deemed essential by the movant.

3. *Waiver of charter regulations.* The Board also proposed increasing the fees for waivers of its charter regulations (Parts 207, 208, 372, 372a, 373, 378, 378a) and placing them on a par with the fees for exemptions from section 401 of the Act. However, NACA alleges that the Board's proposal increases the fee for waivers by 545 percent and that the percentage increase for waivers vastly exceeds those for other items increased by the Board. NACA requests that the Board make no change in its fees for such waivers.

In the first place, we note that NACA's complaint is overstated. The 545 percent figure that NACA complains of is applicable to a very small percentage of all waiver applications, i.e., those applications not restricted to a specified number of flights. For the vast majority of waivers, the correct comparison figures are as follows:

	Present fee	Proposed fee	Percentage increase
Basic	$55	$100	82
Per flight	5	10	100
Maximum	200	300	50

In this light, and notwithstanding NACA's general allegation of discrimination with respect to charter filing fees, it is evident that the proposed increases for the vast majority of such fees are on a par with other increases proposed by the Board.

Furthermore, the Board's proposed charter fees are justified by cost analysis. In this regard we note that our review of the existing level of fees established, *inter alia*, that there was no essential difference between the average costs in handling applications for 401 exemptions and applications for unrestricted waiver of the Board's charter regulations. Accordingly, it is our view that the two categories should be priced the same. However, there is a cost difference between applications for exemptions or waivers that do not involve a specific number of charters and those that do. The unrestricted applications are more costly to process and review than the latter because they are typically more complex and often require Board, as well as staff, action.

Finally, we wish to point out that it was not our intention to increase filing fees on an equally proportionate basis. The purpose of our review was to ascertain the average cost involved in handling the individual fee items in light of current data, and to adjust the fee schedule primarily on that basis.

LICENSE FEES

Section 389.25(a)(2) requires a carrier to pay a license fee if it is issued a certificate, or has its certificate amended, modified, renewed or transferred. The fee is based upon the estimated increase in gross transportation revenue, for the first full year of operations, attributable to such changes in the carrier's operating authority. The Board has proposed certain increases to the existing schedule of license fees in order to more accurately reflect current administrative costs. No objections have been filed to the proposed increase on license fees, *per se*. However, Capitol urges the Board (1) not to charge a license fee for granting temporary authority, or at a minimum, to prorate the fee to reflect the duration of temporary authority; and (2) to further refine the fee schedule and breakdown of annual gross transportation revenue brackets so as to avoid an uneven application of the fee burden.

The Board does not deem it appropriate to impose different fees, based upon whether the carrier's authority is temporary or permanent. The essential purpose of the license fee regulations is to require the special beneficiaries of the Board's regulatory process to bear a fair share of the expense of that process. Certificate proceedings are by their nature costly and these costs are the same regardless of whether the applicant receives temporary or permanent authority. While an applicant must pay the same fee for temporary authority that it would have to pay for permanent rights, it also should be noted that the license fees for temporary certificates have not been shown

to be incommensurate with their value to the recipient.

The Board recognizes that there are circumstances in which one carrier may receive an award more valuable than that received by another even though both are required to pay the same fee. However, the fees involved are believed to be fair and equitable in terms of benefits realized by the recipient of the license authority, and any attempt to refine the schedule so that the fee charged is more precisely commensurate with the benefit received on a comparative basis with other recipients of licenses would create undue administrative problems for the Board and its staff, and would increase the administrative costs associated with the awards of operating authority.

Since the amended rule is one of agency procedure and practice, the Board finds that it may be made effective on less than thirty days notice, and that the rule should be made effective on December 1, 1973.

In consideration of the foregoing, the Civil Aeronautics Board hereby amends Part 389 of the Organization Regulations (14 CFR 389), effective December 1, 1973, as set forth below.

1. Amend § 389.25 to read as follows:

§ 389.25 Schedule of filing and license fees.

(a) *Certificates of public convenience and necessity.* (1) The filing fee for an application, under section 401 of the Act, (i) for a certificate of public convenience and necessity to engage in air transportation, or (ii) to amend, modify, renew, or transfer a certificate or to abandon a route or a part thereof, is $300. The fee will be refunded, on request, if the application is withdrawn prior to hearing, is dismissed under the stale-application rule of § 302.911 of this chapter, is dismissed pursuant to the denial of consolidation rule of § 302.12(e) of this chapter, or is otherwise dismissed by the Chief Administrative Law Judge prior to hearing under the authority delegated to him in § 385.10(b) of this chapter.

(2) In addition to the filing fee, one of the following license fees shall be paid by each carrier which, pursuant to its application, is issued a certificate or has its certificate amended, modified, renewed, or transferred:

(i) A fee based on annual gross transport revenue increase, for the first full year of operations, as estimated by the Board, resulting from new, amended, modified, renewed, or transferred authority in accordance with the following schedule:

Over	Fee
$0 to $100,000	No fee
$100,000 to $1,000,000	$2,000
$1,000,000 to $5,000,000	10,000
$5,000,000 to $10,000,000	20,000
$10,000,000 or over	40,000

(ii) A fee of $1,500 for each point deleted where annual gross transport revenues are not estimated by the Board to increase from deletion or consolidation of points.

(iii) Within the meaning of subdivision (i) of this subparagraph, annual gross transport revenue increase resulting from renewed authority or authority issued to replace exemption authority shall be deemed equivalent to the difference between such revenues which the carrier will earn with the Board's authorization and such revenues which the carrier would have earned if the Board had denied such authority and the carrier's comparable prior certificate or exemption authority had expired. In the case of mergers, such annual gross transport revenue increase from transferred authority shall be deemed equivalent to the difference between such revenues which the new (or surviving) carrier will earn with the Board's authorization and such revenues which the merging carriers would have earned under their pre-existing authority if the Board had disapproved the merger. Except as provided hereinafter, such annual gross transport revenue increase from transferred authority in nonmerger cases shall be deemed equivalent to the difference between such revenues which the person acquiring the route will earn with the Board's authorization and such revenues which such person would have earned if the Board had disapproved the transfer. In cases of transfer of authority due to a reincorporation not involving any merger, consolidation or change of ownership, or to the creation of a new corporation pursuant to an acquisition of control which the Board approves under section 408 of the Act and which involves only a substitution of the new corporation for the old, no gross transport revenue increase shall be deemed to result from the transfer of authority.

(b) *Agreements.* (1) The filing fee for a contract or agreement filed under section 412(a) of the Act is $50; except that the fee is $200 where such filing seeks Board approval prior to the effective date of the contract or agreement: *Provided, however,* That the fee shall be $50 where the Board requires a contract or agreement to be filed for prior approval.

(2) Where a filing seeks approval of more than one contract, agreement, or conference resolution, a separate filing fee will be assessed for each separate contract, agreement, or resolution: *Provided, however,* That identical resolutions in the same filing applicable to different IATA conference areas will be counted as one resolution.

(c) *Air cargo pickup and delivery service.* The filing fee for an application, under § 222.3 of this chapter, for tariff-filing authority providing for pickup and delivery service is $175.

(d) *Airport notice or authorization.* The filing fee (1) for an airport notice, under § 202.3(a) or § 203.5(a) of this chapter, to permit a certificated route carrier to serve a point regularly through an airport not then regularly used by such carrier, or (2) for an application, under § 202.3(b)(2) of this chapter, for permission to use an airport, is $40.

(e) *Change in service pattern.* The filing fee for an application for change in service pattern or an approved service plan is $40 for an application under Part 376 of this chapter and $300 for an application under Parts 202 and 203 of this chapter.

(f) *Change of name.* The filing fee for an application, under Part 215 of this chapter, for a change of name or use of a trade name is $300.

(g) *Delay inauguration of or temporarily suspend service, and applications to extend property embargo notices.* (1) The filing fee for an application, under Part 205 of this chapter, for authority to delay inauguration of service or to temporarily suspend service is $400.

(2) The filing fee for an application, under Subpart B of Part 228 of this chapter to extend a notice of embargo beyond thirty days is $25.

(h) *Exemptions from section 401, waivers of Parts 207, 208, 372, 372a, 373, 378, and 378a, and special operating authorizations.* The filing fee for an application (1) for an exemption under section 416(b) or section 101(3) of the Act from the provisions of section 401 of the Act (except an application dealing with a specific number of charters), or (2) for a waiver of Parts 207, 208, 372, 372a, 373, 378, or 378a (except an application dealing with a specific number of charters), or (3) for a special operating authorization under section 417 of the Act, is $300.

(i) *Exemptions from section 403.* The filing fee for an application for exemption under section 416(b) of the Act from the provisions of section 403 of the Act is $50.

(j) *Exemptions or waivers for the performance of a specific number of charters.* The filing fee for an application for an exemption under section 416(b) or section 101(3) of the Act from the provisions of section 401 of the Act, or a request for a waiver of Parts 207, 208, 372, 372a, 373, 378 or 378a, for the performance of a specific number of charters (one-way or round-trip) is $100 plus $10 for each charter (one-way or round-trip) described, subject to a maximum fee of $300.

(k) *Free or reduced-rate authority, waiver of tariff regulations, and special tariff permission.* The filing fee for applications (1) under § 223.8 of this chapter for authority to furnish free or reduced-rate overseas or foreign air transportation (except an application filed at the request of a U.S. Government agency or a foreign government), (2) under § 221.200 of this chapter for waiver or modification of the provisions of Part 221 of this chapter with respect to the filing and posting of tariffs, or (3) for special permission under § 221.133 or § 221.191 of this chapter, is $10. With respect to applications for waiver or special tariff permission, such fee does not apply to an application which a foreign air carrier files or which a tariff publishing agent files on behalf of foreign air carriers exclusively.

(l) *Inclusive tour charter prospectus.* The filing fee for each tour prospectus filed pursuant to § 378.10 or § 378.19 of this chapter is $50.

(m) *Bulk inclusive tour contracts and bonds.* The filing fee for contracts and bonds covering a bulk inclusive tour or series of tours filed pursuant to § 378a.10 of this chapter is $50.

(n) *Study group statements.* The filing fee for each study group statement filed pursuant to § 373.10 of this chapter is $50.

(o) *Travel group charters.* The filing fee for each travel group charter filing pursuant to § 372a.22(a) of this chapter is $50.

(p) *Interlocking relationships under section 409.* The filing fee for an application for approval of interlocking relationships under section 409 of the Act is $250.

(q) *Merger, acquisition of control, etc., under section 408, and lease or purchase agreements under Part 299.* (1) The filing fee for an application under section 408 of the Act is $150; except that the the filing fee for an application for merger, consolidation, or acquisition of control of certificated air carriers is $3,000 for each certificated air carrier named in the merger, consolidation or acquisition of control.

(2) The filing fee for a lease or purchase agreement filed under Part 299 of this chapter is $50.

(r) *Motions.* The filing fee for a motion to strike, for leave to file an otherwise unauthorized document, or for expedited action is $50; except that there shall be no filing fee for a motion to strike impertinent or scandalous matters or pleadings.

(s) *Operating authorization — air freight forwarder.* The filing fee for an application, under Part 296 or 297 of this chapter, for operating authorization as an air freight forwarder or international air freight forwarder is $400.

(t) *Operating authorization—overseas military personnel charter operator, and bonds covering overseas military personnel charter operations.* (1) The filing fee for an application, under Part 372 of this chapter, for operating authorization as an overseas military personnel charter operator is $400.

(2) The filing fee for bonds covering overseas military personnel charter operations filed pursuant to § 372.24 of this chapter is $50.

(u) *Tariffs issued by carriers.* (1) The filing fee for tariffs (including supplements and revised or additional original pages thereto) issued by an air carrier pursuant to section 403 or 1003 of the Act is $2 per page. That fee is applicable notwithstanding that the tariff contains participating foreign air carriers, but it is not applicable to a blank looseleaf page unless it cancels matter on the preceding issue of the page.

(2) There shall be no filing fee for tariffs issued by a foreign air carrier notwithstanding that the tariff contains participating air carriers.

(v) *Tariffs issued by publishing agents.* The filing fee for tariffs (including supplements and revised or additional original pages thereto) issued by a publishing agent pursuant to section 403 or section 1003 of the Act is $2 per page, subject to the following conditions:

(1) If the tariff is issued on behalf of one or more air carriers exclusively, the filing fee is applicable to any page.

(2) If the tariff is issued on behalf of one or more foreign air carriers exclusively, no filing fee is applicable to any page.

(3) If the tariff is issued on behalf of one or more air carriers and one or more foreign air carriers, the filing fee is applicable to any page except to a page which the issuing agent states in his accompanying letter of tariff transmittal contains only:

(i) Matters pertaining exclusively to foreign air carriers, or

(ii) Changes only in matter pertaining exclusively to foreign air carriers when included on the same page together with matter (other than matter pertaining exclusively to foreign air carriers) which is reissued without change.

(4) The filing fee is not applicable to a blank looseleaf page unless it cancels matter on the preceding issue of the page other than matter pertaining only to foreign air carriers exclusively.

(5) Where two pages are published back-to-back on the same leaf and one page is not subject to a fee pursuant to § 389.25(v)(3) and the page on the reverse side is issued without change (except for pagination, correction number, and issued and effective dates), no fee is applicable to the latter page.

(6) The filing fee is applicable to a loose-leaf page containing a correction number check sheet unless all other pages of the tariff are exempt from filing fees.

(w) *Waivers.* The filing fee for an application under § 389.23 of this chapter for a waiver or modification of fee is $25, or 10 percent of the fee for which a waiver is sought, whichever is less.

(Sec. 204(a) of the Federal Aviation Act of 1953, as amended, 72 Stat. 743, (49 U.S.C. 1324(a); 31 U.S.C. 483(a)).)

By the Civil Aeronautics Board.

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

[FR Doc.73-24693 Filed 11-19-73;8:45 am]

Title 16—Commercial Practices

CHAPTER I—FEDERAL TRADE COMMISSION

[Docket No. C-2469]

PART 13—PROHIBITED TRADE PRACTICES

Robert Trager, Inc., and Robert Trager

Subpart—Invoicing products falsely: § 13.1108 *Invoicing products falsely;* 13.1108-45 Fur Products Labeling Act. Subpart—Misbranding or mislabeling: § 13.1185 *Composition;* 13.1185-30 Fur Products Labeling Act; § 13.1212 *Formal regulatory and statutory requirements;* 13.1212-30 Fur Products Labeling Act. Subpart—Misrepresenting oneself and goods—Goods: § 13.1590 *Composition;* 13.1590-30 Fur Products Labeling Act; § 13.1623 *Formal regulatory and statutory requirements;* 13.1623-30 Fur Products Labeling Act; § 13.1685 *Nature;* 13.1685-35 Fur Products Labeling Act. Subpart—Neglecting, unfairly or deceptively, to make material disclosure: § 13,1852 *Formal regulatory and statutory requirements;* 13.1852-35 Fur Products Labeling Act.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interpret or apply sec. 5, 38 Stat. 719, as amended, sec. 8, 65 Stat. 179 (15 U.S.C. 45, 69f).) [Cease and desist order, Robert Trager, Inc., et al., New York City, N.Y., Docket C-2469, Oct. 17, 1973.]

In the Matter of Robert Trager, Inc., a Corporation, and Robert Trager, individually and as an Officer of Said Corporation

Consent order requiring a New York City manufacturer of fur products, among other things to cease falsely invoicing and misbranding or mislabeling its fur products.

The order to cease and desist, including further order requiring report of compliance therewith, is as follows:

It is ordered, That Robert Trager, Inc., a corporation, its successors and assigns, and its officers, and Robert Trager, individually and as an officer of said corporation, and respondents' representatives, agents and employees, directly or through any corporation, subsidiary, division, or other device, in connection with the introduction, or manufacture for introduction, into commerce, or the sale, advertising or offering for sale in commerce, or the transportation or distribution in commerce, of any fur product; or in connection with the manufacture for sale, sale, advertising, offering for sale, transportation or distribution, of any fur product which is made in whole or in part of fur which has been shipped and received in commerce, as the terms "commerce", "fur" and "fur product" are defined in the Fur Products Labeling Act, do forthwith cease and desist from:

A. Misbranding any fur product by:

1. Representing directly or by implication on a label that the fur contained in such fur product is natural when such fur is pointed, bleached, dyed, tip-dyed, or otherwise artificially colored.

2. Failing to affix a label to such fur product showing in words and in figures plainly legible all of the information required to be disclosed by each of the subsections of section 4(2) of the Fur Products Labeling Act.

B. Falsely or deceptively invoicing any fur product by:

1. Failing to furnish an invoice, as the term "invoice" is defined in the Fur Products Labeling Act, showing in words and figures plainly legible all the information required to be disclosed by each of the subsections of section 5(b)(1) of the Fur Products Labeling Act.

2. Representing directly or by implication on an invoice that the fur contained in such fur product is natural, when such fur is pointed, bleached, dyed, tip-dyed, or otherwise artificially colored.

It is further ordered, That respondents notify the Commission at least 30 days prior to any proposed change in the corporate respondent such as dissolution, assignment or sale resulting in the emer-

gence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of the order.

It is further ordered, That the respondent corporation shall forthwith distribute a copy of this order to each of its operating divisions.

It is further ordered, That the individual respondent named herein promptly notify the Commission of the discontinuance of his present business or employment and of his affiliation with a new business or employment. Such notice shall include respondent's current business address and a statement as to the nature of the business or employment in which he is engaged as well as a description of his duties and responsibilities.

It is further ordered, That the respondents herein shall, within sixty (60) days after service upon them of this order file with the Commission a report in writing setting forth in detail the manner and form in which they have complied with this order.

Issued: October 17, 1973.

By the Commission.

[SEAL] CHARLES A. TOBIN, *Secretary.*

[FR Doc.73-24685 Filed 11-19-73;8:45 am]

Title 17—Commodity and Securities Exchanges

CHAPTER I—COMMODITY EXCHANGE AUTHORITY (INCLUDING COMMODITY EXCHANGE COMMISSION), DEPARTMENT OF AGRICULTURE

PART 15—REPORTS—GENERAL PROVISIONS

PART 16—REPORTS BY CLEARING MARKETS

Reporting and Public Information

On August 21, 1973, notice was published in the FEDERAL REGISTER (38 FR 22489) of proposed revisions of Part 16 and of §§ 15.01 and 15.02 of the regulations under the Commodity Exchange Act. All parties that would be affected by these proposed revisions were informed of their right to request a hearing or to submit written statements regarding this matter. Any submissions were to be received by the Administrator of the Commodity Exchange Authority on or before October 8, 1973. No comments were received, and, accordingly, no hearing was held.

The purpose of the proposed revision of Part 16 and the changes in §§ 15.01 and 15.02 is to place on contract markets responsibility for assembling and reporting to the Commodity Exchange Authority information currently being reported separately by each clearing member and to shift from the Commodity Exchange Authority to the contract markets responsibility for keeping the public informed with regard to the daily volume of trading and open contracts in commodities traded on each such contract market. Early in the history of regulation of commodity exchanges the Grain Futures Administration found that the public needed to know the daily volume of trading and open contract data. In the 1920's, because the contract markets would not make these data public, the Grain Futures Administration began doing so and the Commodity Exchange Authority currently is continuing to release such data daily. However, all exchanges now recognize the necessity of making the data public and all nonregulated exchanges routinely are doing so. With the contract markets assuming the function of assembling such data, they will be in a position to publish it more expeditiously than will the Commodity Exchange Authority.

In consideration of the foregoing, the revisions to these regulations are hereby adopted as set forth below.

1. Section 15.01 (17 CFR 15.01) is amended by revising paragraph (a) to read as follows:

§ 15.01 Persons required to report.

* * * * *

(a) Contract markets—as specified in Part 16 of this chapter:

* * * * *

§ 15.02 [Amended]

2. Section 15.02 (17 CFR 15.02) is amended by revoking the column headed "Clearing Members (series 00 forms)."

3. The heading of Part 16 (17 CFR Part 16) is revised to read as set forth above and Part 16 is revised to read as follows:

Sec.

16.00 Information to be furnished by Contract Market.
16.01 Time and place of filing reports.
16.02 Publication of volume of trading and open contracts.
16.03 Errors or omissions.

AUTHORITY: Sec. 5, 42 Stat. 1000, as amended; sec. 8a, 49 Stat. 1500; (7 U.S.C. 7, 12a).

§ 16.00 Information to be furnished by Contract Markets.

Each contract market shall report for each business day the following information, by commodity, by future, and by clearing member within each such future, in a form and manner approved by the Commodity Exchange Authority Regional Director having local jurisdiction with respect to such contract market:

(a) The total of all long open contracts and the total of all short open contracts carried at the end of the day covered by the report;

(b) The quantity of such contracts bought and the quantity sold during the day covered by the report;

(c) The quantity of purchase transfer trades or office trades and the quantity of sale transfer trades or office trades, which are included in the total quantity of contracts bought and sold during the day covered by the report, and the names of the clearing members who made the transfers;

(d) The quantity of purchases of futures in connection with cash commodity transactions or of futures for cash commodities and the quantity of sales of futures in connection with cash commodity transactions or of futures for cash commodities, which are included in the total quantity of contracts bought and sold during the day covered by the report, and the names of the clearing members who made the exchanges; and

(e) The quantity of the commodity delivered and the quantity received in fulfillment of such contracts during the day covered by the report.

§ 16.01 Time and place of filing reports.

Such reports shall be submitted the business day following the day for which the reports are filed and shall be filed in accordance with the instructions of the Commodity Exchange Authority Regional Director having local jurisdiction with respect to such contract market.

§ 16.02 Publication of volume of trading and open contracts.

Each contract market shall publish for each business day the following information by commodity and by future within each such commodity:

(a) The total volume of trading, excluding transfer trades or office trades;

(b) The total quantity of futures for cash transactions which are included in the total volume of trading;

(c) The total gross open contracts; and

(d) The total quantity of the commodity delivered in fulfillment of such contracts.

Such information shall be made readily available to the news media and the general public in printed form and without charge at the office and trading floor of the contract market not later than the business day following the day for which publication is made.

§ 11.03 Errors or omissions.

Any contract market discovering any errors or omissions in any report which has been filed shall promptly inform the Commodity Exchange Authority with respect thereto.

Effective date. The foregoing amendments shall become effective January 1, 1974.

Issued: November 15, 1973.

CLAYTON YEUTTER, *Assistant Secretary for Marketing and Consumer Services.*

[FR Doc.73-24710 Filed 11-19-73;8:45 am]

Title 18—Conservation of Power and Water Resources

CHAPTER I—FEDERAL POWER COMMISSION

[Docket No. R-454; Order 495]

PART 2—GENERAL POLICY AND INTERPRETATIONS

Measures To Implement Conservation of Natural Resources

NOVEMBER 13, 1973.

This order sets forth policies of the Commission which are designed to promote efficient utilization of electric energy and the conservation of natural resources, involved in the production and consumption thereof. The Policy

Statement constitutes a new section of the Commission's General Policy and Interpretations, § 2.14, Part 2, Subchapter A—General Rules, Chapter I, Title 18 Code of Federal Regulations.

The Statement is directed initially to the Nation's electric utilities, investor owned, publicly owned, including federally owned, and cooperatively owned, and through them to all members of the energy consuming public. Across the country, there are approximately 3,500 electric utilities serving the Nation's 200 million electric consumers.

The Federal Power Act contemplates Commission initiatives "[f]or the purpose of assuring an abundant supply of electric energy throughout the United States with the greatest possible economy and with regard to the proper utilization and conservation of natural resources * * *." (16 U.S.C. 824a(a)), (49 Stat. 848).

Increasing demands upon all of the Nation's energy resources prompted the Commission to initiate this rulemaking action for the policy guidance of all electric suppliers and electric consumers, including those industrial or commercial electric consumers which generate a portion of their electric requirements. See Notice of Proposed Policy Statement and Request For Comments, issued September 14, 1972, 37 FR 20045.[1]

As noticed, the proposed policy objectives were designed to establish general public recognition and acceptance of several basic considerations: That the use of electric resources constitutes the utilization of a number of primary energy or heat rsources; that the inherent nature of energy conservation contemplates a balanced use of natural resources designed to advance all of the Nation's national objectives and purposes; that conservation of natural resources is the individual responsibility of all who are concerned with energy production and consumption; and that implementation of conservation measures necessitates coordinated activities among all elements of government, industry, commerce and the consuming public. A voluntary annual reporting procedure covering conservation activities of electric systems was also proposed to facilitate wide public dissemination of natural resource conservation information.

The substance of comments received in response to that Notice is extensive.[2] Grouped by principal commentary, 47 respondents expressed general approval of the intent of the proposed policy statement; 23 expressed opposition to the annual voluntary reporting of conservation data as being burdensome or lacking significance; 19 found the generalized reporting objectionable because vague and some suggested a standardized reporting questionnaire; 11 concluded that the reporting should be mandatory and more extensive; 10 urged that other Government actions be taken to effect conservation; 10 opposed utility actions to report on comparative energy uses of alternate electric appliance equipment; 15 expressed the view that national energy policies are necessary for effective conservation; 19 proposed detailed word revisions in the proposed statement of policy; and 5 requested staff conferences, public hearings, the circulation of an environmental impact statement or the conclusion of the Commission's current National Power Survey before formal Commission action is taken in this proceeding.

The Commission does not accept the view that it should further defer the promulgation of Commission policy on the conservation of natural resources as it relates to electric power production and consumption. The production of electric energy throughout the United States now accounts for approximately one-fourth of all primary energy consumption within the Nation.[3] By the year 2000 the projected consumption of primary energy in the production of electric energy will aggregate approximately one-half of all primary energy consumption within the United States.[4] Manifestly, a major concern of the Nation during the remainder of the 20th century must be that of promoting and encouraging the efficient utilization of natural resources in the production and consumption of electric energy. By stating policy objectives in this proceeding, utility suppliers and consumers will be better able to work to accomplish these objectives through common efforts.[5]

The various electric utility operating systems are in a unique position to initiate effective programs for their respective consumers on prudent utilization of electric energy in relation to other resources; and to direct their utility operational expertise to the inherent problems of design technology and present limiting efficiencies associated with the production, transmission and consumption processes of electric energy.

In our judgment, meaningful effective stimulation of improved ways to produce and consume electric energy will result from public exposure, focus and discussion of:

Each utility's overall policies for the conservation and efficient utilization of natural resources;

Each utility's program of research and development as it relates to the conservation and efficient utilization of natural resources, and;

Each utility's general implementation plan relative to achieving continually increasing efficiencies in the generation, transmission, distribution and utilization of electric energy, including improvements in system load factors, particularly through the flattening of peak loads, increased consumer knowledge of conservation potentials in the use of electric energy or in the substitution of alternate energy forms for electricity, present or proposed rate incentives for more efficient energy utilization, and actions to effect more efficient energy utilization through design changes in equipment, buildings, industrial and commercial operations and processes.

The comments received in this rulemaking confirm basic assumptions reflected in the proposed notice: namely, that conservation of energy is currently an evolving concept, is without a uniformly accepted definition, is influenced significantly by the particular facts and circumstances of each utility's geographic location, facilities, fuel resources and ultimate consumers served, and is interrelated with various governmental policies (Federal, state and local), pertaining to inter alia public utility responsibilities, economic regulation, energy and resource development, environmental and tax matters.

For these reasons, general Commission policy recommendations such as the Commission is proposing, are most appropriate at this point in time, The present task is to spur increased utility activity and initiatives in the area of pru-

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[1] Under the Commission's administration of the Natural Gas Act (15 U.S.C. 717(a) et seq.), the Commission has instituted a number of general rulemaking actions directed to the utilization and conservation of natural resources—natural gas. See particularly various Commission orders, policy statements, notices of proposed rulemaking, Federal Power Commission Docket Nos. R-467, 468, 469, 474, and RM74-3.

[2] A total of 87 comments were received: 51 from electric utilities, 17 from Federal, state or municipal agencies of government other than those directly responsible for electric production or distribution, 10 from conservation organizations, and 9 from other types of respondents.

[3] 1970 National Power Survey, p. I-3-4.

[4] Actual and projected use of BTU's based upon United States Consumption of Energy by Major Sources, 1971 and Base Case Projections to 1975, 1980, 1985, 1990, 2000, published survey compiled by the Federal Power Commission Office of Economics (December 1972).

[5] The Commission's Notice of Proposed Policy Statement states in part as follows (37 FR 20045):

* * * the Commission seeks to develop, through general comment and public participation, a public appreciation of the inherent problems which the Nation's electric utility industry faces in meeting projected electric energy requirements; the spectrum of areas within which operating utilities and manufacturers of electric generation and transmission equipment may pursue and develop improved technologies leading to increased physical efficiencies in the rendition of electric utility service; the range of possible courses of action which may be followed by manufacturers of electric energy consuming equipment, architects, engineers, building material suppliers, contractors, and ultimate consumers of electric energy so as to maximize realizable efficiencies in the utilization of electric energy; the role of rate design in the conservation and efficient utilization of energy resources; and the areas of public or governmental policy which may influence or control the foregoing. Overall, the Commission's basic purpose is to identify and articulate principles of prudent conduct which may be generally accepted on a voluntary basis in the further development of the Nation's primary energy resources, the conversion of those resources into electric energy and public consumption thereof.

dent, efficient, balanced uses of resources, since they are at the heart of the conservation of resources concept in the supply of electric energy as that concept is used in the Federal Power Act; to encourage the undertaking of energy demonstration and pilot projects in relation to new equipment, buildings, industrial and commercial operations and processes which are aimed at the realization of conservation of resources; and to effectively communicate to the general public the substance of utility initiated programs. Standardized governmentally prescribed report forms for the collection of conservation of natural resources data are not consonant with the current evolutionary nature of the conservation ethic; and if now prescribed they could be highly constricting and counter-productive to the development of innovative approaches to energy conservation, utility by utility, which is what is needed presently.

The Commission recognizes the considerable merit of many of the comments that the Nation does not yet have an overall stated national energy policy and that electric energy conservation can not be optimally effected except as an integral part of energy conservation in all forms, there being too many possible interactions between energy forms and uses.[6] Both complexities are best attacked through a general Commission policy statement and the reporting of utility conservation actions voluntarily initiated, system-by-system. Conservation can be achieved through the operation of the economic process, provided that appropriate costs associated with the production of energy are internalized and reflected in the price of the product. Conservation of resources need not be an outside or externalized economic growth limitation concept applied by regulatory agencies to the operating utility systems. The Commission does not so view it.

Having reached these conclusions, the fundamental question is not whether electric utilities should share in the national responsibilities for the conservation of natural resources, but whether electric utilities are sufficiently able to effect constructive results on the supply side or the demand side of the supply-demand energy equation, as to justify the assignment of major conservation responsibilities to them. In our judgment, the answer is yes. In producing, transmitting, and distributing electric energy, utility systems have the potential for the dedication of substantial human expertise and physical resources for the development of new or improved methods of electric energy supply.[7] In the consumption of electric energy, utilities possess the knowledge by which to influence uses and demands for their product. Electric utility personnel are far more knowledgeable than most of their consumers in various alternative forms of electric energy consumption. They can effectively guide consumer choices in the direction of conservation, just as many present utility marketing programs induced substantially increased electric energy consumption. External to electric utility organizations themselves, there is opportunity for substantial progress in effecting conservation measures through coordinated actions with inter alia builders, designers, equipment manufacturers, industrial engineers, architects, contractors, trade unions, professional societies, governmental authorities, and academia. With the participation and dedication of utility managements, electric utility systems can play a highly significant role in the conservation of natural resources.

The Commission has directed its staff to pay particular attention to utility conservation programs in all proceedings arising under the Federal Power Act and to challenge those programs which do not appear directed toward optimum resource allocation, considering all costs and weighing the future benefits of deferred use against the benefits of present use of resources. To facilitate this activity, and as a part of the Commission's general accounting and reporting responsibilities under the Federal Power Act (16 U.S.C. 825, 825c, 825j) (49 Stat. 854, 855, 859), the Commission intends, in the near future, to undertake further general rulemakings for the purpose of developing accounting and reporting rules and regulations which will provide increased detail on all economic, environmental and other costs associated with the production and consumption of electric energy, as well as provide detailed breakdowns of the ultimate uses of electric energy within the general service categories of industrial, commercial, residential, farm, electrified transport, etc. The detail will cover uses such as electric drive for mechanical equipment, electric process heat, electrically driven building service equipment, space heating, air conditioning, work area illumination, display illumination, street lighting, water heating, cooking, refrigeration, clothes drying, irrigation, and others. It is possible that some demand metering may be required to gather these data both for on-peak and off-peak periods. Aggregated and reported by the various utilities, these data can provide meaningful insights into the conservation of resources problems. In doing so, the Commission intends to work coordinately with the various state regulatory agencies and other agencies of Federal or state government whose responsibilities include some aspect of the conservation of resources. Generally speaking, state public service commissions are administrative agencies charged with the regulatory jurisdiction over retail rates and services of electric utilities.

This Commission has established within the framework of its staffing complement a new energy conservation project under its Chief Engineer. That project will play a major role in the implementation of Commission policies relative to conservation of natural resources. Interested persons having ideas and concepts relative to energy conservation are invited to communicate them to the Chief Engineer, Dr. Charles A. Berg, Federal Power Commission, 825 North Capitol Street NE., Washington, D.C. 20426.

The Commission has considered the several requests of the comments for public hearings, staff conferences and the circulation of a Commission staff draft environmental impact statement in this proceeding. In our judgment, none of these further actions is appropriate.

The Commission is here elucidating general policy to stimulate utility actions on a voluntary basis. The definitive actions to be taken are those which the utilities will themselves initiate and execute through the economic process. As set forth above and in the notice of proposed policy statement, the voluntary utility efforts which the Commission seeks to stimulate, are those designed to improve efficiency in the generation, transmission, distribution and consumption of electric energy, all as a general principle of the evolving concept of energy conservation. The Commission is utilizing the mechanism of a policy statement and a voluntary reporting system for the equally important purpose of stimulating public awareness of the need for a conservation ethic and practical methods for achieving it. These actions are properly characterized as initial, exploratory and instructional efforts to increase industry and public awareness of the importance of energy conservation efforts in the resolution of national energy problems. More specific, conservation policies are, as indicated herein, under active consideration and we have expressly indicated in ordering paragraph (B), infra, that the Commission policies and voluntary reporting procedures here prescribed, are a continuing effort open to further Commission action as may be appropriate. Conservation of natural resources must be viewed as a continuing sifting and winnowing of prior concepts, accomplishments and actions.

In view of the nature of the action we are taking in this proceeding, it is our judgment that this statement of policy does not come within the category of actions described as "major Federal ac-

[6] The 1970 National Power Survey, speaking to the matter of energy policy in the context of economic growth and the environment, notes as follows (p. 1-1-6): "The need for a national energy policy: It is now evident that the concurrence of increasing needs for energy, as well as the national need to improve our environment, emphasize the requirement for coordinated national policy development in both areas. * * *"

[7] The Commission has recently addressed itself to the matter of facilitating even greater utility resources for improvements in the supply of electric energy. See for example, Federal Power Commission Order No. 408, 44 FPC 639 (1970), Accounting Treatment For Expenditures For Research and Development, and Order No. 483, —— FPC ——, issued April 30, 1973, Research and Development, Accounting and Reporting, 38 FR 12113.

tions significantly affecting the quality of the human environment" [a] as specified in the National Environmental Policy Act (NEPA), the revised Guidelines of the Council on Environmental Quality (CEQ), 40 CFR Part 1500, and our regulations implementing NEPA requirements.[b] The CEQ Guidelines specify in § 1500.6(c), for example, that "[t]he identification of major actions significantly affecting the environment is the responsibility of each Federal agency, to be carried out against the background of its own particular operations." In the process of identifying actions that come within the scope of NEPA environmental impact statement requirements, CEQ advises Federal agencies to note that "[t]he words 'major' and 'significantly' are intended to imply thresholds of importance and impact that must be met before a statement is required. The action causing the impact must also be one where there is sufficient Federal control and responsibility to constitute 'Federal action' in contrast to cases where such Federal control and responsibility are not present * * *." We believe, for the reasons expressed herein, that the threshold of which CEQ speaks has not been met in this proceeding.

The Commission has adopted a number of clarifying and organizational changes in the content of the policy statement, many of which are suggested in the comments received in this proceeding. Presently, no further public consideration of this matter is required before the Commission's final action in stating its policy on measures to implement the conservation of natural resources.

The Commission further finds. (1) The public notice and opportunity to participate in this proceeding with respect to the matters presently before the Commission, in the manner described above, are consistent and in accordance with all procedural requirements therefor as prescribed in section 553 of Subchapter II of Chapter 5, Title 5 of the United States Code. The effective date provisions of section 553 do not apply with respect to the policy statement as adopted hereinafter.

(2) It is appropriate and in the public interest in administering the Federal Power Act, 16 U.S.C. 791(a) et seq., to promulgate Commission policy with respect to the conservation of natural resources in the electric energy conversion and consumption processes, and in respect to the public disclosure and requested reporting of utility plans and programs for furthering the conservation of natural resources upon a voluntary basis, all in the manner hereinafter provided.

(3) The basic authority of the Commission to take this action is as set forth in the Federal Power Act (16 U.S.C. 791(a) et seq.), particularly 16 U.S.C. 824a(a), 825h (49 Stat. 848, 858), and the Administrative Procedure Act (5 U.S.C. 553).

The Commission orders. (A) Part 2, General Policy and Interpretations, Subchapter A—General Rules, Chapter I, Title 18 of the Code of Federal Regulations, is amended by adding a new § 2.14 entitled "Conservation of Natural Resources", which Section reads as follows:

§ 2.14 Conservation of natural resources.

(a) *Utility initiatives.* The Federal Power Commission's responsibilities under section 202(a) of the Federal Power Act, for assuring an abundant supply of electric energy throughout the United States with the greatest possible economy and with regard to the proper utilization and conservation of natural resources, can best be carried out if each electric utility supplier within the United States (investor owned, publicly owned, including federally owned, and cooperatively owned), voluntarily adopts and publicly reports:

(1) Policies for the conservation and efficient utilization of natural resources,

(2) A program of research and development as it relates to the conservation and efficient utilization of natural resources, and

(3) A general implementation plan relative to achieving continually increasing efficiencies in the generation, transmission, distribution and utilization of electric energy, including improvements in system load factors, particularly through the flattening of peak loads, increased consumer knowledge of conservation potentials in the use of electric energy or in the substitution of alternate energy forms for electricity, present or proposed rate incentives for more efficient energy utilization, and actions to effect more efficient energy utilization through design changes in equipment buildings, industrial and commercial operations and processes.

(b) *The nature and application of conservation of natural resources measures.* (1) The inherent nature of the electric energy production and consumption processes is that they use parts of an integrated energy resource base comprising numerous, but finite primary energy and non-fuel resources. Accordingly, conservation of electric energy is the conservation of natural resources. Both are the responsibility of all elements of society, the economy and governmental authority, not merely those individuals and organizations who are immediately and directly involved with electric energy production or consumption.

(2) The concept of conservation of natural resources is not one of economic growth limitation or diminished use of energy for beneficial purposes. Measures for conservation of natural resources contemplate coordinated activities among all elements of government, industry, commerce and the consuming public and thus operate to serve and advance the Nation's objectives, purposes and policies.

(3) The application of electric energy conservation policies necessitates consideration of the optimum balance in the use of primary energy and non-fuel resource applications, the timing of present or deferred use of such resources and all relevant national objectives, purposes and policies whether governmental, economic, environmental or social. In any given circumstance, the application of the conservation of natural resources concept may have the effect of reducing or of increasing the application and consumption of primary energy or other non-fuel resources or of reducing some and of increasing others. That is the essence of the balancing procedure.

(c) *Informational reporting.* To facilitate the widest possible dissemination of information relative to the conservation of natural resources in the production and use of electricity, the Commission establishes a system for the voluntary reporting by all electric utilities throughout the United States of data on conservation of natural resources. The Commission asks the cooperation of all electric utility systems, investor owned, publicly owned, including federally owned, and cooperatively owned, in submitting data as set forth in the attached Appendix I to this statement. Where utility systems are engaged in cooperative programs with other utilities for the conservation of natural resources, and all such utilities are actively pursuing such conservation measures, reports may be submitted on a group basis in lieu of individual utility reporting. It further asks that the requested reports be filed with the Secretary of the Federal Power Commission in duplicate on or before December 31, 1973, for the calendar year 1972, and on or before May 31 of each year thereafter for the preceding calendar year. Reports subsequent to the initial reporting year 1972, may be in the form of supplemental reports or addendums to the prior years, showing changes and new developments only. All responses requested and received in respect to this statement of policy will be maintained by the Secretary in a public file of the Commission for general informational purposes. Annually, the Commission's staff will prepare a summary of such filed data to be assembled and published as soon thereafter as practicable. Upon request, copies of any submittals of data, as set forth in Appendix I, will be made available by the Commission's Office of Public Information upon payment of the Commission's document reproduction charge. Established Commission procedures as set forth in § 1.36 of this chapter will apply.

(B) The Commission, in its continuing review of this general subject matter, will take such future actions as may be appropriate.

(C) The amendment herein prescribed shall be effective upon the issuance of this order.

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[a] Sec. 102(2)(C) of the National Environmental Policy Act of 1969, (42 U.S.C. 4332) (83 Stat. 852, 853).

[b] Federal Power Commission Order No. 415-C, —— FPC ——, issued December 18, 1972, Implementation of the National Environmental Policy Act of 1969 (37 FR 28412); Federal Power Commission Order No. 485, —— FPC ——, issued June 7, 1973, Implementation of the National Environmental Policy Act of 1969 (38 FR 15944).

(D) The Secretary shall cause prompt publication of this order to be made in the FEDERAL REGISTER.

By the Commission.

[SEAL] KENNETH F. PLUMB, *Secretary.*

APPENDIX I—INFORMATION TO BE SUPPLIED BY ALL ELECTRIC UTILITIES, INVESTOR OWNED, PUBLICLY OWNED, INCLUDING FEDERALLY OWNED, AND COOPERATIVELY OWNED, ON MEASURES TO IMPLEMENT CONSERVATION OF NATURAL RESOURCES

Information To Be Reported Annually Should Include The Following:

1. A narrative description of the electric utility's program for the conservation and efficient utilization of natural resources as it relates to electric power production and consumption. The information to be reported should include a fully descriptive statement detailing the utility's conservation policies, its program of research and development as the latter relates to conservation of natural resources, and the utility's general implementation plan to achieve increasing efficiencies in the generation, transmission, distribution and consumption of electric energy.

2. An identification of anticipated electric supply savings arising from the conservation and efficient utilization of natural resources by the utility, including physical changes in utility system facilities, generation, heat rates, transmission and distribution losses, monthly and annual peak loads, and monthly and annual system load factors. The information to be reported should quantify these anticipated savings by sources and in terms of BTU equivalents of an identified fuel source, wherever possible.

3. An identification, wherever possible, of anticipated consumption savings arising from the conservation and efficient utilization of natural resources, including changes in ultimate consumer energy use patterns, the substitution of different electric energy consuming devices, design changes in equipment, buildings, industrial and commercial operations and processes and the substitution of other energy forms for electric energy. The information to be reported should quantify these anticipated savings by sources and in terms of Btu equivalents of an identified fuel source, wherever possible.

4. An identification of significant actions or programs initiated by the utility during the year to educate its utility consumers in improved efficiencies which are realizable in respect to the utilization of electric energy. The information to be reported should include copies of the utility's publications or communications with its consumers, governmental authorities or others, explaining these programs.

[FR Doc.73-24656 Filed 11-19-73;8:45 am]

Title 21—Food and Drugs

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

PART 2—ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES

Redelegation of Authority Regarding Review Boards

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 second and third documents 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 Part 273—Biological Products have been reorganized into nine parts as a revised Subchapter F—Biologics and the three remaining parts of former Subchapter F, i.e., Part 281—Enforcement of the Tea Importation Act, Part 285—Regulations under the Federal Caustic Poison Act, and Part 290—Regulations for the enforcement of the Federal Import Milk Act, have been reorganized into a new Subchapter L in an effort to provide greater clarity and adequate space for the development of future regulations.

Regulations that were formerly listed under 21 CFR Part 273 are referenced in § 2.121(b)(2). To provide uniformity and continuity during the recodification the Commissioner concludes that the reference under § 2.121(b)(2) should be made at this time. Therefore, § 2.121(b)(2) is revised to read as follows:

§ 2.121 Redelegation of authority from the Commissioner to other officers of the Administration.

* * * * *

(b) * * *

(2) The Director of the Bureau of Biologics and the Associate Director for Regulatory and Administrative Management of that Bureau are authorized to appoint review boards as provided by § 601.41 of this chapter (21 CFR 601.41).

* * * * *

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

Dated November 5, 1973.

SAM D. FINE, *Associate Commissioner for Compliance.*

[FR Doc.73-24505 Filed 11-19-73;8:45 am]

SUBCHAPTER C—DRUGS

PART 135b—NEW ANIMAL DRUGS FOR IMPLANTATION OR INJECTION

Procaine Penicillin G

The Commissioner of Food and Drugs has evaluated a supplemental new animal drug application (65-174V) filed by E. R. Squibb & Sons, Georges Road, New Brunswick, NJ 08902, proposing revised labeling for the safe and effective use of procaine penicillin G aqueous suspension, veterinary, for treating dogs and cats. The supplemental application is approved.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347; 21 U.S.C. 360b(i)) and under authority delegated to the Commissioner (21 CFR 2.120), Part 135b is amended in § 135b.49 as follows:

By redesignating existing paragraphs (a), (b), and (c)(1), (c)(2) and (c)(3) as paragraphs (a)(1), (a)(2) and (a)(3) (i), (ii) and (iii), respectively and by adding a new paragraph (b). Section 135b.49 is revised to read as follows:

§ 135b.49 Procaine penicillin G aqueous suspension, veterinary.

(a)(1) *Specifications.* Procaine penicillin G aqueous suspension, veterinary, conforms to the standards of identity, strength, quality, and purity prescribed by § 146a.47 of this chapter. Each milliliter contains 300,000 units of penicillin activity.

(2) *Sponsor.* See Code No. 014 in § 135.501(c) of this chapter.

(3) *Conditions of use.* (i) It is used as an intramusclar injection both in the treatment of tonsillitis in dogs and in the treatment of strangles in horses when such conditions are caused by pathogens susceptible to pencillin G.

(ii) It is administered to dogs at 10,000 to 15,000 units per pound of body weight per day and to horses at 3,000 to 5,000 units per pound of body weight per day.

(iii) The label and labeling shall bear, in addition to the other information required by the act, a statement that the drug is not for use in food-producing animals and a statement that Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications.* Procaine penicillin G aqueous suspension, veterinary, conforms to the standards of identity, strength, quality, and purity prescribed by § 146a.47 of this chapter. Each milliliter contains 300,000 units of penicillin activity.

(2) *Sponsor.* See code No. 035 in § 135.501(c) of this chapter.

(3) *Conditions of use.* (i) It is used as an intramuscular injection in dogs and cats in the treatment of infections caused by penicillin sensitive organisms.

(ii) It is administered to dogs and cats at a dosage level of 10,000 units per pound of body weight daily at 24-hour intervals. Daily treatment should be continued for at least 48 hours after temperature has returned to normal and all other signs of infection have subsided.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Effective date. This order shall be effective November 20, 1973.

(Sec. 512(i), 82 Stat. 347; 21 U.S.C. 360b(i).)

Dated: November 14, 1973.

C. D. VAN HOUWELING, *Director, Bureau of Veterinary Medicine.*

[FR Doc.73-24663 Filed 11-19-73;8:45 am]

PART 149b—AMPICILLIN

Ampicillin Trihydrate Boluses, Veterinary; Correction

In FR Doc. 73-19875 appearing at page 26183 in the FEDERAL REGISTER of September 19, 1973, the following correction

is made in § 149b.23(a): In the fourth sentence, the words "moisture content" are changed to read "loss on drying."

Dated: November 14, 1973.

C. D. VAN HOUWELING,
Director,
Bureau of Veterinary Medicine.

[FR Doc.73-24664 Filed 11-19-73;8:45 am]

Title 24—Housing and Urban Development

CHAPTER I—OFFICE OF ASSISTANT SECRETARY FOR EQUAL OPPORTUNITY, DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

SUBCHAPTER B—EMPLOYMENT AND BUSINESS OPPORTUNITY

[Docket No. R 73-100]

PART 135—EMPLOYMENT OPPORTUNITIES FOR BUSINESSES AND LOWER INCOME PERSONS IN CONNECTION WITH ASSISTED PROJECTS

Correction

In FR Doc. 73-22417 appearing at page 29220 in the issue for Tuesday, October 23, 1973, in the third column on page 29223 the section heading reading "§ 135.60 *Good faith effort.*" should read "§ 135.55 *General.*"; and the section heading reading "§ 135.55 *General.*" should read "§ 135.60 *Good faith effort.*"

CHAPTER III—GOVERNMENT NATIONAL MORTGAGE ASSOCIATION, DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

SUBCHAPTER A—INTRODUCTION

[Docket No. R-73-210]

PART 300—GENERAL

List of Attorneys-in-Fact; Additional Names

Paragraph (c) of § 300.11 is amended to add additional names to the list of attorneys-in-fact authorized to act on behalf of the Association and to delete several names from the current list.

Notice and public procedure on this amendment are unnecessary and impracticable because of the large volume of legal documents that must be executed on behalf of the Association in connection with its recent auctions of mortgages.

1. Paragraph (c) of § 300.11 is amended by deleting the following names from the current list of attorneys-in-fact:

Name	*Region*
Angelina C. Alleva	Philadelphia, Pa.
Lawrence S. Banks	Dallas, Tex.
W. D. Cornwell	Atlanta, Ga.
Boyd A. Jakman	Los Angeles, Calif.
C. James Larkin	Do.
Frank E. Moll	Do.
Albert D. Oltman	Do.
Harry Rode	Dallas, Tex.

2. Paragraph (c) of § 300.11 is further amended by adding the following names in alphabetical sequence to the current list of attorneys-in-fact:

Name	*Region*
Angelina P. Alleva	Philadelphia, Pa.
J. M. Benavides	Dallas, Tex.
Earlene P. Carr	Atlanta, Ga.
Heinrich F. Charles	Los Angeles, Calif.
Donna G. Fleming	Philadelphia, Pa.
William J. Gerard	Los Angeles, Calif.
Boyd A. Jackman	Do.
R. E. Long	Dallas, Tex.
Grace G. McKay	Atlanta, Ga.
Francis J. Moncey	Chicago, Ill.

Effective date. This amendment shall be effective on November 20, 1973.

WOODWARD KINGMAN,
President, Government National Mortgage Association.

[FR Doc.73-24675 Filed 11-19-73;8:45 am]

CHAPTER X—FEDERAL INSURANCE ADMINISTRATION, DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

SUBCHAPTER B—NATIONAL FLOOD INSURANCE PROGRAM

[Docket No. FI-251]

PART 1914—AREAS ELIGIBLE FOR THE SALE OF INSURANCE

Status of Participating Communities

Section 1914.4 of Part 1914 of Subchapter B of Chapter X of Title 24 of the Code of Federal Regulations is amended by adding in alphabetical sequence a new entry to the table. In this entry, a complete chronology of effective dates appears for each listed community. Each date appearing in the last column of the table is followed by a designation which indicates whether the date signifies the effective date of the authorization of the sale of flood insurance in the area under the emergency or the regular flood insurance program. The entry reads as follows:

§ 1914.4 **Status of participating communities.**

* * * * * * *

State	County	Location	Map No.	State map repository	Local map repository	Effective date of authorization of sale of flood insurance for area
*	*	*	*	*	*	*
Connecticut	Middlesex	Cromwell, Town of				Nov. 15, 1973, Emergency.
Florida	Putnam	Unincorporated Areas.				Do.
Georgia	Baldwin	Milledgeville, City of.				Do.
Missouri	St. Louis	Berkeley, City of				Do.
Oklahoma	Comanche	Lawton, City of				Do.

*

(National Flood Insurance Act of 1968 (title XIII of the Housing and Urban Development Act of 1968), effective Jan. 28, 1969 (33 FR 17804, Nov. 28, 1968), as amended (secs. 408-410, Pub. L. 91-152, Dec. 24, 1969), 42 U.S.C. 4001-4127; and Secretary's delegation of authority to Federal Insurance Administrator, 34 FR 2680, Feb. 27, 1969)

Issued: November 8, 1973.

GEORGE K. BERNSTEIN,
Federal Insurance Administrator.

[FR Doc.73-24586 Filed 11-19-73;8:45 am]

[Docket No. FI-252]

PART 1914—AREAS ELIGIBLE FOR THE SALE OF INSURANCE

Status of Participating Communities

Section 1914.4 of Part 1914 of Subchapter B of Chapter X of Title 24 of the Code of Federal Regulations is amended by adding in alphabetical sequence a new entry to the table. In this entry, a complete chronology of effective dates appears for each listed community. Each date appearing in the last column of the table is followed by a designation which indicates whether the date signifies the effective date of the authorization of the sale of flood insurance in the area under the emergency or the regular flood insurance program. The entry reads as follows:

§ 1914.4 Status of participating communities.

State	County	Location	Map No.	State map repository	Local map repository	Effective date of authorization of sale of flood insurance for area
California	Los Angeles	San Gabriel, City of.	I 06 037 3300 02 through I 06 037 3300 03	Department of Water Resources, P.O. Box 388, Sacramento, Calif. 95802. California Insurance Department, 107 South Broadway, Los Angeles, Calif. 90012, and 1407 Market St., San Francisco, Calif. 94103.	Public Works Department, City of San Gabriel, 532 West Mission Dr., San Gabriel, Calif. 91776.	Nov. 27, 1970. Emergency. Nov. 23, 1973. Regular.
Do	do	Bradbury, City of.	I 06 037 0433 02	do	Bradbury City Hall, 600 Winston Ave., Bradbury, Calif. 91010.	Dec. 11, 1970. Emergency. Nov. 23, 1973. Regular.
Florida	Volusia	Unincorporated Areas.	I 12 127 0000 01 through I 12 127 0000 34	Department of Community Affairs, 2571 Executive Center Circle East, Howard Bldg., Tallahassee, Fla. 32301. State of Florida Insurance Department, Treasurer's Office, The Capitol, Tallahassee, Fla. 32304.	County Manager, The County of Volusia, P.O. Box 429, DeLand, Fla. 32720.	May 14, 1971. Emergency. Nov. 23, 1973. Regular.
Michigan	Ottawa	Port Sheldon, Township of.				Nov. 16, 1973. Emergency.
Missouri	St. Louis	Maplewood, City of.	I 29 189 4900 01	Water Resources Board, P.O. Box 271, Jefferson City, Mo. 65101. Division of Insurance, P.O. Box 690, Jefferson City, Mo. 65101.	Mayor, City of Maplewood, 7601 Manchester, Maplewood, Mo. 63143.	May 21, 1971. Emergency. Nov. 23, 1973. Regular.
New Jersey	Burlington	Lumberton, Township of.				Nov. 16, 1973. Emergency.
Do	Union	New Providence, Borough of.	I 34 039 2180 01 through I 34 039 2180 02	Bureau of Water Control, Department of Environmental Protection, P.O. Box 1390, Trenton, N.J. 08625. New Jersey Department of Insurance, State House Annex, Trenton, N.J. 08625.	Borough Clerk, Borough Hall, 1243 Springfield Ave., New Providence, N.J. 07974.	July 16, 1971. Emergency. Nov. 23, 1973. Regular.
Ohio	Hamilton	Amberley, Village of.				Nov. 16, 1973. Emergency.
Pennsylvania	Allegheny	Wilmerding, Borough of.				Do.
Do	Lancaster	Washington, Borough of.				Do.

(National Flood Insurance Act of 1968 (title XIII of the Housing and Urban Development Act of 1968), effective Jan. 28, 1969 (33 FR 17804, Nov. 28, 1968), as amended (secs. 408-410, Pub. L. 91-152, Dec. 24, 1969), 42 U.S.C. 4001-4127; and Secretary's delegation of authority to Federal Insurance Administrator, 34 FR 2680, Feb. 27, 1969)

Issued: November 12, 1973.

GEORGE K. BERNSTEIN,
Federal Insurance Administrator.

[FR Doc.73-24585 Filed 11-19-73;8:45 am]

[Docket No. FI-253]

PART 1914—AREAS ELIGIBLE FOR THE SALE OF INSURANCE

Status of Participating Communities

Section 1914.4 of Part 1914 of Subchapter B of Chapter X of Title 24 of the Code of Federal Regulations is amended by adding in alphabetical sequence a new entry to the table. In this entry, a complete chronology of effective dates appears for each listed community. Each date appearing in the last column of the table is followed by a designation which indicates whether the date signifies the effective date of the authorization of the sale of flood insurance in the area under the emergency or the regular flood insurance program. The entry reads as follows:

§ 1914.4 Status of participating communities.

* * * * * * *

State	County	Location	Map No.	State map repository	Local map repository	Effective date of authorization of sale of flood insurance for area
*	*	*	*	*	*	*
New Hampshire	Strafford	Dover, City of				Nov. 19, 1973, Emergency.
Pennsylvania	Allegheny	Baldwin, Borough of.				Do.
Do	Mercer	Sharon, City of				Do.
Do	Northumberland	Delaware, Township of.				Do.
Do	do	Point, Township of.				Do.
Do	do	Ralpho, Township of.				Do.
Do	do	Riverside, Borough of.				Do.
Do	do	Watsontown, Borough of.				Do.

(National Flood Insurance Act of 1968 (title XIII of the Housing and Urban Development Act of 1968), effective Jan. 28, 1969 (33 FR 17804, Nov. 28, 1968), as amended (secs. 408–410, Pub. L. 91–152, Dec. 24, 1969), 42 U.S.C. 4001–4127; and Secretary's delegation of authority to Federal Insurance Administrator, 34 FR 2680, Feb. 27, 1969)

Issued: November 12, 1973.

GEORGE K. BERNSTEIN,
Federal Insurance Administrator.

[FR Doc.73-24584 Filed 11-19-73;8:45 am]

[Docket No. FI-254]

PART 1915—IDENTIFICATION OF SPECIAL HAZARD AREAS

List of Communities With Special Hazard Areas

The Federal Insurance Administrator finds that comment and public procedure and the use of delayed effective dates in identifying the areas of communities which have special flood or mudslide hazards, in accordance with 24 CFR Part 1915, would be contrary to the public interest. The purpose of such identifications is to guide new development away from areas threatened by flooding, a purpose which is accomplished pursuant to statute by denying subsidized flood insurance to structures thereafter built within such areas. The practice of issuing proposed identifications for comment or of delaying effective dates would tend to frustrate this purpose by permitting imprudent or unscrupulous builders to start construction within such hazardous areas before the official identification became final, thus increasing the communities' aggregate exposure to loss of life and property and the agency's financial exposure to flood losses, both of which are contrary to the statutory purposes of the program. Accordingly, the Department is not providing for public comment in issuing this amendment and it will become effective on November 20, 1973. Section 1915.3 is amended by adding in alphabetical sequence a new entry to the table, which entry reads as follows:

§ 1915.3 **List of communities with special hazard areas.**

* * * * * * *

State	County	Location	Map No.	State map repository	Local map repository	Effective date of identification of areas which have special flood hazards
*	*	*	*	*	*	*
Alabama	Escambia	East Brewton, Town of.	H 01 053 0960 01 H 01 053 0960 02	Alabama Development Office, Office of State Planning, State Office Bldg., 501 Dexter Ave., Montgomery, Ala. 36104. Alabama Insurance Department, Room 453, Administrative Bldg., Montgomery, Ala. 36104.	Town Manager, Town of East Brewton, Town Hall, East Brewton, Ala. 36426.	Nov. 23, 1973.
Do	do	Flomaton, Town of.	H 01 053 1180 01 H 01 053 1180 02	do	Town Manager, Town of Flomaton, Town Hall, Flomaton, Ala. 36441.	Do.
Arkansas	Independence	Batesville, City of.	H 05 063 0250 01 through H 05 063 0250 03	Division of Soil and Water Resources, State Department of Commerce, 1920 West Capitol Ave., Little Rock, Ark. 72201. Arkansas Insurance Department, 400 University Tower Bldg., Little Rock, Ark. 72204.	Mayor, City of Batesville, City Hall, Batesville, Ark. 72501.	Do.
California	Los Angeles	Bradbury, City of.	H 06 037 0433 02	Department of Water Resources, P.O. Box 338, Sacramento, Calif. 95802. California Insurance Department, 107 South Broadway, Los Angeles, Calif. 90012, and 1407 Market St., San Francisco, Calif. 94103.	Bradbury City Hall, 600 Winston Ave., Bradbury, Calif. 91010.	Do.
Do	do	San Gabriel, City of.	H 06 037 3300 02 H 06 037 3300 03	do	Public Works Department, City of San Gabriel, 532 West Mission Dr., San Gabriel, Calif. 91776.	Do.
Colorado	Morgan	Brush, City of	H 08 087 0260 01 through H 08 087 0260 03	Colorado Water Conservation Board, Room 102, 1845 Sherman St., Denver, Colo. 80203. Colorado Division of Insurance, 106 State Office Bldg., Denver, Colo. 80203.	Mayor, City of Brush, City Hall, Brush, Colo. 80723.	Do.
Connecticut	Middlesex	Westbrook, Town of.	H 09 007 0822 01 through H 09 007 0822 04	Department of Environmental Protection, Division of Water and Related Resources, Room 207 State Office Bldg., Hartford, Conn. 06115. Connecticut Insurance Deprtment, State Capitol Bldg., 465 Capitol Hartford, Conn. 06115.	Town Clerk, Town Hall, Boston Post Rd., Westbrook, Conn. 06498.	Do.
Florida	Palm Beach	Lake Park, Town of.	H 12 099 1720 01	Department of Community Affairs, 2571 Executive Center Circle East, Howard Bldg., Tallahassee, Fla. 32301. State of Florida Insurance Department, Treasurer's Office, The Capitol, Tallahassee, Fla. 32304.	Town Hall, 535 Park Ave., P.O. Box, 12276, Lake Park, Fla. 33403.	Do.
Do	Sumter	Webster, Town of.	H 12 119 3130 01	do	Mayor, Town of Webster, City Hall, Webster, Fla. 33597.	Do.
Do	Suwanee	Live Oak, City of.	H 12 121 1830 01 H 12 121 1830 02	do	Mayor, City of Live Oak, City Hall, Live Oak, Fla. 32060.	Do.
Do	Volusia	Unincorporated Areas.	H 12 127 0000 01 through H 12 127 0000 34	do	County Manager, The County of Volusia, P.O. Box 429, Deland, Fla. 32720.	Do.
Idaho	Blaine	Bellevue, City of.	H 16 013 0120 01	Department of Water Administration, Statehouse, Annex 2, Boise, Idaho 83707. Idaho Department of Insurance, Room 206, Statehouse, Boise, Idaho 83707.	Mayor, City of Bellevue, City Hall, Bellevue, Idaho 83313. 83707.	Do.
Do	Clearwater	Orofino, City of	H 16 035 1300 01 H 16 035 1300 02	do	Mayor, City of Orofino, City Hall, Orofino, Idaho 83544.	Do.
Do	Lewis	Kamiah, City of.	H 16 061 0850 01	do	Mayor, City of Kamiah, City Hall, Kamiah, Idaho 83536.	Do.
Do	do	Nezperce, City of.	H 16 061 1240 01	do	Mayor, City of Nezperce, City Hall, Nezperce, Idaho 83543.	Do.
Illinois	Cass	Chandlerville, Village of.	H 17 017 1560 01	Governor's Task Force on Flood Control, Natural Resources Service Center, Thornhill Bldg., P.O. Box 475, Lisle, Ill. 60532. Illinois Insurance Department, 525 West Jefferson St., Springfield, Ill. 62702.	Mayor, Village of Chandlerville, Community Bldg., Chandlerville, Ill. 62627.	Do.
Do	Champaign	Mahomet, Village of.	H 17 019 5130 01	do	Mayor, Village of Mahomet, City Hall, Mahomet, Ill. 61853.	Do.
Do	do	St. Joseph, Village of.	H 17 019 7690 01	do	Mayor, Village of St. Joseph, City Hall, St. Joseph, Ill. 61873.	Do.

State	County	Location	Map No.	State map repository	Local map repository	Effective date of identification of areas which have special flood hazards
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Do.	Clark	Martinsville, Village of.	H 17 023 5320 01	do	Village Manager, Village of Martinsville, Village Hall, Martinsville, Ill. 62442.	Do.
Do.	Crawford	Palestine, Town of.	H 17 033 6660 01	do	Mayor, Town of Palestine, City Hall, Palestine, Ill. 62451.	Do.
Do.	Du Page	Wood Dale, City of.	H 17 043 9510 01 through H 17 043 9510 04	do	Wood Dale Municipal Bldg., 404 North Wood Dale Rd., Wood Dale, Ill. 60191.	Do.
Do.	Jersey	Elsah, Village of.	H 17 083 2790 01	do	Elsah Zoning Board, Village of Elsah, Elsah, Ill. 62028.	Do.
Do.	Kendall	Newark, Village of.	H 17 093 6040 01	do	Mayor, Village of Newark, Village Hall, Newark, Ill. 60541.	Do.
Do.	do	Oswego, Village of.	H 17 093 6620 01	do	Mayor, Village of Oswego, Village Hall, Main St., Oswego, Ill. 60543.	Do.
Do.	Lee	Amboy, City of.	H 17 103 0190 01	do	Mayor, City of Amboy, City Hall, Amboy, Ill. 61310.	Do.
Do.	Madison	Madison, Village of.	H 17 119 5120 01 H 17 119 5120 02	do	Village Manager, Village of Madison, Village Hall, Madison, Ill. 62060.	Do.
Do.	Marshall	Sparland, Village of.	H 17 123 8300 01	do	Mayor, Village of Sparland, Sparland, Ill. 61565.	Do.
Do.	Massac	Joppa, Village of.	H 17 127 4320 01	do	Village Manager, Village of Joppa, Village Hall, Joppa, Ill. 62953.	Do.
Do.	Menard	Greenview, Village of.	H 17 129 3630 01	do	Chairman, County Board of Commissioners, Village of Greenview, City Hall, Petersburg, Ill. 62675.	Do.
Do.	Ogle	Leaf River, Village of.	H 17 141 4720 01	do	President, Village of Leaf River, City Hall, Leaf River, Ill. 61047.	Do.
Do.	do	Oregon, City of.	H 17 141 6580 01	do	Mayor, City of Oregon, City Hall, Oregon, Ill. 61061.	Do.
Do.	Piatt	Atwood, Village of.	H 17 147 0430 01	do	President, Village Board, Village of Atwood, Atwood, Ill. 61913.	Do.
Do.	Pulaski	Mound City, City of.	H 17 153 5800 01	do	Mayor, City of Mound City, City Hall, Mound City, Ill. 62963.	Do.
Do.	Randolph	Prairie Du Rocher, Village of.	H 17 157 7130 01	do	Mayor, Village of Prairie Du Rocher, City Hall, Prairie Du Rocher, Ill. 62277.	Do.
Indiana	Adams	Decatur, City of.	H 18 001 1180 01	Division of Water, Department of Natural Resources, 608 State Office Bldg., Indianapolis, Ind. 46204. Indiana Insurance Department, 509 State Office Bldg., Indianapolis, Ind. 46204.	Director, County Planning Commission, Adams County Courthouse, Decatur, Ind. 46733.	Do.
Do.	do	Geneva, Town of.	H 18 001 1770 01	do	do	Do.
Do.	Blackford	Hartford City, City of.	H 18 009 2040 01 through H 18 009 2040 03	do	Administrator, Blackford County Area Plan Commission, City of Hartford City, Hartford City, Ind. 47348.	Do.
Do.	Carroll	Burlington, Town of.	H 18 015 0604 01	do	Town Manager, Town of Burlington, Town Hall, Burlington, Ind. 46915.	Do.
Do.	do	Camden, Town of.	H 18 015 0650 01	do	Town Manager, Town of Camden, Town Hall, Camden, Ind. 46917.	Do.
Do.	do	Delphi, City of.	H 18 015 1200 01	do	Mayor, City of Delphi, City Bldg., Delphi, Ind. 46923.	Do.
Do.	Clark	Sellersburg, Town of.	H 18 019 4420 01	do	Town Board, Town of Sellersburg, 316 East Utica St., Sellersburg, Ind. 47172.	Do.
Do.	Delaware	Albany, City of.	H 18 035 0050 01	do	Mayor, City of Albany, City Hall, Albany, Ind. 47320.	Do.
Do.	do	Eaton, Town of.	H 18 035 1340 01	do	Town Board Chairman, Town of Eaton, 110 North Hartford, Eaton, Ind. 47338.	Do.
Do.	Elkhart	Bristol, Town of.	H 18 039 0480 01 H 18 039 0480 02	do	Town Board Chairman, Town of Bristol, Bristol, Ind. 46507.	Do.
Do.	Fayette	Connersville, City of.	H 18 041 1000 01 through H 18 041 1000 05	do	County Planning and Zoning Commission, City of Connersville, 401 Central Ave., Connersville, Ind. 47331.	Do.
Do.	Gibson	Hazleton, Town of.	H 18 051 2070 01	do	Town Manager, Town of Hazleton, Town Hall, Hazleton, Ind. 47640.	Do.
Do.	do	Patoka, Town of.	H 18 051 3890 01	do	Town Manager, Town of Patoka, Town Hall, Patoka, Ind. 47666.	Do.
Do.	Greene	Bloomfield, Town of.	H 18 055 0360 01	do	Town Manager, Town of Bloomfield, Town Hall, Bloomfield, Ind. 47424.	Do.
Do.	do	Worthington, Town of.	H 18 055 5450 01	do	Town Manager, Town of Worthington, Town Hall, Worthington, Ind. 47471.	Do.
Do.	Hancock	Greenfield, City of.	H 18 059 1890 01 through H 18 059 1890 03	do	City Planning Commission, City of Greenfield, City Bldg., Greenfield, Ind. 46140.	Do.
Do.	Harrison	Corydon, Town of.	H 18 061 1030 01	do	Chairman, Corydon Town Board, Town of Corydon, Corydon, Ind. 47112.	Do.
Do.	Hendricks	Brownsburg, Town of.	H 18 063 0560 01 H 18 063 0560 02	do	Chairman, Town Board, Town of Brownsburg, City Hall, Brownsburg, Ind. 46112.	Do.
Do.	Henry	New Castle, City of.	H 18 065 3450 01 through H 18 065 3450 03	do	Mayor, City of New Castle, 321 South Main St., New Castle, Ind. 47362.	Do.
Do.	Huntington	Warren, Town of.	H 18 069 5090 01	do	Planning Commission Director, Town of Warren, 106 South Wayne, Warren, Ind. 46792.	Do.
Do.	Jackson	Brownstown, Town of.	H 18 071 0570 01	do	Town Manager, Town of Brownstown, Town Hall, Brownstown, Ind. 47220.	Do.
Do.	do	Medora, Town of.	H 18 071 2930 01	do	Chairman, Town Board, Town of Medora, Medora, Ind. 47260.	Do.
Do.	Knox	Edwardsport, Town of.	H 18 083 1485 01	do	Town Manager, Town of Edwardsport, Town Hall, Edwardsport, Ind. 47528.	Do.
Do.	Lake	Crown Point, City of.	H 18 089 1100 01 through H 18 089 1100 03	do	Mayor, City of Crown Point, City Hall, 101 North East St., Crown Point, Ind. 46307.	Do.

State	County	Location	Map No.	State map repository	Local map repository	Effective date of identification of areas which have special flood hazards
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Do.	Madison	Alexandria, Town of.	H 18 095 0070 01 H 18 095 0070 02	do	Mayor, Town of Alexandria, City Hall, Alexandria, Ind. 46001.	Do.
Do.	Marshall	Bremen, Town of.	H 18 099 0470 01	do	Chairman, Town Board, Town of Bremen, 123 South Center St., Bremen, Ind. 46506.	Do.
Do.	Morgan	Martinsville, City of.	H 18 109 2890 01 H 18 109 2890 02	do	Mayor, City of Martinsville, City Hall, Martinsville, Ind. 46151.	Do.
Do.	Orange	Paoli, Town of.	H 18 117 3860 01 through H 18 117 3860 04	do	Town Manager, Town of Paoli, Town Hall, Paoli, Ind. 47454.	Do.
Do.	Owen	Gosport, Town of.	H 18 119 1840 01	do	Town Manager, Town of Gosport, Town Hall, Gosport, Ind. 47433.	Do.
Do.	Pulaski	Winamac, Town of.	H 18 131 5340 01	do	Chairman, Area Plan Commission, Town of Winamac, Courthouse, Winamac, Ind. 46996.	Do.
Do.	Rush	Carthage, Town of.	H 18 139 0720 01	do	Rush County Planning and Zoning Commission, Town of Carthage, County Courthouse, Rushville, Ind. 46173.	Do.
Do.	St. Joseph	Lakeville, Town of.	H 18 141 2530 01	do	Town Board, Town of Lakeville, Lakeville, Ind. 46536.	Do.
Do.	do	Walkerton, Town of.	H 18 141 5060 01	do	Town Board, Town of Walkerton, Walkerton, Ind. 46574.	Do.
Do.	Scott	Austin, City of.	H 18 143 0240 01	do	Mayor, City of Austin, City Hall, Austin, Ind. 47102.	Do.
Do.	do	Scottsburg, City of.	H 18 143 4400 01 H 18 143 4400 02	do	Mayor, City of Scottsburg, City Hall, Scottsburg, Ind. 47170.	Do.
Do.	Vermillion	Clinton, City of.	H 18 165 0940 01	do	Mayor, City of Clinton City Hall, Clinton, Ind. 47842.	Do.
Do.	do	Perrysville, Town of.	H 18 165 3930 01	do	Town Manager, Town of Perrysville, Town Hall, Perrysville, Ind. 47974.	Do.
Do.	Washington	Salem, City of.	H 18 175 4340 01 through H 18 175 4340 04	do	City of Salem, Farmers-Citizens Bank Bldg., P.O. Box 48, Salem, Ind. 47167.	Do.
Do.	Wayne	Cambridge City, Town of.	H 18 177 0640 01	do	Town Board, Town of Cambridge City, City Bldg., 127 North Foote, Cambridge City, Ind. 47327.	Do.
Kansas	Cowley	Arkansas City, City of.	H 20 035 0210 01 through H 20 035 0210 12	Division of Water Resources, State Board of Agriculture, Topeka, Kans. 66612. Kansas Insurance Department, 1st Floor, Statehouse, Topeka, Kans. 66612.	Office of the City Clerk, City Bldg., First and Central, Arkansas City, Kans. 67005.	Do.
Louisiana	Acadia Parish	Estherwood, Town of.	H 22 001 0710 01 H 22 001 0710 02	State Department of Public Works, P.O. Box 44155, Capitol Station, Baton Rouge, La. 70804. Louisiana Insurance Department, Box 44214, Capitol Station, Baton Rouge, La. 70804.	Mayor, Town of Esterwood, City Hall, Esterwood, La. 70534.	Do.
Do.	do	Mermentau, Town of.	H 22 001 1520 01 H 22 001 1520 02	do	Mayor, Town of Mermentau, City Hall, Mermentau, La. 70556.	Do.
Do.	do	Morse, Town of.	H 22 001 1620 01 H 22 001 1620 02	do	Mayor, Town of Morse, City Hall, Morse, La. 70559.	Do.
Do.	St. Landry and St. Martin Parishes.	Arnaudville, Town of.	H 22 097 0030 01	do	Mayor, City of Arnaudville, City Hall, Arnaudville, La. 70512.	Do.
Do.	Vernon Parish	Leesville, Town of.	H 22 115 1300 01 through H 22 115 1300 04	do	Mayor, Town of Leesville, City Hall, Leesville, La. 71446.	Do.
Minnesota	Big Stone	Odessa, Village of.	H 27 011 5340 01	Division of Waters, Soils and Minerals, Department of Natural Resources, Centennial Office Bldg., St. Paul, Minn. 55101. Minnesota Division of Insurance, R-210 State Office Bldg., St. Paul, Minn. 55101.	Mayor, Village of Odessa, Odessa, Minn. 56276.	Do.
Do.	Carver	Mayer, Village of.	H 27 019 4580 01	do	Mayor, Village of Mayer, Village Hall, Mayer, Minn. 55360.	Do.
Do.	Clay	Georgetown, Village of.	H 27 027 2670 01	do	Mayor, Village of Georgetown, Georgetown, Minn. 56546.	Do.
Do.	Dakota	Mendota Heights, Village of.	H 27 037 4673 01 through H 27 037 4673 05	do	Mayor, Village of Mendota Heights, Village Hall, 2040 South Lexington Ave., St. Paul, Minn. 55118.	Do.
Do.	Hennepin and Wright.	Hanover, Village of.	H 27 053 3050 01 H 27 053 3050 02	do	Mayor, Village of Hanover, Hanover, Minn. 55341.	Do.
Missouri	St. Louis	Maplewood, City of.	H 29 189 4900 01	Water Resources Board, P.O. Box 271, Jefferson City, Mo. 65101. Division of Insurance, P.O. Box 690, Jefferson City, Mo. 65101.	Mayor, City of Maplewood, 7601 Manchester, Maplewood, Mo. 63143.	Do.
New Jersey	Burlington	Delran, Township of.	H 34 005 0736 01 through H 34 005 0736 03	Bureau of Water Control, Department of Environmental Protection, P.O. Box 1390, Trenton, N.J. 08625. New Jersey Department of Insurance, State House Annex, Trenton, N.J. 08625.	Township Clerk, Township of Delran, Township Municipal Bldg., Delran, N.J. 08075.	Do.
Do.	Camden	Collingswood, Borough of.	H 34 007 0690 01	do	Municipal Bldg. 678 Haddon Ave., Collingswood, N.J. 08108.	Do.
Do.	Ocean	Point Pleasant Beach, Borough of.	H 34 029 2660 01	do	Borough Engineer, 416 New Jersey Ave., Point Pleasant Beach, N.J. 08742.	Do.
Do.	Union	New Providence, Borough of.	H 34 039 2180 01 H 34 039 2180 02	do	Borough Clerk, Borough Hall, 1343 Springfield Ave., New Providence, N.J. 07974.	Do.
New York	Chemung	Horseheads, Village of.	H 36 015 2800 01 H 36 015 2800 02	New York State Department of Environmental Conservation, Division of Resources Management Services, Bureau of Water Management, Albany, N.Y. 12201. New York State Insurance Department, 123 William St., New York, N.Y. 10038, and 324 State St., Albany, N.Y. 12210.	Village Manager, 202 South Main St., Horseheads, N.Y. 14845.	Do.
Do.	Steuben	Erwin, Town of.	H 36 101 1886 01 through H 36 101 1886 11	do	Town Hall, West Water St., Painted Post, N.Y. 14870.	Do.

State	County	Location	Map No.	State map repository	Local map repository	Effective date of identification of areas which have special flood hazards
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Do.	Westchester	Larchmont, Village of.	H 36 119 3150 01	do.	Village of Larchmont, Municipal Bldg., Larchmont, N.J. 10538.	Do.
North Dakota	Eddy	New Rockford, City of.	H 38 027 2330 01	State Water Commission, State Office Bldg., 900 East Boulevard, Bismarck, N. Dak. 58501. North Dakota Insurance Department, State Capitol, Bismarck, N. Dak. 58501.	Chairman, City Commission, City of New Rockford, New Rockford, N. Dak. 58356.	Do.
Do.	Mercer	Beulah, City of	H 38 057 0330 01	do.	Mayor, City of Beulah, Beulah, N. Dak. 58521.	Do.
Do.	do.	Hazen, City of	H 38 057 1500 01	do.	Mayor, City of Hazen, Hazen, N. Dak. 58545.	Do.
Do.	Ransom	Lisbon, City of	H 38 073 1880 01 H 38 073 1880 02	do.	Mayor, City of Lisbon, City Hall, Lisbon, N. Dak. 58054.	Do.
Ohio	Ashtabula	Geneva, City of	H 39 007 2870 01 H 39 007 2870 02	Ohio Department of Natural Resources, Fountain Square, Columbus, Ohio 43224. Ohio Insurance Department, 115 East Rich St., Columbus, Ohio 43215.	Mayor, City of Geneva, City Hall, Geneva, Ohio 44041.	Do.
Do.	Belmont	Shadyside, City of.	H 39 013 7410 01	do.	Mayor, City of Shadyside, East 39th St., Shadyside, Ohio 43947.	Do.
Do.	Clermont	Neville, Village of.	H 39 025 5540 01	do.	Washington Township Trustees, Village of Neville, 2d and Broadway, Moscow, Ohio 45153.	Do.
Do.	Cuyahoga	Mayfield, Village of.	H 39 035 4800 01 H 39 035 4800 02	do.	Village of Mayfield, 6621 Wilson Mills Rd., Mayfield, Ohio 44124.	Do.
Do.	Fayette	Washington Court House, City of.	H 39 047 8570 01 through H 39 047 8570 03	do.	Zoning Board, City of Washington Court House, Municipal Bldg., Washington Court House, Ohio 43160.	Do.
Do.	Franklin	Reynoldsburg, City of.	H 39 049 6890 01 through H 39 049 6890 03	do.	Building Department, City of Reynoldsburg, 7232 East Main St., Reynoldsburg, Ohio 43060.	Do.
Do.	Huron	Norwalk, City of.	H 39 077 6070 01 through H 39 077 6070 03	do.	Mayor, City of Norwalk, City Bldg., Norwalk, Ohio 44857.	Do.
Do.	Jefferson	Stratton, Village of.	H 39 081 7870 01	do.	Mayor, Village of Stratton, Second Ave., Stratton, Ohio 43961.	Do.
Do.	Marion	La Rue, Village of.	H 39 101 4060 01	do.	Mayor, Village of La Rue, La Rue, Ohio 43332.	Do.
Do.	do.	Prospect, Village of.	H 39 101 6770 01	do.	Mayor, Village of Prospect, Prospect, Ohio 43342.	Do.
Do.	Pike	Piketon, Village of.	H 39 131 6530 01	do.	Mayor, Village of Piketon, Village Hall, Piketon, Ohio 45661.	Do.
Do.	Van Wert	Van Wert, City of.	H 39 161 8380 01 H 39 161 8380 02	do.	Van Wert City Council, 515 East Main St., Van Wert, Ohio 45891.	Do.
Oklahoma	Creek	Drumright, City of.	H 40 037 1410 01	Oklahoma Water Resources Board, 2241 Northwest 40th St., Oklahoma City, Okla. 73112. Oklahoma Insurance Department, Room 408 Will Rogers Memorial Bldg., Oklahoma City Okla. 73105.	Mayor, City of Drumright, City Hall, Drumright, Okla. 74030.	Do.
Do.	Kay	Tonkawa, City of.	H 40 071 4750 01 H 40 071 4750 02	do.	Mayor, City of Tonkawa, City Bldg., Tonkawa, Okla. 74653.	Do.
Do.	Marshall	Madill, City of	H 40 095 2970 01	do.	City Manager, City of Madill, City Hall, Madill, Okla. 73446.	Do.
Oregon	Coos	Myrtle Point, City of.	H 41 011 1470 01	Executive Department, State of Oregon, Salem, Oreg. 97310. Oregon Insurance Division, Department of Commerce, 158 12th St., NE., Salem Oreg. 97310.	Mayor, City of Myrtle Point, City Hall, Myrtle Point, Oreg. 97458.	Do.
Do.	do.	Powers, City of	H 41 011 1670 01	do.	Mayor, City of Powers, City Hall, Powers, Oreg. 97466.	Do.
Do.	Curry	Gold Beach, City of.	H 41 015 0830 01	do.	Mayor City of Gold Beach City Hall, Gold Beach, Oreg. 97444.	Do.
Do.	Morrow	Heppner, City of	H 41 049 0080 01	do.	Mayor, City of Heppner, Heppner, Oreg. 97836.	Do.
Do.	Polk	Dallas, City of	H 41 053 0480 01 H 41 053 0480 02	do.	Mayor, City of Dallas, Dallas, Oreg. 97338.	Do.
Pennsylvania	Dauphin	Hummelstown, Borough of.	H 42 043 3810 01	Department of Community Affairs, Commonwealth of Pennsylvania, Harrisburg, Pa. 17120. Pennsylvania Insurance Department, 108 Finance Bldg., Harrisburg, Pa. 17120.	Hummelstown Borough Bldg., 39 East Main St., P.O. Box 215, Hummelstown, Pa. 17036.	Do.
Do.	Delaware	Darby, Borough of.	H 42 045 1900 01	do.	Municipal Bldg., 44 North Ninth St., Darby, Pa. 19023.	Do.
Do.	Lebanon	Lebanon, City of	H 42 075 4346 01 H 42 075 4346 02	do.	Commissioner's Office, Lebanon Municipal Bldg., 400 South Eighth St., Lebanon, Pa. 17042.	Do.
Do.	Luzerne	Luzerne, Borough of.	H 42 079 4620 01	do.	Luzerne Borough Bldg., 144 Academy St., Luzerne, Pa. 18709.	Do.
Do.	Northampton	Hanover, Township of.	H 42 095 3476 01 through H 42 095 3476 03	do.	Hanover Township Municipal Bldg., 400 Highland Ave., Bethlehem, Pa. 18017.	Do.
Texas	Jones	Stamford, City of.	H 48 253 6570 01 H 48 253 6570 02	Texas Water Development Board, P.O. Box 13087, Capitol Station, Austin, Tex. 78711. Texas Insurance Department, 1110 San Jacinto St., Austin, Tex. 78701.	City Manager, City of Stamford, P.O. Box 191, Stamford, Tex. 79553.	Do.
Wisconsin	Winnebago	Oshkosh, City of	H 55 139 3620 01 through H 55 139 3620 07	Department of Natural Resources, P.O. Box 450, Madison, Wis. 53701. Wisconsin Insurance Department, 212 North Bassett St., Madison, Wis. 53703.	City Manager, City Hall, City of Oshkosh, 215 Church Ave., P.O. Box 1130, Oshkosh, Wis. 54961.	Do.

(National Flood Insurance Act of 1968 (title XIII of the Housing and Urban Development Act of 1968), effective Jan. 28, 1969 (33 FR 17804, Nov. 28, 1968), as amended (secs. 408–410, Pub. L. 91–152, Dec. 24, 1969), 42 U.S.C. 4001–4127; and Secretary's delegation of authority to Federal Insurance Administrator, 34 FR 2680, Feb. 27, 1969)

Issued: November 12, 1973.

GEORGE K. BERNSTEIN,
Federal Insurance Administrator.

[FR Doc.73-24587 Filed 11-19-73;8:45 am]

Title 28—Judicial Administration

CHAPTER I—DEPARTMENT OF JUSTICE

[Order 553-73]

PART 0—ORGANIZATION OF THE DEPARTMENT OF JUSTICE

Subpart K—Criminal Division

DELEGATING AUTHORITY RESPECTING PROCEEDINGS AGAINST JUVENILES

Section 5032 of title 18, United States Code, provides that a juvenile who is alleged to have violated a Federal law not punishable by death or life imprisonment, and who is not turned over to State authorities, shall be proceeded against as a juvenile delinquent, if he so consents, unless the Attorney General directs otherwise. The Attorney General's authority under this section has been delegated to the Assistant Attorney General in charge of the Criminal Division. This order would amend the regulation to delegate the authority to the Deputy Assistant Attorneys General, Criminal Division, as well as to the Assistant Attorney General.

By virtue of the authority vested in me by (28 U.S.C. 509, 510), and (5 U.S.C. 301), § 0.57 of Subpart K of Part 0 of Chapter I of Title 28, Code of Federal Regulations, is revised to read as follows:

§ 0.57 Delegation respecting authorization to institute criminal prosecution against a juvenile.

The Assistant Attorney General in charge of the Criminal Division and his Deputy Assistant Attorneys General are each authorized to exercise the power and authority vested in the Attorney General by section 5032 of title 18 of the United States Code, to direct that criminal prosecution be instituted against a juvenile alleged to have committed one or more acts in violation of a law of the United States not punishable by death or life imprisonment.

Dated: November 12, 1973.

ROBERT H. BORK,
Acting Attorney General.

[FR Doc.73-24682 Filed 11-19-73;8:45 am]

Title 31—Money and Finance: Treasury

CHAPTER IV—SECRET SERVICE, DEPARTMENT OF THE TREASURY

PART 407—REGULATIONS GOVERNING CONDUCT IN THE TREASURY BUILDING AND THE TREASURY ANNEX

Miscellaneous Amendments

These amendments delete from Part 407 the reference to obsolete delegation orders of the Administrator of General Services and the Secretary of the Treasury and insert in lieu thereof references to recently revised delegation orders. In accordance with section 553(a) of title V, U.S. Code, notice and public procedure thereon are found to be impractical, unnecessary, and not required since the amendments pertain to the management of public property.

1. The authority paragraph following the table of contents is amended by deleting "FPMR Temp. Reg. D-22, 35 FR 14426; Treasury Dept. Order 177-25 (Revision 1), 35 FR 15312" and inserting in lieu thereof "FPMR Temp. Reg. D-40, 38 FR 20650; Treasury Dept. Order 177-25 (Revision 2), 38 FR 21947". As amended, the paragraph reads as follows:

AUTHORITY: 5 U.S.C. 301; FPMR Temp. Reg. D-40, 38 FR 20650; Treasury Dept. Order 177-25 (Revision 2), 38 FR 21947.

2. Section 407.1 is amended by deleting "35 FR 14426 (1970)" and inserting in lieu thereof "38 FR 20650 (1973)" and by deleting "(Revision 1) 35 FR 15312 (1970)" and inserting in lieu thereof "(Revision 2) 38 FR 21947 (1973)". As amended, § 407.1 reads as follows:

§ 407.1 Authority.

The regulations in this part governing conduct in and on the Treasury Building and grounds and the Treasury Annex Building and grounds are promulgated pursuant to the authority vested in the Secretary of the Treasury, including (5 U.S.C. 301), and that vested in him by delegation from the Administrator of General Services, 38 FR 20650 (1973), and in accordance with the authority vested in the Director of the U.S. Secret Service by Treasury Department Order No. 177-25 (Revision 2), 38 FR 21947 (1973).

Effective date. These amendments shall become effective on November 20, 1973.

[SEAL] H. STUART KNIGHT,
Director, U.S. Secret Service.

NOVEMBER 15, 1973.

[FR Doc.73-24688 Filed 11-19-73;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

Browns Park National Wildlife Refuge, Colorado

The following special regulation is issued and is effective November 20, 1973.

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

COLORADO

BROWNS PARK NATIONAL WILDLIFE REFUGE

Sport fishing on the Browns Park National Wildlife Refuge, Colorado, is permitted from January 1 through February 28, 1974, inclusive, and from June 16 through December 31, 1974, inclusive, but only on the areas designated by signs as open to fishing. These open areas, Beaver Creek and the Green River, comprise 1,000 acres. Information may be obtained from the Refuge Manager, Greystone, Colorado, or the Regional Director, Bureau of Sport Fisheries and Wildlife, P.O. Box 1306, Albuquerque, New Mexico. Sport fishing shall be in accordance with all applicable State regulations.

The provisions of this special regulation supplement the regulations which govern fishing on wildlife refuge areas generally which are set forth in Title 50, Part 33, and are effective through December 31, 1974.

H. J. JOHNSON,
Refuge Manager, Ouray National Wildlife Refuge, Vernal, Utah.

NOVEMBER 8, 1973.

[FR Doc.73-24614 Filed 11-19-73;8:45 am]

PART 33—SPORT FISHING

Ouray National Wildlife Refuge, Utah

The following special regulation is issued and is effective November 20, 1973.

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

UTAH

OURAY NATIONAL WILDLIFE REFUGE

The Green River channel within Ouray National Wildlife Refuge Uintah County, Utah, shall be open to sport fishing by rod, reel and pole from January 1, 1974 through December 31, 1974. Vehicle access is limited to existing routes delineated on maps available at refuge headquarters and from the Area Manager, Federal Building, Room 2215, 125 South State Street, Salt Lake City, Utah 84111. Sport fishing shall be in accordance with all applicable state regulations.

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 December 31, 1973.

H. J. JOHNSON,
Refuge Manager, Ouray National Wildlife Refuge, Vernal, Utah.

NOVEMBER 8, 1973.

[FR Doc.73-24615 Filed 11-19-73;8:45 am]

Title 6—Economic Stabilization

CHAPTER I—COST OF LIVING COUNCIL

[Phase IV Price Ruling 1973-10]

EMPLOYEE CAFETERIAS AND RESTAURANTS; PRENOTIFICATION

Phase IV Price Rulings

Facts. Firm A is a price category I computer manufacturer which operates employee lunch cafeterias on a nonprofit basis. Prices are set at a level which generates revenue sufficient to cover direct out-of-pocket expenses only. Revenues from the cafeterias amount to $500,000 annually.

In Phase II any price category I firm which operated a cafeteria, restaurant or similar food-service facility on a nonprofit basis primarily for the convenience and benefit of the firm's employees was permitted to raise prices above base price levels in connection with that facility without prenotification, provided that pricing was designed to break even on direct costs with the firm subsidizing overhead and other indirect costs. This exception from the prenotification regu-

lations is not included in the Phase IV price regulations. However, § 150.605(c) of Subpart Q (food industry regulations) provides that prenotification is not required with respect to food service activities.

Issue. May Firm A increase the price of food items in its employee cafeterias without prenotifying?

Ruling. Yes. The food-service prenotification waiver of Subpart Q does not apply only to price category I firms primarily engaged in food service activities. The prenotification waiver applies to the food service activities of any price category I firm, regardless of the amount of revenues derived from those activities and regardless of whether or not those activities are employee-related or conducted on a non-profit basis.

While Subpart Q waives the prenotification requirement with respect to Firm A's food service activities, applicable cost-justification, profit margin and other pricing rules and limitations continue in effect in connection with prices charged in the cafeterias operated by Firm A.

WILLIAM N. WALKER,
General Counsel.

NOVEMBER 16, 1973.

[FR Doc.73-24815 Filed 11-16-73;4:46 pm]

[Phase IV Price Ruling 1973-8]

CONTINUED EFFECT OF PROFIT MARGIN EXCEPTIONS

Phase IV Price Ruling

Facts. On November 28, 1972, Firm A received an exception from the Price Commission to increase prices to reflect a dollar-for-dollar pass-through of the increased cost of gold and silver of certain gold and silver bearing products without such increases being considered price increases for purposes of the profit margin limitation.

6 CFR 150.3 provides that any firm which has been authorized to adjust its base period profit margin pursuant to an exception granted under the authority of the Economic Stabilization Program prior to August 13, 1973, may continue to calculate its base period profit margin pursuant to that exception.

Issue. Does the exception granted to Firm A remain in effect during Phase IV?

Ruling. The exception granted to Firm A does not continue in effect.

As a general rule, an exception granted in a prior phase of the Economic Stabilization Program does not continue to effect in a subsequent phase. This rule applies because of the great likelihood that either the regulation with respect to which the exception was granted has been changed or that the conditions and circumstances under which the exception was granted have changed. A firm which desires to renew an exception from the same or similar regulation in Phase IV and which believes that conditions and circumstances remain such as to qualify the firm for an exception must reapply in Phase IV under Phase IV exceptions procedures.

Section 150.3 modifies the general rule by providing that certain exceptions shall continue in effect in a subsequent phase notwithstanding any changes which may have occurred. However, § 150.3 applies only to cases where a firm was granted a specific numerical adjustment in its base period profit margin prior to August 13, 1973, e.g., an adjustment from 2 percent to 5.3 percent. Merely allowing a firm a cost pass-through without regard to profit margin constraints is not an adjustment to its base period profit margin and therefore not within the scope of the exceptions continued by § 150.3.

WILLIAM N. WALKER,
General Counsel.

NOVEMBER 16, 1973.

[FR Doc.73-24876 Filed 11-19-73;11:50 am]

[Phase IV Price Ruling 1973-9]

FEED BY-PRODUCT REVENUES; ALCOHOLIC BEVERAGE PRODUCERS

Phase IV Price Ruling

Facts. Company A is engaged in the manufacture of distilled spirits and liquors. The distillation and manufacturing process of liquor yields, as a residue of the distilled grain, a substance known as "distiller's dried grain," which is sold as a feed for livestock and fowl. This feed has historically been priced lower in warmer months when livestock is able to feed on pasture and higher in colder months when pasture becomes unavailable. In addition, grain residue prices generally reflect the prevailing market price of corn or other grain which is used for animal feed. In calculating liquor costs, Company A has traditionally treated the revenues or anticipated revenues from the sale of the grain residue (less cost of drying) as a credit against the cost of manufacturing liquor. These costing and pricing practices were permissible under Price Commission Ruling 1972-23, January 28, 1972.

Issue. May Company A continue in Phase IV to price and account for distillers dried grain as it has in the past?

Ruling. Yes. A manufacturer of alcoholic beverages which produces an animal feed by-product (such as distiller's dried grain) and which has customarily treated the revenues from the sale of that by-product as an offset to the cost of producing the primary product or products, may continue to sell the by-product in accordance with established free market pricing practices without prenotification or cost-justification provided those revenues are consistently and appropriately applied to offset the cost of the food raw materials used in production.

This ruling adopts the same position taken in Price Commission Ruling 1972-73, which was based upon a similar fact pattern involving millfeed as a by-product of the processing of wheat into flour. However, this ruling is restricted to the fact pattern here presented and may not be relied upon in Phase IV with respect to other industries and other by-products. Other firms which have problems of cost allocation with respect to by-products, co-products, etc. are encouraged to seek rulings which apply to specific fact situations.

WILLIAM N. WALKER,
General Counsel.

NOVEMBER 16, 1973.

[FR Doc.73-24877 Filed 11-19-73;11:51 am]

[Phase IV Price Ruling 1973-11]

QUARTERLY REPORTING BY LOSS OR LOW PROFIT FIRMS

Phase IV Price Ruling

Facts. X and Y are price category I and II firms which price pursuant to the loss or low profit regulations (§ 150.201).

Issue. Are Firms X and Y subject to the quarterly reporting requirements of Subpart H?

Ruling. Section 150.201 provides that "each price category I or price category II firm, before utilizing this section for any fiscal year or part thereof, in addition to complying with the reporting requirements of Subpart H, and before charging any price under this section, shall furnish to the Council sufficient financial data to support its loss or low profit position." The quarterly reporting requirements of Subpart H apply to X and Y in the same manner as they apply to any other price category I or II firm.

WILLIAM N. WALKER,
General Counsel.

NOVEMBER 16, 1973.

[FR Doc.73-24878 Filed 11-19-73;11:51 am]

Proposed Rules

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[7 CFR Part 981]

ALMONDS GROWN IN CALIFORNIA

Proposed Increase in Expenses Approved for Control Board for 1973–74 Crop Year

Notice is given of a proposal to increase the expenses of the Almond Control Board, previously approved (38 FR 25668) for the 1973–74 crop year. The proposal is pursuant to § 981.80 of the marketing agreement, as amended, and Order No. 981, as amended (7 CFR Part 981). The amended marketing agreement and order regulate the handling of almonds grown in California, and are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). The proposal is based on the unanimous recommendation of the Almond Control Board. On September 14, 1973, an action was published in the FEDERAL REGISTER (38 FR 25668) approving expenses of the Almond Control Board, and rate of assessment, for the 1973–74 crop year. The approved expenses in the amount of $1,945,481 are set forth in § 981.323(a) of Subpart—Budget of Expenses and Rate of Assessment (7 CFR Part 981.300, 981.323; 38 FR 25668, 27381). It now appears likely that the Control Board will exceed the previously approved expenses. The proposal is to increase these expenses by $18,000 to $1,963,481. No change in the assessment rate for the 1973–74 crop year is being proposed because sufficient funds are available to meet the proposed increased expenses.

All persons who desire to submit written data, views, or arguments on this proposal should file the same, in quadruplicate, with the Hearing Clerk, U.S. Department of Agriculture, Room 112, Administration Building, Washington, D.C. 20250, to be received not later than December 5, 1973. All written submissions made pursuant to this notice will be made available for public inspection at the office of the Hearing Clerk during regular business hours (7 CFR 1.27(b)).

The proposal is to amend paragraph (a) of § 981.323 to read as follows:

§ 981.323 Expenses of the Control Board and rate of assessment for the 1973–74 crop year.

(a) *Expenses.* Expenses in the amount of $1,963,481 are reasonable and likely to be incurred by the Control Board during the crop year beginning July 1, 1973, for its maintenance and functioning and for such purposes as the Secretary may, pursuant to the provisions of this part, determine to be appropriate.

* * * * *

Dated: November 15, 1973.

FLOYD F. HEDLUND,
Director,
Fruit and Vegetable Division.

[FR Doc.73-24712 Filed 11-19-73;8:45 am]

[7 CFR Part 1030]

MILK IN CHICAGO REGIONAL MARKETING AREA

Proposed Temporary Revision of Shipping Percentage

Notice is hereby given that, pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 et seq.), and the provisions of § 1030.11(b)(6) of the order, the temporary revision of certain provisions of the order regulating the handling of milk in the Chicago Regional marketing area are being considered for the month of December 1973.

All persons who desire to submit written data, views, or arguments in connection with the proposed revision should file the same with the Hearing Clerk, Room 112-A, Administration Building, United States Department of Agriculture, Washington, D.C. 20250, not later than November 23, 1973. All documents filed should be in quadruplicate.

All written submissions made pursuant to this notice will be made available for public inspection at the office of the Hearing Clerk during regular business hours (7 CFR 1.27(b)).

The provisions proposed to be revised are the supply plant shipping percentages of 30 percent set forth in § 1030.11(b)(4) and 15 percent set forth in § 1030.11(b)(7)(iii), that are applicable during the month of December. Pursuant to the provisions of § 1030.11(b)(6) the supply plant shipping percentages set forth in § 1030.11(b)(4) and in § 1030.11(b)(7)(iii) shall be increased or decreased during the months of August–March, if necessary to obtain needed shipments or to prevent uneconomic shipments.

Central Milk Producers Cooperative (CMPC), whose sixteen cooperative association members represent a substantial majority of the producers supplying the Chicago Regional market, requested that the Director of the Dairy Division investigate the need to increase the supply plant shipping percentages for the month of December 1973. CMPC states that an upward revision (from 30 to 40) in the shipping percentage for a plant qualifying individually and for a unit of supply plants and, in the case of each plant in a unit, from 15 percent to 20 will be necessary to assure that fluid milk bottling plants in the Chicago metropolitan area will obtain needed shipments to fulfill their bottling requirements.

To fulfill their fluid milk requirements, distributing plants obtain a major portion of their milk supplies from supply plants, since about 80 percent of the market's milk supply is assembled at supply plants. In September 1973, for example, receipts of producer milk totaled 465 million pounds at supply plants and 115 million pounds at distributing plants. Shipments of milk from pool supply plants to pool distributing plants amounted to 217 million pounds during September or 46.7 percent of total receipts at supply plants.

Total milk supplies on the market have been declining since November 1972. Each month since then milk production has been significantly below the corresponding month in the previous year. In October 1973, 590 million pounds of milk were pooled under the order compared to 619 million pounds in October 1972, a reduction of 29 million pounds or 4.6 percent from the same month the previous year.

Shipments from supply plants to distributing plants have been greater in recent months than during corresponding months in 1972. In August and September 1972 shipments of supply plant milk totaled 193 and 209 million pounds, respectively. In August and September 1973 shipments amounted to 208 and 217 million pounds, respectively. The percentage of supply plant milk shipped to distributing plants is also up from last year. In August 1973, 41.2 percent of receipts were shipped compared to 36.7 percent in August 1972. During September 1973, shipments from supply plants represented 46.7 percent of plant receipts compared to 43.4 percent in September 1972.

In the month of December the average supply plant shipment percentage amounted to 42.2 in 1972, 42.7 in 1971, and 43.1 in 1970. It can be expected that the percentage of supply plant milk needed to be shipped to distributing plants during December 1973 will be in excess of 40 percent, since shipments in recent months have been at a higher percentage than in corresponding months the previous year.

In the production area for the Chicago Regional market, which primarily consists of the State of Wisconsin, there is extensive competition for milk supplies for use in cheese. Prices paid for milk by cheese plant operators have been advancing sharply in recent months. This circumstance threatens to attract milk supplies away from the Grade A fluid milk market.

Therefore, it may be appropriate to increase the pool supply plant shipping percentages for the month of December 1973 to obtain needed shipments.

Signed at Washington, D.C., on November 15, 1973.

H. L. FOREST,
Director, Dairy Division.

[FR Doc.73-24720 Filed 11-19-73;8:45 am]

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[50 CFR Part 240]

GROUNDFISH FISHERIES

Proposed Catch Quotas for 1974

At its 23rd Annual Meeting held in Copenhagen, Denmark, June 5–15, 1973, and at a special meeting held in Ottawa, Canada, October 15–19, 1973, the International Commission for the Northwest Atlantic Fisheries (ICNAF) recommended that member governments adopt conservation measures for 1974 beginning January 1. These measures include catch quotas on species presently under regulation, adoption of restricted fishing for haddock, a specific annual quota for squid, and a total quota for the United States consisting of all fish species and squid, except menhaden, caught in subarea 5 and statistical area 6. Specific quotas for herring, mackerel, and other finfish will be determined at the midyear meeting of ICNAF in early January. However, the quotas adopted at the midyear meeting will also be in effect beginning January 1, 1974. The catch quotas for 1974 for yellowtail flounder and red hake were not changed from the 1973 quota. Due to changes from the 1973 annual catch quotas, Table 1 has been prepared to advise interested persons of the 1974 catch quotas for regulated species.

In addition to the proposed species quotas, a prohibition to demersal fishing for vessels over 145 feet in length is also recommended in an area from southern New England to the Gulf of Maine during the period July 1 to December 31, 1974.

Therefore, it is proposed to amend the present regulations (38 FR 22399), published in the FEDERAL REGISTER, August 20, 1973, to incorporate the conservation measures adopted by ICNAF for 1974.

It is proposed in § 240.1 to include squid as a regulated species in Subarea 5. This proposed addition of a new regulated species is also included in Subpart D.

It is proposed to change 1973 to 1974 wherever the 1973 date appears in Subparts B, C, and D.

It is proposed in § 240.11(a) to prohibit the unrestricted fishing for haddock in 1974. The only allowable haddock catch on board will be that taken incidental to another fishery and shall not exceed 5,000 pounds or 10 percent of the total catch by weight whichever is greater. The closing requirement for haddock will be deleted in § 240.13(b).

It is proposed to change the annual catch quotas for cod, pollock, redfish, American plaice, and silver hake to the 1974 amount agreed upon by the Commission.

It is proposed in § 240.11 to provide an annual catch quota of 10,000 metric tons of redfish in Divisions 4V, 4W, 4X of Subarea 4.

It is proposed in § 240.13 to prohibit demersal fishing from July 1 to December 31, 1974 of vessels over 145 feet in length in an area extending from southern New England to the Gulf of Maine and eastward to the western edge of Georges Bank. Vessels over 145 feet in length will be retricted to pelagic fishing in this area.

It is proposed in § 240.21 to provide an annual catch quota of 500 metric tons of an aggregate quantity of flounders which include yellowtail flounder, witch flounder, and American plaice in Divisions 4V, 4W, and 4X of Subarea 4.

It is proposed to implement the mesh regulation adopted at the January 1972 ICNAF meeting that requires when fishing for haddock, cod or yellowtail flounder, the trawl net, other than the cod end, shall not be less than 4½ inches (114 mm) and the cod end shall not be less than 5⅛ inches (130 mm).

It is proposed to include in § 240.40 an annual catch quota for squid (all species).

The proposed amendments are to be issued under the authority contained in subsection (a) of section 7 of the Northwest Atlantic Fisheries Act of 1950 (64 Stat. 1069; U.S.C. 986) as modified by Reorganization Plan No. 4, effective October 3, 1970 (35 FR 15637).

Prior to the final adoption of the proposed amendments, consideration will be given to any data, views, or arguments pertaining thereto which are submitted in writing to the Director, National Marine Fisheries Service, Washington, D.C. 20235, on or before December 12, 1973.

Issued at Washington, D.C., and dated November 15, 1973.

JOSEPH W. GEHRINGS,
Acting Director, National Marine Fisheries Service.

TABLE I

1974 SPECIES ALLOCATION FOR THE UNITED STATES

Species	Stock area	Quantity (metric tons)
Haddock	4 and 5	None
Cod	5Y	8,677
	5Z	16,590
Yellowtail flounder	5 (E. of 69°)	15,000
	5 (W. of 69°)	9,000
Silver hake	5Y	8,380
	5Ze	11,056
	5Zw and 6	18,864
Red hake	5Z (W. of 69°) and 6	15,000
Pollock	4 and 5	13,000
Redfish	5	24,747
	4 (4V, 4W, and 4X)	
Other flounders (except Yellowtail)	5 and 6	21,700
Aggregate catch: Yellowtail flounder, Witch flounder, American plaice	4 (4V, 4W, and 4X)	500
Herring [1]	5Y	
	5Z and 6	
Mackerel [1]	5 and 6	
Other finfish [1] (except Menhaden)	5 and 6	
Squid	5 and 6	5,500

[1] Allocations to be set at the Jan. 1974 Meeting of the Commission.

The proposed amendments are described below:

1. Amend Subparts B, C, and D, to change the number 1973 to 1974, wherever the 1973 number appears.

2. Add a new subdivision (xi) in § 240.1(c)(5) to read as follows:

§ 240.1 **Definitions.**

* * * * *

(c) * * *

(5) * * *

(xi) Squid (all species).

3. Amend § 240.11 as follows:

§ 240.11 **Catch quota.**

(a) It shall be unlawful for any person or fishing vessel under the jurisdiction of the United States to possess on board haddock caught in Subareas 4 or 5 in amounts exceeding 5,000 pounds or 10 percent by weight of all fish on board caught in Subareas 4 or 5, whichever is greater.

(b) * * *

(1) The annual catch of cod in Subdivision 4Vs and Division 4W of Subarea 4 by member countries not provided a special allocation shall not exceed 1,700 metric tons.

(2) The annual catch of cod in Division 5Y of Subarea 5 shall not exceed 8,677 metric tons.

(3) The annual catch of cod in Division 5Z of Subarea 5 shall not exceed 16,590 metric tons.

(c) An annual catch limitation is placed upon the quantity of pollock permitted to be taken in Division 4V, 4W, and 4X, of Subarea 4 and Subarea 5. The catch of pollock in the above areas during 1974 by persons under the jurisdiction of the United States shall not exceed 12,000 metric tons.

(d) An annual catch limitation is placed upon the quantity of redfish (ocean perch) permitted to be taken in Subarea 5. The catch of redfish (ocean perch) in the above area during 1974 by persons or fishing vessels under the jurisdiction of the United States shall not exceed 24,747 metric tons.

(e) An annual catch limitation is placed on the quantity of redfish (ocean perch) permitted to be taken in Divisions 4V, 4W, and 4X of Subarea 4. The catch of redfish (ocean perch) in the above area during 1974 by persons or fishing vessels under the jurisdiction of the United States shall not exceed 10,000 metric tons.

4. Delete paragraph (b) and subparagraphs (1), (2) and (3) of § 240.13 and redesignate paragraph (c) to (b) and add new paragraph (c) as follows:

§ 240.13 **Closed seasons and areas.**

* * * * *

(c) It shall be unlawful for any person under the jurisdiction of the United States during the period from 0001 hours local time July 1 to 2400 hours local time December 31, 1974, to take fish, other than crustacea, from vessels over 145 feet in length with fishing gear other than pelagic fishing gear (purse seines or true mid-water trawls, using mid-water trawl doors incapable of being fished on the bottom) in the area adjacent to the United States coast within

that part of Subarea 5 (southern New England and Gulf of Maine) north of 40°20′ N. Latitude and 43°17′ N. Latitude and west of the straight line drawn between the points 68°15′ W.–40°20′ N. and 70°00′ W.–43°17′ N.

(1) It shall be unlawful for any person under the jurisdiction of the United States permitted to fish in the area described in paragraph (c) to attach any protective device to pelagic fishing gear or employ any means that would, in effect, make it possible to fish for demersal species.

5. Amend paragraph (b) of § 240.14 to read as follows:

§ 240.14 Gear restrictions.

* * * * *

(b) In Subareas 4 and 5, no person shall fish for haddock or cod with a trawl net or nets, parts of nets, other than the cod end, or netting of manila or of the trade named twines, under the chemical category of polypropylene having a mesh size of less than 4½ inches (114 mm) and having in the cod end of meshes of less than 5⅛ inches (130 mm).

* * * * *

6. Amend paragraph (a) and add new paragraph (e) of § 240.21 to read as follows:

§ 240.21 Catch quota.

(a) An annual catch limitation is placed upon the quantity of American plaice permitted to be taken in Divisions 3L, 3N, and 3O of Subarea 3 by member countries not provided a special allocation shall not exceed 1,200 metric tons.

* * * * *

(e) An annual catch limitation is placed upon the aggregate quantity of flounders, which include yellowtail flounder, witch flounder, and American plaice in Divisions 4V, 4W, and 4X of Subarea 4. The aggregate catch of flounders (yellowtail flounder, witch flounder, and American plaice) in the above area during 1974 by persons or fishing vessels under the jurisdiction of the United States shall not exceed 500 metric tons.

7. Amend paragraph (a) of § 240.24 to read as follows:

§ 240.24 Gear restrictions.

(a) In Subareas 4 and 5, no person shall fish for yellowtail flounder with a trawl net or nets, parts of nets, other than the cod end, or netting of manila or of the trade named twines, under the chemical category of polypropylene having a mesh size less than 4½ inches (114 mm) and having a cod end of meshes of less than 5⅛ inches (130 mm).

* * * * *

8. Amend subparagraphs (1), (2) and (3) of § 240.31(a) to read as follows:

§ 240.31 Catch quota.

(a) * * *

(1) The annual catch of silver hake in Division 5Y of Subarea 5, shall not exceed 8,380 metric tons.

(2) The annual catch of silver hake in Subdivision 5Z of Subarea 5, shall not exceed 11,056 metric tons.

(3) The annual catch of silver hake in Subdivision 5Zw, shall not exceed 18,864 metric tons.

* * * * *

9. Amend paragraph (b) of § 240.40 to read as follows:

§ 240.40 Definitions.

* * * * *

(b) Regulations in this subpart will apply to herring (*Clupea harengus* L.), mackerel (*Scomber scombrus* L.), and squid (all species).

10. Amend § 240.41 to add new paragraph (c) to read as follows:

§ 240.41 Catch quota.

* * * * *

(c) An annual catch limitation is placed upon the quantity of squid (all species) permitted to be taken in Subarea 5 and in the adjacent waters to the west and south. The catch of squid (all species) in the above area during 1974 by persons or fishing vessels under the jurisdiction of the United States shall not exceed 5,600 metric tons.

[FR Doc.73-24725 Filed 11-19-73;8:45 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 STATE

Agency for International Development

RESEARCH ADVISORY COMMITTEE

Notice of Meeting

Pursuant to Executive Order 11686 and the provisions of Section 10(a)(2), Pub. L. 92-463, Federal Advisory Committee Act, notice is hereby given of the A.I.D. Research Advisory Committee Meeting on December 3 and 4, 1973, at the Pan American Health Organization Building, 23d Street and Virginia Avenue, NW, Conference Room "C", to review, appraise and make recommendations to the Administrator, Agency for International Development, concerning proposals for research contracts in the field of agriculture, health, nutrition, and population. In addition, a portion of the meeting will be devoted to a discussion of the East Asia Research Program. That portion of the meeting concerning proposals for research contracts, will be held from 9:30 a.m. to 6:00 p.m., December 3 and 11:00 a.m. to 5:00 p.m., December 4. The session concerning the East Asia Research Program will be held on December 4 at 8:45 a.m. to 11:00 a.m. This meeting will be open to the public. Dr. Erven Long, Associate Assistant Administrator, is designated as the A.I.D. representative at the meeting. It is suggested that those desiring more specific information contact the Advisory Committee Management Office, Mr. James McMahon, 21st Street and Virginia Avenue, NW, Washington, D.C. 20523, or call area code 202-632-9726.

Dated: November 9, 1973.

CURTIS FARRAR,
Deputy Assistant Administrator for Technical Assistance.

[FR Doc.73-24613 Filed 11-19-73;8:45 am]

Office of the Secretary

[Public Notice CM-87]

STUDY GROUP 1 OF U.S. NATIONAL COMMITTEE FOR INTERNATIONAL TELEGRAPH AND TELEPHONE CONSULTATIVE COMMITTEE (CCITT)

Notice of Meeting

The Department of State announces a scheduled meeting of the United States Study Group on U.S. Government Regulatory Problems concerned with preparation for meetings of Study Groups of the International Telegraph and Telephone Consultative Committee of the International Telecommunication Union. The meeting will take place on Wednesday, December 5, 1973, at 10:00 a.m. in Room 847 of the Federal Communications Commission, 1919 M Street, NW., Washington, D.C.

The agenda of this fourth preparatory meeting will include plans for the development of U.S. Contributions on questions assigned for study during the 1973-1976 period to CCITT Study Group III, "General tariff principles; lease of telecommunication circuits," and the development of U.S. positions on questions where it is decided not to submit U.S. Contributions.

Members of the general public who desire to attend the meeting on December 5 will be admitted up to the limit of the capacity of the meeting room.

RICHARD T. BLACK,
Chairman,
U.S. National Committee.

NOVEMBER 7, 1973.

[FR Doc.73-24680 Filed 11-19-73;8:45 am]

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

NOTICE OF GRANTING OF RELIEF

Notice is hereby given that pursuant to 18 U.S.C., section 925(c), the following named persons have been granted relief from disabilities imposed by Federal laws with respect to the acquisition, transfer, receipt, shipment, or possession of firearms incurred by reason of their convictions of crimes punishable by imprisonment for a term exceeding one year.

It has been established to my satisfaction that the circumstances regarding the convictions and each applicant's record and reputation are such that the applicants will not be likely to act in a manner dangerous to public safety, and that the granting of the relief will not be contrary to the public interest.

Anders, Dennis L., 129 East 13th Street, Port Angeles, Washington, convicted on February 20, 1970, in the United States District Court, Western District of Washington.

Gashion, John A., Route 3, Box 58, Boone, North Carolina, convicted on May 22, 1936, in the United States District Court, Middle District of North Carolina.

Clark, John James, 4020 Yupon, Houston, Texas, convicted on February 17, 1949, in the District Court of Tom Green County, Texas, and on October 15, 1952, in the Criminal District Court of Harris County, Texas.

Flick, Dennis E., 436 South Third Street, Black River Falls, Wisconsin, convicted on November 16, 1970, in the Clark County Court, Wisconsin.

King, Jr., George M., 351 Oxford Street, Hayward, California, convicted on or about March 14, 1966, in the United States District Court, Northern Judicial District of California, Southern Division.

Kubnle, Charles E., 189-14 Crocheron Avenue, Flushing, New York, convicted on or about January 23, 1957, in the Petersburg County Court, Petersburg County, Virginia.

Lacognata, John, 2878 86th Street, Brooklyn, New York, convicted on January 6, 1925, in the Court of General Sessions, New York County, New York.

Marlow, Norman H., 644 Elmhurst Avenue, Bethlehem, Pennsylvania, convicted on September 6, 1968, in the Criminal Court of Record, Dade County, Florida.

Martin, Edward H., P.O. Box 3057, Lynchburg, Virginia, convicted on January 13, 1942, in the Hustings Court, City of Roanoke, Virginia; February 21, 1942, in the Circuit Court of Roanoke County, Salem, Virginia; and on June 27, 1942, in the Circuit Court of Tazewell County, Tazewell, Virginia.

Smith, Nathaniel, 1814 East John, Seattle, Washington, convicted on March 24, 1936, in the Warren County Circuit Court, Vicksburg, Mississippi.

Sowinski, Michael H., Route 1, River Valley Drive, Ixonia, Wisconsin, convicted on May 22, 1970, in the Waukesha County Court Branch II, Wisconsin.

Tooey, Billy Joe, 408 West Broadway, Madison, Missouri, convicted on June 15, 1970, in the Circuit Court of Caldwell County, Missouri.

Vanderveer, Michael M., Route 42, Star Box 51, Woodburne, New York, convicted on January 27, 1931, in the Dutchess County Court, New York.

Signed at Washington, D.C., this 7th day of November 1973.

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

[FR Doc.73-24665 Filed 11-19-73;8:45 am]

DEPARTMENT OF DEFENSE

Department of the Air Force

SCIENTIFIC ADVISORY BOARDS

Notice of Meetings

NOVEMBER 14, 1973.

The USAF Scientific Advisory Board Electronic Systems Division Advisory Group will hold a closed meeting on November 28, 1973, from 9 a.m. until 4 p.m., at the Command Management Center, Building 1606, L. G. Hanscom Field, Bedford, Massachusetts.

The agenda will consist of classified briefings on Radar Space Detection Techniques.

The USAF Scientific Advisory Board ad hoc Committee on Electromagnetic Pulse Vulnerability of USAF Manned Systems will hold closed meetings on December 5 and 6, 1973, from 9 a.m. until 5 p.m., at R&D Associates, Santa Monica, California.

The Committee will receive classified briefings related to modeling electromagnetic pulse effects.

The USAF Scientific Advisory Board Geophysics Panel Task Group on Tropical Cyclone Forecasts will hold open meetings on December 6 and 7, 1973, from 8 a.m. until 5 p.m., at Scott Air Force Base, Illinois.

The Group will receive unclassified information briefings on Air Force requirements and capabilities in forecasting tropical cyclones.

The USAF Scientific Advisory Board Mission Resources Panel will hold a closed meeting on December 13, 1973, from 8 a.m. until 4:30 p.m., at Wright-Patterson Air Force Base, Ohio.

The Panel will receive classified informational briefings on the mission, capabilities, resources and plans of Air Force Logistics Command.

The USAF Scientific Advisory Board ad hoc Committee on Electro-Optics Technology will hold closed meetings on December 13 and 14, 1973, from 9 a.m. until 5 p.m., at Wright-Pattrson Air Force Base, Ohio.

The Committee will receive classified briefings on planned use of electro-optics technology in the Air Force.

The USAF Scientific Advisory Board Mission Resources Panel will hold a closed meeting on December 14, 1973, from 8 a.m. until 4:30 p.m., at Scott Air Force Base, Illinois.

The Panel will receive classified informational briefings on the mission, capabilities, resources, and plans of Military Airlift Command.

For further information on these meetings, contact the Scientific Advisory Board Secretariat at 202-697-8404.

STANLEY L. ROBERTS,
Colonel, USAF, Chief, Legislative Division, Office of The Judge Advocate General.

[FR Doc.73-24617 Filed 11-19-73;8:45 am]

SCIENTIFIC ADVISORY BOARD TACTICAL PANEL

Notice of Meeting

NOVEMBER 14, 1973.

The USAF Scientific Advisory Board Tactical Panel will hold closed meetings on November 27 and 28, 1973, from 9 a.m. until 4 p.m., at Tactical Air Command Headquarters, Langley Air Force Base, Virginia.

The Panel will receive classified briefings from the Tactical Air Command Commander and Staff on Tactical Air Command's resources and operational capabilities.

For further information, contact the Scientific Advisory Board Secretariat at 202-697-8404.

STANLEY L. ROBERTS,
Colonel, USAF Chief, Legislative Division, Office of The Judge Advocate General.

[FR Doc.73-24610 Filed 11-19-73;8:45 am]

Office of the Secretary

ARMY AND AIR FORCE EXCHANGE AND MOTION PICTURE SERVICES CIVILIAN ADVISORY COMMITTEE

Notice of Meeting

DECEMBER 12, 1973.

The Civilian Advisory Committee to the Board of Directors, Army and Air Force Exchange and Motion Picture Services, will hold a closed meeting on December 12, 1973 at Headquarters Army and Air Force Exchange Service, Dallas, Texas 75222.

The purpose of the meeting is to furnish commercial and financial information and advice of a privileged or confidential nature to the Board of Directors on one or more matters under consideration by the Board.

Any persons desiring information about the committee may telephone (202-697-3336) or write the Executive Secretary, Board of Directors, Army and Air Force Exchange and Motion Picture Services, Room 5E483, The Pentagon, Washington, D.C. 20310.

HARLAN W. TUCKER,
Colonel, USA,
Executive Secretary, AAFEMPS.

[FR Doc.73-24636 Filed 11-17-73;8:45 am]

NATIONAL COMMITTEE FOR EMPLOYER SUPPORT OF THE GUARD AND RESERVE

Notice of Open Meeting

Pursuant to the provisions of section 10, Pub. L. 92-463, effective January 5, 1973, notice is hereby given that a regional meeting of the National Committee for Employer Support of the Guard and Reserve Advisory Council will be held on November 26, 1973, at the Union Carbide Building, 270 Park Avenue, New York, New York.

The purpose of the meeting is to develop greater activity by members of the National Advisory Council in the solicitation of employer support of the Guard and Reserve.

The transcript of the meeting will be available to anyone desiring information about the meeting.

Additional information concerning these meetings may be obtained by contacting the Assistant to the National Chairman, National Committee for Employer Support of the Guard and Reserve, Room 3A29, 400 Army Navy Drive, Arlington, Virginia 22202.

MAURICE W. ROCHE,
Director, Correspondence and Directives OASD(C).

NOVEMBER 14, 1973.

[FR Doc.73-24643 Filed 11-19-73;8:45 am]

DEPARTMENT OF JUSTICE

Land and Natural Resources Division

ACTION TO ENJOIN DISCHARGE OF POLLUTANTS

Notice of Proposed Consent Judgment

In accordance with Departmental Policy, 28 CFR 50.7, 38 FR 19029, notice is hereby given that on November 7, 1973, a proposed consent decree in "United States v. Nick Haverlock, Jr." was lodged with the United States District Court for the District of Wyoming. The proposed decree would enjoin the defendant from causing the deposit of debris and refuse matter into the North Platte River, near Casper, Natrona County, Wyoming.

The Department of Justice will receive on or before December 20, 1973, written comments relating to the proposed judgment. Comments should be addressed to either the United States Attorney, PO Box 668, Cheyenne, Wyoming 82001, or the Assistant Attorney General for the Land and Natural Resources Division, Department of Justice, Washington, D.C. 20530, and refer to "United States v. Nick Haverlock, Jr.," D.J. Ref. 90-5-1-1-356.

The proposed consent decree may be examined at the office of the United States Attorney, 2120 Capitol Avenue, Cheyenne, Wyoming, at the Regional Office of the Environmental Protection Agency, 1860 Lincoln Street, Denver, Colorado, and at the Pollution Control Section, Land and Natural Resources Division, Department of Justice, Room 2623, Department of Justice Building, Ninth Street and Pennsylvania Avenue, NW, Washington, D.C. A copy of the proposed judgment may be obtained in person or by mail from the Pollution Control Section, Land and Natural Resources Division of the Department of Justice. In requesting a copy, please enclose a check in the amount of $0.50 (10 cents per page reproduction charge) payable to the Treasurer of the United States.

WALLACE H. JOHNSON,
Assistant Attorney General, Land and Natural Resources Division.

[FR Doc.73-24684 Filed 11-19-73;8:45 am]

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

LANDER DISTRICT ADVISORY BOARD

Notice of Meeting

NOVEMBER 12, 1973.

Notice is hereby given that the Lander, Wyoming, District Advisory Board will hold a business meeting on December 12, 1973, at the Lander District Office of the Bureau of Land Management, Jett Building, Highway 287 South, Lander, Wyoming. The agenda for the meeting will include organization of the Advisory Board, considering applications and making recommendations for grazing privileges on the national resource lands for the 1974 grazing year, reports of district programs, and progress in claiming horses under the Wild Horse and Burro Act.

The meeting will start at 9:00 a.m., m.s.t., and be open to the public as space is available. Time will be available for a limited number of brief statements by members of the public. Those wishing to make an oral statement should inform

the Advisory Board Chairman prior to the meeting of the Board. Any interested person may file a written statement with the Board for its consideration. The Advisory Board Chairman is William B. Ramage, Lysite, Wyoming 82642. Written statements should be submitted to Mr. Ramage, c/o District Manager, Bureau of Land Management, P.O. Box 589, Lander, Wyoming 82520.

FRANK B. PALLO,
District Manager.

[FR Doc.73-24612 Filed 11-19-73;8:45 am]

PINEDALE DISTRICT ADVISORY BOARD

Notice of Meeting

NOVEMBER 12, 1973.

Notice is hereby given that the Pinedale District Advisory Board will hold a meeting on December 11, 1973, 10:00 a.m. at the Pinedale District Office, Bureau of Land Management, Molyneux Building, Pinedale, Wyoming. The agenda for the meeting will include election of chairman and vice-chairman, election of representatives to the Wyoming State Multiple Use Advisory Board, consideration of applications for the 1974 grazing season, consideration of the 1974 range improvement program, and change in grazing regulations in response to the wild horse regulations.

The meeting will be open to the public as space is available. Time will be available for a limited number of brief statements by members of the pubic. Those wishing to make an oral statement should inform the Advisory Board Chairman prior to the meeting of the Board. Any interested person may file a written statement with the Board for its consideration.

Written statements and requests to appear before the Board should be submitted to the Chairman, Pinedale District Advisory Board, c/o District Manager, Bureau of Land Management, P.O. Box 768, Pinedale, Wyoming 82941.

HUGH A. WALL,
District Manager.

[FR Doc.73-24611 Filed 11-19-73;8:45 am]

Office of Hearings and Appeals

[Docket No. m 74-27]

CIMARRON COAL CORP.

Petition for Modification of Application of Mandatory Safety Standard

Correction

In FR Doc. 73-23766, appearing on page 30895 in the issue for Thursday, November 8, 1973, the agency docket number should read as set forth above.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

NATIONAL MEAT AND POULTRY INSPECTION ADVISORY COMMITTEE

Notice of Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given that a meeting of the National Meat and Poultry Inspection Advisory Committee will be held on November 28, 1973, beginning at 9 a.m. in Room 124-E, Administration Building, U.S. Department of Agriculture.

The purpose of this Committee is to advise and make recommendations to the Secretary of Agriculture regarding operations pertaining to meat and poultry inspection programs pursuant to section 301 of the Federal Meat Inspection Act and section 5 of the Poultry Products Inspection Act. Matters to be discussed include residue monitoring, proposed product standards, and other matters relating thereto.

This meeting is open to the public but space and facilities are limited. Comments of interested persons may be filed with the Committee before or after the meeting.

Information pertaining to the meeting may be obtained from James K. Payne, Room 4863-South, Department of Agriculture, 14th and Independence Avenue, SW., Washington, D.C. 20250 (telephone: 202/447-4565).

Dated: November 15, 1973.

F. J. FULLERTON,
Executive Secretary.

[FR Doc.73-24713 Filed 11-19-73;8:45 am]

Packers and Stockyards Administration

WALKERTON LIVESTOCK SALES, INC., ETNA GREEN, INDIANA, ET AL.

Deposting of Stockyards

It has been ascertained, and notice is hereby given, that the livestock markets named herein, originally posted on the respective dates specified below as being subject to the Packers and Stockyards Act, 1921, as amended (7 U.S.C. 181 et seq.), no longer come within the definition of a stockyard under said Act and are, therefore, no longer subject to the provisions of the Act.

Facility No., name, location of stockyard, and date of posting

IN-151 Walkerton Livestock Sales, Inc., Etna Green, Indiana, Dec. 9, 1971.
IN-136 Rushville Community Sale Barn, Rushville, Indiana, Apr. 22, 1959.
IA-135 Decorah Sales Commission, Decorah, Iowa, June 6, 1959.
ME-103 Central Maine Livestock Auction, Randolph, Maine, Nov. 30, 1959.
OK-188 Poor Boy Cattle Company, Wister, Oklahoma, Aug. 14, 1972.
TX-168 Floresville Livestock Commission Co., Floresville, Texas, Mar. 6, 1959.

Notice or other public procedure has not preceded promulgation of the foregoing rule. There is no legal justification for not promptly deposting a stockyard which is no longer within the definition of that term contained in the Act.

The foregoing is in the nature of a rule relieving a restriction and may be made effective in less than 30 days after publication in the FEDERAL REGISTER. This notice shall become effective on November 20, 1973.

(42 Stat. 159, as amended and supplemented (7 U.S.C. 181 et seq.).)

Done at Washington, D.C. this 12th day of November 1973.

EDWARD L. THOMPSON,
Chief, Registrations, Bonds, and Reports Branch, Livestock Marketing Division.

[FR Doc. 73-24672 Filed 11-19-73;8:45 am]

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

BIOSYSTEMS RESEARCH DEPARTMENT

Application for Scientific Research Permit; Notice of Public Hearing

Notice is hereby given that, as authorized by Section 216.34(b) of the regulations governing the taking and importing of marine mammals (38 FR 22133, 22138, August 14, 1973), a hearing will be held at 10:00 a.m., local time, December 13, 1973, in the penthouse conference room, National Marine Fisheries Service, Page Building No. 1, 2001 Wisconsin Avenue NW., Washington, D.C. 20007. The purpose of the hearing is to consider an application for a permit from the Biosystems Research Department, Naval Undersea Center, United States Navy, San Diego, California 92132, to take 275 cetaceans and 36 pinnipeds over a period of two years, and all available stranded, beached, sick, and injured cetaceans and California sea lions, for scientific research.

Individuals and organizations may express their views or opinions by appearing at this hearing or by submitting written comments for inclusion in the record either to the Director, National Marine Fisheries Service, Washington, D.C. 20235, or to the Regional Director, National Marine Fisheries Service, Duval Building, 9450 Gandy Boulevard, St. Petersburg, Florida 33702, or to the Regional Director, National Marine Fisheries Service, 300 South Ferry Street, Terminal Island, California 90731. Any inquiries with respect to this hearing should be directed to the Director, or to the above Regional Directors. Written comments will be accepted for the official record provided they are postmarked or received no later than midnight on January 13, 1974.

JOSEPH W. GEHRINGER,
Acting Director, National Marine Fisheries Service.

NOVEMBER 15, 1973.

[FR Doc.73-24673 Filed 11-19-73;8:45 am]

SEA LIFE AND SEA WORLD, INC.

Marine Mammal Protection Act, Receipt of Applications for Display Permits

Notice is hereby given that the following applicants have applied for public display permits as authorized by section 101(a)(1) of the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361, et seq.) and § 216.12 of the regulations governing the taking and importing of

marine mammals (37 FR 28177, December 21, 1972) and pursuant to the instructions for preparing applications for permits (38 FR 26622, September 24, 1973).

The Secretary considers the following applications sufficient under the provisions of § 216.15(a) of the regulations.

1. Sea Life, Incorporated, Makapuu Point, Waimanalo, Hawaii 96795. The applicant states that:

(a) They wish to capture and hold for public display the following:

Scientific name	Common name	No.
Stenella longirostris	Spinning dolphin	17
Steno bredanensis	Rough-toothed dolphin.	5
Tursiops gilli	Pacific bottle-nose dolphin.	8
Pseudorca crassidens	False killer whale	3
Globicephala macrorhyncha	Pilot whale	3
Feresa attenuata	Pygmy killer whale.	4
Ziphius cavirostris	Cuvier's beaked whale.	2
Grampus griseus	Risso's dolphin	2
Zalophus californianus	California sea lion	14
Phoca vitulina	Harbor seal	4
Hydrurga leptonyx	Leopard seal	2
Mirounga angustirostris	Elephant seal	2

(b) Location of Capture.

All cetacea will be captured near the Hawaiian Islands of Maui, Lanai, Molokai, and Oahu.

California sea lions, elephant seals, harbor seals, and leopard seals will be captured by contractors at unspecified locations. The contractors involved are experienced and competent.

(c) Time of taking will be as weather permits.

(d) After capture, the animals will be transported to Sea Life's facilities in Hawaii for training prior to use as active display elements of the Sea Life program. The animals captured under contract would be acclimatized to captivity prior to transport to Hawaii.

(e) Manner of Taking.

All cetaceans will be captured using a "hoop net."

2. Sea World, Incorporated, 1720 South Shores Road, San Diego, California. The applicant states that:

(a) They wish to capture, transport, and hold for public display five adult or sub-adult male northern elephant seals, *Mirounga angustirostris*.

(b) Location of capture would be offshore Mexican Islands in the Pacific Ocean off Baja California or offshore California islands.

(c) The tentative dates of capture will be between the date of permit and March 30, 1974.

(d) The manner of taking will be by beach hoop net or by direct herding of an animal into a transport enclosure.

(e) Animals will be transported to Sea World via the large commercial fishing boat *Louson*. The animals will be cared for by a veterinarian during capture, transport, and display.

(f) The animals will be acclimated at Sea World, San Diego, and then transported by airplane to the display facility at Sea World, Florida.

Documents submitted in connection with these applications are available as follows:

All documents will be available at the Office of the Director, National Marine Fisheries Service, Washington, D.C. 20235, and at the Regional Director's Office, National Marine Fisheries Service, Terminal Island, California.

Documents concerning Sea World's application will also be available at the Regional Director's Office, National Marine Fisheries Service, St. Petersburg, Florida.

Concurrent with publication of this notice in the FEDERAL REGISTER, the Director, National Marine Fisheries Service, is sending copies of the applications to the Marine Mammal Commission and the Committee of Scientific Advisors.

Pursuant to § 216.15 of the regulations governing the taking and importing of marine mammals, interested parties may submit written data or views on these applications on or before December 20, 1973. Comments should be sent to the Director, National Marine Fisheries Washington, D.C. 20235.

JOSEPH W. GEHRINGER,
Acting Director,
National Marine Fisheries Service.

NOVEMBER 15, 1973.

[FR Doc.73-24674 Filed 11-19-73;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of Education

DESEGREGATION OF PUBLIC EDUCATION

Notice of Acceptance of Applications

The Commissioner of Education hereby gives notice that pursuant to title IV of the Civil Rights Act of 1964 (78 Stat. 241, 20 U.S.C. 2000c–2000c–9) applications are being accepted from State educational agencies, institutions of higher education, and school districts for contracts or grants under sections 403, 404, and 405 of the Act for the purpose of technical assistance, training institutes, and employment of advisory specialists in connection with plans or programs for the desegregation of public elementary and secondary schools. Applications for General Assistance Centers under section 403 of the Act (45 CFR 180.21 of the implementing regulations) are not covered by this notice. Contracts for General Assistance Centers will be governed by the Federal Procurement Regulations, and a Notice of Request for Proposal will be published in the Commerce Business Daily.

Contracts are to be awarded under section 403 of the Act to State educational agencies for the purpose of rendering technical assistance to desegrating or desegregated school districts. Institutions of higher education may apply for grants under section 404 of the Act for the purpose of conducting institutes designed to improve the ability of public school personnel to deal effectively with educational problems incident to desegregation. Grants are also to be awarded under section 405 of the Act to school districts for the purpose of employing specialists to advise on problems incident to desegregation and (in certain limited instances) to conduct inservice training for public school personnel.

Applications for contracts or grant awards as described above must be received by the appropriate Regional Office of Education on or before December 26, 1973, unless such 35th day is a Saturday, Sunday, or Federal holiday, in which case applications must be received by the next following business day. Contract and grant awards will be announced on or about February 8, 1974.

An application sent by mail will be considered to be received on time by the appropriate regional office if:

(1) The application was sent by registered or certified mail not later than the fifth calendar day prior to the closing date (or if such fifth calendar day is a Saturday, Sunday, or Federal holiday, not later than the next following business day), as evidenced by the U.S. Postal Service postmark on the wrapper or envelope, or on the original receipt from the U.S. Postal Service; or

(2) The application is received on or before the closing date by either the Department of Health, Education, and Welfare, or the U.S. Office of Education mail rooms in the appropriate regional office. (In establishing the date of receipt, the Commissioner will rely on the time-date stamp of such mail rooms or other documentary evidence of receipt maintained by the Department of Health, Education, and Welfare, or the U.S. Office of Education.)

Funds will be available pursuant to this notice for authorized activities commencing no earlier than July 1, 1974, and terminating no later than June 30, 1975.

Awards under sections 403, 404, and 405 of the Act will be subject to the regulation in 45 CFR Part 180, as published in the FEDERAL REGISTER June 20, 1973 (38 FR 16065) as such part is or may be amended prior to the award of such assistance. Assistance under sections 404 and 405 of the Act will also be subject to the Office of Education General Provisions Regulations in 45 CFR Part 100, as published in the FEDERAL REGISTER November 6, 1973 (38 FR 30654) as such part is or may be amended prior to the award of assistance.

(Catalog of Federal Education Assistance Programs No. 13.405 Civil Rights Technical Assistance and Training.)

Dated November 15, 1973.

JOHN OTTINA,
U.S. Commissioner of Education.

[FR Doc.73-24770 Filed 11-19-73;8:45 am]

EMERGENCY SCHOOL AID

Notice of Acceptance of Applications

The Commissioner of Education hereby gives notice that pursuant to title VII of Pub. L. 92-318, the Emergency School Aid Act, applications are being accepted from local educational agencies and other public and nonprofit private applicants for basic grants under section 706(a) of the Act, pilot projects under section 706(b) of the Act, projects to be

carried out by public or nonprofit private applicants under section 708(b) of the Act, bilingual/bicultural projects under section 708(c) of the Act, educational television projects under section 711 of the Act, and special reading projects under section 708(a) of the Act.

Basic grants or contracts, pilot projects, and public or nonprofit private projects. Applications for assistance under sections 706(a), 706(b), and 708(b) of the Act must be received by the appropriate Regional Office of Education on or before December 26, 1973, unless such 35th day is a Saturday, Sunday, or Federal holiday, in which case applications must be received by the next following business day. Grant or contract awards will be announced on or about March 15, 1974.

Bilingual/bicultural projects. Applications for assistance under section 708(c) of the Act must be received by the appropriate Regional Office of Education on or before the 35th day following publication of this notice in the FEDERAL REGISTER, unless such 35th day is a Saturday, Sunday, or Federal holiday, in which case applications must be received by the next following business day. Grant or contract awards will be announced on or about March 15, 1974.

Educational television projects. Applications for assistance under section 711 of the Act must be received on or before February 15, 1974. Announcement of grant awards will be made on or about April 6, 1974. Such applications should be submitted to U.S. Office of Education, Application Control Center, 7th & D Streets SW., ROB-3, Room 5673, Washington, D.C. 20202.

Special reading projects. Applications for special reading projects under section 708(a) of the Act must be received on or before February 15, 1974. Grant or contract awards will be announced on or about April 6, 1974. Such applications should be submitted to U.S. Office of Education, Application Control Center, 7th & D Streets SW., ROB-3, Room 5673, Washington, D.C. 20202.

Recipt procedure. An application sent by mail will be considered to be received on time by the regional office or the Application Control Center, as appropriate if:

(1) The application was sent by registered or certified mail not later than the fifth calendar day prior to the closing date (or if such fifth calendar day is a Saturday, Sunday, or Federal holiday, not later than the next following business day), as evidenced by the U.S. Postal Service postmark on the wrapper or envelope, or on the original receipt from the U.S. Postal Service; or

(2) The application is received on or before the closing date by either the Department of Health, Education, and Welfare, or the U.S. Office of Education mail rooms, in the regional office, or in Washington, D.C., as appropriate. (In establishing the date of receipt, the Assistant Secretary will rely on the time-date stamp of such mail rooms or other documentary evidence of receipt maintained by the Department of Health, Education, and Welfare, or the U.S. Office of Education.)

Project periods. Funds will be awarded on the above mentioned dates (except for educational television projects) for authorized activities commencing no earlier than July 1, 1974, and terminating no later than June 30, 1975.

Applicable regulations. Awards under sections 706(a), 706(b) and 708(b) will be subject to 45 CFR Part 185, as such part appeared in the FEDERAL REGISTER on February 6, 1973 (38 FR 3450). Awards under sections 708(c), 711, and 708(a) will be subject to the amendments to 45 CFR Part 185 as such amendments appeared in the FEDERAL REGISTER on April 24, 1973 (38 FR 10092). Awards under all sections of the Act shall be subject to such amendments to 45 CFR Part 185 as may be made in the future. Awards under all sections of the Act as described above are subject to the Office of Education General Provisions Regulations of 45 CFR Part 100 as published in the FEDERAL REGISTER November 6, 1973 (38 FR 30654).

(20 U.S.C. 1609(a))

(Catalog of Federal Education Assistance Programs Nos. 13.525 Emergency School Aid—Basic Grants, 13.526 Emergency School Aid—Pilot Projects, 13.528 Emergency School Aid—Bilingual Projects, 13.529—Emergency School Aid—Nonprofit Organizations, 13.530 Emergency School Aid—Educational Television, 13.532 Emergency School Aid—Special Projects)

Dated: November 15, 1973.

JOHN OTTINA,
U.S. Commissioner of Education.

[FR Doc.73-24771 Filed 11-19-73;8:45 am]

EMERGENCY SCHOOL AID

Notice of Public Meeting

Notice is hereby given, pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), that the National Advisory Council on Equality of Educational Opportunity will meet from 8 a.m. until 4 p.m. Thursday, December 13 and 9 a.m. until 4 p.m. Friday, December 14, in Room 406, U.S. Office of Education, 50 Fulton Street, San Francisco, California.

The National Advisory Council on Equality of Educational Opportunity is established under section 716 of the Emergency School Aid Act (Pub. L. 92-318, Title VII). The Council is established to advise the Assistant Secretary for Education with respect to the operation of programs under the Act, and to review the operation of such programs.

The meeting of the Council shall be open to the public. The proposed agenda includes Subcommittee Reports, a review of the Site Visitation Evaluation Survey, and a Legislative Report with recommendations.

Signed at Washington, D.C., on November 16, 1973.

HERMAN R. GOLDBERG,
Associate Commissioner, Bureau of Equal Educational Opportunity.

[FR Doc.73-24831 Filed 11-19-73;9:26 am]

DEPARTMENT OF TRANSPORTATION

Coast Guard

[CGD 73 263N]

NEW YORK HARBOR VESSEL TRAFFIC SYSTEM ADVISORY COMMITTEE

Notice of Open Meeting

This is to give notice pursuant to Public Law 92-463, Sec. 10(a), approved October 6, 1972, that the New York Harbor Vessel Traffic System Advisory Committee will conduct an open meeting on Thursday, December 13, 1973, in the Auditorium of Building 108, Governors Island, New York beginning at 10:30 a.m.

Members of the Committee and their industry positions are:

Admiral John M. Will, USN (Ret.)
State of New York Board of Commissioners of Pilots
Captain H. C. Breitenfeld
United New York Sandy Hook Pilots' Benevolent Association
Captain W. H. Burrill
State of New Jersey Board of Commissioners of Pilots
Mr. Richard Dewling
U.S. Environmental Protection Agency
Captain L. T. Earl
United New Jersey Sandy Hook Pilots' Benevolent Association
Mr. A. Giallorenzi
American Institute of Merchant Shipping—Petroleum Industry Representative
Mr. Alfred Hammon
Port Authority of New York and New Jersey
Captain T. A. King
U.S. Department of Commerce, Maritime Administration
Commodore F. Lindner
Long Island Sound Commodores Association
Colonel H. W. Lombard, USA
Department of the Army, Corps of Engineers
Mr. Robert W. Sanders
New York Harbor Panel, Marine Towing and Transportation Industry
Captain R. D. Sante, USN
U.S. Navy, Military Sealift Command
Captain S. M. Seledee
American Institute of Marine Underwriters
Captain J. G. Stillwaggon
Interport Pilots' Associates, Inc.
Captain K. C. Torrens
American Institute of Merchant Shipping

The agenda for the December 13, 1973 meeting consists of:

1. Report of the Executive Committee given by Captain K. C. Torrens, Chairman of the Executive Committee.

2. Report from the Long Island Sound Sub-Committee given by Captain D. M. Kennedy, Chairman of the Long Island Sound Sub-Committee.

3. Report from the Hudson River Sub-Committee given by Captain H. C. Breitenfeld, Chairman of the Hudson River Sub-Committee.

4. Report from the New York Vessel Traffic System Staff on:

a. The revised Implementation Schedule.

b. The R&D Radar Van Deployment.

c. The decision for the Vessel Traffic Center location.

d. The progress of the Communications Questionnaire.

5. Comments from the floor.

The New York Harbor Vessel Traffic System Advisory Committee was established by the Commander, Third Coast Guard District on April 1, 1973, to advise on the need for, and development, instal-

lation and operation of a Vessel Traffic System for the New York Harbor. Public members of the Committee serve voluntarily without compensation from the Federal Government, either travel or per diem.

Interested persons may seek additional information by writing Commander H. A. Pledger, Project Officer, Vessel Traffic System, Third Coast Guard District, Governors Island, New York 10004, or by calling 212–264–0409.

Dated: November 8, 1973.

G. W. WAGNER,
Captain, U.S. Coast Guard, Acting Commander, Third Coast Guard District.

[FR Doc.73–24616 Filed 11–19–73;8:45 am]

National Highway Traffic Safety Administration

NATIONAL HIGHWAY SAFETY ADVISORY COMMITTEE

Notice of Public Meeting

On November 26 and 27, 1973, the National Highway Safety Advisory Commitee will hold open meetings in Arlington, Virginia, and Washington, D.C.

The National Highway Safety Advisory Committee is composed of 35 members appointed by the President in accordance with the Highway Safety Act of 1966 (23 U.S.C. 401 et seq.). The Committee consists of representatives of State and local governments, State legislatures, public and private interests contributing to, affected by, or concerned with highway safety, other public and private agencies, organizations, and groups demonstrating an active interest in highway safety, and research scientists and other experts in highway safety.

The Advisory Committee advises, consults with, and makes recommendations to the Secretary of Transportation on matters relating to the activities of the Department in the field of highway safety. The Committee is specifically authorized (1) to review research projects or programs, and (2) to review, prior to issuance, standards proposed to be issued by the Secretary under the national highway safety program.

The following meetings will be held, subject to approval by the Secretary of Transportation:

The full Committee will meet from 9:00 a.m. to 10:00 a.m. on November 26 in the Capital View Ballroom-West of the Quality Inn Hotel, 300 Army-Navy Drive, Arlington, Virginia, with the following agenda:

Opening of General Session
Report of Executive Subcommittee
Trip Reports

From 10:10 a.m. to 12:00 noon the Ad Hoc Task Force on Adjudication will meet in Parlor B, Quality Inn Hotel, with the following agenda:

Review of N–7—Traffic Courts & Adjudication Systems
Review of New York Task Force Meeting
Mandatory Sentencing for DWI Convictions

From 10:10 a.m. to 12:00 noon the Subcommittee on Research and Program Development will meet in the Capital View Ballroom-West of the Quality Inn Hotel with the following agenda:

Standards Revision
Ad Hoc Committee on Driver Education
Review of N–4—Traffic Safety Education

The Subcommittee on Research and Program Development will continue its meeting on November 26 from 1:30 p.m. to 4:30 p.m. in the Capital View Ballroom-West with the following agenda:

Standards Revision

The Subcommittee on Standards Implementation will meet on November 26 from 1:30 p.m. to 4:30 p.m. in Parlor B with the following agenda:

Legislative Liaison
Driver License Revocation
DOT Replies to May 1973 Resolutions

On November 27 the Full Committee will meet in Room 2232 of the DOT Headquarters Building, 400 Seventh Street SW., Washington, D.C., from 9:00 a.m. to 12:00 noon with the following agenda:

Opening Remarks.
Swearing In of New Members.
Award Ceremonies.
Report of Adjudication Task Force.
Status Report—Alcohol Countermeasures Program.
Report of Subcommittee on Research and Program Development.
Dimensions of Bike Safety.
Report of Subcommittee on Standards Implementation.
New Business.

Further information may be obtained from the Executive Secretariat, National Highway Traffic Safety Administration, Department of Transportation, 400 Seventh Street SW., Washington, D.C. 20590, 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: November 13, 1973.

CALVIN BURKHART,
Executive Secretary.

[FR Doc.73–24692 Filed 11–19–73;8:45 am]

ATOMIC ENERGY COMMISSION

[Docket No. 50–201]

NUCLEAR FUEL SERVICES, INC.

Application for Construction Permit

The Atomic Energy Commission has received an application dated October 3, 1973, submitted by Nuclear Fuel Services Inc. (NFS) for appropriate amendments, including any construction permit that may be required, to the provisional operating license for its fuel reprocessing plant at West Valley, New York, which license was issued pursuant to section 104b. of the Atomic Energy Act of 1954, as amended (the Act). The amendments sought would authorize certain modifications of the plant and authorize operation for a term of forty years.

Section 102 of the Act requires any license issued for a utilization or production facility for industrial or commercial purposes to be issued pursuant to section 103, except, among others, a license for such a facility the construction of which was licensed pursuant to subsection 104b. prior to enactment of Public Law 91–560 (December 19, 1970). An application for a license to construct or operate a facility under section 103 is subject to the requirements of section 105c. of the Act for prelicensing antitrust review; an application under section 104b. is not, with certain exceptions not pertinent here, subject to such prelicensing antitrust review.

The NFS application has been reviewed to determine whether it should be treated as an application under section 104b. or whether the modifications of the facility contemplated by the amendments will result in a substantially different facility which should be licensed pursuant to section 103. It has been concluded that the modifications of the facility which the amendments contemplate will result in a substantially different facility. A principal factor considered in reaching this determination was the fact that the capacity of the facility would increase from 300 MTU/year to approximately 750 MTU/year. Such proposed modifications would result in a significant enlargement of NFS' share of the industry reprocessing capacity.

Accordingly, the application of Nuclear Fuel Services will be processed in accordance with the requirements of section 103 of the Act, as amended, and the Commission's regulations pertaining to applications for a license pursuant to section 103.

(Sec. 105c., Pub. L. 91–560, 84 Stat. 1472; sec. 161, Pub. L. 83–703, 68 Stat. 948 (42 U.S.C. 2135, 2201).)

Dated at Bethesda, Md., this 13th day of November 1973.

For the Atomic Energy Commission.

L. MANNING MUNTZING,
Director of Regulation.

[FR Doc.73–24642 Filed 11–19–73;8:45 am]

[License 31–15819–01E]

SELF-POWERED LIGHTING, LTD.

Notice of Issuance of Byproduct Material License

Please take notice that the Atomic Energy Commission has, pursuant to § 32.22 of 10 CFR Part 32, issued License No. 31–15819–01E to Self-Powered Lighting, Limited, 629 Fifth Avenue, Pelham, New York 10803, which authorizes the distribution of gunsight illuminators contained in gunsights mounted on hand guns to persons exempt from the requirements for a license pursuant to § 30.19 of 10 CFR Part 30.

1. The devices are designed to illuminate gunsights mounted on hand guns permitting greater sighting accuracy in low ambient light.

2. The byproduct material incorporated in the device is tritium in Betalights manufactured by Self-Powered Lighting, Limited (Model XPM 62/G/250). The nominal activity contained in the Betalight is 30 millicuries but the maximum activity is 33.3 millicuries. There

are three Betalights and thus a maximum of 100 millicuries per gun.

3. Each gun equipped with a gunsight illuminator will be labeled to identify the manufacturer (SPL, Ltd.) and the by-product material (^3H) contained in the device.

A copy of the license and a safety evaluation containing additional information, prepared by the Directorate of Licensing, are available for public inspection at the Commission's Public Document Room at 1717 H Street NW., Washington, D.C.

Dated at Bethesda, Md.

For the Atomic Energy Commission.

JAMES C. MALARO,
Chief Materials Branch Directorate of Licensing Regulation.

NOVEMBER 12, 1973.

[FR Doc.73-24677 Filed 11-19-73;8:45 am]

ADVISORY COMMITTEE ON REACTOR SAFEGUARDS SUBCOMMITTEE ON ELECTRICAL SYSTEMS, CONTROL AND INSTRUMENTATION

Notice of Meeting

NOVEMBER 16, 1973.

In accordance with the purposes of section 29 and 182.b. of the Atomic Energy Act (42 U.S.C. 2039, 2232b), the Advisory Committee on Reactor Safeguards Subcommittee on Electrical Systems, Control and Instrumentation will hold a meeting on November 28, 1973, in Room 1062, 1717 H Street NW., Washington, D.C. The subject scheduled for discussion is a proposed Regulatory Guide concerning the physical independence of electric systems.

The Subcommittee is meeting to formulate recommendations to the ACRS regarding the above subject.

I have determined, in accordance with subsection 10(d) of Pub. L. 92-463, that the purpose of the meeting will be to discuss draft documents which fall within exemption (5) of (5 U.S.C. 552(b)) and will consist of an exchange of opinions, the discussion of which, if written, would fall within exemption (5) of (5 U.S.C. 552(b)). It is essential to close such meetings to protect the free interchange of internal views and to avoid undue interference with agency and Committee operation.

ROBERT A. KOHLER,
Acting Advisory Committee Management Officer.

[FR Doc. 73-24863 Filed 11-19-73;10:56 am]

[Docket No. 50-271]

VERMONT YANKEE NUCLEAR POWER CORP.

Determination With Respect to Further Action Regarding Vermont Yankee Nuclear Power Station

On October 15, 1973, the Union of Concerned Scientists and the New England Coalition on Nuclear Pollution filed with the Commission a "Joint Petition for Immediate and Indefinite Shutdown of Vermont Yankee Nuclear Power Station and Pilgrim Nuclear Power Station" (the petition). In substance, the petition alleges that defects in fuel channel walls have been observed in the Vermont Yankee reactor and in the KKM reactor in Europe; that the observed defects in Vermont Yankee and KKM are similar and appear to be associated with a design feature common to those reactors and the Pilgrim facility; and that the safety questions posed by these defects are such that neither Vermont Yankee nor Pilgrim should be permitted to operate pending further evaluation. By Order dated October 23, 1973, the Commission, after noting that "[m]aterials on file in the Commission's Public Document Room show that the regulatory staff was aware of the problem, was reviewing it, and was taking action prior to receipt of the petition", treated the petition as a request for the issuance of an order to show cause pursuant to 10 CFR 2.202 and instructed the Director of Regulation to determine whether further action, including any shutdown, is appropriate as an emergency matter; to announce that determination, together with supporting reasons, on or before October 26, 1973 and publish it in the FEDERAL REGISTER as soon as possible thereafter; to provide, in the same notice, for the submission of views by licensees and any interested persons on or before December 5, 1973; and, after receipt of such views, to make a determination, together with supporting reasons, as to whether further actions or proceedings are warranted.

On October 26, 1973, the Director of Regulation, in compliance with the Commission's Order of October 23, 1973, issued a "Determination With Respect to Need for Emergency Action, Notice of Consideration of Need for Further Actions or Proceedings, and Request for Submission of Views". In that Determination, which was published in the FEDERAL REGISTER on October 31, 1973 (38 FR 30048), the Director of Regulation noted that the Vermont Yankee facility was at that time shut down for reasons unrelated to fuel channel box damage; that the licensee had represented to AEC regulatory staff that the facility would remain shut down until the fuel channel box damage had been repaired and the cause of the damage corrected; and that, consequently, there was no need for any shut down or other emergency action respecting Vermont Yankee. The determination also invited the submission, by November 15, 1973, of the views of the licensees and any interested persons.

The observations of damaged channels in the Vermont Yankee core and in the KKM facility and the cause of the damage were discussed in a "Safety Evaluation by the Directorate of Licensing, U.S. Atomic Energy Commission, Relating to Channel Box Wear in the Vermont Yankee Nuclear Power Station and the Pilgrim Nuclear Power Station," which was issued on October 26, 1973 in further support of the Director of Regulation's Determination of that date. As noted therein, the damage to the channel boxes was found to be caused by vibration of the temporary control curtains due to the high velocity flow of coolant exiting from bypass flow holes in the core support plate. That flow impinged on the control curtain blade and caused the entire curtain to vibrate. Because of the vibration, the stainless steel curtain stiffner contacted the channel box and caused wear and fretting of the zircaloy channel.

In response to the Determination published in the FEDERAL REGISTER on October 31, 1973, comments have been filed by the Union of Concerned Scientists and the New England Coalition on Nuclear Pollution, the Vermont Yankee Nuclear Power Corporation, and the Boston Edison Company. The comments of the Union of Concerned Scientists, and the New England Coalition on Nuclear Pollution, are addressed "principally to the Pilgrim reactor," and the comments of Boston Edison Company relate only to the Pilgrim reactor. The submission of views of Vermont Yankee Nuclear Power Corporation includes (1) a request for Proposed Change No. 16 to the Technical Specifications of the Vermont Yankee facility, dated November 6, 1973; (2) a letter, dated November 13, 1973, which, in substance, urges adoption of the licensee's previously submitted Proposed Change No. 16; and (3) a telegram, dated November 15, 1973, in which the licensee stated, among other things, that for each day of delay in return to power, beginning Friday, November 16, 1973, an additional 30,000 barrels of fuel oil will be consumed in the New England Area. The State of Vermont, as communicated to the AEC regulatory staff by telephone on November 15, 1973, believes that the Vermont Yankee facility should not be permitted to resume operation before staff has issued a Safety Evaluation of Proposed Change No. 16 and interested parties have had an opportunity to comment thereon.

All of these views have been considered to the extent they are pertinent to a determination of the need for further actions or proceedings, including the issuance of an order to show cause. With respect to the State of Vermont's comment, the staff believes, based on the Safety Evaluation referred to below and the need to conserve energy resources, that the proper course of action is to permit the resumption of operation simultaneously with the issuance of this determination.

Proposed Change No. 16 contained a "Summary Report on Vermont Yankee Channel Wear Investigation and Corrective Measures Taken" in which the licensee described the problem involved; the inspection, analysis, and testing done to determine the cause of the damage and develop a solution to it; and its proposed solution. On November 16, 1973, a "Safety Evaluation By the Directorate of Licensing, Vermont Yankee Nuclear Power Corporation, Docket No. 50-271, Change No. 12 to the Technical Specifications" was issued by the AEC regula-

tory staff. The Safety Evaluation sets forth the AEC regulatory staff's conclusion based on observation of the fuel channels and control curtains at Vermont Yankee, and flow tests performed at GE, that the observed damage was caused by flow-induced vibration of the control curtains, and that such damage to the Vermont Yankee reactor can be prevented in the future by plugging the bypass flow holes, the source of the flow which vibrates the curtains. The damaged fuel channels in the Vermont Yankee core have been replaced with new fuel channels. All of the fuel channels which are adjacent to a control curtain stiffener and therefore subject to possible damage by vibration of the curtain have been inspected. In addition, approximately 20% of the remaining fuel channels have been inspected. Based on these inspections, all channels which experienced wear of greater than 0.010 inch on the corners have been replaced with new fuel channels. The staff also concludes that the design and installation method of the bypass plugs as proposed by the licensee and modified by staff does not present a significant hazards consideration and finds there is reasonable assurance that the health and safety of the public will not be endangered by operation of the reactor as proposed.

Accordingly, the Director of Regulation has determined that the matter of channel box wear in the Vermont Yankee Nuclear Power Station has been resolved and that consequently there is no need to undertake further actions or proceedings, including the issuance of an order to show cause, with respect to this problem. The licensee may resume operation of the Vermont Yankee facility in accordance with the provisions of the license and the amended Technical Specifications issued this date pursuant to the provisions of 10 CFR 50.59. The reasons supporting this determination are set forth in detail in the Directorate of Licensing's Safety Evaluation dated November 16, 1973.

The Director of Regulation will consider any further comments received in regard to the Determination of October 26, 1973, this Determination or the action being taken with respect to the Vermont Yankee Nuclear Power Station, with a view to possible amendment of the instant Determination, and with respect to action to be taken regarding the Pilgrim Nuclear Power Station.

On or before December 20, 1973, the licensee may file a request for a hearing with respect to the action authorized and any person whose interest is affected may file a petition for leave to intervene. Requests for a hearing and petitions for leave to intervene shall be filed in accordance with the Commission's rules of practice in 10 CFR Part 2.

Copies of (1) the Safety Evaluation; (2) the note to the files concerning the telephone conversation of November 15, 1973 with a representative of the State of Vermont; and (3) the views submitted by licensees and interested persons in response to the Director of Regulation's Determination of October 26, 1973 are being made available for public inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, D.C.; and at the Brooks Memorial Library, 224 Main Street, Brattleboro, Vermont. Copies of the Safety Evaluation may be obtained upon request directed to the Director of Licensing, United States Atomic Energy Commission, Washington, D.C. 20545.

Dated at Bethesda, Md., this 16th day of November 1973.

LEE V. GOSSICK,
Acting Director of Regulation.

[FR Doc.73-24862 Filed 11-19-73;10:55 am]

AD HOC ADVISORY GROUP ON PUERTO RICO

DELIBERATIONS OF SELF-GOVERNMENT

Notice of Public Hearings

The Ad Hoc Advisory Group on Puerto Rico will hold one day of public hearings from 9:30 a.m. to 12 noon and from 2 p.m. to 5 p.m. as follows, unless the Co-Chairman extend the time: Saturday, December 8, 1973, the Capitol Building, San Juan, Puerto Rico.

The purpose of the public hearings is to permit any interested persons to participate with the Advisory Group in its deliberations on the maximum of self-government for Puerto Rico within the framework of Commonwealth.

In order to insure maximum participation, the Ad Hoc Advisory Group will use the following procedure: All who wish to testify should file, in our office, either at 1016 16th Street NW., Washington, D.C. 20036, or Room 802 Treasury Building, San Juan, Puerto Rico, on or before November 30, 1973, one (1) copy of the statement, either handwritten or typed, they wish to present to the Ad Hoc Advisory Group. The statement should also give the name, address, and any organization the witness may represent. The statement and the testimony may be presented either in Spanish or in English.

PETER J. GALLAGHER,
Executive Director.

[FR Doc.73-24691 Filed 11-19-73;8:45 am]

CIVIL AERONAUTICS BOARD

[Docket No. 25280; Order 73-11-48]

INTERNATIONAL AIR TRANSPORT ASSOCIATION

Order Regarding Cargo Rate Matters

NOVEMBER 12, 1973.

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., on the 12th day of November 1973.

By Order 73-9-30, September 10, 1973, the Board established procedural dates for the receipt of justification, comments, and replies concerning, among other things, certain resolutions adopted by the Composite Traffic Conference of the International Air Transport Association (IATA) in May/June 1973 at Mexico City.[1] The Board addressed itself specifically to Resolutions 503 (Charges in Relation to Value); 511 (Rates for Live Animals); 508 (Charges for Stalls); 509 (Charges for Disbursements); and 512a (C.O.D. Procedures).

The Board has long held that excess-value charges in foreign air transportation should be assessed only on that amount by which a shipment's value exceeds the carrier's limit of liability under terms of the Warsaw Convention, and that any valuation charges should be cost-justified. Resolution 503 (Charges in Relation to Value) would now establish a valuation charge of 0.40 percent of that portion of the shipper's declared value for carriage which exceeds the present basic Warsaw liability limit of $18.00 per kilogram, with the minimum charge per consignment set at $1.00. The carriers' excess-value charges presently in effect reflect charges which were established by prior IATA resolutions which were disapproved by the board by Order 72-6-137.

Resolution 511 (Rates for Live Animals) would b erevalidated in essentially its present form; generally speaking, live animals are carried at the general under-45 kg. cargo rate regardless of the weight of the consignment. Thus this traffic is charged a rate in excess of three times the basic rate depending on the spread of quantity discounts in the general cargo rate structure for a particular city pair.[2] On June 26, 1973, the Board concluded the Investigation of Premium Rates for Live Animals and Birds (Docket 21474) in U.S. domestic carriage, and in Order 73-6-103 found that the maximum lawful rates for cold-blooded animals are the general cargo rates, and the maximum lawful rates for warm-blooded animals are 110 percent of the general cargo rates.[3] In its procedural order, the Board saw no reason why the pertinent considerations would be any different in international air transportation, and said that in this light it appeared clear that the IATA-agreed rates for live animals, encompassing significant premiums were excessive on their face. A related IATA resolution, 508, establishes a charge for stalls used in carrying large animals which is calculated on the basis of the rate for a certain weight of the animal transported rather than the weight of the stall or pen. The Board also questioned this rate's relationship to the appropriate costs of service, and called for submission of full, adequate cost justification for both resolutions.

[1] The order also fixed procedural dates with reference to other IATA agreements directly involving cargo rates to/from United States points. This order deals only with resolutions adopted by the Composite Traffic Conference. Action on rates proposed to be applied in various world areas will be dealt with in separate orders.

[2] See examples in the Appendix.

[3] The Board denied petitions for reconsideration of its decision, by Order 73-8-68 (August 13, 1973).

Substantial increases are proposed for charges assessed under Resolution 509 (Charges for Disbursements) and Resolution 512a (C.O.D. Procedures). Resolution 509 presently specifies a charge to the consignee of three percent of any amount collected by the air carrier on behalf of a third party (such as a customs broker), or collected on behalf of the air carrier in connection with services performed prior to air carriage (such as cartage to the point of departure). This disbursement charge would now be increased to five percent, and the present $5.50 minimum would be raised to $10.00. Charges for C.O.D. services are proposed to be increased from two to four percent of the C.O.D. amount, while the minimum C.O.D. charge would now be $10.00 in place of the present $5.50.

The agreement would also revalidate and/or amend numerous other resolutions which affect air cargo transportation. A new resolution, 001x, would provide for a review of effective cargo rate agreements in April/May of 1974. Other changes would standardize and clarify certain rounding-off procedures for cargo rates, demurrage provisions in connection with unit load devices, references to rates in currency conversion resolutions, and provisions for the use of surface transportation. The agreement would also increase from $5.50 to $6.50 the charge for amendment of an air waybill after departure of the goods from the point of origin.

Statements of justification and support for one or more of these resolutions have been received from four of the nine U.S. carriers[4] who are active members of IATA. Joint objections to the live animal rates, and a reply to the pertinent carrier justifications, have been filed by the Pet Industry Parties.[5]

Pan American, TWA, and American have submitted material in support of the excess-value charges. Pan American contends that it is unreasonable to relate valuation charges solely to the liability and claims experience of the carriers, and goes on to cite certain security precautions taken to protect declared-value cargo from theft and pilferage. The carrier estimates these extra handling costs at $8.07 per shipment, and estimates the present average excess-valuation revenue per shipment at $13.00 per shipment. Under the proposed charge, Pan American estimates the average revenue per shipment at $7.85, for a net loss of $10.22 per shipment. No details are given as to the methodology employed for the cost estimate, and the only additional information in reference to the revenue estimates is that the $13.00 figure was arrived at from an unidentified two-month sample of 193 shipments with excess-valuation charges of $11,845.

TWA and American cite data generated by an international industry claims survey taken in connection with the Liability and Claims Rules and Practices Investigation, Docket 19923 et al., which showed annualized claims payments of $1.42 million on an industry basis due to excess value declaration, while corresponding excess-value revenues were $1.65 million.[6] The carriers allege that the $230,000 difference will be more than offset by the reduction in revenue under the proposed charge. TWA also refers to an analysis performed on international excess-value shipments extracted from a two-month (September-October 1971) claims survey which was submitted to the Board on October 10, 1972, after our approval of Resolution 503 had expired and tariff rejection notices had been issued. The analysis, which purported to show that a charge of 95 cents per $100 excess-value declaration was justified by TWA's claims experience, was rejected by the Board and Resolution 503 remained disapproved. TWA has now conducted a full year's survey of international excess-value claims and revenue (September 1972 through August 1973), and alleges that it will incur a net annual loss of $13,583.54 under the revised charge. Finally, the carrier states that a charge of 50 cents per $100 declaration is needed to cover claims expense, but that the proposed $1.00 minimum charge on excess-value declaration will partially offset the shortfall.

Pan American, TWA and Delta have responded to the Board's directive that the carriers submit justification for the IATA live animal rates. Pan American has also included support for Resolution 508 (Charges for Stalls). Pan American notes the Board's decision in the domestic live animal investigation, but takes the position that there is reason to differentiate between domestic and international carriage of live animals. Pan American alleges that the greater distances involved in international transportation increase the potential danger and discomfort to live animals and consequently necessitate greater care and more elaborate planning. Pan American also states that governmental health clearance and quarantine regulations impose added handling costs since the carriers must provide specially trained personnel and special quarantine holding pens.

In reference to Resolution 508 (Charges for Stalls) Pan American states that stalls for carrying large animals are expensive, in short supply and consequently must be constantly repositioned. The carrier also alludes to exceptional maintenance costs for these containers, including government regulations which require disinfection after each use.

TWA and Delta also make note of the domestic investigation in Docket 21474, and cite the greater length-of-haul in international transportation as justification for substantial premiums for warmblooded animals, since it is even more crucial than in domestic carriage that sufficient air space be provided around each animal container to prevent suffocation.[7] TWA also alleges that the longer international distances and transit times, and the more numerous connections, dictate a higher priority for live animals than in domestic carriage, and consequently a higher premium. TWA also makes claims similar to those advanced by Pan American in regard to additional handling costs due to health inspection regulations and the generally greater complexity of international documentation for live animals.

In support of the proposed increases in Charges for Disbursements (Resolution 509) and C.O.D. Charges (Resolution 512a) the four carriers responding (Pan American, TWA, Delta and American) take the general position that these ancillary services are a convenience to customers and require supplemental documentation and accounting procedures which impose additional costs on the carriers.

Specifically, Pan American indicates that the original intent of Resolution 509 was to provide a method of passing costs, which were directly related to the movement of the shipment and incurred prior to air transportation, along to the consignee for collection. Pan American states that this has been abused in recent years and is being used for other (unspecified) costs which ordinarily require normal banking transactions, and that consignees are not prompt in remitting monies due. Consequently, the charge must be raised to recover these added costs.

TWA lists several necessary communications and accounting services provided in connection with disbursements, and also adverts to a lag between disbursement by the carrier and collection of the corresponding amount (plus charge) from the consignee. Although no cost estimates are provided TWA also cites a recent unidentified survey of air waybills with disbursements over $50.00, which shows an average disbursement of $211.15. Whereas the present charge for this amount under Resolution 509 is $6.33 (three percent), the proposed charge would be $10.56 (five percent). Finally, TWA states that disbursement services are a convenience to customers and are not directly related to air transportation, and that the carriers' intent in raising the charges is to discourage use of this facility which imposes extra workload and cash requirements on the carriers.

In reference to C.O.D. procedures, Pan American states that this service represents a special, voluntary concession on the part of the carriers for consignees unable to use normal banking channels. Pan American believes the proposed increase in C.O.D. charges to be justified by improved communication procedudes which have been adopted to provide more

[4] American Airlines, Braniff International Airways, Delta Air Lines, Eastern Air Lines, National Airlines, Northwest Airlines, Pan American World Airways, Trans World Airlines, and The Flying Tiger Line.

[5] Twenty-two retail and wholesale live animal merchants who were parties to the Investigation of Premium Rates for Live Animals and Birds, Docket 21474.

[6] Survey results are estimates of the international operations of 13 U.S. carriers based on data submissions of American, Braniff, Delta and TWA.

[7] TWA states that its average international length of haul in 1972 was 4511 miles compared to 1070 miles for a domestic shipment by a trunkline carrier in 1971.

prompt payment of the C.O.D. amount to the shipper. TWA lists additional communication and accounting functions for C.O.D. shipments similar to those cited in connection with disbursements, and goes on to estimate their average amount to be collected is $1125.00 per C.O.D. shipment. On this basis the average present service charge is $22.50 at 2 percent, while the proposed four percent charge would average $45.00. Delta contends that the carriers' customers will still be advantaged by use of the carriers' money at fees far below the commercial rates of interest the carriers themselves are paying. Delta also cites domestic C.O.D. service charges ranging from three to five percent which carry minimums of $10.00 for $2000 shipments and $22.00 for $5000 shipments.

The Pet Industry Parties, in their complaint against the IATA live animal rates, point out that all but one of the U.S. carrier members of IATA were parties to the live animal investigation in Docket 21474, where similar issues on the domestic front were considered. In that case, based on an elaborate record of cost, operational and market requirements, it was decided that no premium for cold-blooded animals, and a maximum rate of 110 percent for warm-blooded animals, was justified in domestic live animal carriage. The Pet Industry Parties contend that establishment of a comparable record for the international area would reaffirm the Board's conclusions, and that no premium in excess of the domestic is justified. The IATA rates, it is alleged, bear no relationship to the service provided, the burdens imposed, or the costs incurred. The complainants also refer to additional anomalies in international live animal rates which represent premiums over and above the IATA-agreed rates. For example, American applies a flat 200-percent premium over the under-45 kg. general cargo rate for "Live Animals, N.E.S.," for "Monkeys and Primates," and 150 percent for "Baby Poultry" and for "Cats and Dogs." These and other "exceptions to exceptions" in live animal tariffs result in even more confusion to the shipper.

In a separate document filed in reply to the carriers' justifications, the Pet Industry Parties point out that inasmuch as only three of the U.S. carrier members of IATA have submitted justification for the IATA live animal rates, silence on the part of the others must be interpreted as acquiescence to the final decision of the Board in the domestic live animals investigation. The Parties reiterate their belief that there is no basic difference in the conditions of international as opposed to domestic carriage of live animals, and that the same rates should apply. They attack as spurious and unsupported the carriers' arguments that the greater stage lengths in international transportation require more air space around live animal containers and therefore justify greater premiums, and point out that the 110 percent premium rate set by the Board for warm-blooded animals in domestic carriage was based on other factors, i.e., ground handling costs and practices.[8]

In reference to Pan American's arguments pertaining to the stringency of government regulations and the special handling accorded international live animal shipments, the complainants state that there are government regulations outlining proper procedures for the importation of all sorts of commodities, many of which are inspected by the Public Health Service, and that not all live animals are so inspected upon importation. The Pet Industry Parties then claim that none of them have ever used Pan American's "special quarantine holding pens" or "specially trained personnel"—personnel the carrier cannot identify because they are not required by law and simply do not exist. The specially trained personnel who clear live animal shipments through the various regulatory processes are employees of a customs house broker or the shipper or consignee.

Finally, the complainants allege that TWA's assignment of a high priority to international live animal shipments to justify the unusual rate premium is patently inconsistent with that carrier's position in Docket 21474, where TWA assigned a lower priority to live animals in connection with advance arrangements and space requirements.[9]

American Airlines has submitted a letter in which it is alleged that some IATA carriers are interpreting Resolution 507 (Use of Surface Transportation) as allowing them to serve any U.S. city by truck even though that city is not included in the carrier's route authority. American claims that these carriers accept traffic at off-line points and then ship the traffic on their own waybills to gateways from which they have flights. The carrier requests that the Board, in approving the resolution, clarify the meaning of these provisions and emphasize that the privilege of substituted service applies only between points included in a carrier's certificate or permit.

Upon consideration of the carrier justification, complaints and replies, the Board has determined to disapprove Resolutions 503, 511, 508, 509 and 512a insofar as they would apply in air transportation. Only four[10] of the nine concerned U.S. carrier members of IATA have submitted material in compliance with the Board's directive in Order 73-9-30 to provide justification for those five resolutions. The bulk of the material submitted in this regard consists of broad, unsupported allegations and generalizations concerning carrier procedures and responsibilities, exhibits an absence of cost estimates, and is clearly insufficient as justification for substantial charges to the shipping public.

The carriers cite an estimated $1.65 million/$1.42 million valuation revenue/claims expense relationship developed in the Liability and Claims Rules and Practices Investigation, Docket 19923 et al., but fail to make any estimate of the effects of the proposed amendments on this industry relationship. We applaud TWA's efforts in conducting a full 12-month survey of international excess value revenues and claims, but we are not convinced that the carrier will incur a $13,583.54 loss under the proposed charges, as TWA alleges. TWA contends that excess value revenues will be reduced by 40 percent due to the revised application of the charges, but gives no basis for this estimate. Examination of the 59 identified shipments in the 12-month claims survey indicates a reduction of only ten percent in revenue under the new system, which would still leave TWA with more than a $12,000 profit. In any event, the experience of a single carrier is insufficient to justify a charge to be applied by all carriers. One carrier cannot be placed in the position of "carrying the ball" for the entire industry.

The major thrust of the carriers' arguments on live animal rates (Resolution 511) is that the generally longer stage lengths on international transportation justify unusual premiums due to the more critical need for air circulation in the case of warm-blooded animals. The other arguments concern special ground handling necessitated by unspecified government regulations but include no cost estimates. None of the carriers give any explanation for use of the under-45 kg. general cargo rate as the basic rate for live animals, or for the lack of distinction between warm- and cold-blooded animals. The Board can perceive no rationale for the application of premium rates for animal shipments ranging up to in excess of three times the general cargo rate for high weight shipments, while no premium would be imposed for shipments of 45 kilograms or under. In this light the IATA live animal rates can only be viewed as unreasonable, arbitrary, and excessive on their face.[11] We will also disapprove Resolution 508, which generally establishes charges for stalls on the basis of the applicable rate for 250 kg for the animal being transported rather than the weight of the stall itself. The shipper

[8] Here the Parties note that Delta fails to distinguish between warm- and cold-blooded animals—a distinction that carrier supported in Docket 21474.

[9] On November 5, Pan American filed a motion for leave to file an unauthorized document, and an answer in reply to the complaint by the Pet Industry Parties. The motion is hereby granted.

[10] Pan American, TWA, Delta and American.

[11] In its answer to the Pet Industry Parties' arguments, Pan American cites routine international non-stop operations of 7 to 11 hours (compared to the 2½ hour domestic trunkline average) as proof that air space access is much more critical internationally and justifies a much higher premium. Here the carrier makes other allegations concerning international live animal loading procedures, and finally contends that governmental regulations are in fact much more burdensome when international carriage is involved. Pan American has provided no data or cost estimates to substantiate these claims, and we remain unconvinced that the proposed premiums are justified.

already pays a substantial rental fee,[13] and it appears unreasonable and discriminatory to impose an additional charge on this basis. The whole procedure appears to represent an extra premium for the carriage of live animals.

Pan American and TWA are quite candid in stating that the purpose of amendments to the Disbursement and C.O.D. charges is punitive, and designed to discourage the use of these services which impose an extra workload on carrier personnel, and additional problems in the way of tardy remittance of the charges by some consignees. But this is no justification for imposing a 66 percent (disbursement charges) or 100 percent (C.O.D. charges) increase on all the carriers' customers. It appears that even the present IATA charges may be punitive. Delta cites U.S. domestic disbursement and C.O.D. charges in connection with its support of the corresponding IATA resolutions. Yet we note that domestic disbursement fees are only one percent, with a $2.00 minimum,[14] while the IATA charge is now proposed to be raised from three to five percent (and the minimum from $5.50 to $10.00). Domestic C.O.D. charges are calculated on a sliding scale based on the C.O.D. amount, expressed in $100 increments; in percentage terms they range from 0.30 percent to 0.50 percent.[15]

Thus TWA's estimated $1125 average international C.O.D. shipment would be assessed a fee of $6.00 in domestic carriage, whereas the current IATA charge is $22.50 and is now to be increased to $45.00.

In response to the points raised by American in regard to Resolution 507 (Use of Surface Transportation), we believe it is up to the carriers—not the Board—to clarify the meaning and intent of IATA resolutions. In any event, whatever the intent of the Resolution, carriers cannot rely on IATA resolutions to authorize the performance of services in violation of their tariffs, the Act or Board regulations. If American considers that other carriers are improperly using surface transportation for substitute service, this is not the appropriate proceeding to determine the validity of the practice.

In this connection we note that although the Board conditioned Resolution 511 (Rates for Live Animals) last year to require quantity discounts in rates applicable to baby poultry and monkeys and primates,[16] the vast majority of the carriers have not changed their tariffs to comply with the Board's condition to its order of approval of the IATA resolution.

The Board invites the carriers' attention to the fact that the Board's prior actions and the instant disapproval of these resolutions removes the anti-trust immunity granted in connection with their participation in these IATA agreements by maintaining tariff rates geared to such disapproved agreements. We encourage the carriers to return to the conference table to consider anew the issues adjudicated here or, alternatively, to make individual tariff filings for new charges accompanied by adequate economic justification.

We will approve the balance of the agreement subject to conditions previously imposed by the Board.[17] The resolutions are generally procedural and clarifying in nature and/or reflect minimal increases in ancillary charges which are related to increased costs of doing business. The Board does not find these provisions to be unreasonable or adverse to the public interest.

The Board, acting pursuant to sections 102, 224(a) and 412 of the Act, makes the following findings:

1. It is found that the following resolutions, incorporated in Agreement C.A.B. 23773 as indicated, are adverse to the public interest and in violation of the Act insofar as they would apply in air transportation as defined by the Act:

Agreement CAB	IATA No.	Title	Application
23773:			
R-3	003	Standard Revalidation Resolution, insofar as it would revalidate Resolutions 508 and 511.	1 (Reso. 508); 1;2;3; 1/2(M & S); 2;3; 3/1; 1/2/3 (Reso. 511).
R-9	503	Charges in Relation to Value (Revalidating and Amending)	1;2;3; 1/2; 2/3; 3/1; 1/2/3.
R-11	508	Charges for Stalls (Revalidating and Amending)	2;3; 1/2; 2/3; 3/1; 1/2/3.
R-12	509	Charges for Disbursements (Revalidating and Amending)	1;2;3; 1/2; 2/3; 3/1; 1/2/3.
R-13	511	Rates for Live Animals (Revalidating and Amending)	1/2 (N. Atlantic).
R-14	512a	C.O.D. Procedures (Revalidating and Amending)	1;2;3; 1/2; 2/3; 3/1; 1/2/3.

2. It is not found that the following resolutions, incorporated in Agreement C.A.B. 23773 as indicated, are adverse to the public interest or in violation of the Act: *Provided*, That approval is subject, where applicable, to conditions previously imposed by the Board:

Agreement CAB	IATA No.	Title	Application
23773:			
R-1	001r	Review of Cargo Rates (New)	1;2;3; 1/2; 2/3; 3/1; 1/2/3.
R-2	001j	2-Year Effectiveness Escape-Cargo (Revalidating and Amending).	2;3; 1/2 (M. & S. Atlantic) 2;3; 3/1; 1/2/3 (Except N. Atlantic).
R-3	002	Standard Revalidating Resolution, insofar as it would not revalidate Resolutions 045a, 405c, 508 and 511.	1;2;3; 1/2; 2/3; 3/1; 1/2/3.
R-4	014b	Construction Rule for Cargo Rates (Revalidating and Amending).	1;2;3; 1/2; 2/3; 3/1; 1/2/3.
R-5	014r	Computer Constructed Rates (Revalidating and Amending)	1;2;3; 1/2; 2/3; 3/1; 1/2/3.
R-6	021j	Special Definition Resolution Cargo (New)	1;2;3.
R-8	023b	Rounding Off Cargo Rates (Amending)	1;2;3; 1/2; 2/3; 3/1; 1/2/3.
R-10	507b	Use of Surface Transportation (Revalidating and Amending)	1;2;3; 1/2; 2/3; 3/1; 1/2/3.
R-15	512b	Air Cargo Rates—Airport to Airport (Revalidating and Amending).	1;2;3; 1/2; 2/3; 3/1; 1/2/3.
R-16	512c	Charge for Preparation of Air Waybill (Revalidating and Amending).	1;2;3; 1/2; 2/3; 3/1; 1/2/3.
R-17	512d	Charge for Amendment of Air Waybill (Revalidating and Amending).	1;2;3; 1/2; 2/3; 3/1; 1/2/3.
R-18	521	Use of Unit Load Devices (Revalidating and Amending)	1;2;3; 1/2; 2/3; 3/1; 1/2/3.
R-19	590	Specific Commodity Rates Board (Revalidating and Amending)	1;2;3; 1/2; 2/3; 3/1; 1/2/3.
R-20	595	Special Rates for Valuable Cargo (Amending)	1;2;3; 1/2; 2/3; 3/1; 1/2/3.
R-21	600j	Manual Air Waybill/Consignment Note (AWB) (Amending)	1;2;3.

3. It is not found that the following resolution, incorporated in Agreement C.A.B. 23773 as indicated, is adverse to the public interest or in violation of the Act: *Provided*, That approval is subject to the condition hereinafter stated:

Agreement CAB	IATA No.	Title	Application
23773:			
R-7	021LL	Special Rules for Currency Adjustments (Cargo Rates) (Revalidating and Amending).	1;2;3.

Accordingly, it is ordered, That:

1. Those portions of Agreement C.A.B. 23773 set forth in finding paragraph 1 above be and hereby are disapproved, insofar as they would apply in air transportation;

2. Those portions of Agreement C.A.B. 23773 set forth in finding paragraph 2 above be and hereby are approved subject, where applicable, to conditions previously imposed by the Board; and

[13] $65—Pan American (IATTC Tariff CAB No. 193, Rule 4–S–2).

[14] See Air Tariffs Corp. Agent, Tariff C.A.B. No. 96, Rule 70.

[15] See Air Tariffs Corp. Agent, Tariff C.A.B. No. 96, Rule 66G.

[16] Order 72–3–104, March 30, 1972.

[17] We will also condition our approval of Resolution 021LL (Special Rules for Currency Adjustment-Cargo), so it shall not be construed to constitute approval of Resolution 022p (JT31-North & Central Pacific-Special Rules for Sale of Cargo Air Transportation), to which reference is made in 021LL. The Board disapproved Resolution 022p, which would have established a five percent surcharge on all U.S.-originating transpacific shipments, in Order 73–8–124 of August 24, 1973.

3. That portion of Agreement C.A.B. 23773 set forth in finding paragraph 3 above be and hereby is approved: *Provided*, That such approval shall not extend to Resolution 022p; and

4. Pan American World Airways' motion to file an otherwise unauthorized document filed on November 5, 1973, is hereby granted.

This order will be published in the FEDERAL REGISTER.

By the Civil Aeronautics Board.

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

APPENDIX—SELECTED PREMIUMS FOR SHIPMENTS OF LIVE ANIMALS IN INTERNATIONAL CARRIAGE

	General cargo rates, in cents per kilograms				
	—45 kgs.	45 kgs.	100 kgs.	300 kgs.	500 kgs.
JT12 (North Atlantic):					
New York-London	285	218	154	101	86
Premium [1] percentage	0	30.7	85.1	182	231
TC1 (Western Hemisphere):					
Miami-Caracas	90	67	64	64	52
Premium [1] percentage	0	34.3	40.6	40.6	73
JT31 (South Pacific):					
Los Angeles-Sydney	541	406	387	350	329
Premium [1] percentage	0	33.3	40.0	54.6	64.4

[1] Premium over other freight = percentage differential of under —45 kg. rate over otherwise applicable weightbreak.

[FR Doc.73-24696 Filed 11-19-73;8:45 am]

[Docket No. 23333; Order 73-11-39]

INTERNATIONAL AIR TRANSPORT ASSOCIATION

Order Regarding Commodity Rates

NOVEMBER 9, 1973.

Issued under delegated authority November 9, 1973.

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 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, adopted pursuant to unprotested notices to the carriers and promulgated in IATA letters dated October 16, 1973 (Agreement C.A.B. 24004), R-1 through R-5, R-7, and October 22, 1973 (Agreement C.A.B. 24023) name nine new specific commodity rates as set forth in the attachment hereto.[1] These rates reflect reductions from the otherwise applicable general cargo rates, and will be approved herein.

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. Agreement C.A.B. 24004, R-1 through R-5, R-7, and Agreement C.A.B. 24023 be and hereby are approved: *Provided*, That approval shall not constitute approval of the specific commodity descriptions contained herein for purposes of tariff publication: *Provided further*, That tariff filings shall be marked to become effective on not less than 30 days' notice from the date of filing; and

2. The findings and approval herein shall not be deemed to modify the findings and Orders 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 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.73-24695 Filed 11-19-73;8:45 am]

[Docket No. 25535; Order 73-11-60]

NEW JOINT AIRLINE CREDIT CARD PROGRAMS

Order Amending Order Regarding Discussions

NOVEMBER 14, 1973.

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., on the 14th day of November 1973.

By Order 73-8-74, adopted August 15, 1973, the Board authorized, subject to conditions, inter-carrier discussions concerning the possible establishment of a new commercial credit card program to replace the Universal Air Travel Plan (UATP), and the possible establishment of an industry-wide personal credit card to replace the numerous individual air carrier credit card programs now in effect.

Since the issuance of that order four events have taken place relating directly or indirectly to the authorized discussions. These will be discussed below, and are: (1) A petition that the Board require the maintenance of a transcript of the discussions, (2) the filing of the UATP Silver Card amendments, (3) a motion to hold the discussion authority in abeyance until the Board acts on the Silver Card amendments, and (4) the calling of a meeting to discuss an industry-wide personal credit card program.

(1) After the adoption of Order 73-8-74, American Express Company (Amexco) petitioned for leave to intervene in this docket and for reconsideration of Order 73-8-74 to require that a full transcript be maintained of the authorized discussions. Answers to Amexco's petitions were received from Trans World Airlines, Inc., United Air Lines, Inc., and from National BankAmericard Incorporated (NBI).[2]

Amexco requests the Board to reconsider the discussion authorization order and require that a full transcript of the discussions be maintained and made available.[3] It says the agreement that might result from the discussions would raise antitrust issues, and would affect non-participants in the discussions. These issues include, according to Amexco, the competitive impact of such an agreement on the air carriers and others who offer and are affected by credit card programs and the propriety of a joint air carrier agreement to engage in a business activity entirely distinct from the sale of air transportation, especially when the air carriers themselves and some of their subsidiaries are users of credit card services.

NBI supports this request because it is similarly concerned with the possibility of there resulting from the discussions an agreement which would violate antitrust principles on concerted refusals to deal, tying arrangements, and the establishment of uniform rates and prices for credit card services. It alleges that it is important that the discussions be scrutinized by interested parties and the Board to assure the avoidance of undesirable anti-competitive problems. NBI says that it is often necessary to refer to the discussions of those who drafted particular language to fully understand their intent.

TWA does not object to Amexco's suggestion that a transcript be made of that portion of the discussions involving general or travel credit card services, provided that those desiring such a transcript bear the full cost.

UAL opposes Amexco's petition for reconsideration. It says Order 73-8-74 specifically rejected a transcript requirement and that nothing has been presented to warrant a modification of that decision. UAL contends that the condi-

[1] Filed as part of the original document.

[2] The NBI answer was accompanied by a motion for leave to file an unauthorized document, which we will grant.

[3] If there is objection to full access to such a transcript, Amexco suggests that confidential treatment of parts could be requested, or the agenda could be arranged to allow for the separate discussion of those aspects with which Amexco is concerned and the maintenance of a transcrip of those portions only.

tions and requirements imposed in the discussion authorization order will fully protect Amexco's interests.

(2) Subsequent to Order 73–8–74, the parties to UATP adopted and filed with the Board the Silver Card amendments. The effects of these amendments are described in Order 73–9–81, issued September 21, 1973, which deferred action and requested comments in favor of, or in opposition to, their approval by the Board.[3]

(3) TWA requests the suspension of the discussion authority until after the Board acts on the Silver Card amendments. It says that some of the same points which TWA was interested in discussing with other carriers are included in the Silver Card amendments, and that there therefore is no need at this time to engage in such discussions. If the discussion authorization continues after Board action on the Silver Card amendments to UATP, TWA says the carriers could decide then whether they should meet to establish a new credit card program.

(4) UAL requests that the Board defer action on TWA's motion. It agrees that discussions now on a new commercial credit card program would not be appropriate, but it has already called a meeting to discuss an industry-wide personal credit card program.[4]

The Board has decided to deny TWA's motion to suspend the discussion authority, to dismiss Amexco's petition for intervention, to consider Amexco's petition for reconsideration as a request for amendment of Order 73–8–74, and to grant such request in view of developments that have taken place and information that has come to our attention since the issuance of that order.

There is no precedent or need for the action TWA requests. If the carriers desire to meet after the Board has acted on the Silver Card amendments they can apply for authorization to do so at that time. We have already shown that if the proper reasons are presented we will authorize inter-carrier discussions. We do not know at this time whether circumstances will exist after the Silver Card amendments have been acted upon that the Board may feel indicate the need for more or less conditions on discussion authorization, or may indicate that discussions at that time should not be authorized. The purpose of a limited grant of authorization is, after all, to insure that the discussions do not extend beyond the time within which it appears that the reasons for such authorization will continue to exist. Since we do not know if discussions should be authorized, and if so under what conditions, after the Board deals with the Silver Card amendments, TWA's motion will be denied.

As to the Amexco petition for intervention, the Board's rules do not provide for formal intervention in nonhearing matters.[5] There was no hearing on the application for discussion authorization and there has been no indication that a hearing will be ordered on any agreement that may result from the discussions. Therefore, the Amexco petition for intervention will be dismissed, and its petition for reconsideration will not be considered as such.[6] However, there is no need for reconsideration of Order 73–8–74 since ordering paragraph 3(h) thereof provides that the Board may at any time revoke or amend the relief granted therein. Rather than require Amexco to file a new document asking for an amendment of Order 73–8–74 to require a transcript, we will consider its petition for reconsideration as such a request.

The Board has decided to grant this request in light of relevant information that has been presented since the adoption of the discussion authorization order. In that order we stated that we would not require the maintenance of a full transcript of the discussions because "we are unable to envision that the contemplated discussions will raise anticompetitive issues of the degree and importance of those envisioned in our approval of the discussions authorized in Order 73–4–98." The answers which were considered before that order was adopted asserted only that non-participants in the discussions were interested in the subject to be discussed. No allegation was made that antitrust issues were presented by the authorization of discussions on these subjects, and the issues in this matter did not seem to be, and are not, similar to those involved in the discussions authorized by Order 73–4–98.

Since that time the Board has received extensive documentation pertaining to the adoption of the Silver Card amendments.[7] Among other things, this documentation includes references to possible ways of increasing the use of UATP cards as personal credit cards.[8] It also indicates that there is a close relationship between the attempts of some of the UATP parties to secure adoption of the Silver Card amendments and the application and supporting answers for discussion authorization for new credit card programs. We now find that the discussions authorized by Order 73–8–74 might themselves involve the exchange of information which could lead to undesirable anticompetitive consequences and that the issues involved in these discussions are therefore seen now, in view of the new information which we have received, to raise significant issues involving antitrust principles.[9] Therefore, we will amend Order 73–8–74 to provide that a transcript be maintained of all discussions held pursuant to its authorization. The cost of such transcript should be borne by the participants in the discussions, with copies available to any persons so requesting, at cost.[10]

The Board will also amend the order, as indicated below, on our own motion, to provide more flexibility to amend the authorization in the future, if necessary.

Accordingly, it is ordered, That:

1. Order 73–8–74 be and it hereby is amended by the addition to ordering paragraph 3 of a new subparagraph (j) to read as follows:

> (j) the air carrier responsible for the call of each meeting authorized herein shall provide for the taking of a complete transcript of each meeting, at the expense of the participants, copies of this transcript to be filed with the Board and with the Director of its Bureau of Operating Rights within ten days after the conclusion of each meeting and available for purchase by any person at the cost of production of such copy;

and by the amendment of subparagraph (h) of ordering paragraph 3 as follows:

> * * * and may be extended, modified, or revoked at any time by the Board or by the Director of its Bureau of Operating Rights; [11]

2. The petition of Amexco for leave to intervene be and it hereby is dismissed;

3. The petition of Amexco for reconsideration of Order 73–8–74, considered as a request for amendment of that order, be and it hereby is granted to the extent indicated herein;

4. The motion of NBI for leave to file an unauthorized document be and it hereby is granted;

5. The motion of TWA to amend Order 73–8–74 to hold in suspension the authorization granted therein be and it hereby is denied;

6. Copies of this order shall be served on all certificated scheduled air carriers, the Universal Air Travel Plan, American Express Company, Inc., National Bank-Americard, Inc., the American Society of Travel Agents, Inc., the National Passenger Traffic Association, Inc., and the United States Departments of Transportation and Justice, and it shall be published in the FEDERAL REGISTER; and

7. To the extent not granted herein, all outstanding requests be and they hereby are dismissed.

By the Civil Aeronautics Board.

[SEAL] EDWIN Z. HOLLAND,
Secretary.

[FR Doc.24694 Filed 11–19–73;8:45 am]

[3] Comments and reply and/or supplemental comments are due November 14, and 28, 1973, respectively.

[4] To be held November 14, 1973, in Washington, D.C.

[5] Rule 15(a) of the Board's rules of practice (14 CFR 302.15(a)).

[6] Since the Board does not grant formal intervention (and, thus, party status) in non-hearing matters, we would be disposed to consider a petition for reconsideration of an order adopted in a non-hearing matter by any person interested in that matter.

[7] UATP materials submitted pursuant to ordering paragraph 5 of Order 73–9–81.

[8] Id., at B–14, p. 2.

[9] Cf., Order 70–11–35, November 6, 1970.

[10] If there is objection to public disclosure of any information in the transcript, the procedures of Rule 39 of the Board's rules of practice (14 CFR 302.39) are available.

[11] Such delegated action by the Director of the Bureau of Operating Rights will be subject to the appeal provisions of Part 385 of the Board's Regulations.

[Docket No. 25990; Order 73-11-50]

MANDATORY FUEL ALLOCATION PROGRAM

Discussions on Implementation

Adopted by the Civil Aeronautics Board at its office in Washington, D.C. on the 13th day of November 1973.

On October 12, 1973, the Energy Policy Office adopted regulations pursuant to the Economic Stabilization Act of 1970, as amended by P.L. 93-28, April 30, 1973, establishing a mandatory fuel allocation program that imposes controls on "middle distillate fuels," including airline turbine fuel.[1] On the same day, the Board issued Order 73-10-50 authorizing carrier discussions to consider adjustment of schedules to the extent necessary to deal with the fuel emergency. By Order 73-10-79, the Board amended that order to broaden the scope of the authorized discussions to include formulation of an industry-wide plan for carrier operations under the fuel allocation program.

As a result of the carrier discussions, certain agreements between American Airlines, Trans World Airlines, and United Air Lines were filed covering capacity reductions in some 20 markets. By Order 73-10-110, the Board granted provisional approval of those agreements, subject to various conditions. The Board there found that the best present estimate was that the airlines are going to have to make do with 10 percent less fuel than amounts their planned level of service would have required. In light of this necessitated reduction in airline service, the Board concluded that the agreements would fulfill an important transportation need in providing a vehicle which would help the Board insure that capacity reductions stemming from the fuel shortage would be made in a rational manner, and that available capacity would be operated under schedules which provided the public with the most convenient service practicable under the circumstances.

Specifically, the Board envisioned a program whereby the carriers would be given sufficient leeway to consult for the purpose of adjusting their operations, so that advance coordination would minimize the resulting disruption. However, the Board would, through its approval, close monitoring, and attachment of conditions to the carriers' agreements, act as an impartial arbitrator of the competing needs of passengers, shippers, communities, and the Postal Service regarding the relative level of service provided.

The furtherance of this program for rational and equitable schedule adjustments to accommodate the fuel emergency will, we believe, best be facilitated if provision is made for relaxation in appropriate circumstances of unnecessary restrictions on air carrier consultations looking toward an industry-wide plan for carriers' operations under the fuel allocation program. The Board would anticipate that on most occasions, consultations would be held only following appropriate notice, as provided for in Order 73-10-50, as amended by Order 73-10-79. However, there may be occasions where circumstances justify additional flexibility for less formal carrier consultations (i.e., by phone, telegram, or otherwise), without a requirement for formal meetings. We would not anticipate extensive use of such broader flexibility, and would expect carriers to justify their use of such informal procedures in connection with their filing of reports of such consultations with the Board. However, the Board believes that the program for schedule adjustments necessitated by the fuel crisis can be furthered by giving the carriers sufficient leeway to utilize such procedures if and when necessary.

We believe that the interests of the public can be adequately protected, despite such informal consultations, through the process of a system of full reporting to the Board as to the substance of the consultations, and the requirement under section 412 of the Act that all agreements or understandings reached be filed with the Board for approval. The Board will, as we emphasized in Order 73-10-110, closely scrutinize and monitor such agreements to insure that the primary consideration, the interests of the traveling public, remains paramount.[2]

Specifically, we contemplate the establishment by the carriers of a coordinating body which will do the following: (1) Arrange and carry out, in such manner as may be required, all discussions authorized herein; (2) serve as a central source of information to the Board and to interested persons respecting the status and content of discussions and resulting joint arrangements; (3) prepare and submit to the Board a daily report specifying the circumstances which justify utilization of informal procedures, summarizing all discussions held, and setting forth the details of any arrangements entered into;[3] and (4) arrange for the carrier parties to prepare and file with the Board for approval the arrangements agreed to by the participants. We shall expect that copies of such agreements will be amply supported by affidavits regarding such items as fuel savings, estimated load factors in markets having reduced capacity, and a detailed report from each participant of the proposed changes to be effected by the revision of schedules pursuant to the agreement (see Appendix).

We further will require the applicants to serve a copy of the agreement on each city and airport at which service will be reduced.

Accordingly, we will amend Order 73-10-50, as amended by Order 73-10-79, to permit discussions and resulting joint arrangements respecting scheduling as well as any other appropriate joint arrangements whose implementation would otherwise require Board approval under section 412 of the Act free of the notice and situs limitations presently provided by those orders.[4] Similar leeway was provided for carrier discussions in a past scheduling emergency arising from the 1970 absenteeism of certain air traffic control personnel.[5]

We do anticipate that the carriers will recognize certain minimum guidelines. First, fully satisfactory service in the aggregate should be maintained at all airports, including multiple airports serving a single metropolitan area. Secondly, any reductions, however achieved should be geographically distributed. Additionally, cutbacks should not occur in markets experiencing load factors of 72 percent or more, and reductions in nonstop service below one daily round-trip nonstop flight will not be approved except in extenuating circumstances.

Additionally, the carriers should be put on notice that, with respect to any subsequent agreements or joint arrangements, we shall not permit slots freed by service reductions at controlled airports to be used by any carriers.[6] Moreover, we will not tolerate the use of freed aircraft time (or fuel saved) for the increase of other services, including but not limited to nonscheduled operations or extra sections.

Subject to these guidelines, the restrictions of Order 73-10-50, as amended by Order 73-10-79, will be modified as noted above.

Accordingly, it is ordered, That:

1. Ordering paragraph 1 of Order 73-10-50, as amended by Order 73-10-79, be and it hereby is amended to read as follows:

1. All certificated route and supplemental air carriers be and they hereby are authorized to conduct discussions and to enter into joint arrangements to reduce or otherwise arrange schedules, or to enter into other joint arrangements, to the extent necessary to accommodate the fuel allocation program, and to consider the formulation of an industry-

[1] EPO Reg. 1, 38 FR 28660.

[2] Thus, in Order 73-10-110 the Board disapproved the proposed deletion of all eastbound morning and westbound afternoon flights, in the Philadelphia-San Francisco market.

[3] This report should describe any communications between or among the carriers, whether by telephone, telegram, prearranged meeting or otherwise, which are made in furtherance of any agreement or joint arrangement authorized pursuant to this order. Such communications shall include initial inquiries respecting discussions and/or joint arrangements, irrespective of whether further negotiations result. At minimum, each airline officer engaging in such communications should submit to the coordinating body, for transmission to the Board, a daily description of all such communications to other air carriers, a short statement as to the subject and substance of the communication, and a statement as to any determination reached.

[4] The authorization will permit discussions of certain nonschedule matters which might be pertinent, such as cruise speeds, utilization of extra sections, and traffic control problems related to gate delay during peak traffic hours. Moreover, in view of the potential impact of the fuel crisis, the authorization is not intended to preclude discussion, if necessary, of the possibility of complete temporary withdrawal and bilateral allocation of markets by competing air carriers.

[5] See Order 70-4-5, April 2, 1970.

[6] Airport scheduling agreements affecting John F. Kennedy International Airport, O'Hare International Airport, Washington National Airport, and LaGuardia Airport, Order 72-11-72.

wide plan, for carrier operations under the fuel allocation program, subject to the following conditions:

(a) The markets to be discussed shall be limited to markets in interstate and overseas air transportation;

(b) Except as provided in subparagraph (c) below, the discussions shall be conducted in accordance with the following procedures:

(i) The discussions shall be held in Washington, D.C. and representatives of the Civil Aeronautics Board and of any other interested persons shall be permitted to attend the discussions as observers;

(ii) Notices of any meeting held pursuant to this order shall be served on all certificated route and supplemental air carriers, and the Civil Aeronautics Board, as least 24 hours prior to said meeting;

(iii) A full transcript shall be maintained at all meetings, at the expense of the carriers, and two copies of said transcript shall be filed with the Board;

(c) If compliance with the procedures set forth in subparagraph (b) above would be impracticable, the carriers may adopt other less formal procedures subject to the following requirements:

(i) Prior to commencement of any such informal discussions the carriers shall establish a discussion coordinating body;

(ii) The discussion coordinating body shall: (1) Arrange and carry out, in such a manner as may be required, procedures for any discussions authorized pursuant to this order; (2) serve as a central source of information to the Board and to interested persons respecting the status and content of discussions and resulting joint arrangements; (3) prepare and file with the Board, in connection with any informal discussions held, a daily report specifying the circumstances which justify utilization of informal procedures, summarizing all discussions held, and setting forth the details of any arrangements entered into during or as a result of such discussions; and (4) arrange for the carrier parties to prepare and file with the Board for approval the arrangements agreed to by the participants;

(iii) The daily report referred to in (ii)(3) above shall be filed in triplicate with the Board's Docket Section by the close of business on the day following such discussion or arrangement;

(iv) All carriers participating in informal discussions as authorized pursuant to this subparagraph (c) shall be responsible for submitting to the discussion coordinating body such information as may be required to fully comply with the reporting procedure provided for in (ii) above;

(d) Joint arrangements reached as a result of discussions herein authorized shall not be implemented without prior Board approval, and prior notice of any schedules change shall be given to each city and airport affected, and to the Board and each governmental entity specified in ordering paragraph 2, infra; and

(e) The authorization granted herein shall expire 119 days from the date of issuance of this order, and may be earlier revoked or amended at any time in the discretion of the Board;

2. And copies of this order shall be served on the Departments of Defense, Justice and Transportation; the U.S. Postal Service; and all certificated and supplemental air carriers.

This order shall be published in the FEDERAL REGISTER.

By the Civil Aeronautics Board:

[SEAL] EDWIN Z. HOLLAND,
Secretary.

APPENDIX

	Type of Equipment				
	2-Engine	3-Engine narrow body	4-Engine narrow body	3-Engine wide body	4-Engine wide body
CAPACITY MARKETS					
Miles scheduled weekly in preceding general schedule filed with CAB.					
Changes contained in this general schedule.					
Miles scheduled weekly in this general schedule.					
NONCAPACITY MARKETS					
Miles scheduled weekly in preceding general schedule filed with CAB.					
Changes contained in this general schedule.					
Miles scheduled weekly in this general schedule.					

[FR Doc.73-24601 Filed 11-19-73;8:45 am]

CONSUMER PRODUCT SAFETY COMMISSION

PROVISION OF PROPOSED CHILDREN'S SLEEPWEAR FLAMMABILITY STANDARD, SIZES 7 THROUGH 14

Change of Meeting Location

In the FEDERAL REGISTER of October 30, 1973 (38 FR 29910), the Consumer Product Safety Commission gave notice of a meeting to be held at the request of the National Wool Growers Association to discuss the requirements of § .5(b) of the proposed flammability standard for children's sleepwear, sizes 7 through 14. (The proposal was published March 12, 1973; 38 FR 6700).

To accommodate all parties who have asked to attend, notice is given that the location of the meeting has been changed to the hearing room, Consumer Product Safety Commission, sixth floor, 1750 K Street NW., Washington, DC. The meeting will be held on Wednesday, November 28, 1973, at 1:00 p.m., as previously announced.

Dated: November 14, 1973.

SADYE E. DUNN,
Secretary, Consumer Product Safety Commission.

[FR Doc.73-24686 Filed 11-19-73;8:45 am]

COST OF LIVING COUNCIL

[Notice No. 73-3]

PROSPECTIVE REIMBURSEMENTS

Institutional Providers of Health Services

The Cost of Living Council has determined that strict compliance with the provisions of the Economic Stabilization regulations creates substantial difficulties for institutional providers of health services with respect to reimbursement by certain third party payors.

Institutional providers of health services in some States are reimbursed by certain third party payors on the basis of prospective rates established at the beginning of a fiscal year for the entire year. If the institutional provider's costs exceed those on which its prospective rate of reimbursement is based, the provider is prevented from further reimbursement from the third party payor, except for extraordinary circumstances. Moreover, prior to the Economic Stabilization Program, if the institutional provider maintained its costs below those on which the prospective fixed rate of reimbursement was based at the beginning of a year, it was able to retain the cost savings. Under the provisions of the Economic Stabilization regulations, specifically 6 CFR 300.18, the institutional provider can no longer retain its cost savings and must refund any increase in its aggregate annual revenues which has not been justified by an equivalent net increase in allowable costs. Since cost savings to an institutional provider in one year may result in lower prospective reimbursement rates in the succeeding year, the application of the Economic Stabilization regulations acts to deter those particular institutional providers from reducing their costs below the level of those used in establishing the prospective reimbursement rates.

Because an objective of the Economic Stabilization Program is to reduce the rate of increase in costs and prices, and since prospective reimbursement by third party payors is an innovation in the health industry that has demonstrated a potential for encouraging such reductions, the Cost of Living Council has concluded that some relief from the limitations established in Title 6, Code of Federal Regulations, § 300.18 is necessary. Under the following conditions, increases in aggregate annual revenues due to prospectively applicable price increases to third party payors need not be justified by allowable costs:

1. The effect of all price changes during a fiscal year must not increase the institutional provider's aggregate annual revenues (adjusted for volume differences) at an annualized rate of more than 6 percent of its aggregate annual revenues for its last fiscal year, as calculated in accordance with instructions for the appropriate S-52 (September 1972 or revised July 1973).

2. The increases in aggregate annual revenues from price increases to charge payors and those third party cost reimbursers not using prospectively determined rates must be justified by an in-

crease in net allowance cost increases proportionate to that attributable to these nonprospective rate payors.

In order to determine whether the price increase revenues from charge payors and from third party cost payors not using prospectively determined prices are cost justified or the amount of allowable costs which may be used to justify the price increase revenues, an institutional provider of health services must make the following computations:

STEP 1. Determine the proportion of total patient service revenues to be paid by nonprospective rate payors to total patient service revenues for the institution in the aggregate for the fiscal year in which relief from the limitations of § 300.18 is desired:

Total Patient Service Revenues—Nonprospective Payors

Total Patient Service Revenues—All Payors

Other methods of determining the above proportion must be approved in writing by the Cost of Living Council.

STEP 2. Multiply the proportion determined in Step 1 by the institutional provider's justified allowable cost increases (Item 54, Form S–52, Revised July 1973, or Item 82, Addendum to Form S–52, Revised September 1972) to determine the proportionate dollar amount of justified allowable cost increases.

STEP. 3. Determine the increase in annualized aggregate annual revenues due to price increases to charge payors and to third party cost payors not using prospectively determined prices in accordance with Schedule A to Form S–52, Revised July 1973, or by the Table of Price Increases, Item 18(b), Instructions for Form S–52, Revised September 1972. Other methods of calculating price increase revenues must be approved in writing by the Cost of Living Council.

The increase in aggregate annual revenues due to price increases determined in Step 3 may not exceed the proportionate amount of justified allowable cost increases determined in Step 2.

If the aggregate annual revenues due to price increases to charge payors and to third party cost payors not using prospectively determined prices exceed the proportionate amount of justified allowable cost increases, the institutional provider must refund to those payors the excess price increase revenues in order to comply with the conditions established for relief under this notice. The institutional provider remains subject to the base period net revenue margin or profit margin limitation (whichever is applicable). However, the amount of excess revenues due to price increases to third party payors using prospectively determined prices that are not justified by allowable cost increases shall not cause the provider to be in violation of the base period net revenue or profit margin limitation.

Relief provided in this notice may be implemented on a self-executing basis by providers for fiscal years not yet completed as of the date of issuance of this Notice, when all conditions above have been satisfied. If reports of increases in aggregate annual revenues due to price increases in excess of 2.5 percent but not more than 6 percent have previously been filed with any one of the Internal Revenue Service, the Medicare Intermediary, or the Cost of Living Council for that fiscal year, an amended report should be filed with the Medicare Intermediary and the Cost of Living Council, noting in the letter of transmittal that the reason for submission of the amended report is to implement relief under this Notice. Further, if such reports are required and have not previously been filed and relief has been implemented under this Notice, the letter of transmittal must so note.

If the increase in aggregate annual revenues due to price increases is 2.5 percent or less and relief is implemented under this Notice, no report is required. Providers, however, must maintain documentation to validate their calculation of relief. All third party reimbursers must be provided with copies of the documentation at their request. Relief in fiscal years already completed as of the date of issuance of this Notice may be considered by the Cost of Living Council upon application by individual providers.

Issued in Washington, D.C., on November 16, 1973.

JOHN T. DUNLOP,
Director,
Cost of Living Council.

[FR Doc.73-24816 Filed 11-16-73;4:46 pm]

FEDERAL COMMUNICATIONS COMMISSION

[Report 674]

COMMON CARRIER SERVICES INFORMATION [1]

Domestic Public Radio Services Applications Accepted for Filing [2]

NOVEMBER 12, 1973.

Pursuant to §§ 1.227(b)(3) and 21.30 (b) of the Commission's rules, an application, in order to be considered with any domestic public radio services application appearing on the attached list, must be substantially complete and tendered for filing by whichever date is earlier: (a) The close of business one business day preceding the day on which the Commission takes action on the previously filed application; or (b) within 60 days after the date of the public notice listing the first prior filed application (with which subsequent applications are in conflict) as having been accepted for filing. An application which is subsequently amended by a major change will be considered to be a newly filed application. It is to be noted that the cut-off dates are set forth in the alternative—applications will be entitled to consideration with those listed in the appendix if filed by the end of the 60 day period, only if the Commission has not acted upon the application by that time pursuant to the first alternative earlier date. The mutual exclusivity rights of a new application are governed by the earliest action with respect to any one of the earlier filed conflicting applications.

The attention of any party in interest desiring to file pleadings pursuant to section 309 of the Communications Act of 1934, as amended, concerning any domestic public radio services application accepted for filing, is directed to §§ 21.27 of the Commission's rules for provisions governing the time for filing and other requirements relating to such pleadings.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] VINCENT J. MULLINS,
Secretary.

APPLICATIONS ACCEPTED FOR FILING:

DOMESTIC PUBLIC LAND MOBILE RADIO SERVICE:

20492-C2-TC-(2)-74—All Services, Inc. Consent to Transfer of Control from Howard R. Chapman, TRANSFEROR to Southeastern Tele-Com, Inc., TRANSFEREE. Stations: KLF484, Charleston, South Carolina and KSV905, Charleston, South Carolina.

20493-C2-P-74—Two-Way Radio of Carolina, Inc. C.P. for a new 1-way station to operate on 152.24 MHz to be located at County Rd., 1851, 0.2 mile West of Metcalf Road, ½ mile N. of Shelby, North Carolina. (NEW)

20494-C2-P-(2)-74—Contact of New Mexico C.P. for additional facilities to operate on 454.275 and 454.325 MHz at Loc. #1: Tortugas Mtn., 4 miles SE of Las Cruces, New Mexico. (KLB668)

20495-C2-P-74—General Telephone Company of Pa. C.P. for additional facilities to operate on 35.8 MHz to be located at a new site described as Loc. #2: 217 W. Spring Street, Titusville, Pennsylvania. (KTR988)

20496-C2-P-74—General Communications Service, Inc. C.P. to change antenna system operating on 152.24 MHz located at WTCG-TV Tower, 1018 Peachtree St., N.W., Atlanta, Georgia. (KRM947)

20497-C2-P-(5)-74—General Communications Service, Inc. C.P. to change antenna system operating on 152.06, 152.09, 152.12, 152.18, 152.21, 454.15, 454.125, 454.175, 454.200, 454.300, and 454.350 MHz located at WTCG-TV Tower, 1018 W. Peachtree Street, N.W., Atlanta, Georgia. (KIG296)

20498-C2-P-74—Elkhart Telephone Company, Inc. C.P. for a new 2-way station to operate on 152.72 MHz to be located 4 miles West & 1 mile North of center of Elkhart, Kansas. (NEW)

20499-C2-P-(5)-74—The Mountain States Telephone and Telegraph Company C.P. to relocate antenna operating on 152.78, 152.66, 152.75, 152.81, and 152.51 MHz located at Ranger Peak, Franklin Mountains, El Paso, Texas. (KKG417).

20500-C2-P-74—The Offshore Telephone Company C.P. for a new 2-way station to operate on 35.30 MHz to be located in the Gulf of Mexico, Block 261A, East Cameron Area, South of Galveston, Texas. (NEW)

20501-C2-P-74—Palo Pinto Telephone Company, Inc. C.P. for a new 2-way station to operate on 152.81 MHz to be located at intersection of 2nd Street and Elm Street, Palo Pinto, Texas. (NEW).

20502-C2-P-74—Valliant Telephone Company C.P. for a new 2-way station to operate on 152.81 MHz to be located at CATV Tower, ½ mile W. and 2 miles North of center of Valliant, Oklahoma. (NEW)

[1] All applications listed in the appendix are subject to further consideration and review and may be returned and/or dismissed if not found to be in accordance with the Commission's rules, regulations and other requirements.

[2] The above alternative cut-off rules apply to those applications listed in the aappendix as having been accepted in Domestic Public Land Mobile Radio, Rural Radio, Point-to-Point Microwave Radio and Local Television Transmission Services (Part 21 of the rules).

20503–C2–P–(2)–74—Southeastern Telephone Company C.P. to change antenna system operating on 152.63 and 152.66 MHz located on Red Road, 2.5 miles West of Florida Hwy #85, approx. 8 miles South of Crestview, Fort Walton Beach, Florida. (KIY737)

20504–C2–P–74—General Telephone Company of California C.P. to change antenna system and replace transamitter operating on 454.600 MHz located at Santa Ynez Park, 8 miles SE of Santa Ynez, California (KME440)

20505–C2–P–(3)–74—Radio Dispatch Company C.P. for a new 2-way station to operate on 454.075, 454.250, and 454.275 MHz to be located at 360 Clayton Road, Lakewood, New Jersey. (NEW)

20506–C2–P–(6)–74—Radio Broadcasting Company C.P. for a new 2-way station to operate on 454.050, 454.125, 454.200, 454.225, 454.325, 454.350 MHz to be located at 2210 Boardwalk, Atlantic City, New Jersey. (NEW)

20507–C2–TC–74—Public Communications, Inc. Consent to Transfer of Control from Elwyn M. Gipson and Thomas P. Carter, TRANSFERORS to Maynard C. Campbell, Jr. et al., TRANSFEREES, Station: KLB761, Lufkin, Texas.

20508–C2–P–(4)–74—Metro Fone Communications, Inc. C.P. for additional facilities to operate on 454.125, 454.175, 454.275, and 454.325 MHz located at 4659 Stinson Blvd., N.E., Columbia Heights, Minnesota. (KRS655)

MAJOR AMENDMENT

4185–C2–P–73—Radiofone Corporation of New Jersey (New). Change location to adjacent to railroad tracks on Mizzen, Beachwood (Ocean) New Jersey. All other particulars to remain the same as reported on PN #627 dated December 18, 1972.

RURAL RADIO SERVICE

Renewal of Licenses expiring November 1, 1973 TERM: 11–1–73 to 11–1–78.

Licensee	*Call sign*
Atlas Radiophone	KOA74
Delta Valley Radiotelephone Co., Inc.	KOA82
General Telephone Company of the Southwest	KKA94
Same as above	KKA95
Same	KLH27
Same	WCZ21
Same	WCZ22
Marianas Telephone Company	KZS77
Stockton Mobilphone, Inc.	KOA79

CORRECTION

Renewal of license expiring November 1, 1973 for South Central Bell Telephone Company should read WHA79 instead of WHA37. All other particulars to remain the same as reported on PN #668 dated October 1, 1973.

POINT-TO-POINT MICROWAVE RADIO SERVICE

1530–C1–P–74—American Telephone and Telegraph Company (KLN24), corner of George & East Streets, Greenwood, Mississippi. Lat. 33°31'15" N., Long. 90°10'43" W. C.P. to add freq. 4070H MHz toward Tchula, Miss. on azimuth 175°56'.

1531–C1–P–74—Same, (KLN23), 4.6 Miles ESE. of Tchula (Holmes) Mississippi. Lat. 33°09'33" N., Long. 90°08'53" W. C.P. to add freq. 4030H MHz toward Pickens, Miss. on azimuth 172°12'.

1532–C1–P–74—Same (KLN22), 7.6 Miles West of Pickens (Yazoo) Mississippi. Lat. 32°52'11" N., Long. 90°06'04" W. C.P. to add freq. 4070H MHz toward Bentonia, Miss. on azimuth 234°36'.

1533–C1–P–74—Same (KLN21), 4.8 Miles North of Bentonia (Yazoo) Mississippi. Lat. 32°42'26" N., Long. 90°22'16" W. C.P. to add freq. 4030H MHz toward Redwood, Miss. on azimuth 230°46'.

1534–C1–P–74—Same (KLN20), 6.8 Miles East of Redwood, Mississippi. Lat. 32°29'05" N., Long. 90°41'31" W. C.P. to add freq. 4070V MHz toward Vicksburg, Miss. on azimuth 211°29'.

1535–C1–P–74—Same (KLV41), 3.7 Miles SE. of Talisheek, Louisiana. Lat. 30°29'40" N., Long. 89°49'47" W. C.P. to change antenna system on freqs. 3730H, 3810H, 3830V, 3890H, 3910V, 3970H, 4050H, 4130H MHz toward a new point of communication at Lacombe, La. on azimuth 217°13'.

1536–C1–P–74—Same (New), 2.5 Miles NW. of Lacombe, Louisiana. Lat. 30°20'25" N., Long. 89°57'53" W. C.P. for a new station on freqs. 3770H, 3850H, 3930H, 4010H, 4090H, 4170H MHz toward Talisheek, La. on azimuth 37°09'; freqs. 3770V, 3790H, 3850V, 3870H, 3930V, 4010V, 4090V, 4170V MHz toward New Orleans 2, La. on azimuth 16°41'.

1537–C1–P–74—Same (WDE72), 3951 Erato St., New Orleans, Louisiana. Lat. 29°57'14" N., Long. 90°05'54" W. C.P. to change antenna system and add freqs. 3730V, 3810V, 3890V, 3970V, 4050V, 4130V MHz toward a new point of communication at Lacombe, La. on azimuth 16°41'.

1538–C1–P–74—Southwestern Bell Telephone Company (KOA60), 5.2 Miles SE. of Gillett, Texas. Lat. 29°02'50" N., Long. 97°46'23" W. C.P. to change antenna system and add freqs. 3770V, 3850V MHz toward Floresville, Tex. on azimuth 296°0'; freq. 4090V MHz toward Choate, Tex. on azimuth 175°01'.

1539–C1–P–74—Same (KOA59), 5 Miles NE. of Floresville, Texas. Lat. 29°11'21" N., Long. 98°06'20" W. C.P. to change antenna system and add freq. 4050V MHz toward Ecleto, Tex. on azimuth 115°50'.

1540–C1–P–74—Southwestern Bell Telephone Company (KOA61), 9 Miles SE. of Kenedy, Texas. Lat. 28°43'28" N., Long. 97°44'28" W. C.P. to change antenna system and add freqs. 3730V, 3810V MHz toward Ecleto, Tex. on azimuth 355°02'; freq. 4050V MHz toward Beeville, Tex. on azimuth 190°31'.

1541–C1–P–74—Same (KOA62), 4 Miles SW. of Beeville, Texas. Lat. 28°23'14" N., Long. 97°48'43" W. C.P. to change antenna system and add freqs. 3770V, 3850V MHz toward Choate, Tex. on azimuth 10°29'; freq. 4090V MHz toward Orange Grove, Tex. on azimuth 207°53'.

1542–C1–P–74—Same (KOA63), 7.2 Miles NW. of Orange Grove, Texas. Lat. 28°00'50" N., Long. 98°02'04" W. C.P. to change antenna system and add freqs. 3730V, 3810V MHz toward Beeville, Tex. on azimuth 27°47'; freqs. 3710H, 3790H MHz toward Rabb, Tex. on azimuth 121°59'; freq. 4050V MHz toward San Diego, Tex. on azimuth 215°55'.

1543–C1–P–74—Same (KOA64), Rabb, 5 Miles NW. of Robstown, Texas. Lat. 27°50'21" N., Long. 97°43'13" W. C.P. to add freqs. 4090V, 4170V, 3750H MHz toward Orange Grove, Tex. on azimuth 302°08'; freqs. 3750H, 3830H MHz toward Corpus Christi, Tex. on azimuth 99°02'.

1544–C1–P–74—Same (KKW21), 401 North Broadway, Corpus Christi, Texas. Lat. 27°47'35" N., Long. 97°23'48" W. C.P. to add freqs. 3710H, 4050V, 4310V MHz toward Rabb, Tex. on azimuth 279°11'.

1545–C1–P–74—Same (WDD59), 3.5 Miles SW. of San Diego, Texas. Lat. 27°43'26" N., Long. 98°16'13" W. C.P. to add freq. 4090V MHz toward Falfurrias, Tex. on azimuth 163°07'; freq. 3930V MHz toward Orange Grove, Tex. on azimuth 35°48'.

1546–C1–P–74—Same (KKW24), 4.5 Miles north of Falfurrias, Texas. Lat. 27°17'20" N., Long. 98°07'21" W. C.P. to add freq. 4050V MHz toward Rachal, Tex. on azimuth 181°30'; freq. 3890V MHz toward San Diego, Tex. on azimuth 343°11'.

1547–C1–P–74—Same (KKW25), 2.1 Miles north of Rachal, Texas. Lat. 26°55'12" N., Long. 98°08'00" W. C.P. to add freq. 4090V MHz toward Linn, Tex. on azimuth 176°41'; freq. 3930V MHz toward Falfurrias, Tex. on azimuth 61°30'.

1548–C1–P–74—Same (KKW26), 1 Mile SE. of Linn, Texas. Lat. 26°32'57" N., Long. 98°06'34" W. C.P. to add freq. 4050V MHz toward Monte Alto, Tex. on azimuth 136°47'; freq. 3890V MHz toward Rachal, Tex. on azimuth 356°42'.

1549–C1–74—Same (WDD60), 2.2 Miles east of Monte, Alto, Texas. Lat. 26°22'48" N., Long. 97°55'59" W. C.P. to add freq. 4090V MHz toward Harlingen, Tex. on azimuth 130°45'; freq. 3830V MHz toward Linn, Tex. on azimuth 316°51'.

1550–C1–P–74—Same (KKK53), 401 East Van Buren, Harlingen, Texas. Lat. 26°11'30" N., Long. 97°41'28" W. C.P. to add freq. 3890V MHz toward Monte Alto, Tex. on azimuth 310°52'.

1593–C1–P–74—American Telephone and Telegraph Company (KID72), 3 Miles SE. of Thomasville, North Carolina. Lat. 35°50'22" N., Long. 80°03'33" W. C.P. to add freq. 4050V MHz toward Greensboro, N.C. on azimuth 42°39'.

1594–C1–P–74—Same (KIQ99), 124 South Eugene St., Greensboro, North Carolina. Lat. 36°04'19" N., Long. 79°47'42" W. C.P. to add freq. 4090V MHz toward Thomasville, N.C. on azimuth 222°49'.

1595–C1–P–74—Same (WGN65), 4.7 Miles SE. of Ellisville, Florida. Lat. 29°56'53" N., Long. 28°33'29" W. C.P. to add freqs. 3750V, 4090H, 4170H MHz toward Lake City, Fla. on azimuth 343°48'.

1596–C1–P–74—Same (KJM70), 130 W. Nassau St., Lake City, Florida. Lat. 30°11'17" N., Long. 82°38'18" W. C.P. to add freqs. 3710V, 4050H, 4130H MHz toward Ellisville, Fla. on azimuth 163°45'.

1597–C1–P–74—General Telephone Company of Wisconsin (New), Columbia Generating Station, 4 Miles South of Portage, Wisconsin. Lat. 43°29'04" N., Long 89°25'11" W. C.P. for a new station on freq. 2122.0H MHz toward Poynette, Wisc. on azimuth 157°14'.

1598–C1–P–74—General Telephone Company of the Southeast (KTG52), 3 South Farr Avenue, Andrews, South Carolina. Lat. 33° 27'03" N., Long. 79°33'44" W C.P. to change antenna system and add freq. 6256.5H MHz toward Georgetown, S.C. on azimuth 109°36'.

1599–C1–P/L–74—American Telephone and Telegraph Company (KEA77), 0.8 Mile North of Cherryville, New Jersey. Lat. 40° 34'18" N., Long. 74°54'22" W. C.P. & License to add freqs. 3750V, 3830V MHz toward Iselin, N.J. on azimuth 89°54'.

1600–C1–P/L–74—Same (KEA76), 0.9 Mile West of Iselin, New Jersey. Lat. 40°34'16" N., Long. 74°20'49" W. C.P. & License to add freqs. 3710V, 3790V MHz toward Cherryville, N.J. on azimuth 270°15'; freqs. 3710V, 3790V MHz toward New York #7, N.Y. on azimuth 54°08'.

1601–C1–P/L–74—Same (KEL79), 811 Tenth Avenue, New York, New York. Lat. 40°45' 59" N., Long. 73°59'27" W. C.P. & License to said freqs. 3750V, 3830V MHz toward Iselin, N.J. on azimuth 234°21'.

1459–C1–P–74—Pacific Northwest Bell Telephone Company (WJM83), Kamiak Butte, 5.5 Miles SW. of Palouse, Washington. Lat. 46°51'37" N., Long. 117°10'49" W. C.P. to change antenna system and add freq. 2114H MHz toward a new point of communication at La Crosse, Wash. via Passive Reflector.

1604–C1–P–74—The Mountain States Telephone and Telegraph Company (KGG29), 5.2 Miles NW. of Sweet, Idaho. Lat. 44°01'-08" N., Long. 116°24'15" W. C.P. to add freqs. 11265H 11465V MHz toward a new point of communication at Horseshoe Bend, Idaho via Passive Reflector.

1605–C1–P–74—Wisconsin Telephone Company (WDE41), 4.0 Miles NNE. of Waunakee, Wisconsin. Lat. 43°15'20" N., Long. 89°25'14" W. C.P. to add freq. 2112.4V MHz toward a new point of communication at Poynette, Wisc. on azimuth 17°54'.

1606–C1–P–74—Same (New), 1.5 Miles East of Poynette, Wisconsin. Lat. 43°23'13" N., Long. 89°21'49" W. C.P. for a new station on freq. 2162.4V MHz toward Waunakee, Wisc. on azimuth 197°34'; freq. 2172.0H MHz toward Portage, Wisc. on azimuth 337°16'.

1607–C1–P–74—The Pacific Telephone and Telegraph Company (KMM99), 1206 West 8th Avenue, Chico, California. Lat. 39°44'-16" N., Long. 121°52'02" W. C.P. to add freq. 6226.9H MHz toward High Plateau Mountain, Calif. on azimuth 135°36'.

1608–C1–P–74—Same (KMJ96), High Plateau Mountain, California. Lat. 39°16'38" N., Long. 121°17'19" W. C.P. to add freq. 5974.8V MHz toward Chico, Calif. on azimuth 315°58'; freq. 6974.8V MHz toward Wolf Creek, Calif. on azimuth 133°28'.

1609–C1–P–74—Same (KMQ41), Wolf Creek, 6 Miles SW. of Grass Valley, California. Lat. 39°08'17" N., Long. 121°06'01" W. C.P. to add freq. 6226.9V MHz toward High Plateau Mountain, Calif. on azimuth 313°35'.

1610–C1–P–74—American Telephone and Telegraph Company (WGI26), 5 Miles NW. of Monticello, Georgia. Lat. 33°20'16" N., Long. 83°45'59" W. C.P. to add freq. 3710H, 3790H MHz toward Rutledge, Ga. on azimuth 30°57'.

1611–C1–P–74—Same (WIV54), 6.0 Miles NE of Rutledge, Georgia. Lat. 33°40'52" N., Long. 83°31'12" W. C.P. to add freqs. 3750H, 3830H MHz toward Monticello, Ga. on azimuth 211°05'; freqs. 3750V, 3830V MHz toward Statham, Ga. on azimuth 349°06'.

1612–C1–P–74—Same (KRT22), 1.2 Miles North of Statham, Georgia. Lat. 33°59'15" N., Long. 83°35'27" W. C.P. to add freqs. 3710V, 3790V MHz toward Rutledge, Ga. on azimuth 169°04'.

1613–C1–TC–(8)–74—Southwest Texas Transmission Company. Consent to Transfer of Control from Southwest Texas Transmission Company, Transferor to Viacom International Inc., Transferee for Stations: KLR38—D'Hanis, Tex.; KKY45—Uvalde, Tex.; KKY46—Las Moras, Tex.; KLP99—Wardlaw Ranch, Tex.; KJK31—Smarr, Ga.; KLR36—Mayfield Ranch, Tex.; KLR37—Sonora, Tex.; KKK27—Beeler Farm, Tex.

1614–C1–TC–(36)–74—CPI Microwave, Inc. Consent to Transfer of Control from CPI Microwave, Inc., Transferor to Viacom International Inc., Transferee for Stations: WPE37—Fort Worth, Tex.; WPE35—Dallas, Tex., WPE36—Midlothian, Tex.; WPE38—Midway, Tex.; WPE39—Axtell, Tex.; WPE40—Waco, Tex.; WPE41—Lott, Tex.; WPE42—Holland, Tex.; WPE43—Cele, Tex.; WPE44—Bastrop, Tex.; WPE45—Driftwood, Tex.; WPE49—Austin, Tex.; WPE46—Rt. 46, New Braunfels, Tex.; WPE47—Bracken, Tex.; WPE48—San Antonio, Tex.; WPE50—Giddings, Tex.; WPE51—Welcome, Tex.; WPE52—Hempstead, Tex.; WPE53—Rose Hill, Tex.; WPE54—Spring, Tex.; WPE55—Crosby, Tex.; WPE59—Houston, Tex.; WPE56—Ames, Tex.; WPE57—Sour Lake, Tex.; WPE58—Beaumont, Tex.; WQP49—Floresville, Tex.; WQP50—Pawnee, Tex.; WQP51—Beeville, Tex.; WQP52—Mathis, Tex.; WQP53—Violet, Tex.; WJK95—Bishop, Tex.; WJK96—Falfurias, Tex.; WJK97—Encino, Tex.; WJL33—Linn, Tex.; WJL35—LaVilla, Tex.; and WQQ88—Parkway Central, Tex.

1615–C1–TC–(10)–74—Tower Communication Systems Corporation. Consent to Transfer of Control from Tower Communication Systems Corporation, Transferor to Viacom International, Inc., Transferee for Stations: KQO40—St. Louisville, Ohio; KQO41—Coshocton, Ohio; KQO42—Shanesville, Ohio; KQO43—New Philadelphia, Ohio; KQA33—South Portsmouth, Ohio; KQA36—Ball Knob, Ohio; WPF49—Stoutsville, Ohio; WKS45—Newark, Ohio; WSL41—Hillsboro, Ohio; and WPY99—Columbus, Ohio.

1616–C1–TC–(40)–74—West Texas Microwave Company. Consent to Transfer of Control from West Texas Microwave Company, Transferor to Viacom International, Inc., Transferee for Stations: WPE24—Fort Worth, Tex.; KLU86—Aledo, Tex.; KLU87—Mineral Wells, Tex.; KLU88—Brackeen, Tex.; KLU89—Breckenridge, Tex.; KLU91—Albany, Tex.; KTQ81—Colorado City, Tex.; KTR33—Snyder, Tex.; KTR34—Griffins Creek, Tex.; KTR35—Pleasant Valley, Tex.; KYS49—Big Spring, Tex.; KZI25—Lubbock, Tex.; KZI26—Abernathy, Tex.; KZI27—Anson, Tex.; KZI82—Stamford, Tex.; KLR75—Estes Ranch, Tex. KZS70—Seminole, Tex.; KZS71—Brownfield, Tex.; KKT90—Levelland, Tex.; KKU85—Midland, Tex.; WAY37—Cotton Center, Tex.; WAY38—McClurg Farm, Tex.; WAY39—Jennings Farm, Tex.; WHB26—Amarillo, Tex.; WPE26—Amarillo, Tex.; WHB27—Purvines, Tex.; WHB28—Community Center, Tex.; WHB29—South Tower, Tex.; KTQ80—Sweetwater, Tex.; WQE31—Odessa, Tex.; WPE27—Odessa, Tex.; WQE32—Goldsmith, Tex.; WPE28—Goldsmith, Tex.; WPE29—Wink, Tex.; WPE30—Mason, Tex.; WPE31—Guadalupe, Tex.; WPE32—Borrego Tex.; WPE33—Commanche Peak, Tex.; WPE34—El Paso, Tex. and WPE25—Hobbs, N. Mex.

CORRECTIONS

1097–C1–P–74—South Central Bell Telephone Company (KLR71), Correct to Read: C.P. to add freq. 3770V MHz toward a new point of communication at Blackland, Miss. (All other particulars same as reported on Public Notice #669, dated 10–9–73.)

1444–C1–P–74—United Video, Inc. (New), North Meadowbrook Terrace, Florida. Correct to Read: File No. 1444–C1–P–74. (All other particulars same as reported on Public Notice #673, dated 11–5–73.)

[FR Doc.73-24581 Filed 11-19-73;8:45 am]

FEDERAL POWER COMMISSION

[Docket Nos. RI74–62, etc.]

CHEVRON 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]

NOVEMBER 8, 1973.

Respondents have filed proposed changes in rates and charges for jurisdictional sales of natural gas, as set forth in Appendix A below.

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 lawfulnes 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.
RI74-62	Chevron Oil Co.	26	10	Transwestern Pipeline Co., (Atoka Field, Eddy County, N. Mex.) (Permian Basin).	$64,885	10-15-73		4-15-74	[1] 24.84	[1] 29.5181	
	do	27	11	Transwestern Pipeline Co., (Kermit and South Kermit Fields, Winkler County, Tex. R. R. No. 8) (Permian Basin).	14,060	10-15-73		4-15-74	[1] 26.5825	[1] 29.6411	
	do	28	11	do	8,043	10-15-73		4-15-74	[1] 26.5825	[1] 29.6411	
	do	29	11	do	178,924	10-15-73		4-15-74	[1] 26.5825	[1] 29.6411	
RI71-193	Amoco Production Co.	329	7	Transwestern Pipeline Co. (South Kermit Field, Winkler County, Tex., Permian Basin).	(13,972)	10-16-73	8-7-73	[12] Accepted	27.32	[2] [3] [4] 24.825	RI71-193.
	do	329	8	do	13,972	10-16-73		10-17-73	[2] [3] 24.825	27.32	
RI73-167	do	494	[5] 10	El Paso Natural Gas Co., (Gomez Field, Pecos County, Tex.) (Permian Basin).	(10,157)	10-15-73	8-7-73	[12] Accepted	31.12	[2] [3] [4] 22.21	RI73-167.
	do	494	[5] 11	do	10,157	10-15-73		10-16-73	[2] [3] 22.21	31.12	
RI73-265	Shell Oil Co.	168	14	West Texas Gathering Co., (Emperor Field, Winkler County, Tex.) (Permian Basin).	659,872	10- 9-73		10-10-73	[2] 23.0	[6] 28.105	
RI73-175	do	249	15	El Paso Natural Gas Co., (Brown Bassett Field, Terrell County, Tex., Permian Basin).	(19,177)	8-15-73	8-7-73	[12] Accepted	[1] 24.355	[1] [4] 23.0	RI73-175.
	do	249	16	do	19,177	10- 9-73		10-10-73	[2] 23.0	[1] 24.355	
RI73-308	do	253	12	El Paso Natural Gas Co., (James Ranch Field, Eddy County, N. Mex., Permian Basin).	31,536	10- 9-73		[1] 11-22-73	[1] 23.0	[7] 28.0	
RI73-294	Sun Oil Co.	94	12	Northern Natural Gas Co., (Emperor Field, Winkler County, Tex.) (Permian Basin).	186,486	10-12-73		[11] 11-28-73	[1] 23.0	[10] 28.105	
RI73-162	Union Oil Company of California.	118	9	West Texas Gathering Co. (Emperor and South Kermit Fields, Winkler County, Tex.) (Permian Basin).	(276,675)	10-15-73	8-7-73	Accepted[13]	29.5103	[4] [9] 24.1500	RI73-162.
					276,675	10-15-73		10-16-73	[1] 24.1500	29.5103	

* Unless otherwise stated, the pressure base is 14.65 p.s.i.a.
[1] Includes quality adjustments and gathering allowance, if applicable pursuant to Opinion No. 662.
[2] Subject to quality adjustments and gathering allowance, if applicable pursuant to Opinion No. 662.
[3] Includes quality adjustments.
[4] Rate decrease in compliance with Opinion No. 662.
[5] Applicable only to Price Estate gas sold pursuant to Supplement No. 7.
[6] Previously suspended in Docket No. RI73-265 until Sept. 21, 1973.
[7] Previously suspended until Nov. 22, 1973, in Docket No. RI73-308.
[8] Date prior increase to 28 cents per Mcf would have become ESR in Docket No. RI73-308.
[9] Subject to quality adjustments pursuant to Opinion No. 662.
[10] Rate previously suspended until Nov. 28, 1973, in Docket No. RI73-294.
[11] Date prior increase to 28.105 cents per Mcf would have become effective subject to refund in Docket No. RI74-294.
[12] The proposed rate is accepted as of the date shown in the "Effective Date Unless Suspended" column, the date of issuance of Opinion No. 662. The proposed rate accepted herein shall not exceed the applicable area rate as adjusted for quality, and gathering allowance if applicable, pursuant to Opinion No. 662.

Amoco Production Company, Shell Oil Company (Rate Schedule No. 249), Sun Oil Company, and Union Oil Company of California (Respondents) were collecting increased rates subject to refund prior to Opinion No. 662 (Permian II) which were in excess of the just and reasonable rates established in that opinion. They have filed herein decreased rates down to the levels prescribed in that opinion, and concurrently have filed rate increases back up to the rate levels in effect, subject to refund, prior to that opinion. The proposed decreases are accepted as of August 7, 1973, the effective date of Opinion No. 662, and the proposed rate increases are suspended in the same suspension proceedings applicable to their earlier filings for one day from the date of filing with waiver of the 30 day notice period granted.

Shell Oil Company (Rate Schedule Nos. 168 and 253) and Sun Oil Company have submitted rate increases from the applicable area ceiling rates prescribed in Opinion No. 662 back up to the same levels under suspension at the time of issuance of Opinion No. 662. The suspension period for these proposed increased rates will expire as of the date each earlier filing would have become effective subject to refund under the prior suspension order or one day from the date of the subject filing, whichever is later.

The proposed increases of Chevron Oil Company exceed the applicable area ceiling rates prescribed in Opinion No. 662. Accordingly, they are suspended for five months.

[FR Doc.73-24323 Filed 11-19-73;8:45 am]

[Docket Nos. CP74-113, CI74-276]

CONSOLIDATED GAS SUPPLY CORP. ET AL.

Notice of Application

NOVEMBER 9, 1973.

Take notice that on October 26, 1973, Consolidated Gas Supply Corporation (Supply Corporation), CNG Producing Company (CNG), and Consolidated Natural Gas Company (Consolidated), 445 West Main Street, Clarksburg, West Virginia 26301, filed in Docket No. CP74-113, a joint application pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing transfer through Consolidated all of Supply Corporation's developed gas producing leases and related facilities in the Louisiana area to CNG. Take further notice that concurrently with this joint application CNG filed in Docket No. CI74-276 an application pursuant to section 7(c) of the Natural Gas Act for authorization to continue, as successor in interest to Supply Corporation, thirteen off-system sales now being made by Supply Corporation in the South Louisiana area and to initiate eleven sales of gas to Supply Corporation from production offshore and onshore Louisiana. These proposals are more fully set forth in the applications which are on file with the Commission and open to public inspection.

Pursuant to the Agreement to Transfer Oil and Gas Leases dated October 19, 1973, Applicants seek authorization for Supply Corporation to transfer to Consolidated its leasehold interest in approximately 11,800 net acres of producing gas properties and underlaying gas reserves estimated to total approximately 105,191,000 Mcf as of July 1, 1973, located offshore and onshore Louisiana. Consolidated will upon said transfer cancel a portion of Supply Corporation's long-term indebtedness equal to the lesser of the net book value of the properties to be transferred multiplied by the ratio of Supply Corporation's long-term indebtedness to the total net book value of Supply Corporation's plant or the basis, for federal income tax purposes, of the properties transferred.

Consolidated agrees further to transfer the subject properties to CNG, in consideration for which CNG will issue shares of its capital stock to Consolidated equal in principal amount to the net book value of the properties so transferred. The application in Docket No.

CP74–113 states that the net book cost of the production property proposed herein for transfer was $46,101,145 as of June 30, 1973. Applicants state that upon the subject transfer to CNG, Supply Corporation will remove said costs from its books and records.

CNG requests in Docket No. CI74–276 authorization to continue Supply Corporation's sales subject to the terms and conditions of contracts which are on file with the Commission as Consolidated's Rate Schedules F–8, F–10, F–12; F–14 through F–17; F–19 through F–21; and F–24 through F–26, to its FPC Gas Tariff, Original Volume No. 3. Said sales are described in the Appendix hereto.

In addition to the continuance of said sales CNG requests authorization to initiate eleven sales of gas to Supply Corporation as set forth in the appendix low. The application states that CNG proposes to sell gas being produced or which will be produced, from various fields offshore and onshore Louisiana, which it received as a result of these subject transfer arrangements, to Supply Corporation. CNG expresses its willingness to accept a certificate conditioned to just and reasonable area ceiling rates promulgated by the Commission's Opinion No. 598 issued July 16, 1971, in Docket No. AR61–2, et al. (46 FPC 86).

Applicants allege that the proposed reorganization of most production activities into a single corporate entity and the proposed sales of natural gas will allow for the most effective means of assuring that sufficient gas supplies are developed and dedicated to the Consolidated system to permit the rendering of adequate service to its customers.

Any person desiring to be heard or to make any protest with reference with said application should on or before December 4, 1973, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10) and the regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by sections 7 and 15 of the Natural Gas Act and the Commission's rules of practice and procedure, a hearing will be held without further notice before the Commission on these applications if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

KENNETH F. PLUMB,
Secretary.

APPENDIX

Docket No. and date filed	Applicant	Purchaser and location	Price per Mcf	Pressure base
CI74–276..... A 10–26–73	CNG Producing Co. 445 West Main St., Clarksburg, W. Va. 26301.	Consolidated Gas Supply Corp., Block 186. Block 186 Field, Ship Shoal Area, offshore Louisiana.	[1] 45.0	15.025
	do	Blocks 255 and 256 of the Block 255 Field, Vermilion Area, offshore Louisiana (Shallow).	[1] 26.0	15.025
	do	Blocks 255 and 256 of the Block 255 Field, Vermilion Area, offshore Louisiana (Deep).	[1] 45.0	15.025
	do	Block 287 of the Block 292 Field, Eugene Island Area, offshore Louisiana.	[1] 35.0	15.025
	do	Block 307 of the Block 292 Field, Eugene Island Area, offshore Louisiana.	[1] 45.0	15.025
	do	Block 314 of the Block 292 Field, Eugene Island Area, offshore Louisiana.	[1] 45.0	15.025
	do	Blocks 267 and 268 of the Block 255 Field, Vermilion Area, offshore Louisiana.	[1] 45.0	15.025
	do	Block 315 of the Block 292 Field, Eugene Island Area, offshore Louisiana.	[1] 45.0	15.025
	do	Blocks 3 and 18 of the Block 16 Field, Vermilion Area, offshore Louisiana.	[1] 45.0	15.025
	do	Block 118 Field, East Cameron Area, offshore Louisiana.	[1] 45.0	15.025
	do	Choudrant Field, Lincoln Parish, Louisiana.....	[1] 45.0	15.025
CI74–276 (CP60–75) E 10–26–73	CNG Producing Co (successor to Consolidated Gas Supply Corp.) 445 West Main St., Clarksburg, W. Va. 26301.	Texas Gas Transmission Corp., Bayou Chevreuil Field, Lafourche Parish, La.	[2] 23.250	15.025
(CP61–152)	do	Texas Gas Transmission Corp., Pass Wilson and Bay Round Fields, Terrebonne Parish, La.	[2][3] 23.25 [2][4] 26.625	15.025 15.025
(CP64–119)	do	Texas Gas Transmission Corp., Lake Palourde Field, St. Mary and St. Martin Parish La.	[2] 23.25	15.025
(CP65–282)	do	Transcontinental Gas Pipe Line Corp., Block 23 Field, South Marsh Island Area, offshore Louisiana.	[2] 20.0	15.025
(CP66–225)	do	Texas Gas Transmission Corp., Hell Hole Bayou Area, Vermilion Parish, La.	[2] 22.375	15.025
(CP67–108)	do	Texas Gas Transmission Corp., Block 40 field, Ship Shoal Area, Terreonne Parish, La.	[2] 23.0	15.025
(CP69–17)	do	Natural Gas Pipeline Co. of America, Block 225 and 229 Fields, West Cameron Area, offshore Zone Four, Louisiana.	[2][3] 21.375 [2][4] 26.0	15.025 15.02
(CP69–235)	do	Texas Gas Transmission. Corp., Block 272 and 292 Fields, Eugene s land Area, offshore Zone Four, Louisiana.	[2] 26.0	15.025
(CP70–294)	do	Transcontinental Gas Pipe Line Corp., Block 101 Field, Vermilion Area, offshore Zone Four, Louisiana.	[2] 26.0	15.025
CI74–276 (CP71–100) E 10–26–73	do	Southern Natural Gas Co., Fish Island Field, Iberia Parish, La.	[2] 22.0	15.025
(CP71–103)	do	Texas Gas Transmission Corp., Duson Field, Lafayette Basin, La.	[2] 22.0	15.025
(CP71–104)	do	Texas Gas Transmission Corp., Chalkley Field, Cameron Parish, La.	[2] 23.0	15.025
(CP71–105)	do	Texas Gas Transmission Corp., Bayou Chevreuil Field, Lafourche, St. James, and St. John the Baptist Parishes, La.	[2] 23.0	15.025

Filing code: A—Initial service.
B—Abandonment.
C—Amendment to add acreage.
D—Amendment to delete acreage.
E—Succession.
F—Partial succession.

[1] Subject to upward and downward B.t.u. adjustment.
[2] Subject to downward B.t.u. adjustment.
[3] Rate for old reservoir.
[4] Rate for new reservoir.

[FR Doc.73–24322 Filed 11–19–73;8:45 am]

[Docket No. RP72–134]

EASTERN SHORE NATURAL GAS CO.

Notice of Proposed Changes in Rates and Charges

NOVEMBER 13, 1973.

Take notice that on October 29, 1973, Eastern Shore Natural Gas Company (Eastern Shore) tendered for filing as a part of its FPC Tariff the following revised tariff sheets:

Fifth Revised Sheet No. 3A
Fifth Revised PGA–1

Eastern Shore states that the revised tariff sheets increase its Rate Schedule GSS–1 to reflect an increase in purchased gas cost occasioned by filing of purchased gas cost increase by Transcontinental Gas Pipe Line Corporation on October 15, 1973, in FPC Docket No. RP73–3. Eastern Shore requests waiver of the notice requirements of § 154.22 of the regulations

under the Natural Gas Act and of § 20.2 of its General Terms and Conditions to the extent necessary to permit the tariff sheets to become effective as of December 1, 1973.

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 and 1.10). All such petitions or protests should be filed on or before November 23, 1973. 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, unless such petition has been filed previously in this proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.73-24651 Filed 11-19-73;8:45 am]

[Docket No. CP74-110]

NORTHERN NATURAL GAS CO.

Notice of Application

NOVEMBER 13, 1973.

Take notice that on October 26, 1973, Northern Natural Gas Company (Applicant), 2223 Dodge Street, Omaha, Nebraska 68102, filed in Docket No. CP74-110 an application pursuant to section 7 (c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing Applicant to construct and operate certain pipeline loop and compression facilities on Applicant's main transmission system east of its Ogden, Iowa, Compressor Station, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant proposes to construct and operate 14.3 miles of 26-inch pipeline loop which will complete the 26-inch loopline between Applicant's Ogden and Waterloo compressor Stations located in eastern Iowa. In addition, Applicant proposes to construct a 7,000 horsepower compressor station (East Dubuque) in Jo Daviess County, Illinois to increase compression in said loopline facilities and thereby to provide Applicant with approximately 80,000 Mcf per day of additional delivery capability.

Applicant states this additional delivery capability will provide it operational flexibility for use in various special operating arrangements entered into by Applicant with certain utility customers and pipeline companies to provide additional winter peaking service during the 1973-74 heating season.

Applicant states this increased capability is of particular use in an existing gas exchange and storage arrangement between Applicant and Michigan Wisconsin Pipeline Company (Michigan Wisconsin). Applicant states that the proposed facilities will provide Applicant with aproximately 80,000 Mcf of natural gas per day of additional off-peak delivery volume, which could be delivered to Michigan-Wisconsin at the existing Jamesville, Wisconsin, delivery point, located near the terminus of the east leg of Applicant's transmission system, for transportation and injection into storage fields in lower Michigan to be returned to Applicant during peak periods to meet wintertime requirements. Applicant alleges that this added flexibility will enable Applicant to accommodate this special gas exchange storage arrangement with Michigan Wisconsin for the purpose of providing reliable and adequate service to Applicant's high-priority markets.

The estimated cost of the proposed facilities is $5,020,400 which will be financed from cash on hand, funds generated through operations, and short-term bank notes as required.

Any person desiring to be heard or to make any protest with reference with said application should on or before December 4, 1973, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10) and the regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by sections 7 and 15 of the Natural Gas Act and the Commission's rules of practice and procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

KENNETH F. PLUMB,
Secretary.

[FR Doc.73-24652 Filed 11-19-73;8:45 am]

[Docket No. E-8459]

NORTHERN STATES POWER CO.

Notice of Purchase Agreement

NOVEMBER 13, 1973.

Take notice that Northern States Power Company (NSP), on October 29, 1973, tendered for filing, an Agreement dated October 24, 1973, with Dairyland Power Cooperative (Dairyland). NSP states that the Agreement provides for the sale of 20 mw of power and associated energy to Dairyland for the period December 1, 1973 through May 31, 1974, and requests an effective date of December 1, 1973.

NSP states that the rate for subject transactions has been established as follows:

Capacity charge	$20.00 per KW year.
Energy charge	5.8 mills per KWH.

NSP further states that the capacity charge is a negotiated rate which will remain constant over the entire period of associated transactions for sales by Northern States to Dairyland and for the equivalent sales by Dairyland to Northern States.

Any person desiring to be heard or to protest said application 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 and protests should be filed on or before November 23, 1973. 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.73-24650 Filed 11-19-73;8:45 am]

[Docket No. CP74-120]

TENNESSEE GAS PIPELINE CO. AND TENNECO INC.

Notice of Application

NOVEMBER 13, 1973.

Take notice that on November 2, 1973, Tennessee Gas Pipeline Company, a Division of Tenneco Inc. (Applicant), P.O. Box 2511, Houston, Texas 77001, filed in Docket No. CP74-120 an application pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the construction and operation of certain pipeline facilities necessary to connect to Applicant's system new gas reserves to be purchased from Tenneco Oil Company (Tenneco) in Eugene Island Block 215, offshore Louisiana, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant proposes to construct and operate approximately 5.1 miles of 12-inch pipeline extending from Eugene Island Block 215 to Applicant's existing 30-inch pipeline in Eugene Island Block 230, offshore Louisiana. The application indicates that the total cost of the proposed facilities is estimated to be $1,732,400, which cost will be financed from

general funds and/or revolving credit.

Applicant estimates that approximately 25,000,000 Mcf of recoverable natural gas will be available to it under its agreement with Tenneco and that the proposed facilities will permit it to purchase up to 20,000 Mcf per day.

Any person desiring to be heard or to make any protest with reference with said application should on or before December 4, 1973, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10) and the regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by sections 7 and 15 of the Natural Gas Act and the Commission's rules of practice and procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

KENNETH F. PLUMB,
Secretary.

[FR Doc.73-24653 Filed 11-19-73;8:45 am]

[Docket No. RI74-47]

CHAMPLIN PETROLEUM CO.

Notice of Petition for Special Relief

NOVEMBER 12, 1973.

Take notice that on September 12, 1973, Champlin Petroleum Company (Petitioner), P.O. Box 9365, Fort Worth, Texas 76107, filed a petition for special relief in Docket No. RI74-47, pursuant to § 2.77 of the Commission's General Policy and Interpretations. Petitioner requests that it be granted special relief from the area rates set forth in Opinion No. 586, issued September 18, 1970, at Docket Nos. AR64-1, et al. and that a 45 cent rate be authorized for sales of casinghead gas to Panhandle Eastern Pipe Line Company under its FPC Gas Rate Schedule No. 105.

Petitioner is presently producing casinghead gas from acreage dedicated under the subject rate schedule which it claims is being flared because the current effective rate for such sales is insufficient to warrant the installation of necessary gathering and compressing facilities with respect to such gas. Petitioner states that its proposed rate will be sufficient to warrant the installation of the compressing and gathering facilities necessary to deliver the casinghead gas to the purchaser.

Any person desiring to be heard or to make any protest with reference to said petition should on or before November 30, 1973, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any party wishing to become a party to a proceeding, or to participate as a party in any hearing therein, must file a petition to intervene in accordance with the Commission's rules.

KENNETH F. PLUMB,
Secretary.

[FR Doc.73-24657 Filed 11-19-73;8:45 am]

[Docket No. CI74-285]

CRYSTAL OIL CO.

Notice of Application

NOVEMBER 13, 1973.

Take notice that on November 1, 1973, Crystal Oil Company (Applicant), P.O. Box 1101, Shreveport, Louisiana 71163, filed in Docket No. CI74-285 an application pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the sale for resale and delivery of natural gas in interstate commerce to United Gas Pipe Line Company from the Northeast Dubach Field, Lincoln Parish, Louisiana, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant states that it commenced the sale of natural gas on October 19, 1973, within the contemplation of § 157.29 of the Regulations under the Natural Gas Act (18 CFR 157.29) for sixty days and proposes to continue said sale for one year from the end of the sixty-day emergency period within the contemplation of § 2.70 of the Commission's general policy and interpretations (18 CFR 2.70). Applicant proposés to sell approximately 6,000 Mcf of gas per month at 45.0 cents per Mcf at 15.025 p.s.i.a.

It appears reasonable and consistent with the public interest in this case to prescribe a period shorter than 15 days for the filing of protests and petitions to intervene. Therefore any person desiring to be heard or to make any protest with reference to said application should on or before November 26, 1973, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by sections 7 and 15 of the Natural Gas Act and the Commission's rules of practice and procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

KENNETH F. PLUMB,
Secretary.

[FR Doc.73-24647 Filed 11-19-73;8:45 am]

[Docket No. CP67-181, CP70-216, etc.]

EAST TENNESSEE NATURAL GAS CO.

Notice of Petition To Amend

NOVEMBER 13, 1973.

Take notice that on November 1, 1973, East Tennessee Natural Gas Company (Petitioner), P.O. Box 10245, Knoxville, Tennessee 37919 filed in Docket Nos. CP67-181, et al., and CP70-216 a petition to amend the Commission's orders issuing certificates of public convenience and necessity pursuant to section 7(c) of the Natural Gas Act in said dockets on August 2, 1970 (38 FPC 237), and July 22, 1970 (44 FPC 146), as amended on January 11, 1972 (47 FPC 72), respectively, by authorizing the sale of presently certificated volumes of natural gas to two existing customers under different rate schedules than previously authorized, all as more fully set forth in the petition to amend which is on file with the Commission and open to public inspection.

By our order of August 2, 1970, Petitioner is authorized to sell 3,696 Mcf of natural gas per day to the Natural Gas Utility District of Hawkins County (Hawkins County) and by our order of January 11, 1970, Petitioner is authorized to sell to United Cities Gas Company (United Cities) a total of 21,988 Mcf of gas per day to be delivered at four service areas. Petitioner presently sells such gas to

Hawkins under its Rate Schedule No. SG–2 and sells gas to United Cities delivered at its Lynchburg Service Area under its Rate Schedule No. SG–1 and at its Maryville-Alcoa, Columbia and Shelbyville Service Areas under its CR–1 Rate Schedule. Petitioner herein seeks authorization to sell such gas to Hawkins County under its G–2 Rate Schedule and to United Cities under its CR–1 Rate Schedule.

Petitioner indicates that Hawkins County by purchasing the gas under Rate Schedule No. G–2 will be able to reduce its average cost of gas. Petitioner also indicates that United Cities by electing to consolidate the aforesaid service areas under one rate schedule will be able to enhance its ability to meet the peak day requirements for the aforesaid service areas, which extend from middle to eastern Tennessee, as the weather conditions vary from one service area to another. Petitioner states that if the proposed change is not authorized United Cities will have to construct additional peak shaving facilities, face curtailment of firm service, or experience unnecessary unauthorized overrun penalties.

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before December 4, 1973, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's rules.

KENNETH F. PLUMB,
Secretary.

[FR Doc.73-24658 Filed 11-19-73;8:45 am]

[Docket No. CI74-292]

KIRBY PETROLEUM CO.

Notice of Application

NOVEMBER 13, 1973.

Take notice that on November 1, 1973, Kirby Petroleum Co. (Applicant), P.O. Box 1745, Houston, Texas 77001, filed in Docket No. CI74-292 an application pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the sale for resale and delivery of natural gas in interstate commerce to Texas Eastern Transmission Corporation from the White Castle Area, Iberville Parish, Louisiana, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant states that it intends to commence the sale of natural gas for sixty days within the contemplation of § 157.29 of the regulations under the Natural Gas Act (18 CFR 157.29) and proposes to continue said sale for six months from the end of the sixty-day emergency period within the contemplation of § 2.70 of the Commission's general policy and interpretations (18 CFR 2.70). Applicant proposes to sell up to 2,000 Mcf of gas per day, plus additional gas which may be available and which the purchaser can receive, at 55.0 cents per Mcf at 15.025 psia, subject to upward and downward Btu adjustment from a base of 1,000 Btu per cubic foot with upward adjustment limited to 1,100 Btu per cubic foot. Initial upward Btu adjustment is estimated at 5.5 cents per Mcf.

It appears reasonable and consistent with the public interest in this case to prescribe a period shorter than 15 days for the filing of protests and petitions to intervene. Therefore, any person desiring to be heard or to make any protest with reference to said application should on or before November 26, 1973, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by sections 7 and 15 of the Natural Gas Act and the Commission's rules of practice and procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

KENNETH F. PLUMB,
Secretary.

[FR Doc.73-24644 Filed 11-19-73;8:45 am]

[Docket No. E-8428, etc.]

NORTHEAST UTILITIES ET AL.

Notice of Applications

NOVEMBER 13, 1973.

Take notice that each of the Applicants listed herein has filed an application pursuant to Section 205 of the Federal Power Act and Part 35 of the Regulations issued thereunder.

Any person desiring to be heard or to make any protest with reference to these applications should on or before December 4, 1973, file with the Federal Power Commission, Washington, D.C. 20426, petitions to intervene or protests in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10). Persons wishing to become parties to a proceeding or to participate as a party in a hearing related thereto must file petitions to intervene in accordance with 18 CFR 1.8.

All protests filed with the Commission will be considered by it in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding.

The applications referred to herein are on file with the Commission and are available for public inspection.

Docket No. E-8428, Filing Date, October 4, 1973, Name of Applicant, Northeast Utilities.

Applicant submits for filing a Transmission Agreement dated August 20, 1973 between the Connecticut Light and Power Company, the Hartford Electric Light Company, Western Massachusetts Electric Company and Consolidated Edison Company of New York, Inc.

The above mentioned agreement provides for transmission service to Consolidated Edison for the period from September 3, 1973 to a date not later than October 31, 1973. Applicant will be wheeling power that Consolidated Edison has purchased from the United Illuminating Company of New Haven, Connecticut.

Pursuant to § 35.11 of the Commission's regulations, Applicant requests waiver of the thirty-day period required by § 35.3(a) of the Commission's regulations; Applicant proposes that this filing be made effective as of September 3, 1973.

Docket No. E-8430, Filing Date, October 5, 1973, Name of Applicant, Public Service of Indiana.

By letter dated October 3, 1973, Applicant submits for filing a supplement to the Interconnection Agreement dated October 13, 1969, between Applicant and the City of Washington, Indiana. This supplement provides for an amendment to the Fuel Adjustment Clause included in Service Schedule A-Firm Power, Exhibit I to the Interconnection Agreement.

Docket No. E-8431, Filing Date, October 5, 1973, Name of Applicant, Kansas Gas & Electric Co.

Applicant submits for filing an Initial Rate Schedule between Applicant and the city of Mulvane, Kansas, June 1, 1973 is the effective date of the agreement; however, due to construction, the actual interconnection may not be closed for some time.

Included with this filing are three service schedules. Schedule A relates to Firm Power Serivce at $1.725 per kw per month of billing demand, plus 4.5 mills per kwh if Applicant must purchase firm power

from other sources. Schedule A also contains a Fuel Adjustment Clause, Schedule B relates to emergency service under the party's Agreement, and Schedule C covers economy energy.

Due to contingencies involved in each of these service schedules, Applicant is unable to furnish a comparison of sales, service and revenues for the twelve months succeeding the date of initial service.

Docket No. E-8433, Filing Date, October 9, 1973, Name of Applicant, Virginia Electric & Power Co.

By letter dated October 4, 1973, Applicant submits a supplement to its agreement with the Northern Piedmont Electric Cooperative. This supplement provides for a new delivery point to be designated as the "Orleans Delivery Point". Applicant requests that the Commission allow this supplement to become effective on the date the facilities are connected with the understanding that Applicant will notify the Commission of that date. Furthermore, on that date of connection, the Warrenton Delivery Point will be abandoned.

Docket No. E-8440, Filing Date, October 11, 1973, Name of Applicant, Northern States Power Co.

By letter dated October 5, 1973, Applicant submits for filing the stepped rates schedule for the period November 1, 1973 through October 31, 1974. Applicant indicates that this schedule will become effective 30 days after filing. Applicant is acting on behalf of the members of the Mid-Continent Area Power Pool Agreement.

Exhibit A, included with Applicants letter, shows the investment cost per kilowatt of generating units installed or planned from 1960 to 1977 by the signatories to the MAPP Agreement. Exhibit B shows the Average Production Costs for some typical generating units. Exhibit C is a tabulation of Service Schedule B and Service Schedule I. The rates provided in Service Schedule B, Seasonal Participation Power Interchange Service, and Service Schedule I, Short Term Power Interchange Service, of the subject agreement are negotiated rates.

Docket No. E-8441, Filing Date, October 11, 1973, Name of Applicant, Virginia Electric & Power Co.

By letter dated October 10, 1973, Applicant indicates that on June 25, 1973, the transformer capacity at the Garner Delivery Point for Northern Neck Electric Cooperative was changed from 5 MVA capacity to 10/12.5 MVA capacity. This supplement is designated as proposed FPC No. 80-16 and would supersede FPC Rate Schedule No. 80-10 dated October 6, 1969.

Applicant requests June 25, 1973 as the effective date for this supplement.

Applicant indicates that there will be no increase in the unit cost of electricity, and therefore, requests waiver of the required billing date.

Docket No. E-8444, Filing Date, October 12, 1973, Name of Applicant, The Washington Water Power Co.

By letter dated October 10, 1973, Applicant submits for filing with the Commission an agreement between Applicant and Portland General Electric Company (Portland General). This Agreement provides the delivery of capacity by Portland General to Applicant on a monthly basis in the amount of 50,000 kw during the period November 1, 1973 through March 31, 1974. In exchange for this capacity Applicant will deliver 2,404 mwh of energy per week to Portland General during the same time period.

KENNETH F. PLUMB,
Secretary.

[FR Doc.73-24626 Filed 11-19-73;8:45 am]

[Docket No. E-8470]

STOCKTON LIGHT & POWER CO., AND DELMARVA POWER & LIGHT CO., ET AL.

Notice of Application

NOVEMBER 13, 1973.

Take notice that on November 1, 1973, a joint application on behalf of Stockton Light & Power Company, and its wholly-owned Virginia subsidiary (Stockton), and Delmarva Power & Light Company, and its wholly-owned Maryland and Virginia subsidiaries (Delmarva), was filed with the Federal Power Commission pursuant to section 203 of the Federal Power Act for authorization of Stockton to transfer, and Delmarva's Maryland and Virginia subsidiaries to acquire the electric utility business and assets of Stockton in Maryland and Virginia, for a total price of $425,000.00, payable in common stock of Delmarva, as provided in the Contract of Sale.

The facilities to be transferred and acquired are situate in the southeastern area of Worcester County, Maryland, and the northeastern area of Accomack County, Virginia.

The Application states in part that on July 21, 1978, the Applicants entered into a contract of sale, which contains the proposed terms of the transaction. All of the Applicants state that the proposed sale is in the public interest.

Any person desiring to be heard or to make any protest with reference to said Application should on or before December 7, 1973, file with the Federal Power Commission, Washington, D.C. 20426, petitions to intervene or protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Persons wishing to become parties to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules. The Application is on file with the Commission and is available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.73-24648 Filed 11-19-73;8:45 am]

[Docket No. E-8215]

UNION ELECTRIC CO.

Notice of Extension of Time

NOVEMBER 13, 1973.

On November 7, 1973, the Cities of Kirkwood, Farmington, and Fredericktown, Missouri and West Point, Iowa and Citizens Electric Corporation (Cities) filed a motion for an extension of the service dates. The motion states that the staff has consented to the request.

Upon consideration, notice is hereby given that the procedural dates are modified as follows:

Intervener's Testimony Service Date, November 16, 1973.
Company's Rebuttal Service Date, November 30, 1973.
Prehearing Conference (unchanged), December 4, 1973 (10:00 a.m., e.s.t.).
Hearing (unchanged), December 11, 1973 (10:00 a.m., e.s.t.).

KENNETH F. PLUMB,
Secretary.

[FR Doc.73-24645 Filed 11-19-73;8:45 am]

[Docket No. E-8454]

UPPER PENINSULA POWER CO.

Notice of Agreement

NOVEMBER 13, 1973.

Take notice that Upper Peninsula Power Company (Upper Peninsula) on October 19, 1973, tendered for filing an agreement between Upper Peninsula and the City of Escanaba, Michigan (Escanaba), dated June 1, 1973, which amends the original agreement between the parties dated January 4, 1956, as amended by an agreement dated July 6, 1967, and designated Rate Schedule FPC No. 9.

Upper Peninsula states that the new agreement is primarily designed to reimburse Upper Peninsula for its services in maintaining and operating Escanaba's steam electric generating station. The agreement further provides that the fee for such management services will be adjusted for changes in the cost of fuel as set forth in the agreement. Upper Peninsula requests that this agreement be accepted for filing to become effective June 1, 1973. According to Upper Peninsula, this date would coincide with the effective date of the new fee for the management services provided by Upper Peninsula.

Upper Peninsula also states that service upon Escanaba has been made in accordance with § 35.2(d) of the Commission's regulations (18 CFR 35.2(d)).

Any person desiring to be heard or to protest said application 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 November 27, 1973. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make pro-

testants 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.73-24649 Filed 11-19-73;8:45 am]

FEDERAL RESERVE SYSTEM

AMERICAN FLETCHER CORP.

Proposed Acquisition of Charg-It of Florida, Inc.

American Fletcher Corporation, Indianapolis, Indiana, has applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.4(b)(2) of the Board's Regulation Y, for permission to acquire the assets of Charg-It of Florida, Inc., Coral Gables, Florida. Notice of the application was published on September 5, 1973, in The Miami Herald, a newspaper circulated in Miami, Florida and on September 7, 1973, in the Sentinel Star, Orlando, Florida, a newspaper circulated in Orlando, Florida.

Applicant states that the proposed subsidiary would engage in the activities of issuing credit cards to individuals covering lines of credit granted by the Company to the cardholders, and purchasing from retail merchants the accounts receivable resulting from sales made by such merchants to the holders and users of the credit cards. Such activities have been specified by the Board in § 225.4(a) of Regulation Y as permissible for bank holding companies, subject to Board approval of individual proposals in accordance with the procedures of § 225.4(b).

Interested persons may express their views on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question should be accompanied by a statement summarizing the evidence the person requesting the hearing proposes to submit or to illicit at the hearing and a statement of the reasons why this matter should not be resolved without a hearing.

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Chicago.

Any views or requests for hearing should be submitted in writing and received by the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, not later than December 13, 1973.

Board of Governors of the Federal Reserve System, November 9, 1973.

[SEAL] THEODORE E. ALLISON,
Assistant Secretary of the Board.

[FR Doc.73-24627 Filed 11-19-73;8:45 am]

BANCOHIO CORP.

Proposed Acquisition of Midwest Econometrics, Inc.

BancOhio Corporation, Columbus, Ohio, has applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.4(b)(2) of the Board's Regulation Y, for permission to acquire voting shares of Midwest Econometrics, Inc., Columbus, Ohio. Notice of the application was published on October 3, 1973, in The Columbus Dispatch, and the Columbus Citizens-Journal newspapers circulated in Columbus, Ohio.

Applicant states that the proposed subsidiary would engage in the activity of providing for economic forecasting services to business organizations and to State and local governments. Such activities have been specified by the Board in § 225.4(a) of Regulation Y as permissible for bank holding companies, subject to Board approval of individual proposals in accordance with the procedures of § 225.4(b).

Interested persons may express their views on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question should be accompanied by a statement summarizing the evidence the person requesting the hearing proposes to submit or to elicit at the hearing and a statement of the reasons why this matter should not be resolved without a hearing.

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Cleveland.

Any views or requests for hearing should be submitted in writing and received by the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, not later than December 6, 1973.

Board of Governors of the Federal Reserve System, November 9, 1973.

[SEAL] THEODORE E. ALLISON,
Assistant Secretary of the Board.

[FR Doc. 73-24620 Filed 11-19-73;8:45 am]

BARNETT BANKS OF FLORIDA, INC.

Acquisition of Bank

Barnett Banks of Florida, Inc., Jacksonville, Florida, 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 90 per cent or more of the voting shares of First Peoples Bank of Fort Walton Beach, Fort Walton Beach, Florida. 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 Atlanta. Any person wishing to comment on the application should submit his views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, to be received not later than December 9, 1973.

Board of Governors of the Federal Reserve System, November 12, 1973.

[SEAL] THEODORE E. ALLISON,
Assistant Secretary of the Board.

[FR Doc.73-24624 Filed 11-19-73;8:45 am]

COMMONWEALTH NATIONAL CORP.

Order Approving Acquisition of Bank

Commonwealth National Corporation, Boston, Massachusetts, 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 up to 100 per cent of the voting shares of Town Bank and Trust Company, Brookline, Massachusetts ("Town 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 the Board has considered the application and all comments received in light of the factors set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Applicant, the 22nd largest commercial banking organization in Massachusetts, controls one bank, Commonwealth Bank and Trust Company ("Commonwealth Bank"), with deposits of about $45 million, representing approximately .3 per cent of total commercial bank deposits in the State.[1] Town Bank ($13.8 million in deposits) accounts for less than .1 per cent of total Statewide commercial bank deposits. Consummation of the transaction would not result in a significant increase in the concentration of banking resources in Massachusetts.

Town Bank is the 46th largest commercial banking organization in the Boston banking market (approximated by the Boston SMSA)[2] and controls about .1 percent of total market deposits.[3] Applicant's present banking subsidiary, Commonwealth Bank, with six banking offices in Suffolk County, controls .5 percent of commercial bank deposits in the Boston banking market and is the 19th largest commercial banking organization in that market. Town Bank's two offices are located in Norfolk County.

There are a total of 59 commercial banking organizations, operating 463 offices, which compete in the Boston banking market. The Boston market has

[1] All banking data are as of December 31, 1972, unless otherwise indicated, and reflect bank holding company formations and acquisitions approved by the Board through September 30, 1973.

[2] The Boston SMSA encompasses all of Suffolk County and portions of Essex, Middlesex, Norfolk, and Plymouth Counties.

[3] All market data are as of June 30, 1972

a high level of deposit concentration, as the five largest commercial banking organizations—which are also the five largest in the State—control in excess of 80 percent of market deposits.[4] Acquisition of Town Bank would increase Applicant's share of market deposits by only .1 percent. Moreover, a large number of small banks would remain available for acquisition.

Commonwealth Bank is located in the city of Boston in Suffolk County, while Town Bank is located in the town of Brookline in Norfolk County. Under Massachusetts law, neither bank may branch into the other's home office town. While the service areas of the two banks overlap, the amount of existing competition between the two institutions is not regarded as substantial. Neither bank does substantial business throughout the entire Boston SMSA and the present degree of competition between Town Bank and Commonwealth Bank is tempered by the existence of intervening banks and numerous banking alternatives. Located in Town Bank's primary service area are a number of other commercial banks; thus, other banking alternatives would remain to the community served by Town Bank. Further, in view of Town Bank's position in its service area, Applicant's acquisition would probably increase its competitive effectiveness. Also, it does not appear likely Applicant would enter Norfolk County in view of its limited financial resources. Accordingly, competitive considerations are consistent with approval of the application.

The financial and managerial resources and prospects of Applicant and Town Bank are satisfactory in light of Applicant's intent to reduce part of its acquisition debt by means of a public offering; therefore, banking factors are consistent with approval of the application. Although there is no evidence in the record to indicate that the banking needs of the area are currently not being satisfied by existing financial institutions, Applicant proposes to make trust and computer services available to Town Bank's customers. In addition, Applicant will seek to shift Bank's loan portfolio away from participations to more direct lending. Thus, considerations relating to the convenience and needs of the community to be served lend slight weight toward approval. It is the Board's judgment that consummation of the proposed transaction would be in the public interest and that the application should be approved.

Applicant owns a nonbanking subsidiary, Combank Corporation, acquired October 14, 1969, which engages in mortgage lending. Neither Town Bank nor Combank Corporation are significant competitors in the Boston mortgage lending market. Accordingly, it is the Board's conclusion that approval would not adversely affect competition in mortgage lending in the Boston area.

Applicant's banking and nonbanking activities remain subject to Board review, and the Board retains the authority to require Applicant to modify or terminate its nonbanking activities or holdings if the Board at any time determines that the combination of Applicant's banking and nonbanking activities is likely to have adverse effects on the public interest.

Accordingly, 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 Boston pursuant to delegated authority.

By order of the Board of Governors,[5] effective November 12, 1973.

[SEAL] CHESTER B. FELDBERG,
Secretary of the Board.

[FR Doc.73-24633 Filed 11-19-73;8:45 am]

[4] Excluded from this market share determination are deposits held by mutual savings banks which approximate $10.4 billion (as of June 30, 1972).

[5] Voting for this action: Vice Chairman Mitchell and Governors Brimmer, Sheehan, Bucher, and Holland. Absent and not voting: Chairman Burns and Governor Daane.

DOMINION BANKSHARES CORP.

Order Approving Acquisition of Fitton Insurance Agency, Inc.

Dominion Bankshares Corporation, Roanoke, Virginia, a bank holding company within the meaning of the Bank Holding Company Act, has applied for the Board's approval, under section 4(c)(8) of the Act and § 225.4(b)(2) of the Board's Regulation Y, to acquire all of the voting shares of The Fitton Insurance Agency, Inc., Alexandria, Virginia ("Agency") and thereby to engage in insurance agency activities. Certain insurance agency activities have been determined by the Board to be closely related to banking (12 CFR 225.4(a)(9)).

Notice of the application, affording opportunity for interested persons to submit comments and views, has been duly published (38 Federal Register 916).[1] The time for filing comments and views has expired, and the Board has considered all comments received in light of the public interest factors set forth in section 4(c)(8) of the Act.[2]

Applicant, the fifth largest banking organization in Virginia, controls nine banks with aggregate deposits of $840 million, representing 7.4 per cent of commercial bank deposits in the State. (All banking data are as of June 30, 1973, adjusted to reflect bank holding company formations and acquisitions approved through September 30, 1973.) Applicant's principal nonbanking subsidiaries consist of a service company, a bank premises company, a second mortgage corporation and a leasing corporation. In addition, Applicant earlier this year received Board approval to acquire The Fitton Company, Alexandria, Virginia ("Company"), which engages indirectly through its subsidiaries in mortgage lending and related data processing activities.

Agency was established in 1961 by Company's former controlling shareholders to operate in connection with Company's mortgage lending activities; and Agency's sole office is at the same address as is Company, in Alexandria, Virginia. For the nine-month period ending August 31, 1972, Applicant had gross commission income of $83 thousand. Approximately $49 thousand of this commission income resulted from the sale of declining coverage term life insurance policies where the coverage was equal to the outstanding balance of the mortgage held or serviced by Company, the sale of accident and health insurance policies where the coverage was equal to the monthly mortgage payment of an outstanding mortgage held or serviced by Company, and the sale of homeowners' insurance policies and fire and extended coverage policies where the primary coverage of the policy protects collateral which formed the basis for an extension of credit by Company or secures a mortgage serviced by Company. Thus, approximately 60 per cent of Agency's gross commission income appears to be directly related to an extension of credit by Company or directly related to the provision of other financial services by Company. Applicant states that the remaining insurance sales relate to persons to whom it had extended credit in the past or with whom a special relationship exists.

[1] The published notice of this application included notice of a related application to acquire The Fitton Company, Alexandria, Virginia. When the National Association of Insurance Agents, Inc. and related parties objected to the proposed acquisition of Agency and requested a hearing thereon, Applicant requested separate consideration of the two applications to avoid delay in Board consideration of the application to acquire The Fitton Company. The Board announced approval of the acquisition of The Fitton Company on April 23, 1973 (38 FR 10675).

[2] The National Association of Insurance Agents, Inc. and related parties objected to approval of this application and by petition dated January 22, 1973, requested that a hearing be held upon the application. On March 6, 1973, the Board directed that a hearing be held on this application, among others. The Administrative Law Judge designated to conduct the proceedings upon the application scheduled a hearing thereon. Subsequently, the objectors to the application and Applicant reached agreement among themselves whereby the objections to the application were withdrawn and whereby Applicant agreed to be bound by the final outcome of other specified applications to engage in insurance agency activities. On May 23, 1973, the Administrative Law Judge dismissed the application from the hearing docket and referred the application back to the Board.

It appears that a substantial portion (approximately 40 percent) of Agency's business is not directly related to an extension of credit or the provision of financial services by Company or by any other subsidiary of Applicant. The Board has indicated that the "convenience" provision of § 225.4 (a)(9)(ii)(c) is not designed to permit entry into the general insurance agency business. In order to assure that Agency is not operated as a general insurance agency, approval of the proposed acquisition is conditioned upon reduction of that portion of Agency's premium income which is not directly related to an extension of credit by Company or directly related to the provision of other financial services by Company to less than 5 percent of the aggregate premium income of Agency sold pursuant to § 225.4(a)(9)(ii) of Regulation Y. Although Applicant engages in certain insurance activities through a number of its existing subsidiaries, approval of the proposed acquisition would not eliminate any significant existing competition between Applicant's subsidiaries and Agency because of the limited nature of the respective insurance activities. Nor does it appear that affiliation of Agency with Applicant would adversely affect the numerous existing competitors in the Washington, D.C. metropolitan area where Company and Agency are engaged in business. It is anticipated that the sale of insurance by Agency will provide a convenient alternative source of insurance agency services for customers of Company. There is no evidence in the record indicating that consummation of the proposed transaction would result in any undue concentration of resources, unfair competition, conflicts of interest, unsound banking practices, or other adverse effects.

Based upon the foregoing and other considerations reflected in the record, the Board has determined that the balance of the public interest factors the Board is required to consider under section 4(c)(8) is favorable. Accordingly, the application is hereby approved conditioned upon the reduction of Agency's premium income which is not directly related to an extension of credit by Company or directly related to the provision of other financial services by Company to less than 5 percent of the aggregate premium income of Agency sold pursuant to § 225.4(a)(9)(ii) of Regulation Y and that such reduction be accomplished within two years from the effective date of this order. This determination is also subject to the conditions set forth in § 225.4(c) of Regulation Y (12 CFR 225.4(c)) and to the Board's authority to require such modification or termination of the activities of a holding company or any of its subsidiaries as the Board finds necessary to assure compliance with the provisions and purposes of the Act and the Board's regulations and orders issued thereunder, or to prevent evasion thereof. The transaction shall be made not 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 Richmond.

By order of the Board of Governors,[1]

[SEAL] CHESTER B. FELDBERG,
Secretary of the Board.

[FR Doc.73-24631 Filed 11-19-73;8:45 am]

FIDELITY AMERICAN BANKSHARES, INC.

Order Approving Acquisition of Bank

Fidelity American Bankshmares, Incorporated, Lynchburg, 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 pursuant to section 3(a)(3) of the Act to acquire 90 percent or more of the voting shares of Planters Bank and Trust Company, Chatham, Pittsylvania County, Virginia (Bank), a State member 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 (12 CFR 265.2(f)(24)).

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, 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)), and finds that:

Applicant controlled eleven banking affiliates operating 71 offices with aggregate deposits of $595.4 million, an amount equivalent to 5.3 percent of total commercial bank deposits in Virginia, as of June 30, 1973. In terms of deposits it is the Commonwealth's eighth largest banking organization. Applicant has recently acquired two de novo banking institutions and has received approval of an application for the acquisition of an additional de novo bank. An application to acquire an existing bank is currently pending. Applicant also controls seven nonbanking subsidiaries which engage in mortgage, consumer finance, credit-related insurance agency, and bank service activities. Acquisition of Bank (deposits of $9.4 million as of June 30, 1973) would increase Applicant's share of deposits in Virginia by approximately .08 percent. Consummation of the proposed transaction would not significantly increase the concentration of banking resources within the Commonwealth.

Bank is one of ten banking organizations located in the relevant geographic market, which includes Pittsylvania County and the independent City of Danville. At the present time, four bank holding companies are represented within this market. Of the ten banking institutions, Bank ranks eighth, with 4.5 percent of market deposits. Applicant's lead bank, Fidelity National Bank, is headquartered in Lynchburg and serves the Lynchburg SMSA, which constitutes a separate banking market from that in which Bank competes. The closest office of any of Applicant's subsidiary banks to Bank is a branch of its lead bank in Altavista, Campbell County, approximately 22 miles north of Chatham. Virginia law prohibits either Applicant's lead bank or Bank from establishing branches within the geographic market served by the other. There is no significant competition existing between Bank and any banking subsidiary of Applicant, and there appears to be little incentive for Applicant to enter Bank's geographic market de novo. Consummation of the proposed acquisition would not result in a substantial lessening of banking competition within the relevant geographic market; the effects of the transaction on competition are not inconsistent with approval of the application.

The financial and managerial resources of Applicant and Bank are generally satisfactory, and future prospects appear to be favorable. Banking factors, therefore, lend weight toward approval of the application. Although there is no evidence to indicate that significant banking needs of the relevant geographic market are going unserved, consummation of the proposed acquisition should enable Bank to initiate new services now offered by Applicant's other banking subsidiaries, including data processing, commercial financing, and trust services, especially in the rural areas of Pittsylvania County, away from Danville. Convenience and needs considerations thus favor approval. It is the Reserve Bank's judgment that consummation of the proposed acquisition would be in the public interest.

On the basis of the record in this case, the application is approved for the reasons summarized above. However, 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 November 8, 1973.

[SEAL] ROBERT P. BLACK,
President.

[FR Doc.73-24623 Filed 11-19-73;8:45 am]

FINANCIAL SERVICES CORPORATION OF THE MIDWEST

Formation of Bank Holding Company

Financial Services Corporation of the Midwest, Rock Island, Illinois, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company through

[1] Voting for this action: Vice Chairman Mitchell and Governors Brimmer, Sheehan, Bucher, and Holland. Absent and not voting: Chairman Burns and Governor Daane. effective November 12, 1973.

acquisition of 100 percent of the voting shares (less directors' qualifying shares) of the successor by merger with Rock Island Bank and Trust Company. 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 Chicago. Any person wishing to comment on the application should submit his views in writing to the Reserve Bank, to be received not later than November 26, 1973.

Board of Governors of the Federal Reserve System, November 12, 1973.

[SEAL] THEODORE E. ALLISON,
Assistant Secretary of the Board.

[FR Doc.73-24626 Filed 11-19-73;8:45 am]

FIRST MARYLAND BANCORP

Formation of Bank Holding Company

First Maryland Bancorp, Baltimore, Maryland, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company through acquisition of 100 percent (less directors' qualifying shares) of the voting shares of The First National Bank of Maryland, Baltimore, Maryland. 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 Richmond. Any person wishing to comment on the application should submit his views in writing to the Reserve Bank, to be received not later than November 26, 1973.

Board of Governors of the Federal Reserve System, November 12, 1973.
November 12, 1973.

[SEAL] THEODORE E. ALLISON,
Assistant Secretary of the Board.

[FR Doc.73-24619 Filed 11-19-73;8:45 am]

FIRST NATIONAL FINANCIAL CORP.

Order Approving Acquisition of an Existing Bank

First National Financial Corporation, Kalamazoo, 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 100 percent of the voting shares of the successor by consolidation to The Moline State Bank, Moline, Michigan ("Bank"). The bank into which Bank is to be consolidated has no significance except as a means to facilitate the acquisition of the voting shares of Bank. Accoridngly, 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 this Reserve Bank has considered the application and all comments received in light of the factors set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Applicant controls seven banks with aggregate deposits of approximately $397.6 million representing 1.6 percent of the total deposits in commercial banks in Michigan.[1] It is the tenth largest banking organization in the State. Since no subsidiary of Applicant and Bank are engaged in any meaningful competition, and since Bank is the 396th largest bank in Michigan with $4.1 million in deposits, approval of the proposed acquisition would not eliminate any existing competition or result in any significant increase in the concentration of banking resources in Michigan.

Bank ranks tenth in the concentrated Moline-Grand Rapids market area with 0.3 per cent of the total deposits. Three multi-bank holding companies with 44 offices account for approximately 90 per cent of the total deposits in that area. It is concluded that the acquisition of Bank by Applicant would be procompetitive in that Bank would be able to more effectively compete with these larger banking organizations. Therefore, consummation of the proposal should stimulate competition without having any undue adverse effect on other banks in the banking market.

The financial and managerial considerations of Applicant and its existing subsidiary banks are satisfactory. Bank also has sound financial resources, satisfactory management, adequate capitalization, and favorable earnings and future prospects. Banking factors are consistent with approval of the application.

It appears that the convenience and needs in the Moline area are being satisfactorily served by Bank and other banks in the area or by the larger Grand Rapids banks. However, approval of the subject proposal would enable Bank, through Applicant, to provide a wider range of services and to improve services now available to the community. Therefore, convenience and needs considerations lend some weight toward approval.

It is this Federal Reserve Bank's judgment that the proposed transaction is in the public interest and that the application should be approved.

On the basis of the record as summarized above, the Federal Reserve Bank of Chicago approves the application, provided that 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 or this Federal Reserve Bank pursuant to delegated authority.

By order of the Federal Reserve Bank of Chicago, acting pursuant to delegated authority for the Board of Governors of the Federal Reserve System, effective November 6, 1973.

[SEAL] ROBERT P. MAYO,
President.

[FR Doc. 73-24628 Filed 11-19-73;8:45 am]

[1] All Banking data are of December 31, 1972.

FROSTBANK CORP.

Order Approving the Retention of the Assets of Data Processing Center

FrostBank Corporation (formerly Frost Realty Company), San Antonio, Texas, a bank holding company within the meaning of the Bank Holding Company Act ("Act"), has applied for the Board's approval, under section 4(c)(8) of the Act and § 225.4(b)(2) of the Board's Regulation Y, to retain the assets of Data Processing Center, San Antonio, Texas, ("Data Center") an operating division of Applicant's wholly-owned subsidiary, Main Plaza Corporation, San Antonio, Texas ("Main Plaza"). The activities of Data Center consist of performing data processing services for Applicant, its subsidiaries and other business enterprises. Such activities have been determined by the Board to be closely related to banking (12 CFR 225.4(a)(8)).

Notice of the application, affording opportunity for interested persons to submit comments and views on the public interest factors, has been duly published (38 FR 23989). The time for filing comments and views has expired, and none has been timely received.

Applicant, the ninth largest multibank holding company in Texas, controls two banks[1] with aggregate deposits of $519 million, representing 1.5 per cent of the total deposits in commercial banks in the State.[2]

Applicant's lead bank performs data processing services of a banking nature such as demand deposits, time and savings deposits and loan accounting for its internal operations and for other banks. Data Center performs data processing services of an accounting nature, such as payroll, accounts payable and inventory control for banks and other business enterprises. Applicant's banking subsidiaries accounted for 57 per cent of Data Center's total billing for 1972. Within the relevant market, which is approximated by the San Antonio SMSA, Data Center competes with 27 other data processing companies. In view of the distinct types of services provided by Applicant's lead bank and Data Center, as well as the large number of competitors in the market, it does not appear that the retention of Data Center would have an adverse effect on either existing or potential competition. Nor is there any evidence in the

[1] Applicant, in addition to these two banks, owns 20.6 per cent of Texas State Bank, San Antonio, Texas, and 24.9 per cent of Harlandale State Bank, San Antonio, Texas. Both of the interests are subject to divestiture by Applicant by May 1, 1975, pursuant to the Board's Order of March 21, 1973.

[2] All banking data are as of December 31, 1972, and reflect holding company acquisitions and formations approved by the Board through September 10, 1973.

record indicating that the retention of Data Center would lead to an undue concentration of resources, conflicts of interest, or unsound banking practices. On the other hand, approval of the application should enable Data Center to remain a viable competitor in serving the data processing needs of the community.

Based upon the foregoing and other considerations reflected in the record, the Board has determined that the balance of the public interest factors the Board is required to consider under section 4(c)(8) is favorable. Accordingly, the application is hereby approved. This determination is subject to the conditions set forth in § 225.4(c) of Regulation Y and to the Board's authority to require such modification or termination of the activities of a holding company or any of its subsidiaries as the Board finds necessary to assure compliance with the provisions and purposes of the Act and the Board's regulations and orders issued thereunder, or to prevent evasion thereof.

By order of the Board of Governors,[1] effective November 12, 1973.

[SEAL] CHESTER B. FELDBERG,
Secretary of the Board.

[FR Doc.73-24634 Filed 11-19-73;8:45 am]

HAWKEYE BANCORPORATION

Acquisition of Bank

Hawkeye Bancorporation, Des Moines, Iowa, 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 50 per cent or more of the voting shares of American State Bank, Mason City, Iowa. 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 Chicago. Any person wishing to comment on the application should submit his views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, to be received not later than December 9, 1973.

Board of Governors of the Federal Reserve System, November 12, 1973.

[SEAL] THEODORE E. ALLISON,
Assistant Secretary of the Board.

[FR Doc.73-24629 Filed 11-19-73;8:45 am]

HERITAGE BANCORPORATION

Order Approving Acquisition of Bank

Heritage Bancorporation, Cherry Hill, New Jersey, 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 (less directors' qualifying shares) of the successor by merger to First Charter National Bank, Monroe Township, New Jersey ("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, the seventh largest banking organization in New Jersey, presently controls two banks with aggregate deposits of approximately $622 million, representing 3.2 percent of the total commercial bank deposits in the State.[1] Acquisition of Bank (approximately $129 million in deposits) would increase Applicant's share of State deposits by less than 1 percent and would not result in a significant increase in the concentration of banking resources in New Jersey.

Bank is the second largest of 21 banking organizations in the New Brunswick banking market which is the relevant market (approximated by most of Middlesex County, the eastern third of Somerset County, and the northern tip of Monmouth County), and controls deposits of $113.6 million, representing 12.1 percent of the total commercial bank deposits in the market.[2] Applicant's subsidiary bank closest to Bank is located about 17 miles away, in a separate banking market, and no meaningful present competition exists between either of Applicant's subsidiary banks and Bank.

Although Applicant could enter the market de novo, or through the acquisition of a smaller bank, or by branching, Applicant's acquisition of Bank would not have a substantially adverse effect on potential competition because consummation of the proposal would not result in Applicant's gaining a dominant share of the market's banking resources, nor would it appear to foreclose the entry of other banking organizations into this market. Recent changes in New Jersey's banking statutes now allow commercial banks to branch statewide, and there are a substantial number of banking organizations in the State which could be considered potential entrants. Accordingly, the Board concludes that competitive considerations are consistent with approval of the application.

The financial and managerial resources and future prospects of Bank, and of Applicant and its present subsidiary banks are regarded as satisfactory, particularly in view of Applicant's commitment to increase Bank's capital. Considerations relating to the banking factors are consistent with approval of the application. Although there is no evidence in the record to indicate that the banking needs of the residents of the communities served by Bank are not currently being met, Applicant's acquisition will enable Bank to extend maturities on mortgage loans, increase Bank's customer lending limit, and participate in loans with Applicant's other subsidiaries. Considerations relating to the convenience and needs of the communities to be served lend some weight toward 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 Philadelphia pursuant to delegated authority.

By order of the Board of Governors,[3] effective November 12, 1973.

[SEAL] CHESTER B. FELDBERG,
Secretary of the Board.

[FR Doc.73-24635 Filed 11-19-73;8:45 am]

INDIAN HEAD BANKS, INC.

Order Approving Acquisition of Bank

Indian Head Banks, Inc., Nashua, New Hampshire, 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 80 percent or more of the voting shares of Keene National Bank, Keene, New Hampshire ("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 eight banks with aggregate deposits of approximately $199 million, representing 15.2 percent of total deposits in commercial banks in New Hampshire and is the only multibank holding company and the largest banking organization in the State. (All banking data are as of December 31, 1972, and reflect holding company formations and acquisitions approved by the Board through September 30, 1973.) The ac-

[1] Voting for this action: Vice Chairman Mitchell and Governors Brimmer, Sheehan, Bucher, and Holland. Absent and not voting: Chairman Burns and Governor Daane.

[1] All banking data are as of June 30, 1973, unless otherwise noted.

[2] Banking data as of June 30, 1972.

[3] Voting for this action: Vice Chairman Mitchell and Governors Brimmer, Sheehan, Bucher, and Holland. Absent and not voting: Chairman Burns and Governor Daane.

quisition of Bank ($17 million deposits) would increase Applicant's share of State deposits by 1.3 percentage points.

Bank is the third largest of the four commercial banks located in the Cheshire County banking market. It holds 28.7 percent of total market deposits, and the largest and second largest banks hold 35 percent and 28.8 percent, respectively, of such total deposits. Four savings banks hold 89 percent of the market's IPC time and savings deposits. Only 17 percent of Bank's total deposits are time and savings accounts, and Bank is not a major competitor for these deposits. However, Bank has the largest volume of IPC demand deposit accounts in the market.

Applicant does not operate in the Cheshire County Banking market, and its closest subsidiary bank is located approximately 33 miles east of Keene in Hillsboro County. Only a small amount of demand and savings deposits and loans is derived by Applicant's subsidiary offices from the Cheshire County market, and Bank derives no loans or deposits from any of the areas served by Applicant's banking offices. It appears that no significant amount of present competition would be eliminated by this proposal, and in view of the distances separating Bank and Applicant's nearest bank and State laws restricting branching, it appears unlikely that any meaningful competition would develop between the offices served by Applicant and Bank in the future. It is the Board's opinion that the acquisition of Bank by Applicant would have no adverse effect on existing or potential competition and would not tend to create a monopoly or in any manner be in restraint of trade in the relevant areas.

The financial condition and managerial resources of Applicant and its present subsidiaries are considered to be satisfactory in view of Applicant's commitment to increase the capital position of one of its subsidiaries. These same conditions are also deemed satisfactory as pertains to Bank, and prospects for each appear favorable. Considerations relating to banking factors lend some support for approval since Bank has need of the managerial resources available through Applicant's system.

Although there is no evidence that the major banking needs of the area are not presently served, Bank proposes to offer new and expanded services to the communities, including dealer floor planning, indirect dealer automobile financing and accounts receivable financing, expanded trust services, portfolio management and computer services. The affiliation would also increase the availability of credit in the area through Bank's increased loan participation capability. Considerations relating to the convenience and needs of the communities to be served are consistent with and lend some support to approval of the application. It is the Board's judgment that consummation of the proposed transaction 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 acquisition 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 Boston pursuant to delegated authority.

By order of the Board of Governors,[2] effective November 12, 1973.

[SEAL] CHESTER B. FELDBERG,
Secretary of the Board.

[FR Doc.73-24632 Filed 11-19-73;8:45 am]

IRWIN UNION CORP.

Order Approving Acquisition of Irwin Union Credit Insurance Company

Irwin Union Corporation, Columbus, Indiana, a bank holding company within the meaning of the Bank Holding Company Act, has applied for the Board's approval, under section 4(c)(8) of the Act and § 225.4(b)(2) of the Board's Regulation Y, to acquire all of the voting shares of Irwin Union Credit Insurance Company, Phoenix, Arizona ("Company"), a company that will engage de novo in the underwriting, as reinsurer, of credit life and credit accident and health insurance in connection with extensions of credit by Applicant's banking subsidiary. Such activities have been determined by the Board to be closely related to banking (12 CFR 225.4(a)(10)).

Notice of the application, affording opportunity for interested persons to submit comments and views on the public interest factors, has been duly published (38 FR 20299 and 21825). The time for filing comments and views has expired, and none has been timely received.

Applicant controls one bank with total deposits of $120.5 million, representing 0.9 percent of total deposits in commercial banks in Indiana, and is the 18th largest banking organization in the State. (All banking data are as of December 31, 1972.)

Company will be formed under Arizona law as a limited capital stock life insurance company. As Company will be qualified to underwrite insurance directly only in Arizona, its activities will be limited to acting as reinsurer of credit life and credit accident and health insurance policies made available in connection with extensions of credit by Applicant's banking subsidiary. Such insurance will be directly underwritten by an insurer qualified to underwrite in Indiana and will thereafter be assigned or ceded to Company under a reinsurance agreement. Certain larger policies will be "retroceded" or "reassigned" in part back to the insurer by Company so as to avoid Company being exposed to liabilities in excess of those permitted by Arizona law.[1]

Credit life and credit accident and health insurance is generally made available by banks and other lenders and is designed to assure repayment of a loan in the event of death or disability of a borrower. Applicant also proposes to underwrite joint credit life insurance. The Board has previously permitted such insurance to be underwritten when the credit extension was dependent upon the income of both the husband and wife.[2] The Board finds that joint credit life insurance, like other forms of credit life insurance, is offered in connection with an extension of credit and is designed to assure repayment of an extension of credit in the event of death of a cosigner or co-maker of a note. Since each of the co-signers or co-makers may be individually responsible for repayment of the credit extension, the Board finds insurance covering each to be directly related to an extension of credit. Accordingly, the Board has concluded that the sale and underwriting of joint credit life insurance is directly related to an extension of credit when both of the insured parties are co-makers or co-signers of the note issued in connection with the extension of credit.

In connection with its addition of credit life underwriting to the list of permissible activities for bank holding companies the Board stated:

> To assure that engaging in the underwriting of credit life and credit accident and health insurance can reasonably be expected to be in the public interest, the Board will only approve applications in which an applicant demonstrates that approval will benefit the consumer or result in other public benefits. Normally such a showing would be made by a projected reduction in rates or increase in policy benefits due to bank holding company performance of this service.

Applicant has stated that Company and the direct underwriter in Indiana which issues the credit life and credit accident and health insurance policies made available by Applicant's banking subsidiary will reduce the rates for credit life insurance and credit accident and health insurance by amounts ranging between 5 and 15 percent depending upon the specific coverage being offered. The Board believes the reduced cost of credit life and credit accident and health insurance is procompetitive and is in the public interest. The Board concludes that such public benefits outweigh any possible adverse effects of approval of the application.

Based upon the foregoing and other considerations reflected in the record, the Board has determined that the balance of the public interest factors the Board is required to consider under section 4(c)(8) is favorable. Accordingly, the application is hereby approved. This determination is subject to the conditions set forth in § 225.4(c) of Regulation Y and

[2] Voting for this action: Vice Chairman Mitchell and Governors Brimmer, Sheehan, Bucher and Holland. Absent and not voting: Chairman Burns and Governor Daane.

[1] The maximum amounts which may be insured by a limited capital stock life insurance company under Arizona law are $3,000 on any one life and $5,000 on any total disability claim.

[2] Application of Northwest Bancorporation to acquire Banco Credit Life Insurance Company (38 FR 14205).

to the Board's authority to require such modification or termination of the activities of a holding company or any of its subsidiaries as the Board finds necessary to assure compliance with the provisions and purposes of the Act and the Board's regulations and orders issued thereunder, or to prevent evasion thereof.

The transaction shall be made not 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.

By order of the Board of Governors,[1] effective November 12, 1973.

[SEAL] CHESTER B. FELDBERG,
Secretary of the Board.

[FR Doc.73-24630 Filed 11-19-73;8:45 am]

JACOB SCHMIDT COMPANY AND AMERICAN BANCORPORATION

Acquisition of Bank

Jacob Schmidt Company, St. Paul, Minnesota, through American Bancorporation of St. Paul, Minnesota, 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 per cent of the voting shares (less directors' qualifying shares) of First Burnsville State Bank, Burnsville, Minnesota. 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 Minneapolis. Any person wishing to comment on the application should submit his views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, to be received not later than December 9, 1973.

Board of Governors of the Federal Reserve System, November 12, 1973.

[SEAL] THEODORE E. ALLISON,
Assistant Secretary of the Board.

[FR Doc.73-24618 Filed 11-19-73;8:45 am]

MERCANTILE BANKSHARES CORP.

Acquisition of Bank

Mercantile Bankshares Corporation, Baltimore, Maryland, 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 not less than 80 percent or more of the voting shares of The Fidelity Bank, Frostburg, Maryland. 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 Richmond. Any person wishing to comment on the application should submit his views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, to be received not later than November 26, 1973.

Board of Governors of the Federal Reserve System, November 12, 1973.

[SEAL] THEODORE E. ALLISON,
Assistant Secretary of the Board.

[FR Doc.73-24625 Filed 11-19-73;8:45 am]

OLD KENT FINANCIAL CORP.

Acquisition of Bank

Old Kent Financial Corporation, Grand Rapids, Michigan, has applied for the Board's approval under section 3(a)(5) of the Bank Holding Company Act (12 U.S.C. 1842(a)(5)) to merge with Century Financial Corporation of Michigan, Saginaw, Michigan, and thereby to acquire 100 percent of the voting shares (less directors' qualifying shares) of Second National Bank of Saginaw, Saginaw, Michigan. 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 Chicago. Any person wishing to comment on the application should submit his views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, to be received not later than December 5, 1973.

Board of Governors of the Federal Reserve System, November 8, 1973.

[SEAL] THEODORE E. ALLISON,
Assistant Secretary of the Board.

[FR Doc.73-24621 Filed 11-19-73;8:45 am]

NORTHERN STATES BANCORPORATION, INC.

Acquisition of Bank

Northern States Bancorporation, Inc., Detroit, Michigan, 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 of National Bank of Rochester, Rochester, Michigan. 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 Chicago. Any person wishing to comment on the application should submit his views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, to be received not later than December 5, 1973.

Board of Governors of the Federal Reserve System, November 8, 1973.

[SEAL] THEODORE E. ALLISON,
Assistant Secretary of the Board.

[FR Doc.73-24622 Filed 11-19-73;8:45 am]

[1] Voting for this action: Chairman Burns and Governors Mitchell, Daane, Brimmer, Bucher and Holland. Absent and not voting: Governor Sheehan.

INTERNATIONAL BOUNDARY AND WATER COMMISSION, UNITED STATES AND MEXICO

ENVIRONMENTAL IMPACT STATEMENTS

Operational Procedures

NOVEMBER 9, 1973.

OPERATIONAL PROCEDURE FOR IMPLEMENTING SECTION 102 OF THE "NATIONAL ENVIRONMENTAL POLICY ACT OF 1969"

NOVEMBER 1973.

TABLE OF CONTENTS

NOTE: See Title 40—Protection of the Environment, Chapter V—Council on Environmental Quality, Part 1500—Preparation of Environmental Impact Statements: Guidelines, published at 38 FR 20549, in the issue of Wednesday, August 1, 1973.

OPERATIONAL PROCEDURES FOR IMPLEMENTING SECTION 102 OF THE "NATIONAL ENVIRONMENTAL POLICY ACT OF 1969"

The National Environmental Policy Act of 1969 (NEPA or the Act) (Pub. L. 91-190), Executive Order 11514 (E.O. 11514) dated March 5, 1970, and the Guidelines of the Council on Environmental Quality (CEQ or Council) dated August 1, 1973, provide that environmental considerations are to be given careful attention and appropriate weight in every recommendation or report on proposals for legislation and for other major Federal actions significantly affecting the quality of the human environment.

1. *Purpose and scope.* This manual provides general policies, procedures and guidance required by section 102 of the NEPA to:

(a) Identify actions requiring environmental impact statements;

(b) Obtain information and internal United States Section review required for the preparation of environmental statements;

(c) Designate the official(s) who are to be responsible for preparation, review and approval of the statements;

(d) Consult with and take into account the comments of appropriate Federal, State and local agencies, as well as interested individuals, associations, and groups.

(e) Meet requirements for providing timely public information on proposals for legislation and for other major actions having a potential significant adverse effect on the human environment.

2. *Applicability.* This manual applies to all elements of this Section concerned with the investigation, planning, development, construction and management of projects (including leasing and licensing of land and issuing of permits in regard thereto) or activities that affect ecological systems and the human environment.

3. *References.* (a) Environmental Control—Message from the President (H. Doc. No. 91–225); Congressional Record, February 10, 1970, pp. H–743–748.

(b) Budget Message of the President, 1971; Congressional Record, February 2, 1970; see pages S–968, S–970, and S–973.

(c) The State of the Union Address by the President (H. Doc. No. 91–226); Congressional Record, January 22, 1970; pp. H–186–188.

(d) Executive Order No. 11507; Prevention, Control, and Abatement of Air and Water Pollution at Federal Facilities, February 4, 1970; 35 FR 2573 (Feb. 1970)—(supersedes Executive Orders Nos. 11282 and 11288).

(e) Executive Order 11514; Protection and Enhancement of Environmental Quality, March 5, 1970; 35 FR 4247 (March 7, 1970).

(f) National Environmental Policy Act of 1969 (Pub. L. 91–190).

(g) Water Quality Improvement Act of 1970 (Pub. L. 91–224).

(h) Section 309 of the Clean Air Act Amendments of 1970 (Pub. L. 91–604).

(i) Freedom of Information Act (5 U.S.C. 552).

(j) National Historic Preservation Act of 1966 (Pub. L. 89–665).

(k) Guidelines of the Council on Environmental Quality, August 1, 1973, pp. 20550–20562.

(l) Bulletin No. 71–3, August 31, 1970, Executive Office of the President, Office of Management and Budget.

(m) Circular No. A–95, dated June 15, 1970, and all revisions thereto, Executive Office of the President, Office of Management and Budget.

(n) Memo entitled "Federal Agencies with jurisdiction by law or special expertise to make comments with respect to various types of environmental impact of proposed actions," dated July 29, 1970, by Timothy Atkeson, General Counsel, Council on Environmental Quality.

(o) Memo entitled "Environmental impact statements prepared by the International Boundary and Water Commission," dated April 21, 1971, by Timothy Atkeson, General Counsel, Council on Environmental Quality.

(p) Memo entitled "Revision of agency procedures for preparation of Environmental Impact Statements" August 2, 1973, by Russell E. Train, Chairman, Council on Environmental Quality.

(q) Department of State Final Procedures for Compliance with Federal Environmental Statutes, 37 FR 19167 (Sept. 19, 1972).

(r) Forest Service NEPA procedures, 36 FR 23670 (1971).

(s) Water Resources Council "Principles and Standards for Planning Water and Related Land Resources," 36 FR 24778 (1973).

4. *Requirements of the National Environmental Policy Act of 1969.* Section 101 of the National Environmental Policy Act of 1969, hereinafter referred to as the Act or NEPA, establishes a broad Federal policy on environmental quality. Section 102 directs that policies, regulations, and public laws will be interpreted and administered to the fullest extent possible in accordance with the policies of the Act, and imposes upon all Federal agencies the requirements to—

(a) Utilize a systematic, interdisciplinary approach which will insure the integrated use of the natural and social sciences and the environmental design arts in planning and in decision making which may have an impact on man's environment (sec. 102(2)(A)).

(b) Identify and develop methods and procedures which will give the environment appropriate consideration in decision making along with economic and technical considerations (sec. 102(2)(B)).

(c) Include with every recommendation, report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment, a detailed environmental statement (sec. 102(2)(C)).

(d) Study, develop and describe appropriate alternatives (section 102(2)(D)).

(e) Recognize the worldwide and long-range character of environmental problems (section 102(2)(E)).

(f) Make available to States, counties, municipalities, institutions and individuals, advice and information useful in restoring, maintaining, and enhancing the quality of the environment (section 102(2)(F)).

(g) Initiate and utilize ecological information in the planning and development of resources-oriented projects (section 102(2)(G)).

(h) Assist the Council on Environmental Quality (section 102(2)(H)).

Both section 102(2)(C), which requires a detailed five-point statement of environmental impact, and section 102(2)(D), which requires analysis of alternatives where unresolved conflicts occur, are interpreted to be applicable to feasibility reports and to requests for funds to initiate construction of previously authorized projects. Under certain conditions they are also applicable to continuing construction and maintenance projects and to the granting of leases, licenses and permits.

5. *Policy.* In formulating plants for construction, operation and maintenance, water resource development or management, impact on the environment will be fully considered from the very initiation of preauthorization planning. Early and continuing search in cooperation with appropriate local, State, and Federal agencies, as well as interested individuals, associations and groups, will be undertaken to develop alternatives and measures which will enhance, protect and restore the quality of the environment, or, at least, minimize and mitigate unavoidable deleterious effects. Preparation of the five-point statement required by the Act will constitute an integral part of the preauthorization feasibility report process. The statement will serve as a summation of evaluations of the effects that alternative actions will have on the environment and as an explanation of the alternatives considered in arriving at the finally recommended plan. The preliminary environmental assessment, draft or final environmental statement and comments thereon, as appropriate to the status of the proposal, shall accompany the proposal through the agency review process.

6. *Responsibility within the United States Section.* (a) The Chief, Planning and Reports Section, Engineering Division, under the supervision of Principal Engineer Supervising, is hereby designated as the responsible official within the meaning of section 102 of the Act and is responsible for the implementation of the requirements of the Act as they relate to the making of environmental assessments and the preparation of and the processing of environmental statements. When appropriate to supplement work in evaluating the environmental impact of a proposed action, he will solicit information from within the United States Section, other Government agencies (Federal, State, and local) with jurisdiction by law or special expertise with respect to any environmental impact involved, and interested individuals, associations or groups. He shall consult with the Special Legal Assistant concerning legislative actions covered by the Act and for interpretations of the Act, the Executive Orders and the Guidelines, and for advice on legal requirements for filing environmental impact statements and on legal requirements regarding their contents.

In the case of an agency or agencies acting as agent for the United States Section in the design and construction of a project (as distinguished from merely preparing an environmental statement for the Section's use) that agent will prepare, distribute and coordinate the review of the statement according to its established procedures. This includes transmittal to Council on Environmental Quality. However, the agent has the responsibility to confer with the United States Section and to keep it fully informed.

When uncertainty persists within the United States Section as to the requirement in a specific case for filing an environmental impact statement, the Special Legal Assistant will initiate consultations with the Office of Environmental Affairs, (SCI/EN—Department of State) and the Assistant Legal Adviser for Environmental Affairs (L/EN—Department of State) and follow through to a final determination. In every case where the United States Section determines that no environmental impact statement is required, it shall so inform SCI/EN.

(b) The Special Legal Assistant will be responsible for the publishing of the necessary notices in the Federal Register and shall act as coordinator of the United States Section's activities.

7. *Procedure for preparation, planning, and coordination of the statement*—(a) *Preparation.* Statements to be meaningful for review and decision making shall utilize, along with any other points the responsible official deems appropriate, the following categories of criteria:

(1) Describe physical and environmental aspects sufficiently to permit evaluation and independent appraisal of the favorable and adverse environmental effects of each proposal. They should be simple and concise, yet should include all pertinent facts. Length would depend upon the particular proposal and the nature of its impacts and the environmental setting.

(2) Be submitted as a separate document, not as an inclosure or appendix to other documents such as preauthorization studies or design memorandums. Such reports and design memorandums must contain adequate background information to support fully the conclusions and recommendations on environmental matters. The statements should not be construed as a further means for assisting or supporting project justification.

(3) Not be limited to ultimate conclusions, but should demonstrate that the United States Section has adequately considered the potential impact of the proposal upon the environment. The statement should summarize information and cite sources of overall appraisals which are based upon judgments of complex matters (e.g., water quality by Environmental Protection Agency (EPA)). In most cases any activity that will significantly affect the quality of the following elements of the human environment will require an environmental statement:

(a) Rare and endangered species—plants or animals.
(b) Formally classified areas, such as wilderness areas, primitive areas, wild and scenic rivers, national recreation areas, natural areas, scenic areas, historical areas, archeological areas, geological areas, and national trails.
(c) Municipal watersheds.
(d) Shorelines.
(e) Open and green spaces.
(f) Large unroaded areas.
(g) Lakes.
(h) Beaches and shores.
(i) Scenic attractions, and other areas of natural beauty.
(j) Wetlands and estuaries.
(k) Adjacent national parks and monuments, wildlife refuges, or similar State and locally designated areas.
(l) Free-flowing streams.
(m) Air quality.
(n) Water quality.
(o) Key wildlife or fish areas.
(p) Prescribed burning program, including roller chopping, rock raking, shearing, cabling, etc.
(q) Rights-of-way permits for major transmission lines.
(r) Major sewage treatment facilities.
(s) Major acquisition or exchange.
(t) Estuaries.
(u) Biological resources.
(v) Ecological systems.

A definitive list of activities requiring environmental statements cannot be specified. The above list is certainly not all-inclusive, nor will all plans and actions within the activities require statements. The responsible official must consider all available factors.

(4) In the final statement include and comment on the views of those opposing the proposal for environmental reasons, if any. The summarized views of agencies having environmental responsibilities, and with which the proposals have been coordinated, should be included.

(5) Include a full and objective appraisal of the environmental effects, good and bad, and of available alternatives. Where available, include the benefit to cost ratio of alternatives, or differences in annual costs. In no case will adverse effects, either real or potential, be ignored or slighted in an attempt to justify an action previously recommended. Similarly, care must be taken to avoid overstating favorable effects.

(6) Discuss the proposal's impact on environmental resources of regional significance (draw attention to national versus regional and local importance) whenever the impact extends beyond the immediate area.

(7) Discuss the significant relationships between the proposal and other developments (existing and authorized). For example, a statement on a project which would convert a free-flowing section of a stream into a reservoir should contain information on the amount of flowing and flat water available in the area. Draw attention to cumulative effects of many small actions, and the chain reactions or secondary effects of interrelated activities.

(8) Where possible, the statements should show an indication of the magnitude of the effect including short-term changes. This may include changes in flow in cfs for both peak and low-flow periods or changes in dissolved oxygen or temperature, which are key parameters for measuring water quality, and other factors vital to the ecology of the area, such as degree of ecosystem disturbance—both on site and off site effects.

(9) Include an appropriate summary. Regardless of the type of summary used within the Section for review purposes, when the statements (draft and final) are submitted to the Council on Environmental Quality, the Council's prescribed format for a summary shall be utilized.

(10) Discuss the probable impact of the proposed action on the environment, including impact on ecological systems such as wildlife, fish and marine life.

(11) Point out any probable adverse environmental effects which cannot be avoided.

(12) Review all reasonable alternatives to the proposed action, and the environmental impacts of each.

(13) Discuss the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity.

(14) Comment on any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented.

(15) Where appropriate, discuss problems and objections raised by other Federal, State and local agencies and by interested individuals, associations and groups, in the review process and the disposition of issues involved.

(16) Contain a bibliography to assist readers and reviewers to determine the sources of information used.

(17) Discuss any existing State or Federal legislation, program, or study that concerns the study area or would have an effect upon it. Examples of such legislation and studies are those dealing with wild and scenic rivers, wilderness or wild areas, national recreation areas, estuaries, or preservation of natural areas and Fish and Wildlife coordination.

(18) Indicate that (a) the National Register of Historic Places has been consulted and that no National Register porperties will be affected by the project or (b) a listing of the properties to be affected, an analysis of the nature of the effects, a discussion of the ways in which the effects were taken into account, and an account of steps taken to assure compliance with section 106 of the National Historic Preservation Act of 1966 (80 Stat. 915) in accordance with procedures of the Advisory Council on Historic Preservation as they appear in the FEDERAL REGISTER, February 20, 1971. In the case of properties under the control or jurisdiction of the United States Government, the statement should include a discussion of steps taken to comply with section 2(b) of Executive Order 11593 of May 13, 1971. The statement should contain evidence of contact with the State Liaison Officer for Historic Preservation for the State involved and a copy of his comments concerning the effect of the undertaking upon historical and archeological resources.

(19) Develop uniqueness or rareness of resources.

(20) Draw attention to scope of anticipated public involvement and controversy anticipated.

The Guidelines dated August 1, 1973, of the Council on Environmental Quality, Appendix A (see note), and the guidance contained in Appendix B below, will be considered and utilized in preparing environmental statements, using the prescribed format or any revision thereto.

In each instance where it is determined, after the necessary investigation and assessment, that no environmental impact statement will be prepared by the United States Section, a memorandum will be prepared for United States Section files indicating the extent of the investigation and assessment conducted and the reasons for the determination that no impact statement will be prepared.

A list of such actions, along with a list of impact statements to be prepared, will be submitted to the Council on Environmental Quality not less than quarterly. The Council on Environmental Quality will publish such list in the FEDERAL REGISTER.

(b) *Planning relationships.* (1) In the development of new projects or proposals, the rationale of environmental statement and assessment of environmental considerations will be integrated into the planning process from the beginning. Preliminary identification and assessment of possible environmental impacts and effects will be made and fully discussed at an early milestone in the study. Even where it is clear from the start that a proposed action will not require an environmental impact statement, the results of that investigation will be an integral part of the decision making process. When kept current, such an environmental assessment can provide valuable assistance in the investigation and study process. The first meeting with the public should be scheduled early in the development stages so that the environmental "pulse" may be felt from the beginning. Agencies and conservation associations will be advised of the initiation of the investigation, and be requested to provide environmental information for the area.

The following actions will be taken early in an investigation:

(a) Data needs will be determined initially and actions scheduled to obtain such information to have it available for use in environmental assessments.

(b) An initial preliminary environmental assessment, including assembly of data, will be made of the present environment of the area being considered, and of the effects of each reasonable alternative considered. This preliminary assessment will be up-dated as significant additional data become available or as additional alternatives are considered, and will be used as a planning reference.

(c) In the event preliminary planning studies indicate a possibility of a future major Federal action, a determination will be made of whether an environmental statement is warranted on the basis of the criteria described later herein.

(2) Environmental evaluations will be prepared and incorporated into the planning and review process as follows:

(a) In initial planning, the responsible officer will provide a preliminary environmental assessment to the appropriate staff officers for their use prior to their forwarding for review any intermediate study recommendations. This preliminary assessment shall accompany any such recommendation memoranda.

(b) As planning progresses, the environmental assessment shall be kept current, as appropriate, and revisions provided as in paragraph (a).

(c) Following a determination of the need for an environmental statement, and its preparation, the draft statement will be provided to the appropriate officers, together with copies of any substantive comments received, for consideration before completion of the proposal.

(d) The final environmental statement will be included with any staff recommendations made to the Principal Engineer, Supervising, together with a discussion, as appropriate of environmental effects of the proposal.

(e) All recommendations being transmitted to the Commissioner for action which may have a significant environmental effect, will be accompanied by the appropriate environmental information.

(3) Beginning with the formulation stage, all anticipated environmental impacts and effects of each solution under consideration will be identified and discussed. This may entail the preparation of an environmental memorandum. After consideration of all the preliminary factors, including those which may have been forthcoming as a result of the first meeting with the public, a second meeting with the public should be scheduled. Any environmental factors known to the United States Section should be summarized and made available prior to the meeting. This will generate a meaningful and thorough discussion during the meeting. Interested citizens and citizen groups must be informed of the fact a public meeting is scheduled so that their views may be considered.

By the time the late stage in the planning has been reached, the United States Section's environmental position should have been formulated. A third meeting with the public should be scheduled so that the environmental discussions regarding any proposal and alternatives will be specific and thorough insofar as the environmental impacts and effects are concerned.

A draft environmental impact statement will be made available at one of the public meetings. The particular meeting will depend upon the stage of the preparation of the statement and the extent of the input received at the time a meeting is held.

(4) On projects which were recommended, authorized or under construction prior to the National Environmental Policy Act of 1969, the range of alternatives and the opportunity to study and evaluate them may be more limited. However, to the maximum extent feasible, alternative solutions and opportunities for environmental enhancement, preservation, and mitigation will be investigated prior to preparation of the statement. Regardless of the level at which formal coordination is to take place, the environmental impact of all reasonable alternatives will be carefully examined and evaluated in coordination with appropriate Federal, State and local agencies prior to preparing a recommendation or an environmental statement.

(5) As a "follow-up" the public will be informed of the general content of all statements before or at the time that the recommendation or report is furnished to the Council by publishing of an appropriate notice in the FEDERAL REGISTER, by public notice to all parties known to be interested, by press release, or by a combination of such means. In addition, prior to formulation of recommendations and preparation of the statement, in all cases where public hearings are held, there will be presented a notice of the hearing and at the hearing a discussion setting forth the information upon which a statement is based will be conducted. The discussion will include a listing of alternatives; the environmental impacts—positive or negative—associated with each fundamental alternative; the nature of environmental trade-off implied by various alternatives; including irretrievable commitments of each alternative; and the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity under the various alternatives. Whenever public announcement of recommendations or reports is made prior to submission of the statement to the Council, the announcement will contain an appropriate summary of the proposed statements and comments of other agencies. The draft statement may be provided interested agencies, groups and citizens. In certain cases, where critical and sensitive environmental effects and widespread public concern have been identified, a pre-announcement clearance to hold a public meeting will be requested. Requests will be supported by full recitation of the problems at issue with analysis of the pros and cons of the proposed and alternative courses of action.

Section 2(b) of Executive Order 11514 envisions use of public hearings wherever appropriate. Public hearings will be employed by the United States Section on any occasion where it is felt same will enable the taking of the "environmental pulse" unless it is determined that the requirements of carrying on international relations, including the constraints of time and the posture of the United States in negotiation, do not allow such hearings to be carried out without prejudice to the national interest. The provisions of the Administrative Procedures Act do not apply to hearings involving "foreign affairs functions"; however, in each case where hearings are employed in accordance with this paragraph, a public notice of the hearing indicating the time and place of the hearing and the matters to be considered will be made available to the public at least fifteen days prior to the hearings. Chief, Planning and Reports, shall arrange for the hearing and the publication of the prescribed notice, and shall conduct the hearing. If such hearings cannot be carried out, arrangements should still be made, where practicable, for an expedited opportunity for mem-

bers of the public to present their views orally.

(c) *Coordination of statement.* Coordination of the statement with Federal, State and local agencies, as well as interested individuals, associations and groups, will be in accordance with existing policies and the following clarification:

(1) Coordination with responsible agencies will include transmittal of draft environmental statements for their review and comment. Upon receipt, agency comments will be reviewed and summarized in the statement. Copies of the agency comments will be included as an attachment to the statement when forwarded for further action. The agency comments and the views expressed should be no older than three calendar years for previously authorized projects. More recent coordination will be required if significant changes in the proposal or in the associated environment have occurred in the meantime. Copies of the statement will be forwarded to the appropriate contact points listed in Appendix III, CEQ's Guidelines dated August 1, 1973, as well as to the field offices. The transmittal letter to field offices will advise that a statement has been furnished to the contact listed in Appendix III. Insofar as distribution of statements within a State is necessary, the clearing houses established by Budget Circular No. A-95 dated June 15, 1970, or any revisions thereto, will be utilized.

(2) In the event environmental statements are being prepared on two or more units in the same area, the work on preparing statements will be scheduled and consolidated to result in one statement being transmitted to the Department and Council for all units in an area.

8. *Administrative action.* No administrative action—to the maximum extent practicable—is to be taken sooner than ninety (90) days after a draft environmental statement has been furnished to and received by the Council, circulated for comment, and, except where advance public disclosure will result in significantly increased cost of procurement to the Government, made available to the public pursuant to the Guidelines. Further, no administrative action should be taken sooner than thirty (30) days after the final text of an environmental statement (together with comments) has been received by the Council and made available to the public. In the event the final text of an environmental statement is filed within ninety (90) days after a draft statement has been circulated for comment, received by the Council and made public pursuant to this manual, the thirty (30) day period and ninety (90) day period may run concurrently to the extent that they overlap. The time periods shall be computed from the date the Council on Environmental Quality publishes in the FEDERAL REGISTER that the statement has been received and is available for public comment.

9. *Criteria for determining whether a Federal project or activity will significantly affect the quality of the human environment.* The action must be: (1) A "major" action, (2) which is a "Federal" action, (3) which has a "significant" effect, and (4) which involves the quality of the human environment—either by directly affecting human beings or by indirectly affecting human beings through adverse effects on the environment. The following criteria will be employed in deciding whether a proposed action requires the preparation of an environmental statement:

(a) "Actions" include but are not limited to:

(1) Projects that are part of treaties and which significantly affect the quality of the human environment in the United States or in countries other than that in which the project is located.

(2) Recommendations or reports to the Congress on proposals for legislation affecting proposals to authorize projects.

(3) Recommendations or reports on proposals for authorization of projects except for emergency measures.

(4) Initiation of construction or land acquisition on projects which are not yet started for which funds have been appropriated or are provided by an Appropriation Act.

(5) Budget submissions requesting funds for the initiation of construction or real estate acquisition on authorized projects.

(6) Policy and procedure making, especially proposed actions which are highly controversial.

(b) The statutory clause "major Federal actions significantly affecting the quality of the human environment" is to be construed with a view to the overall, cumulative impact of the action proposed (and of further actions contemplated) and reasonable alternatives thereto (including those not within the authority of the United States Section). Such actions may be localized in their impact, but if there is potential that the quality of the human environment may be significantly affected, the statement is to be prepared. Proposed actions, the environmental impact of which is likely to be highly controversial or unresolved conflicts concerning alternative use of available resources exist, should be covered in all cases.

In considering what constitutes major action significantly affecting the quality of the human environment, United States Section personnel should bear in mind that the effect of many Federal decisions about a project or complex of projects can be individually limited but cumulatively considerable. This can occur when one or more agencies over a period of years put into a project individually minor but collectively major resources, when one decision involving a limited amount of money is a precedent for action in much larger cases or represents a decision in principle about a future major course of action, or when several Government agencies individually make decisions about partial aspects of a major action. The lead agency should prepare an environmental statement if it is reasonable to anticipate a cumulatively significant effect on the quality of the human environment from the Federal action.

(c) Section 101(b) of the NEPA indicates the broad range of aspects of the environment to be surveyed in any assessment of significant effect. The NEPA also indicates that adverse significant effects include those that degrade the quality of the environment, curtail the range of beneficial uses of the environment or serve short-term, to the disadvantage of long-term, environmental goals. Significant effects can also include actions which may have both beneficial and detrimental effects, even if, on balance, the agency believes that the effect will be beneficial. Significant adverse effects on the quality of the human environment include both those that directly affect human beings and those that indirectly affect human beings through adverse effects on the environment.

(d) Careful attention should be given to identifying and defining the purpose and scope of the action which would most appropriately serve as the subject of the statement. In many cases broad program statements will be required in order to assess the environment effects of a number of individual actions on a given geographical area, or environmental impacts that are generic or common to a series of agency actions, or the overall impact of a large-scale program or chain of contemplated projects. Subsequent statements on major individual actions will be necessary where such actions have significant environmental impacts not adequately evaluated in the program statement. An assessment will be made to form the basis for determining whether a subsequent statement on a major individual action is necessary.

(e) Not every United States Section activity will be considered a major Federal action significantly affecting the quality of the human environment for the purposes of the Act. For example, the following general classes of actions ordinarily do not require the filing of an environmental impact statement:

(1) Participation in research or study projects.

(2) Mandatory actions required under any treaty or international agreement to which the United States is a party, or required by the decision of international organizations (including courts), authorities, or consultations in which the United States is a member or participant.

(3) Mapping and surveying activities.

(4) Stream gaging, routine hydrologic test drilling, well logging, aquifer response testing, and similar data gathering activities in connection with water resources investigations.

(5) Operation and maintenance of project facilities, including dams, channels, floodways, power plants, buildings, fences, gates, and other appurtenant facilities including but not limited to:

(a) Storage of waters in reservoirs and releases therefrom for both flood control and conservation purposes.

(b) Grazing leases.

(c) Licenses and permits for recreation facilities at existing projects.

(d) Maintaining low vegetative growth in floodways and channels.

(e) Sediment removal from river channels.

(f) Restoration and repair of banks at reservoirs and on rivers that may involve riprap activities.

(g) Restoration and repair of earth embankments.

(6) Administrative procurements (e.g., general supplies).

(7) Contract for personal services.

(8) Legislative proposals originating in another agency.

10. *Use of statements in United States Section's review process; distribution to Council on Environmental Quality.* (a) The principle to be applied is to obtain views of other agencies at the earliest possible time in the development of a program and project proposals. Care should be exercised so as not to duplicate the clearance process, but when actions being considered differ significantly from those that have already been reviewed, an environmental statement should be provided.

(b) Ten (10) copies of draft environmental statements (when prepared) and ten (10) copies of the final text of environmental statements (together with all comments received thereon by the responsible agency from Federal, State, and local agencies and from interested individuals, associations and groups) shall be supplied to the Council in the Executive Office of the President. (This will serve as making environmental statements available to the President.) It is important that draft environmental statements be prepared and circulated for comment and furnished to the Council early enough in the agency review process before an action is taken in order to permit meaningful consideration of the environmental issues involved.

11. *Availability of environmental statement and comments to public.* The United States Section, when it prepares the statement, is responsible for making such statement and the comments received available to the public pursuant to the provisions of the Freedom of Information Act (5 U.S.C.A. 552).

A copy of the final environmental statement will be furnished to each agency, individual, or association providing substantive comments on the draft statement.

12. *Publication in the* FEDERAL REGISTER. Notices will be placed in the FEDERAL REGISTER when:

(a) The draft statement has been approved by the Commissioner and transmitted to the Council on Environmental Quality.

(b) The final statement has been approved by the Commissioner and transmitted to the Council on Environmental Quality.

(c) Comments are received after the final statement has been approved, transmited to Council on Environmental Quality, and publication regarding final statement has previously been published.

(d) Public meetings are held if deemed feasible.

The notice will contain sufficient information to inform those reading it of the location and purpose of a project, where copies of the statement may be obtained and where the meeting is to be held.

When comments are being sought by a publication, a time limit of not less than forty-five (45) days may be established for local, State and Federal agencies to reply. The United States Section will, in all cases possible, allow private individuals sixty (60) days in which to comment. In cases where extensions of time are requested in which to comment, an endeavor will be made to comply with requests for extension of time up to fifteen (15) days. If no reply is received within the period allowed for comments, it will be presumed the agency consulted has no comments to make.

13. *Budget process.* The requirement of NEPA, Water Quality Improvement Act, Executive Order 11514, the Guidelines, and Office of Management and Budget Bulletin No. 72-6 shall be met through the United States Section's budget process to the maximum extent practicable. The following requirements of the budget process will be met:

(a) *Legislation.* This Section is responsible for identifying those of its legislative proposals, or favorable reports on bills on which it is the principal agency concerned, that would require the preparation of the statements and receipt of the comments required under Section 102 of the Act. When there is doubt as to which is the principal agency concerned, Special Legal Assistant shall consult with the Office of Management and Budget's Legislative Reference Division.

The proposed section 102(2)(C) statements and the required comments shall accompany legislative proposals and reports when these are sent to the Office of Management and Budget for clearance. Copies of this material shall have been previously furnished directly to the Council for its information. As a part of the normal clearance process, the Office of Management and Budget will circulate the proposed statements, along with the proposals or reports, to appropriate Federal agencies, and will consult with the Council. In certain cases, the clearance process may disclose the need for a section 102(2)(C) statement where none has been prepared. In this event, the Office of Management and Budget will request the United States Section to develop and submit such a statement.

After differences with other agencies over the legislative proposal or report have been resolved, and after the legislative proposal or report has been cleared by the Office of Management and Budget, the final statement and comments shall accompany the proposal or report to the Congress as supporting material.

(b) *Annual budget estimates.* In the event the United States Section has major program actions which significantly affect the quality of the human environment, annual budget estimates shall be accompanied by a special summary statement explaining generally the environmental impact expected to result from those activities and programs for which it is not possible to make an assessment of the potential impact on specific areas of the environment. Special summary statements shall include relevant information about general environmental impact and alternatives, and, to the extent possible, important environmental problems that may be caused by proposed actions but which still must be assessed as plans for programs and activities are further refined. The special summary statement shall also include, in the form illustrated in Appendix C below, the following information by appropriation or fund account:

Column A—*Action, project, or activity.* Identify the agency actions and individual projects and activities, and the amounts of funds involved, that are considered subject to section 102(2)(C). Where the action is a part of a larger activity, identify only the project or action subject to section 102(2)(C) and the amount involved.

Column B—*Final statement completed.* Check the appropriate category. If there are significant unresolved issues with other agencies, include a copy of the statement with the submission to the Office of Management and Budget.

Column C—*Statement being prepared.* Give the status (e.g., awaiting comments from interested agencies) and estimated completion date.

Agencies that prepare section 102(2)(C) statements for annual authorizing legislation shall submit the proposed section 102(2)(C) statements in lieu of a special summary statement required by paragraph (b) above, except that the information required for the special summary exhibit shall be submitted along with the proposed section 102(2)(C) statement. Copies of the special summary statement or proposed section 102(2)(C) statement (accompanied by information for the special summary exhibit) shall be furnished directly to the Council on Environmental Quality.

14. *Lease, license and permit applications.* As required by existing regulations, lease, license and permit applications will be coordinated with Federal, State, and local agencies which are authorized to develop and enforce environmental standards, unless granting of the lease, license or permit could not significantly affect the quality of the human environment. Comments from such agencies or from the United States Section will be presented to the applicant who will be given the opportunity to modify his application so as to remove the cause, if any, for an agency's objection that there will be a significant affect on the quality of the human environment.

In the event an applicant does not take action to remove an objection, the United States Section will prepare the statement required by section 102(2)(C) of NEPA. The applicant is required to carry out at his expense the necessary environmental assessment and investigation as may be required by the United States Section for use in preparation of the statement, in addition to any information the applicant may wish to furnish in order to demonstrate that granting of the lease, license or permit is in

the public interest. A summary of the information on which the statement is based will be furnished to the public in the Notice of Public Hearing and at the hearing, if one be held.

The granting of the lease, license or permit is the "Federal action" which may require the statement. While applicant has the duty and responsibility to undertake the environmental assessment and investigation, the United States Section has primary and nondelegable responsibility for determining environmental impact of an action at every distinctive and comprehensive stage. The preparation of a statement by an applicant and the later adoption of same by the United States Section would be abdication by the United States Section of a significant part of its responsibility to determine environmental impact.

Failure of an applicant to furnish the requested information shall result in the denial of an application.

Leases, licenses or permits granted or approved by the United States Section will contain provisions to assure compliance with applicable air and water quality standards; to conserve and protect the environment; and to avoid, minimize or correct hazards to the public health and safety. The lessee, licensee or permittee will be required to provide adequate measures to avoid, control, minimize or correct erosion, contamination, or other abuses and damages to the environment within or without the premises under lease, license or permit that may result from or have been caused by operations conducted on the premises.

Farming and grazing operations shall be conducted in accordance with recognized principles of good practice, conservation, and prudent management. Land use stipulations or conservation plans to define such use and the measures necessary for the conservation, protection and control of the environment shall be incorporated in and made a part of the lease, license or permit.

Commercial and industrial developments shall be constructed and operations conducted on the premises under lease, license or permit to control and minimize environmental pollution and abuses so that the quality of the human environment will not be significantly affected. Leases, licenses and permits shall contain provisions for the lessee, licensee or permittee to submit, for advance approval, general and comprehensive plans of any proposed construction or developments for the use and conduct of operations as authorized for the premises prior to commencing any actual construction or development activities. Such plans, including architects' designs, construction specifications, machinery or equipment installation and operation or specifications for other operations or developments, shall provide measures necessary to protect, control or abate environmental pollution or abuses and avoid, minimize, or correct hazards to the public health and safety.

Other uses as authorized by leases, licenses or permits issued shall conform to the requirements and provisions formulated for each such use as adapted to local conditions and the environmental factors which are in need of protection and control measures.

Due to the nature of this Section's leasing, licensing and permit program, all factors are to be carefully considered before determining what is needed for the protection of the environment, conservation and land use requirements.

Applications involving power transmission lines will be prepared in accordance with Bureau of Land Management, Department of the Interior, regulations as published in Subchapter B, Subpart 2850 of 43 CFR 2851.2–1 or any revisions or amendments thereto. (Reference attached Appendix D below.)

15. *Operations at construction sites.* Some operations that contribute to pollution and noise at construction sites and therefore require close surveillance, are enumerated in the following list:

(a) *Air Pollution.*
(1) Burning.
(2) Earth moving operations (dust).
(3) Sandblasting.
(4) Sprayed-on coatings.
(5) Soil stabilization operations (cement or lime).
(6) Concrete mixing plant (dust).
(7) Batch truck operation (dust).
(8) Winter heating equipment (smoke and fumes).
(9) Gunite operations (rebound).
(10) Asphalt operations (dust—smoke—volatiles).
(b) *Water Pollution.*
(1) Solid wastes.
(2) Earth moving operations (runoff).
(3) Clearing operations (erosion).
(4) Core drilling and grouting operations (waste water).
(5) Wellpoint system runoff (erosion).
(6) Concrete operations:
(a) Aggregate washing.
(b) Spillage.
(c) Water curing.
(d) Washing of mixers and batch trucks.
(c) *Noise.*
(1) Pile driving.
(2) Equipment noise.
(3) Drilling and blasting.
(4) Rock crushing.

The construction engineer should ascertain that the contractor complies with:

(i) The current applicable Federal regulations.

(ii) The current applicable local regulations.

(iii) Methods and restrictions of operations that are contract requirements.

On projects where regulations and contract requirements do not specifically outline procedures, the contractor's cooperation should be encouraged in an effort to run a clean and safe operation.

Appropriate provisions will be included in the contract specifications for the works to be performed requiring compliance with Federal, State and local pollution laws, regulations and rules. Examples of contract specifications are attached at Appendix E below.

16. *Section 309 of the Clean Air Act Amendments of 1970.* Section 1500.3(a), 1500.9(b), and 1500.10(b) of the Council's Guidelines requires that, in addition to normal coordination procedures, the following rules apply to coordination with EPA:

(a) Comments of the Administrator or his designated representative will accompany each final statement on matters related to air or water quality, noise control, solid waste disposal, radiation criteria and standards, or other provisions relating to the authority of EPA.

(b) Copies of basic proposals (studies, proposed legislation, rules, leases, permits, etc.) will be furnished to EPA with each statement. For actions for which statements are not being prepared but which involve the authority of EPA, EPA will be informed that no statement will be prepared and that comments are requested on the proposal.

Upon circulation of draft statement to the EPA, comments shall be requested under both the NEPA and section 309 of the Clean Air Act.

17. *Exceptions.* The nature of negotiations and relations at the international level may make it necessary to depart in some instances from the procedures in the Guidelines. CEQ foresaw the need for such departures in its Guideline 1500.4 and 1500.11(e). Exceptions applicable to the United States Section are set forth below.

(a) The statements which are written to comply with the Act should not normally include any classified or administratively controlled material, nor should they normally include statements with respect to positions other than the optimum position of the United States in any ensuing negotiation or discussion. Although environmental impact statements should, whenever possible, be unclassified and hence available to the public, there may be situations where such statements cannot adequately discuss environmental effects without disclosure of classified information. In these instances, the statement should be appropriately classified. Whenever possible, the classification should terminate on a specified date or upon the happening of a described event. Such statements, so long as they are classified, will not be made available to the public.

(b) Since final statements may not be available until the conclusion of negotiations for an agreement or of a discussion, the 30-day time delay between submission of such a document and final Federal action set out in CEQ Guideline 1500.11(b) will not apply to actions taken in these situations. Every attempt will be made to comply with the 90-day period which Guideline 1500.11(b) requires between submission of the draft statement and final action. Where schedules of international conferences make this impossible, the United States Section will notify the Council on Environmental Quality as soon as possible of the circumstances, with the purpose of fulfilling the intent of the Act insofar as possible.

(c) In certain exceptional instances it may be necessary at times to reduce the 45-day period for agency comments set out in Council on Environmental Quality Guidelines of August 1, 1973 at § 1500.11

(e). When this is the case, all agencies to whom the draft statement has been sent will be informed by the United States Section of the reduced time period. The reduced time period must also be included in the public notice published in the FEDERAL REGISTER.

(d) Section 2(b) of Executive Order 11514 establishes requirements for providing public information on Federal actions and impact statements and envisions extensive use of public hearings. Public hearings will be employed by the United States Section only upon a determination by the United States Commissioner that the requirements of carrying on international relations, including the constraints of time and the posture of the United States in negotiation, allow such hearings to be carried out without prejudice to the national interests.

(e) In those instances wherein the draft and/or final statement is submitted to the Department (SCI/EN) for concurrence before distribution outside the United States Section, the Department has agreed to make its comments within thirty (30) days of receipt of a statement from the United States Section.

18. *Responsibility as a Commenting Agency.* The Chief, Planning and Reports, will review draft and final environmental statements submitted by other agencies and prepare a letter of comments for the Principal Engineer, Supervising. Such comments should be as specific, substantive and factual as possible without undue attention to matters of form in the statement. Emphasis should be placed on the assessment of the environmental impacts of the proposed action, including the international aspects and the acceptability of those impacts on the quality of the environment, particularly as contrasted with impacts of reasonable alternatives to the action. The agency may in its comments recommend modifications to the proposed action and/or new alternatives that will enhance environmental quality and avoid or minimize adverse environmental impacts. Our comments should indicate the environmental interrelationship of the proposed action to any of our existing projects, or those being planned. The comments may include the nature of any monitoring of the environmental effects of the proposed project that appears particularly appropriate. If comments cannot be provided in the forty-five (45) day comment period, a request should be made for an extension of time, normally of fifteen (15) days. In the event there is a significant international factor to be considered, and completion of comments will require a longer extension of time, the request should explain the reason for the longer period.

19. *Effective date.* These procedures supersede any draft of proposed procedures which has been published in the FEDERAL REGISTER or circulated to other agencies (local, State or Federal), interested individuals, associations or groups. These procedures become effective upon the date of their publication in final form in the FEDERAL REGISTER.

FRANK P. FULLERTON,
Special Legal Assistant.

APPENDIX B—PREPARATION OF ENVIRONMENTAL STATEMENTS

1. *General.* Preparation of environmental statements will be based on considerations discussed in the procedures to which this appendix forms a part, the Guidelines and the detailed guidance to follow. These directions are intended to assure consistency of effort in preparing statements and are not proposed to induce unthinking uniformity or limit flexibility when preparing statements. These statements have several levels of importance with reference to the decision-making process, United States Section relations with the public, and internal project planning activities. A careful, objective detailing of environmental impacts, alternatives, and implications of a proposed project should give reviewers both within and outside the United States Section insight into the particular trade-offs and commitments associated with the action. The general public, environmental agencies, and Congressional Committees will all expect the statements to be a valid source of information of project effects, as well as a reflection of how this Section views environmental factors and seeks to accommodate them. Since the statements must be made available to the public and may receive broad exposure in the media, it can be assumed that they will receive careful scrutiny. Most importantly, preparation of the statements should cause systematic consideration of environmetal impacts. An imaginative evaluation of alternatives and their implications should begin in the earliest stages of project formulation, with planners contemplating the criteria and range of information to be employed in preparation of final statements.

2. *Working papers.* In order to assure a comprehensive treatment of environmental concerns, a working document check list of pertinent environmental elements should be compiled and periodically updated by the environmental planners. A discussion of these elements should establish their importance, placing emphasis on whether they are unique, endangered, old, popular, etc.—in essence, explore the ecological, aesthetic, cultural, and other values which appear to make the elements environmentally significant. The manner in which economic considerations affect those values should also be discussed. For projects on which initial formulation has been completed, much of the information needed to characterize the elements may already be contained in existing survey documents, design memoranda, and project files. Conversely, the organization of working papers at an early stage in the planning process will assist in subsequent survey studies and post-authorization design. Planners should keep abreast of current literature and information sources to aid in compiling environmental data.

3. *Environmental elements.* Logical categories and sample elements for the working papers follow.

(a) *Geological elements.* Land forms (mountains, canyons), rock and mineral features, paleontologic items (fossils), structures (faults, synclines).

Related. Soils, erosion, strip mined areas, caves.

(b) *Hydrological elements.* Lakes, reservoirs, estuaries, rivers, subsurface water, marshes, valley storage, springs.

Related. Turbidity, pollutants, aquifer recharge areas, surf.

(c) *Botanical elements.* Trees, shrubs, aquatic plants, microflora.

Related. Seasonal colors, virgin forests.

(d) *Zoological elements.* Mammals, birds, amphibians, fish, shellfish, microfauna.

Related. Migration routes, breeding characteristics.

(e) *Archeological/historical/cultural elements.* Ruins, artifact sites, ghost towns, battlefields, cemeteries, festival sites, ethnic colonies.

(f) *Miscellaneous elements.* Scientific areas, National Parks or forests, hunting clubs wildlife refuges, contemporary human features (buildings, transportation systems).

It should be noted that the elements under the last two categories are relevant to the human environment and are not strictly environmental in nature. Their consideration is essential to assure treatment responsive to the full concern of the NEPA.

4. *Format.* Environmental statements will constitute a separate document from other United States Section papers. It will include a cover sheet and a summary statement and be prepared on 8½ x 11 white paper (without letterhead), with clear black type. The cover sheet identifying the project will contain the following:

Date
(Draft, Final) Environmental Statement
Official Project Name
associated water feature, State
prepared by
United States Section, International
Boundary and Water Commission
El Paso, Texas

5. *Content of statement.* The body of environmental statements will contain, as a minimum, the following eight separate sections (and attachment containing coordination letters) with the length of each being adequate to identify and develop the required information.

(a) *Project description.* Describe the proposal by name, specific location, purposes, authorizing document (if applicable), current status, and benefit-cost ratio. Generally delineate the project purpose and what the plan of the proposal entails.

(b) *Environmental setting without the project.* Describe the area, the present level of economic development, existing land and water uses, and other environmental determinants. Discuss the environmental setting without focusing only on the immediate area at the risk of ignoring important regional aspects critical to the assessment of environmental impacts. It is possible and often desirable to treat the project setting in relation to river basins, watersheds or functional ecosystems. Discuss the interrelations of projects and alternatives proposed, under construction or in operation by any agency or organization.

(c) *The environmental impact of the proposed action.* (1) Identify environmental impacts as changes or conversions of environmental elements which result from the direct and indirect consequences of the proposed action. Identification should include, and the statement should set forth: the relation of the proposed action to secondary environmental effects likely to result from the proposed action; an indication of what other interests and considerations of Federal policy, including international considerations, are thought to offset the proposed actions adverse environmental effects; and, where appropriate, alternative designs or details of their proposed actions which would significantly conserve energy. A thoughtful

assessment of the environmental elements under both a "with" and "without the project" condition should aid in determining impacts. For example, the filling of a portion of the wetlands of an estuary would involve the obvious conversion of aquatic/marsh areas to terrestrial environments, the loss of wetland habitats and associated organisms, a gain in area for terrestrial organisms, a change in the nutrient regime of the runoff water entering that portion of the estuary, alteration of the hydrology of some given area, perhaps the introduction of buildings or roads, curtailment of certain commercial uses, disruption of water-based recreational pursuits, conversion of wildland aesthetics to less-pristine attributes, perhaps the removal of some portion of popular duck hunting grounds or unique bird nesting area, etc. Such impacts shall be detailed in a dispassionate manner to provide a basis for a meaningful treatment of the trade-offs involved. Quantitative estimates of losses or gains (e.g. areas of marshland, number of ducks nesting or harvested) will be set forth whenever practicable.

(2) Discuss both the beneficial and detrimental aspects of the environmental changes or conversions on both the national and international environment placing some relative value on the impacts described. A distinction should be observed here, whereby the impacts (changes) were initially detailed without making value judgments which at this point are discussed in terms of their effects (who are what is affected by the changes). Identify the recipient (environmental element, interest group, industry, agency) of these effects and the nature and extent of the impacts on them. Discuss these effects not only with reference to the project area, but in relation to any applicable region, basin, watershed or ecosystem. In the example given, the loss of wetland might have relevance to different areas depending on the uniqueness of the filled area, the developmental plans and state of adjacent and regional wetlands, and the extent of the secondary effects of the filling (alteration of estuarine salinity wedge, sedimentation effects on adjacent shellfish, the modification of the surficial and groundwater hydrology of contiguous marsh and upland areas, etc.).

(3) Identify remedial, protective, and mitigation measures which would be taken in response to adverse effects of environmental impacts. Such measures taken for the minor or short-lived negative aspects of the project will be discussed in this section. The adverse effects which cannot be satisfactorily dealt with will be considered in greater detail along with their abatement and mitigation measures in the following section.

(d) *Any adverse environmental effects which cannot be avoided should the proposal be implemented.* Discuss the unavoidable adverse effects that significantly affect the quality of the human environment and the implications thereof, and identify the abatement or mitigation measures proposed to rectify these and the extent of their effectiveness. The loss of a given acreage of wetland by filling may be mitigated by purchase of a comparable land area, but this does not eliminate the adverse effect. Certainly the effects on the altered elements will not disappear simply because additional land is purchased. Identify the nature and extent of the principal adverse effects and the parties affected. For example, the effects of the filled wetland might include the loss of shellfish through sedimentation actions (turbidity and burial), the loss of organisms through the leaching of toxic substances from polluted marsh sediments used in the fill, the loss of a popular/valuable waterfowl census site in the estuary or the burial of ancient Indian midden sites of indeterminate archeological value. Present and comment on the objections of all concerned parties.

(e) *Alternatives to the proposed action.* Describe the various alternatives considered, their general environmental impact, and the reason(s) why each was not recommended. Identify alternatives as to their beneficial and detrimental effects on the environmental elements, specifically taking into account the alternative of no action. This latter alternative requires a projection of the future environmental setting if the project is not accomplished. Discuss both natural and man-induced changes. Discuss economically justified alternatives predicated upon standard evaluation methods, but additionally, insofar as possible, identify and evaluate other ways of providing functions similar to those provided by the proposed project but which were specifically formulated with environmental quality objectives in mind. For example, the environmental trade-offs involved in filling the marsh would be different for alternatives such as: utilizing an inland site rather than filling in the marsh, hauling fill material from an upland borrow pit rather than dredging it from the estuary, or providing construction on piles or floats rather than on fill material.

(f) *The relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity.* Assess the cumulative and long-term impacts of the proposed action with the view that each generation is a trustee of the environment for succeeding generations. give special attention to considerations that would narrow the range of beneficial uses of the environment or pose long-term risks to health or safety. The propriety of any action should be weighed against the potential for damage to man's life support system—the biosphere—thereby guarding against the short-sighted foreclosure of future options or needs. It is appropriate to make such evaluations on land-use patterns and development, alterations in the organic productivity of biological communities and ecosystems and modifications in the proportions of environmental components (water, uplands, wetland, vegetation, fauna) for a region or ecosystem. For example, if a coastal marsh is extensively filled, the ability of an associated estuary to support its normal biota might be seriously impaired. Altered sediment, nutrient and biocide additions to the waters might well affect the inherent biological productivity of the estuary. In other words, if the estuary's marshes are modified enough to affect basic estuarine processes, certain amenities, biota, products, industry, and recreation opportunities could be lost. The long-term implications of these changes are directly related to the degree that the losses are sizeable or unique.

(g) *Any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented.* Discuss irrevocable uses of resources, changes in land use, destruction of archeological or historical sites, unalterable disruptions in the ecosystem, and other effects that would curtail the diversity and range of beneficial uses of the environment should the proposal be implemented. For example, in filling a marsh there could be a number of potential irreversible or irretrievable effects. The particular aquatic habitat filled in the marsh would be permanently lost for aquatic organisms and fill would be removed from one area and deposited in another.

(h) *Coordination with other agencies.* List all government and private entities with whom coordination has been accomplished, as well as a discussion of public participation efforts and specific coordination measures with environmental interests. All views expressed, both pro and con, concerning the environmental effects of the proposal should be summarized, identified, and included. When formal coordination measures have been accomplished, a copy of all comments received concerning the proposal will be attached to the statement. If formal comments are not included, state what coordination measures have been taken and the resultant comments.

(i) *Bibliography.* Statements should indicate at appropriate points in the text any underlying studies, reports and other information obtained and considered in preparing the statement, with these references included in a Bibliography. In the case of documents not likely to be easily accessible (such as internal studies or reports), the bibliography should indicate how such information may be obtained.

APPENDIX C—STATUS OF SECTION 102(2)(C) STATEMENTS UNITED STATES SECTION

INTERNATIONAL BOUNDARY AND WATER COMMISSION

APPROPRIATION OR FUND ACCOUNT

(ACCOUNT IDENTIFICATION CODE)

Column A	Column B		Column C
Action, project or activity	Final statement completed (check one column)		Statement being prepared
	Unresolved issues	No unresolved issues	

APPENDIX D—STATEMENTS INVOLVING POWER TRANSMISSION LINES—ENVIRONMENTAL CONSIDERATIONS

TITLE 43—PUBLIC LANDS: INTERIOR

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

Subchapter B—Land Resource Management

PART 2850—POWER TRANSMISSION LINES

SECTION 2851.2-1 *Applications.*

* * * * *

(c) * * *

(6) (i) A detailed description of the environmental impact of the project shall be included with the application. It shall provide, among other things, information about the impact of the project on airspace, air and water quality, scenic and esthetic features, historical and archeological features, and wildlife, fish, and marine life.

(ii) The proposed site, design, and construction of the project shall be consistent with the "Environmental Criteria for Electric Transmission Lines," prescribed jointly by the Secretary of the Interior and the Secretary of Agriculture, as well as such other environmental criteria and guidelines as the Department shall from time to time prescribe. "Environmental Criteria for Electric Transmission Systems" is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20420.

(iii) If all other requirements are met, the application may be approved if it is determined that the beneficial purposes and effects of the project will not be outweighed by an adverse environmental impact. If the authorized officer determines that the application cannot be approved as proposed, he will, whenever possible, suggest alternative routes or methods of construction, or other modifications which if adopted by the applicant would make the application acceptable.

APPENDIX E—EXAMPLES OF CONTRACT SPECIFICATIONS

SC. ____ LANDSCAPE PRESERVATION

(a) *General.* The Contractor shall exercise care to preserve the natural landscape and shall conduct his construction operations so

as to prevent any unnecessary destruction, scarring, or defacing of the natural surroundings in the vicinity of the work. Except where clearing is required for permanent works, for approved construction roads and for excavation operations, all trees, native shrubbery, and vegetation shall be preserved and shall be protected from damage which may be caused by the Contractor's construction operations and equipment. Movement of crews and equipment within the right-of-way and over routes provided for access to the work shall be performed in a manner to prevent damage to grazing land, crops, or property.

No special reseeding or replanting will be required under these specifications; however, on completion of the work and in addition to the requirements of any general conditions of a contract, all work areas shall be smoothed and graded in a manner to conform to the natural appearance of the landscape. Where unnecessary destruction, scarring, damage, or defacing may occur as a result of the Contractor's operations, as determined by the Contracting Officer, the same shall be repaired, replanted, reseeded, or otherwise corrected at the Contractor's expense.

(b) *Construction roads.* The location, alignment and grade of construction roads shall be subject to approval of the Contracting Officer. When no longer required by the Contractor, construction roads shall be made impassable to vehicular traffic and the surfaces shall be scarified and left in a condition which will facilitate natural revegetation.

(c) *Contractor's yard area.* The Contractor's shop, office, and yard area shall be located and arranged in a manner to preserve trees and vegetation to the maximum practicable extent. On abandonment all storage and construction buildings including concrete footings and slabs, and all construction materials and debris shall be removed from the site, or subject to the Contracting Officer's approval, may be buried on the site. The yard area shall be left in a neat and natural appearing condition.

(d) *Borrow areas and quarry sites.* Before being abandoned, the sides of borrow pits and quarry sites shall be brought to stable slopes with slope intersections rounded and shaped to provide a natural appearance. All rubbish, Contractor's equipment and structures shall be removed from site. Waste piles shall be leveled and trimmed to regular lines and shaped to provide a neat appearance.

(e) *Blasting precautions.* In addition to the requirements of Paragraph SC.____, the Contractor shall adopt precautions when using explosives which will prevent scattering of rocks, stumps, or other debris outside the work area.

(f) *Costs.* The cost of all work required by this paragraph shall be included in the price bid in the schedule for other items of work.

SC. ____ PREVENTION OF WATER POLLUTION

The Contractor shall comply with applicable Federal and State laws, orders, and regulations concerning the control and abatement of water pollution.

The Contractor's construction activities shall be performed by methods that will prevent entrance, or accidental spillage, of solid matter, contaminants, debris, and other objectionable pollutants and wastes into streams, flowing or dry watercourses, lakes, and underground water sources. Such pollutants and wastes include, but are not restricted to, refuse, garbage, cement, concrete, sewage effluent, industrial waste, radioactive substances, oil and other petroleum products, aggregate processing tailings, mineral salts, and thermal pollution. Sanitary wastes shall be disposed of in accordance with State and local laws and ordinances.

Unwatering work for structure foundations or earthwork operations near streams or watercourses shall be conducted in a manner to prevent excessive muddy water and eroded materials from entering the streams or watercourses by construction of intercepting ditches, bypass channels, barriers, settling ponds, or by other approved means.

Waste waters from aggregate processing, concrete batching, or other construction operations shall not enter streams, watercourses, or other surface waters without the use of such turbidity control methods as settling ponds, gravel-filter entrapment dikes, approved flocculating processes that are not harmful to fish, recirculation systems for washing of aggregates, or other approved methods. Any such waste waters discharged into surface waters shall be essentially free of settleable material. For the purpose of these specifications, settleable material is defined as that material which will settle from the water by gravity during a 1-hour quiesecent detention period.

Sanitary facilities shall be provided and maintained in accordance with Section III of the Corps of Engineers' Manual "General Safety Requirements."

The costs of complying with this paragraph shall be included in the prices bid in the schedule for the various items of work.

SC.____ ABATEMENT OF AIR POLLUTION

The Contractor shall comply with applicable Federal, State, interstate, and local laws and regulations concerning the prevention and control of air pollution.

In conduct of construction activities and operation of equipment, the Contractor shall utilize such practicable methods and devices as are reasonably available to control, prevent, and otherwise minimize atmospheric emissions or discharges of air contaminants. Equipment and vehicles that show excessive emissions shall not be operated until corrective repairs or adjustments are made.

The Contractor's methods of storing and handling cement and pozzolans shall include means of controlling atmospheric discharges of dust.

Burning of rubbish will not be permitted. Rubbish, trash, and combustible materials shall be removed from the site and disposed of in an approved manner.

During the performance of the work required by these specifications or any operations appurtenant thereto, whether on right-of-way provided by the Government or elsewhere, the Contractor shall furnish all the labor, equipment, materials, and means required, and shall carry out proper and efficient measures wherever and as often as necessary to reduce the dust nuisance, and to prevent dust which has originated from his operations from damaging land and dwellings, or causing a nuisance to persons. The Contractor will be held liable for any damage resulting from dust originating from his operations under these specifications on Government right-of-way or elsewhere.

The costs of complying with this paragraph, including the cost of sprinkling for dust control or other methods of reducing formation of air pollution shall be included in the prices bid in the schedule for the various items of work.

[FR Doc.73-24531 Filed 11-19-73;8:45 am]

NATIONAL ADVISORY COMMITTEE ON OCEANS AND ATMOSPHERE

NOTICE OF OPEN MEETING

The National Advisory Committee on Oceans and Atmosphere (NACOA) will hold a two-day meeting on November 29–30, 1973. The meeting will be open to the public and will be held in Suite 5110, New Senate Office Building (Dirksen Office Building), Washington, D.C. The sessions will commence at 9:00 a.m. on both days.

The Committee, consisting of 25 non-Federal members appointed by the President from State and local governments, industry science, and other appropriate areas, was established by Congress by Pub. L. 92–125, on August 16, 1971. Its duties are to: (1) Undertake a continuing review of the progress of the marine and atmospheric science and service programs of the United States, (2) submit a comprehensive annual report to the President and to the Congress setting forth an overall assessment of the status of the Nation's marine and atmospheric activities on or before June 30 of each year, and (3) advise the Secretary of Commerce with respect to the carrying out of the purposes of the National Oceanic and Atmospheric Administration.

The meeting will address the following subjects:

NOVEMBER 29, 1973

Marine Transportation.
Reports of NACOA Subcommittees.
Federal Marine and Atmospheric Affairs.

NOVEMBER 30, 1973

The Sea Grant Program.
Energy, Thermal Pollution and Climatic Change.

Members of the public will be admitted on a first-come, first-serve basis up to the limits of the capacity of the meeting room. A detailed agenda will be available on the day of the meeting. Questions from the public will be permitted during specific periods announced by the Chairman. Persons wishing to make formal statements must notify the Chairman in advance of the meeting.

Additional information concerning meeting may be obtained through the Committee's Executive Director, Dr. Douglas L. Brooks, whose mailing address is: National Advisory Committee on Oceans and Atmosphere, Department of Commerce Building, Room 5225, Washington, D.C. 20230. The telephone number is 202–967–3343.

Issued in Washington, D.C., November 16, 1973.

DOUGLAS L. BROOKS,
Executive Director.

[FR Doc.73-24818 Filed 11-19-73;8:45 am]

NATIONAL SCIENCE FOUNDATION

INTERNATIONAL DECADE OF OCEAN EXPLORATION ADVISORY PANEL

Notice of Meeting

Pursuant to the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of a meeting of the International Decade of Ocean Exploration Advisory Panel to be held at 1:00 p.m. on December 6 and at 9:00 a.m. on December 7, 1973, in Room 642 at 1800 G Street, NW., Washington, D.C. 20550.

The purpose of this panel is to provide advice and recommendations concerning

the overall International Decade of Ocean Exploration program and new areas of research for consideration or modifications to ongoing research to strengthen the effort; and to provide guidance on ways to strengthen the international participation.

The agenda for this meeting shall include:

	DECEMBER 6	
1:00 to 1:15.	Introduction and Overview.	Head, Office for the International Decade of Ocean Exploration (IDOE).
1:15 to 1:45.	Environmental Forecasting.	Program Manager, Environmental Forecasting Program.
1:45 to 2:15.	Environmental Quality.	Program Manager, Environmental Quality Program.
2:15 to 2:45.	Living Resources...	Program Manager, Living Resources Program.
2:45 to 3:00.	Coffee Break.....	
3:00 to 3:30.	Seabed Assessment..	Program Manager, Seabed Assessment Program.
3:30 to 4:00.	International Aspects.	International Affairs Officer.
4:00 to 4:45.	Summarization of NSF and IDOE Data Management Policy.	Head IDOE.
	DECEMBER 7	
9:00 to 11:45.	General Discussion: 1. Program Management in IDOE. 2. Future International Aspects.	
11:45 to 12:00.	Concluding Comments.	Head, IDOE.

This meeting shall be open to the public. Individuals who wish to attend should inform Mrs. Martena Baker, Administrative Assistant, Office for the International Decade of Ocean Exploration, by telephone (202–632–7356) or by mail (Room 710, 1800 G Street, NW., Washington, D.C. 20550) by November 30, 1973. Persons requiring further information concerning this Panel should contact Mrs. Martena Baker at the above address. Summary minutes relative to this meeting may be obtained from the Management Analysis Office, Room K–720, 1800 G Street, NW., Washington, D.C. 20550.

T. E. JENKINS,
Assistant Director for Administration.

NOVEMBER 6, 1973.

[FR Doc.73–24671 Filed 11–19–73;8:45 am]

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–10490; File No. 4–170]

COMMISSION STUDY OF MULTIPLE EXCHANGE OPTION TRADING AND OPTION TRADING IN GENERAL

Notice of Commission Review, Request for Comments and Oral Hearing

The Commission has announced that it has under study and is requesting public comment on various questions that have arisen in connection with the interest expressed by several exchanges in using their facilities for option trading. Two of these exchanges, the American ("Amex") and the PBW ("PBW") Stock Exchanges, have each formulated programs for the trading of options before the end of this year, and each exchange has prepared drafts of proposed rules to implement its programs. Upon the formal filing of these rules, which is expected to occur shortly, the Commission will immediately invite public comment on them.

On February 1, 1973, the Commission granted the application of the Chicago Board Options Exchange, Inc. ("CBOE") for registration as a national securities exchange "to permit it to test the market for such options within a controlled environment."[1] As part of its pilot program, the CBOE gave assurances that it would study closely and submit regular reports on its operations. While the CBOE's recent report covering its first three months of operation represents a constructive initial step in implementing this program, it is inconclusive on a number of major questions, including the impact of its option trading on the markets for underlying securities, the composition and investment objectives of investors buying and selling in the CBOE market and the nature of the economic functions performed by, and viability of, an options exchange.

As previously announced,[2] the Commission has not made any definitive determinations with respect to a number of basic questions concerning option trading on exchanges including whether options should be traded, on a pilot basis or otherwise, on more than one exchange or on exchanges that also trade other forms of securities. The Commission believes that these questions are matters of great significance, not only to the nation's registered securities exchanges but also to the members of the securities industry and to public investors. Accordingly, the Commission has decided to invite all persons interested in, or affected by, option trading to provide the Commission with the benefit of their views. Inasmuch as a full assessment of trading in options on the CBOE has not yet been made and may have to await further study, the views and data solicited herein will be of assistance to the Commission at such time as it is in a posture to decide the questions now before it regarding option trading. In order to assist those persons wishing to comment on these various questions, certain background is set forth below. The CBOE has been able to create a secondary market for options by applying, among other approaches, various commodity futures trading and clearing principles to options and by creating fungible options. The CBOE option is made fungible by limiting its variables—the expiration date, the striking price and the premium. The options expire either on the last day of January, April, July or October. The striking prices (the price per share at which the underlying stock may be purchased upon exercise of the option) of CBOE options are fixed at 5-point intervals for stocks trading below $50, 10-point intervals for stocks trading between $50 and $100, and 20-point intervals for stocks trading above $100. If the price of the underlying security fluctuates substantially, new options may be written with the same expiration dates but with different striking prices, but the number of different striking prices of options on that stock are limited. The premium, the price paid for the option itself, is determined by the secondary market.

Both the Amex and the PBW draft proposals are based very largely on CBOE's plan. The major difference between CBOE's program and those of Amex and PBW is that Amex and PBW would expect to utilize their present specialist systems instead of segregating the agent and dealer functions between board brokers and competing market makers. Furthermore, CBOE permits competing market makers for options traded on its floor, whereas Amex would propose the traditional approach of having only one market maker for each issuer's options traded on its exchange. PBW's program differs from both the CBOE and the Amex programs in that it would extend its system of alternate specialists to options trading and in that the options on the PBW would expire in different months.[3] Amex and PBW intend to trade options having the same underlying issuers as some options which are traded on the CBOE as well as options on other securities; however, all securities subject to such options would be listed and traded on the New York Stock Exchange.

The Commission views its various Congressional mandates under the Securities Exchange Act[4] as requiring that it proceed with caution in permitting the expansion of option trading on exchanges and that it take all steps necessary to maintain close surveillance over such trading to insure investor protection. Accordingly, the Commission believes that there should be broad public participation in the consideration and resolution of the many basic questions arising out of trading in options on the CBOE as well as the proposals for such trading on the Amex and PBW. Because of the significance and the wide-ranging nature and

[1] In the Matter of the Application of the Chicago Board Options Exchange, Inc., for Registration as a National Securities Exchange, Securities Exchange Act Release No. 34–9985 (February 1, 1973) p. 2. Only call options (the right to purchase a security at a certain price, within a specified time period) are traded on the CBOE. Both the Amex and PBW plans include only call options.

[2] Securities Exchange Act Release No. 34–10397 (September 21, 1973), "Republication of Proposed Rule 9b–1 Concerning Exchange Transactions in Options; Request for Comments on the Chicago Board Options Exchange, Inc. Plan Pursuant to Rule 9b–1."

[3] CBOE now trades and Amex intends to trade options that expire in the months of January, April, July, and October. The PBW intends to trade options expiring in the months of December, March, June, and September plus an additional fifteen month option (i.e. options that expire one year and three months after the commencement date of trading).

[4] Especially, sections 6, 9 (b) and (c), 19(b) and 23(a).

scope of the Commission's inquiry, written submissions by interested persons appear appropriate. After these submissions are reviewed, the Commission will entertain oral statements by those persons desiring to make such presentations that have submitted written statements.

To aid the Commission, commentators are specifically asked to address themselves to the following considerations. Commentators, of course, should feel free to comment on other aspects of these issues that may not be specifically set forth below.

I. Option Trading in General

As previously indicated, the following are basic areas of inquiry in the Commission's evaluation of the CBOE's pilot project and should be addressed by commentators:

(a) What economic functions are served by the writing and purchasing of options in today's markets (e.g., hedging, leveraging, speculation)? If there are several economic functions, to what extent is each served and likely to be served in the option market? By whom? Do these functions, either individually or in net effect, serve the public interest?

(b) What is the nature of the investor population that now participates, or that likely will participate, in the trading of options in an exchange option market? To what extent are the present participants and likely future participants: sophisticated; unsophisticated; professional; institutional; small; or investors that would not otherwise participate in the securities market?

(c) What is the actual and potential impact of an option market on the investment and trading habits (including the use of margin) of the categories of investors mentioned in (b) above respecting direct investment in the securities underlying the options; in securities not underlying the options; in low priced securities; in new issues? Would such impacts be, in the public interest?

(d) Of special concern to the Commission has been the subject of the writing of "uncovered options."[5] What economic function(s) are served by uncovered options? In this connection, consider how these functions may vary depending on the type of writer—e.g., market maker, specialists, floor traders, institutional investors or small investors?[6] How do these functions, either individually or together, serve the public? What are the actual and potential impacts of uncovered options on the market for the underlying securities? Would such impacts be in the public interest?

(e) To what extent should limits be prescribed regarding the number of option contracts which can be outstanding relative to any given security issue or, taking convertibles into account, issues? Should there be limits on the number of options to purchase or sell such securities which can be written or held by the same person? How should such limits be developed? In this regard should options or uncovered options be prohibited with respect to certain security issues?

(f) Should options having a life in excess of a specified period of time be prohibited? If so, what should that specified period of time be? Should the writing of options with a remaining life less than a specific period of time be prohibited? If so, should such prohibition be predicated on whether the writing is covered or uncovered?

II. Exchange Option Trading

A. Multiple Pilots

1. Should exchange option trading be limited to the CBOE pilot project, which is now underway and being monitored by the Commission, until sufficient information along the lines described in the previous questions can be developed and evaluated? To what extent would additional pilots facilitate or obstruct the resolution of those questions? How?

2. If multiple exchange pilot programs should be permitted, on what conditions? In this regard consideration should be given to the following interrelated factors:

(a) The regulatory scheme which should govern such multiple trading, if it is to be permitted, including the necessity for and desirability of uniform trading rules, clearing procedures, and surveillance mechanisms;

(b) The burdens on and costs to exchanges and their members arising from such multiple trading and the accompanying regulatory programs, including the development of single or multiple systems for trade executions, settlement, and clearance and necessary surveillance organizations or systems;

(c) The necessity for or desirability of intermarket competition and/or coordination in each of the various principal aspects[7] of a multiple exchange system for option trading noted in (a) and (b) above—e.g., in trading, clearance, settlement, and surveillance systems. In this connection, for example, commentators should consider whether option trading should be permitted prior to the development and implementation of an appropriate composite tape and/or quotations system and whether, in the clearing area, largely separate competing systems should be allowed to proceed, as not proposed;

(d) Should the Commission permit the introduction of the traditional exchange specialist system in connection with option trading, as now proposed by Amex and PBW?[8] Is the nature of exchange option trading such that the total segregation of the agency and dealer functions would be appropriate in the public interest? With respect to the specialist dealer function in option trading, is it necessary or desirable to require competitive market making in each exchange market?

B. Multiple Permanent Markets

The Commission is of the opinion that it is now appropriate to consider not only the immediate questions raised under A above, but also the longer range question as to whether (and, if so, under what conditions) it ultimately would be in the public interest to have multiple exchange markets engaged in trading options as a permanent part of the nation's securities markets. In this regard, commentators should consider the factors summarized in paragraph 2 of A above.

Both the CBOE and the Amex have submitted comments on the questions raised by the proposed multiple exchange option trading. These submissions, which are in the public file of this study, raise similar as well as additional questions on which commentators may wish to express their views.

Written statements of views and comments in regard to the foregoing should be addressed to: George A. Fitzsimmons, Secretary, Securities and Exchange Commission, 500 North Capitol Street, Washington, D.C. 20549 on or before January 11, 1974. Reference should be made to file number 4–170. All such communications will be available for public inspection.

Oral Presentation Procedures

In light of the significance of the issues involved, the Commission has determined to entertain oral statements by those persons submitting written comments. In order to facilitate the Commission's consideration of any oral statements, the following procedures will be employed:

1. Oral statements shall be heard commencing January 29, 1974, and shall be limited to 15 minutes each. Persons desiring additional time should request a specified additional amount of time, and accompany their request with an adequate explanation of their need for additional time. Thereafter, the Commission will notify all persons requesting an opportunity to make an oral presentation of the date and amount of time allocated therefor.

2. The written text of the oral statement to be given must be received by the Office of the Secretary of the Commission no later than one week prior to the scheduled oral statement.

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[5] Securities Exchange Act Release No. 34–9994 (February 8, 1973), "Proposal of Rule 9b–2 under the Securities Exchange Act of 1934."

[6] Securities Exchange Act Release No. 34–10312 (August 1, 1973), "Commission Review of Option Trading by Specialists, Market Makers, Floor Traders, and Block Positioners."

[7] *See* n. 3, *supra*.

[8] *See* p. 2 *supra*. for discussion on the difference between CBOE's specialist system and the traditional specialist systems Amex and PBW intend to utilize.

3. Persons making oral presentations should be prepared to respond to inquiries from the Commission and its staff.

By the Commission.

[SEAL] GEORGE A. FITZSIMMONS, *Secretary.*

NOVEMBER 14, 1973.

[FR Doc.73-24678 Filed 11-19-73;8:45 am]

[File No. 500-1]

ROYAL PROPERTIES, INC.

Notice of Suspension of Trading

NOVEMBER 8, 1973.

It appearing to the Securities and Exchange Commission that the summary suspension of trading in the common stock of Royal Properties Incorporated being traded otherwise than on a national securities exchange is required in the public interest and for the protection of investors;

Therefore, pursuant to section 15(c)(5) of the Securities Exchange Act of 1934, trading in such securities otherwise than on a national securities exchange is suspended, for the period from November 9, 1973 through November 18, 1973.

By the Commission.

[SEAL] GEORGE A. FITZSIMMONS, *Secretary.*

[FR Doc.73-24679 Filed 11-19-73;8:54 am]

INTERSTATE COMMERCE COMMISSION

[Notice 389]

ASSIGNMENT OF HEARINGS

NOVEMBER 15, 1973.

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 135754 Sub 1, Robert E. Williamson, Jr., Common Carrier Application, now assigned December 6, 1973, at Columbia, S.C., will be held in the Mental Health Conference Room 118-119, 2414 Bull Street.

MC 97904 Sub 13, Knoxville-Maryville Motor Express, Inc., now assigned December 11, 1973, at Nashville, Tenn., will be held in Room 651, U.S. Courthouse, 8th & Broadway.

MC 125820 Sub 7, Elk Valley Freight Line, Inc., continued to January 21, 1974 (1 week), at the Holiday Inn, 3810 University Dr., Huntsville, Alabama.

MC 112304 Sub 65, Ace Doran Hauling & Rigging Co., now assigned December 3, 1973, at Columbus, Ohio, will be held in Room 2, Public Utilities Commission of Ohio, 111 North High St., instead of Room 228 Federal Bldg., 85 Marconi Blvd.

I&S No. 8878, Increased Minimum Weights, Grain Products & Related Articles, and No. 42731, Grain Products in the United States now assigned November 27, 1973, at Washington, D.C., is postponed to November 28, 1973, at the Offices of the Interstate Commerce Commission, Washington, D.C.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[FR Doc.73-24101 Filed 11-19-73;8:45 am]

[Notice 394]

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 December 10, 1973. 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-74509. By order entered November 13, 1973, the Motor Carrier Board approved the transfer to Sutco, Inc., Scranton, Pa., of those portions of the operating rights set forth in Certificates Nos. MC-2371 and MC-2871 (Sub-No. 2), issued by the Commission November 9, 1973, and July 2, 1973, respectively, to Carlton Repsher, Laceyville, Pa., authorizing the transportation of poultry and eggs, from points in Bradford, Tioga, Wyoming, Susquehanna, and Sullivan Counties, Pa., to New York, N.Y., and Newark and Jersey City, N.J.; meat scraps, groceries, sugar, and stock feed, from New York, N.Y., and Edgewater, Newark, and Jersey City, N.J., to points in Bradford, Tioga, Wyoming, Susquehanna, and Sullivan Counties, Pa., and Chemung and Steuben Counties, N.Y.; and dry sugar, in bulk, in insulated hopper-type trailers, from Philadelphia, Pa., to points in New Jersey, Delaware, Maryland, and a described area in Virginia and West Virginia. Kenneth R. Davis, 999 Union St., Taylor, PA 18517, practitioner for applicants.

No. MC-FC-74604. By order of November 14, 1973, the Motor Carrier Board approved the transfer to Keys Trucking Company, Inc., 902 S. Randolph St., Arlington, Va., of the operating rights in Permits Nos. MC-127095 (Sub-No. 1), and MC-127095 (Sub-No. 2) issued November 21, 1966 and April 20, 1970 respectively to Rosa Mae Keys, 902 S. Randolph St., Arlington, Va., authorizing the transportation of various commodities from Arlington, Va. and Clinton, Md. to points in Washington, D.C. and a described area in Maryland and Arlington, Va.

No. MC-FC-74735. By order of November 14, 1973, the Motor Carrier Board aproved the transfer to Santiago Alfaro, 1821 King Arthur Street, Eagle Pass, Tex. 78852, of Certificate No. MC-96552 issued on February 25, 1948, to Jesus M. Herrera, Eagle Pass, Tex., authorizing the transportation of general commodities between the boundary of the United States and Mexico at Eagle Pass, Tex., and points in Eagle Pass, Tex.

No. MC-FC-74746. By order of November 14, 1973, the Motor Carrier Board approved the transfer to Hebden & McKenzie Transport, Inc., Boston, Mass., of Certificate of Registration No. MC-98550 (Sub-No. 1) issued on January 16, 1964, to Hebden & McKenzie Express, Inc., Somerville, Mass., evidencing the authority to perform a transportation service in interstate or foreign commerce corresponding in scope to the intrastate authority granted in Certificate No. 1013 by the Massachusetts Department of Public Utilities. Mr. George C. O'Brien, attorney at law, 15 Court Square, Boston, Mass. 02108.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[FR Doc.73-24700 Filed 11-19-73;8:45 am]

[Notice 155]

MOTOR CARRIER TEMPORARY AUTHORITY APPLICATIONS

NOVEMBER 14, 1973.

The following are notices of filing of application, except as otherwise specifically noted, each applicant states that there will be no significant effect on the quality of the human environment resulting from approval of its application, for temporary authority under section 210a(a) of the Interstate Commerce Act provided for under the new rules of Ex Parte No. MC-67 (49 CFR Part 1131) published in the FEDERAL REGISTER, issue of April 27, 1965, effective July 1, 1965. These rules provide that protests to the granting of an application must be filed with the field official named in the FEDERAL REGISTER publication, on or before December 5, 1973. One copy of such protests must be served on the applicant, or its authorized representative, if any, and the protests must certify that such service has been made. The protests must be specific as to the service which such protestant can and will offer, and must consist of a signed original and six (6) copies.

A copy of the application is on file, and can be examined at the Office of the Secretary, Interstate Commerce Commission, Washington, D.C., and also in field

office to which protests are to be transmitted.

MOTOR CARRIERS OF PROPERTY

No. MC 2226 (Sub-No. 105 TA), filed November 1, 1973. Applicant: RED ARROW FREIGHT LINES, INC., P.O. Box 1897, 3901 Sequin Road, San Antonio, Tex. 78297. Applicant's representative: Eugene C. Daniel (same address as above). Authority sought to operate as a *common carrier*, by motor vehicle, over regular routes, transporting: *Engine blocks, tools, dies, frames, windshields, and parts for automobiles*, between (a) Laredo, Tex., and the United States-Mexico International Boundary line at or near Laredo, Tex. and (b) Beeville, Tex. and San Antonio, Tex. as follows: (1) from Laredo, Tex., to Beeville, Tex. over U.S. Highway 59 and return over the same and (2) from Laredo, Tex. to San Antonio, Tex. over U.S. Highway 81 (I.H. 35) and return over the same route, for 180 days.

NOTE.—Applicant proposes to tack with all existing authority in Docket MC 2226 and Subs and to interline with other carriers at common points.

SUPPORTING SHIPPER: Ford Motor Company, S.A., Hugo Briones, Traffic Manager, Mexico 1, D.F., Mexico. SEND PROTESTS TO: Richard H. Dawkins, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 301 Broadway Building, Room 206, San Antonio, Tex. 78205.

No. MC 82079 (Sub-No. 34 TA), filed November 1, 1973. Applicant: KELLER TRANSFER LINE, INC., 1239 Randolph Avenue SW., Grand Rapids, Mich. 49507. Applicant's representative: J. M. Neath, Jr., 900 One Vandenberg Center, Grand Rapids, Mich. 49502. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Frozen prepared foods and frozen bakery goods*, from Solon, Ohio, to points in the Lower Peninsula of Michigan, restricted, however, to traffic originating at the plant and warehouse sites of Stouffer Foods, Division of Litton Industries, Inc., at Solon, Ohio and terminating in the destination area, for 180 days. SUPPORTING SHIPPER: Stouffer Frozen Foods, 5750 Harper Road, Solon, Ohio 44139. SEND PROTESTS TO: C. R. Flemming, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 225 Federal Building, Lansing, Mich. 48933.

No. MC 87720 (Sub-No. 156 TA), filed November 2, 1973. Applicant: BASS TRANSPORTATION CO., INC., P.O. Box 391, Flemington, N.J. 08822. Applicant's representative: Bert Collins, Suite 6193, 5 World Trade Center, New York, N.Y. 10048. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Plastic bottles, jars, jugs; and closures for plastic bottles, jars, jugs; and cartons, partitions, and refused or rejected shipments returned*, for the account of Bemis Company, Inc., from Indianapolis, Ind., to Bensenville, Blue Island, Calumet City, Elk Grove Village, Chicago, Mount Prospect, Schiller Park, and Franklin Park, Ill.; Livonia, Mich.; St. Louis, Mo.; Akron, Cincinnati, Cleveland, Columbus, Dayton, Delaware, Holmesville, Toledo, Ohio; Morgantown, W. Va.; Green Bay, Milwaukee, Rice Lake, and Waukesha, Wis., for 180 days. SUPPORTING SHIPPER: Bemis Company, Inc., 1940 Barth Avenue, Indianapolis, Ind. SEND PROTESTS TO: Richard M. Regan, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 428 East State Street, Room 204, Trenton, N.J. 08608.

No. MC 101075 (Sub-No. 115 TA), filed November 1, 1973. Applicant: TRANSPORT, INC., 1215 Center Avenue, P.O. Box 396, Moorhead, Minn. 56560. Applicant's representative: Ronald B. Pitsenbarger (same address as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum and petroleum products*, in bulk, from ports of entry on the International Boundary line between the United States and Canada located in Minnesota and North Dakota on and east of U.S. Highway 281, points in Minnesota, North Dakota, South Dakota, and Wisconsin, for 180 days. SUPPORTING SHIPPER: Radio Oil Ltd., Munroe & Watt Streets, Winnipeg 15, Manitoba, Canada. SEND PROTESTS TO: J. H. Ambs, District Supervisor, Interstate Commerce Commission, Bureau of Operations, P.O. Box 2340, Fargo, N. Dak. 58102.

No. MC 103993 (Sub-No. 786 TA), filed November 5, 1973. Applicant: MORGAN DRIVE-AWAY, INC., 2800 W. Lexinton Avenue, Elkhart, Ind. 46514. Applicant's representative: Paul D. Borghesani (same address as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Amusement rides* on undercarriages, from San Antonio, Tex., to points in the United States (except Alaska and Hawaii), for 180 days. SUPPORTING SHIPPER: San Antonio Roller Works, 229 Noland Street, San Antonio, Tex. 78202. SEND PROTESTS TO: J. H. Gray, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 345 W. Wayne St., Room 204, Ft. Wayne, Ind. 46802.

No. MC 105269 (Sub-No. 55 TA), filed November 5, 1973. Applicant: GRAFF TRUCKING COMPANY, INC., 2110 Lake Street, Box 986 (Box zip 49001), Kalamazoo, Mich. 49005. Applicant's representative: John M. Veale, Suite 1700, One Woodward Avenue, Detroit, Mich. 48226. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Wrapping papers, plain and indented, and packaging pads, machine pressed*, from Broadview, Chicago, Danville, East Peoria, Galva, Kankakee, Ottawa, River Forest and Salem, Ill.; Davenport, Iowa; Louisville, Ky.; Brownstown Township, Wayne County, Detroit, Ecorse, Grand Rapids, Kalamazoo, Mt. Clemens and Utica, Mich.; St. Louis, Mo.; Cincinnati, Cleveland, Crestline, Lockland, Toledo, Warren, West Marion, Youngstown and Zanesville, Ohio; Pittsburgh and Roscoe, Pa.; Huntington, W. Va.; Columbus, Kaukauna, Kewaskum and Sheboygan, Wis. and (2) *Waste paper*, from the aforementioned destinations to Brownstown, Ind., for 180 days. SUPPORTING SHIPPER: Kieffer Paper Mills, Inc., 1220 West Spring Street, Brownstown, Ind. 47220. SEND PROTESTS TO: C. R. Flemming, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 225 Federal Building, Lansing, Mich. 48933.

No. MC 107403 (Sub-No. 827 TA), filed November 1, 1973. Applicant: MATLACK, INC., 10 West Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same address as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Lubricating oil*, in bulk, in tank vehicles, from Gretna, La., to Clinton, Iowa, for 180 days. SUPPORTING SHIPPER: Mr. Mitchell B. Carbo, Jr., Southwest Regional Traffic Manager, Witco Chemical Corporation, P.O. Box 308, Gretna, La. 70053. SEND PROTESTS TO: Ross A. Davis, District Supervisor, Interstate Commerce Commission, Bureau of Operations, William J. Green, Jr., Federal Bldg., 600 Arch Street, Room 3238, Philadelphia, Pa. 19106.

No. MC 107496 (Sub-No. 918 TA), filed November 1, 1973. Applicant: RUAN TRANSPORT CORPORATION, Third and Keosauqua Way, P.O. Box 855 (Box zip 50304), Des Moines, Iowa 50309. Applicant's representative: E. Check (same address as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Liquid animal and poultry feed*, in bulk, in tank vehicles, from Elwood, Kans., to points in Iowa, Missouri, and Nebraska, for 150 days. SUPPORTING SHIPPER: Allied Mills, Inc., P.O. Box 1058, St. Joseph, Mo. 64502. SEND PROTESTS TO: Herbert W. Allen, Transportation Specialist, Interstate Commerce Commission, Bureau of Operations, 875 Federal Building, Des Moines, Iowa 50309.

No. MC 107496 (Sub-No. 919 TA), filed November 7, 1973. Applicant: RUAN TRANSPORT CORPORATION, Third and Keosauqua Way, P.O. Box 855 (Box zip 50304), Des Moines, Iowa 50309. Applicant's representative: E. Check (same address as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Crude oil*, in bulk, in tank vehicles, from Clearbrook, Minn., to Superior and Saxon, Wis., for 150 days. SUPPORTING SHIPPER: Lakehead Pipeline Company, P.O. Box 665, Bemidji, Minn. 56601. SEND PROTESTS TO: Herbert W. Allen, Transportation Specialist, Interstate Commerce Commission, Bureau of Operations, 875 Federal Building, Des Moines, Iowa 50309.

No. MC 107678 (Sub-No. 52 TA), filed November 6, 1973. Applicant: HILL & HILL TRUCK LINE, INC., 14942 Talcott Street, Mail: P.O. Box 9698, Houston, Tex. 77015. Applicant's representative: Jay W. Elston, 800 Bank of the South-

west Bldg., Houston, Tex. 77002. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Conduit pipe, iron or steel*, from the plantsite of Torrance Tubing Division of Cyprus Mines Corporation at Houston, Tex., to ports of entry on the international boundary lines between the United States and Canada located in Montana and North Dakota, restricted to shipments destined to points in Alberta and Saskatchewan, Canada, for 180 days.

NOTE.—Applicant does intend to tack with Canadian authority in Alberta and Saskatchewan.

SUPPORTING SHIPPER: Torrance Tubing, Division of Cyprus Mines Corporation, 1739 W. 213th Street, Torrance, Calif. 90509. SEND PROTESTS TO: John Mensing, District Supervisor, Interstate Commerce Commission, Bureau of Operations, Room 8610 Federal Bldg., 515 Rusk Avenue, Houston, Tex. 77002.

No. MC 108449 (Sub-No. 364 TA), filed November 5, 1973. Applicant: INDIANHEAD TRUCK LINE, INC., 1947 West County Road "C", St. Paul, Minn. 55113. Applicant's representative: W. A. Myllenbeck (same address as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Litharge*, dry, in bulk, in tank vehicles, from St. Paul, Minn., to West Kankakee, Ill., for 180 days. SUPPORTING SHIPPER: Gould Inc., P.O. Box 3140, St. Paul, Minn. 55165. SEND PROTESTS TO: Raymond T. Jones, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 448 Federal Building & U.S. Court House, 110 S. 4th Street, Minneapolis, Minn. 55401.

No. MC 110541 (Sub-No. 11 TA), filed November 5, 1973. Applicant: MARK E. YODER, INC., P.O. Box 346, Rte. 1, Schuylkill Haven, Pa. 17972. Applicant's representative: Christian V. Graf, 407 North Front Street, Harrisburg, Pa. 17101. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum coke*, from the refinery of Getty Oil Company at Delaware City, Del., to the plant of Pennsylvania Power & Light Company in Derry Township, Montour County, Pa., for 90 days. SUPPORTING SHIPPERS: Pennsylvania Power & Light Company, 2 North Ninth Street, Allentown, Pa. 18101, and Hecla Machinery & Equipment Company, R.D. 1, New Ringgold, Pa. 17960. SEND PROTETS TO: Paul J. Kenworthy, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 309 U.S. Post Office Building, Scranton, Pa. 18503.

No. MC 114533 (Sub-No. 286 TA), filed November 1, 1973. Applicant: BANKERS DISPATCH CORPORATION, 4970 S. Archer Avenue, Chicago, Ill. 60632. Applicant's representative: Stanley Komosa (same address as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Audit media and other business records*, between Jefferson City, Mo., on the one hand, and, on the other, points in Madison and St. Claire Counties, Ill., for 180 days. SUPPORTING SHIPPER: Missouri Division of Employment, Assistant Director-Administration J. R. Kratochvil, 421 East Dunklin, Jefferson City, Mo. SEND PROTESTS TO: Robert G. Anderson, District Supervisor, Bureau of Operations, Interstate Commerce Commission, Everett McKinley Dirksen Bldg., 219 S. Dearborn St., Room 1086, Chicago, Ill. 60604.

No. MC 116063 (Sub-No. 130 TA), filed November 1, 1973. Applicant: WESTERN - COMMERCIAL TRANSPORT, INC., 2929 W. 5th Street, P.O. Box 270 (Box zip 76101), Fort Worth, Tex. 76106. Applicant's representative: H. C. Cole (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Paint primer*, in bulk, in tank vehicles, from Garland, Tex., to Norfolk, Nebr., for 180 days. SUPPORTING SHIPPER: The Sherwin-Williams Company, Manager-Transportation Operations, 101 Prospect Ave., N.W., Cleveland, Ohio 44115. SEND PROTESTS TO: H. C. Morrison, Sr., District Supervisor, Interstate Commerce Commission, Bureau of Operations, Room 9A27 Federal Building, 819 Taylor St., Fort Worth, Tex. 76102.

No. MC 116063 (Sub-No. 131 TA), filed November 1, 1973. Applicant WESTERN-COMMERCIAL TRANSPORT, INC., 2929 W. 5th Street, P.O. Box 270 (Box zip 76101), Fort Worth, Tex. 76106. Applicant's representative: H. C. Cole (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Vegetable oils, animal fats and blends thereof*, in bulk, in tank vehicles, from Fort Worth, Tex., to points in Georgia, for 180 days. SUPPORTING SHIPPER: A. A. Johnson, Swift Edible Oil Company, a division of Swift & Co., 115 W. Jackson Blvd., Chicago, Ill. 60604. SEND PROTESTS TO: H. C. Morrison, Sr., District Supervisor, Interstate Commerce Commission, Bureau of Operations, 819 Taylor St., Fort Worth, Tex. 76102.

No. MC 116254 (Sub-No. 139 TA), filed October 30, 1973. Applicant: CHEM-HAULERS, INC., 1510 Martin Avenue, P.O. Box 245, Sheffield, Ala. 35660. Applicant's representative: Walter Harwood, 1822 Parkway Towers, Nashville, Tenn. 37219. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Spent phosphoric acid*, in bulk, from Adel, Carrollton, Moultrie, Tifton and Valdosta, Ga., to the plant site of Union Carbide, Taft, La., for 150 days. SUPPORTING SHIPPER: Mobil Chemical Company, P.O. Box 26683, Richmond, Va. 23261. SEND PROTESTS TO: Clifford W. White, District Supervisor, Interstate Commerce Commission, Bureau of Operations, Room 814, 2121 Building, Birmingham, Ala. 35203.

No. MC 117119 (Sub-No. 491 TA), filed October 31, 1973. Applicant: WILLIS SHAW FROZEN EXPRESS, INC., P.O. Box 188, Elm Springs, Ark. 72728. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Foodstuffs and specialty gift items*, from points in Wisconsin, to points in Arizona, California, New Mexico, Oklahoma, Oregon, Utah, and Washington, for 180 days. SUPPORTING SHIPPER: The Wisconsin Cheeseman, P.O. Box 1, Madison, Wis. SEND PROTESTS TO: District Supervisor William H. Land, Jr., Interstate Commerce Commission, Bureau of Operations, 2519 Federal Office Building, 700 West Capitol, Little Rock, Ark. 72201.

No. MC 117119 (Sub-No. 492 TA), filed October 31, 1973. Applicant: WILLIS SHAW FROZEN EXPRESS, INC., P.O. Box 188, Elm Springs, Ark. 72728. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Anti-freeze/summer coolant*, in containers in cases (except in bulk, in tank vehicles), from Texas City, Tex., to Idabel, Hugo, Sallisaw, Tahlequah, Claremore, Pryor, Miami, Poteau, Broken Arrow, Bartlesville, Vinita, Wagoner, and Stilwell, Okla., and Bentonville, Ark., restricted to traffic destined to Wal-Mart in named destinations, for 180 days. SUPPORTING SHIPPER: Wal-Mart Stores, Inc., P.O. Box 116, Bentonville, Ark. 72712. SEND PROTESTS TO: District Supervisor William H. Land, Jr., Interstate Commerce Commission, Bureau of Operations, 2519 Federal Office Building, 700 West Capitol, Little Rock, Ark. 72201.

No. MC 118377 (Sub-No. 4 TA), filed October 30, 1973. Applicant: RICHARD R. JOHNCOX, Route 104, Williamson, N.Y. 14589. Applicant's representative: Morton E. Kiel, Suite 6193, 5 World Trade Center, New York, N.Y. 10048. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Frozen foods*, from the facilities of Empire Freezers of Syracuse, Inc. at or near Geddes, N.Y., to Altoona, Barnesboro, Beaver Falls, Bedford, Belle Vernon, Bradford, Butler, Carnegie, Dunbar, Eighty-Four, Ebensburg, Erie, Franklin, Greensburg, Huntingdon, Leetsdale, Ligonier, McKeesport, McKees Rocks, New Brighton, New Castle, Pittsburgh, Pleasant Hills, Portersville, Punxutawney, Republic, Slippery Rock, State College, Thornburg, Union Town, Washington, Waynesburg, Wheatland, White Oak, Wilkinsburg and Williamsburg, Pa., for 180 days. SUPPORTING SHIPPER: Charles A. Cleveland, Director of Sales and Customer Service, Empire Freezers of Syracuse, Inc., Box 770, Farrell Road, Syracuse, N.Y. 13201. SEND PROTESTS TO: Morris H. Gross, District Supervisor, Interstate Commerce Commission, Bureau of Operations, Room 104, 301 Erie Blvd., West, Syracuse, N.Y. 13202.

No. MC 119388 (Sub-No. 15 TA), filed November 1, 1973. Applicant: GLEN R. ELLIS, INC., 3911 Jerome Avenue, Chattanooga, Tenn. 37407. Applicant's representative: Blaine Buchanan, 1024 James Building, Chattanooga, Tenn. 37402. Au-

thority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Malt beverages and incidental advertising material* when shipped in connection with malt beverages, from the plant site of the G. Heileman Brewing Co. of Indiana, Inc., Evansville, Ind., to Anniston, Attalla, Selma, and Sylacauga, Ala.; Helena, Hot Springs, Little Rock, and West Memphis, Ark.; and Gulfport and Jackson, Miss., for 180 days. SUPPORTING SHIPPER: G. Heileman Brewing Co., Inc., 925 South Third Street, La Crosse, Wis. 54601. SEND PROTESTS TO: Joe J. Tate, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 803–1808 West End Bldg., Nashville, Tenn. 37203.

No. MC 119656 (Sub-No. 19 TA), filed November 1, 1973. Applicant: NORTH EXPRESS, INC., 219 E. Main Street, Winamac, Ind. 46996. Applicant's representative: Alki E. Scopelitis, 815 Merchants Bank Bldg., Indianapolis, Ind. 46204. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Pressed fireplace logs*, from Monticello, Ind., to points in Michigan, Illinois, Ohio, Pennsylvania and Kentucky, for 180 days. SUPPORTING SHIPPER: Convenience Products, Inc., West Fisher, P.O. Box 278, Monticello, Ind. 47960. SEND PROTESTS TO: J. H. Gray, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 345 W. Wayne Street, Room 204, Ft. Wayne, Ind. 46802.

No. MC 123778 (Sub-No. 20 TA), filed November 5, 1973. Applicant: JALT CORP., doing business as UNITED NEWSPAPER DELIVERY SERVICE, 75 Cutters Doch Road, P.O. Box 398, Woodbridge, N.J. 07095. Applicant's representative: Morton E. Kiel, Suite 6193, 5 World Trade Center, New York, N.Y. 10048. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Newspapers*, (otherwise exempt from economic regulations under Section 203(b)7 of the Act) when transported in the same vehicle with a regulated commodity, from Woodbridge, N.J., to Wilmington, Del.; Baltimore, Md.; the District of Columbia, and points in New Jersey and Connecticut, and those in that part of Pennsylvania on and east of U.S. Highway 15 and those in New York on the east of New York Highway 14, under contract with Midnight Publishing Corp. and Select Magazines, Inc., for 180 days. SUPPORTING SHIPPERS: Midnight Publishing Corp., 1440 St. Catherine West, Montreal 107 Quebec, Canada and Felix L. D. D'Arienzo, Director of Traffic, Select Magazines, Inc., 229 Park Ave. South, New York, N.Y. SEND PROTESTS TO: District Supervisor Robert S. H. Vance, Interstate Commerce Commission, Bureau of Operations, 9 Clinton St., Newark, N.J. 07102.

No. MC 124692 (Sub-No. 124 TA), filed October 31, 1973. Applicant: SAMMONS TRUCKING, P.O. Box 1447, Missoula, Mont. 59801. Applicant's representative: Gene P. Johnson, 425 Gate City Bldg., Fargo, N. Dak. 58102. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Wood fibre board, faced or finished with decorative or protective material*, from Bloomington, Minn., to points in Wisconsin and the Upper Peninsula of Michigan, restricted to traffic originating at the facilities of Masonite Corporation at Bloomington, Minn., for 180 days. SUPPORTING SHIPPER: Masonite Corporation, 29 N. Wacker Drive, Chicago, Ill. 60606. SEND PROTESTS TO: Paul J. Labane, District Supervisor, Interstate Commerce Commission, Bureau of Operations, Rm. 222, U.S. Post Office Building, Billings, Mont. 59101.

No. MC 127355 (Sub-No. 14 TA), filed November 1, 1973. Applicant: M & N GRAIN COMPANY, P.O. Box 21, Nevada, Mo. 64772. Applicant's representative: Donald J. Quinn, Suite 900, 1012 Baltimore, Kansas City, Mo. 64105. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Soybean meal*, from Des Moines, Eagle Grove and Ft. Dodge, Iowa; Emporia, Fredonia and Wichita, Kans.; Lincoln, Nebr.; and Mankato, Minn., to points in Idaho and Utah, for 180 days. SUPPORTING SHIPPER: The Pillsbury Company, 608 Second Avenue South, Minneapolis, Minn. 55402. SEND PROTESTS TO: John V. Barry, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 600 Federal Office Building, 911 Walnut Street, Kansas City, Mo. 64106.

No. MC 128985 (Sub-No. 7 TA), filed November 1, 1973. Applicant: WILKERSON TRUCKING COMPANY, INC., Route 5, Lenoir City, Tenn. 37771. Applicant's representative: Walter Harwood, 404 James Robertson Parkway, Nashville, Tenn. 37219. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Ranges, gas and electric, loose, uncrated, in special equipment*, from Los Angeles, Calif. and City of Industry, Calif., to points in Washington, Oregon, Montana, Wyoming, New Mexico, North Dakota, South Dakota, Nebraska, Kansas, Minnesota, Iowa, Missouri, Arkansas, Louisiana, Wisconsin, Illinois, Indiana, Michigan, Ohio, Kentucky and Tennessee, for 150 days.

NOTE.—Applicant will also transport same items in same vehicles pursuant to Sub 4 TA, but no tacking or interline involved.

SUPPORTING SHIPPER: Gaffers & Sattler, Inc., 4851 S. Alameda Street, Los Angeles, Calif. 90058. SEND PROTESTS TO: Joe J. Tate, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 1803–1808 West End Building, Nashville, Tenn. 37203.

No. MC 129350 (Sub-No. 34 TA), filed November 2, 1973. Applicant: CHARLES E. WOLFE, doing business as EVERGREEN EXPRESS, 410 N. 10th Street, P.O. Box 212, Billings, Mont. 59101. Applicant's representative: Clayton Brown (same address as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Meat, meat products, meat by-products, and articles distributed by meat packing houses*, as described in Sections A, B, and C of Appendix I, 61 M.C.C. 209 and 766 (except commodities in bulk, in tank vehicles, and hides), from Billings, Mont., to points in Arizona, Arkansas, California, Colorado, Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, Oregon, South Dakota, Texas, Washington, Wisconsin and Wyoming, for 150 days. SUPPORTING SHIPPER: Pierce Packing Company, 21 North 15th St., Billings, Mont. 59101. SEND PROTESTS TO: Paul J. Labane, District Supervisor, Interstate Commerce Commission, Bureau of Operations, Rm. 222, U.S. Post Office Building, Billings, Mont. 59101.

No. MC 133296 (Sub-No. 5 TA), filed November 1, 1973. Applicant: DRACHE TRUCK LINE, INC., P.O. Box 42, Medford, Minn. 55049. Applicant's representative: Val M. Higgins, 1000 First National Bank Bldg., Minneapolis, Minn. 55402. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Malt beverages and related advertising materials*, from Trenton, N.J., to Minneapolis, Minn., for 150 days. SUPPORTING SHIPPER: Rex Distributing Co., Inc., 740–24th Ave. S.E., Minneapolis, Minn. SEND PROTESTS TO: A. N. Spath, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 448 Federal Building & U.S. Court House, 110 S. 4th St., Minneapolis, Minn. 55401.

No. MC 133576 (Sub-No. 1 TA), filed October 31, 1973. Applicant: BUSBOOM TRUCKING, INC., Filley, Nebr. 68357. Applicant's representative: James E. Ryan, 214 Sharp Building, Lincoln, Nebr. 68508. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Calcium chloride*, in containers, from Midland, Mich., to points in Nebraska, for 180 days. SUPPORTING SHIPPER: Oldfather O.K. Tire Co., Beatrice, Nebr. 68310. SEND PROTESTS TO: Carroll Russell, District Supervisor, Interstate Commerce Commission, Bureau of Operations, Suite 620, Union Pacific Plaza Building, 110 North 14th Street, Omaha, Nebr. 68102.

No. MC 135513 (Sub-No. 7 TA), filed November 1, 1973. Applicant: ECHO TRUCKING COMPANY, P.O. Drawer AY, Benson, Ariz. 85602. Applicant's representative: Earl H. Carroll, 363 N. First Avenue, Phoenix, Ariz. 85003. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Coal*, from points in McKinley County, N. Mex., to Morenci, Ariz., for 180 days. SUPPORTING SHIPPER: Phelps Dodge Corporation, Douglas, Ariz. SEND PROTESTS TO: Andrew V. Baylor, District Supervisor, Interstate Commerce Commission, Bureau of Operations, Room 3427, Federal

Building, 230 N. First Avenue, Phoenix, Ariz. 85025.

No. MC 136008 (Sub-No. 16 TA), filed November 1, 1973. Applicant: JOE BROWN COMPANY, INC., 20 Third Street, NE, P.O. Box 1669, Ardmore, Okla. 73401. Applicant's representative: Rufus H. Lawson, 2400 N.W. 23rd Street, P.O. Box 75124, Oklahoma City, Okla. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Coal*, from Porum, Okla., to the plantsite of Texas Lime Company, Cleburne, Tex., for 180 days. SUPPORTING SHIPPER: Texas Lime Co., Floyd J. Carroll, Box 851, Cleburne, Tex. 76031. SEND PROTESTS TO: C. L. Phillips, District Supervisor, Interstate Commerce Commission, Bureau of Operations, Rm. 240—Old P.O. Bldg., Oklahoma City, Okla. 73102.

No. MC 136069 (Sub-No. 6 TA), filed November 2, 1973. Applicant: COIN DEVICES CORP., 68 Broad Street, Elizabeth, N.J. 07201. Applicant's representative: Charles J. Williams, 47 Lincoln Park, Newark, N.J. 07201. Authority sought to operate as a *contract carrier*, by motor vehicle, over irreguar routes, transporting: *Coins, currency, checks, negotiable and non-negotiable instruments and valuable documents*, for the account of The National State Bank, Elizabeth, N.J., between Elizabeth, N.J. and New York, N.Y., for 180 days SUPPORTING SHIPPER: The National State Bank, Elizabeth, N.J. 07207. SEND PROTESTS TO: Robert E. Johnston, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 9 Clinton Street, Newark, N.J. 07102.

No. MC 138548 (Sub-No. 4 TA), filed November 2, 1973. Applicant: INDIAN-OAKS TRANSPORTATION CO., 10346 South Indianapolis Blvd., Chicago, Ill. 60617. Applicant's representative: James R. Madler, 327 South LaSalle St., Chicago, Ill. 60604. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Aluminum, iron and steel articles* (except commodities described in *Mercer Extension—Oil Field Commodities* 74 M.C.C. 459 and 543 (1946)), from Indiana Oaks, Ill., to Hillsboro and Wahpeton, N. Dak.; Big Stone City, S. Dak.; Alliance and Omaha, Nebr.; Hutchinson, Kans.; Clearbrook, Wescott, and Red Wing, Minn., for 180 days. SUPPORTING SHIPPER: Joseph A. Aliosius, Traffic Manager, Chicago Bridge & Iron Company, P.O. Box 774, Kankakee, Ill. 60901. SEND PROTESTS TO: Robert G. Anderson, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 219 South Dearborn St., Room 1086, Chicago, Ill. 60604.

No. MC 138946 (Sub-No. 1 TA), filed November 1, 1973. Applicant: MARKET INDUSTRIES, LTD., 920 S. W. 4th Avenue (Room 927), Portland, Oreg. 97204. Applicant's representative: Philip G. Skofstad, 3076 E. Burnside, Portland, Oreg. 97214. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Pickles, relishes and sauerkraut*, from Portland and Scappoose, Oreg., to points in California to include, but not limited to the following: Brisbane, Chico, City of Commerce, City of Industry, Colma, Compton, Corona, East Stockton, Fremont, Fresno, Gilroy, Hayward, La Habra, La Mirada, Los Angeles, Lyoth, Marina, Milpitas, Modesto, North Highlands, Oakland, Pico Rivera, Redding, Richmond, Sacramento, Salinas, San Diego, San Fernando, San Francisco, San Jose, San Leandro, Santa Clara, Santa Cruz, Santa Rosa, South San Francisco, Stockton, Tracy, and Union City, Calif., for 180 days. SUPPORTING SHIPPER: Steinfeld's Products Company, 1001 N. Polk Avenue, P.O. Box 03129, Portland, Oreg. 97203. SEND PROTESTS TO: District Supervisor W. J. Huetig, Interstate Commerce Commission, Bureau of Operations, 450 Multnomah Bldg., 319 S. W. Pine St., Portland, Oreg. 97204.

No. MC 139160 (Sub-No. 1 TA), filed October 29, 1973. Applicant: CHARLES W. (Bill) KOENIG, doing business as KOENIG TRUCKING, Box 622, Dubois, Wyo. 82513. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: (1) *Acrylic fiberglass products, and related items and parts;* (2) *iron and steel articles, automotive hoists, and related items, and parts;* and (3) *materials and supplies* used in the manufacture of plastic and iron and steel articles, between Jackson, Wyo., on the one hand, and, on the other, points in Wyoming, Oregon, Idaho, Washington, Utah, Nevada, Colorado, Montana, Kansas, Arizona, North and South Dakota, Minnesota, and California, for 180 days. SUPPORTING SHIPPER: Cameo West, Inc., Box 164, Jackson, Wyo. 83001. SEND PROTESTS TO: District Supervisor Paul A. Naughton, Interstate Commerce Commission, Bureau of Operations, Rm. 1006 Federal Bldg. & Post Office, 100 East "B" Street, Casper, Wyo. 82601.

No. MC 139233 TA, filed November 1, 1973. Applicant: MELVIN T. DICKERSON, INC., Route 2, Box 337, Dallas, Oreg. 97338. Applicant's representative: B. Gayle Bergstrom, P.O. Box 8, Beaverton, Oreg. 97005. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Salads and prepared foods, meats, cooked, cured or preserved*, from Beaverton, Oreg., to Denver, Colo.; Spokane, Wash.; Caldwell and Twin Falls, Idaho; Salt Lake City, Utah; Chicago, Ill.; Omaha, Nebr.; Des Moines, Iowa; Minneapolis, Minn.; Oklahoma City, Okla.; Kansas City, Mo.; St. Louis, Mo.; Memphis, Tenn.; Little Rock, Ark.; Dallas, Tex.; Phoenix and Tucson, Ariz.; El Paso, Midland, San Antonio, Corpus Christie, Houston, Waco and Fort Worth, Tex.; San Francisco, Calif; Bend and Klamath Falls, Oreg.; Sacramento, Stockton, Modesto, and Oakland, Calif.; Los Angeles, Calif.; Bellingham, Olympia and Seattle, Wash.; New Orleans, Shreveport and Jackson, La.; Aberdeen, S. Dak.; Bismarck and Fargo, N. Dak. and Rapid City, S. Dak., for 180 days. SUPPORTING SHIPPER: Reser's Fine Foods, Inc., 11150 S.W. Allen Blvd., Beaverton, Oreg. 97005. SEND PROTESTS TO: A. E. Odoms, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 450 Multnomah Building, 319 S.W. Pine, Portland, Oreg. 97204.

By the Commission.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[FR Doc.73-24698 Filed 11-19-73;8:45 am]

[Notice 393]

MOTOR CARRIER TRANSFER PROCEEDINGS

NOVEMBER 15, 1973.

Application filed for temporary authority under section 210a(b) in connection with transfer application under section 212(b) and transfer rules, 49 CFR Part 1132:

No. MC-FC-74835. By application filed November 9, 1973, THOMAS W. AHERN, doing business as AHERN MOVERS & RIGGERS, 11 Lafayette Park, Lynn, MA 01902, seeks temporary authority to lease the operating rights of RAYMOND E. HAPGOOD AND EDNA F. HAPGOOD, doing business as HAPGOOD's EXPRESS, 15 Lander Ave., Lynn, MA 01902, under section 210a(b). The transfer to THOMAS W. AHERN, doing business as AHERN MOVERS & RIGGERS, of the operating rights of RAYMOND E. HAPGOOD AND EDNA F. HAPGOOD, doing business as HAPGOOD's EXPRESS, is presently pending.

By the Commission.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[FR Doc.73-24699 Filed 11-19-73;8:45 am]

CUMULATIVE LISTS OF PARTS AFFECTED—NOVEMBER

The following numerical guide is a list of parts of each title of the Code of Federal Regulations affected by documents published to date during November.

45 CFR—Continued

46 CFR

47 CFR

49 CFR

50 CFR

FEDERAL REGISTER PAGES AND DATE—NOVEMBER

Pages	*Date*
30091–30243	Nov. 1
30245–30420	2
30421–30524	5
30525–30716	6
30717–30858	7
30859–30984	8
30985–31157	9
31159–31269	12
31271–31400	13
31401–31498	14
31499–31660	15
31661–31801	16
31803–31945	19
31947–32113	20

federal register

TUESDAY, NOVEMBER 20, 1973

WASHINGTON, D.C.

Volume 38 ■ Number 223

PART II

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

REORGANIZATION AND REPUBLICATION

Title 21—Food and Drugs

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

[Recodification Docket No. 2]

SUBCHAPTER F—BIOLOGICS

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 second document in a series of recodification documents that will eventually include all regulations administered by the Food and Drug Administration.

The regulations formerly under Part 273—Biological Products have been reorganized into nine parts in an effort to provide greater clarity and adequate space for the development of future regulations pertaining to biologics.

The new heading of Subchapter F reflects the transfer of the three other parts that were formerly in this subchapter to a new Subchapter L elsewhere in this issue of the FEDERAL REGISTER.

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 the revised Subchapter F—Biologics is set forth below.

Dated: November 13, 1973.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

Therefore, Part 273 of Chapter I of Title 21 of the Code of Federal Regulations is redesignated as Subchapter F, Parts 600, 601, 610, 620, 630, 640, 650, 660, and 680 and republished to read as follows:

SUBCHAPTER F—BIOLOGICS

PART 600—BIOLOGICAL PRODUCTS: GENERAL

Subpart A—General Provisions

Subpart B—Establishment Standards

Subpart C—Establishment Inspection

AUTHORITY: Sec. 215, 58 Stat. 690, as amended; 42 U.S.C. 216. Sec. 351, 58 Stat. 702, as amended; 42 U.S.C. 262, unless otherwise noted.

CROSS REFERENCES: For U.S. Customs Service regulations relating to viruses, serums, and toxins, see 19 CFR 12.21–12.23. For U.S. Postal Service regulations relating to the admissibility to the United States mails see 39 CFR Parts 124 and 125, esp. § 125.2.

Subpart A—General Provisions

§ 600.3 Definitions.

As used in this subchapter:

(a) "Act" means the Public Health Service Act (58 Stat. 682), approved July 1, 1944.

(b) "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.

(c) "Commissioner of Food and Drugs" means the Commissioner of the Food and Drug Administration.

(d) "Bureau of Biologics" means the Bureau of Biologics of the Food and Drug Administration.

(e) "State" means a State or the District of Columbia, Puerto Rico, or the Virgin Islands.

(f) "Possession" includes among other possessions, Puerto Rico and the Virgin Islands.

(g) "Products" includes biological products and trivalent organic arsenicals.

(h) "Biological product" means any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man:

(1) A virus is interpreted to be a product containing the minute living cause of an infectious disease and includes but is not limited to filterable viruses, bacteria, rickettsia, fungi, and protozoa.

(2) A therapeutic serum is a product obtained from blood by removing the clot or clot components and the blood cells.

(3) A toxin is a product containing a soluble substance poisonous to laboratory animals or to man in doses of 1 milliliter or less (or equivalent in weight) of the product, and having the property, following the injection of non-fatal doses into an animal, of causing to be produced therein another soluble substance which specifically neutralizes the poisonous substance and which is demonstrable in the serum of the animal thus immunized.

(4) An antitoxin is a product containing the soluble substance in serum or other body fluid of an immunized animal which specifically neutralizes the toxin against which the animal is immune.

(5) A product is analogous:

(i) To a virus if prepared from or with a virus or agent actually or potentially infectious, without regard to the degree of virulence or toxicogenicity of the specific strain used.

(ii) To a therapeutic serum, if composed of whole blood or plasma or containing some organic constituent or product other than a hormone or an amino acid, derived from whole blood, plasma, or serum.

(iii) To a toxin or antitoxin, if intended, irrespective of its source of origin, to be applicable to the prevention, treatment, or cure of disease or injuries of man through a specific immune process.

(i) "Trivalent organic arsenicals" means arsphenamine and its derivatives (or any other trivalent organic arsenic compound) applicable to the prevention, treatment, or cure of diseases or injuries of man.

(j) A product is deemed "applicable to the prevention, treatment, or cure of diseases or injuries of man" irrespective of the mode of administration or application recommended, including use when intended through administration or application to a person as an aid in diagnosis, or in evaluating the degree of susceptibility or immunity possessed by a person, and including also any other use for purposes of diagnosis if the diagnostic substance so used is prepared from or with the aid of a biological product.

(k) "Proper name", as applied to a product, means the name designated in the license for use upon each package of the product.

(l) "Dating period" means the period beyond which the product cannot be expected beyond reasonable doubt to yield its specific results.

(m) "Expiration date" means the calendar month and year, and where applicable, the day and hour, that the dating period ends.

(n) The word "standards" means specifications and procedures applicable to an establishment or to the manufacture or release of products, which are prescribed in this subchapter and which are designed to insure the continued safety, purity and potency of such products.

(o) The word "continued" as applied to the safety, purity and potency of products is interpreted to apply to the dating period.

(p) The word "safety" means the relative freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time.

(q) The word "sterility" is interpreted to mean freedom from viable contaminating microorganisms, as determined by

the tests prescribed in § 610.12 of this chapter.

(r) "Purity" means relative freedom from extraneous matter in the finished product, whether or not harmful to the recipient or deleterious to the product. "Purity" includes but is not limited to relative freedom from residual moisture or other volatile substances and pyrogenic substances.

(s) The word "potency" is interpreted to mean the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to effect a given result.

(t) "Manufacturer" means any legal person or entity engaged in the manufacture of a product subject to license under the act.

(u) "Manufacture" means all steps in propagation or manufacture and preparation of products and includes but is not limited to filling, testing, labeling, packaging, and storage by the manufacturer.

(v) "Location" includes all buildings, appurtenances, equipment and animals used, and personnel engaged by a manufacturer within a particular area designated by an address adequate for identification.

(w) "Establishment" includes all locations.

(x) "Lot" means that quantity of uniform material identified by the manufacturer as having been thoroughly mixed in a single vessel.

(y) A "filling" refers to a group of final containers identical in all respects, which have been filled with the same product from the same bulk lot without any change that will affect the integrity of the filling assembly.

(z) "Process" refers to a manufacturing step that is performed on the product itself which may affect its safety, purity or potency, in contrast to such manufacturing steps which do not affect intrinsically the safety, purity or potency of the product.

(aa) "Selling agent" or "distributor" means any person engaged in the unrestricted distribution, other than by sale at retail, of products subject to license.

(bb) "Container" (referred to also as "final container") is the immediate unit, bottle, vial, ampule, tube, or other receptacle containing the product as distributed for sale, barter, or exchange.

(cc) "Package" means the immediate carton, receptacle, or wrapper, including all labeling matter therein and thereon, and the contents of the one or more enclosed containers. If no package, as defined in the preceding sentence, is used, the container shall be deemed to be the package.

(dd) "Label" means any written, printed, or graphic matter on the container or package or any such matter clearly visible through the immediate carton, receptacle, or wrapper.

Subpart B—Establishment Standards

§ 600.10 Personnel.

(a) *Responsible head.* A person shall be designated as the responsible head who shall exercise control of the establishment in all matters relating to compliance with the provisions of this subchapter, with authority to represent the manufacturer in all pertinent matters with the Bureau of Biologics, and with authority to enforce or to direct the enforcement of discipline and the performance of assigned functions by employees engaged in the manufacture of products. The responsible head shall have an understanding of the scientific principles and the techniques involved in the manufacture of products. The responsible head shall have the responsibility for the training of employees in manufacturing methods and for their being informed concerning the application of the pertinent provisions of this subchapter to their respective functions.

(b) *Other personnel.* Personnel shall have capabilities commensurate with their assigned functions, a thorough understanding of the manufacturing operations which they perform, the necessary training and experience relating to individual products, and adequate information concerning the application of the pertinent provisions of this subchapter to their respective functions. Personnel shall include such professionally trained persons as are necessary to insure the competent performance of all manufacturing processes.

(c) *Restrictions on personnel*—(1) *Specific duties.* Persons whose presence can affect adversely the safety and purity of a product shall be excluded from the room where the manufacture of a product is in progress.

(2) *Sterile operations.* Personnel performing sterile operations shall wear clean or sterilized protective clothing and devices to the extent necessary to protect the product from contamination.

(3) *Pathogenic viruses and spore-bearing organisms.* Persons working with viruses pathogenic for man or with spore-bearing microorganisms, and persons engaged in the care of animals or animal quarters, shall be excluded from areas where other products are manufactured, or such persons shall change outer clothing, including shoes, or wear protective covering prior to entering such areas.

(4) *Live vaccine work areas.* Persons may not enter a live vaccine processing area after having worked with other infectious agents in any other laboratory during the same working day. Only persons actually concerned with propagation of the culture, production of the vaccine, and unit maintenance, shall be allowed in live vaccine processing areas when active work is in progress. Casual visitors shall be excluded from such units at all times and all others having business in such areas shall be admitted only under supervision. Street clothing, including shoes, shall be replaced or covered by suitable laboratory clothing before entering a live vaccine processing unit. Persons caring for animals used in the manufacture of live vaccines shall be excluded from other animal quarters and from contact with other animals during the same working day.

§ 600.11 Physical establishment, equipment, animals, and care.

(a) *Work areas.* All rooms and work areas where products are manufactured or stored shall be kept orderly, clean, and free of dirt, dust, vermin and objects not required for manufacturing. Precautions shall be taken to avoid clogging and back-siphonage of drainage systems. Precautions shall be taken to exclude extraneous infectious agents from manufacturing areas. Work rooms shall be well lighted and ventilated. The ventilation system shall be arranged so as to prevent the dissemination of microorganisms from one manufacturing area to another and to avoid other conditions unfavorable to the safety of the product. Filling rooms, and other rooms where open, sterile operations are conducted, shall be adequate to meet manufacturing needs and such rooms shall be constructed and equipped to permit thorough cleaning and to keep air-borne contaminants at a minimum. If such rooms are used for other purposes, they shall be cleaned and prepared prior to use for sterile operations. Refrigerators, incubators and warm rooms shall be maintained at temperatures within applicable ranges and shall be free of extraneous material which might affect the safety of the product.

(b) *Equipment.* Apparatus for sterilizing equipment and the method of operation shall be such as to insure the destruction of contaminating microorganisms. The effectiveness of the sterilization procedure shall be no less than that achieved by an attained temperature of 121.5°C. maintained for twenty minutes by saturated steam or by an attained temperature of 170°C. maintained for two hours with dry heat. Processing and storage containers, filters, filling apparatus and other pieces of apparatus and accessory equipment, including pipes and tubing, shall be designed and constructed to permit thorough cleaning and, where possible, inspection for cleanliness. All surfaces that come in contact with products shall be clean and free of extraneous material. For products for which sterility is a factor, equipment shall be sterile unless sterility of the product is assured by subsequent procedures.

(c) *Laboratory and bleeding rooms.* Rooms used for the processing of products, including bleeding rooms, shall be effectively fly-proofed and kept free of flies and vermin. Such rooms shall be so constructed as to insure freedom from dust, smoke and other deleterious substances and to permit thorough cleaning and disinfection. Rooms for animal injection and bleeding, and rooms for smallpox vaccine animals, shall be disinfected and be provided with the necessary water, electrical and other services.

(d) *Animal quarters and stables.* Animal quarters, stables and food storage areas shall be of appropriate construction, fly-proofed, adequately lighted and ventilated, and maintained in a clean, vermin-free and sanitary condition. No manure or refuse shall be stored as to permit the breeding of flies on the premises, nor shall the establishment be lo-

cated in close proximity to off-property manure or refuse storage capable of engendering fly breeding.

(e) *Restrictions on building and equipment use*—(1) *Work of a diagnostic nature.* Laboratory procedures of a clinical diagnostic nature involving materials that may be contaminated, shall not be performed in space used for the manufacture of products except that manufacturing space which is used only occasionally may be used for diagnostic work provided spore-bearing pathogenic microorganisms are not involved and provided the space is thoroughly cleaned and disinfected before the manufacture of products is resumed.

(2) *Spore-bearing organisms for supplemental sterilization procedure control test.* Spore-bearing organisms used as an additional control in sterilization procedures may be introduced into areas used for the manufacture of products, only for the purposes of the test and only immediately before use for such purposes: *Provided,* That (i) the organism is not pathogenic for man or animals and does not produce pyrogens or toxins, (ii) the culture is demonstrated to be pure, (iii) transfer of test cultures to culture media shall be limited to the sterility test area or areas designated for work with spore-bearing organisms, (iv) each culture be labeled with the name of the microorganism and the statement "Caution: microbial spores. See directions for storage, use and disposition.", and (v) the container of each culture is designed to withstand handling without breaking.

(3) *Work with spore-bearing organisms.* Except as provided in the previous paragraph, all work with spore-bearing microorganisms shall be done in an entirely separate building: *Provided,* That such work may be done in a portion of a building used in the manufacture of products not containing spore-bearing microorganisms if such portion is completely walled-off and is constructed so as to prevent contamination of other areas and if entrances to such portion are independent of the remainder of the building. All vessels, apparatus and equipment used for spore-bearing microorganisms shall be permanently identified and reserved exclusively for use with those organisms. Materials destined for further manufacturing may be removed from such an area only under conditions which will prevent the introduction of spores into other manufacturing areas.

(4) *Live vaccine processing.* Space used for processing a live vaccine shall not be used for any other purpose during the processing period for that vaccine and such space shall be decontaminated prior to initiation of the processing. Live vaccine processing areas shall be isolated from and independent of any space used for any other purpose by being either in a separate building, in a separate wing of a building, or in quarters at the blind end of a corridor and shall include adequate space and equipment for all processing steps up to filling into final containers. Test procedures which potentially involve the presence of microorganisms other than the vaccine strains, or the use of tissue culture cell lines other than primary cultures, shall not be conducted in space used for processing live vaccine.

(5) *Equipment and supplies—contamination.* Equipment and supplies used in work on or otherwise exposed to any pathogenic or potentially pathogenic agent shall be kept separated from equipment and supplies used in the manufacture of products to the extent necessary to prevent cross-contamination.

(f) *Animals used in manufacture*—(1) *Care of animals used in manufacturing.* Caretakers and attendants for animals used for the manufacture of products shall be sufficient in number and have adequate experience to insure adequate care. Animal quarters and cages shall be kept in sanitary condition. Animals on production shall be inspected daily to observe response to production procedures. Animals that become ill for reasons not related to production shall be isolated from other animals and shall not be used for production until recovery is complete. Competent veterinary care shall be provided as needed.

(2) *Quarantine of animals*—(i) *General.* No animal shall be used in processing unless kept under competent daily inspection and preliminary quarantine for a period of at least 7 days before use, or as otherwise provided in this subchapter. Only healthy animals free from detectable communicable diseases shall be used. Animals must remain in overt good health throughout the quarantine periods and particular care shall be taken during the quarantine periods to reject animals of the equine genus which may be infected with glanders and animals which may be infected with tuberculosis.

(ii) *Quarantine of monkeys.* In addition to observing the pertinent general quarantine requirements, monkeys used as a source of tissue in the manufacture of vaccine shall be maintained in quarantine for at least 6 weeks prior to use, except when otherwise provided in this part. Only monkeys that have reacted negatively to tuberculin at the start of the quarantine period and again within 2 weeks prior to use shall be used in the manufacture of vaccine. Due precaution shall be taken to prevent cross-infection from any infected or potentially infected monkeys on the premises. Monkeys to be used in the manufacture of a live vaccine shall be maintained throughout the quarantine period in cages closed on all sides with solid materials except the front which shall be screened, with no more than two monkeys housed in one cage. Cage mates shall not be interchanged.

(3) *Immunization against tetanus.* Horses and other animals susceptible to tetanus, that are used in the processing steps of the manufacture of biological products, shall be treated adequately to maintain immunity to tetanus.

(4) *Immunization and bleeding of animals used as a source of products.* Toxins or other nonviable antigens administered in the immunization of animals used in the manufacture of products shall be sterile. Viable antigens, when so used, shall be free of contaminants, as determined by appropriate tests prior to use. Injections shall not be made into horses within 6 inches of bleeding site. Horses shall not be bled for manufacturing purposes while showing persistent general reaction or local reaction near the site of bleeding. Blood shall not be used if it was drawn within 5 days of injecting the animals with viable microorganisms. Animals shall not be bled for manufacturing purposes when they have an intercurrent disease. Blood intended for use as a source of a biological product shall be collected in clean, sterile vessels. When the product is intended for use by injection, such vessels shall also be pyrogen-free.

(5) [Reserved]

(6) *Reporting of certain diseases.* In cases of actual or suspected infection with foot and mouth disease, glanders, tetanus, anthrax, gas gangrene, equine infectious anemia; equine encephalomyelitis, or any of the pock diseases among animals intended for use or used in the manufacture of products, the manufacturer shall immediately notify the Director, Bureau of Biologics.

(7) *Monkeys used previously for experimental or test purposes.* Monkeys that have been used previously for experimental or test purposes with live microbiological agents shall not be used as a source of kidney tissue for the manufacture of vaccine. Except as provided otherwise in this subchapter, monkeys that have been used previously for other experimental or test purposes may be used as a source of kidney tissue upon their return to a normal condition, provided all quarantine requirements have been met.

(8) *Necropsy examination of monkeys.* Each monkey used in the manufacture of vaccine shall be examined at necropsy under the direction of a qualified pathologist, physician, or veterinarian having experience with diseases of monkeys, for evidence of ill health, particularly for (i) evidence of tuberculosis, (ii) presence of herpes-like lesions, including eruptions or plaques on or around the lips, in the buccal cavity or on the gums, and (iii) signs of conjunctivitis. If there are any such signs or other significant gross pathological lesions, the tissue shall not be used in the manufacture of vaccine.

(g) *Filling procedures.* Filling procedures shall be such as will not affect adversely the safety, purity or potency of the product.

(h) *Containers and closures.* All final containers and closures shall be made of material that will not hasten the deterioration of the product or otherwise render it less suitable for the intended use. All final containers and closures shall be clean and free of surface solids, leachable contaminants and other materials that will hasten the deterioration of the product or otherwise render it less suitable for the intended use. After filling, sealing shall be performed in a manner that will maintain the integrity of the product during the dating period. In addition, final containers and closures for products intended for use by injection shall be sterile and free from pyrogens. Except as otherwise provided in the regulations of this subchapter, final con-

tainers for products intended for use by injection shall be colorless and sufficiently transparent to permit visual examination of the contents under normal light. As soon as possible after filling final containers shall be labeled as prescribed in § 610.60 et seq. of this chapter, except that final containers may be stored without such prescribed labeling provided they are stored in a sealed receptacle labeled both inside and outside with at least the name of the product, the lot number, and the filling identification.

§ 600.12 Records.

(a) *Maintenance of records.* Records shall be made, concurrently with the performance, of each step in the manufacture and distribution of products, in such a manner that at any time successive steps in the manufacture and distribution of any lot may be traced by an inspector. Such records shall be legible and indelible, shall identify the person immediately responsible, shall include dates of the various steps, and be as detailed as necessary for clear understanding of each step by one experienced in the manufacture of products.

(b) *Records retention*—(1) *General.* Records shall be retained for such interval beyond the expiration date as is necessary for the individual product, to permit the return of any clinical report of unfavorable reactions. The retention period shall be no less than five years after the records of manufacture have been completed or six months after the latest expiration date for the individual product, whichever represents a later date.

(2) *Records of recall.* Complete records shall be maintained pertaining to the recall from distribution of any product upon notification by the Director, Bureau of Biologics, to recall for failure to conform with the standards prescribed in the regulations of this subchapter, because of deterioration of the product or for any other factor by reason of which the distribution of the product would constitute a danger to health.

(3) *Suspension of requirement for retention.* The Director, Bureau of Biologics, may authorize the suspension of the requirement to retain records of a specific manufacturing step upon a showing that such records no longer have significance for the purposes for which they were made: *Provided,* That a summary of such records shall be retained.

(c) *Records of sterilization of equipment and supplies.* Records relating to the mode of sterilization, date, duration, temperature and other conditions relating to each sterilization of equipment and supplies used in the processing of products shall be made by means of automatic recording devices or by means of a system of recording which gives equivalent assurance of the accuracy and reliability of the record. Such records shall be maintained in a manner that permits an identification of the product with the particular manufacturing process to which the sterilization relates.

(d) *Animal necropsy records.* A necropsy record shall be kept on each animal from which a biological product has been obtained and which dies or is sacrificed while being so used.

(e) *Records in case of divided manufacturing responsibility.* If two or more establishments participate in the manufacture of a product, the records of each such establishment must show plainly the degree of its responsibility. In addition, each participating manufacturer shall furnish to the manufacturer who prepares the product in final form for sale, barter or exchange, a copy of all records relating to the manufacturing operations performed by such participating manufacturer insofar as they concern the safety, purity and potency of the lots of the product involved, and the manufacturer who prepares the product in final form shall retain a complete record of all the manufacturing operations relating to the product.

§ 600.13 Retention samples.

Manufacturers shall retain for a period of at least 6 months after the expiration date, unless a different time period is specified in additional standards, a quantity of representative material of each lot of each product, sufficient for examination and testing for safety and potency, except Whole Blood (Human), Antihemophilic Plasma (Human), Cryoprecipitated Antihemophilic Factor (Human), Red Blood Cells (Human), Single Donor Plasma (Human), Source Plasma (Human), Normal Human Plasma and Allergenic Products prepared to physician's prescription. Samples so retained shall be selected at random from either final container material, or from bulk and final containers, provided they include at least one final container as a final package, or package-equivalent of such filling of each lot of the product as intended for distribution. Such sample material shall be stored at temperatures and under conditions which will maintain the identity and integrity of the product. Samples retained as required in this section shall be in addition to samples of specific products required to be submitted to the Bureau of Biologics. Exceptions may be authorized by the Director, Bureau of Biologics, when the lot yields relatively few final containers and when such lots are prepared by the same method in large number and in close succession.

§ 600.14 Reporting of errors.

The Director, Bureau of Biologics, shall be notified promptly of errors or accidents in the manufacture of products that may affect the safety, purity, or potency of any product.

§ 600.15 Temperatures during shipment.

The following products shall be maintained during shipment at the specified temperatures:

Product	*Temperature*
Cryoprecipitated Antihemophilic Factor (Human)	—18° or colder.
Poliovirus Vaccine, Live, Oral, Type 1	A temperature which will maintain ice continuously in a solid state.
Poliovirus Vaccine, Live, Oral, Type 2	
Poliovirus Vaccine, Live, Oral, Type 3	
Poliovirus Vaccine, Live, Oral, Trivalent	
Red Blood Cells (Human), Frozen.	—65° C. or colder.
Red Blood Cells (Human), Liquid.	Between 1° and 10° C.
Single Donor Plasma (Human), Frozen.	—18° C. or colder.
Smallpox Vaccine, Liquid.	A temperature which will maintain ice continuously in a solid state.
Source Plasma (Human).	—5° C. or colder.
Whole Blood (Human).	Between 1° and 10° C.
Yellow Fever Vaccine.	A temperature which will maintain ice continuously in a solid state.

Subpart C—Establishment Inspection

§ 600.20 Inspectors.

Inspections shall be made by an officer of the Food and Drug Administration having special knowledge of the methods used in the manufacture and control of products and designated for such purposes by the Commissioner of Food and Drugs, or by any officer, agent, or employee of the Department of Health, Education, and Welfare specifically designated for such purpose by the Secretary.

§ 600.21 Time of inspection.

The inspection of an establishment for which a license is pending need not be made until the establishment is in operation and is manufacturing the complete product for which a product license is desired. In case the license is denied following inspection for the original license, no reinspection need be made until assurance has been received that the faulty conditions which were the basis of the denial have been corrected. An inspection of each licensed establishment shall be made at least once each year. Inspections may be made with or without notice, and shall be made during regular business hours unless otherwise directed.

§ 600.22 Duties of inspector.

The inspector shall:

(a) Call upon the active head of the establishment, stating the object of his visit,

(b) Interrogate the proprietor or other personnel of the establishment as he may deem necessary,

(c) Examine the details of location, construction, equipment and maintenance, including stables, barns, warehouses, manufacturing laboratories, bleeding clinics maintained for the collection of human blood, shipping rooms, record rooms, and any other structure or appliance used in any part of the manufacture of a product,

(d) Investigate as fully as he deems necessary the methods of propagation, processing, testing, storing, dispensing, recording, or other details of manufacture and distribution of each licensed product, or product for which a license has been requested, including observation of these procedures in actual operation.

(e) Obtain and cause to be sent to the Director, Bureau of Biologics, adequate samples for the examination of any product or ingredient used in its manufacture.

(f) Bring to the attention of the manufacturer any fault observed in the course of inspection in location, construction, manufacturing methods, or administration of a licensed establishment which might lead to impairment of a product.

(g) Inspect and copy, as circumstances may require, any records required to be kept pursuant to § 600.12.

(h) Certify as to the condition of the establishment and of the manufacturing methods followed and make recommendations as to action deemed appropriate with respect to any application for license or any license previously issued.

PART 601—LICENSING

Subpart A—General Provisions

Sec.

Subpart B—Establishment Licensing

Subpart C—Product Licensing

Subpart D—Licensing of Foreign Establishments and Products

Subpart E—Suspension of Licenses and Appeals Procedure

AUTHORITY: Sec. 215, 58 Stat. 690, as amended; 42 U.S.C. 216. Sec. 351, 58 Stat. 702, as amended; 42 U.S.C. 262, unless otherwise noted.

CROSS REFERENCES.—For U.S. Customs Service regulations relating to viruses, serums, and toxins, see 19 CFR 12.21–12.23. For U.S. Postal Service regulations relating to the admissibility to the United States mails see 39 CFR Parts 124 and 125, esp. § 125.2.

Subpart A—General Provisions

§ 601.1 Two forms of licenses.

There shall be two forms of licenses: establishment and product.

§ 601.2 Application for establishment and product licenses; procedure for filing.

To obtain a license for any establishment or product, the manufacturer shall make application to the Director, Bureau of Biologics, on forms prescribed for such purpose, and in the case of an application for a product license, shall submit data derived from laboratory and clinical studies which demonstrate that the manufactured product meets prescribed standards of safety, purity and potency, a full description of manufacturing methods, data establishing stability of the product through the dating period, sample(s) representative of the product to be sold, bartered or exchanged or offered, sent, carried or brought for sale, barter or exchange, summaries of results of tests performed on the lot(s) represented by the submitted sample(s), and specimens of the labels enclosures and containers proposed to be used for the product. An application for license shall not be considered as filed until all pertinent information and data shall have been received from the manufacturer by the Bureau of Biologics.

§ 601.3 License forms.

(a) *Establishment license.* The establishment license form shall be prescribed by the Commissioner of Food and Drugs and shall include:

(1) The name and address of the manufacturer.

(2) The name and address of the establishment.

(3) The names and addresses of all locations of the establishment.

(4) The license number.

(5) The date of issuance.

(b) *Product license.* The product license form shall be prescribed by the Commissioner of Food and Drugs and shall include:

(1) The name and address of the manufacturer.

(2) The name and address of the establishment.

(3) The name and address of each location at which the product is manufactured.

(4) The license number of the establishment.

(5) The proper name of the product, with additional specifications, if any, which may be approved or required for additional labeling purposes.

§ 601.4 Issuance, revocation or suspension.

A license shall be issued by the Secretary upon the recommendation of the Commissioner of Food and Drugs and upon the determination by the Commissioner of Food and Drugs that the establishment or the product, as the case may be, meets the standards established by the regulations in this subchapter as herein prescribed or hereafter amended. Licenses shall be valid until suspended or revoked. An establishment or product license shall be revoked upon application of the manufacturer giving notice of intention to discontinue the manufacture of all products or of intention to discontinue the manufacture of a particular product for which a license is held. The Commissioner of Food and Drugs shall recommend to the Secretary that a license be suspended or revoked whenever he finds, after notice and opportunity for hearing, that (a) Food and Drug Administration inspectors after reasonable efforts have been unable to gain access to an establishment or a location for the purpose of carrying out the inspection required under § 600.21 of this chapter, or that (b) manufacturing of products or of a product has been discontinued to an extent that a meaningful inspection cannot be made, or (c) the establishment or any location thereof, or the product for which the license has been issued, fails to conform to the standards in the regulations in this subchapter, as herein prescribed or as hereafter amended, designed to insure the continued safety, purity, and potency of the manufactured product. In case of suspension, unless assurances satisfactory to the Commissioner of Food and Drugs (a) that access will be permitted or (b) that manufacturing will be resumed, have been provided or (c) if the faulty condition is not corrected within 60 days or within such other period as may be specified in the notice of suspension, whichever is applicable, he shall recommend that the license be revoked. Except as provided in § 601.40 prior to the institution of proceedings looking to the suspension or revocation of a license the licensee shall be advised in writing of the facts or conduct which may warrant such action and shall be accorded opportunity within a reasonable period prescribed by the Commissioner of Food and Drugs to demonstrate or achieve compliance with the regulations in this subchapter.

§ 601.5 Licenses heretofore issued.

Any license heretofore issued and in effect upon the effective date of the regulations in this subchapter shall remain in effect unless and until superseded by a new license, or suspended or revoked, pursuant to the regulations in this subchapter.

§ 601.6 Changes to be reported.

(a) *General.* Important proposed changes in location, equipment, management and responsible personnel, or in manufacturing methods and labeling, of any product for which a license is in effect or for which an application for license is pending, shall be reported to the Director, Bureau of Biologics, by the manufacturer, and unless in case of an emergency, not less than 30 days in advance of the time such changes are intended to be made.

(b) *Manufacturing methods and labeling.* Proposed changes in manufacturing methods and labeling may not become effective until notification of acceptance is received from the Director, Bureau of Biologics.

(c) *Failure to report.* Failure to report a change as required shall constitute a ground for summary suspension of a license.

Subpart B—Establishment Licensing

§ 601.10 Establishment licenses; issuance and conditions.

(a) *Inspection—compliance with standards.* An establishment license shall be issued only after inspection of the establishment and upon a determination that the establishment complies with the applicable standards prescribed in the regulations in this subchapter.

(b) *Availability of product; simultaneous request for and issuance of product license.* No establishment license shall be issued unless (1) a product intended for sale, barter or exchange or intended to be offered, sent, carried or brought for sale, barter or exchange is available for examination, (2) such product is available for inspection during all phases of manufacture and (3) a product license is requested and issued simultaneously with the establishment license.

(c) *One establishment license to cover all locations.* One establishment license shall be issued to cover all locations meeting the establishment standards.

§ 601.11 Registration of blood banks and other firms collecting, manufacturing, preparing, or processing human blood or blood products.

(a) All owners or operators of establishments that engage in the collection, manufacturing, preparation, propagation, compounding, or processing of human blood or blood products are required to register, pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act. Registration and listing of products shall comply with Part 132 of this chapter. Registration does not permit any blood bank or similar establishment to ship blood or blood products in interstate commerce.

(b) Forms for registration of an establishment are obtainable on request from the Bureau of Drugs (HFD–315), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, or at any of the Food and Drug Administration district offices.

(c) The completed form should be mailed to Drug Registration Section, Bureau of Drugs (HFD–315), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852.

Subpart C—Product Licensing

§ 601.20 Product licenses; issuance and conditions.

(a) *Examination—compliance with standards.* A product license shall be issued only upon examination of the product and upon a determination that the product complies with the standards prescribed in the regulations in this subchapter: *Provided*, That no product license shall be issued except upon a determination that the establishment complies with the establishment standards prescribed in the regulations contained in this subchapter, applicable to the manufacture of such product.

(b) *Manufacturing process—impairment of assurances.* No product shall be licensed if any part of the process of or relating to the manufacture of such product, in the judgment of the Commissioner of Food and Drugs, would impair the assurances of continued safety, purity and potency as provided by the regulations contained in this subchapter.

§ 601.21 Products under development.

A biological product or trivalent organic arsenical undergoing development, but not yet ready for a product license, may be shipped or otherwise delivered from one State or possession into another State or possession provided such shipment or delivery is not for sale, barter or exchange and is in accordance with section 505 of the Federal Food, Drug, and Cosmetic Act, as amended, and the regulations thereunder.

§ 601.22 Products in short supply; initial manufacturing at other than licensed establishment.

Licenses issued to a manufacturer for an establishment shall authorize persons other than such manufacturer to conduct at places other than such establishment the initial, and partial manufacturing of a product for shipment solely to such manufacturer only to the extent that the names of such persons and places are registered with the Commissioner of Food and Drugs and he finds, upon application of such manufacturer, that (a) the product is in short supply due either to the peculiar growth requirements of the organism involved or to the scarcity of the animal required for manufacturing purposes, and (b) such manufacturer has established with respect to such persons and places such procedures, inspections, tests or other arrangements as will assure full compliance with the applicable regulations of this subchapter related to continued safety, purity, and potency. Such persons and places shall be subject to all regulations of this subchapter except §§ 601.1 to 601.6, 601.10, 601.20, 601.21, 601.30 to 601.33, 601.40 to 601.44, and 610.60 to 610.65 of this chapter. Failure of such manufacturer to maintain such procedures, inspections, tests, or other arrangements, or failure of any person conducting such partial manufacturing to comply with applicable regulations shall constitute a ground for summary suspension or revocation of the authority conferred pursuant to this section on the same basis as provided in §§ 601.40, 601.42, and 601.43 with respect to the summary suspension and the revocation of licenses.

§ 601.25 Review procedures to determine that licensed biological products are safe, effective, and not misbranded under prescribed, recommended, or suggested conditions of use.

For purposes of reviewing biological products that have been licensed prior to July 1, 1972, to determine that they are safe and effective and not misbranded, the following regulations shall apply. Prior administrative action exempting biological products from the provisions of the Federal Food, Drug, and Cosmetic Act is superseded to the extent that these regulations result in imposing requirements pursuant to provisions therein for a designated biological product or category of products.

(a) *Advisory review panels.* The Commissioner of Food and Drugs shall appoint advisory review panels (1) to evaluate the safety and effectiveness of biological products for which a license has been issued pursuant to section 351 of the Public Health Service Act, (2) to review the labeling of such biological products, and (3) to advise him on which of the biological products under review are safe, effective, and not misbranded. An advisory review panel shall be established for each designated category of biological product. The members of a panel shall be qualified experts, appointed by the Commissioner, and shall include persons from lists submitted by organizations representing professional, consumer, and industry interests. Such persons shall represent a wide divergence of responsible medical and scientific opinion. The Commissioner shall designate the chairman of each panel, and summary minutes of all meetings shall be made.

(b) *Request for data and views.* (1) The Commissioner of Food and Drugs 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 biological products.

(2) 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 evaluation of the biologics under review and the full report or reports 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.

(3) To be considered, 12 copies of the submission on any marketed biological product within the class shall be submitted, preferably bound, indexed, and on standard sized paper, approximately 8½ x 11 inches. The time allotted for submissions will be 60 days, unless otherwise indicated in the specific notice requesting data and views for a particular category of biological products. When requested, abbreviated submissions should be sent. All submissions shall be in the following format, indicating "none" or "not applicable" where appropriate, unless changed in the FEDERAL REGISTER notice:

BIOLOGICAL PRODUCTS REVIEW INFORMATION

I. Label or labels and all other labeling (preferably mounted. Facsimile labeling is acceptable in lieu of actual container labeling), including labeling for export.

II. Representative advertising used during the past 5 years.

III. The complete quantitative composition of the biological product.

IV. 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 biological product.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

V. 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 biological 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 biological product.

5. Pertinent medical and scientific literature.

VI. 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 as to the effectiveness of combinations of the individual active components.

5. Pertinent medical and scientific literature.

C. Finished biological 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 effectiveness of the finished biological product.

5. Pertinent medical and scientific literature.

VII. A summary of the data and views setting forth the medical rational and purpose (or lack thereof) for the biological product and its components and the scientific basis (or lack thereof) for the conclusion that the biological product, including its components, has been proven safe and effective and is properly labeled for the intended use or uses. If there is an absence of controlled studies in the materials submitted, an explanation as to why such studies are not considered necessary or feasible shall be included.

VIII. If the submission is by a licensee, a statement signed by the responsible head (as defined in § 600.10 of this chapter) of the licensee shall be included, stating that to the best of his knowledge and belief, it includes all information, favorable and unfavorable, pertinent to an evaluation of the safety, effectiveness, and labeling of the product, including information derived from investigation, commercial marketing, or published literature. If the submission is by an interested person other than a licensee, a statement signed by the person responsible for such submission shall be included, stating that to the best of his knowledge and belief, it fairly reflects a balance of all the information, favorable and unfavorable, available to him pertinent to an evaluation of the safety, effectiveness, and labeling of the product.

(c) *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 of Food and Drugs with respect to the safety, effectiveness, and labeling of the biological products in the designated category under review.

(1) A panel may also consult any individual or group.

(2) Any interested person may request in writing an opportunity to present oral views to the panel. Such written requests for oral presentations should include a summarization of the data to be presented to the panel. Such request may be granted or denied by the panel.

(3) 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 (b) (3) of this section and within the time period established for the biological product category in the notice for review by a panel.

(d) *Standards for safety, effectiveness, and labeling.* The advisory review panel, in reviewing the submitted data and preparing the panel's conclusions and recommendations, and the Commissioner of Food and Drugs, in reviewing and implementing the conclusions and recommendations of the panel, shall apply the following standards to determine that a biological product is safe and effective and not misbranded.

(1) Safety means the relative freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time. Proof of safety shall consist of adequate tests by methods reasonably applicable to show the biological product is safe under the prescribed conditions of use, including results of significant human experience during use.

(2) Effectiveness means a reasonable expectation that, in a significant proportion of the target population, the pharmacological or other effect of the biological product, when used under adequate directions, for use and warnings against unsafe use, will serve a clinically significant function in the diagnosis, cure, mitigation, treatment, or prevention of disease in man. Proof of effectiveness shall consist of controlled clinical investigations as defined in § 130.12(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 biological product or essential to the validity of the investigation, and that an alternative method of investigation is adequate to substantiate effectiveness. Alternate methods, such as serological response evaluation in clinical studies and appropriate animal and other laboratory assay evaluations may be adequate to substantiate effectiveness where a previously accepted correlation between data generated in this way and clinical effectiveness already exists. 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.

(3) The benefit-to-risk ratio of a biological product shall be considered in determining safety and effectiveness.

(4) A biological product may combine two or more safe and effective active components: (i) When each active component makes a contribution to the claimed effect or effects; (ii) when combining of the active ingredients does not decrease the purity, potency, safety, or effectiveness of any of the individual active components; and (iii) if the combination, when used under adequate directions for use and warnings against unsafe use, provides rational concurrent preventive therapy or treatment for a significant proportion of the target population.

(5) Labeling shall be clear and truthful in all respects and may not be false or misleading in any particular. It shall comply with section 351 of the Public Health Service Act and sections 502 and 503 of the Federal Food, Drug, and Cosmetic Act, and in particular with the applicable requirements of §§ 610.60 through 610.65 and 1.106 of this chapter.

(e) *Advisory review panel report to the Commissioner.* An advisory review panel shall submit to the Commissioner of Food and Drugs a report containing the panel's conclusions and recommendations with respect to the biological products falling within the category covered by the panel. Included within this report shall be:

(1) A statement which designates those biological products determined by the

panel to be safe and effective and not misbranded. This statement may include any condition relating to active components, labeling, tests required prior to release of lots, product standards, or other conditions necessary or appropriate for their safety and effectiveness.

(2) A statement which designates those biological products determined by the panel to be unsafe or ineffective, or to be misbranded. The statement shall include the panel's reasons for each such determination.

(3) A statement which designates those biological products determined by the panel not to fall within either subparagraph (1) or (2) of this paragraph on the basis of the panel's conclusion that the available data are insufficient to classify such biological products, and for which further testing is therefore required. The report shall recommend with as much specificity as possible the type of further testing required and the time period within which it might reasonably be concluded. The report shall also recommend whether the product license should or should not be revoked, thus permitting or denying continued manufacturing and marketing of the biological product pending completion of the testing. This recommendation will be based on an assessment of the present evidence of the safety and effectiveness of the product and the potential benefits and risks likely to result from the continued use of the product for a limited period of time while the questions raised concerning the product are being resolved by further study.

(f) *Proposed order.* After reviewing the conclusions and recommendations of the advisory review panel, the Commissioner of Food and Drugs shall publish in the FEDERAL REGISTER a proposed order containing:

(1) A statement designating the biological products in the category under review that are determined by the Commissioner of Food and Drugs to be safe and effective and not misbranded. This statement may include any condition relating to active components, labeling, tests required prior to release of lots, product standards, or other conditions necessary or appropriate for their safety and effectiveness, and may propose corresponding amendments in other regulations under this Subchapter F.

(2) A statement designating the biological products in the category under review that are determined by the Commissioner of Food and Drugs to be unsafe or ineffective, or to be misbranded, together with the reasons therefor. All licenses for such products shall be proposed to be revoked.

(3) A statement designating the biological products not included in either of the above two statements on the basis of the Commissioner of Food and Drugs determination that the available data are insufficient to classify such biological products under either subparagraphs (1) or (2) of this paragraph. Licenses for such products may be proposed to be revoked or to remain in effect on an interim basis. Where the Commissioner determines that the potential benefits outweigh the potential risks, the proposed order shall provide that the product license for any biological product, falling within this paragraph will not be revoked but will remain in effect on an interim basis while the data necessary to support its continued marketing are being obtained for evaluation by the Food and Drug Administration. The tests necessary to resolve whatever safety or effectiveness questions exist shall be described.

(4) The full report or reports of the panel to the Commissioner of Food and Drugs.

The summary minutes of the panel meeting or 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.

(g) *Final order.* After reviewing the comments, the Commissioner of Food and Drugs shall publish in the FEDERAL REGISTER a final order on the matters covered in the proposed order. The final order shall become effective as specified in the order.

(h) *Additional studies.* (1) Within 30 days following publication of the final order, each licensee for a biological product designated as requiring further study to justify continued marketing on an interim basis, pursuant to paragraph (f) (3) of this section, shall satisfy the Commissioner of Food and Drugs in writing that studies adequate and appropriate to resolve the questions raised about the product have been undertaken, or the Federal Government may undertake the studies. The Commissioner may extend this 30-day period if necessary, either to review and act on proposed protocols or upon indication from the licensee that the studies will commence at a specified reasonable time. If no such commitment is made, or adequate and appropriate studies are not undertaken, the product license or licenses shall be revoked.

(2) A progress report shall be filed on the studies every January 1 and July 1 until completion. If the progress report is inadequate or if the Commissioner of Food and Drugs concludes that the studies are not being pursued promptly and diligently, or if interim results indicate the potential benefits do not outweigh the potential risks, the product license or licenses shall be revoked.

(3) Promptly upon completion of the studies undertaken on the product, the Commissioner of Food and Drugs will review all available data and will either retain or revoke the product license or licenses involved. In making this review and evaluation the Commissioner may again consult the advisory review panel which prepared the report on the product, or other advisory committees, professional organizations, or experts. The Commissioner shall take such action by notice published in the FEDERAL REGISTER.

(i) *Court Appeal.* The final order(s) published pursuant to paragraph (g) of this section, and any notice published pursuant to paragraph (h) of this section, constitute 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 of Food and Drugs may, at his discretion, stay the effective date for part or all of the final order or notice, pending appeal and final court adjudication.

Subpart D—Licensing of Foreign Establishments and Products

§ 601.30 Licenses required; products for controlled investigation only.

Any biological or trivalent organic arsenical manufactured in any foreign country and intended for sale, barter or exchange shall be refused entry by collectors of customs unless manufactured in an establishment holding an unsuspended and unrevoked establishment license and license for the product. Unlicensed products which are not imported for sale, barter or exchange and which are intended solely for purposes of controlled investigation are admissible only if in accord with section 505 of the Federal Food, Drug, and Cosmetic Act, as amended, and the regulations thereunder.

§ 601.31 Procedure.

Except as otherwise provided in this subchapter, licenses for foreign establishments and products shall be issued, suspended, and revoked in the same manner as licenses for domestic establishments and products. Each foreign establishment holding a license and sending, carrying, or bringing any licensed product into any State or possession for sale, barter, or exchange shall file with the Director, Bureau of Biologics, the name and address of each person to whom such a product is thus sent, carried, or brought. Foreign licensees shall notify each person in the United States to whom such a product is thus sent, carried, or brought, to keep such records of distribution as are required of domestic licensed establishments. Failure to give such notice to maintain records shall constitute ground for revocation of license.

§ 601.32 Form of license.

Licenses for establishments located in foreign countries shall be in form similar to that for domestic establishments except that they shall authorize manufacture for sending, carrying, or bringing for sale, barter or exchange from the foreign country designated in the license into any State or possession of the United States and shall specify that it is issued upon the condition that the licensee will permit the inspection during all reasonable hours of the establishment by any officer, agent, or employee of the Department of Health, Education, and Welfare authorized by the Secretary for such purpose.

§ 601.33 Samples for each importation.

Random samples of each importation, obtained by the District Director of Customs and forwarded to the Director, Bureau of Biologics, shall be at least two final containers of each lot of product. A copy of the associated documents which describe and identify the shipment shall accompany the shipment for forwarding with the samples to the Director, Bureau of Biologics. For shipments of 20 or less final containers, samples need not be forwarded, provided a copy of an official release from the Bureau of Biologics accompanies each shipment.

Subpart E—Suspension of Licenses and Appeals Procedure

§ 601.40 Summary suspension.

Whenever the Commissioner of Food and Drugs has reasonable ground to believe that an establishment or product for which a license has been issued fails to conform to the standards prescribed in the regulations in this subchapter, and that by reason of such failure and of failure of the manufacturer to take prompt corrective measures on notice thereof, the distribution or sale of a licensed product would constitute a danger to health, or that the establishment and manufacturing methods have been so changed as to require in order to protect the public health a new showing that the establishment or product meets the standards prescribed in the regulations in this subchapter, he may recommend to the Secretary that the license for the establishment or the product be summarily suspended and the manufacturer be required (a) to notify the selling agents and distributors to whom such product or products have been delivered of such suspension, (b) to furnish complete records of such deliveries and notice of suspension, and (c) to show cause within 60 days or such other period as may be specified in the order why the license should not be revoked.

§ 601.41 Review Board.

When deemed advisable by the Commissioner of Food and Drugs, in matters involving the safety, purity, and potency of licensed products or products for which an application for license is pending, the reports of inspection and laboratory examinations, together with any pertinent data the establishment may submit, shall be passed upon by a special board of three officers appointed by the Commissioner of Food and Drugs for that purpose. The board shall report its findings to the Commissioner of Food and Drugs who will forward its report, together with his findings and recommendations, to the Secretary.

§ 601.42 Opportunity for hearing.

Any manufacturer whose application for a license has been denied, or whose establishment or product license has been summarily suspended, without prior opportunity for hearing, may appeal from such denial or suspension and shall be entitled to a hearing thereon before a review body constituted as provided in § 601.41. The Commissioner of Food and Drugs, upon review of the record, may affirm, reverse, or modify the findings of the review board, or may direct the taking of further testimony, and shall forward his determinations and recommendations to the Secretary.

§ 601.43 Suspension and revocation; publication.

Notice of suspension or revocation of license, with statement of cause therefor, may be published by the Secretary.

§ 601.44 Licenses; reissuance.

(a) *Compliance with standards.* An establishment or product license, previously suspended or revoked, whether upon application, or for failure to comply with standards or changes in standards prescribed in the regulations in this subchapter, may be reissued or reinstated upon a showing of compliance with required standards and upon such inspection and examination as may be considered necessary by the Director of the Bureau of Biologics.

(b) *Exclusion of noncomplying location.* An establishment or product license, excluding a location or locations that fail to comply with prescribed standards, may be issued without further application and concurrently with the suspension or revocation of the license for noncompliance at the excluded location or locations.

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

Subpart A—Release Requirements

Sec.
610.1 Tests prior to release required for each lot.
610.2 Requests for samples and protocols; official release.

Subpart B—General Provisions

610.10 Potency.
610.11 General safety.
610.12 Sterility.
610.13 Purity.
610.14 Identity.
610.15 Constituent materials.
610.16 Total solids in serums.
610.17 Permissible combinations.
610.18 Cultures.

Subpart C—Standard Preparations and Limits of Potency

610.20 Standard preparations.
610.21 Limits of potency.

Subpart D—Mycoplasma

610.30 Test for *Mycoplasma*.

Subpart E—Hepatitis Requirements

610.40 Test for hepatitis associated (Australia) antigen.
610.41 History of hepatitis associated (Australia) antigen.

Subpart F—Dating Period Limitations

610.50 Date of manufacture.
610.51 Periods of cold storage.
610.52 Dating period.
610.53 Dating periods for specific products.

Subpart G—Labeling Standards

610.60 Container label.
610.61 Package label.
610.62 Proper name; package label; legible type.
610.63 Divided manufacturing responsibility to be shown.
610.64 Name of selling agent or distributor.
610.65 Products for export.

AUTHORITY: Sec. 215, 58 Stat. 690, as amended; 42 U.S.C. 216. Sec. 351, 58 Stat. 702, as amended; 42 U.S.C. 262, unless otherwise noted.

CROSS REFERENCES. For U.S. Customs Service regulations relating to viruses, serums, and toxins, see 19 CFR 12.21–12.23. For U.S. Postal Service regulations relating to the admissibility to the United States mails see 39 CFR Parts 124 and 125, esp. § 125.2.

Subpart A—Release Requirements

§ 610.1 Tests prior to release required for each lot.

No lot of any licensed product shall be released by the manufacturer prior to the completion of tests for conformity with standards applicable to such product. Each applicable test shall be made on each lot after completion of all processes of manufacture which may affect compliance with the standard to which the test applies. The results of all tests performed shall be considered in determining whether or not the test results meet the test objective, except that a test result may be disregarded when it is established that the test is invalid due to causes unrelated to the product.

§ 610.2 Requests for samples and protocols; official release.

Samples of any lot of any licensed product, together with the protocols showing results of applicable tests, may at any time be required to be sent to the Director, Bureau of Biologics. Upon notification by the Director, Bureau of Biologics, a manufacturer shall not distribute a lot of a product until the lot is released by the Director, Bureau of Biologics: *Provided*, That the Director shall not issue such notification except when deemed necessary for the safety, purity or potency of the product.

Subpart B—General Provisions

§ 610.10 Potency.

Tests for potency shall consist of either in vitro or in vivo tests, or both, which have been specifically designed for each product so as to indicate its potency in a manner adequate to satisfy the interpretation of potency given by the definition in § 600.3(s) of this chapter.

§ 610.11 General safety.

In addition to specified safety tests prescribed in this subchapter for individual products, a general safety test shall be performed in final container material, from each filling of each lot of all products intended for administration to man, either after the labels have been affixed to the final container, or affixed, both outside and inside, to the multiple container storage receptacle just prior to its sealing for storage purposes. Exceptions to this procedure may be authorized by the Director, Bureau of Biologics, when more than one lot is processed each day. The general safety test shall consist of the parenteral injection

of the maximum volume tolerated into each of two mice weighing approximately 20 gms. each and into each of two guinea pigs weighing approximately 350 gms. each but no more than 0.5 ml. need be inoculated into each mouse and no more than 5.0 ml. need be inoculated into each guinea pig. After injection the animals shall be observed for a period of no less than seven days and if neither significant symptoms nor death results during the observation period, the product meets the requirements for general safety. Variations of this test, either in the volume injected or in the species of test animal used shall be made whenever required because of the human dose level demanded of the product or because of any individual demands of the product itself.

§ 610.12 Sterility.

Except as provided in paragraphs (f) and (g) of this section, the sterility of each lot of each product shall be demonstrated by the performance of the tests prescribed in paragraphs (a) and (b) of this section for both bulk and final container material.

(a) *The test.* Bulk material shall be tested separately from final container material and material from each final container shall be tested in individual test vessels as follows:

(1) *Using Fluid Thioglycollate Medium*—(i) *Bulk and final container material.* The volume of product, as required by paragraph (d) of this section (hereinafter referred to also as the "inoculum"), from samples of both bulk and final container material, shall be inoculated into test vessels of Fluid Thioglycollate Medium. The inoculum and medium shall be mixed thoroughly and incubated at a temperature of 30° to 32° C. for a test period of no less than 14 days and examined visually for evidence of growth on the third, fourth, or fifth day and on the seventh or eighth day and on the last day of the test period. Results of each examination shall be recorded. If the inoculum renders the medium turbid so that the absence of growth cannot be determined reliably by visual examination, portions of this turbid medium in amounts of no less than 1.0 ml. shall be transferred on the third, fourth, or fifth day of incubation, from each of the test vessels and inoculated into additional vessels of medium. The material in the additional vessels shall be incubated at a temperature of 30° to 32° C. for no less than 14 days. Notwithstanding such transfer of material, examination of the original vessels shall be continued as prescribed above. The additional test vessels shall be examined visually for evidence of growth on the third, fourth, or fifth day of incubation and on the seventh or eighth day and on the last day of the incubation period. If growth appears, repeat tests may be performed as prescribed in paragraph (b) of this section and interpreted as specified in paragraph (c) of this section.

(ii) *Final container material containing a mercurial preservative.* In addition to the test prescribed in subparagraph (1) (i) of this paragraph, final container material containing a mercurial preservative shall be tested using Fluid Thioglycollate Medium following the procedures prescribed in such subparagraph, except that the incubation shall be at a temperature of 20° to 25° C.

(2) *Using Soybean-Casein Digest Medium.* Except for products containing a mercurial preservative, a test shall be made on final container material, following the procedures prescribed in subparagraph (1) (i) of this paragraph, except that the medium shall be Soybean-Casein Digest Medium and the incubation shall be at a temperature of 20° to 25° C.

(b) *Repeat tests*—(1) *Repeat bulk test.* If growth appears in the test of the bulk material, the test may be repeated to rule out faulty test procedures by testing at least the same volume of material.

(2) *First repeat final container test.* If growth appears in any test (Fluid Thioglycollate Medium or Soybean-Casein Digest Medium) of final container material, the test may be repeated to rule out faulty test procedures by testing material from a sample of at least the same number of final containers.

(3) *Second repeat final container test.* If growth appears in any first repeat final container test (Fluid Thioglycollate Medium or Soybean-Casein Digest Medium), that test may be repeated provided there was no evidence of growth in any test of the bulk material and material from a sample of twice the number of final containers used in the first test is tested by the same method used in the first test.

(c) *Interpretation of test results.* The results of all tests performed on a lot shall be considered in determining whether or not the lot meets the requirements for sterility, except that tests may be excluded when demonstrated by adequate controls to be invalid. The lot meets the test requirements if no growth appears in the tests prescribed in paragraph (a) of this section. If repeat tests are performed, the lot meets the test requirements if no growth appears in the tests prescribed in paragraph (b) (2) or (3) of this section, whichever is applicable.

(d) *Test samples and volumes*—(1) *Bulk.* Each sample for the bulk sterility test shall be representative of the bulk material and the volume tested shall be no less than 10 ml. (Note exceptions in paragraph (g) of this section.)

(2) *Final containers.* The sample for the final container and first repeat final container test shall be no less than 20 final containers from each filling of each lot, selected to represent all stages of filling from the bulk vessel. If the amount of material in the final container is 1.0 ml. or less, the entire contents shall be tested. If the amount of material in the final container is more than 1.0 ml., the volume tested shall be the largest single dose recommended by the manufacturer or 1.0 ml., whichever is larger, but no more than 10 ml. of material or the entire contents from a single final container need be tested. If more than two filling machines, each with either single or multiple filling stations, are used for filling one lot, no less than 10 filled containers shall be tested from each filling machine, but no more than 100 containers of each lot need be tested. The items tested shall be representative of each filling assembly and shall be selected to represent all stages of the filling operation. (Note exceptions in paragraph (g) of this section.)

(e) *Culture medium*—(1) *Formulae.* (i) The formula for Fluid Thioglycollate Medium is as follows:

FLUID THIOGLYCOLLATE MEDIUM

l-cystine	0.5 Gm.
Sodium chloride	2.5 Gm.
Dextrose ($C_6H_{12}O_6 \cdot H_2O$)	5.5 Gm.
Granular agar (less than 15% moisture by weight).	0.75 Gm.
Yeast extract (water-soluble)	5.0 Gm.
Pancreatic digest of casein	15.0 Gm.
Purified water	1,000.0 ml.
Sodium thioglycollate (or thioglycolic acid—0.3 ml.).	0.5 Gm.
Resazurin (0.10% solution, freshly prepared).	1.0 ml.
pH after sterilization 7.1±0.2	

(ii) The formula for Soybean-Casein Digest Medium is as follows:

SOYBEAN-CASEIN DIGEST MEDIUM

Pancreatic Digest of Casein	17.0 Gm.
Papaic Digest of Soybean Meal.	3.0 Gm.
Sodium Chloride	5.0 Gm.
Dibasic Potassium Phosphate	2.5 Gm.
Dextrose ($C_6H_{12}O_6 \cdot H_2O$)	2.5 Gm.
Purified water	1,000.0 ml.
pH after sterilization 7.3±0.2	

(2) *Culture media requirements*—(i) *Growth promoting qualities.* Each lot of dehydrated medium bearing the manufacturer's identifying number, or each lot of medium prepared from basic ingredients, shall be tested for its growth-promoting qualities using not more than 100 organisms of two or more strains of microorganisms that are exacting in their nutritive and aerobic-anaerobic requirements.

(ii) *Conditions of medium and design of test vessels.* A medium shall not be used if the extent of evaporation affects its fluidity, nor shall it be reused in a sterility test. Fluid Thioglycollate Medium shall not be used if more than the upper one-third has acquired a pink color. The medium may be restored once by heating on a steam bath or in free-flowing steam until the pink color disappears. The design of the test vessel for Fluid Thioglycollate Medium shall be such as is shown to provide favorable aerobic and anaerobic growth of microorganisms throughout the test period.

(iii) *Ratio of the inoculum to culture medium.* The ratio of the inoculum to the volume of the culture medium resulting in a dilution of the product that is not bacteriostatic or fungistatic shall be determined for each product, except for those tested by membrane filtration. Vessels of the product-medium mixture(s) and control vessels of the medium shall be inoculated with dilutions of cultures of bacteria or fungi which are sensitive to the product being tested, and incubated at the appropriate temperature for no

less than 7 days. Inhibitors or neutralizers of preservatives may be considered in determining the proper ratio.

(f) *Membrane filtration.* Bulk and final container material of products containing oil or products in water insoluble ointments shall be tested for sterility using the membrane filtration procedure set forth in The United States Pharmacopeia [1] (18th Revision, 1970), section entitled "Membrane Filtration," pages 853–854, except that (1) the test samples shall conform with paragraph (d) of this section, (2) the temperature of incubation for the test using Fluid Thioglycollate Medium shall be 30° to 32° C. and (3) in addition, for products containing a mercurial preservative, the product shall be tested in a second test using Fluid Thioglycollate Medium incubated at 20° to 25° C. in lieu of the test in Soybean-Casein Digest Medium. Such Membrane Filtration section is hereby incorporated by reference and deemed published herein. The United States Pharmacopeia is available at most medical and public libraries and copies of the pertinent section will be provided to any manufacturer affected by the provisions of this subchapter upon request to the Director, Bureau of Biologics or the appropriate Information Center Offices listed in 45 CFR Part 5. In addition, an official historic file of the material incorporated by reference is maintained in the office of the Director, Bureau of Biologics.

(g) *Exceptions.* Bulk and final container material shall be tested for sterility as described above in this section, except as follows:

(1) *Different sterility tests prescribed.* When different sterility tests are prescribed for a product in this subchapter.

(2) *Alternate incubation temperatures.* Two tests may be performed, in all respects as prescribed in paragraph (a) (1) (i) of this section, one test using an incubation temperature of 18° to 22° C., the other test using an incubation temperature of 35° to 37° C., in lieu of performing one test using an incubation temperature of 30° to 32° C.

(3) *Different tests equal or superior.* A different test (such as membrane filtration as set forth in paragraph (f) of this section) may be performed provided that prior to the performance of such test a manufacturer submits data which the Commissioner of Food and Drugs, finds adequate to establish that the different test is equal or superior to the tests described in paragraphs (a) and (b) of this section in detecting contamination and makes the finding a matter of official record.

(4) *Test precluded or not required.* The tests prescribed in this section need not be performed for Whole Blood (Human), Cryoprecipitated Antihemophilic Factor (Human), Leukocyte Typing Serum, Red Blood Cells (Human), Single Donor Plasma (Human), Source Plasma (Human), Smallpox Vaccine and other similar products concerning which the Commissioner of Food and Drugs, finds that the mode of administration, the method of preparation or the special nature of the product precludes or does not require a sterility test.

(5) *Viscid or turbid products.* Alternative Thioglycollate Medium may be used in place of Fluid Thioglycollate Medium for the testing of products that are viscid or turbid or otherwise do not lend themselves to culturing in Fluid Thioglycollate Medium, provided it has been freshly prepared or has been heated on a steam bath or in free-flowing steam and cooled just prior to use and is used in a suitable vessel that will maintain aerobic and anerobic conditions throughout the incubation period. The formula for the Alternative Thioglycollate Medium follows:

ALTERNATIVE THIOGLYCOLLATE MEDIUM

l-cystine	0.5 Gm.
Sodium chloride	2.5 Gm.
Dextrose ($C_6H_{12}O_6 \cdot H_2O$)	5.5 Gm.
Yeast extract (water soluble)	5.0 Gm.
Pancreatic digest of casein	15.0 Gm.
Purified water	1,000.0 ml.
Sodium thioglycollate (or thioglycollic acid—0.3 ml.)	0.5 Gm.

pH after sterilization 7.1±0.2.

(6) *Number of final containers more than 20, less than 200.* If the number of final containers in the filling is more than 20 or less than 200, the sample shall be no less than 10 percent of the containers.

(7) *Number of final containers—20 or less.* If the number of final containers in a filling is 20 or less, the sample shall be two final containers, or the sample need be no more than one final container, provided (i) the bulk material met the sterility test requirements and (ii) after filling, it is demonstrated by testing a simulated sample that all surfaces to which the product was exposed were free of contaminating microorganisms. The simulated sample shall be prepared by rinsing the filling equipment with sterile 1.0 percent peptone solution, pH 7.1±0.1, which shall be discharged into a final container by the same method used for filling the final containers with the product.

(8) *Samples—large volume of product in final containers.* For Normal Serum Albumin (Human), Normal Human Plasma, Antihemophilic Plasma (Human), Plasma Protein Fraction (Human) and Fibrinogen (Human), when the volume of product in the final container is 50 ml. or more, the final containers selected as the test sample may contain less than the full volume of product in the final containers of the filling from which the sample is taken: *Provided,* That the containers and closures of the sample are identical with those used for the filling to which the test applies and the sample represents all stages of that filling.

(9) *Diagnostic products not intended for injection.* For diagnostic products not intended for injection, (i) only the Thioglycollate Medium test incubated at 30° to 32° C. is required, (ii) the volume of material for the bulk test shall be no less than 2.0 ml., and (iii) the sample for the final container test shall be no less than three final containers if the total number filled is 100 or less, and, if greater, one additional container for each additional 50 containers or fraction thereof, but the sample need be no more than 10 containers.

(10) *Immune globulin preparations.* For immune globulin preparations, the test samples from the bulk material and from each final container need be no more than 2.0 ml.

§ 610.13 Purity.

Products shall be free from extraneous material except for unavoidable bacteriophage. In addition, products shall be tested as provided in paragraphs (a) and (b) of this section.

(a) *Test for residual moisture.* Each lot of dried product shall be tested for residual moisture and other volatile substances.

(1) *Procedure.* The test for dried products shall consist of measuring the maximum loss of weight in a weighed sample equilibrated over anhydrous P_2O_5 at a pressure of not more than one mm. of mercury, and at a temperature of 20° to 30° C. for as long as it has been established is sufficient to result in a constant weight.

(2) *Test results; standard to be met.* The residual moisture and other volatile substances shall not exceed 1 percent except that for BCG Vaccine they shall not exceed 1½ percent, for Measles Virus Vaccine, Live, Attenuated, Measles-Smallpox Vaccine, Live; Rubella Virus Vaccine, Live and Antihemophilic Factor (Human), they shall not exceed 2 percent, and for Modified Plasma (Bovine); Thrombin; Fibrinogen; Streptokinase; Streptokinase - Streptodornase; and Anti-Influenza Virus Serum for the Hemagglutination Inhibition Test, they shall not exceed 3 percent.

(b) *Test for pyrogenic substances.* Each lot of any product intended for use by injection shall be tested for pyrogenic substances by intravenous injection into rabbits as provided in subparagraphs (1) and (2) of this paragraph: *Provided,* That notwithstanding any other provision of this subchapter, the test for pyrogenic substances is not required for the following products: Products containing formed blood elements; Cryoprecipitated Antihemophilic Factor (Human); Single Donor Plasma (Human); Source Plasma (Human); Normal Horse Serum; Normal Rabbit Serum; bacterial viral and rickettsial vaccines and antigens; toxoids; toxins, allergenic extracts; venoms; diagnostic substances and trivalent organic arsenicals.

(1) *Test dose.* The test dose for each rabbit shall be at least 3 milliliters per kilogram of body weight of the rabbit and also shall be at least equivalent proportionately, on a body weight basis, to the maximum single human dose recommended, but need not exceed 10 ml. per kilogram of body weight of the rabbit, except that: (i) Regardless of the human dose recommended, the test dose per kilogram of body weight of each rabbit shall be, at least 1 milliliter for immune globulins derived from human

[1] Copies may be obtained from: United States Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852.

blood, at least 3 milliliters for Normal Human Plasma, and at least 30 milligrams for Fibrinogen (Human); (ii) for Streptokinase, Streptokinase-Streptodornase, Aggregated Radio-Iodinated (I^{131}) Albumin (Human), Radio-Chromater (Cr^{51}) Serum Albumin (Human), Radio-Iodinated (I^{125}) Serum Albumin (Human) and Radio-Iodinated (I^{131}) Serum Albumin (Human), the test dose shall be at least equivalent proportionately on a body weight basis to the maximum single human dose recommended.

(2) *Procedure.* Products shall be tested for freedom from pyrogenic substances by intraveneous injection of the test dose into three or more rabbits in overt good health and by recording for each rabbit a control temperature taken within one hour prior to injection, and three additional temperatures taken one, two, and three hours after injection. For purposes of subparagraph (3) of this paragraph, if there is no temperature increase over the control temperature (i.e. where the temperature remains unchanged or falls), the temperature rise shall be considered as zero. If there is an increase in temperature over the control temperature, the temperature rise shall be the difference between the highest of the three hourly readings and the control temperature reading.

(3) *Test results; standards to be met.* The results recorded for all rabbits used in all tests of a lot of a product shall be included in determining whether the standard for purity is met. The product fails to meet test requirements if one-half or more of all rabbits show a temperature rise of 0.6° C. or more or if the average temperature rise of all rabbits is 0.5° C. or more.

(c) *Different tests equal or superior.* A different test for residual moisture may be performed provided that prior to its performance the manufacturer submits data which the Commissioner of Food and Drugs finds adequate to establish that the different test is equal or superior to the test described in paragraph (a) of this section and makes the finding a matter of official record.

§ 610.14 Identity.

The contents of a final container of each filling of each lot shall be tested for identity after all labeling operations shall have been completed. The identity test shall be specific for each product in a manner that will adequately identify it as the product designated on final container and package labels and circulars, and distinguish it from any other product being processed in the same laboratory. Identity may be established either through the physical or chemical characteristics of the product, inspection by macroscopic or microscopic methods, specific cultural tests, or in vitro or in vivo immunological tests.

§ 610.15 Constituent materials.

(a) *Ingredients, preservative, diluents, adjuvants.* All ingredients used in a licensed product, and any diluent provided as an aid in the administration of the product, shall meet generally accepted standards of purity and quality. Any preservative used shall be sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient, and in the combination used shall not denature the specific substances in the product below the minimum acceptable potency within the dating period when stored at the recommended temperature. Products in multiple dose containers shall contain a preservative, except that a preservative need not be added to Yellow Fever Vaccine, Poliovirus Vaccine, Live, Oral, or to viral vaccines labeled for use with the jet injector, or to dried vaccines when the accompanying diluent contains a preservative. An adjuvant shall not be introduced into a product unless there is satisfactory evidence that it does not affect adversely the safety or potency of the product. In no event shall the recommended individual dose of a biological product contain more than 0.85 milligram of aluminum, determined by assay, or more than 1.14 milligrams of aluminum, determined by calculation on the basis of the amount of aluminum compound added.

(b) *Extraneous protein; cell culture produced vaccines.* Extraneous protein known to be capable of producing allergenic effects in human subjects shall not be added to a final virus medium of cell culture produced vaccines intended for injection. If serum is used at any stage, its calculated concentration in the final medium shall not exceed 1:1,000,000.

(c) *Antibiotics.* A minimum concentration of antibiotics, other than penicillin, may be added to the production substrate of viral vaccines.

§ 610.16 Total solids in serums.

Except as otherwise provided by regulation, no liquid serum or antitoxin shall contain more than 20 percent total solids.

§ 610.17 Permissible combinations.

Licensed products may not be combined with other licensed products, either therapeutic, prophylactic or diagnostic, except as a license is obtained for the combined product. Licensed products may not be combined with nonlicensable therapeutic, prophylactic, or diagnostic substances except as a license is obtained for such combination.

§ 610.18 Cultures.

(a) *Storage and maintenance.* Cultures used in the manufacture of products shall be stored in a secure and orderly manner, at a temperature and by a method that will retain the initial characteristics of the organisms and insure freedom from contamination and deterioration.

(b) *Identity and verification.* Each culture shall be clearly identified as to source strain. A complete identification of the strain shall be made for each new stock culture preparation. Primary and subsequent seed lots shall be identified by lot number and date of preparation. Periodic tests shall be performed as often as necessary to verify the integrity of the strain characteristics and freedom from extraneous organisms. Results of all periodic tests for verification of cultures and determination of freedom from extraneous organisms shall be recorded and retained.

Subpart C—Standard Preparations and Limits of Potency

§ 610.20 Standard preparations.

Standard preparations made available by the Bureau of Biologics shall be applied in testing, as follows:

(a) *Potency standards.* Potency standards shall be applied in testing for potency all forms of the following:

ANTIBODIES

Botulism Antitoxin, Type A.
Botulism Antitoxin, Type B.
Botulism Antitoxin, Type E.
Diphtheria Antitoxin.
Dysentery Antitoxin (Shiga).
Anti-Hemophilus Influenzae Type b Serum.
Histolyticus Antitoxin.
Oedematiens Antitoxin.
Perfringens Antitoxin.
Antipertussis Serum.
Antirabies Serum.
Scarlet Fever Streptococcus Antitoxin.
Sordellii Antitoxin.
Staphylococcus Antitoxin.
Tetanus Antitoxin.
Vibrion Septique Antitoxin.

ANTIGENS

Diphtheria Toxin for Schick Test.
Pertussis Vaccine.
Scarlet Fever Streptococcus Toxin.
Tuberculin, Old.
Tuberculin, Purified Protein Derivative.
Typhoid Vaccine.

BLOOD DERIVATIVE

Thrombin.

(b) *Opacity standard.* The U.S. Opacity Standard shall be applied in estimating the bacterial concentration of all bacterial vaccines. The assigned value of the standard when observed visually is 10 units. The assigned value of the standard when observed with a photometer is (i) 10 units when the wavelength of the filter is 530 millimicrons, (ii) 10.6 units when the wavelength of the filter is 650 millimicrons, and (iii) 9 units when the wavelength of the filter is 420 millimicrons.

§ 610.21 Limits of potency.

The potency of the following products shall be not less than that set forth below and products dispensed in the dried state shall represent liquid products having the stated limitations.

ANTIBODIES

Diphtheria Antitoxin, 500 units per milliliter.
Scarlet Fever Streptococcus Antitoxin, 400 units per milliliter.
Tetanus Antitoxin, 400 units per milliliter.
Tetanus Immune Globulin (Human), 50 units of tetanus antitoxin per milliliter.

ANTIGENS

Pertussis Vaccine, 12 units per total human immunizing dose.
Typhoid Vaccine, 8 units per milliliter.

Subpart D—Mycoplasma

§ 610.30 Test for *Mycoplasma*.

Except as provided otherwise in this subchapter, prior to clarification or filtration in the case of live virus vaccines

produced from in vitro living cell cultures, and prior to inactivation in the case of inactivated virus vaccines produced from such living cell cultures, each virus harvest pool and control fluid pool shall be tested for the presence of *Mycoplasma*, as follows:

Samples of the virus for this test shall be stored either (1) between 2° and 8° C. for no longer than 24 hours, or (2) at −20° C. or lower if stored for longer than 24 hours. The test shall be performed on samples of the viral harvest pool and on control fluid pool obtained at the time of viral harvest, as follows: No less than 2.0 ml. of each sample shall be inoculated in evenly distributed amounts over the surface of no less than 10 plates of at least two agar media. No less than 1.0 ml. of sample shall be inoculated into each of four tubes containing 10 ml. of a semisolid broth medium. The media shall be such as have been shown to be capable of detecting known *Mycoplasma* and each test shall include control cultures of at least two known strains of *Mycoplasma*, one of which must be *M. pneumoniae*. One half of the plates and two tubes of broth shall be incubated aerobically at 36° C. ±1° C. and the remaining plates and tubes shall be incubated anaerobically at 36° C. ±1° C. in an environment of 5–10 percent CO_2 in N_2. Aerobic incubation shall be for a period of no less than 14 days and the broth in the two tubes shall be tested after 3 days and 14 days, at which times 0.5 ml. of broth from each of the two tubes shall be combined and subinoculated on to no less than 4 additional plates and incubated aerobically. Anaerobic incubation shall be for no less than 14 days and the broth in the two tubes shall be tested after 3 days and 14 days, at which times 0.5 ml. of broth from each of the two tubes shall be combined and subinoculated on to no less than four additional plates and incubated anaerobically. All inoculated plates shall be incubated for no less than 14 days, at which time observation for growth of *Mycoplasma* shall be made at a magnification of no less than 300×. If the Dienes Methylene Blue-Azure dye or an equivalent staining procedure is used, no less than a one square cm. plug of the agar shall be excised from the inoculated area and examined for the presence of *Mycoplasma*. The presence of the *Mycoplasma* shall be determined by comparison of the growth obtained from the test samples with that of the control cultures, with respect to typical colonial and microscopic morphology. The virus pool is satisfactory for vaccine manufacture if none of the tests on the samples show evidence of the presence of *Mycoplasma*.

Subpart E—Hepatitis Requirements

§ 610.40 Test for hepatitis associated (Australia) antigen.

(a) *General.* Each donation of human blood, plasma, or serum to be used in preparing a biological product shall be tested for the presence of hepatitis associated (Australia) antigen. Such test shall be performed on blood, plasma, or serum taken from the donor at the time of donation or, for such material collected prior to the effective date of this section, upon removal from storage by the manufacturer. Only hepatitis associated antibody (anti-Australia antigen) licensed under this subchapter shall be used in performing the test and the test method(s) used shall be that for which the antibody product is specifically designed to be effective as recommended by the manufacturer in the package enclosure.

(b) *Restrictions on use*—(1) *Injectable biological products.* Blood, plasma, or serum that is reactive when tested for hepatitis associated (Australia) antigen shall not be used in manufacturing injectable biological products.

(2) *In vitro diagnostic biological products.* Blood, plasma, or serum that is reactive when tested for hepatitis associated (Australia) antigen may be used in manufacturing in vitro diagnostic biological products, provided that the package label of the biological products prepared from such blood, plasma, or serum conspicuously indicates that the product was prepared from material that was reactive when tested for hepatitis associated antigen and may transmit viral hepatitis.

§ 610.41 History of hepatitis associated (Australia) antigen.

A person testing positive, or known to have previously tested positive, for hepatitis associated (Australia) antigen may not serve as a donor of human blood, plasma, or serum to be used in preparing any injectable biological product, except that a person known to have previously tested positive for hepatitis associated (Australia) antigen may serve as a source of hepatitis associated antibody when such antibody is required for the manufacture of a licensed biological product provided such person meets the requirements of § 610.40 at the time of donation.

Subpart F—Dating Period Limitations

§ 610.50 Date of manufacture.

The date of manufacture shall be determined as follows:

(a) For products for which an official standard of potency is prescribed in either § 610.20 or § 610.21, or which are subject to official potency tests, the date of initiation by the manufacturer of the last valid potency test.

(b) For products which are not subject to official potency tests, (1) the date of removal from animals, (2) the date of extraction, (3) the date of solution, or (4) the date of cessation of growth, whichever is applicable.

§ 610.51 Periods of cold storage.

Except as otherwise provided in the regulations of this subchapter, products may be held in cold storage by the manufacturer as follows:

At a temperature not above 5°C.—1 year.
At a temperature not above 0°C.—2 years.

§ 610.52 Dating period.

The dating period for a combination of two or more products shall be no longer than the dating period of the component product with the shortest dating period. The dating period for a product shall begin on the date of manufacture, except that the dating period may begin on the date of issue from the manufacturer's cold storage, provided the product was maintained as prescribed in § 610.51. If held in the manufacturer's cold storage beyond the period prescribed, the dating period shall be reduced by a corresponding period.

§ 610.53 Dating periods for specific products.

The following dating periods are based on data relating to usage, clinical experience or laboratory tests that establish the period beyond which the product cannot be expected beyond reasonable doubt to yield its specific results and retain its safety, purity, and potency, provided the product is maintained at the recommended temperatures. The standards prescribed by the regulations in this subchapter, designed to insure continued safety, purity, and potency of the products, are based on the dating periods set forth below. Cold storage periods and temperatures prescribed in § 610.51 shall apply and outside labels shall recommend storage between 2° C. and 8° C., except when specifically provided otherwise. (Storage temperatures and storage periods are given in parentheses after the dating periods below when they differ from those specified in § 610.51.)

Adsorbed Anti-A Serum	One year.
Adenovirus and Influenza Virus Vaccines Combined Aluminum Hydroxide Adsorbed.	Six months (5° C., six months).
Adenovirus and Influenza Virus Vaccines Combined Aluminum Phosphate Adsorbed.	Six months (5° C., six months).
Adenovirus Vaccine	Six months (5° C., six months).
Aggregated Radio-Iodinated (I^{131}) Albumin (Human).	Thirty days. § 610.51 does not apply.
Allergenic Extracts	With 50 percent or more glycerin, three years (5° C., three years). With less than 50 percent glycerin, eighteen months (5° C., eighteen months). Products for which cold storage conditions are inappropriate, eighteen months, provided labeling recommends storage at no warmer than 30° C. § 610.51 does not apply. Powders and tablets, five years, provided labeling recommends storage at no warmer than 30° C. § 610.51 does not apply. Freeze dried products, five years (5° C., three years).
Allergenic Extracts, Alum Precipitated	Eighteen months (5° C., eighteen months).
Anthrax Vaccine, Adsorbed	One year (5° C., two years). § 610.51 does not apply.
Anti-A Blood Grouping Serum	*Liquid:* One year. *Dried:* Five years.

Anti-A, B Blood Grouping Serum	*Liquid:* One year. *Dried:* Five years.
Anti-B Blood Grouping Serum	*Liquid:* One year. *Dried:* Five years.
Anti-Di^a Serum (Anti-Diego)	One year.
Anti-Fy^a Serum (Anti-Duffy)	One year.
Anti-Fy^b Serum	One year.
Anti-Gr (Vw) Serum	One year.
Antihemophilic Factor (Human)	One year. § 610.51 does not apply.
Antihemophilic Globulin (Human)	One year.
Antihemophilic Plasma (Human)	Five years.
Anti-*Hemophilus influenzae* Type b Serum.	*Liquid:* Two years. *Dried:* Five years.
Anti-Human Chorionic Gonadotropic Serum.	One year. § 610.51 does not apply.
Anti-Human Serum	*Liquid:* One year. *Dried:* Five years.
Anti-I Serum	One year.
Anti-Influenza Virus Serum for the Hemagglutination Inhibition Test.	Two years.
Anti-Jk^a Serum (Anti-Kidd)	One year.
Anti-Jk^b Serum	One year.
Anti-Js^a Serum (Anti-Sutter)	One year.
Anti-k Serum (Anti-Cellano)	One year.
Anti-K Serum (Anti-Kell)	One year.
Anti-Kp^a Serum (Anti-Penney)	One year.
Anti-Kp^b and Anti-K Serum (Anti-Rautenberg and Anti-Kell).	One year.
Anti-Kp^b Serum (Anti-Rautenberg)	One year.
Anti-Le^a Serum (Anti-Lewis)	*Liquid:* One year. *Dried:* Five years.
Anti-Le^b Serum	*Liquid:* One year. *Dried:* Five years.
Anti-Lu^a Serum (Anti-Lutheran)	One year.
Anti-M Serum	One year.
Anti-M^g Serum	One year.
Anti-Mi^a Serum (Anti-Miltenberger)	One year.
Anti-N Serum	One year.
Anti-P Serum	One year.
Antirabies Serum	Two years.
Anti-Rh Typing Serum, Anti-hr$'$ (Anti-c).	One year.
Anti-Rh Typing Serum, Anti-hr$''$ (Anti-e).	One year.
Anti-Rh Typing Serum, Anti-hr^s (Anti-V).	One year.
Anti-Rh Typing Serum, Anti-rh$'$ (Anti-C).	*Liquid:* One year. *Dried:* Five years.
Anti-Rh Typing Serum, Anti-rh$''$ (Anti-E).	*Liquid:* One year. *Dried:* Five years.
Anti-Rh Typing Serum, Anti-Rh$_o$ (Anti-D).	*Liquid:* One year. *Dried:* Five years.
Anti-Rh Typing Serum, Anti-Rh$_o$$'$ (Anti-CD).	*Liquid:* One year. *Dried:* Five years.
Anti-Rh Typing Serum, Anti-Rh$_o$$''$ (Anti-DE).	One year.
Anti-Rh Typing Serum, Anti-Rh$_o$rh$'$rh$''$ (Anti-CDE).	One year.
Anti-Rh Typing Serum, Anti-Rh$_o$+ (Anti-D+D^u).	One year.
Anti-Rh Typing Serum, Anti-rh^w (Anti-C^w).	One year.
Anti-rh^w and Anti-K Serum (Anti-(C^w+Kell)).	One year.
Anti-s Serum	*Liquid:* One year. *Dried:* Five years.
Anti-S Serum	One year.
Antivenin (*Crotalidae*) Polyvalent	Five years with an initial 10 percent excess of potency, provided labeling recommends storage at no warmer than 37° C.
Antivenin (*Latrodectus mactans*)	Five years with an initial 10 percent excess of potency.
Antivenin (*Micrurus fulvius*)	Five years with an initial 10 percent excess of potency.
Anti-U Serum (Anti-Su)	One year.
Anti-Wr^a Serum (Anti-Wright)	One year.
B. histolyticus Antitoxin	Five years with an initial 20 percent excess of potency.
B. oedematiens Antitoxin	Five years with an initial 20 percent excess of potency.
B. sordellii Antitoxin	Five years with an initial 20 percent excess of potency.
BCG Vaccine	Six months (5° C., one year).
Blastomycin	Two years (5° C., one year).
Blood Group Specific Substances A and B.	Two years.
Blood Group Specific Substance A	Two years.
Blood Group Specific Substance B	Two years.
Botulism Antitoxin	Five years with an initial 20 percent excess of potency.
Chicken Pox Immune Serum (Human)	*Liquid:* One year. *Dried:* Five years.
Cholera Vaccine	Eighteen months (5° C., one year).
Cobra Venom with Silicic and Formic Acids.	Eighteen months (5° C., one year).
Cobra Venom Solution	Eighteen months (5° C., one year).
Coccidioidin	Three years (5° C., one year).
Collagenase	Eighteen months, provided labeling recommends storage at no warmer than 25° C. § 610.51 does not apply.
Cryoprecipitated Antihemophilic Factor (Human).	12 months from the date of collection of source blood, provided labeling recommends storage at not above −18° C. § 610.51 does not apply.
Diphtheria Antitoxin	*Liquid:* Five years with an initial 20 percent excess of potency. *Dried:* Five years with an initial 10 percent excess of potency.
Diphtheria and Tetanus Toxoids and Pertussis and Poliomyelitis Vaccines Adsorbed.	Four months (5° C., two months).
Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed and Poliomyelitis Vaccine.	(a) Four months (5° C., two months). (b) One year, provided the pertussis and poliomyelitis components unmixed when issued (5° C., one year).
Diphtheria and Tetanus Toxoids and Pertussis Vaccine.	Eighteen months (5° C., one year).
Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed.	Eighteen months (5° C., one year).
Diphtheria and Tetanus Toxoids and Poliomyelitis Vaccine.	One year (5° C., one year).

Diphtheria and Tetanus Toxoids	Two years (5° C., one year).
Diphtheria and Tetanus Toxoids Adsorbed.	Two years (5° C., one year).
Diphtheria Toxin for Schick Test	One year (5° C., one year).
Diphtheria Toxoid	Two years (5° C., one year).
Diphtheria Toxoid Adsorbed	Two years (5° C., one year).
Diphtheria Toxoid and Pertussis Vaccine	Eighteen months (5° C., one year).
Diphtheria Toxoid and Pertussis Vaccine Adsorbed.	Eighteen months (5° C., one year).
Dysentery Antitoxin, Shiga	Five years with an initial 20 percent excess of potency.
Equine Encephalomyelitis Vaccine (Eastern).	One year.
Equine Encephalomyelitis Vaccine (Western).	One year.
Fibrinogen (Human)	Five years.
Fibrinogen with Antihemophilic Factor (Human).	Five years.
Fibrinolysin (Human)	Two years.
Fibrinolysin and Desoxyribonuclease Combined (Bovine).	Three years, provided labeling recommends storage at no warmer than 30° C.
Fibrinolysin and Desoxyribonuclease Combined (Bovine) with Chloramphenical.	Three years, provided labeling recommends storage at no warmer than 30° C.
Gas Gangrene Polyvalent Antitoxin	Five years with an initial 20 percent excess of potency.
Haemophilus influenzae Typing Serum	One year.
Hepatitis Associated Antibody (Anti-Australia Antigen)	Six months (5° C., 6 months) except Iodinated (^{125}I) products.
	Iodinated (^{125}I) products, 45 days. § 610.51 does not apply.
Histamine Azoprotein	Two years.
Histoplasmin	Two years (5° C., one year).
Immune Serum Globulin (Human)	Three years (5° C., three years).
Influenza Virus Hemagglutinating Antigen.	Two years (5° C., one year).
Influenza Virus Vaccine	Eighteen months (5° C., one year).
Leukocyte Typing Serum (Dried)	Two years.
Anti-HL-A 1	Two years.
Anti-HL-A 2	Two years.
Anti-HL-A 3	Two years.
Anti-HL-A 5	Two years.
Anti-HL-A 7	Two years.
Anti-HL-A 8	Two years.
Anti-HL-A 9	Two years.
Anti-HL-A 10	Two years.
Anti-HL-A 11	Two years.
Anti-HL-A 12	Two years.
Anti-HL-A 13	Two years.
Lymphogranuloma Venereum Antigen	One year (5° C., one year).
Measles Immune Serum (Human)	*Liquid:* One year.
	Dried: Five years.
Measles Immune Globulin (Human)	Three years (5° C., three years).
Measles-Smallpox Vaccine, Live	One year. § 610.51 does not apply.
Measles Virus Vaccine, Inactivated	One year (5° C., one year).
Measles Virus Vaccine, Live, Attenuated	One year. § 610.51 does not apply.
Modified Plasma (Bovine)	Twenty months. § 610.51 does not apply.
Mumps Immune Serum (Human)	*Liquid:* One year.
	Dried: Five years.
Mumps Immune Globulin (Human)	Three years from date the dried or frozen bulk product is placed in final solution (5° C., three years).
Mumps Skin Test Antigen	Eighteen months (5° C., one year).
Mumps Vaccine	Eighteen months (5° C., one year).
Mumps Virus Vaccine, Live	One year. § 610.51 does not apply.
Normal Bovine Serum	Five years.
Normal Horse Serum	Five years.
Normal Human Plasma	*Liquid:* Three years provided product is maintained between 15° and 30° C., and labeling recommends storage between 15° and 30° C. § 610.51 does not apply.
	Dried: Seven years provided labeling recommends storage not above 37° C. § 610.51 does not apply.
Normal Human Serum	*Liquid:* Eighteen months.
	Dried: Five years.
	Frozen: Three years, provided labeling recommends storage at no warmer than −18° C. § 610.51 does not apply.
	Melted: One year after the date of melting. § 610.51 does not apply.
Normal Rabbit Serum	Five years.
Normal Serum Albumin (Human)	(a) Five years, provided labeling recommends storage between 2° and 10° C. (5° C., three years).
	or
	(b) Three years, provided labeling recommends storage at room temperature, no warmer than 37° C. (5° C., three years).
	or
	(c) Ten years, if in an hermetically sealed metal container and provided labeling recommends storage between 2° and 10° C. § 610.51 does not apply.
Oxophenarsine Hydrochloride	Three years (5° C., one year).
Perfringens Antitoxin	Five years with an initial 20 percent excess of potency.
Pertussis Immune Globulin (Human)	Three years from date the dried or frozen bulk product is placed in final solution (5° C., three years).
Pertussis Immune Serum (Human)	*Liquid:* One year.
	Dried: Five years.
Pertussis Vaccine	Eighteen months (5° C., one year).
Plague Vaccine	Eighteen months (5° C., one year).
Plasma Protein Fraction (Human)	(a) Five years (5° C., one year).
	(b) Three years, provided labeling recommends storage at no warmer than 30° C. (5° C., one year).
Pneumococcus Typing Serum	One year.
Poliomyelitis Immune Globulin (Human).	Three years (5° C., three years).
Poliomyelitis Vaccine	One year (5° C., one year).
Poliomyelitis Vaccine Adsorbed	One year (5° C., one year).
Poliovirus Vaccine, Live, Oral, Trivalent	*Frozen:* One year, provided labeling recommends storage at a temperature which will maintain ice continuously in a solid state (−10° C., one year).
	Liquid: Thirty days, provided labeling recommends storage between 2° and 8° C. § 610.51 does not apply.
Poliovirus Vaccine, Live, Oral, Type I	*Frozen:* One year, provided labeling recommends storage at a temperature which will maintain ice continuously in a solid state (−10° C.,

	one year). *Liquid:* Thirty days, provided labeling recommends storage between 2° and 8° C. § 610.51 does not apply.
Poliovirus Vaccine, Live, Oral, Type II	*Frozen:* One year, provided labeling recommends storage at a temperature which will maintain ice continuously in a solid state (−10° C., one year). *Liquid:* Thirty days, provided labeling recommends storage between 2° and 8° C. § 610.51 does not apply.
Poliovirus Vaccine, Live, Oral, Type III	*Frozen:* One year, provided labeling recommends storage at a temperature which will maintain ice continuously in a solid state (−10° C., one year). *Liquid:* Thirty days, provided labeling recommends storage between 2° and 8° C. § 610.51 does not apply.
Polyvalent bacterial antigens with "No U.S. Standard of Potency."	*Liquid:* Eighteen months (5° C., one year). *Dried:* Five years (5° C., one year).
Polyvalent bacterial vaccines with "No U.S. Standard of Potency."	*Liquid:* Eighteen months (5° C., one year). *Dried:* Five years (5° C., one year).
Polyvalent modified bacterial antigens with "No U.S. Standard of Potency."	*Liquid:* Eighteen months (5° C., one year). *Dried:* Five years (5° C., one year).
Polyvalent sensitized bacterial vaccines with "No U.S. Standard of Potency."	*Liquid:* Eighteen months (5° C., one year). *Dried:* Five years (5° C., one year).
Profibrinolysin (Human)	Two years.
Pseudomonas Polysaccharide	Eighteen months.
Q Fever Vaccine	One year (5° C., one year).
Rabies Vaccine	*Liquid:* Six months (5° C., three months). *Dried:* Eighteen months.
Radio-Chromated (Cr^{51}) Serum Albumin (Human).	Sixty days from the date chromium is added. § 610.51 does not apply.
Radio-Iodinated (I^{125}) Serum Albumin (Human).	120 days from date iodination is completed. § 610.51 does not apply.
Radio-Iodinated (I^{131}) Serum Albumin (Human).	Thirty days from date iodination is completed. § 610.51 does not apply.
Reagent Red Blood Cells (Human)	Twenty-one days. § 610.51 does not apply.
Reagent Blood Group Specific Substances A and B.	Two years.
Red Blood Cells (Human)	(a) Twenty-one days from date of collection of source blood, provided labeling recommends storage between 1° and 10° C. and the hermetic seal is not broken during processing. § 610.51 does not apply. Twenty-four hours after plasma removal, provided labeling recommends storage between 1° and 10° C., if the hermetic seal is broken during processing. § 610.51 does not apply. (b) *Frozen:* Three years, provided labeling recommends storage at −65° C. or colder. Twenty-four hours after removal from storage at −65° C. or colder, provided labeling recommends storage between 1° and 10° C. § 610.51 does not apply.
Resuspended Red Blood Cells (Human)	Ten days. § 610.51 does not apply.
Rh$_0$ (D) Immune Globulin (Human)	Six months (5° C., six months).
Rocky Mountain Spotted Fever Vaccine	Eighteen months (5° C., one year).
Rubella Virus Vaccine, Live	One year. § 610.51 does not apply.
Russell Viper Venom	Five years.
Scarlet Fever Immune Serum (Human)	*Liquid:* One year. *Dried:* Five years.
Scarlet Fever Streptococcus Toxin for Dick Test.	One year (5° C., one year).
Scarlet Fever Streptococcus Toxin for Immunization.	One year (5° C., one year).
Shick Test Control	One year (5° C., one year).
Single Donor Plasma (Human)	(a) Five years, provided labeling recommends storage at not above −18° C. § 610.51 does not apply. (b) If used in coagulation defects, one year, provided labeling recommends storage at not above −18° C. § 610.51 does not apply.
Smallpox Vaccine	*Liquid:* Three months, provided labeling recommends storage at no warmer than 0° C. (−10° C., nine months, if product is maintained as glycerinated or equivalent vaccine in bulk or final containers). *Dried:* Eighteen months (5° C., six months).
Source Plasma (Human)	In lieu of an expiration date, the collection date shall appear on the label, as prescribed in § 640.69(e)(4) of this chapter.
Staphylococcus Antitoxin	Five years with an initial 20 percent excess of potency.
Staphylococcus Toxoid	Two years (5° C., one year).
Staphylococcus Toxoid and Bacterial Antigen made from Staphylococcus (Albus and Aureus).	Eighteen months (5° C., one year).
Staphylococcus Toxoid and Bacterial Vaccine made from Staphylococcus (Aureus).	Eighteen months (5° C., one year).
Staphylococcus Toxoid, Streptococcus Toxin, and Bacterial Vaccine made from Staphylococcus (Aureus), Streptococcus (Hemolyticus), Pneumococcus, *Hemophilus influenzae.*	One year (5° C., one year).
Streptococcus Erythrogenic Toxin	One year (5° C., one year).
Streptokinase	Eighteen months.
Streptokinase-Streptodornase	*Dried:* Two years (5° C., one year). *Tablets:* Eighteen months, provided labeling recommends storage at no warmer than 30° C. (5° C., six months).
Tetanus and Diphtheria Toxoids Adsorbed (For Adult Use).	Two years (5° C., one year).
Tetanus and Gas Gangrene Polyvalent Antitoxin.	Five years with an initial 20 percent excess of potency.
Tetanus Immune Globulin (Human)	Three years with an initial 10 percent excess of potency (5° C., one year).
Tetanus Antitoxin	*Liquid:* Five years with an initial 20 percent excess of potency. *Dried:* Five years with an initial 10 percent excess of potency.
Tetanus Toxoid	Two years (5° C., one year).
Tetanus Toxoid Adsorbed	Two years (5° C., one year).
Tetanus Toxoid and Pertussis Vaccine	Eighteen months (5° C., one year).
Thrombin	Three years.
Trichinella Extract	Eighteen months (5° C., one year).

Tuberculin	*Old, concentrated:* Containing 50 percent glycerin, five years. *Old diluted:* One year. *Purified Protein Derivative, concentrated:* Two years containing 50 percent glycerin (5° C., one year). *Purified Protein Derivative, diluted:* One year. § 610.51 does not apply. *Purified Protein Derivative, dried:* Five years. *Old, dried on multiple puncture device:* Two years, provided labeling recommends storage at no warmer than 30° C. (30° C., one year).
Typhoid and Paratyphoid Vaccine	Eighteen months (5° C., one year).
Typhoid Vaccine	Eighteen months (5° C., one year).
Typhus Vaccine	Eighteen months (5° C., one year).
Vibrion Septique Antitoxin	Five years with an initial 20 percent excess of potency.
Whole Blood (Human) collected in	(a) ACD solution—Twenty-one days, provided labeling recommends storage between 1° and 10° C. § 610.51 does not apply. (b) Heparin solution—Forty-eight hours, provided labeling recommends storage between 1° and 10° C. § 610.51 does not apply. (c) CPD solution—Twenty-one days, provided labeling recommends storage between 1° and 10° C. § 610.51 does not apply.
Yellow Fever Vaccine	One year, provided labeling recommends storage at no warmer than 5° C. (−20° C., one year).

Subpart G—Labeling Standards

§ 610.60 Container label.

(a) *Full label.* The following items shall appear on the label affixed to each container of a product capable of bearing a full label:

(1) The proper name of the product;

(2) The name, address, and license number of manufacturer;

(3) The lot number or other lot identification;

(4) The expiration date;

(5) The recommended individual dose, for multiple dose containers.

(b) *Package label information.* If the container is not enclosed in a package, all the items required for a package label shall appear on the container label.

(c) *Partial label.* If the container is capable of bearing only a partial label, the container shall show as a minimum the name (expressed either as the proper or common name), the lot number or other lot identification and the name of the manufacturer; in addition, for multiple dose containers, the recommended individual dose. Containers bearing partial labels shall be placed in a package which bears all the items required for a package label.

(d) *No container label.* If the container is incapable of bearing any label, the items required for a container label may be omitted, provided the container is placed in a package which bears all the items required for a package label.

(e) *Visual inspection.* When the label has been affixed to the container a sufficient area of the container shall remain uncovered for its full length or circumference to permit inspection of the contents.

§ 610.61 Package label.

The following items shall appear on the label affixed to each package containing a product:

(a) The proper name of the product;

(b) The name, address, and license number of manufacturer;

(c) The lot number or other lot identification;

(d) The expiration date;

(e) The preservative used and its concentration, or if no preservative is used and the absence of a preservative is a safety factor, the words "no preservative";

(f) The number of containers, if more than one;

(g) The amount of product in the container expressed as (1) the number of doses, (2) volume, (3) units of potency, (4) weight, (5) equivalent volume (for dried product to be reconstituted), or (6) such combination of the foregoing as needed for an accurate description of the contents, whichever is applicable;

(h) The recommended storage temperature;

(i) The words "Shake Well", "Do not Freeze" or the equivalent, as well as other instructions, when indicated by the character of the product;

(j) The recommended individual dose if the enclosed container(s) is a multiple-dose container;

(k) The route of administration recommended, or reference to such directions in an enclosed circular;

(l) Known sensitizing substances, or reference to an enclosed circular containing appropriate information;

(m) The type and calculated amount of antibiotics added during manufacture;

(n) The inactive ingredients when a safety factor, or reference to an enclosed circular containing appropriate information;

(o) The adjuvant, if present;

(p) The source of the product when a factor in safe administration;

(q) The identity of each microorganism used in manufacture, and, where applicable, the production medium and the method of inactivation, or reference to an enclosed circular containing appropriate information;

(r) Minimum potency of product expressed in terms of official standard of potency or, if potency is a factor and no U.S. standard of potency has been prescribed, the words "No U.S. standard of potency."

(s) For injectable products prepared from human blood, plasma, or serum, indication that the product was prepared from blood that was nonreactive when tested for hepatitis associated (Australia) antigen. In lieu of inclusion on the package label, such information may be included in a circular enclosed with the package.

§ 610.62 Proper name; package label; legible type.

(a) *Position.* The proper name of the product on the package label shall be placed above any trademark or trade name identifying the product and symmetrically arranged with respect to other printing on the label.

(b) *Prominence.* The point size and typeface of the proper name shall be at least as prominent as the point size and typeface used in designating the trademark and trade name. The contrast in color value between the proper name and the background shall be at least as great as the color value between the trademark and trade name and the background. Typography, layout, contrast, and other printing features shall not be used in a manner that will affect adversely the prominence of the proper name.

(c) *Legible type.* All items required to be on the container label and package label shall be in legible type. "Legible type" is type of a size and character which can be read with ease when held in a good light and with normal vision.

§ 610.63 Divided manufacturing responsibility to be shown.

If two or more establishments participate in the manufacture of a product, the name, address, and license number of each must appear on the package label, and on the label of the container if capable of bearing a full label.

§ 610.64 Name of selling agent or distributor.

The name and address of the selling agent or distributor of a product may appear on the label under the designation of "selling agent" or "distributor" provided that the name and address of the manufacturer is given precedence in prominence.

§ 610.65 Products for export.

Labels on packages or containers of products for export may be adapted to meet specific requirements of the regulations of the country to which the product is to be exported provided that in all such cases the minimum label requirements prescribed in § 610.60 are observed.

PART 620—ADDITIONAL STANDARDS FOR BACTERIAL PRODUCTS

Subpart A—Pertussis Vaccine

Sec.

AUTHORITY: Sec. 215, 58 Stat. 690, as amended; 42 U.S.C. 216. Sec. 351, 58 Stat. 702, as amended; 42 U.S.C. 262, unless otherwise noted.

CROSS REFERENCES.—For U.S. Customs Service regulations relating to viruses, serums, and toxins, see 19 CFR 12.21–12.23. For U.S. Postal Service regulations relating to the admissibility to the United States mails see 39 CFR Parts 124 and 125, esp. § 125.2.

Subpart A—Pertussis Vaccine

§ 620.1 Pertussis Vaccine.

The proper name of this product shall be "Pertussis Vaccine", which shall be an aqueous preparation of either killed whole *Bordetella pertussis* bacteria or a fraction of *Bordetella pertussis* bacteria. The vaccine may be precipitated or adsorbed and may be combined with other antigens.

§ 620.2 Production.

(a) *Propagation of bacteria.* Human blood shall not be used in culture medium for propagating bacteria either for seed or for vaccine. The culture medium for propagating bacteria for vaccine shall not contain ingredients known to be capable of producing allergenic effects in human subjects, except blood or blood products from lower animals other than the horse. When blood or a blood product is used, it shall be removed by washing the harvested bacteria. The bacterial concentrate shall be free of extraneous bacteria, fungi, and yeasts, as demonstrated by microscopic examination and cultural methods.

(b) *Bacterial content.* (1) The opacity of the bacterial concentrate shall be determined in terms of the U.S. Opacity Standard not later than 2 weeks after the harvest of the bacteria and before any treatment capable of altering the opacity of the bacterial concentrate.

(2) The total immunizing dose of a vaccine prepared with whole bacteria shall contain (i) in the case of nonadsorbed vaccine no more bacteria than the equivalent of 60 opacity units and (ii) in the case of adsorbed vaccine no more than the equivalent of 48 opacity units.

(c) *Detoxification.* After removing a sample for purity testing, the bacteria shall be killed and detoxified either (1) by heating, (2) by addition of a chemical agent and appropriate aging, or (3) by any combination of the stated procedures. The procedure used shall be one that has been shown to have no adverse effect on required safety, purity, and potency.

(d) *Preservative.* The vaccine shall contain a preservative.

§ 620.3 U.S. Standard preparations.

(a) The U.S. Standard Pertussis Vaccine shall be used for determining the potency of Pertussis Vaccine.

(b) The U.S. Opacity Standard shall be used in estimating the bacterial content of the vaccine and of the challenge culture.

§ 620.4 Potency test.

The number of protective units of the total human immunizing dose shall be estimated for each lot of vaccine from the results of simultaneous intracerebral mouse protection tests of the vaccine under test and the U.S. Standard Pertussis Vaccine. The potency test shall be performed as follows:

(a) *Mice.* Healthy mice shall be used, all from a single strain and of the same sex, or an equal number of each sex in each group, with individual weight varying no more than 4 grams in a single test. In no event shall any of the mice weigh less than 10 grams or more than 20 grams. A system of randomization shall be used to distribute the mice into the groups, with respect to shelf position and to determine the order of challenge. There shall be at least 3 groups consisting of no less than 16 mice each, for each vaccine. In addition, there shall be at least 4 groups consisting of no less than 10 mice each, for control purposes: one group for the challenge dose and 3 groups for titrating the virulence of the challenge dose.

(b) *Vaccination.* (1) Five-fold serial dilutions of the vaccine to be tested and of the standard vaccine shall be made in 0.85 percent sodium chloride solution. The dilutions of the vaccine under test shall have the same protective unitage, based on an estimate of 12 units per total human immunizing dose, as the unitage of the corresponding dilution of the standard vaccine. Each mouse in each group for vaccination shall be injected intraperitoneally with 0.5 ml. of the appropriate dilution.

(2) The interval between vaccination and challenge shall be 14 to 17 days. At least 87.5 percent of the mice in each group shall survive the period between vaccination and challenge and each mouse challenged shall appear healthy.

(c) *The challenge.* (1) The challenge culture of *Bordetella pertussis* for each test shall be taken from a batch of cultures which have been maintained by a method, such as freeze-drying, that retains constancy of virulence.

(2) The challenge and virulence titration doses shall be prepared as follows: The bacteria shall be harvested from a 20 to 24 hour culture grown on Bordet-Gengou medium seeded from a rapidly growing culture less than 48 hours old and uniformly suspended in a solution containing 1.0 percent casein peptone and about 0.6 percent sodium chloride at pH 7.1±0.1. The suspension, freed from agar particles and clumps of bacteria, and adjusted to an opacity of 10 units, shall be diluted in the solution used for suspending the bacteria, to provide in a volume of 0.03 ml. (i) a challenge dose of 0.0001 opacity units (1: 3000) and (ii) virulence titration doses of $\frac{1}{50}$, $\frac{1}{250}$ and $\frac{1}{1250}$ respectively of the challenge dose.

(3) Each vaccinated mouse shall be injected intracerebrally with the challenge dose. The four groups of control mice shall be injected intracerebrally with the challenge dose and its three dilutions, respectively. The challenge-dose control mice shall be injected last. The interval between the removal of the bacteria from the culture medium and the injection of the last mouse shall not exceed 2½ hours.

(d) *Recording the results.* The mice shall be observed for 14 days. Mice dying within 72 hours after challenge shall be excluded from the test. Records shall be maintained of the number of mice that die after 72 hours and of the number of mice showing both paralysis and enlargement of the head at the end of 14 days. All mice that show both paralysis and enlargement of the head shall be considered as deaths for the purposes of determining the ED_{50}.

(e) *Validity of the test.* The test shall be valid provided (1) the ED_{50} of the vaccine under test and the standard vaccine is between the largest and smallest vaccinating doses; (2) the limits of one standard deviation of each ED_{50} fall within the range of 64 percent to 156 percent; (3) the protective response is graded in relation to the vaccinating doses; (4) the dose-response curves of the vaccine under test and the standard vaccine are parallel; (5) the challenge dose contains approximately 200 LD_{50}; (6) the LD_{50} contains no more than 300 colony forming units; and (7) the $\frac{1}{1250}$ dilution of the challenge dose contains no less than 10 and no more than 50 colony forming units.

(f) *Estimate of the potency.* The ED_{50} of each vaccine shall be calculated by a method that provides an estimate of the standard deviation. The protective unit value per total human immunizing dose of the vaccine under test shall be calculated in terms of the unit value of the standard vaccine.

(g) *Potency requirements.* The vaccine shall have a potency of 12 units per total human immunizing dose based upon either a single test estimate of no less than 8 units or a two-, three- or four-test geometric mean estimate of no less than 9.6, 10.8, or 12 units, respectively, except that for the vaccine in a multiple antigen product containing Poliomyelitis Vaccine, the estimate shall be no less than 14 units. In no event shall the estimate be more than 36 units.

(h) *Test design variation.* Variations in the design of the potency test may be permitted providing the results are demonstrated to be of equal or greater precision.

§ 620.5 Mouse toxicity test.

The final vaccine shall be demonstrated to be free from toxicity by the following test:

A group of no less than 10 mice, each mouse weighing 14 to 16 grams, shall have free access to food and water for no less than 2 hours before injection. The group weight of the mice shall be determined immediately prior to injection. Each mouse shall be injected intraperitoneally with a test dose of one-half of the largest recommended single human dose of the final vaccine in a volume of no less than 0.5 ml. nor more than 0.75 ml. The group weight of the mice shall be determined at the end of 72 hours and at the end of 7 days after injection. At the end of 72 hours the average weight per mouse may be no less than the average weight per mouse immediately preceding the injection; at the end of 7 days the average weight gain per mouse may be no less than 3.0 grams; and at the end of 7 days there may be vaccine-related deaths of no more than 5 percent of the total number of mice in all the toxicity tests performed.

§ 620.6 General requirements.

(a) *Safety.* The safety test prescribed in § 610.11 of this chapter shall be made on final container material except that the test shall consist of the intraperitoneal injection of no less than one-half of the largest individual human dose recommended into each of at least two mice weighing approximately 20 grams each, and either the intraperitoneal injection of no less than 3 times the largest individual human dose recommended or the subcutaneous injection of 5.0 ml., into each of at least two guinea pigs weighing approximately 350 grams each. The last sentence of § 610.11 of this chapter does not apply.

(b) *Dose.* These additional standards are based on a single injection of 0.5 ml., 1.0 ml., or 1.5 ml., and a total human immunizing dose of three single injections of a nonadsorbed vaccine, and two or three single injections of an adsorbed vaccine.

(c) *Product characteristics.* Recommendations shall be made through appropriate labeling that the product after issue should not be frozen and should be well shaken immediately prior to use.

(d) *Labeling.* In addition to the items required by other applicable labeling provisions of this part, the package label shall give the following information:

1. For a vaccine containing a precipitant or an adsorbent, the word "Adsorbed" shall follow the proper name in the same style of type and prominence as the proper name.
2. The total immunizing dose contains 12 units of pertussis vaccine.

(e) *Multiple antigen products.* The Pertussis Vaccine component of multiple antigen products shall be manufactured pursuant to these additional standards, except that the mouse toxicity test (§ 620.5) and the potency test (§ 620.4) shall be performed on the multiple antigen product.

(f) *Adsorbed vaccines.* Only aluminum compound reagents shall be introduced into the product to cause precipitation or adsorption of either Pertussis Vaccine or other antigens incorporated with Pertussis Vaccine.

(g) *Freezing prohibition.* Pertussis Vaccine and multiple antigen products of which Pertussis Vaccine is a component shall not be frozen at any time during storage.

(h) *Samples and protocols.* For each lot of vaccine, the following material shall be submitted to the Director, Bureau of Biologics, Food and Drug Administration, Building 29A, 9000 Rockville Pike, Bethesda, MD 20014.

(1) A sample of no less than 20 milliliters of the final product for pertussis vaccine testing.

(2) Protocols showing summaries of the manufacturing processes and the results of all mouse toxicity (§ 620.5) and potency (§ 620.4) tests performed.

§ 620.7 Equivalent methods.

Modification of any particular manufacturing method or process or the conditions under which it is conducted as set forth in the additional standards relating to Pertussis Vaccine shall be permitted whenever the manufacturer presents evidence that demonstrates the modification will provide assurances of the safety, purity, and potency of the vaccine that are equal to or greater than the assurances provided by such standards, and the Commissioner of Food and Drugs so finds and makes such finding a matter of official record.

Subpart B—Typhoid Vaccine

§ 620.10 Typhoid Vaccine.

The proper name of this product shall be Typhoid Vaccine which shall be an aqueous or dried preparation of killed *Salmonella typhosa* bacteria.

§ 620.11 Production.

(a) *Strain of bacteria.* Strain Ty 2 of *Salmonella typhosa* shall be used in the manufacture of Typhoid Vaccine.

(b) *Propagation of bacteria.* The culture medium for propagation of *S. typhosa* shall not contain ingredients known to be capable of producing allergenic effects in human subjects. The harvested bacteria shall be free of extraneous bacteria, fungi and yeasts, as demonstrated by microscopic examination and cultural methods.

(c) *Bacterial content.* (1) The number of bacteria in the concentrate of harvested bacteria shall be estimated not later than 2 weeks after harvest and before any treatment capable of altering the accuracy of the estimate.

(2) The number of *S. typhosa* bacteria in the vaccine shall not exceed 10^9 per ml.

(d) *Nitrogen content.* The total nitrogen content of the vaccine shall not exceed 0.035 mg./ml. for nonextracted bacteria preparations and shall not exceed 0.023 mg./ml. for acetone-extracted bacteria preparations.

(e) *Preservative.* Aqueous vaccine and the solution for reconstitution supplied with dried vaccine shall contain a preservative. Dried vaccine shall not contain a preservative.

§ 620.12 U.S. Standard preparations.

(a) The U.S. Standard Typhoid Vaccine shall be used for determining the potency of Typhoid Vaccine.

(b) The U.S. Opacity Standard shall be used to adjust the opacity of the suspension from which the challenge culture is prepared.

§ 620.13 Potency test.

The number of potency units per milliliter shall be estimated for each lot of vaccine from the results of simultaneous mouse protection tests of the vaccine under test and of the U.S. Standard Typhoid Vaccine. The test shall be performed as follows:

(a) *Mice.* Healthy mice shall be used, all from a single strain and of the same sex, or an equal number of each sex in each group, with individual weights between 13 and 16 grams. A system of randomization shall be used to distribute the mice into the groups, with respect to shelf position and to determine the order of challenge. There shall be at least three groups consisting of no less than 16 mice each, for each vaccine. In addition, there shall be at least four groups consisting of no less than 10 mice each, for control purposes; one group for the challenge dose and three groups for titrating the virulence of the challenge dose.

(b) *Inoculation of vaccine.* (1) Serial dilutions, no greater than 5-fold, of the vaccine to be tested and of the standard vaccine shall be made in saline (0.85 percent sodium chloride solution). The mid-dilution of each vaccine shall contain that amount of vaccine which will afford protection to approximately 50 percent of the mice. Each mouse in each group for inoculation shall be injected intraperitoneally with 0.5 ml. of the appropriate dilution.

(2) The interval between inoculation of the vaccine and challenge shall be no less than 7 days nor more than 14 days. At least 87.5 percent of the mice in each group shall survive the period between vaccine inoculation and challenge and each mouse challenged shall appear healthy.

(c) *The challenge.* (1) The challenge culture of Strain Ty 2 of *S. typhosa* for each test shall be taken from a batch of cultures maintained by a method, such as freeze-drying, that retains constancy of virulence.

(2) The challenge and virulence titration doses shall be prepared as follows: The bacteria shall be harvested from a 5- to 6-hour culture grown at 36°±1° C. on a nutrient agar medium which shall have been seeded from a 16- to 20-hour culture grown at 36°±1° C. on a nutrient agar medium, and the harvested bacteria then shall be uniformly suspended in saline. The suspension, freed from agar particles and clumps of bacteria and adjusted to an opacity of 10 units, shall be diluted in saline by 10-fold increments. The suspensions for the challenge and virulence titration doses shall be put into a sterile gastric mucin preparation. The challenge suspension shall be prepared from whichever bacterial dilution provides about 1,000 colony forming units for an 0.5 ml. challenge dose. The virulence titration suspensions shall be 10^1, 10^2, and 10^3 dilutions respectively of the challenge suspension.

(3) Each mouse inoculated with vaccine shall be injected intraperitoneally

with an 0.5 ml. dose of the challenge suspension. Each mouse in the four groups of control mice shall be injected intraperitoneally with an 0.5 ml. dose of the challenge suspension and its three dilutions, respectively. The challenge dose control mice shall be injected last. The interval between removal of the bacteria from the culture medium and the injection of the last mouse shall not exceed 2½ hours.

(d) *Recording the results.* The mice shall be observed daily for 3 days. A record shall be maintained of the number of mice that die. A record of the number of mice that survive shall be made at the end of the observation period.

(e) *Validity of the test.* The test is valid provided: (1) the ED_{50} of the vaccine under test and the Standard Vaccine is between the largest and smallest doses inoculated into the mice; (2) the limits of one standard deviation of the ED_{50} of each vaccine fall within the range of 61 percent to 163 percent; (3) a graded protective response is obtained in relation to the vaccine dilutions; (4) the dose response curves of the vaccine under test and the standard vaccine are parallel; (5) the challenge dose contains approximately 1,000 colony forming units; and (6) the LD_{50} of the challenge dose contains no more than 10 colony forming units.

(f) *Repeat tests.* If the test does not meet the criteria prescribed in paragraph (e) of this section, repeat tests may be performed, and the combined results of all tests shall meet the paragraph (e) criteria, except that the limits of one standard deviation of the ED_{50} shall be reduced in proportion to the total number of mice in a test group. Tests established as invalid pursuant to § 610.1 of this chapter may be disregarded.

(g) *Estimate of the potency.* The ED_{50} of each vaccine shall be calculated by a method that provides an estimate of the standard deviation. The protective unit value per milliliter of the vaccine under test shall be calculated in terms of the unit value of the standard vaccine.

(h) *Potency requirements.* The vaccine shall have a potency of 8 units per milliliter. Variations in potency unit estimates are acceptable provided the estimate is not less than 5.0 units per milliliter.

§ 620.14 General requirements.

(a) *Dose.* These standards are based on a human adult dose of 0.5 ml. for a single injection and a total immunizing dose of two injections of 0.5 ml. given at appropriate intervals.

(b) *Labeling.* In addition to the items required by other applicable labeling provisions of this subchapter, the package label shall state that the vaccine contains 8 units per milliliter.

(c) *Samples; protocols; official release.* For each lot of vaccine, the following material shall be submitted to the Director, Bureau of Biologics, Food and Drug Administration, Building 29A, 9000 Rockville Pike, Bethesda, MD 20014.

(1) A sample of no less than 40 ml. of the product distributed in no less than four containers.

(2) A protocol which consists of a summary of the history of manufacture of each lot including all results of each test for which test results are requested by the Director, Bureau of Biologics.

The product shall not be issued by the manufacturer until notification of official release is received from the Director, Bureau of Biologics, for each filling lot of dried vaccine and for each bulk lot of aqueous vaccine.

§ 620.15 Equivalent methods.

Modification of any particular manufacturing method or process or the conditions under which it is conducted as set forth in the additional standards relating to Typhoid Vaccine, shall be permitted whenever the manufacturer presents evidence that demonstrates the modification will provide assurances of the safety, purity, and potency of the vaccine that are equal to or greater than the assurances provided by such standards, and the Commissioner of Food and Drugs, so finds and makes such finding a matter of official record.

Subpart C—Anthrax Vaccine, Adsorbed

§ 621.20 Anthrax Vaccine, Adsorbed.

The proper name of this product shall be Anthrax Vaccine, Adsorbed, which shall consist of an aqueous preparation of a fraction of *Bacillus anthracis* which contains the protective antigen adsorbed on aluminum hydroxide.

§ 620.21 Production.

(a) *Strain of bacteria.* A nonencapsulated, nonproteolytic, avirulent strain of *Bacillus anthracis* shall be used in the manufacture of anthrax vaccine.

(b) *Medium.* A chemically defined medium shall be used for the propagation of *Bacillus anthracis* which has protective-antigen promoting properties that are no less effective than the protective-antigen promoting properties of the Puziss and Wright 1095 medium as set forth in U.S. Patent No. 3,208,909, issued September 28, 1965, which patent is hereby incorporated by reference and deemed published herein. U.S. Patent No. 3,208,909 has been assigned to the Federal Government and copies will be provided to persons affected by the provisions of this subchapter upon request to the Director, Bureau of Biologics, or to the appropriate Information Center Officer listed in 45 CFR, Part 5. Copies also may be obtained upon request from the U.S. Patent Office, Washington, DC. The medium shall not contain ingredients known to be capable of producing allergenic effects in human subjects.

(c) *Propagation of bacteria.* The medium shall be inoculated with a 24-hour old vegetative culture seeded from a stock suspension of spores. The propagation culture, flushed with nitrogen, shall be incubated at 37° C.±1.0° C., agitated for approximately 27 hours, cooled to about 20° C., the pH adjusted to 8.0±0.1 and then filtered through a sterilizing filter(s) using nitrogen gas under pressure.

(d) *Adsorption of the protective antigen.* The sterile filtrate shall be adsorbed on sterile aluminum hydroxide gel and the recovered precipitate shall be resuspended and diluted in sterile 0.85 percent sodium chloride solution.

§ 620.22 U.S. Reference preparation.

The U.S. Reference Anthrax Vaccine distributed by the Bureau of Biologics shall be used for determining the potency of anthrax vaccine.

§ 620.23 Potency test.

The potency of each lot of vaccine shall be estimated from the results of simultaneous tests of the vaccine under test and the U.S. Reference Anthrax Vaccine. The test shall be performed as follows:

(a) *Guinea pigs.* Healthy guinea pigs shall be used, all from a single strain and of the same sex, or an equal number of each sex in each group, with individual weights between 325 and 350 grams. The diet of the guinea pigs shall be supplemented with vitamin C throughout the test period. At least three groups of no less than eight guinea pigs shall be used for each vaccine and at least one group of four guinea pigs shall be used for the challenge control.

(b) *Vaccination.* Serial dilutions, not greater than three-fold, of each vaccine shall be made in 0.85 percent sodium chloride solution. The mid-dilution of the vaccine under test shall contain that amount of vaccine which will afford protection to approximately 50 percent of the guinea pigs in the group vaccinated with that dilution. Each guinea pig in the test and reference vaccine groups shall be injected subcutaneously with 0.5 ml. of the appropriate dilution on the left side of the abdomen and about 2 cm. from the midline. The interval between vaccination and challenge shall be 14 days.

(c) *The challenge.* Each vaccinated and control guinea pig shall be injected intracutaneously on the right side of the abdomen with 0.1 ml. of a spore suspension of the virulent Vollum strain of *Bacillus anthracis* diluted in sterile distilled water to contain 10,000 spores per milliliter.

(d) *Recording the results.* The guinea pigs shall be observed daily for 10 days and the deaths recorded. The number of survivors shall be recorded at the end of the observation period.

(e) *Validity of the test.* The test shall be valid provided (1) the protective response to each vaccine is graded in relation to the amount of vaccine in the respective dilutions and (2) all control animals die within 10 days.

(f) *Potency requirement.* The potency of the product is satisfactory if the vaccine is no less potent than the reference. The potency of the product is considered to be equal to the reference when (1) the average time of death of the product-vaccinated guinea pigs is no less than the average time of death of the reference-vaccinated guinea pigs and the number of survivors of the product-vaccinated guinea pigs is no less than the number of survivors of the reference-vaccinated guinea pigs, or (2) the use of another statistical procedure, shown to be adequate for evaluating the potency of anthrax vaccine, demonstrates that

the product is no less potent than the reference.

§ 620.24 General requirements.

(a) *Dose.* These standards are based on a single human dose of 0.5 ml. and a total primary immunizing doses of three single doses, each given at appropriate intervals.

(b) *Product characteristics.* Recommendation shall be made through appropriate labeling that the product after issue should not be frozen.

(c) *Samples; protocols; official release.* For each lot of vaccine, the following material shall be submitted to the Director, Bureau of Biologics, Food and Drug Administration, Building 29A, 9000 Rockville, Pike, Bethesda, MD 20014:

(1) A protocol which consists of a summary of the manufacture of each lot including all results of all tests for which test results are requested by the Director, Bureau of Biologics.

(2) A sample of no less than 40 ml. of the final product distributed in approximately equal amounts into four final containers.

The product shall not be issued by the manufacturer until notification of official release of the lot is received from the Director, Bureau of Biologics.

§ 620.25 Equivalent methods.

Modification of any particular manufacturing method or process or the conditions under which it is conducted as set forth in the additional standards relating to anthrax vaccine, shall be permitted whenever the manufacturer presents evidence that demonstrates the modification will provide assurances of the safety, purity and potency of the vaccine that are equal to or greater than the assurances provided by such standards, and the Commissioner of Food and Drugs so finds and makes such findings a matter of official record.

PART 630—ADDITIONAL STANDARDS FOR VIRAL VACCINES

Subpart A—Poliomyelitis Vaccine

Sec.
630.1 Poliomyelitis Vaccine.
630.2 Manufacture of Poliomyelitis Vaccine.
630.3 Potency test.
630.4 Tests for safety.
630.5 General requirements.
630.6 Equivalent methods.

Subpart B—Poliovirus Vaccine, Live, Oral

630.10 Poliovirus Vaccine, Live, Oral.
630.11 Clinical trials to qualify for license.
630.12 Animal source; quarantine; personnel.
630.13 Manufacture of Poliovirus Vaccine, Live, Oral.
630.14 Reference strains.
630.15 Potency test.
630.16 Test for safety.
630.17 General requirements.
630.18 Equivalent methods.

Subpart C—Adenovirus Vaccine

630.20 Adenovirus Vaccine.
630.21 General requirements.
630.22 Manufacture of Adenovirus Vaccine.
630.23 Tests for safety.
630.24 Potency test.
630.25 Equivalent methods.

Subpart D—Measles Virus Vaccine, Live, Attenuated

630.30 Measles Virus Vaccine, Live, Attenuated.
630.31 Clinical trials to qualify for license.
630.32 Manufacture of live, attenuated Measles Virus Vaccine.
630.33 Reference virus.
630.34 Potency test.
630.35 Test for safety.
630.36 General requirements.
630.37 Equivalent methods.

Subpart E—Measles Virus Vaccine, Inactivated

630.40 Measles Virus Vaccine, Inactivated.
630.41 General requirements.
630.42 Manufacture of Measles Virus Vaccine, Inactivated.
630.43 Test for safety.
630.44 Potency test.
630.45 Equivalent methods.

Subpart F—Mumps Virus Vaccine, Live

630.50 Mumps Virus Vaccine, Live.
630.51 Clinical trials to qualify for license.
630.52 Manufacture of Mumps Virus Vaccine, Live.
630.53 Reference virus.
630.54 Potency test.
630.55 Test for safety.
630.56 General requirements.
630.57 Equivalent methods.

Subpart G—Rubella Virus Vaccine, Live

630.60 Rubella Virus Vaccine, Live.
630.61 Clinical trials to qualify for license.
630.62 Production.
630.63 Reference virus.
630.64 Potency test.
630.65 Test for safety.
630.66 General requirements.
630.67 Equivalent methods.

Subpart H—Smallpox Vaccine

630.70 Smallpox Vaccine.
630.71 Production.
630.72 Reference vaccine.
630.73 Potency test.
630.74 Tests for safety.
630.75 General requirements.
630.76 Equivalent methods.

Subpart I—Measles-Smallpox Vaccine, Live

630.80 Measels-Smallpox Vaccine, Live.
630.81 Clinical trials to qualify for license.
630.82 Production.
630.83 Reference vaccines.
630.84 Potency tests.
630.85 Tests for safety.
630.86 General requirements.
630.87 Equivalent methods.

AUTHORITY: Sec. 215, 58 Stat. 690, as amended; 42 U.S.C. 216. Sec. 351, 58 Stat. 702, as amended; 42 U.S.C. 262, unless otherwise noted.

CROSS REFERENCES.—For U.S. Customs Service regulations relating to viruses, serums, and toxins, see 19 CFR 12.21–12.23. For U.S. Postal Service regulations relating to the admissibility to the United States mails see 39 CFR Parts 124 and 125, esp. § 125.2.

Subpart A—Polimyelitis Vaccine

§ 630.1 Poliomyelitis Vaccine.

(a) *Proper name and definition.* The proper name of this product shall be "Poliomyelitis Vaccine", which shall consist of an aqueous preparation of poliovirus types 1, 2, and 3, grown in monkey kidney tissue cultures, inactivated by a suitable method.

(b) *Strains of virus.* Strains of poliovirus used in the manufacture of vaccine shall be identified by historical records, infectivity tests and immunological methods. Any strain of virus may be used that produces a vaccine meeting the requirements of §§ 630.2, 630.3, and 630.4, but the Commissioner of Food and Drugs may from time to time prohibit the use of any specific strain whenever he finds that it is practicable to use another strain of the same type that is potentially less pathogenic to man and that will produce a vaccine of at least equivalent safety and potency.

(c) *Monkeys; species permissible as source of kidney tissue.* Only Macaca or Cercopithecus monkeys, or a species found by the Director, Bureau of Biologics, to be equally suitable, which have met all requirements of §§ 600.11(f)(2) and 600.11(f)(8) of this chapter shall be used as a source of kidney tissue for the manufacture of Poliomyelitis Vaccine.

§ 630.2 Manufacture of Poliomyelitis Vaccine.

(a) *Cultivation of virus.* Virus for manufacturing vaccine shall be grown with aseptic techniques in monkey kidney cell cultures. Suitable antibiotics in the minimum concentration required may be used (§ 610.15(c) of this chapter).

(b) *Filtration.* Within 72 hours preceding the beginning of inactivation, the virus suspensions shall be filtered or clarified by a method having an efficiency equivalent to that of filtration through an S1 Seitz type filter pad.

(c) *Virus titer.* The 50 percent endpoint ($TCID_{50}$) of the virus fluids after filtration shall be $10^{6.0}$ or greater as confirmed by comparison in a simultaneous test (using groups of 10 tubes at 1 log steps or groups of 5 tubes at 0.5 log steps) with a reference virus distributed by the Bureau of Biologics. Acceptable titrations of the reference virus shall not vary more than ± 0.5 $\log_{10}$ from its labeled titer using 0.5 milliliter inoculum in tissue culture.

(d) *Inactivation of virus.* The virus shall be inactivated, as evidenced by the tests described in § 630.4, through the use of an agent or method which has been demonstrated to be consistently effective in the hands of the manufacturer in inactivating a series of lots of poliovirus. If formaldehyde is used for inactivation, it shall be added to the virus suspension to a final concentration of U.S.P. solution of formaldehyde of 1:4000, and the inactivation conducted under controlled conditions of pH and time, at a temperature of 36° to 38° C. Three or more virus titers, suitably spaced to indicate rate of inactivation, shall be determined during the inactivation process. Filtration equivalent to that described in paragraph (b) of this section shall be performed after the estimated baseline time (time at which the 50 percent end-point reaches one tissue culture infective dose per milliliter), but prior to sampling for the first single strain tissue culture test required in § 630.4(b), except that this filtration may be omitted for strains of a virulence

for monkeys equal to or less than that of the MEF–1 Type 2 strain of poliovirus.

(e) *Additional processing.* Single strain or trivalent pools that have failed to pass safety tests prescribed in § 630.4 (b), (c), or (e) may be treated as follows:

(1) Filtration or clarification by a method having an efficiency equivalent to that of filtration through an S1 Seitz type filter pad.

(2) Negative tests performed as described in § 630.4 (b) and (c) must be obtained on each of two successive samples taken so as to be separated by an interval of at least 3 days while the material is being subjected to treatment with 1:4000 U.S.P. formaldehyde solution and heat at 36° to 38° C. The first sample may be taken before incubation is begun and the second sample shall be taken after the incubation of at least 3 days is completed. For both single strain and trivalent pools the volume tested for each tissue culture safety test shall be equivalent to at least 1,500 human doses.

(3) Pools which are positive following such additional processing shall not be used for the manufacture of poliomyelitis vaccine.

(f) *Supplemental inactivation.* Supplemental inactivation employing a method capable of reducing the titer of a similarly produced virus suspension by a factor of 10^{-6} may be applied at any point after the filtration step described in paragraph (d) or (e)(1) of this section.

§ 630.3 Potency test.

Each lot of vaccine shall be subjected to a potency test which permits an estimation of the antigenic capacity of the vaccine. This is done by means of a simultaneous comparison of the serum antibody levels produced in monkeys by the vaccine under test with the antibody level of the reference serum distributed by the Bureau of Biologics. The potency test shall be performed on samples taken after all final processing of the product has been completed, including addition of preservative, except that when the final product contains material having an adjuvant effect an additional test shall be performed with a sample taken before the addition of the adjuvant material. The volume of the test sample for the additional test shall be adjusted to the equivalent volume of poliomyelitis vaccine in the final product. The test shall be conducted as follows:

(a) *Inoculation of monkeys.* A group of 12 or more Macaca monkeys, or a species found by the Director, Bureau of Biologics, to be equally suitable for the purpose, shall be used. Animals shall weigh between 4 and 8 pounds and shall be in overt good health. Animals that become ill and remain ill during the course of immunization shall be excluded from the group. The test shall not be valid unless at least 10 animals survive the test period and their preinoculation serum antibody levels are as prescribed in paragraph (d) of this section. The test vaccine shall be given intramuscularly to each monkey in 3 doses at 7-day intervals, each dose to be the recommended individual human dose. Only undiluted vaccine shall be used.

(b) *Serum samples.* A blood sample shall be taken from each monkey prior to vaccination and then again 7 days after the last injection. Serum shall be separated aseptically, and stored under refrigeration.

(c) *Serum-virus neutralization test.* The titers of individual monkey serums shall be determined in comparison with the reference serum in tests designed to include controls for all the variables of significance including the following:

(1) Serum toxicity control;

(2) Cell control and cell titration;

(3) Virus titration control (at least 4 tubes for each dilution at 0.5 log steps); and

(4) Serum controls using type-specific serums to identify the type of virus used in the neutralization test.

(d) *Interpretation of the test.* Animals showing preinoculation titers of 1:4 or over when tested against not more than 1,000 $TCID_{50}$ of virus, shall be excluded from the test. The geometric mean titer of antibody induced in the monkeys surviving the course of immunization and bleeding, shall be calculated. A comparison of the value so obtained shall be made with the value for the reference serum that was tested simultaneously and expressed as the ratio between the geometric mean titer value of the serums under test and the mean titer value of the reference serum.

(e) *Potency requirements.* A lot of vaccine tested against the reference serum shall be satisfactory if the geometric mean value of the group of individual monkey serums representing the lot of vaccine tested is at least 1.29 times the mean value of the reference serum for Type 1, at least 1.13 times for Type 2, and at least 0.72 times for Type 3.

§ 630.4 Tests for safety.

In the manufacture of the product, the following tests relating to safety shall be conducted by the manufacturer.

(a) *The virus pool—tests prior to inactivation*—(1) *B virus and Mycobacterium tuberculosis.* Prior to inactivation, each individual virus harvest or virus pool shall be tested for the presence of B virus and Mycobacterium tuberculosis.

(2) *SV–40.* Prior to inactivation, the material shall be tested for the presence of SV–40 as follows (or by any other test producing equally reliable results): A sample of at least 5 ml. from the virus harvest or virus pool shall be neutralized by high titer specific antiserum of other than primate origin. A similar sample from the pool of tissue culture fluids from control vessels representing the tissue from which the virus was prepared may be tested in place of the virus sample. The sample shall be tested in primary cercopithecus tissue cultures or in a cell line demonstrated as at least equally susceptible to SV–40. Each tissue culture system shall be observed for at least 14 days and at the end of the observation period at least one subculture of fluid shall be made in the same tissue culture system and the subculture shall be observed for at least 14 days.

(3) *Test results.* The virus harvest or virus pool is satisfactory for poliomyelitis vaccine only if the tests produce no evidence of the presence of B virus, Mycobacterium tuberculosis or SV–40.

(b) *Single strain pool tissue culture tests for poliovirus.* (1) Before pooling to make the final poliomyelitis vaccine, during inactivation at 36° to 38° C., two samples of each monovalent bulk strain pool shall be tested for the presence of virus by tissue culture methods, the second sample to be taken at least 3 days after taking the first sample.

(2) Each sample shall be no smaller than the equivalent of 1,500 human doses and shall be subjected to the complete testing process and each test shall be performed on a different monkey kidney tissue culture cell preparation. The test sample for one of these tests may be used also for the test prescribed in paragraph (f) of this section provided the cell cultures used have been demonstrated as fully susceptible to SV–40 and poliovirus. Each sample shall be inoculated into five or more tissue culture bottles of a suitable capacity, the ratio of the vaccine to the nutrient fluid being approximately 1:1 to 1:3, and the area of the surface growth of cells being at least 3 square centimeters per milliliter of sample. The tissue culture bottles shall be observed for at least 14 days.

(3) A first subculture shall be made at the end of 7 days from date of inoculation by planting at least 2 percent of the volume from each original bottle into suitable tissue culture vessels, followed by refeeding.

(4) A second subculture shall be made from each original bottle in the same manner at the end of 14 days from date of inoculation.

(5) Each of the first and second subcultures shall be observed for at least 7 days.

(6) If cytopathogenic effects occur either in the original bottles of the two tests or in the subcultures from them, or if cellular degeneration appears in the original bottles or in the subcultures before degeneration occurs in uninoculated cultures, the pool shall be held until the matter is resolved. If active poliovirus is indicated, the strain pool shall not be used for inclusion in a final vaccine unless effectively reprocessed as described in § 630.2(e). If other viruses are present, the pool shall not be used unless it can be demonstrated that such viruses have originated from other than the strain pool being tested.

(c) *Trivalent vaccine pool tissue culture test.* No less than 1,500 human doses of the trivalent vaccine pool, without final preservative, prepared by pooling the three type pools, each of which has passed all tests prescribed in paragraph (b) of this section, shall be subjected to the complete tissue culture test prescribed in such paragraph (b) in at least two approximately equal tests in separate monkey kidney tissue culture prep-

arations. This test sample may be used also for the test prescribed in paragraph (f) of this section provided the cell cultures used have been demonstrated as fully susceptible to SV–40 and poliovirus.

(d) *Trivalent vaccine pool lymphocytic choriomeningitis test.* The final vaccine shall be shown to be free of lymphocytic choriomeningitis virus by intracerebral inoculation of the maximum volume tolerated into 10 or more mice which shall be observed daily for at least 21 days and a negative test shall not be valid unless at least eight mice survive for this period.

(e) *Test in monkeys for active virus.* (1) Vaccine from final containers selected at random from each filling of each lot shall be pooled to provide a test sample of at least 400 milliliters representing the various fillings. An equal volume of bulk vaccine may be substituted for test samples from each filling lot provided the procedure has been approved by the Director, Bureau of Biologics.

(2) A total of not less than 20 monkeys shall be inoculated with the test sample. A preinjection serum sample from each monkey must not contain neutralizing antibody against the three poliovirus types detectable in a dilution of 1:4 when tested against not more than 1,000 $TCID_{50}$ of virus. At least 80 percent of the test animals representing each filling or each bulk sample must survive the test period without significant weight loss, except that if at least 60 percent of the test animals survive the first 48 hours after injection, those animals which do not survive this 48-hour test period may be replaced by an equal number of test animals. At least 80 percent of the animals used in the test must show microscopic evidence of inoculation trauma in the lumbar region of the spinal cord, and gross or microscopic evidence of inoculation trauma in the thalamic area. If less than 60 percent of the test animals survive the first 48 hours, or if less than 80 percent of the animals fail to meet the other criteria prescribed in this section, the test must be repeated.

(3) Vaccines shall be injected by combined intracerebral, intraspinal, and intramuscular routes into Macaca or Cercopithecus monkeys or a species found by the Director, Bureau of Biologics, to be equally suitable for the purpose. The animals shall be in overt good health and injected under deep barbiturate anesthesia. The intracerebral injection shall consist of 0.5 milliliter of test sample into the thalamic region of each hemisphere. The intraspinal inpection shall consist of 0.5 milliliter of concentrated test sample into the lumbar spinal cord enlargement, the test sample to be concentrated 100 fold in the ultracentrifuge by a method demonstrated to recover at least 90 percent of the virus particles in the sediment after it has been resuspended in the same lot of unconcentrated test sample. The intramuscular injection shall consist of 1.0 milliliter of test sample into the right leg muscles. At the same time, 200 milligrams of cortisone acetate shall be injected into the left leg muscles, and 1.0 milliliter of procaine pencillin (300,000 units) into the right arm muscles. The monkeys shall be observed for 17 to 19 days and signs suggestive of poliomyelitis shall be recorded.

(4) At the end of the observation period, samples of cerebral cortex and of cervical and lumbar spinal cord enlargements shall be taken for virus recovery and identification. Histological sections shall be prepared from both spinal cord enlargements and examined.

(5) Doubtful histopathological findings necessitate (i) examination of a sample of sections from several regions of the brain in question, and (ii) attempts at virus recovery from the nervous tissues previously removed from the animal. The test results must be negative. Test results are negative if the histological and other studies leave no doubt that poliomyelitis infection did not occur.

(f) *Tissue culture safety test for SV–40.* At least 500 human doses of each monovalent or trivalent pool of vaccine shall be tested for the presence of SV–40 using primary cercopithecus monkey tissue cultures or using a cell line demonstrated as at least equally susceptible to SV–40. The test shall be conducted as described in paragraph (b) of this section, except for the volume of test sample and except that one subculture of at least 2 percent of the volume of the fluids shall be made no less than 14 days from the date of inoculation and examined for at least 14 days from the date of subinoculation. The vaccine is satisfactory only if there is no evidence of the presence of SV–40 in any of the cultures or subcultures.

§ 630.5 General requirements.

(a) *Consistency of manufacture.* No lot of final vaccine shall be released unless it is one of a series of five consecutive lots produced by the same manufacturing process, all of which have shown negative results with respect to all tests for the presence of live poliovirus, and unless each of the monovalent pools of which a polyvalent final vaccine is composed similarly is one of a series of five consecutive monovalent pools of the same type of inactivated poliovirus, all of which have shown negative results in all tests for the presence of live poliovirus.

(b) *Dose.* These additional standards are based on a human dose of 1.0 milliliter for a single injection and a total human immunizing dose of three injections of 1.0 milliliter given at appropriate intervals.

(c) *Samples and protocols.* For each lot of vaccine, the following material shall be submitted to the Director, Bureau of Biologics, Food and Drug Administration, Building 29A, 9000 Rockville Pike, Bethesda, MD 20014:

(1) A 2,500 milliliter sample, neutralized, not dialyzed, and without final preservative, taken at the latest possible stage of manufacturing before the addition of such preservative.

(2) A 200 milliliter bulk sample of the final vaccine containing final preservative.

(3) A total of not less than a 200 milliliter sample of the final vaccine in final labeled containers.

(4) A protocol which consists of a summary of the history of manufacture of each lot including all results of each test for which test results are requested by the Director, Bureau of Biologics.

§ 630.6 Equivalent methods.

Modification of any particular manufacturing method or procedure or the conditions under which it is conducted as set forth in the additional standards relating to poliomyelitis vaccine (§§ 630.1 to 630.5, inclusive) shall be permitted whenever the manufacturer presents evidence to demonstrate that such modification will provide equal or greater assurances of the safety, purity and potency of the vaccine as the assurances provided by such standards, and the Commissioner of Food and Drugs so finds and makes such finding a matter of official record.

Subpart B—Poliovirus Vaccine, Live, Oral

§ 630.10 Poliovirus Vaccine, Live, Oral.

(a) *Proper name and definition.* The proper name of this product shall be "Poliovirus Vaccine, Live, Oral," followed by a designation of the type. The vaccine shall be a preparation of one or more live, attenuated polioviruses grown in monkey kidney cell cultures, or a strain of human cell cultures found by the Director, Bureau of Biologics, to meet the requirements of § 630.12(b) and shall be prepared in a form suitable for oral administration.

(b) *Criteria for acceptable strains and acceptable seed virus.* (1) Strains of attenuated poliovirus Types 1, 2, and 3 used in the manufacture of the vaccine shall be identified by: (i) Historical records including origin and techniques of attenuation, (ii) antigenic properties, (iii) neurovirulence for monkeys, (iv) pathogenicity for other animals and tissue cultures of various cell types, and (v) established virus markers including rct/40, d, and other markers shown to be associated with strain virulence.

(2) Poliovirus strains shall not be used in the manufacture of Poliovirus Vaccine, Live, Oral, unless, (i) data are submitted to the Commissioner of Food and Drugs which establish that each such strain is free of harmful effect upon administration in the recommended dosage to at least 1 million people susceptible to poliomyelitis, under circumstances where adequate epidemiological surveillance of neurological illness has been maintained, and, (ii) each such strain produces a vaccine meeting the safety and potency requirements of §§ 630.11, 630.15, and 630.16(b). Susceptibility shall be demonstrated by §§ 630.11, 630.15, and 630.16 (b). Susceptibility shall be demonstrated by blood tests, stool examinations and other appropriate methods.

(3) Each seed virus used in manufacture shall be demonstrated to be free of extraneous microbial agents except for unavoidable bacteriophage.

(4) No seed virus shall be used for the manufacture of poliovirus vaccine unless its neurovirulence in Macaca monkeys

is no greater than that of the Reference Attenuated Poliovirus distributed by the Bureau of Biologics. The neurovirulence of the seed virus shall be demonstrated by the following tests to be performed by the manufacturer: (i) The test prescribed in § 630.16(b)(1) using seed virus as test material in place of monovalent virus pool material and (ii) the following comparative intramuscular neurovirulence test: Each of at least 10 monkeys shall be injected with a total of 5.0 ml. of the seed virus under test in one or more proximate locations of either a gluteus or gastrocnemius muscle. Similar injections shall be made in another group of 10 monkeys using the Reference Attenuated Poliovirus. Each monkey shall be injected intramuscularly with no less than $10^{7.7}$ $TCID_{50}$ of viral inoculum. All monkeys shall be observed for 17 to 21 days and a comparative evaluation shall be made of the evidence of neurovirulence of the virus under test and the Reference Attenuated Poliovirus, as prescribed in § 630.16(b)(1)(iii).

(5) Subsequent and identical neurovirulence tests shall be performed in monkeys whenever there is evidence of a change in the neurovirulence of the production virus, upon introduction of a new production seed lot, and as often as necessary otherwise to establish to the satisfaction of the Commissioner of Food and Drugs that the seed virus strains for vaccine manufacture have maintained their neurovirulence properties as set forth in § 630.16(b)(1)(iii).

(6) The Commissioner of Food and Drugs may, from time to time, prohibit the use of a specified strain whenever he finds it is practicable to use another strain of the same type which is potentially less pathogenic for man, and that it will produce a vaccine of greater safety and of at least equivalent potency.

§ 630.11 Clinical trials to qualify for license.

To qualify for license, the antigenicity of the vaccine shall have been determined by clinical trials of adequate statistical design. Such clinical trials shall be conducted with five consecutive lots of poliovirus vaccine which have been manufactured by the same methods, each of which has shown satisfactory results in all prescribed tests. Type specific neutralizing antibody (from less than 1:4 before vaccine treatment, to 1:16 or greater after treatment) shall be induced in 80 percent or more of susceptibles when administered orally as a single dose, or in excess of 90 percent of susceptibles when administered orally after a series of doses. A separate clinical trial shall have been conducted for each monovalent and each polyvalent vaccine for which license application is made.

§ 630.12 Animal source; quarantine; personnel.

(a) *Monkeys*—(1) *Species permissible as source of kidney tissue.* Only Macaca found by the Director, Bureau of Biologics, to be equally suitable, which have met all the requirements of §§ 600.11(f)(2) and 600.11(f)(8) of this chapter shall be used as the source of kidney tissue for the manufacture of Poliovirus Vaccine, Live, Oral.

(2) *Experimental and test monkeys.* Monkeys that have been used previously for experimental or test purposes shall not be used as a source of kidney tissue in the processing of vaccine.

(3) *Quarantine; additional requirements.* Excluding deaths from accidents or causes not due to infectious diseases, if the death rate of any group of monkeys being conditioned in accordance with § 600.11(f)(2) of this chapter exceeds 5 percent per month, the remaining monkeys may be used for the manufacture of Poliovirus Vaccine only if they survive a new quarantine period.

(b) *Human cell culture strains.* Strains of human cell cultures used for the manufacture of Poliovirus Vaccine, Live, Oral shall be (1) identified by historical records, (2) demonstrated to be free of oncogenic properties in a suitable animal test and free of adventitious microbial agents, and (3) shown to be capable of producing a vaccine which, by experience in at least 10,000 persons, has been found to be safe and antigenic. The field studies shall be so conducted that at least 5,000 of the individuals must reside when given vaccine in areas where health related statistics are regularly compiled in accordance with procedures such as those used by the National Center for Health Statistics. Data in such form as will identify each person receiving vaccine shall be furnished to the Director, Bureau of Biologics.

(c) *Personnel.* All reasonably possible steps shall be taken to insure that personnel involved in processing the vaccine are immune to and do not excrete poliovirus.

§ 630.13 Manufacture of Poliovirus Vaccine, Live, Oral.

(a) *Virus passages.* Virus in the final vaccine shall represent no more than five tissue culture passages from the original strain, each of which shall have met the criteria of acceptability prescribed in § 630.10(b).

(b) *Virus propagated in monkey kidney cell cultures*—(1) *Continuous line cells.* When primary monkey kidney cell cultures are used in the manufacture of poliovirus vaccine, continuous line cells shall not be introduced or propagated in vaccine manufacturing areas.

(2) *Identification of processed kidneys.* The kidneys from each monkey shall be processed and the viral fluid resulting therefrom shall be identified as a separate monovalent harvest and kept separately from other monovalent harvests until all samples for the tests prescribed in the following subparagraph relating to that pair of kidneys shall have been withdrawn from the harvest.

(3) *Monkey kidney tissue production vessels prior to virus inoculation.* Prior to inoculation with the seed virus, the tissue culture growth in vessels representing each pair of kidneys shall be examined microscopically for evidence of cell degeneration at least 3 days after complete formation of the tissue sheet. If such evidence is observed, the tissue cultures from that pair of kidneys shall not be used for poliovirus vaccine manufacture. To test the tissue found free of cell degeneration for further evidence of freedom from demonstrable viable microbial agents, the fluid shall be removed from the cell cultures immediately prior to virus inoculation and tested in each of four culture systems: (i) Macaca monkey kidney cells, (ii) Cercopithecus monkey kidney cells, (iii) primary rabbit kidney cells, and (iv) human cells from one of the systems described in § 630.16(a)(6), in the following manner: Aliquots of fluid from each vessel shall be pooled and at least 10 ml. of the pool inoculated into each system, with ratios of inoculum to medium being 1:1 to 1:3 and with the area of surface growth of cells at least 3 square centimeters per milliliter of test inoculum. The cultures shall be observed for at least 14 days. At the end of the observation period, at least one subculture of fluid from the Cercopithecus monkey kidney cell cultures shall be made in the same tissue culture system and the subculture shall be observed for at least 14 days. If these tests indicate the presence in the tissue culture preparation of any viable microbial agent, the tissue cultures so implicated shall not be used for poliovirus vaccine manufacture.

(4) *Control vessels.* Before inoculation with seed virus, sufficient tissue culture vessels to represent at least 25 percent of the cell suspension from each pair of kidneys shall be set aside as controls. The control vessels shall be examined microscopically for cell degeneration for an additional 14 days. The cell fluids from such control vessels shall be tested, both at the time of virus harvest and at the end of the additional observation period, by the same method prescribed for testing of fluids in subparagraph (b)(3) of this paragraph. In addition, the cell sheet in each control vessel shall be examined for presence of hemadsorption viruses by the addition of guinea pig red blood cells.

(5) *Virus harvest; interpretation of test results.* If the tissue culture in less than 80 percent of the control vessels is not free of cell degeneration at the end of the observation period, no tissue from the kidneys implicated shall be used for poliovirus vaccine manufacture. If the test results of the control vessels indicate the presence of any extraneous agent at the time of virus harvest, the entire virus harvest from that tissue culture preparation shall not be used for poliovirus vaccine manufacture. If any of the tests or observations described in subparagraphs (3) or (4) of this paragraph demonstrate the presence in the tissue culture preparation of any microbial agent known to be capable of producing human disease, the virus grown in such tissue culture preparation shall not be used for poliovirus vaccine manufacture.

(6) *Kidney tissue production vessels after virus inoculation—temperature.* After virus inoculation, production vessels shall be maintained at a tempera-

ture not to exceed 35.0° C. during the course of virus propagation.

(7) *Kidney tissue virus harvests.* Virus harvested from vessels containing the kidney tissue from one monkey may constitute a monovalent virus pool and be tested separately, or viral harvests from more than one pair of kidneys may be combined, identified and tested as a monovalent pool. Each pool shall be mixed thoroughly and samples withdrawn for testing as prescribed in § 630.16(a). The samples shall be withdrawn immediately after harvesting and prior to further processing, except that samples of test materials frozen immediately after harvesting and maintained at −60° C. or below, may be tested upon thawing, provided no more than one freeze-thaw cycle is employed.

(8) *Filtration.* After harvesting and removal of samples for the safety tests prescribed in § 630.16(a), the pool shall be passed through sterile filters having a sufficiently small porosity to assure bacteriologically sterile filtrates.

(c) *Virus propagated in human cell cultures*—(1) *Use of continuous line cells.* When a human cell culture strain, previously found to be suitable by the Director, Bureau of Biologics, is used in the manufacture of poliovirus vaccine, no other continuous line cells or primary cell cultures shall be introduced or propagated in vaccine manufacturing areas.

(2) *Identification of human cell cultures.* The cell culture growth shall be charatcerized as to (i) identification as human cells, (ii) passage level, and (iii) karyology. Chromosome monitoring of the cell cultures used for vaccine production shall be made on permanent stained slide preparations which shall be maintained by the manufacturer as a permanent record. Monitoring shall be performed on each cell growth used for virus vaccine production. The karyologic determination shall include analysis of the exact chromosome count, karotype, polyploidy, chromosome breaks, structural chromosome abnormalities, other abnormalities such as despiralization or marked attenuations of the primary or secondary constrictions and the presence of minute chromosome. Findings based on these determinations shall not exceed the 95 percent confidence limits of the values established for the cell strain used. Cell cultures shall be processed in such a manner that the viral fluid resulting therefrom shall be identified as a separate monovalent harvest and kept separately from other monovalent harvests until all samples for the tests prescribed in the following subparagraph shall have been withdrawn from the harvest.

(3) *Human cell culture production vessels prior to virus inoculation.* Prior to inoculation with the seed virus, the cell culture growth shall be examined microscopically for evidence of cell degeneration after complete formation of the cell sheet. If such evidence is observed, the cell production lot shall not be used for poliovirus vaccine manufacture. To test the cell cultures found free of cell degeneration for further evidence of freedom from demonstrable viable microbial agents, the fluid shall be removed from the cell cultures immediately prior to virus inoculation and tested in each of three culture systems: (i) Cercopithecus monkey kidney cells, (ii) primary rabbit kidney cells, and (iii) human cells from one of the systems described in § 630.16(a)(6), in the following manner. Aliquots of fluid from each vessel shall be pooled and at least 10 ml. of the pool inoculated into each system, with ratios of inoculum to medium being 1:1 to 1:3 and with the area of surface growth of cells at least 3 square centimeters per milliliter of test inoculum. The cultures shall be observed for at least 14 days. At the end of the observation period, at least one subculture of fluid from the Cercopithecus monkey kidney cell cultures shall be made in the same tissue culture system and the subculture shall be observed for at least 14 days. If these tests indicate the presence in the tissue culture preparation of any viable microbial agent, the cell cultures so implicated shall not be used for poliovirus vaccine manufacture.

(4) *Control vessels.* Before inoculation with seed virus, a portion of the cell culture shall be set aside as control material. Such a portion either shall represent at least 25 percent of the cell suspension of a single cell growth or a volume of the fluid derived from the cell cultures equivalent to at least 25 percent of the volume of the final vaccine. The control vessels shall be examined microscopically for cell degeneration for an additional 14 days. The cell fluids from such control vessels shall be tested, both at the time of virus harvest and at the end of the additional observation period, by the same method prescribed for testing of fluids in subparagraph (3) of this paragraph. In addition, the cell sheet in each control vessel shall be examined (i) for presence of hemadsorption viruses by the addition of guinea pig red blood cells and (ii) a pool of cell suspension containing at least 10^5 cells shall be tested in embryonated chicken eggs by the allantoic cavity route of inoculation for the presence of adventitious agents.

(5) *Virus harvest; interpretation of test results.* If more than 20 percent of the cell substrates in the control vessels demonstrate cell degeneration at the end of the observation period, the cells implicated shall not be used for poliovirus vaccine manufacture. If the test results of the control vessels indicate the presence of any extraneous agent at the time of virus harvest, the entire virus harvest from that cell culture preparation shall not be used for poliovirus vaccine manufacture. If any of the tests or observations described in subparagraph (3) or (4) of this paragraph demonstrate the presence in the cell culture preparations of any microbial agent known to be capable of producing human disease, the virus grown in such cell culture preparation shall not be used for poliovirus vaccine manufacture.

(6) *Human cell culture production vessels after virus inoculation—temperature.* After virus inoculation, production vessels shall be maintained at a temperature not to exceed 35.0° C. during the course of virus propagation.

(7) *Virus harvest from human cell cultures.* Virus harvested from vessels representing a single cell growth may constitute a monovalent virus pool and be tested separately, or viral harvests from vessels representing more than one cell growth may be combined, identified and tested as a monovalent pool. Each pool shall be mixed thoroughly and samples withdrawn for testing for safety as prescribed in § 630.16(a). The samples shall be withdrawn immediately after harvesting and prior to further processing, except that samples of test materials frozen immediately after harvesting and maintained at −60° C. or below, may be tested upon thawing, provided no more than one freeze-thaw cycle is employed.

(8) *Filtration.* After harvesting and removal of samples for the safety tests prescribed in § 630.16(a), the pool shall be passed through sterile filters having a sufficiently small porosity to assure bacteriologically sterile filtrates.

§ 630.14 Reference strains.

The following reference viruses shall be obtained from the Bureau of Biologics.

Reference Poliovirus, Live, Attenuated, Type 1, as a control for correlation of virus titers in tissue cultures.

Reference Poliovirus, Live, Attenuated, Type 2, as a control for correlation of virus titers in tissue cultures.

Reference Poliovirus, Live, Attenuated, Type 3, as a control for correlation of virus titers in tissue cultures.

Reference Attenuated Poliovirus, Type 1, as a control for correlation of monkey neurovirulence tests.

§ 630.15 Potency test.

The concentration of live virus expressed as $TCID_{50}$ of each type in the vaccine shall constitute the measure of its potency. The accuracy of the titration to determine the concentration of live virus in the lot under test shall be confirmed by performing a titration with the Reference Poliovirus, Live, Attenuated of the appropriate type as a check on titration technique. The concentration of each type of live virus contained in the vaccine of the lot under test shall be between 200,000 and 500,000 $TCID_{50}$ per human dose.

§ 630.16 Test for safety.

(a) *Tests prior to filtration.* Monovalent virus pools shall contain no demonstrable viable microbial agent other than the attenuated live poliovirus intended except for unavoidable bacteriophage. The vaccine shall be tested for the absence of adventitious and other infectious agents including polioviruses of other types or strains, simian agents Mycobacterium tuberculosis, pox virus, lymphocytic choriomeningitis virus Echo viruses, Coxsackie viruses, and B virus. Testing of each monovalent pool shall include the following procedures:

(1) *Inoculation of rabbits.* A minimum of 100 ml. of each monovalent virus pool shall be tested by inoculation into at least 10 health rabbits, each weighing

1,500–2,500 grams. Each rabbit shall be injected intradermally in multiple sites, with a total of 1.0 ml. and subcutaneously with 9.0 ml., of the viral pool, and the animals observed for at least 3 weeks. Each rabbit that dies after the first 24 hours of the test or is sacrificed because of illness shall be necropsied and the brain and organs removed and examined. The virus pool may be used for poliovirus vaccine only if at least 80 percent of the rabbits remain healthy and survive the entire period and if all the rabbits used in the test fail to show lesions of any kind at the sites of inoculation and fail to show evidence of B virus or any other viral infection.

(2) *Inoculation of adult mice.* Each of at least 20 adult mice, each weighing 15–20 grams, shall be inoculated intraperitoneally with 0.5 ml. and intracerebrally with 0.03 ml. of each monovalent virus pool to be tested. The mice shall be observed for 21 days. Each mouse that dies after the first 24 hours of the test, or is sacrificed because of illness, shall be necropsied and examined for evidence of viral infection by direct observation and subinoculation of appropriate tissue into at least five additional mice which shall be observed for 21 days. The monovalent virus pool may be used for poliovirus vaccine only if at least 80 percent of the mice remain healthy and survive the entire period and if all the mice used in the test fail to show evidence of lymphocytic choriomeningitis virus or other viral infection.

(3) *Inoculation of suckling mice.* Each of at least 20 suckling mice less than 24 hours old, shall be inoculated intracerebrally with 0.01 ml. and intraperitoneally with 0.1 ml. of the monovalent virus pool to be tested. The mice shall be observed daily for at least 14 days. Each mouse that dies after the first 24 hours of the test, or is sacrificed because of illness, shall be necropsied and all areas examined for evidence of viral infection. Such examination shall include subinoculation of appropriate tissue suspensions into an additional group of at least five suckling mice by the intracerebral and intraperitoneal routes and observed daily for 14 days. In addition, a blind passage shall be made of a single pool of the emulsified tissue (minus skin and viscera) of all mice surviving the original 14-day test. The virus pool under test is satisfactory for poliovirus vaccine only if at least 80 percent of the mice remain healthy and survive the entire period and if all the mice used in the test fail to show evidence of Coxsackie or other viral infection.

(4) *Inoculation of guinea pigs.* Each of at least five guinea pigs, each weighing 350–450 grams, shall be inoculated intracerebrally with 0.1 ml. and intraperitoneally with 5.0 ml. of the monovalent virus pool to be tested. The animals shall be observed for at least 42 days and daily rectal temperatures recorded for the last 3 weeks of the test. Each animal that dies after the first 24 hours of the test, or is sacrificed because of illness, shall be necropsied and its tissues shall be examined both microscopically and culturally for evidence of tubercle bacilli, and by passage of tissue suspensions into at least three other guinea pigs by the intracerebral and intraperitoneal routes of inoculation for evidence of viral infection. If clinical signs suggest infection with lymphocytic choriomeningitis virus, serological tests shall be performed on blood samples of the test guinea pigs to confirm the clinical observations. Animals that die or are sacrificed during the first 3 weeks after inoculation with poliovirus shall be examined for infection with lymphocytic choriomeningitis virus. Animals that die in the final 3 weeks shall be examined both microscopically and culturally for Mycobacterium tuberculosis. The monovalent virus pool is satisfactory for poliovirus vaccine only if at least 80 percent of all animals remain healthy and survive the observation period and if all the animals used in the test fail to show evidence of infection with Mycobacterium tuberculosis, or any viral infection.

(5) *Inoculation of monkey kidney tissue cultures.* At least 500 doses or 50 ml., whichever represents a greater volume of virus, of each undiluted monovalent virus pool, or in equal proportions from individual harvests or subpools, shall be tested for simian viruses in Macaca, and the same volume in Cercopithecus, monkey kidney tissue cultures, in a ratio of inoculum to medium of from 1: 1 to 1: 3, and with the area of surface growth of cells at least 3 square centimeters per milliliter of test inoculum, after neutralization of the poliovirus by high titer specific antiserum of nonprimate origin. The immunizing antigens used for the preparation of antisera shall be grown in a human tissue culture cell line. The cultures shall be observed for no less than 14 days. At the end of the observation period at least one subculture of fluid from the Cercopithecus kidney cell culture shall be made in the same tissue culture system and the subculture shall be observed for at least 14 days. The monovalent virus pool is satisfactory for poliovirus vaccine only if all the tissue cultures fail to show evidence of the presence of simian viruses or any other viral infection.

(6) *Inoculation of human cell cultures.* At least 500 doses or 50 ml., whichever represents a greater volume of virus, taken from either a single monovalent pool, or in equal proportions from individual harvests or subpools, shall be tested in a ratio of inoculum to medium of 1:1 to 1:3, and with the area of surface growth of cells at least 3 square centimeters per milliliter of test inoculum, for the presence of measles virus in either (i) primary human amnion cells, (ii) primary human kidney cells, or (iii) any other cell system of comparable susceptibility to unmodified measles virus. The test material shall be neutralized with poliovirus antiserum of other than primate origin if the tissue culture cell system used is susceptible to poliovirus. The culture shall be observed for no less than 14 days. The monovalent virus pool is satisfactory for poliovirus vaccine only if all tissue cultures fail to show evidence of the presence of measles virus or any other viral infection.

(7) *Inoculation of rabbit kidney tissue cultures.* At least 500 ml. of virus pool taken from either a single monovalent pool, or in equal proportions from individual harvests or subpools, shall be tested in a ratio of inoculum to medium of from 1:1 to 1:3, and with the area of surface growth of cells at least 3 square centimeters per milliliter of test inoculum, in primary rabbit kidney tissue culture preparations for evidence of B virus. The culture shall be observed for no less than 14 days. The monovalent virus pool is satisfactory for poliovirus vaccine only if all tissue cultures fail to show evidence of the presence of B virus.

(b) *Tests after filtration.* The following tests relating to safety shall be performed after the filtration process, on each monovalent virus pool or on each multiple thereof (monovalent lot):

(1) *Neurovirulence in monkeys.* Each monovalent virus pool or monovalent lot shall be tested in comparison with the Reference Attenuated Poliovirus for neurovirulence in Macaca mulatta (rhesus) monkeys by both the intrathalamic and intraspinal routes of injection. A preinjection serum sample obtained from each monkey must be shown to contain no neutralizing antibody in a dilution of 1: 4 when tested against no more than 1,000 $TCID_{50}$ of each of the three types of poliovirus. The neurovirulence tests are not valid unless the sample contains at least $10^{7.6}$ $TCID_{50}$ per ml. when titrated in comparison with the Reference Poliovirus, Live, Attenuated of the appropriate type. All monkeys shall be observed for 17 to 21 days, under the supervision of a qualified pathologist, physician or veterinarian, and any evidence of physical abnormalities indicative of poliomyelitis or other viral infections shall be recorded.

(i) *Intrathalamic inoculation.* Each of at least 30 monkeys shall be injected intracerebrally by placing 0.5 ml. of virus pool material into the thalamic region of each hemisphere. Comparative evaluations shall be made with the virus pool under test and the Reference Attenuated Poliovirus. Only monkeys that show evidence of inoculation into the thalamus shall be considered as having been injected satisfactorily. If on examination there is evidence of failure to inoculate virus pool material into the thalamus, additional monkeys may be inoculated in order to reestablish the minimum number of 30 monkeys for the test.

(ii) *Intraspinal inoculation.* Each of a group of at least five monkeys shall be injected intraspinally with 0.2 ml. of virus pool material containing at least $10^{7.6}$ $TCID_{50}$ per ml. and each monkey in additional groups of at least five monkeys shall be injected intraspinally with 0.2 ml of a 1:1,000 and 1:10,000 dilution respectively, of the same virus pool material. Comparative evaluations shall be made with the virus pool under test and the reference material. Only monkeys that show microscopic evidence of inoculation into the gray matter of the lumbar cord shall be considered as hav-

ing been injected satisfactorily. If on examination there is evidence of failure to inoculate intraspinally, additional animals may be inoculated in order to reestablish the minimum number of five animals per group.

(iii) *Determination of neurovirulence.* At the conclusion of the observation period comparative histopathological examinations shall be made of the lumbar cord, cervical cord, lower medulla, upper medulla, mesencephalon and motor cortex of each monkey in the groups injected with virus under test and those injected with the Reference Attenuated Poliovirus, except that for animals dying during the test period, these examinations shall be made immediately after death. If at least 60 percent of the animals of a group survive 48 hours after inoculation, those animals which did not survive may be replaced by an equal number of animals tested as prescribed in paragraph (b)(1) of this section. If less than 60 percent of the animals of a group survive 48 hours after inoculation, the test must be repeated. At the conclusion of the observation the animals shall be examined to ascertain whether the distribution and histological nature of the lesions are characteristics of poliovirus infection. A comparative evaluation shall be made of the evidence of neurovirulence of the virus under test and the Reference Attenuated Poliovirus with respect to (a) the number of animals showing lesions characteristic of poliovirus infection, (b) the number of animals showing lesions other than those characteristic of poliovirus infection, (c) the severity of the lesions, (d) the degree of dissemination of the lesions, and (e) the rate of occurrence of paralysis not attributable to the mechanical injury resulting from inoculation trauma. The virus pool under test is satisfactory for poliovirus vaccine only if at least 80 percent of the animals in each group survive the observation period and if a comparative analysis of the test results demonstrate that the neurovirulence of the test virus pool does not exceed that of the Reference Attenuated Poliovirus.

(iv) *Test with Reference Attenuated Poliovirus.* The Reference Attenuated Poliovirus shall be tested as prescribed in paragraph (b)(1) (i) and (ii) of this section at least once for every 10 production lots of vaccine, except that the interval between the test of the reference and the test of any lot of vaccine shall not be greater than 3 months. The test procedure shall be considered acceptable only if lesions of poliomyelitis are seen in monkeys inoculated with the reference material at a frequency statistically compatible with all previous tests with this preparation.

(2) *Test for virus titer.* The concentration of living virus in each monovalent virus pool or lot shall be determined, using the Reference Poliovirus Live, Attenuated of the same type as a control. The test shall be a 50 percent end-point titration calculation ($TCID_{50}$), performed with either groups of 10 tubes at 1 log dilution steps or groups of five tubes of 0.5 log dilution steps, or a test of demonstrated equivalent sensitivity. Acceptable titrations of the reference virus shall not vary more than ±0.5 log from its labeled titer.

(3) *Tests for In Vitro Markers.* A test shall be performed on each monovalent virus pool or each monovalent lot resulting therefrom, using the rct/40 Marker. A second test shall be performed using the d Marker or another marker method shown to be of value in identification of the attenuated strain. The test results shall demonstrate that the virus under test and the seed virus have substantially the same marker characteristics.

(i) *rct/40 Marker.* Attenuated strains which grow readily at 40° C. (±0.5° C.) are classified as rct/40 positive (+) in contrast to the rct/40 negative (−) strains which show an increased growth of at least 100,000 fold at 36° C. over that obtained at 40° C. Comparative determinations shall be made in either tube or bottle cultures.

(ii) *d Marker.* Attenuated strains which grow readily at low concentrations of bicarbonate under agar are classified as d positive (+) in contrast to the d negative (−) strains which exhibit delayed growth under the same conditions. The cultures shall be grown in a 36° C. incubator either in stoppered bottles or in plates in an environment of 5 percent CO_2 in air.

§ 630.17 General requirements.

(a) *Final container sterility test.* The final container sterility test need not be performed provided aseptic techniques are used in the filling process.

(b) *Consistency of manufacture.* No lot of vaccine shall be released unless each monovalent pool contained therein is one of a series of five consecutive pools of the same type, each pool having been manufactured by the same procedures, and each having met the criteria of neurovirulence for monkeys prescribed in § 630.16(b)(1), and of in vitro markers prescribed in § 630.16(b)(3).

(c) *Dose.* The individual human dose of vaccine shall contain from 200,000 to 500,000 $TCID_{50}$ of each type of virus in the final monovalent vaccine, and for polyvalent vaccine not more than 1,000,000 $TCID_{50}$ of Type 1 virus, 100,000 to 200,000 $TCID_{50}$ of Type 2 virus and 200,000 to 500,000 $TCID_{50}$ of Type 3 virus.

(d) *Labeling.* In addition to the items required by other applicable labeling provisions of this part, the final container label shall bear a statement indicating that liquid vaccine may not be used for more than 7 days after opening the container. Labeling may include a statement indicating that for frozen vaccine a maximum of 10 freeze-thaw cycles is permissible provided the total cumulative duration of thaw does not exceed 24 hours, and provided the temperature does not exceed 8° C. during the periods of thaw.

(e) *Samples and protocols.* For each lot of vaccine, the following materials shall be submitted to the Director, Bureau of Biologics, Food and Drug Administration, Building 29A, 9000 Rockville Pike, Bethesda, MD 20014:

(1) A protocol which consists of a summary of the history of manufacture of each lot including all results of each test for which test results are requested by the Director, Bureau of Biologics.

(2) A 500 milliliter bulk sample of each final monovalent pool having a virus titer of no less than $10^{7.5}$ $TCID_{50}$ per milliliter, except that if the titer is greater, a correspondingly smaller volume may be submitted.

(3) A total of no less than 200 doses or no less than six final containers, whichever is the larger amount.

§ 630.18 Equivalent methods.

Modification of any particular manufacturing method or process or the conditions under which it is conducted as set forth in the additional standards relating to Poliovirus Vaccine, Live, Oral, shall be permitted whenever the manufacturer presents evidence that demonstrates the modification will provide assurances of the safety, purity, and potency of the vaccine that are equal to or greater than the assurances provided by such standards, and the Commissioner of Food and Drugs so finds and makes such finding a matter of official record.

Subpart C—Adenovirus Vaccine

§ 630.20 Adenovirus Vaccine.

(a) *Proper name and definition.* For the purpose of section 351(a)(2) of the act and § 600.3(k) of this chapter, the proper name of this product shall be "Adenovirus Vaccine" with a designation of the types of virus included in the vaccine. Such vaccine shall consist of an aqueous preparation of one or more adenoviruses grown in monkey kidney tissue cultures inactivated by a suitable method. Where more than one type of virus is used in the manufacture of the vaccine, equal proportions of each type shall be combined with a tolerance for each component of 5 percent of the total volume.

(b) *Strains of virus.* Strains of adenovirus used in the manufacture of the vaccine shall be identified by historical records, infectivity tests, and immunological methods. Only those strains of virus may be used that (1) produce a vaccine meeting the safety and potency requirements in §§ 630.23 and 630.24, (2) never had any passage in malignant cells of human or animal origin, and (3) have been maintained in monkey kidney cultures for at least 10 passages prior to use.

(c) *Monkey kidney tissue.* Only cynomolgus or rhesus monkeys or other species of equal suitability, in overt good health, that have reacted negatively to tuberculin within 2 weeks prior to use shall be used as a source of kidney tissue for the production of virus. Each animal shall be examined at necropsy under the supervision of a qualified pathologist for gross signs of disease. If there is any gross pathological lesion of any significance to their use in the manufacture of vaccine, the kidneys shall be discarded. Kidney tissue from monkeys that have been used previously for experimental purposes shall not be used, ex-

cept that monkeys in overt good health, used for the safety or potency tests of adenovirus vaccines with negative clinical findings (§§ 630.23 and 630.24) that have reacted negatively to tuberculin prior to such test, may be used within two weeks of the end of the test period. The monkeys shall not at any time have been housed in the same building where monkeys actually infected with or exposed to poliovirus are housed, and due precautions shall be taken to prevent cross-infection from any infected or potentially infected monkeys on the premises.

§ 630.21 General requirements.

(a) *Separate facilities.* The personnel, equipment and supplies used in the manufacture of adenovirus vaccine shall be separated from personnel, equipment or supplies used in connection with any other pathogenic virus to the extent necessary to prevent cross-contamination.

(b) *Final container tests.* Tests shall be made on final containers for safety, sterility and identity, in accordance with §§ 610.11, 610.12, and 610.14 of this chapter, respectively.

(c) *Release of vaccine.* A lot of vaccine shall not be released unless all required safety tests have given negative results.

(d) *Extraneous protein.* Extraneous protein capable of producing allergenic effects on human subjects shall not be added to the final virus production medium. If animal serum is used at any stage, its calculated concentration in the final medium shall not exceed 1:1,000,000.

(e) *Nitrogen content.* The final vaccine shall have a protein nitrogen content of less than 0.02 milligram per milliliter.

(f) *Dose.* These additional standards for adenovirus vaccine are based on a human dose not exceeding 1.0 milliliter for a single injection.

(g) *Labeling.* In addition to compliance with the requirements of §§ 610.60 to 610.65 of this chapter inclusive, the label or package enclosure shall include an appropriate statement indicating the type and amount of each antibiotic added, if any. The preservative used shall be stated on the label, as well as allergenic substances added, if any, and the source, composition, and method of inactivation of the viruses.

(h) [Reserved]

(i) *Requirements for samples and protocols.* For each lot of vaccine, the following material shall be submitted to the Director, Bureau of Biologics, Food and Drug Administration, Building 29A, 9000 Rockville Pike, Bethesda, MD 20014:

(1) A 2,500-milliliter sample of the final vaccine taken at the latest possible stage of manufacture before the addition of preservative.

(2) A 200-milliliter bulk sample of the final vaccine containing all preservatives.

(3) A total of at least 200-milliliter sample of the final vaccine in final labelled containers.

(4) Protocol showing the history of the lot and the results of all of the tests which were carried out by the manufacturer.

§ 630.22 Manufacture of Adenovirus Vaccine.

(a) *Cultivation of virus.* Virus for manufacturing vaccine shall be grown with aseptic technique in monkey kidney cell cultures using a synthetic medium. Suitable antibiotics in the minimum concentration required may be used. If penicillin is used, not more than 200 units per milliliter may be added. Phenol red may not exceed a concentration of 0.002 percent.

(b) *Filtration.* Within 72 hours preceding the beginning of inactivation, the virus suspensions shall be filtered or clarified by a method having an efficiency at least equivalent to that of a Selas 02 type filter.

(c) *Virus titer.* The titer of each virus pool after filtration shall be determined by a suitable method. It shall also be demonstrated that each virus pool possesses adenovirus group antigen by the complement-fixing test.

(d) *Inactivation of virus.* The virus shall be inactivated, as evidenced by the test in tissue culture as set forth in § 630.23 through the use of an agent or method which has been demonstrated to be effective in the hands of the manufacturer in inactivating a series of at least 5 consecutive lots of adenovirus vaccine. If formaldehyde is used for inactivation, it shall be added to the virus suspension to a final concentration of U.S.P. formaldehyde solution of at least 1:4000. The inactivation shall be conducted under controlled conditions of pH and time at a temperature of 36° to 38° C. As an indication of inactivation, not less than two samples shall be removed during the inactivation process and treated as prescribed in § 630.23(b)(1). Regardless of the concentration of formaldehyde used, the total heating period shall be not less than 20 hours and at least three times the period required for the reduction of live virus to a point where no virus is detected in a 5 milliliter sample when tested in accordance with § 630.23(b)(1). At the end of the heating period a sample shall be removed for the single strain tissue culture safety test.

§ 630.23 Tests for safety.

In the manufacture of the product, the following tests relating to safety shall be conducted by the manufacturer:

(a) *The virus pool—(1) Tests prior to inactivation—(i) B virus and Mycobacterium tuberculosis.* Prior to inactivation, each individual virus harvest or virus pool shall be tested for the presence of B virus and Mycobacterium tuberculosis.

(ii) *SV_{40}.* Prior to inactivation, the material shall be tested for the presence of SV_{40} as follows (or by any other test producing equally reliable results): A sample of at least five ml. from the virus harvest or virus pool or pool of tissue culture fluids from corresponding control vessels shall be neutralized by high titer antiserum of an origin other than human, chicken, or simian. The sample shall be tested in the same tissue culture system used for propagating the virus vaccine, and in primary cercopithecus tissue cultures or in a cell line demonstrated as equally susceptible to SV_{40}. Each tissue culture system shall be observed for at least 14 days and at the end of the observation period at least one subculture of fluid shall be made in the same tissue culture system and observed for an additional 14 days.

(iii) *Test results.* The virus harvest or virus pool is satisfactory for adenovirus vaccine only if the tests produce no evidence of the presence of B virus, Mycobacterium tuberculosis and SV_{40}.

(2) Each single strain virus pool shall be shown to be free of lymphocytic choriomeningitis virus and other mouse pathogens by intracerebral injection into 10 or more mice which shall be observed daily for at least 21 days. All mice which die during the observation period shall be studied as to the possible cause of death. A negative test shall not be valid unless at least 8 mice survive the full observation period and unless the virus pool was found free of agents pathogenic for mice; and

(3) An identity test shall be done on each virus pool using monovalent adenovirus serums free from poliomyelitis antibodies. Such serums shall have been prepared from animals immunized with virus grown in other than the tissue used for the neutralization test. The identity tests shall be done (i) in monkey kidney and (ii) in HeLa or other equally susceptible cells. The tissue cultures shall be observed for 7 days. Those showing cytopathogenic effect in the presence of type specific serum shall be subcultured in monkey kidney cells or HeLa cells. The subcultures shall be maintained for 7 days and observed for cytopathogenic effect. Only virus pools free of unidentified cytopathogenic agents and free of all viruses pathogenic to man other than adenoviruses may be used for vaccine manufacture.

(b) *Single strain tissue culture test for adenovirus.* (1) The samples specified in § 630.22(d) shall be placed immediately after sampling in contact with sodium bisulfite or a similar formaldehyde neutralizing substance that will stop the inactivation process. Each sample shall be dialyzed or rendered non-toxic to tissue culture cells by an appropriate method which does not affect the detection of live virus. An amount of fluid representing at least 5 milliliters of the original virus pool shall be inoculated into monkey kidney or other equally susceptible tissue cultures. The tissue cultures shall be maintained for 7 to 12 days and examined at intervals. At the end of the above period, the cell sheet shall be removed from each culture vessel, broken up by an appropriate means, suspended in a portion of its culture fluid equal to at least 10 percent of the volume which was present during incubation, and inoculated into corresponding fresh tissue culture preparations. Any fluids recovered prior to refeeding during original observation period shall be held at 2° to 5°C. A volume of each fluid representing at least 10 percent of the total volume shall be

subcultured to fresh tissue culture. All subcultures shall be examined for at least 7 days. This test shall be considered negative only if no cellular degeneraton occurs attributable to any virus.

(2) A sample of at least 500 milliliters of each single strain pool shall be fully subjected to the following testing procedure in tissue culture cells, with half the sample in monkey kidney cells and half in suitable human cells of demonstrated high susceptibility to adenovirus and poliovirus. The entire sample shall be dialyzed and rendered non-toxic for tissue culture cells. Each half of the sample shall be inoculated into 4 or more tissue culture bottles of suitable capacity so that direct observation of the culture cells is possible under conditions which assure the growth of adenovirus, poliovirus or simian viruses should infective particles of any of these viruses be present in the vaccine. The monkey kidney cell cultures shall be performed as described in § 630.4(b) except that a third subculture shall be included after 21 days of incubation of the initial culture and that this subculture shall be made by suspending the cell sheet. The initial human cell cultures shall be observed for at least 12 days. A subculture shall be made on each fluid at each refeeding and on the suspension of each cell sheet in the culture fluid removed at the end of the observation period. The inoculum for the subcultures shall be a volume of at least 2 percent of that of the fluid being studied. The subculture shall be examined frequently and refed as required, and maintained for a period of at least 12 days. If a cytopathogenic effect occurs during the test, the vaccine pool shall be held until the matter is resolved. If active poliomyelitis virus or adenovirus is indicated, the strain pool shall not be used for inclusion in a final vaccine. If other viruses are present, the pool shall not be used unless it can be demonstrated that such viruses did not originate from the strain pool being tested.

(c) *Final vaccine pool tissue culture test.* No less than 1,500 milliliters of the final vaccine pool without final preservative, prepared by pooling the individual single strain preparations, shall be tested in accordance with § 630.4 (b) and (c).

(d) *Final vaccine test for active virus in monkeys.* Final bulk vaccine shall be tested in monkeys as prescribed in § 630.4(e) except that the test may be applied to vaccine before it is placed in final containers, and the sample may be dialyzed in order to remove sodium bisulfite or the sodium bisulfite formaldehyde complex before injection intraspinally and intracerebrally into monkeys. In no case, however, shall dialyzed vaccine be used for the intramuscular injection of the monkeys. The test is considered negative if the histological and other studies leave no doubt that virus infections attributable to the vaccine did not occur.

(e) *Exclusion of certain pools from final vaccine.* Pools which fail to pass the tissue culture safety tests prescribed in this section shall not be included in final vaccine, unless it can be clearly shown that the cytopathogenic agent occurred in the test system and not in the vaccine pool. No pool shall be subjected to reprocessing.

§ 630.24 Potency test.

Each lot of vaccine shall be subjected to a potency test which permits an estimation of the antigenic capacity of the vaccine in comparison with a reference vaccine distributed by the Food and Drug Administration. This shall be done using at least 6 animals for each dilution of each vaccine tested and measuring the neutralizing antibody response of the animals receiving test vaccine and others receiving reference vaccine in simultaneous tests. The average antibody level for each type shall equal or exceed the corresponding value of the reference vaccine.

§ 630.25 Equivalent methods.

The provisions of § 630.6 permitting modifications in methods if found equivalent in assuring safety, purity, and potency, shall be applicable to the additional standards relating to adenovirus vaccine (§§ 630.20 to 630.24, inclusive).

Subpart D—Measles Virus Vaccine, Live, Attenuated

§ 630.30 Measles Virus Vaccine, Live, Attenuated.

(a) *Proper name and definition.* The proper name of this product shall be Measles Virus Vaccine, Live, Attenuated, which shall consist of a preparation of live, attenuated, measles virus.

(b) *Criteria for acceptable strains of attenuated measles virus.* Strains of attenuated measles virus used in the manufacture of vaccine shall be identified by (1) historical records including origin and manipulation during attenuation, (2) antigenic specificity as measles virus as demonstrated by tissue culture neutralization tests. Strains used for the manufacture of Measles Virus Vaccine, Live, Attenuated, shall have been shown to be safe and potent in man by field studies with experimental vaccines. Vaccine prepared from measles virus strains propagated in chick embyro or canine renal tissue cultures shall have been demonstrated as safe and potent in at least 10,000 susceptible persons. Susceptibility shall be shown by the absence of neutralizing or other antibodies against measles virus, or by other appropriate methods. Vaccine prepared from measles virus strains propagated in canine renal tissue cultures shall also have been demonstrated to be free from harmful effects in not less than 100,000 persons. Seed virus used for vaccine manufacture shall be free of all demonstrable extraneous viable microbial agents except for unavoidable bacteriophage.

(c) *Neurovirulence safety test of the virus seed strain in monkeys*—(1) *The test.* A demonstration shall be made in monkeys of the lack of neurotropic properties of the seed strain of attenuated measles virus used in manufacture of measles virus vaccine. For this purpose, vaccine from each of the five consecutive lots (§ 630.31) used by the manufacturer to establish consistency of manufacture of the vaccine shall be tested separately in the following manner:

(i) Samples of each of the five lots of vaccine shall be tested in measles susceptible monkeys. Immediately prior to initiation of a test each monkey shall have been shown to be serologically negative for neutralizing antibodies by means of a tissue culture neutralization test with undiluted serum from each monkey tested at approximately 100 $TCID_{50}$ of Edmonston strain measles virus, or negative for measles virus antibodies as demonstrated by tests of equal sensitivity.

(ii) A test sample of vaccine removed after clarification but before final dilution for standardization of virus content shall be used for the test.

(iii) Vaccine shall be injected by combined intracerebral, intraspinal, and intramuscular routes into not less than 20 Macaca or Cercopithecus monkeys or a species found by the Director, Bureau of Biologics, to be equally suitable for the purpose. The animals shall be in overt good health and injected under deep barbiturate anesthesia. The intramuscular injection shall consist of 1.0 milliliter of test sample into the right leg muscles. At the same time, 200 milligrams of cortisone acetate shall be injected into the left leg muscles, and 1.0 milliliter of procaine penicillin (300,000 units) into the right arm muscles. The intracerebral injection shall consist of 0.5 milliliter of test sample into each thalamic region of each hemisphere. The intraspinal injection shall consist of 0.5 milliliter of test sample into the lumber spinal cord enlargement.

(iv) The monkeys shall be observed for 17–21 days and symptoms of paralysis as well as other neurologic disorders shall be recorded.

(v) At least 90 percent of the test animals must survive the test period without losing more than 25 percent of their weight except that, if at least 70 percent of the test animals survive the first 48 hours after injection, those animals which do not survive this 48-hour test period may be replaced by an equal number of qualified test animals which are tested pursuant to subdivisions (i) through (iv) of this subparagraph. At least 80 percent of the injected animals surviving beyond the first 48 hours must show gross or microscopic evidence of inoculation trauma in the thalamic area and microscopic evidence of inoculation trauma in the lumbar region of the spinal cord. If less than 70 percent of the test animals survive the first 48 hours, or if less than 80 percent of the animals meet the inoculation criteria prescribed in this paragraph, the test must be repeated.

(vi) At the end of the observation period, each surviving monkey shall (a) be bled and the serum tested for evidence of serum antibody conversion to measles virus and (b) be autopsied and samples of cerebral cortex and of cervical and lumbar spinal cord enlargements shall be taken for virus recovery and identi-

fication if needed pursuant to subdivision (vii) of this subparagraph. Histological sections shall be prepared from both spinal cord enlargements and appropriate sections of the brain and examined.

(vii) Doubtful histopathological findings necessitate (*a*) examination of a sample of sections from several regions of the brain in question, and (*b*) attempts at virus recovery from the nervous systems tissues previously removed from the animal.

(viii) The lot is satisfactory if the histological and other studies demonstrate no evidence of changes in the central nervous system attributable to unusual neurotropism of the seed virus or of the presence of extraneous neurotropic agents.

(2) *Wild virus controls.* As a check against the inadvertent introduction of wild measles virus, at least four uninoculated measles susceptible control monkeys shall be maintained as either cage mates to, or within the same immediate area of, the 20 inoculated test animals for each lot of vaccine for the entire period of observation (17–21 days) and an additional 10 days. Serum samples from these control contact monkeys drawn at the time of seed virus inoculation of the test animals, and again after completion of the test, shall be shown to be free of measles neutralizing antibodies.

(3) *Test results.* (i) For each lot of vaccine under test, at least 80 percent of the monkeys must show measles antibody serological conversion (1:4 or greater) when the serum as obtained from the monkey is tested and the control contact monkeys must demonstrate no immunological response indicative of measles virus infection.

(ii) The measles virus seed has acceptable neurovirulence properties for use in vaccine manufacture only if for each of the five lots (*a*) 90 percent of the monkeys survive the observation period, (*b*) the histological and other studies produce no evidence of changes in the central nervous system attributable to unusual neurotropism of the seed virus, and (*c*) there is no evidence of the presence of extraneous neurotropic agents.

(4) *Need for additional neurovirulence safety testing.* A neurovirulence safety test as prescribed in this paragraph shall be performed on vaccine from five consecutive lots whenever a new production seed lot is introduced or whenever the source of cell culture substrate must be reestablished and recertified as prescribed in § 630.32 (a), (b), and (c).

§ 630.31 Clinical trials to qualify for license.

To qualify for license, the antigenicity of the vaccine shall have been determined by clinical trials of adequate statistical design, by subcutaneous administration of the product. Such clinical trials shall be conducted with five consecutive lots of measles virus vaccine which have been manufactured by the same methods, each of which has shown satisfactory results in all prescribed tests. There shall be a demonstration under circumstances wherein adequate clinical and epidemiological surveillance of illness has been maintained to show that the Measles Virus Vaccine, when administered as recommended by the manufacturer—i.e., either with or without human gamma globulin—is free of harmful effect upon administration to approximately 1,000 susceptible individuals, in that there were no detectable neutralizing antibodies before vaccination and there was serological conversion after vaccination. The five lots of vaccine used to qualify for consistency of vaccine manufacture shall be distributed as evenly as possible among the 1,000 individuals tested. Demonstration shall be made of immunogenic effect by the production of specific measles neutralizing antibodies (i.e., sero-conversion less than 1:4 to 1:8 or greater) in at least 90 percent of each of five groups of measles suspectible individuals, each having received the parenteral administration of a virus vaccine dose which is not greater than that which was demonstrated to be safe in field studies (§ 630.30(b)) when used under comparable conditions.

§ 630.32 Manufacture of live, attenuated Measles Virus Vaccine.

(a) *Virus cultures.* Virus shall be propagated in chick embryo tissue cultures or canine renal tissue cultures.

(b) *Virus propagated in chick embryo tissue cultures.* Embryonated chicken eggs used as the source of chick embryo tissue for the propagation of measles virus shall be derived from flocks certified to be free of Salmonella pullorum, avian tuberculosis, fowl pox, Rous sarcoma, avian leucosis and other adventitious agents pathogenic for chickens. If eggs are procured from flocks that are not so certified, tests shall be performed to demonstrate freedom of the vaccine from such agents. (See § 630.35(a)(8) for test for avian leucosis.)

(c) *Virus propagated in canine renal tissue cultures.* Only dogs in overt good health which have been maintained in quarantine in vermin-proof quarters for a minimum of six months, having had no exposure to other dogs or animals throughout the quarantine period, or dogs born to dogs while so quarantined, provided the progeny have been kept in the same type of quarantine continuously from birth, shall be used as a source of kidney tissue for the propagation of measles virus.

(1) *Dogs used for experimental purposes.* Dogs that have been used previously for experimental or testing purposes with microbiological agents shall not be used as a source of kidney tissue in the manufacture of vaccine.

(2) *Quarantine and necropsy.* Each dog shall be examined periodically during the quarantine period as well as at the time of necropsy under the direction of a qualified pathologist, physician or veterinarian having experience with diseases of dogs, for the presence of signs or symptoms of ill health, particularly for evidence of tuberculosis, infectious canine hepatitis, canine distemper, rabies, leptospirosis, and other diseases indigenous to dogs. If there are any such signs, symptoms, or other significant pathological lesions observed, tissue from such animals shall not be used in the manufacture of Measles Virus Vaccine, Live, Attenuated.

(d) *Passage of virus strain in vaccine manufacture.* Virus in the final vaccine shall represent no more than ten tissue culture passages beyond the passage used to perform the clinical trials (§ 630.30 (b)) which qualified the manufacturer's vaccine strain for license.

(e) *Tissue culture preparation.* Only primary cell tissue cultures shall be used in the manufacture of Measles Virus Vaccine. Continuous cell lines shall not be introduced or propagated in Measles Virus Vaccine manufacturing areas.

(f) *Control vessels.* (1) From the tissue used for the preparation of tissue cultures for growing attenuated measles virus, an amount of processed cell suspension equivalent to that used to prepare 500 ml. of tissue culture shall be used to prepare uninfected tissue control materials. This material shall be distributed in control vessels and observed microscopically for a period of no less than 14 days beyond the time of inoculation of the production vessels with measles virus; but if the production vessels are held for use in vaccine manufacture for more than 14 days, the control vessels shall be held and observed for the additional period. At the end of the observation period or at the time of virus harvest, whichever is later, fluids from the control cultures shall be tested for the presence of adventitious agents as follows:

Samples of fluid from each control vessel shall be collected at the same time as fluid is harvested from the corresponding production vessels. If multiple virus harvests are made from the same cell suspension, the control samples for each harvest shall be frozen and stored at −60° C. until the last viral harvest for that cell suspension is completed. The fluid from all the control samples from that suspension shall be pooled in proportionate amounts and at least five ml. inoculated into human and simian cell tissue culture systems and in the tissue culture system used for virus production. The cultures shall be observed for the presence of changes attributable to growth of adventitious viral agents including hemadsorption viral agents.

(2) The cell sheets of one quarter to one third of the control vessels shall be examined at the end of the observation period (14 days or longer) for the presence of hemadsorption viruses by the addition of guinea pig red blood cells. If the chick embryo cultures were not derived from a certified source (§ 630.32 (b)), the remaining tissue culture controls may be used to test for avian leucosis virus using either Rubin's procedure for detecting Resistance Inducing Factor (RIF) or a method of equivalent effectiveness.

(3) The test is satisfactory only if there is no evidence of adventitious viral agents and if at least 80 percent of the control vessels are available for observa-

tion at the end of the observation period (14 days or longer).

(g) *Test samples.* Samples of virus harvests or pools for testing by inoculation into animals, into tissue culture systems, into embryonated hens' eggs, and into bacteriological media, shall be withdrawn immediately after harvesting or pooling but prior to freezing except that samples of test materials frozen immediately after harvesting or pooling and maintained at −60° C. or below, may be tested upon thawing, provided no more than two freeze-thaw cycles are employed. The required tests shall be initiated without delay after thawing.

§ 630.33 Reference virus.

A U.S. Reference Measles Virus, Live, Attenuated, shall be obtained from the Bureau of Biologics as a control for correlation of virus titers.

§ 630.34 Potency test.

The concentration of live measles virus shall constitute the measure of potency. The titration shall be performed in a suitable cell culture system, free of wild viruses, using either the U.S. Reference Measles Virus, Live, Attenuated or a calibrated equivalent strain as a titration control. The concentration of live measles virus contained in the vaccine of each lot under test shall be no less than the equivalent of 1,000 $TCID_{50}$ of the U.S. reference per human dose.

§ 630.35 Test for safety.

(a) *Tests prior to clarification of vaccine manufactured in chick embryo tissue cultures.* Prior to clarification, the following tests shall be performed on each virus pool of chick embryo tissue culture:

(1) *Inoculation of adult mice.* Each of at least 20 adult mice each weighing 15–20 grams shall be inoculated intraperitoneally with 0.5 ml. and intracerebrally with 0.03 ml. amounts of each virus pool to be tested. The mice shall be observed for 21 days. Each mouse that dies after the first 24 hours of the test, or is sacrificed because of illness, shall be necropsied and examined for evidence of viral infection by direct observation and subinoculation of appropriate tissue into at least five additional mice which shall be observed for 21 days. The virus pool may be used only if at least 80 percent of the original group of mice remain healthy and survive the observation period and if none of the mice show evidence of a transmissible agent or other viral infection, other than measles virus, attributable to the vaccine.

(2) *Inoculation of suckling mice.* Each of at least 20 suckling mice less than 24 hours old shall be inoculated intracerebrally with 0.01 ml. and intraperitoneally with 0.1 ml. of the virus pool to be tested. The mice shall be observed daily for at least 14 days. Each mouse that dies after the first 24 hours of the test, or is sacrificed because of illness, shall be necropsied and examined for evidence of viral infection. Such examination shall include subinoculation of appropriate tissue suspensions into an additional group of at least five suckling mice by intracerebral and intraperitoneal routes and observed daily for 14 days. In addition, a blind passage shall be made of a single pool of the emulsified tissue (minus skin and viscera) of all mice surviving the original 14-day test. The virus pool is satisfactory for Measles Virus Vaccine only if at least 80 percent of the original inoculated mice remain healthy and survive the entire observation period, and if none of the mice used in the test show evidence of a transmissible agent or viral infection, other than measles virus, attributable to the vaccine.

(3) *Inoculation of monkey tissue cell cultures.* A volume of virus suspension of each undiluted virus pool, equivalent to at least 500 human doses or 50 ml., whichever represents a greater volume, shall be tested for adventitious agents in cercopithecus monkey kidney tissue culture preparations, after neutralization of the measles virus by a high titer antiserum of nonhuman, nonsimian, and nonchicken origin. The immunizing antigen used for the preparation of the measles antiserum shall be grown in tissue culture cells that shall be free of extraneous viruses which might elicit antibodies that could inhibit growth of extraneous viruses present in the measles virus pool. The tissue culture of the virus pool shall be observed for no less than 14 days. The virus pool is satisfactory for measles virus vaccine only if all the tissue culture tests fail to show evidence of any extraneous transmissible agent other than measles virus attributable to the vaccine.

(4) *Inoculation of other cell cultures.* The measles virus pool shall be tested in the same manner as prescribed in subparagraph (3) in rhesus or cynomolgus monkey kidney, chick embryo, and human tissue cell cultures.

(5) *Inoculation of embryonated chicken eggs.* A volume of virus suspension of each undiluted virus pool, equivalent to at least 100 doses or 10 ml., whichever represents a greater volume, after neutralization of the measles virus by a high titer antiserum of nonhuman, nonsimian, nonchicken origin, shall be tested in embryonated eggs by the allantoic cavity route of inoculation and a separate group tested by the yolk sac route of inoculation, using 0.5 ml. of inoculum per egg. The virus pool is satisfactory if there is no evidence of adventitious agents.

(6) [Reserved]

(7) *Bacteriological tests.* Each virus pool shall be tested for sterility in accordance with § 610.12 of this chapter. In addition each virus pool shall be tested for the presence of M. tuberculosis, both avian and human, by appropriate culture methods.

(8) *Test for avian leucosis.* If the cultures were not derived from a certified source (§ 630.32(b)), and the control fluids were not tested for avian leucosis (§ 630.32(f)), at least 500 doses or 50 ml., whichever represents a greater volume of each undiluted vaccine pool, shall be tested and found negative for avian leucosis, using either Rubin's procedure for detecting Resistance Inducing Factor (RIF) or another method of equivalent effectiveness.

(b) *Tests prior to clarification of vaccine manufactured in canine renal tissue cultures.* Prior to clarification, the following tests shall be performed on each virus pool of canine renal tissue culture:

(1) *Inoculation of adult mice.* Virus grown in canine renal tissue cultures shall be tested in adult mice, as prescribed in paragraph (a)(1) of this section for virus grown in chick embryo tissue cultures. Test result standards are those prescribed therein.

(2) *Inoculation of suckling mice.* Each of at least 20 suckling mice less than 24 hours old shall be inoculated intracerebrally with 0.01 ml. and interperitoneally with 0.1 ml. of the canine renal tissue culture virus pool to be tested. The mice shall be observed daily for at least 28 days. Each mouse that dies after the first 48 hours of the test, or is sacrificed because of illness, shall be necropsied and all areas examined for evidence of viral infection. Such examination shall include subinoculation of appropriate tissue suspensions into an additional group of at least five suckling mice by intracerebral and intraperitoneal routes and observed daily for 28 days. The virus pool is satisfactory for Measles Virus Vaccine only if at least 80 percent of the originally inoculated mice remain healthy and survive the entire observation period, and if none of the mice used in the test show evidence of having been infected with rabies virus or any other transmissible agent or viral infection other than measles virus.

(3) *Inoculation of monkey tissue cell cultures.* Virus grown in canine renal tissue cultures shall be tested in monkey tissue cell cultures as prescribed in paragraph (a)(3) of this section for virus grown in chick embryo tissue cultures. Test result standards are those prescribed therein.

(4) *Inoculation of other cell cultures.* Virus grown in canine renal tissue cultures shall be tested in rhesus or cynomolgus monkey kidney tissue, canine renel tissue and human tissue cell cultures as prescribed in paragraph (a)(3) of this section for testing virus grown in chick embryo tissue culture in cercopithecus monkey kidney tissue culture preparations. Test result standards are those prescribed therein.

(5) *Inoculation of embryonated eggs.* Virus grown in canine renal tissue cultures shall be tested in embryonated eggs as prescribed in paragraph (a)(5) of this section for virus grown in chick embryo tissue cultures. Test result standards are those prescribed therein.

(6) [Reserved]

(7) *Bacteriological test.* Each virus pool shall be tested for sterility in accordance with § 610.12 of this chapter. In addition each virus pool shall be tested for M. tuberculosis, human, by appropriate culture methods.

(8) *Tests for adventitious agents.* Each virus pool shall be tested for the presence of such adventitious agents as canine distemper virus, canine hepati-

tis virus, leptospira and toxoplasma and the following fungi: coccidiomyces, histoplasma and blastomyces. The virus pool is satisfactory only if the results of all tests show no evidence of any extraneous agent attributable to the canine renal tissue or the vaccine.

(c) *Clarification.* After harvesting and removal of samples for testing as prescribed above in this section, the virus fluids shall be clarified by centrifugation, by passage through filters of sufficiently small porosity, or by any other method that will assure removal of all intact tissue cells which may have been collected in the harvesting process.

§ 630.36 General requirements.

(a) *Final container tests.* In addition to the tests required pursuant to § 610.14 of this chapter, an immunological and virological identity test shall be performed on the final container if it was not performed on each pool or the bulk vaccine prior to filling.

(b) [Reserved]

(c) [Reserved]

(d) *Dose.* These standards are based on an individual human immunizing dose of no less than 1,000 $TCID_{50}$ of Measles Virus Vaccine, Live, Attenuated, expressed in terms of the assigned titer of the U.S. reference measles virus.

(e) *Labeling.* In addition to the items required by other applicable labeling provisions of this subchapter, single-dose container labeling for vaccine which is not protected against photochemical deterioration shall include a statement cautioning against exposure to sunlight.

(f) *Dried vaccine.* Measles Vaccine, Live, Attenuated, may be dried immediately after completion of processing to final bulk material and stored in the dried state, provided its residual moisture and other volatile substances content is not in excess of 2 percent, as provided in § 610.13(a) of this chapter.

(g) *Photochemical deterioration; protection.* Vaccine in multiple dose final containers shall be protected against photochemical deterioration. Such containers may be colored, or outside coloring or protective covering may be used for this purpose, provided (1) the method used is shown to provide the required protection, and (2) visible examination of the contents is not precluded. Vaccine in single dose containers may be protected in the same manner provided the same conditions are met.

(h) *Samples and protocols.* For each lot of vaccine, the following materials shall be submitted to the Director, Bureau of Biologics, Food and Drug Administration, Building 29A, 9000 Rockville Pike, Bethesda, MD 20014:

(1) A protocol which consists of a summary of the history of the manufacture of each lot including all results of each test for which test results are requested by the Director, Bureau of Biologics.

(2) A total of no less than 120 ml. in 10 ml. volumes, in a frozen state (−60° C.), of preclarification bulk vaccine containing no preservative or adjuvant, and no less than 100 ml. in 10 ml. volumes, in a frozen state (−60° C.), of post-clarification bulk vaccine containing stabilizer but no preservative or adjuvant, taken prior to filling into final containers.

(3) A total of no less than 200 recommended doses of the vaccine in final labeled containers distributed equally between the number of fillings made from each bulk lot, except that the representation of a single filling shall be no less than 30 final containers.

§ 630.37 Equivalent methods.

Modification of any particular manufacturing method or process or the conditions under which it is conducted as set forth in the additional standards relating to Measles Virus Vaccine, Live, Attenuated, shall be permitted whenever the manufacturer presents evidence that demonstrates the modification will provide assurances of the safety, purity, and potency of the vaccine that are equal to or greater than the assurances provided by such standards, and the Commissioner of Food and Drugs so finds and makes such finding a matter of officials record.

Subpart E—Measles Virus Vaccine, Inactivated

§ 630.40 Measles Virus Vaccine, Inactivated.

(a) *Proper name and definition.* The proper name of this product shall be Measles Virus Vaccine, Inactivated. The vaccine shall consist of a preparation of measles virus inactivated by an appropriate method.

(b) *Criteria for acceptable strains of measles virus.* Strains of measles virus used in the manufacture of vaccine shall be identified by (1) historical records including origin and manipulation and (2) antigenic specificity as measles virus as demonstrated by tissue culture neutralization tests. Strains used for the manufacture of Measles Virus Vaccine, Inactivated, shall have been shown to be safe and potent in man by field studies with experimental vaccines. Vaccine prepared from measles virus strains propagated in chick embryo tissue cultures, monkey kidney tissue cultures or canine renal tissue cultures, shall have been demonstrated as safe and potent in at least 10,000 susceptible persons. Susceptibility shall be shown by the absence of neutralizing or other antibodies against measles virus, or by other appropriate methods. Vaccine prepared from measles virus strains propagated in canine renal tissue cultures shall also have been demonstrated to be free from harmful effects in not less than 100,000 persons. Seed virus used for vaccine manufacture shall be free of all demonstrable extraneous viable microbial agents.

§ 630.41 General requirements.

(a) [Reserved]

(b) *Extraneous protein.* The final vaccine shall have a protein nitrogen content of less than 0.02 milligram per individual human dose.

(c) *Dose.* These standards are based on an individual human dose of 1.0 ml. for a single injection.

(d) [Reserved]

(e) [Reserved]

(f) *Requirements for samples and protocols.* For each lot of vaccine, the following material shall be submitted to the Director, Bureau of Biologics, Food and Drug Administration, Building 29A, 9000 Rockville Pike, Bethesda, MD 20014.

(1) A sample of 1,500 doses of the vaccine taken after the last stage of manufacture before the addition of preservative or adjuvant.

(2) A sample of 100 doses of the final vaccine containing all preservatives.

(3) A sample of 200 doses of the final vaccine in final labeled containers.

(4) A protocol which consists of a summary of the history of the manufacture of each lot including all results of each test for which test results are requested by the Director, Bureau of Biologics.

§ 630.42 Manufacture of Measles, Virus Vaccine, Inactivated.

(a) *Virus cultures.* Virus shall be propagated in chick embryo tissue cultures, monkey kidney tissue cultures, or canine renal tissue cultures.

(b) *Virus propagated in chick embryo tissue cultures.* Embryonated chicken eggs used as a source of chick embryo tissue for the propagation of measles virus shall be derived from flocks certified to be free of Salmonella pullorum and avian tuberculosis, fowl pox, Rous sarcoma, avian leucosis and other adventitious agents pathogenic for chickens. If eggs are procured from flocks that are not so certified, tests shall be performed to demonstrate that the virus pool be free from such agents prior to inactivation.

(c) *Virus propagated in monkey kidney tissue cultures.* Only Macaca or Cercopithecus monkeys, or a species found by the Director, Bureau of Biologics, to be equally suitable, which have met all the quarantine requirements, shall be used as the source of kidney tissue for the manufacture of Measles Virus Vaccine, Inactivated.

(1) *Monkeys used for experimental purposes.* Monkeys that have been used previously for experimental purposes with microbiological agents shall not be used as a source of kidney tissue for the manufacture of vaccine. Monkeys that have been used previously for other experimental purposes may be used upon their return to a normal condition.

(2) *Quarantine.* Only monkeys that during the quarantine period, as provided by § 600.11(f)(2) of this chapter, have been tested with and have reacted negatively to tuberculin shall be used as a source of kidney tissue for vaccine manufacture.

(3) *Necropsy.* Each animal at necropsy shall be examined under the direction of a qualified pathologist, physician or veterinarian having experience with diseases of monkeys, for the presence of signs or symptoms of ill health, particularly for (i) evidence of tuberculosis, (ii) presence of herpes-like lesions, including eruptions or plaques on or around the lips, in the buccal cavity or on the gums and (iii) signs of conjunctivitis. If any such signs or other

significant gross pathological lesions are present, the kidney shall not be used in the manufacture of Measles Virus Vaccine, Inactivated.

(d) *Virus propagated in canine renal tissue cultures.* Only dogs in overt good health which have been kept in quarantine in vermin-proof quarters for a minimum of six months, having had no exposure to other dogs or animals throughout the quarantine period, or dogs born to dogs while so quarantined, provided the progeny have been kept in the same type of quarantine continuously from birth, shall be used as a source of kidney tissue for the propagation of measles virus.

(1) *Dogs used for experimental purposes.* Dogs that have been used previously for experimental or testing purposes with microbiological agents shall not be used as a source of kidney tissue in the manufacture of vaccine.

(2) *Quarantine and necropsy.* Each dog shall be examined periodically during the quarantine period as well as at the time of necropsy under the direction of a qualified pathologist, physician or veterinarian having experience with diseases of dogs, for the presence of signs or symptoms of ill health, particularly for evidence of tuberculosis, infectious canine hepatitis, canine distemper, rabies, leptospirosis, and other diseases indigenous to dogs. If there are any such signs, symptoms, or other significant pathological lesions observed, the kidneys from such animals shall not be used in the manufacture of Measles Virus Vaccine, Inactivated.

(e) *U.S. Reference Measles Virus.* The following U.S. reference viruses shall be obtained from the Bureau of Biologics:

(1) U.S. Reference Measles Virus for titration.

(2) U.S. Reference Measles Vaccine for potency testing.

(f) *Passage of virus strain in vaccine manufacture.* Virus in the final vaccine shall represent no more than ten tissue culture passages beyond the passage used to perform the clinical trials which qualified the vaccine strain for license (§ 630.40(b)), and the virus of that passage shall represent vaccine that shall have met the following criteria of acceptability:

(1) *Clinical safety.* The vaccine shall be free from harmful effects. Freedom from harmful effects shall be demonstrated by administration, as recommended by the manufacturer, and while maintaining adequate clinical and epidemiological surveillance of illness, to approximately 1,000 individuals, having no detectable neutralizing antibodies before vaccination and showing serological conversion after vaccination. Five consecutive lots of vaccine shall be used to qualify the vaccine for license and shall be distributed as evenly as possible among the 1,000 individuals tested.

(2) *Clinical potency.* The immunogenic effect (i.e., sero-conversion less than 1: 4 to 1: 8 or greater) shall be demonstrated in at least 90 percent of each of five groups of measles susceptible individuals, each group receiving vaccine from one of the five consecutive lots of vaccine which were used to qualify the vaccine for license, and each of which shall have met the safety standards prescribed in these regulations. The dose of vaccine shall be no greater than that which was demonstrated to be safe pursuant to subparagraph (1) of this paragraph and the vaccine shall be used under comparable conditions.

(g) *Types of tissue culture preparation permissible.* Measles Virus Vaccine, Inactivated, shall be produced only in primary cell tissue culture. Continuous line cells shall not be used and shall not be introduced into vaccine production areas.

(h) *Use of antibiotics.* Virus for manufacturing vaccine may be grown in cultures which contain minimum concentration of suitable antibiotics except that penicillin shall not be used in the tissue culture medium or added to the final product.

(i) *Clarification.* After harvesting, the virus fluids shall be clarified by centrifugation, by passage through filters of sufficiently small porosity, or by any other method that will assure removal of all intact tissue cells which may have been collected in the harvesting process.

§ 630.43 Test for safety.

(a) *Tests prior to the inactivation process.* Samples of virus pools for testing by inoculation into animals or into bacteriological media shall be withdrawn immediately after pooling but prior to freezing or further processing, and tested, prior to the inactivation process, as provided in paragraphs (b) and (c) of this section except that samples of test materials frozen immediately after pooling and maintained at −60° C. or below, may be tested upon thawing, provided no more than two freeze thaw cycles are employed. The required tests shall be conducted without delay after thawing.

(1) *Measles virus propagated in chick embryo tissue cultures*—(i) *Inoculation of adult mice; test for adventitious agents.* Each chick embryo virus pool shall be shown to be free of contaminating agents pathogenic for mice by the intracerebral inoculation of 0.03 ml. and intraperitoneal inoculation of 0.5 ml. amounts of the pool into each of ten or more adult mice (15–20 gms.). The mice shall be observed for at least 21 days. The virus pool is satisfactory for measles virus vaccine only if at least 80 percent of the inoculated animals survive the observation period and none of the animals inoculated shows evidence of infection with extraneous transmissible agents attributable to the vaccine.

(ii) [Reserved]

(iii) *Bacteriological tests.* Each chick embryo virus pool shall be tested for bacteriological sterility in accordance with the procedures prescribed in § 610.12 of this chapter. In addition each virus pool shall be tested and found negative for the presence of M. tuberculosis, both avian and human, by appropriate culture methods.

(iv) *Test for avian leucosis.* The equivalent of at least 50 doses of final vaccine from each undiluted virus pool, or in proportionate amounts from individual harvests or subpools, shall be tested and found negative for avian leucosis, using either Rubin's procedure for detecting Resistance Inducing Factor (RIF) or a procedure of equivalent effectiveness. These tests may be performed on corresponding amounts of fluids from control vessels instead of on the undiluted virus pool or individual harvests of subpools.

(2) *Measles virus propagated in monkey kidney tissue cultures*—(i) *Inoculation of rabbits; test for B virus and other adventitious agents.* A minimum of 100 ml. of each monkey kidney virus pool shall be tested by inoculation into at least ten healthy rabbits, each weighing 1500–2500 grams. Each rabbit shall be injected intradermally at multiple sites with a total of 1.0 ml. and subcutaneously with 9.0 ml. of the virus, and the animals observed for at least three weeks. Each rabbit that dies after the first 24 hours of the test or is sacrificed because of illness shall be necropsied and the brain and organs removed and examined. The virus pool may be used for measles virus vaccine only if at least 80 percent of the rabbits remain healthy and survive the entire period and if none of the rabbits used in the test shows lesions of any kind at the sites of inoculation or shows evidence of B virus or any other transmissible agent attributable to the vaccine.

(ii) *Inoculation of adult mice; test for adventitious agents.* Each virus pool grown in monkey kidney tissue culture shall be tested in adult mice. The test shall be performed and the results measured against the standards prescribed in subparagraph (1)(i) of this paragraph for chick embryo tissue culture.

(iii) *Inoculation of guinea pigs; test for M. tuberculosis.* Each of at least five guinea pigs, each weighing 350–450 grams shall be inoculated intraperitoneally with 5.0 ml. of the monkey kidney virus pool to be tested. The animals shall be observed for at least 42 days for death or signs of disease. Each animal that dies after the first 24 hours of the test, or is sacrificed because of illness, shall be necropsied. The tissues shall be examined both microscopically and culturally for evidence of M. tuberculosis. The virus pool is satisfactory for measles virus vacine only if at least 80 percent of the original group of guinea pigs remain healthy and survive the observation period, and if none of the animals used in the test shows evidence of infection with M. tuberculosis or any extraneous transmissible agent attributable to the vaccine.

(iv) *Bacteriological tests.* Each monkey kidney virus pool shall be tested for bacteriological sterility in accordance with the procedures prescribed in § 610.12 of this chapter. In addition each virus pool shall be tested for the presence of M. tuberculosis (human) by appropriate culture methods.

(v) *Tissue culture test for SV_{40}.* Each individual harvest or virus pool, or a pool

of tissue culture fluids from corresponding control vessels, shall be tested for the presence of SV_{40} either as follows or by a test producing equally reliable results: five ml. of a measles virus pool shall be neutralized by high titer antiserum of an origin other than human, chicken or simian. The sample shall be tested in the same tissue culture system used for propagating the virus vaccine, and in primary cercopithecus tissue cultures or in a cell line of demonstrated equal susceptibility to SV_{40}. The tissue cultures shall be observed for at least 14 days and at the end of the observation period at least one subculture of fluid shall be made in the same tissue culture system and the test continued for an additional 14 days. The virus harvest or virus pool is satisfactory for measles virus vaccine only if the test produces no evidence of the presence of SV_{40}.

(3) *Measles virus propagated in canine renal tissue cultures*—(i) *Inoculation of adult mice; test for adventitious agents.* Each virus pool prepared from canine renal tissue cultures shall be shown to be free from contaminating agents pathogenic for mice by the test prescribed in subparagraph (1)(i) of this section for chick embryo virus pools. Test result standards are those prescribed therein.

(ii) *Inoculation of suckling mice.* Suckling mice shall be inoculated as prescribed in § 630.35(b)(2) for virus (live, attenuated) grown in canine renal tissue cultures. Test result standards are those prescribed therein.

(iii) *Inoculation of monkey tissue cell cultures.* Monkey tissue cell cultures shall be inoculated as prescribed in § 630.35(a)(3) for virus (live, attenuated) grown in chick embryo tissue cultures. Test result standards are those prescribed therein.

(iv) *Inoculation of other cell cultures.* Virus grown in canine renal tissue cultures shall be tested in rhesus or cynomolgus monkey kidney tissue, canine renal tissue and human tissue cell cultures as prescribed in § 630.35(a)(3) for testing virus grown in chick embryo tissue cultures in cercopithecus monkey kidney tissue culture preparations. Test result standards are those prescribed therein.

(v) *Inoculation of embryonated chicken eggs.* Embryonated chicken eggs shall be inoculated as prescribed in § 630.35(a)(5) for virus (live, attenuated) grown in chick embryo tissue cultures. Test result standards are those prescribed therein.

(vi) [Reserved]

(vii) *Bacteriological test.* Each virus pool shall be tested for sterility in accordance with § 610.12 of this chapter. In addition each virus pool shall be tested for M. tuberculosis, human, by appropriate culture methods.

(viii) *Test for adventitious agents.* Each virus pool shall be tested for the presence of the adventitious agents enumerated in § 630.35(b)(8) for virus (live, attenuated) grown in canine renal tissue cultures. Test result standards are those prescribed therein.

(b) *Inactivation of virus.* The measles virus shall be inactivated through the use of an agent or method which the manufacturer has demonstrated to be effective in inactivating a series of at least five consecutive lots of measles virus vaccine. If formaldehyde is used for inactivation, it shall be added to the virus suspension to a final concentration of U.S.P. formaldehyde solution of a least 1:4,000. The inactivation shall be conducted under controlled conditions of pH and temperature. As an indication of inactivation not less than two samples shall be removed at the time of inactivation, and titrated in an appropriate tissue cell culture for viable measles virus. Regardless of the concentration of formaldehyde or other inactivating agent used, the total inactivation period shall be not less than three times the period demonstrated by the manufacturer to be necessary to reduce the concentration of live virus to a point where no virus is detectable in a 5.0 ml. sample.

(c) *Tests after inactivation for viable measles virus and adventitious agents*—(1) *Test in tissue cultures.* A sample representing the equivalent of at least 500 doses of final vaccine of each lot shall be rendered nontoxic for tissue culture cells and tested as follows: One half of the sample shall be tested in the same tissue culture system used for propagating the virus vaccine and one half of the sample shall be tested in primary cercopithecus monkey kidney tissue or another suitable cell line of demonstrated high susceptibility to measles virus, poliovirus, and SV_{40} or other adventitious viral agents. Each half of the sample shall be inoculated so that direct microscopic observation of the culture cells is possible under conditions which assure the growth of measles virus, poliovirus, and simian viruses which might have survived the inactivation procedure. After inoculation of the test sample, the tissue cultures shall be observed for at least 14 days. At the end of the observation period the fluids from all the culture bottles in a system shall be removed and pooled. At least two percent of each pool shall be subinoculated in the same cell system as that from which the pooled sample was drawn. The subcultures shall be observed for a period of at least 14 days and examined for cell changes indicative of viral growth. The lot of final vaccine is satisfactory for measles virus vaccine only if none of the tissue culture tests show evidence of viable measles virus or any extraneous transmissible agents attributable to the vaccine.

(2) *Test in embryonated chicken eggs.* For vaccine produced in chick embryo tissue culture, the equivalent of at least 100 doses of each vaccine lot shall be tested in embryonated eggs by the allantoic cavity route and of 100 doses by the yolk sac route of inoculation, using 0.5 ml. of inoculum per egg, and found negative for the presence of extraneous agents in the vaccine.

(3) *Test in monkeys for neurotropic agents.* Each lot of vaccine shall be tested for neurotropic agents following the procedure prescribed in § 630.4(e) except that antibody determinations for measles need not be performed, the test shall be performed before the product is placed in final containers and prior to the addition of an adjuvant, and that symptoms suggestive of all neurotropic agents shall be recorded during the observation period of 17 to 19 days. The lot is satisfactory only if the histological and other studies produce no clinical or histological evidence of central nervous system involvement attributable to the presence of a neurotropic agent in the vaccine.

§ 630.44 Potency test.

A potency test shall be performed on each lot of vaccine by determining the antigenic capacity of the vaccine under tests in comparison with a reference vaccine of antigenic capacity at least equal to that required for the clinical trials specified in § 630.42(h)(2). The test shall be performed using at least ten animals for each dilution of the test vaccine and of the reference vaccine. The average antibody levels of the animals injected with the vaccine under test shall equal or exceed the average antibody levels of the animals injected with the reference vaccine.

§ 630.45 Equivalent methods.

Modification of any particular method of process or the conditions under which it is conducted as set forth in the additional standards relating to Measles Virus Vaccine, Inactivated, shall be permitted whenever the manufacturer presents evidence that demonstrates the modification will provide assurances of the safety, purity, and potency of the vaccine that are equal to or greater than the assurances provided by such standards, and the Commissioner of Food and Drugs so finds and makes such finding a matter of official record.

Subpart F—Mumps Virus Vaccine, Live

§ 630.50 Mumps Virus Vaccine, Live.

(a) *Proper name and definition.* The proper name of this product shall be Mumps Virus Vaccine, Live, which shall consist of a preparation of live, attenuated mumps virus.

(b) *Criteria for acceptable strains of attenuated mumps virus.* Strains of attenuated mumps virus used in the manufacture of vaccine shall be identified by (1) historical records including origin and manipulation during attenuation, (2) antigenic specificity as mumps virus as demonstrated by tissue culture neutralization tests. Strains used for the manufacture of Mumps Virus Vaccine, Live, shall have been shown to be safe and potent in at least 5,000 susceptible individuals by field studies with experimental vaccines. Susceptibility shall be shown by the absence of neutralizing or other antibodies against mumps virus, or by other appropriate methods. Seed virus used for vaccine manufacture shall be free of all demonstrable extraneous viable microbial agents except for unavoidable bacteriophage.

(c) *Neurovirulence safety test of the virus seed strain in monkeys*—(1) *The test.* A demonstration shall be made in monkeys of the lack of neurotropic properties of the seed strain of attenuated mumps virus used in the manufacture of mumps vaccine. For this purpose, vaccine from each of the five consecutive lots (§ 630.51) used by the manufacturer to establish consistency of manufacture of the vaccine shall be tested separately in monkeys shown to be serologically negative for mumps virus antibodies in the following manner:

(i) A test sample of vaccine removed after clarification but before final dilution for standardization of virus content shall be used for the test.

(ii) Vaccine shall be injected by combined intracerebral, intraspinal, and intramuscular routes into not less than 20 Macaca or Cercopithecus monkeys or a species found by the Director, Bureau of Biologics, to be equally suitable for the purpose. The animals shall be in overt good health and injected under deep barbiturate anesthesia. The intramuscular injection shall consist of 1.0 milliliter of test sample into the right leg muscles. At the same time, 200 milligrams of cortisone acetate shall be injected into the left leg muscles, and 1.0 milliliter of procaine penicillin (300,000 units) into the right arm muscles. The intracerebral injection shall consist of 0.5 milliliter of test sample into each thalamic region of each hemisphere. The intraspinal injection shall consist of 0.5 milliliter of test sample into the lumbar spinal cord enlargement.

(iii) The monkeys shall be observed for 17–21 days and symptoms of paralysis as well as other neurologic disorders shall be recorded.

(iv) At least 90 percent of the test animals must survive the test period without losing more than 25 percent of their weight except that, if at least 70 percent of the test animals survive the first 48 hours after injection, those animals which do not survive this 48-hour test period may be replaced by an equal number of qualified test animals which are tested pursuant to subdivisions (i) through (iii) of this subparagraph. At least 80 percent of the injected animals surviving beyond the first 48 hours must show gross or microscopic evidence of inoculation trauma in the thalamic area and microscopic evidence of inoculation trauma in the lumbar region of the spinal cord. If less than 70 percent of the test animals survive the first 48 hours, or if less than 80 percent of the animals meet the inoculation criteria prescribed in this paragraph, the test must be repeated.

(v) At the end of the observation period, each surviving animal shall be autopsied and samples of cerebral cortex and of cervical and lumbar spinal cord enlargements shall be taken for virus recovery and identification if needed pursuant to subdivision (vi) of this subparagraph. Histological sections shall be prepared from both spinal cord enlargements and appropriate sections of the brain and examined.

(vi) Doubtful histopathological findings necessitate (*a*) examination of a sample of sections from several regions of the brain in question, and (*b*) attempts at virus recovery from the nervous system tissues previously removed from the animals.

(vii) The lot is satisfactory if the histological and other studies demonstrate no evidence of changes in the central nervous system attributable to unusual neurotropism of the seed virus or of the presence of extraneous neurotropic agents.

(2) *Test results.* The mumps virus seed has acceptable neurovirulence properties for use in vaccine manufacture only if for each of the five lots (i) 90 percent of the monkeys survive the observation period, (ii) the histological and other studies produce no evidence of changes in the central nervous system attributable to unusual neurotropism or replication of the seed virus and (iii) there is no evidence of the presence of extraneous neurotropic agents.

(3) *Need for additional neurovirulence safety testing.* A neurovirulence safety test as prescribed in this paragraph shall be performed on vaccine from five consecutive lots whenever a new production seed lot is introduced or whenever the source of cell culture substrate must be reestablished and recertified as prescribed in § 630.52(a).

§ 630.51 Clinical trials to qualify for license.

To qualify for license, the antigenicity of Mumps Virus Vaccine, Live, shall be determined by clinical trials that follow the procedures prescribed in § 630.31 except that the immunogenic effect shall be demonstrated by establishing that a protective antibody response has occurred in at least 90 percent of each of the five groups of mumps susceptible individuals, each having received the parenteral administration of a virus vaccine dose which is not greater than that which was demonstrated to be safe in field studies (§ 630.50(b)) when used under comparable conditions.

§ 630.52 Manufacture of Mumps Virus Vaccine, Live.

(a) *Virus cultures.* Mumps virus shall be propagated in chick embryo cell cultures. The embryonated chicken eggs used as the source of chick embryo tissue for the propagation of mumps virus shall be derived from flocks certified or tested as prescribed in § 630.32(b).

(b) *Passage of virus strain in vaccine manufacture.* Virus in the final vaccine shall represent no more than five cell culture passages beyond the passage used to perform the clinical trials (§ 630.50(b)) which qualified the manufacturer's vaccine strain for license.

(c) *Cell culture preparation.* Only primary cell cultures shall be used in the manufacture of mumps virus vaccine. Continuous cell lines shall not be introduced or propagated in mumps virus vaccine manufacturing areas.

(d) *Control vessels.* From the tissue used for the preparation of cell cultures for growing attenuated mumps virus, an amount of processed cell suspension equivalent to that used to prepare 500 ml. of cell culture shall be used to prepare uninfected tissue control materials which shall be prepared and tested by following the procedures prescribed in § 630.32(f).

(e) *Test samples.* Test samples of mumps virus harvests or pools shall be withdrawn and maintained by following the procedures prescribed in § 630.32(g).

§ 630.53 Reference virus.

An NIH Reference Mumps Virus, Live, shall be obtained from the Bureau of Biologics as a control for correlation of virus titers.

§ 630.54 Potency test.

The concentration of live mumps virus shall constitute the measure of potency. The titration shall be performed in a suitable cell culture system, free of wild viruses, using either the Reference Mumps Virus, Live, or a calibrated equivalent strain as a titration control. The concentration of live mumps virus contained in the vaccine of each lot under test shall be no less than the equivalent of 5,000 $TCID_{50}$ of the reference virus per human dose.

§ 630.55 Test for safety.

(a) *Tests prior to clarification.* Prior to clarification, the following tests shall be performed on each mumps virus pool prepared in chick embryo cell culture:

(1) *Inoculation of adult mice.* The test shall be performed in the volume and following the procedures prescribed in § 630.35(a)(1), and the virus pool is satisfactory only if equivalent test results are obtained.

(2) *Inoculation of suckling mice.* The test shall be performed in the volume and following the procedures prescribed in § 630.35(a)(2), and the virus pool is satisfactory only if equivalent test results are obtained.

(3) *Inoculation of monkey cell cultures.* A mumps virus pool shall be tested for adventitious agents in the volume and following the procedures prescribed in § 630.35(a)(3), and the virus pool is satisfactory only if equivalent test results are obtained.

(4) *Inoculation of other cell cultures.* The mumps virus pool shall be tested for adventitious agents in the volume and following the procedures prescribed in § 630.35(a)(3), in rhesus or cynomolgus monkey kidney, in whole chick embryo and in human cell cultures. In addition, each virus pool shall be tested in chick embryo kidney and in chick embryo liver in the same manner except that the volume tested in each cell culture shall be equivalent to 250 human doses or 25 ml., whichever represents a greater volume. The mumps virus pool is satisfactory only if results equivalent to those in § 630.35(a)(3) are obtained.

(5) *Inoculation of embryonated chicken eggs.* A neutralized suspension of each undiluted mumps virus pool shall be tested in the volume and following the

procedures prescribed in § 630.35(a)(5), and the virus pool is satisfactory only if there is no evidence of adventitious agents.

(6) *Bacteriological tests.* In addition to the tests for sterility required pursuant to § 610.12 of this chapter, bacteriological tests shall be performed on each mumps virus pool for the presence of M. tuberculosis, both avian and human, by appropriate culture methods. The virus pool is satisfactory only if found negative for M. tuberculosis, both avian and human.

(7) *Test for avian leucosis.* If the cultures were not derived from a certified source and control fluids were not tested for avian leucosis, the vaccine shall be tested in the volume and following the procedures prescribed in § 630.35(a)(8). The cultures are satisfactory for vaccine manufacture if found negative for avian leucosis.

(b) *Clarification.* The mumps virus fluids shall be clarified by following the procedures prescribed in § 630.35(c).

§ 630.56 General requirements.

(a) *Final container tests.* In addition to the tests required pursuant to § 610.14 of this chapter, an immunological and virological identity test shall be performed on the final container if it was not performed on each pool or the bulk vaccine prior to filling.

(b) *Dose.* These standards are based on an individual human immunizing dose of no less than 5,000 $TCID_{50}$ of Mumps Virus Vaccine, Live, expressed in terms of the assigned titer of the Reference Mumps Virus, Live.

(c) *Labeling.* In addition to the items required by other applicable labeling provisions of this part, single dose container labeling for vaccine which is not protected against photochemical deterioration shall include a statement cautioning against exposure to sunlight.

(d) *Dried vaccine.* Mumps Virus Vaccine, Live, may be dried immediately after completion of processing to final bulk material and stored in the dried state provided its residual moisture and other volatile substances content is not in excess of 2 percent when tested as prescribed in § 610.13(a) of this chapter.

(e) *Photochemical deterioration; protection.* Mumps Virus Vaccine, Live, in multiple dose containers, shall be protected against photochemical deterioration in accordance with the procedures prescribed in § 630.36(g).

(f) *Samples and protocols.* For each lot of vaccine, the following materials shall be submitted to the Director, Bureau of Biologics, Food and Drug Administration, Building 29A, 9000 Rockville Pike, Bethesda, MD 20014:

(1) A protocol which consists of a summary of the history of manufacture of each lot including all results of each test for which test results are requested by the Director, Bureau of Biologics.

(2) A total of no less than a 500 ml. sample of bulk vaccine or an equivalent sample prior to addition of any preservative, stabilizer or adjuvant, in the frozen state (—60° C.) prior to filling into final containers.

(3) A total of no less than 200 recommended human doses of the vaccine in final labeled containers.

§ 630.57 Equivalent methods.

Modification of any particular manufacturing method or process or the conditions under which it is conducted as set forth in the additional standards relating to Mumps Virus Vaccine, Live, shall be permitted whenever the manufacturer presents evidence that demonstrates the modification will provide assurances of the safety, purity, and potency of the vaccine that are equal to or greater than the assurances provided by such standards, and the Commissioner of Food and Drugs so finds and makes such finding a matter of official record.

Subpart G—Rubella Virus Vaccine, Live

§ 630.60 Rubella Virus Vaccine, Live.

(a) *Proper name and definition.* The proper name of this product shall be Rubella Virus Vaccine, Live, which shall consist of a preparation of live, attenuated rubella virus.

(b) *Criteria for acceptable strains of attenuated rubella virus.* Strains of attenuated rubella virus used in the manufacture of vaccine shall be identified by (1) historical records including origin and manipulation during attenuation and (2) antigenic specificity as rubella virus as demonstrated by tissue culture neutralization tests.

(c) *Extraneous agents.* Seed virus used for vaccine manufacture shall be free of all demonstrable extraneous viable microbial agents except for unavoidable bacteriophage.

(d) *Field studies with experimental vaccines.* (1) Strains used for the manufacture of Rubella Virus Vaccine, Live, shall have been shown in field studies with experimental vaccines to be safe and potent in the group of individuals inoculated, which must include at least 10,000 susceptible individuals. Susceptibility shall be shown by the absence of neutralizing or hemagglutination-inhibiting antibodies against rubella virus or by other appropriate methods.

(2) The virus strain used in the field studies shall be propagated in the same cell culture system that will be used in the manufacture of the product.

(3) The field studies shall be so conducted that at least 5,000 of the susceptible individuals must reside when inoculated in areas where health related statistics are regularly compiled in accordance with procedures such as those used by the National Center for Health Statistics. Data in such form as will identify each inoculated person shall be furnished to the Director, Bureau of Biologics.

(4) Inoculated persons shall be shown not to be contagious for contacts through surveillance of rubella susceptible contacts of the inoculated persons.

(e) *Neurovirulence safety test of the virus seed strain in monkeys*—(1) *The test.* A demonstration shall be made in monkeys of the lack of neurotropic properties of the seed strain of attenuated rubella virus used in the manufacture of rubella vaccine. For this purpose, vaccine from each of the five consecutive lots (§ 630.61) used by the manufacturer to establish consistency of manufacture of the vaccine shall be tested separately in monkeys shown to be serologically negative for rubella virus antibodies in the following manner:

(i) A test sample of vaccine removed after clarification but before final dilution for standardization of virus content shall be used for the test.

(ii) Vaccine shall be injected by combined intracerebral, intraspinal, and intramuscular routes into not less than 20 Macaca or Cercopithecus monkeys or a species found by the Director, Bureau of Biologics, to be equally suitable for the purpose. The animals shall be in overt good health and injected under deep barbiturate anesthesia. The intramuscular injection shall consist of 1.0 milliliter of test sample into the right leg muscles. At the same time, 200 milligrams of cortisone acetate shall be injected into the left leg muscles, and 1.0 milliliter of procaine penicillin (300,000 units) into the right arm muscles. The intracerebral injection shall consist of 0.5 milliliter of test sample into each thalamic region of each hemisphere. The intraspinal injection shall consist of 0.5 milliliter of test sample into the lumbar spinal cord enlargement.

(iii) The monkeys shall be observed for 17–21 days and symptoms of paralysis as well as other neurologic disorders shall be recorded.

(iv) At least 90 percent of the test animals must survive the test period without losing more than 25 percent of their weight except that, if at least 70 percent of the test animals survive the first 48 hours after injection, those animals which do not survive this 48-hour test period may be replaced by an equal number of qualified test animals which are tested pursuant to subdivisions (i) through (iii) of this subparagraph. At least 80 percent of the injected animals surviving beyond the first 48 hours must show gross or microscopic evidence of inoculation trauma in the thalamic area and microscopic evidence of inoculation trauma in the lumbar region of the spinal cord. If less than 70 percent of the test animals survive the first 48 hours, or if less than 80 percent of the animals meet the inoculation criteria prescribed in this paragraph, the test must be repeated.

(v) At the end of the observation period, each surviving animal shall be autopsied and samples of cerebral cortex and of cervical and lumbar spinal cord enlargements shall be taken for virus recovery and identification if needed pursuant to subdivision (vi) of this subparagraph. Histological sections shall be prepared from both spinal cord enlargements and appropriate sections of the brain and examined.

(vi) Doubtful histopathological findings necessitate (*a*) examination of a sample of sections from several regions of the brain in question, and (*b*) attempts at virus recovery from the nervous system tissues previously removed from the animal.

(vii) The lot is satisfactory if the histological and other studies demonstrate no evidence of changes in the central nervous system attributable to the presence of unusual neurotropism of the seed virus or of the presence of extraneous neurotropic agents.

(2) *Test results.* The rubella virus seed has acceptable neurovirulence properties for use in vaccine manufacture only if for each of the five lots: (i) 90 percent of the monkeys survive the observation period, (ii) the histological and other studies produce no evidence of changes in the central nervous system attributable to the presence of unusual neurotropism or replication of the seed virus and (iii) there is no evidence of the presence of extraneous neurotropic agents.

(3) *Need for additional neurovirulence safety testing.* A neurovirulence safety test as prescribed in this paragraph shall be performed on vaccine from five consecutive lots whenever a new production seed lot is introduced or whenever the source of cell culture substrate must be reestablished and recertified as prescribed in § 630.62(a), (b), (c), and (d).

§ 630.61 Clinical trials to qualify for license.

To qualify for license, the antigenicity of Rubella Virus Vaccine, Live, shall be determined by clinical trials that follow the procedures prescribed in § 630.31 except that the immunogenic effect shall be demonstrated by establishing that a protective antibody response has occurred in at least 90 percent of each of the five groups of rubella susceptible individuals, each having received the parenteral administration of a virus vaccine dose which is not greater than that which was demonstrated to be safe in field studies when used under comparable conditions.

§ 630.62 Production.

(a) *Virus cultures.* Rubella virus shall be propagated in duck embryo cell cultures, canine renal cell cultures or rabbit renal cell cultures.

(b) *Virus propagated in duck embryo tissue cell cultures.* Embryonated duck eggs used as a source of duck embryo tissue for the propagation of rubella virus shall be derived from flocks certified to be free of avian tuberculosis, the avian leucosis-sarcoma group of viruses and other agents pathogenic for ducks. Only ducks so certified and in overt good health and which are maintained in quarantine shall be used as a source of duck embryo tissue used in the propagation of rubella virus. Ducks in the quarantined flock that die shall be necropsied and examined for evidence of significant pathologic lesions. If any such signs or pathologic lesions are observed, eggs from that flock shall not be used for the manufacture of Rubella Virus Vaccine, Live. Control vessels shall be prepared, observed and tested as prescribed in § 630.32(f).

(c) *Virus propagated in canine renal tissue cell cultures.* When canine renal cell cultures are used for the propagation of rubella virus the renal tissue shall be obtained from dogs meeting the requirements specified in § 630.32(c). Control vessels shall be prepared, observed and tested as prescribed in § 630.32(f).

(d) *Virus propagated in rabbit renal tissue cell cultures.* Only rabbits in overt good health which have been maintained in quarantine individually caged in vermin-proof quarters for a minimum of 6 months, having had no exposure to other rabbits or animals throughout the quarantine period, or rabbits born to rabbits while so quarantined, provided the progeny have been kept in the same type of quarantine continuously from birth shall be used as a source of kidney tissue. Animals shall be free of antibodies for agents potentially pathogenic for man unless it has been demonstrated in the license application that the tests required by § 630.65(c) to be performed on each lot of vaccine are capable of detecting contamination of agents capable of producing such antibodies.

(1) *Rabbits used for experimental purposes.* Rabbits that have been used previously for experimental or testing purposes with microbiological agents shall not be used as a source of kidney tissue in the production of vaccine.

(2) *Quarantine and necropsy.* Each rabbit shall be examined periodically during the quarantine period as well as at the time of necropsy under the direction of a qualified pathologist, physician or veterinarian having experience with diseases of rabbits, for the presence of signs or symptoms of ill health, particularly for evidence of tuberculosis, myxomatosis, fibromatosis, rabbit pox, and other diseases indigenous to rabbits. If there are any such signs, symptoms or other significant pathological lesions observed, tissues from that colony shall not be used in the production of vaccine.

(3) *Control vessels.* Control vessels shall be prepared, observed and tested as prescribed in § 630.32(f).

(e) *Passage of virus strain in vaccine manufacture.* Virus in the final vaccine shall represent no more than five cell culture passages beyond the passage used as the seed strain for the manufacture of the vaccines used to perform the field studies (§ 630.60(d)), which qualified the manufacturer's vaccine strain for license.

(f) *Cell cultures in vaccine production areas.* Only the cell cultures used in the propagation of rubella virus vaccine shall be introduced into rubella virus vaccine production areas.

(g) *Test samples.* Test samples of rubella virus harvests or pools shall be withdrawn and maintained by following the procedures prescribed in § 630.32(g).

§ 630.63 Reference virus.

A Reference Rubella Virus, Live, shall be obtained from the Bureau of Biologics as a control for correlation of virus titers.

§ 630.64 Potency test.

The concentration of live rubella virus shall constitute the measure of potency. The titration shall be performed in a suitable cell culture system, using either the Reference Rubella Virus, Live, or a calibrated equivalent strain as a titration control. The concentration of live rubella virus contained in the vaccine of each lot under test shall be no less than the equivalent of 1,000 $TCID_{50}$ of the reference virus per human dose.

§ 630.65 Test for safety.

(a) *Tests prior to clarification of vaccine manufactured in duck embryo cell cultures.* Prior to clarification, the following tests shall be performed on each rubella virus pool prepared in duck embryo cell cultures:

(1) *Inoculation of adult mice.* The test shall be performed in the volume and following the procedures prescribed in § 630.35(a)(1), and the virus pool is satisfactory only if equivalent test results are obtained.

(2) *Inoculation of suckling mice.* The test shall be performed in the volume and following the procedures prescribed in § 630.35(a)(2), and the virus pool is satisfactory only if equivalent test results are obtained.

(3) *Inoculation of monkey tissue cell cultures.* A rubella virus pool shall be tested for adventitious agents in the volume and following the procedures prescribed in § 630.35(a)(3), except that the virus need not be neutralized by antiserum. The rubella virus pool is satisfactory only if equivalent test results are obtained.

(4) *Inoculation of other cell cultures.* The rubella virus pool shall be tested for adventitious agents in the volume and following the procedures prescribed in § 630.35(a)(3), in rhesus or cynomolgus monkey kidney, in chick embryo, duck embryo, and in human cell cultures, except that the virus need not be neutralized by antiserum. The rubella virus pool is satisfactory only if results equivalent to those in § 630.35(a)(3) are obtained.

(5) *Inoculation of embryonated chicken eggs.* A suspension of each undiluted rubella virus pool shall be tested in the volume and following the procedures prescribed in § 630.35(a)(5) except that the virus need not be neutralized by antiserum. The virus pool is satisfactory only if there is no evidence of adventitious agents.

(6) *Inoculation of embryonated duck eggs.* A suspension of each undiluted rubella virus pool shall be tested in embryonated duck eggs, in the volume and following the procedures prescribed in § 630.35(a)(5) except, that the virus need not be neutralized by antiserum. The virus pool is satisfactory only if there is no evidence of adventitious agents.

(7) *Bacteriological tests.* In addition to the tests for sterility required pursuant to § 610.12 of this chapter, bacteriological tests shall be performed on each rubella virus pool for the presence of M. tuberculosis, both avian and human, by appropriate culture methods. The virus pool is satisfactory only if found negative for M. tuberculosis, both avian and human.

(8) *Test for avian leucosis.* The vaccine shall be tested for avian leucosis, in the volume and following the procedures prescribed in § 630.35(a)(8). The cultures are satisfactory for vaccine manufacture if found negative for avian leucosis.

(9) *Inoculation of cell cultures and embryonated eggs after neutralization of the virus with antiserum.* Each of the tests prescribed in subparagraphs (3), (4), (5), and (6) of this paragraph shall be carried out also with rubella virus that has been neutralized by the addition of high titer antiserum of nonhuman, nonsimian and nonavian origin except that the volume of virus suspension of each undiluted virus pool tested shall be no less than 5 ml. The rubella antiserum shall have been prepared by using a rubella virus propagated in a cell culture system other than that used for the manufacture of the vaccine under test, and the cell culture system shall be free of extraneous agents which might elicit antibodies that could inhibit growth of any known extraneous agents which might be present in the vaccine under test. These tests may be performed either before or after clarification of the virus. The virus pool is satisfactory only if the results obtained are equivalent to those required in those subparagraphs.

(b) *Tests prior to clarification of vaccine manufactured in canine renal cell cultures.* Prior to clarification each rubella virus pool prepared in canine renal cell cultures shall be tested as follows:

(1) *Inoculation of adult mice.* The test shall be performed in the volume and following the procedures prescribed in § 630.35(a)(1), and the virus pool is satisfactory only if equivalent test results are obtained.

(2) *Inoculation of suckling mice.* The test shall be performed in the volume and following the procedures prescribed in § 630.35(b)(2), and the virus pool is satisfactory only if equivalent test results are obtained.

(3) *Inoculation of monkey tissue cell cultures.* The test shall be performed in the volume and following the procedures prescribed in § 630.35(a)(3), except that the virus need not be neutralized by antiserum. The rubella virus pool is satisfactory only if equivalent test results are obtained.

(4) *Inoculation of other cell cultures.* The tests shall be performed in the volume and following the procedures prescribed in § 630.35(a)(3), in rhesus or cynomolgus monkey kidney tissue, canine renal tissue and human tissue cell cultures, except that the virus need not be neutralized by antiserum. The rubella virus pool is satisfactory only if equivalent test results are obtained.

(5) *Inoculation of embryonated chicken eggs.* The tests shall be performed in the volume and following the procedures prescribed in § 630.35(a)(5) except that the virus need not be neutralized by antiserum. The rubella virus pool is satisfactory only if equivalent test results are obtained.

(6) *Bacteriological tests.* In addition to the tests for sterility required pursuant to § 610.12 of this chapter, bacteriological tests shall be performed on each rubella virus pool for the presence of M. tuberculosis, human, by appropriate culture methods. The rubella virus pool is satisfactory only if found negative for M. tuberculosis, human.

(7) *Tests for adventitious agents.* Tests shall be performed for the presence of adventitious agents as prescribed in § 630.35(b)(8), and the rubella virus pool is satisfactory only if equivalent test results are obtained.

(8) *Inoculation of cell cultures and embryonated eggs after neutralization of the virus with antiserum.* Each of the tests prescribed in subparagraphs (3), (4), and (5) of this paragraph shall be carried out also with rubella virus that has been neutralized following the procedures and in the volume prescribed in paragraph (a)(9) of this section. The virus pool is satisfactory only if the results obtained are equivalent to those required by that subparagraph.

(c) *Tests prior to clarification of vaccine manufactured in rabbit renal cell cultures.* Prior to clarification each rubella virus pool prepared in rabbit renal cell cultures shall be tested as follows:

(1) *Inoculation of adult mice.* The test shall be performed in the volume and following the procedures prescribed in § 630.35(a)(1), and the virus pool is satisfactory only if equivalent test results are obtained.

(2) *Inoculation of suckling mice.* The test shall be performed in the volume and following the procedures prescribed in § 630.35(a)(2), and the virus pool is satisfactory only if equivalent test results are obtained.

(3) *Inoculation of monkey tissue cell cultures.* A rubella virus pool shall be tested for adventitious agents in the volume and following the procedures prescribed in § 630.35(a)(3), except that the virus need not be neutralized by antiserum. The rubella virus pool is satisfactory only if equivalent test results are obtained.

(4) *Inoculation of other cell cultures.* The tests shall be performed in the volume and following the procedures prescribed in § 630.35(a)(3) in rhesus or cynomolgus monkey kidney tissue, rabbit renal tissue and human tissue cell cultures, except that the virus need not be neutralized by antiserum. The rubella virus pool is satisfactory only if equivalent test results are obtained.

(5) *Inoculation of embryonated chicken eggs.* A suspension of each undiluted rubella virus pool shall be tested in the volume and following the procedures prescribed in § 630.35(a)(5) except that the virus need not be neutralized by antiserum. The virus pool is satisfactory only if there is no evidence of adventitious agents.

(6) *Inoculation of rabbits.* A minimum of 15 ml. of each virus pool shall be tested by inoculation into at least five healthy rabbits, each weighing 1500–2500 grams. Each rabbit shall be injected intradermally in multiple sites with a total of 1.0 ml. and subcutaneously with 2.0 ml., of the virus pool, and the animals observed for at least 30 days. Each rabbit that dies after the first 24 hours of the test or is sacrificed because of illness shall be necropsied and the brain and organs removed and examined. The virus pool is satisfactory only if at least 80 percent of the rabbits remain healthy and survive the entire period and if all the rabbits used in the test fail to show lesions of any kind at the sites of inoculation and fail to show evidence of any viral infection.

(7) *Inoculation of guinea pigs.* Each of at least five guinea pigs, each weighing 350–450 grams, shall be inoculated intracerebrally with 0.1 ml. and intraperitoneally with 5 ml. of the undiluted virus pool. The animals shall be observed for at least 42 days. Each animal that dies after the first 24 hours of the test or is sacrificed because of illness, shall be necropsied. All remaining animals shall be sacrificed and necropsied at the end of the observation period. The virus pool is satisfactory only if at least 80 percent of all animals remain healthy and survive the observation period and if all the animals used in the test fail to show evidence of infection with *M. tuberculosis* or any viral infection.

(8) *Bacteriological tests.* In addition to the tests for sterility required pursuant to § 610.12 of this chapter, bacteriological tests shall be performed on each rubella virus pool for the presence of *M. tuberculosis*, human, by appropriate culture methods. The rubella virus pool is satisfactory only if found negative for *M. tuberculosis*, human.

(9) *Tests for adventitious agents.* Each virus pool shall be tested for the presence of such known adventitious agents of rabbits as toxoplasma, encephalitozoon, herpes cuniculi, the vacuolating virus of rabbits, rabbit syncytial virus, myxoviruses and reoviruses. The virus pool is satisfactory only if the results of all tests show no evidence of any extraneous agent attributable to the rabbit renal tissue or the vaccine.

(10) *Inoculation of cell cultures and embryonated eggs after neutralization of the virus with antiserum.* Each of the tests prescribed in subparagraphs (3), (4), and (5) of this paragraph shall be carried out also with rubella virus that has been neutralized by the addition of high titer antiserum of nonhuman, nonsimian and nonrabbit origin following the procedures and in the volume prescribed in paragraph (a)(9) of this section. The virus pool is satisfactory only if the results obtained are equivalent to those required by that paragraph.

(d) *Clarification.* The rubella virus fluids shall be clarified by following the procedures prescribed in § 630.35(c).

§ 630.66 General requirements.

(a) *Final container tests.* In addition to the tests required pursuant to § 610.14 of this chapter, an immunological and virological identity test shall be performed on the final container if it was not performed on each pool or on the bulk vaccine prior to filling.

(b) *Dose.* These standards are based on an individual human immunizing dose of no less than 1,000 $TCID_{50}$ of Rubella Virus Vaccine, Live, expressed in terms of the assigned titer of the Reference Rubella Virus, Live.

(c) *Labeling.* In addition to the items required by other applicable labeling provisions of this subchapter, single dose container labeling for vaccine which is not protected against photochemical deterioration shall include a statement cautioning against exposure to light.

(d) *Photochemical deterioration; protection.* Rubella Virus Vaccine, Live, in multiple dose containers, shall be protected against photochemical deterioration in accordance with the procedures prescribed in § 630.36(g).

(e) *Samples; protocols; official release.* For each lot of vaccine, the following shall be submitted to the Director, Bureau of Biologics, Food and Drug Administration, Building 29A, 9000 Rockville Pike, Bethesda, MD. 20014:

(1) A protocol which consists of a summary of the history of the manufacture of each lot including all results of each test for which test results are requested by the Director, Bureau of Biologics.

(2) A total of no less than 120 ml. in 10 ml. volumes, in a frozen state (−60° C.), of preclarification bulk vaccine containing no preservative or adjuvant, and no less than 100 ml. in 10 ml. volumes, in a frozen state (−60° C.), of postclarification bulk vaccine containing stabilizer but no preservative or adjuvant, taken prior to filling into final containers.

(3) A total of no less than 200 recommended doses of the vaccine in final labeled containers distributed equally between the number of fillings made from each bulk lot, except that the representation of a single filling shall be no less than 30 single dose final containers or six multiple dose final containers.

The product shall not be issued by the manufacturer until notification of official release of the lot is received from the Director, Bureau of Biologics.

§ 630.67 Equivalent methods.

Modification of any particular manufacturing method or process or the conditions under which it is conducted as set forth in the additional standards relating to Rubella Virus Vaccine, Live, shall be permitted whenever the manufacturer presents evidence that demonstrates the modification will provide assurances of the safety, purity, and potency of the vaccine that are equal to or greater than the assurances provided by such standards, and the Commissioner of Food and Drugs so finds and makes such finding a matter of official record.

Subpart G—Smallpox Vaccine

§ 630.70 Smallpox Vaccine.

(a) *Proper name and definition.* The proper name of this product shall be Smallpox Vaccine, which shall be a preparation of live vaccinia virus obtained from inoculated calves or chicken embryos.

(b) *Strains of virus.* The strain of seed virus used in the manufacture of Smallpox Vaccine shall be identified by historical records including origin and manipulation, shall be sterile when tested by the procedure prescribed in § 610.12 of this chapter and shall be dermatropic according to the test prescribed in § 630.73(a). In addition, any new strain shall be shown not to produce a reactivity in man exceeding that produced by the Reference Smallpox Vaccine.

§ 630.71 Production.

Vaccinia virus used for the manufacture of vaccine shall be obtained from vesicles on the skin of an inoculated calf or from inoculated chorioallantoic membranes of chicken embryos, as set forth below:

(a) *Virus from calves*—(1) *Quarantine.* Only calves which, prior to being placed in quarantine have reacted negatively to tuberculin, were afebrile and free of ectoparasites, and which shall have met all other applicable quarantine requirements of § 600.11(f)(2)(i) of this chapter, shall be used for vaccinia virus production. The quarantine period shall be at least 14 days. During the last 7 days of the quarantine period daily morning and afternoon rectal temperatures shall be taken and calves that do not remain afebrile during that period shall not be used for virus production.

(2) *Inoculation.* A larger area of the calf than will be used for production purposes shall be prepared in a manner comparable to that appropriate for aseptic surgery, except that the area to be inoculated must be washed free of all antiseptics that may have a deleterious effect on virus propagation. The instrument and method used for scarification must produce a uniform penetration into the epidermis but must not extend through into the corium.

(3) *Incubation.* The inoculated calf shall remain in the incubation room confined to its stall and daily morning and afternoon rectal temperatures shall be taken to determine that only the expected febrile condition occurs. If any signs of disease other than vesiculation at the inoculation site occur, the virus from that calf shall not be used for vaccine manufacture.

(4) *Harvesting.* Before harvesting, the calf shall be anesthetized and killed by exsanguination. Prior to harvesting, the inoculated area shall be thoroughly cleansed by aseptic techniques. Only the vesicular material shall be harvested.

(5) *Necropsy.* A necropsy shall be made of each production calf. The harvested material shall not be used from any animal suspected of having an infection other than vaccinia.

(b) *Virus from embryonated chicken eggs*—(1) *Eggs for production.* Embryonated chicken eggs used for propagation of vaccinia virus shall be derived from flocks found to be free of, and continuously monitored for freedom from *Salmonella pullorum*, Mycoplasma species, avian tuberculosis, fowl pox, Newcastle disease virus, Rous sarcoma virus, avian leucosis complex of viruses, and other agents pathogenic for chickens, or appropriate tests shall be performed to demonstrate freedom of the vaccine from such agents.

(2) *Harvesting.* Aseptic techniques shall be used in harvesting the chorioallantoic membranes exhibiting vesicles characteristic of vaccinia infection.

§ 630.72 Reference vaccine.

Reference Smallpox Vaccine and reconstitution fluid shall be obtained from the Bureau of Biologics and shall be used in all tests for determining the potency of Smallpox Vaccine.

§ 630.73 Potency test.

Each filling of Smallpox Vaccine shall be tested for potency either by the "rabbit scarification" method or by the "pock count" method as follows:

(a) *Rabbit scarification*—(1) *Reconstitution of reference vaccine.* The Reference Smallpox Vaccine shall be reconstituted with the reconstitution fluid furnished by the Bureau of Biologics with the reference vaccine, and shall be used immediately after reconstitution.

(2) *Dilutions.* Dilutions shall be made starting with no less than 0.5 ml. each of the test vaccine and of the reference vaccine, including dilutions 1 : 3,000, 1 : 9,000, and 1 : 27,000. The same diluent shall be used for all the dilutions of both vaccines. The sample for vaccine in capillary tubes shall be obtained by pooling the contents of no less than 50 capillaries into a sterile container.

(3) *Preparation of test animals.* At least two rabbits with skin free of blemishes shall be used. The skin of the areas to be scarified must be free of hair, abrasions and virucidal and virustatic chemicals. Test sites measuring 2.5 x 5.0 cm. shall be marked off on the denuded skin of each rabbit without stretching the skin. All test sites shall be sacrificed uniformly.

(4) *Inoculation of test animals.* Immediately following thorough mixing, 0.2 ml. of each dilution of the test vaccine and of the reference shall be applied to the skin of each rabbit and rubbed into the appropriate scarified test area. After completion of all inoculations for each animal, the site shall be air dried with cool air and the animal then returned to its cage.

(5) *Recording the results.* The rabbits shall be observed daily. The reading shall be recorded at the height of reaction and such reading shall be used to calculate the maximum degree of reactivity for each dilution, which shall be determined by calculating the average percentage

reaction of at least two nonrefractive animals used in testing each lot. The arithmetic mean of the average reactions occurring at the 1 : 3,000, 1 : 9,000, and 1 : 27,000 dilutions shall be computed and used to determine the potency ratio between the test vaccine and the reference.

(6) *Potency requirements*—(i) *Vaccine intended for multiple pressure administration.* Vaccine intended for multiple pressure administration shall have a minimum potency ratio of 0.7 of the reference vaccine.

(ii) *Vaccine intended for jet injection.* One human dose of vaccine intended for administration by jet injector shall have a minimum potency ratio of 0.7 times that of 0.1 ml. of the reference vaccine, diluted 1 : 30.

(iii) *Heated liquid vaccine.* Samples of liquid vaccine from final containers taken at random shall be incubated at 35° to 37° C. for at least 18 hours, after which a 1:1,000 dilution of the heated sample and a 1:3,000 dilution of an unheated sample from the same lot shall be tested in parallel using the same rabbit, as prescribed in this paragraph. The vaccine is satisfactory if the potency of the heated sample is at least equal to that of the unheated sample.

(iv) *Heated dried vaccine.* Samples of dried vaccine from final containers taken at random shall be incubated at 35° to 37° C. for 30 days, after which a 1:1,000 dilution of the heated sample and a 1:3,000 dilution of an unheated sample from the same lot shall be tested in parallel using the same rabbit, as prescribed in this paragraph. The vaccine is satisfactory if the potency of the heated sample is at least equal to that of the unheated sample.

(b) *Pock counting in embryonated chicken eggs*—(1) *Dilutions.* Dilutions shall be made starting with no less than 0.5 ml. of the test vaccine and of the reference vaccine. The same diluent shall be used for all dilutions of both vaccines. The sample of vaccine in capillary tubes shall be obtained by pooling the contents of no less than 50 capillaries into a sterile vessel.

(2) *Inoculation of embryonated chicken eggs.* The chorioallantoic membranes of each of at least five embryonated chicken eggs shall be inoculated with 0.2 ml. for each virus dilution of the test vaccine and the reference vaccine, after which the eggs shall be incubated at 37° C. for 48 hours.

(3) *Estimation of potency.* Only membranes from living embryos shall be removed and the number of specific lesions thereon shall be counted and recorded. The number of pock forming units in 1.0 ml. of vaccine shall be calculated from the number of lesions, the dilution factor and the volume used, to determine the titer of the undiluted vaccine. The accuracy of the titration shall be confirmed in each test by performing simultaneously the same type of titration with the reference vaccine which shall demonstrate its assigned titer.

(4) *Potency requirements*—(i) *Vaccine intended for multiple pressure administration.* Vaccine intended for multiple pressure administration shall have a titer at least equivalent to the reference vaccine.

(ii) *Vaccine intended for jet injection.* Vaccine intended for administration by jet injector shall have a number of pock forming units in one human dose at least equivalent to that contained in 0.1 ml. of the reference vaccine diluted 1:30.

(iii) *Heated liquid vaccine.* Samples of liquid vaccine from final containers taken at random shall be incubated at 35° to 37° C. for at least 18 hours, after which the heated sample shall be tested in parallel with a sample of unheated vaccine of the same lot, as prescribed in this paragraph. The vaccine is satisfactory if the heated sample retains at least one tenth of the potency of the unheated sample.

(iv) *Heated dried vaccine.* Samples of dried vaccine from final containers taken at random shall be incubated at 35° to 37° C. for 30 days, after which the heated sample shall be tested in parallel with a sample of unheated vaccine of the same lot, as prescribed in this paragraph. The vaccine is satisfactory if the heated sample retains at least one-tenth of the potency of the unheated sample.

§ 630.74 Tests for safety.

(a) *Clostridium tetani.* A 10 ml. sample representative of the homogenized viral harvest or pool of several viral harvests shall be tested for the presence of *Clostridium tetani* in the following manner: Prior to the addition of preservatives other than glycerin, the test sample shall be inoculated into freshly heated Fluid Thioglycollate Medium or Smith fermentation tubes containing freshly heated Thioglycollate Broth Medium using a ratio of inoculum to culture medium sufficient for optimal bacterial growth. The test vessels shall be incubated at 35° to 37° C. and observed daily for at least 9 days for evidence of bacterial growth. Within 24–48 hours of an indication that there may be anaerobic growth, 1.0 ml. samples from each test vessel showing growth shall be injected subcutaneously into each of at least three mice, each weighing not more than 20 grams, or into each of at least three guinea pigs, each weighing not more than 350 grams, or into both such groups of mice and guinea pigs. The animals shall be observed daily for 6 days for signs of tetanus. If the animals show no signs of tetanus, additional groups of the same types and numbers of animals shall be injected 9 days after the original planting, with 1.0 ml. samples from each test vessel showing growth. The animals shall be observed daily for 6 days for signs of tetanus. If any animals die within 3 days without having shown signs of tetanus, the test shall be repeated within 18 hours of the deaths, with 0.1 ml. samples of the culture from which that animal was inoculated. Samples from the culture shall be injected into each of three additional test animals of the same species and the animals observed daily for 6 days. If there is any evidence of the presence of *Clostridium tetani*, the viral harvest may not be used in the manufacture of Smallpox Vaccine.

(b) *Anaerobes.* Prior to the addition of preservatives other than glycerin, a 10 ml. sample representative of the homogenized viral harvest or pool of viral harvests shall be inoculated into freshly heated Fluid Thioglycollate Medium or Smith fermentation tubes containing freshly heated Thioglycollate Broth Medium using a ratio of inoculum to culture medium sufficient for optimal bacterial growth. The test vessels shall be held at 65° C. for one hour, then incubated at 35° to 37° C. and observed daily for 10 days for evidence of bacterial growth. Within 24–48 hours of the first appearance of anaerobic growth, 1.0 ml. samples from each vessel showing growth shall be inoculated subcutaneously into each of at least three mice weighing not more than 20 grams and three guinea pigs weighing not more than 350 grams. Additional groups of animals shall be inoculated 9 days after the original planting if growth appears and provided the first set of test animals is negative. All test animals shall be observed daily for at least 6 days. If there is any evidence of the presence of heat resistant pathogenic anaerobes, the viral harvest may not be used in the manufacture of Smallpox Vaccine.

(c) *Coliform organisms.* A 5.0 ml. sample of bulk vaccine shall be tested for the presence of coliform organisms by the method published by the American Public Health Association, Inc., in "Standard Methods for the Examination of Water and Wastewater" (13th edition, 1971), section entitled "Multiple-Tube Fermentation Technic for Members of the Coliform Group," pages 662–678[1] and any amendments or revisions thereof, which section is hereby incorporated by reference and deemed published herein. Said publication is available at most medical and public libraries and copies of the pertinent section will be provided to any manufacturer affected by the provisions of this part upon request to the Director, Bureau of Biologics, or to the appropriate Information Center Officer listed in 45 CFR Part 5. In addition, an official historic file of the material incorporated by reference is maintained in the Office of the Director, Bureau of Biologics. A method different than that contained in the above cited section may be used to test for the presence of coliform organisms upon a showing that it is of equal or greater sensitivity. The ratio of the volume of inoculum to the volume of culture medium shall be such as will dilute the preservative to a level that does not inhibit growth of contaminating organisms. The vaccine is satisfactory if there is no evidence of coliform organisms.

(d) *Hemolytic streptococci and coagulase-positive staphylococci.* Each of three 1.0 ml. samples of bulk vaccine shall be spread uniformly on the surface of separate blood agar plates. The plates shall be incubated for 48 hours at 35° to 37° C. The vaccine is satisfactory if there is no evidence of the presence of either

[1] Copies may be obtained from: American Public Health Association, 1015 Eighteenth St. NW., Washington, DC 20036.

hemolytic streptococci or coagulase-positive staphylococci.

(e) *Viable bacteria*—(1) *Vaccine intended for multiple pressure administration.* Samples of each lot of both bulk and final container vaccine shall be tested for viable bacteria by a procedure designed to detect both aerobic and anaerobic growth through a period of 7 days. At least three 1.0 ml. samples of bulk vaccine and three 0.2 ml. samples of vaccine derived from not less than three final containers or dilutions thereof shall be inoculated into a volume of culture medium sufficient for optimal bacterial growth. The vaccine is satisfactory if it contains no more than 200 viable organisms per ml.

(2) *Vaccine intended for jet injection.* Samples of each lot of both bulk and final container vaccine shall be tested for viable bacteria in Fluid Thioglycollate Medium prepared in accordance with § 610.12(e)(1)(i) of this chapter for at least a 7-day test period. A sample of at least 10.0 ml. of bulk vaccine and 1.0 ml. from each of at least 20 final containers shall be tested. The ratio of the volume of the inoculum to the volume of culture medium shall be such as will dilute the preservative in the inoculum to a level that does not inhibit growth of contaminating micro-organisms. The vaccine is satisfactory if it contains no more than one organism per 100 doses of vaccine.

(f) *Sterile vaccine.* If any lot of smallpox Vaccine meets the sterility requirements prescribed in § 610.12 of this chapter the tests prescribed in paragraphs (b), (c), (d), and (e) of this section need not be performed.

§ 630.75 General requirements.

(a) *General safety.* Each lot of vaccine shall be tested for safety as prescribed in § 610.11 of this chapter and shall meet the safety requirements of that section, except that for liquid Smallpox Vaccine distributed in capillaries, the test may be performed with a sample of bulk vaccine taken at the time of filling into final containers.

(b) *Preservative.* A preservative that meets the requirements of § 610.15 of this chapter may be used, provided that if the preservative is phenol, its concentration shall not exceed 0.5 percent.

(c) *Labeling.* In addition to complying with all other applicable labeling provisions of this subchapter the package label shall bear the following:

(1) *Vaccine intended for jet injection.* (i) A conspicuous statement that the vaccine is intended for administration by jet injector.

(ii) A statement that the vaccine has been shown by appropriate test methods to contain not more than one organism per 100 doses or reference to an enclosed circular that contains such information, except that such a statement is not required for vaccine which meets the sterility requirements of § 610.12 of this chapter.

(2) *Vaccine intended for multiple pressure administration.* A statement that the vaccine has been shown by appropriate test methods to contain not more than 200 organisms per ml. or reference to an enclosed circular that contains such information, except that such a statement is not required for vaccine which meets the sterility requirements of § 610.12 of this chapter.

(d) *Samples; protocols; official release.* (1) For each lot of vaccine the following shall be submitted to the Director, Bureau of Biologics, Food and Drug Administration, Building 29A, 9000 Rockville Pike, Bethesda, MD 20014:

(i) A protocol which consists of a summary of the history of manufacture of each filling including all results of each test for which test results are requested by the Director, Bureau of Biologics.

(ii) Three hundred capillaries from the first filling of a lot of liquid vaccine, and 200 capillaries from each subsequent filling.

(iii) Two 10 ml. samples of bulk liquid vaccine to be submitted along with the capillaries from the first filling and taken from the same vessel from which such capillaries were filled.

(iv) A sample from each drying, consisting of no less than the equivalent of 30 ml. of reconstituted vaccine, packaged in final containers, but in no event less than six filled final containers.

(2) Smallpox Vaccine shall not be issued by the manufacturer until notification of official release of the lot is received from the Director, Bureau of Biologics.

§ 630.76 Equivalent methods.

Modification of any particular manufacturing method or procedure or the conditions under which it is conducted as set forth in the additional standards relating to smallpox vaccine (§§ 630.70 to 630.75, inclusive) shall be permitted whenever the manufacturer presents evidence that demonstrates the modification will provide equal or greater assurances of the safety, purity, and potency of the vaccine as the assurances provided by such standards, and the Commissioner of Food and Drugs so finds and makes such finding a matter of official record.

Subpart I—Measles-Smallpox Vaccine, Live

§ 630.80 Measles-Smallpox Vaccine, Live.

(a) *Proper name and definition.* The proper name of this product shall be Measles-Smallpox Vaccine, Live. The product shall consist of a preparation of live attenuated measles virus combined with live vaccinia virus.

(b) *Strains of virus.* Any strain of attenuated measles seed virus used in the manufacture of this product shall meet the requirements of § 630.30(b) and any strain of vaccinia seed virus used in the manufacture of this product shall meet the requirements of § 630.70(b).

(c) *Neurovirulence of measles virus and seed strain.* The neurovirulence of the measles virus seed strain shall be tested as prescribed in, and meet the requirements of, § 630.30(c).

§ 630.81 Clinical trials to qualify for license.

In addition to demonstrating that the measles component meets the requirements of § 630.31, the measles and smallpox antigenicity of the final product shall have been determined by clinical trials of adequate statistical design conducted with five consecutive lots of the final vaccine manufactured by the same methods and administered as recommended by the manufacturer. Such clinical trials shall include administration of the product to measles and smallpox susceptible individuals and to persons previously immunized with smallpox vaccine. At least 95 percent of the smallpox susceptible persons shall show a primary vaccination reaction and at least 95 percent of persons previously immunized with smallpox vaccine shall show a revaccination reaction. At least 90 percent of the measles susceptible individuals shall demonstrate measles neutralizing antibodies at the 1:8 dilution or greater. There shall also be a demonstration of the safety of the product, by administration as recommended by the manufacturer, under circumstances wherein adequate clinical and epidemiological surveillance of illness has been maintained.

§ 630.82 Production.

The measles vaccine component of this product shall be manufactured in accordance with, and meet the requirements of, § 630.32. The smallpox vaccine component of this product shall be manufactured in accordance with, and meet the requirements of, § 630.71, and in addition, prior to any filtration or dilution, shall be tested for potency in accordance with § 630.73 and shall have a potency at least equivalent to that of the Reference Smallpox Vaccine.

§ 630.83 Reference vaccines.

Reference Measles Virus Vaccine, Live, Attenuated, and Reference Smallpox Vaccine and reconstitution fluid shall be obtained from the Bureau of Biologics. The reference measles vaccine shall be used as a control for correlation of virus titers for the measles component of the product. The reference smallpox vaccine shall be used to determine the potency of the smallpox component of the product.

§ 630.84 Potency tests.

Each lot of Measles-Smallpox Vaccine, Live, shall be tested for potency, as follows:

(a) *Measles.* After neutralization of the vaccinia virus, each lot of the product shall be tested for, and shall meet the measles vaccine requirements of, potency prescribed in § 630.34.

(b) *Smallpox.* Each lot of the product shall be tested for potency as prescribed in § 630.73. The product is satisfactory if the vaccinia virus contained in one human dose is at least equivalent to that contained in 0.5 ml. of the Reference Smallpox Vaccine diluted 1:100.

(c) *Heated vaccine.* Samples of dried vaccine from final containers shall be taken at random and tested as prescribed

in, and shall meet the potency requirements of, § 630.73(a)(6)(iv) or (b)(4)(iv).

§ 630.85 Tests for safety.

The measles virus component of this product shall be tested for safety as prescribed in § 630.35. The smallpox component of this product shall be tested for safety as prescribed in § 630.74(a). The product is satisfactory if the safety test results meet the requirements of §§ 630.35 and 630.74(a), respectively.

§ 630.86 General requirements.

(a) *Sterility.* Each lot of vaccine shall be tested for, and meet the sterility requirements of, § 610.12 of this chapter, regardless of the source of the vaccinia virus.

(b) *Identity.* An immunological and virological identity test shall be performed either on each pool or the bulk vaccine prior to filling into final containers, or for each filling. If the immunological and virological identity test was performed only on the pool or bulk vaccine, a final container identity test must be performed pursuant to § 610.14 of this chapter.

(c) *Photochemical deterioration; protection.* Vaccine final containers shall be protected against photochemical deterioration. Such containers may be colored, or outside coloring or protective covering may be used for this purpose, provided (1) the method used is shown to provide the required protection, and (2) visible examination of the contents is not precluded.

(d) *Labeling.* In addition to the items required by other applicable labeling provisions of this subchapter, labeling shall contain a statement that the product is intended for administration only by jet injector and a description of the method of administration.

(e) *Samples; protocols; official release.* For each lot of vaccine the following materials shall be submitted to the Director, Bureau of Biologics, Food and Drug Administration, Building 29A, 9000 Rockville Pike, Bethesda, MD 20014.

(1) A protocol which consists of a summary of the history of manufacture of each filling including all results of each test for which test results are requested by the Director, Bureau of Biologics.

(2) A total of no less than 120 ml. in 10 ml. volumes, in a frozen state (−60° C.), of the bulk measles component prior to clarification and containing no preservative or adjuvant, and no less than 100 ml. in 10 ml. volumes, in a frozen state (−60°C.), of the bulk measles component after clarification and containing stabilizer but no preservative or adjuvant, taken prior to filling into final containers.

(3) A frozen 5 ml. sample of the smallpox component prior to any dilution or filtration.

(4) A frozen 5 ml. sample of the smallpox component taken subsequent to any dilution or filtration.

(5) A sample consisting of no less than the equivalent of 25 ml. of reconstituted vaccine packaged in no less than five final containers.

The product shall not be issued by the manufacturer until notification of official release of the filling is received from the Director, Bureau of Biologics.

§ 630.87 Equivalent methods.

Modification of any particular manufacturing method or process or the conditions under which it is conducted as set forth in the additional standards relating to Measles-Smallpox Vaccine, Live (§§ 630.80 to 630.86, inclusive), shall be permitted whenever the manufacturer presents evidence that demonstrates the modification will provide assurances of the safety, purity, and potency of the vaccine that are equal to or greater than the assurances provided by such standards, and the Commissioner of Food and Drugs so finds and makes such finding a matter of official record.

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

Subpart A—Whole Blood (Human)

Sec.
640.1 Whole Blood (Human).
640.2 General requirements.
640.3 Suitability of donor.
640.4 Collection of the blood.
640.5 Testing the blood.
640.6 Modifications of Whole Blood (Human).
640.7 Labeling.

Subpart B—Red Blood Cells (Human)

640.10 Red Blood Cells (Human).
640.11 General requirements.
640.12 Suitability of donor.
640.13 Collection of the blood.
640.14 Laboratory tests.
640.15 Pilot samples.
640.16 Processing.
640.17 Modifications for specific products.
640.18 Labeling.

Subparts C, D, and E—[Reserved]

Subpart F—Cryoprecipitated Antihemophilic Factor (Human)

Sec.
640.50 Cryoprecipitated Antihemophilic Factor (Human).
640.51 General requirements.
640.52 Processing.

Subpart G—Source Plasma (Human)

640.60 Source Plasma (Human).
640.61 Informed consent.
640.62 Medical supervision.
640.63 Suitability of donor.
640.64 Collection of blood for Source Plasma (Human).
640.65 Plasmapheresis.
640.66 Immunization of donors.
640.67 Test for hepatitis B antigen.
640.68 Processing.
640.69 General requirements.
640.70 Modification of Source Plasma (Human).

Subparts H and I—[Reserved]

Subpart J—Immune Serum Globulin (Human)

640.100 Immune Serum Globulin (Human).
640.101 General requirements.
640.102 Manufacture of Immune Serum Globulin (Human).
640.103 The final product.
640.104 Potency.

Subpart K—Measles Immune Globulin (Human)

640.110 Measles Immune Globulin (Human).
640.111 General requirements.
640.112 Manufacture of Measles Immune Globulin (Human).
640.113 The final product.
640.114 Potency.

AUTHORITY: Sec. 215, 58 Stat. 690, as amended; 42 U.S.C. 216. Sec. 351, 58 Stat. 702, as amended; 42 U.S.C. 262, unless otherwise noted.

CROSS REFERENCES: For U.S. Customs Service regulations relating to viruses, serums, and toxins, see 19 CFR 12.21–12.23. For U.S. Postal Service regulations relating to the admissibility to the United States mails see 39 CFR Parts 124 and 125, esp. § 125.2.

Subpart A—Whole Blood (Human)

§ 640.1 Whole Blood (Human).

The proper name of this product shall be Whole Blood (Human). Whole Blood (Human) is defined as blood collected from human donors for transfusion to human recipients.

§ 640.2 General requirements.

(a) *Manufacturing responsibility.* All manufacturing of Whole Blood (Human), including donor examination, blood collection, laboratory tests, labeling, storage and issue, shall be done under the supervision and control of the same licensed establishment except that the Commissioner of Food and Drugs may approve arrangements, upon joint request of two or more licensed establishments, which he finds are of such a nature as to assure compliance otherwise with the provisions of this subchapter.

(b) *Periodic check on sterile technique.* Where blood is collected in an open system, that is, where the blood container is entered, at least one container of such blood that upon visual examination appears normal shall be tested each month between the 18th and 24th day after collection, as a continuing check on technique of blood collection, as follows:

The test shall be performed with a total sample of no less than 10 ml. of blood and a total volume of fluid thioglycollate or thioglycollate broth medium 10 times the volume of the sample of blood. The test sample shall be inoculated into one or more test vessels in a ratio of blood to medium of 1 to 10 for each vessel, mixed thoroughly, incubated for seven to nine days at a temperature of 30° to 32° C., and examined for evidence of growth of microorganisms every workday throughout the test period. On the third, fourth, or fifth day at least 1 ml. of material from each test vessel shall be subcultured in additional test vessels containing the same culture medium and in such proportion as will permit significant visual inspection, mixed thoroughly, incubated for seven to nine days at a temperature of 30° to 32° C. and examined for evidence of growth of microorganisms every workday throughout the test period. If growth is observed in any test vessel, the test shall be repeated to rule out faulty test procedure, using another sample of blood from either, (1) the container from which the initial test sample was taken, (2) the residual cells or plasma

from that blood, or (3) two different containers of blood, each 18 to 24 days old and each tested separately. The formula for fluid thioglycollate medium shall be as prescribed in § 610.12(e)(1) of this chapter and the formula for thioglycollate broth medium shall be as prescribed in § 610.12(f)(5) of this chapter. Media and design of container shall meet the requirements prescribed in § 610.12(e)(2)(i) of this chapter. In lieu of performing one test using an incubation temperature of 30° to 32° C., two tests may be performed, each in all respects as prescribed in this paragraph, one at an incubation temperature of 18° to 22° C. and one at an incubation temperature of 35° to 37° C. A different test may be performed provided that prior to the performance of such a test a manufacturer submits data which the Commissioner of Food and Drugs finds adequate to establish that the different test is equal or superior to the test herein prescribed as a check on sterile technique and makes the finding a matter of official record.

(c) *Final container.* The original blood container shall be the final container and shall not be entered prior to issue for any purpose except for blood collection. Such container shall be uncolored and transparent to permit visual inspection of the contents and any closure shall be such as will maintain an hermetic seal and prevent contamination of the contents. The container material shall not interact with the contents under the customary conditions of storage and use, in such a manner as to have an adverse effect upon the safety, purity, or potency of the blood.

(d) [Reserved]

(e) *Reissue of blood.* Blood that has been removed from storage controlled by a licensed establishment shall not be reissued by a licensed establishment unless the following conditions are observed:

(1) The container has a tamper-proof seal when originally issued and this seal remains unbroken;

(2) An original pilot sample is properly attached and has not been removed, except that blood lacking a pilot sample may be reissued in an emergency provided it is accompanied by instructions for sampling and for use within six hours after entering the container for sampling;

(3) The blood has been maintained continuously at 1° to 10° C.;

(4) The blood is held for observation until a significant inspection consistent with the requirements of § 640.5(e) can be made.

(f) *Issue prior to determination of test results.* Notwithstanding the provisions of § 610.1 of this chapter, blood may be issued by the licensee on the request of a physician, hospital, or other medical facility, before results of all tests prescribed in § 640.5 and the test for hepatitis associated (Australia) antigen prescribed in § 610.40 of this chapter have been determined where such issue is essential to allow time for transportation to assure arrival of the blood by the time when needed for transfusion of such blood provided (1) the blood is shipped directly to such physician or medical facility, (2) the records of the licensee contain a full explanation of the need for such issue, (3) the label on each container of such blood bears the information required by § 640.7(e), (4) the label does not bear results of tests other than those made on pilot samples of the blood to be shipped, taken at the time of its collection, and (5) the label does not bear the name or any other identification of the intended recipient.

§ 640.3 Suitability of donor.

(a) *Method of determining.* The suitability of a donor as a source of Whole Blood (Human) shall be determined by a qualified physician or by persons under his supervision and trained in determining suitability. Such determination shall be made on the day of collection from the donor by means of medical history, a test for hemoglobin level, and such physical examination as appears necessary to a physician who shall be present on the premises when examinations are made, except that the suitability of donors may be determined when a physician is not present on the premises, provided the establishment (1) maintains on the premises, and files with the Bureau of Biologics, a manual of standard procedures and methods, approved by the Director of the Bureau of Biologics, that shall be followed by employees who determine suitability of donors, and (2) maintains records indicating the name and qualifications of the person immediately in charge of the employees who determine the suitability of donors when a physician is not present on the premises.

(b) *Qualifications of donor; general.* Except as provided in paragraph (f), a person may not serve as a source of Whole Blood (Human) more than once in 8 weeks. In addition, donors shall be in good health, as indicated in part by:

(1) Normal temperature;

(2) Demonstration that systolic and diastolic blood pressures are within normal limits, unless the examining physician is satisfied that an individual with blood pressures outside these limits is an otherwise qualified donor under the provisions of this section;

(3) A blood hemoglobin level which shall be demonstrated to be no less than 12.5 gm. of hemoglobin per 100 ml. of blood;

(4) Freedom from acute respiratory diseases;

(5) Freedom from any infectious skin disease at the site of phlebotomy and from any such disease generalized to such an extent as to create a risk of contamination of the blood;

(6) Freedom from any disease transmissible by blood transfusion, insofar as can be determined by history and examinations indicated above; and

(7) Freedom of the arms and forearms from skin punctures or scars indicative of addiction to self-injected narcotics.

(c) *Additional qualifications of donor; viral hepatitis.* No individual shall be used as a source of Whole Blood (Human) if he has—

(1) A history of viral hepatitis;

(2) A history of close contact within six months of donation with an individual having viral hepatitis;

(3) A history of having received within six months human blood, or any derivative of human blood which the Food and Drug Administration has advised the licensed establishment is a possible source of viral hepatitis.

(d) *Therapeutic bleedings.* Blood withdrawn in order to promote the health of a donor otherwise qualified under the provisions of this section, shall not be used as a source of Whole Blood (Human) unless the container label conspicuously indicates the donor's disease that necessitated withdrawal of blood.

(e) *Immunized donors.* Blood withdrawn from donors known to have been immunized to human blood cell antigens shall not be used for Whole Blood (Human) unless the container label conspicuously indicates such information.

(f) *Qualifications; donations within less than 8 weeks.* A person may serve as a source of Whole Blood (Human) more than once in 8 weeks only if at the time of donation the person is examined and certified by a physician to be in good health, as indicated in part in paragraph (b).

§ 640.4 Collection of the blood.

(a) *Supervision.* Blood shall be drawn from the donor by a qualified physician or under his supervision by assistants trained in the procedure. A physician shall be present on the premises when blood is being collected, except that blood may be collected when a physician is not present on the premises, provided the establishment (1) maintains on the premises, and files with the Bureau of Biologics, a manual of standard procedures and methods, approved by the Director of the Bureau of Biologics, that shall be followed by employees who collect blood, and (2) maintains records indicating the name and qualifications of the person immediately in charge of the employees who collect blood when a physician is not present on the premises.

(b) *The donor clinic.* The pertinent requirements of §§ 600.10 and 600.11 of this chapter shall apply at both the licensed establishment and at any other place where the bleeding is performed.

(c) *Blood containers.* Blood containers and donor sets shall be pyrogen-free, sterile and identified by lot number. The amount of anticoagulant required for the quantity of blood to be collected shall be in the blood container when it is sterilized. In addition, all container and donor set surfaces that come in contact with blood used in the processing of Heparinized Whole Blood (Human) shall be water repellent.

(d) *The anticoagulant solution.* The anticoagulant solution shall be sterile and pyrogen-free. One of the following formulae shall be used in the indicated volumes:

(1) *Anticoagulant acid citrate dextrose solution (ACD).*

	Solution A	Solution B
Tri-sodium citrate ($Na_3C_6H_5O_7 \cdot 2H_2O$).	22.0 gm.	13.2 gm.
Citric acid ($C_6H_8O_7 \cdot H_2O$)	8.0 gm.	4.8 gm.
Dextrose ($C_6H_{12}O_6 \cdot H_2O$)	24.5 gm.	14.7 gm.
Water for injection (U.S.P.) to make.	1,000 ml.	1,000 ml.
Volume per 100 ml. blood	15 ml.	25 ml.

(2) *Anticoagulant heparin solution.*

Heparin sodium (U.S.P.)	75,000 units.
Sodium chloride injection (U.S.P.) to make.	1,000 ml.
Volume per 100 ml. blood	6 ml.

A buffer to maintain stability shall be added, if necessary.

(3) *Anticoagulant citrate phosphate dextrose solution (CPD).*

Tri-sodium citrate ($Na_3C_6H_5O_7 \cdot 2H_2O$).	26.3 gm.
Citric acid ($C_6H_8O_7 \cdot H_2O$)	3.27 gm.
Dextrose ($C_6H_{12}O_6 \cdot H_2O$)	25.5 gm.
Monobasic sodium phosphate ($NaH_2PO_4 \cdot H_2O$).	2.22 gm.
Water for injection (U.S.P.) to make.	1,000 ml.
Volume per 100 ml. blood	14 ml.

(e) *Donor identification.* Each unit of blood shall be so marked or identified by number or other symbol as to relate it to the individual donor whose identity shall be established to the extent necessary for compliance with § 640.3.

(f) *Prevention of contamination of the blood.* The skin of the donor at the site of phlebotomy shall be prepared thoroughly and carefully by a method that gives maximum assurance of a sterile container of blood. The blood shall be collected by aseptic methods in a sterile system which may be closed or may be vented if the vent protects the blood against contamination.

(g) *Pilot samples for laboratory tests.* Pilot samples for laboratory tests shall meet the following standards:

(1) One or more pilot samples shall be provided with each unit of blood when issued or reissued except as provided in § 640.2(e)(2) and all pilot samples shall be from the donor who is the source of the unit of blood.

(2) All samples for laboratory tests performed by the manufacturer and all pilot samples accompanying a unit of blood shall be collected at the time of filling the final container by the person who collects the unit of blood.

(3) All containers for all samples shall bear the donor's identification before collecting the samples.

(4) All containers for pilot samples accompanying a unit of blood shall be attached to the whole blood container before blood collection, in a tamper-proof manner that will conspicuously indicate removal and reattachment.

(h) *Phlebotomy for Heparinized Whole Blood (Human).* Heparinized Whole Blood (Human) shall be collected with minimal damage to and minimal manipulation of the donor's tissue, and with a single, uninterrupted, free-flowing venipuncture.

(i) *Storage.* Immediately after collection, the blood shall be placed in storage within a 2° range between 1° and 6° C., unless it must be transported from the donor clinic to the processing laboratory. In the latter case the blood shall be placed in temporary storage having sufficient refrigeration capacity to cool the blood continuously toward a 2° range between 1° and 6° C. until it arrives at the processing laboratory where it shall be stored within a 2° range between 1° and 6° C.

§ 640.5 Testing the blood.

All laboratory tests shall be made on a pilot sample specimen of blood taken from the donor at the time of collecting the unit of blood, and these tests shall include the following:

(a) *Serological test for syphilis.* Whole Blood (Human) shall be negative to a serological test for syphilis.

(b) *Determination of blood group.* Each container of Whole Blood (Human) shall be classified as to ABO blood group. At least two blood group tests shall be made and the unit shall not be issued until grouping tests by different methods or with different lots of antiserums are in agreement. Only those Anti-A and Anti-B Blood Grouping Serums licensed under, or that otherwise meet the requirements of, the regulations of this subchapter shall be used, and the technique used shall be that for which the serum is specifically designed to be effective.

(c) *Determination of the Rh factors.* Each container of Whole Blood (Human) shall be classified as to Rh type on the basis of tests done on the pilot sample. The label shall indicate the extent of typing and the results of all tests performed. If the test, using Anti-Rh$_o$ (Anti-D) Typing Serum, is positive, the container may be labeled "Rh Positive". If this test is negative, the results shall be confirmed by further testing which may include tests for the Rh$_o$ variant (D^u) and for other Rh-Hr factors. Blood may be labeled "Rh Negative" if negative to tests for the Rh$_o$ (D) and Rh$_o$ variant (D^u) factors. If the test using Anti-Rh$_o$ (Anti-D) Typing Serum is negative, but not tested for the Rh$_o$ variant (D^u), the label must indicate that this test was not done. Only Anti-Rh Typing Serums licensed under, or that otherwise meet the requirements of, the regulations of this subchapter shall be used, and the technique used shall be that for which the serum is specifically designed to be effective.

(d) *Sterility test.* Whole Blood (Human) intended for transfusion shall not be tested for sterility by a method that entails entering the final container before the blood is used for transfusion.

(e) *Inspection.* Whole Blood (Human) shall be inspected visually during storage and immediately prior to issue. If the color or physical appearance is abnormal or there is any indication or suspicion of microbial contamination the unit of Whole Blood (Human) shall not be issued for transfusion.

§ 640.6 Modifications of Whole Blood (Human).

Upon approval by the Director, Bureau of Biologics, of an amendment to the product license application for Whole Blood (Human), a manufacturer may prepare Whole Blood (Human) from which the antihemophilic factor has been removed, provided the Whole Blood (Human) meets the applicable requirements of this subchapter and the following conditions are met:

(a) The antihemophilic factor shall be removed in accordance with paragraphs (a), (b), and (c) of § 640.52.

(b) Although the closed system between the red blood cells and plasma shall be maintained, the red blood cells shall be maintained between 1 and 6° C. at all times, including that time when the plasma is being frozen for removal of the antihemophilic factor.

(c) If containers for pilot samples are detached from the blood container during removal of the antihemophilic factor the pilot samples shall be reattached to the unit of Whole Blood (Human), modified, as soon as the plasma is returned to the red blood cells. The reattachement of the pilot samples shall be in a tamper-proof manner that will conspicuously indicate removal and reattachment.

§ 640.7 Labeling.

In addition to all other applicable labeling requirements, the following, except as prescribed in paragraphs (e) and (f) of this section, shall appear on the label of each container:

(a) *Anticoagulant*—(1) *Name.* The name of the anticoagulant immediately preceding and of no less prominence than the proper name, expressed as follows:

(i) either "ACD", or "acid citrate dextrose solution",

(ii) either "Heparinized" or "heparin solution",

(iii) either "CPD" or "citrate phosphate dextrose solution".

(2) *Quantity.* The quantity and kind of anticoagulant used and the volume of blood corresponding with the formula prescribed under § 640.4(d).

(b) *Serological test and test for hepatitis associated (Australia) antigen.* Indication of the method used for serological test for syphilis and the test for hepatitis associated (Australia) antigen, and the results.

(c) *Blood group and type.* Designation of blood group and Rh factors:

(1) The blood group and Rh factors shall be designated conspicuously.

(2) If a color scheme for differentiating the ABO blood groups is used, the color used to designate each blood group on the container shall be:

Blood Group A: Yellow.
Blood Group B: Pink.
Blood Group O: Blue.
Blood Group AB: White.

(d) *Additional information for labels of Group O Bloods.* Each Group O blood shall be labeled with a statement indicating whether or not isoagglutinin titers or other tests to exclude so-called "dan-

gerous" Group O bloods were performed, and indicating the classification based on such tests.

(e) *Issue prior to determination of test results.* The label on each container of blood that is issued pursuant to the provisions of § 640.2(f) shall bear the following information and instructions in lieu of the information specified in paragraphs (b), (c), and (d) of this section.

EMERGENCY SHIPMENT FOR USE ONLY BY

(Name of physician, hospital or other medical facility.)

CAUTION

BEFORE TRANSFUSION

1. Do not use until test results received from (name of licensee).
2. Perform crossmatch.

(f) *Whole Blood (Human), Modified.* The label on each container of blood that is issued pursuant to the provisions of § 640.6 shall bear, in addition to the other applicable labeling requirements, the following:

(1) Immediately following and in no less prominence than the proper name, the word "Modified."

(2) A prominent statement indicating that antihemophilic factor has been removed by cryoprecipitation. Such statement may appear on a separate label affixed to the container.

(3) Instructions not to use the unit of blood for patients requiring antihemophilic factor.

Subpart B—Red Blood Cells (Human)

§ 640.10 Red Blood Cells (Human).

The proper name of this product shall be Red Blood Cells (Human). The product is defined as red blood cells remaining after separating plasma from human blood.

§ 640.11 General requirements.

(a) *Check on sterile technique.* If Red Blood Cells (Human) are prepared in a vented or open system, a check on sterile technique shall be made each month by performing a test 20–28 hours after the preparation of at least one container of Red Blood Cells (Human), by the method prescribed in § 640.2(b).

(b) *Storage.* Immediately after processing, the Red Blood Cells (Human) shall be placed in storage and maintained within a 2° range between 1° and 6° C.

(c) *Inspection.* The product shall be inspected immediately after separation of the plasma, periodically during storage, and at the time of issue. The product shall not be issued if there is any abnormality in color or physical appearance or if there is any indication of microbial contamination.

§ 640.12 Suitability of donor.

The source blood for Red Blood Cells (Human) shall be obtained from a donor who meets the criteria for donor suitability prescribed in § 640.3.

§ 640.13 Collection of the blood.

(a) The source blood shall be collected as prescribed in § 640.4, except that paragraphs (d)(2), and (g), and (h) shall not apply.

(b) Source blood may also be derived from Whole Blood (Human) manufactured in accordance with applicable provisions of this subchapter.

§ 640.14 Laboratory tests.

A sample of source blood shall be taken from the donor at the time of collection and it shall be used for a serological test for syphilis, for tests to determine blood group and Rh factors, as prescribed in § 640.5 (a), (b), and (c).

§ 640.15 Pilot samples.

Pilot samples collected in integral tubing or in separate pilot tubes shall meet the following standards:

(a) One or more pilot samples of either the original blood or of the Red Blood Cells (Human) being processed shall be provided with each unit of Red Blood Cells (Human) when issued or reissued.

(b) Before they are filled, all pilot sample tubes shall be marked or identified so as to relate them to the donor of that unit of red cells.

(c) Before the final container is filled or at the time the final product is prepared, the pilot sample tubes to accompany a unit of cells shall be attached securely to the final container in a tamper proof manner that will conspicuously indicate removal and reattachment.

(d) All pilot sample tubes accompanying a unit of Red Blood Cells (Human) shall be filled at the time the blood is collected or at the time the final product is prepared, in each instance by the person who performs the collection or preparation.

§ 640.16 Processing.

(a) *Separation.* Red Blood Cells (Human) may be prepared either by centrifugation done in a manner that will not tend to increase the temperature of the blood, and no later than 6 days after the date of blood collection or by normal, undisturbed sedimentation no later than 21 days after the date of blood collection. A portion of the plasma sufficient to assure optimal cell preservation shall be left with the red cells except when a cryophylactic substance is added for prolonged storage.

(b) *Sterile system.* All surfaces that come in contact with the red cells shall be sterile and pyrogen-free. If an open system is used, that is, where the transfer container is not integrally attached to the blood container, and the blood container is entered after blood collection, the plasma shall be separated from the red blood cells with positive pressure maintained on the original container until completely sealed. If the method of separation involves a vented system, that is, when an airway must be inserted in the container for withdrawal of the plasma, the airway and vent shall be sterile and constructed so as to exclude microorganisms and maintain a sterile system.

(c) *Final containers.* Final containers used for Red Blood Cells (Human) shall be the original blood containers unless the method of processing requires a different container. The final container shall meet the requirements for blood containers prescribed in § 640.2(c). At the time of filling, if a different container is used, it shall be marked or identified by number or other symbol so as to relate it to the donor of that unit of red cells.

§ 640.17 Modifications for specific products.

Red Blood Cells (Human), Frozen: A cryophylactic substance may be added to the Red Blood Cells (Human) for extended manufacturer's storage at −65° C. or colder, provided the manufacturer submits data considered by the Director, Bureau of Biologics, as adequately demonstrating through in vivo cell survival and other appropriate tests that the addition of the substance, the materials used and the processing methods result in a final product that meets the required standards of safety, purity, and potency for Red Blood Cells (Human), and that the frozen product will maintain those properties for the prescribed dating period. Section 640.11 (b) and (c) do not apply while a cryophylactic substance is present.

§ 640.18 Labeling.

In addition to the items required by other applicable labeling provisions of this subchapter, labels for Red Blood Cells (Human) shall bear the following:

(a) The information required by § 640.7(a)(2), (b), and (c) for Whole Blood (Human), except the proper name.

(b) Immediately following or immediately below and in no less prominence than the proper name, appropriate words describing each approved variation applicable to the product in the final container; for example, Red Blood Cells (Human), Frozen, and Red Blood Cells (Human), Deglycerolized.

(c) Instructions to use a filter in the administration equipment.

(d) Where source blood has been derived from Whole Blood (Human), such fact and the name, address, and license number of the establishment.

Subparts C, D, and E—[Reserved]

Subpart F—Cryoprecipitated Antihemophilic Factor (Human)

§ 640.50 Cryoprecipitated Antihemophilic Factor (Human).

(a) *Proper name and definition.* The proper name of this product shall be Cryoprecipitated Antihemophilic Factor (Human) which shall consist of a preparation containing the antihemophilic factor obtained from a single unit of human blood.

(b) *Source.* Cryoprecipitated Antihemophilic Factor (Human) shall be prepared from human blood meeting the following criteria:

(1) *Suitability of the donor.* Blood for Cryoprecipitated Antihemophilic Factor (Human) shall be obtained only from a donor who meets the criteria for suitability prescribed in § 640.3.

(2) *Collection of the blood.* Blood for Cryoprecipitated Antihemophilic Factor

(Human) shall be collected as prescribed in § 640.4 except that paragraphs (d) (2), (g), and (h) shall not apply.

(3) *Testing the blood.* Blood for Cryoprecipitated Antihemophilic Factor (Human) shall be tested as prescribed in § 640.5 (a), (b), and (c).

§ 640.51 General requirements.

(a) *Diluent.* No diluent shall be added to the product by the manufacturer.

(b) *Storage.* Immediately after processing the product shall be placed in storage and maintained at −18° C. or colder.

(c) *Labeling.* In addition to the items required by other provisions of this subchapter, the package label shall bear the following:

(1) Designation of blood group and type of the source blood.

(2) A warning against using the product if there is evidence of thawing during storage.

(3) Instructions to thaw Cryoprecipitated Antihemophilic Factor (Human) in a water bath maintained at not warmer than 37° C.

(4) Instructions to store the product at room temperature after thawing, to use the product within 6 hours after thawing and within 2 hours of entering the container.

(5) Instructions to use a filter in the administration equipment.

(6) A statement indicating the volume of the source plasma and the type of anticoagulant solution present in the source plasma from which the product was prepared.

(7) Indication of the test method for hepatitis associated (Australia) antigen used and the result.

§ 640.52 Processing.

(a) *Separation of plasma.* The plasma shall be separated from the red blood cells in a closed sterile system within 4 hours after collection by centrifugation to obtain an essentially cell-free material.

(b) *Freezing the plasma.* The plasma shall be frozen within 2 hours after separation. A combination of dry ice and organic solvent may be used for freezing provided the procedure has been shown not to cause the solvent to penetrate the container or leach plasticizers from the container into the frozen plasma.

(c) *Separation of Cryoprecipitated Antihemophilic Factor (Human).* The Cryoprecipitated Antihemophilic Factor (Human) shall be separated from the plasma in a closed system by a procedure that precludes contamination and has been shown to produce a product which has demonstrated potency in patients having a factor VIII deficiency.

(d) *Final container.* Final containers used for Cryoprecipitated Antihemophilic Factor (Human) shall be uncolored and transparent to permit visual inspection of the contents and any closure shall be such as will maintain an hermetic seal and prevent contamination of the contents. The container material shall not interact with the contents under the customary conditions of storage and use, in such a manner as to have an adverse effect upon the safety, purity, and potency of the product. At the time of filling, the final container shall be marked or identified by number or other symbol so as to relate it to the donor.

Subpart G—Source Plasma (Human)

§ 640.60 Source Plasma (Human).

The proper name of this product shall be Source Plasma (Human). The product is defined as the fluid portion of human blood which has been stabilized against clotting, collected by plasmapheresis, and is intended as source material for further manufacture into blood derivatives (a portion of pooled plasma separable by chemical means) intended for injection.

§ 640.61 Informed consent.

The written consent of a prospective donor shall be obtained after a qualified licensed physician has explained the hazards of the procedure to the prospective donor. The explanation shall include the risks of a hemolytic transfusion reaction if he is given the cells of another donor, and the hazards involved if he is hyperimmunized. The explanation shall consist of such disclosure and be made in such a manner that intelligent and informed consent be given and that a clear opportunity to refuse is presented.

§ 640.62 Medical supervision.

A qualified licensed physician shall be on the premises when donor suitability is being determined, immunizations are being made, whole blood is being collected, and red blood cells are being returned to the donor.

§ 640.63 Suitability of donor.

(a) *Method of determining.* The suitability of a donor for Source Plasma (Human) shall be determined by a qualified licensed physician or by persons under his supervision and trained in determining donor suitability. Such determination shall be made on the day of collection from the donor by means of a medical history, tests, and such physical examination as appears necessary to the qualified licensed physician.

(b) *Initial medical examination.* Each donor shall be examined by a qualified licensed physician on the day of the first donation, or no more than one week prior to the first donation, and shall be certified to be in good health by the examining physician. The certification of good health shall be on a form supplied by the licensed establishment that indicates the certification is with respect to the suitability of the individual to be a plasmapheresis donor.

(c) *Qualification of donor.* Donors shall be in good health on the day of donation, as indicated in part by:

(1) Normal temperature;

(2) Demonstration that systolic and diastolic blood pressures are within normal limits, unless the examining physician is satisfied that an individual with blood pressures outside these limits is an otherwise qualified donor under the provisions of this section;

(3) A blood hemoglobin level of no less than 12.5 grams of hemoglobin per 100 milliliters of blood;

(4) A normal pulse rate;

(5) A total serum protein of no less than 6.0 grams per 100 milliliters of serum;

(6) Weight, which shall be at least 110 pounds;

(7) Freedom from acute respiratory diseases;

(8) Freedom from any infectious skin disease at the site of phlebotomy and from any such disease generalized to such an extent as to create a risk of contamination of the plasma;

(9) Freedom from any disease, other than malaria, transmissible by blood transfusion, insofar as can be determined by history and examinations indicated in this section;

(10) Freedom of the arms and forearms from skin punctures or scars indicative of addiction to self-injected narcotics;

(11) Freedom from a history of viral hepatitis;

(12) Freedom from a history of close contact within six months of donation with an individual having viral hepatitis;

(13) Freedom from a history of having received, within six months, human blood or any derivative of human blood which the Food and Drug Administration has advised the licensed establishment is a possible source of viral hepatitis, except for specific immunization performed in accordance with § 640.66 of this part.

(d) *General.* Any donor who, in the opinion of the interviewer, appears to be under the influence of any drug, alcohol, or for any reason does not appear to be providing reliable answers to medical history questions, shall not be considered a suitable donor.

§ 640.64 Collection of blood for Source Plasma (Human).

(a) *Supervision.* All blood for the collection of Source Plasma (Human) shall be drawn from the donor by a qualified licensed physician or by persons under his supervision trained in the procedure.

(b) *Blood containers.* Blood containers and donor sets shall be pyrogen-free, sterile and identified by lot number. The amount of anticoagulant required for the quantity of blood to be collected shall be in the blood container when it is sterilized.

(c) *The anticoagulant solution.* The anticoagulant solution shall be sterile and pyrogen-free. One of the following formulae shall be used in the indicated volumes:

(1) *Anticoagulant acid citrate dextrose solution (ACD).*

Tri-sodium citrate ($Na_3C_6H_5O_7 \cdot 2H_2O$)	22.0 grams
Citric acid ($C_6H_8O_7 \cdot H_2O$)	8.0 grams
Dextrose ($C_6H_{12}O_6H_2O$)	24.5 grams
Water for injection (U.S.P.) to make	1,000 milliliters
Volume per 100 milliliters blood	15 milliliters

(2) *Anticoagulant acid citrate dextrose dextrose solution (CPD).*

Tri-sodium citrate ($Na_3C_6H_5O_7 \cdot 2H_2O$)	26.3 grams
Citric acid ($C_6H_8O_7 \cdot H_2O$)	3.27 grams
Dextrose ($C_6H_{12}O_6 \cdot H_2O$)	25.5 grams
Monobasic sodium phosphate ($NaH_2PO_4 \cdot H_2O$)	2.22 grams
Water for injection (U.S.P.) to make	1,000 milliliters
Volume per 100 milliliters blood	14 milliliters

(3) *Anticoagulant sodium citrate solution.*

Tri-sodium citrate ($Na_3C_6H_5O_7 \cdot 2H_2O$)	40 grams
Water for injection (U.S.P.) to make	1,000 milliliters
Volume per 100 milliliters of blood	10 milliliters

(d) *Donor identification.* Each unit of blood and plasma shall be so marked or identified by number or other symbol so as to relate it directly to the donor.

(e) *Prevention of contamination of the blood and plasma.* The skin of the donor at the site of phlebotomy shall be prepared thoroughly and carefully by a method that gives maximum assurance of a sterile container of blood. The blood shall be collected, the plasma separated, and the cells returned to the donor by aseptic methods in a sterile system which may be closed, or may be vented if the vent protects the blood cells and plasma against contamination.

§ 640.65 Plasmapheresis.

(a) *Procedure-general.* The plasmapheresis procedure, which is defined as that procedure in which blood is removed from a donor, the plasma separated from the formed elements and the formed elements returned to the donor, during a single visit to the establishment, shall be described in detail in the product license application.

(b) *Procedures-specific requirements.* The plasmapheresis procedure shall meet the following requirements:

(1) A sample of blood shall be drawn from each donor by a qualified licensed physician or by persons under his supervision and trained in such procedure on the day of the first plasmapheresis and at least every four months thereafter on which a serologic test for syphilis and a serum protein electrophoresis or quantitative immunodiffusion test for immunoglobulins to determine the immunoglobulin composition of the serum shall be performed. The results of the tests shall be reviewed by a qualified licensed physician within 10 days after the sample is drawn to determine whether or not the donor may continue on the program. If the plasma protein composition is not within normal limits established by the testing laboratory, the donor shall be removed from the program until these values return to normal. A donor with a reactive serologic test for syphilis shall not be plasmapheresed again until his serum tests nonreactive to a serologic test for syphilis.

(2) At least every four months, the accumulated laboratory data and collection records of each donor shall be reviewed by a qualified licensed physician to determine continuing suitability of the donor. Only those donors found suitable upon such a review shall remain in the plasmapheresis program. Such a review shall be signed by the reviewing physician.

(3) A donor identification system shall be established that positively identifies each donor and relates such donor directly to his blood and its components as well as to his accumulated records and laboratory data. Such system shall include either a photograph of each donor which shall be used on each visit to confirm the donor's identity, or some other method that provides equal or greater assurance of positively identifying the donor.

(4) The amount of whole blood, not including anticoagulant, removed from a donor during a plasmapheresis procedure or in any 48-hour period shall not exceed 1,000 milliliters unless the donor's weight is 175 pounds or greater, in which case the amount of whole blood, not including anticoagulant, removed from the donor during a plasmapheresis procedure or in any 48-hour period shall not exceed 1,200 milliliters.

(5) The amount of whole blood, not including anticoagulant, removed from a donor within a seven-day period shall not exceed 2,000 milliliters unless the donor's weight is 175 pounds or greater, in which case the amount of whole blood, not including anticoagulant, removed from the donor during a seven-day period shall not exceed 2,400 milliliters.

(6) No more than 500 milliliters of whole blood shall be removed from a donor at one time, unless the donor's weight is 175 pounds or greater, in which case no more than 600 milliliters of whole blood shall be removed from the donor at one time.

(7) The plasma shall be separated from the red blood cells immediately after blood collection. The maximum feasible volume of red blood cells shall be returned to the donor before another unit is collected.

§ 640.66 Immunization of donors.

If specific immunization of a donor is to be performed, the selection and scheduling of the injection of the antigen, and the evaluation of each donor's clinical response, shall be by a qualified licensed physician or physicians. The administration of the antigen may be performed by a licensed physician or a trained person under his supervision. Any material used for immunization shall be either a product licensed under section 351 of the Public Health Service Act for such purpose or one specifically approved by the Director, Bureau of Biologics, Food and Drug Administration. Immunization procedures shall be on file at each plasmapheresis center where immunizations are performed.

§ 640.67 Test for hepatitis B antigen.

Each unit of Source Plasma (Human) shall be nonreactive to a test for the hepatitis B antigen as prescribed in §§ 610.40 and 610.41 of this chapter.

§ 640.68 Processing.

(a) *Sterile system.* All surfaces that come in contact with the plasma shall be both sterile and pyrogen-free. If the method of separation involves a vented system (i.e., where an airway must be inserted into a container for withdrawal of the plasma), the airway and vent shall be sterile and constructed so as to exclude microorganisms and maintain a sterile system.

(b) *Final containers.* Final containers used for Source Plasma (Human), whether integrally attached or separated from the original blood container, shall not be entered prior to issuance for any purpose except for filling with the plasma. Such containers shall be uncolored and hermetically sealed, and shall permit clear visibility of the contents. Final containers and their components shall not interact with the plasma contents under conditions of storage and use so as to alter the safety, quality, purity, or potency of the plasma and shall provide adequate protection against external factors that may cause deterioration or contamination. Prior to filling, the final container shall be marked or identified by number or other symbol which will relate it directly to the donor.

(c) *Preservative.* Source Plasma (Human) shall not contain a preservative.

§ 640.69 General requirements.

(a) *Pooling.* Pooling of plasma by the manufacturer of Source Plasma (Human) from two or more donors is not permitted. Two units of plasma from the same donor may be pooled if such units are collected during one plasmapheresis procedure, provided the pooling is done by a procedure that gives maximum assurance of a sterile container of plasma.

(b) *Storage.* Immediately after filling, the plasma shall be stored at not warmer than −20° C., except for plasma collected as provided for in § 640.70.

(c) *Inspection.* Source Plasma (Human) shall be inspected at the time of issuance. If there is any evidence of thawing, the unit shall not be issued.

(d) *Pilot samples.* If pilot samples are provided, they shall meet the following standards:

(1) Prior to filling, all pilot samples shall be marked or identified so as to relate them directly to the donor of that unit of plasma.

(2) All pilot samples shall be filled at the time the final product is prepared by the person who prepares the final product.

(3) All pilot samples shall be representative of the contents of the final product.

(4) All pilot samples shall be collected in a manner that does not contaminate the contents of the final container.

(e) *Labeling.* In addition to the labeling requirements of § 610.62 of this chapter, and in lieu of the requirements in §§ 610.60 and 610.61 of this chapter, the following information shall appear on the label affixed to each container of Source Plasma (Human):

(1) The proper name of the product.
(2) Name, address, and license number of the manufacturer.
(3) Donor number.
(4) Collection date of the plasma.
(5) The statement: "Caution: For Manufacturing Use Only".
(6) The statement: "Store at −20° C. or colder".
(7) A statement as to whether the plasma was collected from normal donors or from immunized donors. In the case of immunized donors, the label shall state the immunizing antigen.
(8) The total volume of plasma and total quantity and type of anticoagulant used.
(9) The test for hepatitis B antigen used and the results.

(f) *Manufacturing responsibility.* All steps in the manufacture of Source Plasma (Human), including donor examination, blood collection, plasmapheresis, laboratory testing, labeling, storage, and issuing shall be performed by the establishment licensed to manufacture Source Plasma (Human), except that the following tests may be performed by a clinical laboratory licensed under section 353 of the Public Health Service Act, or by an establishment licensed for blood or blood derivatives under section 351 of the Public Health Service Act, provided such arrangements are approved by the Director, Bureau of Biologics, Food and Drug Administration:

(1) The test for hepatitis B antigen pursuant to § 640.67.
(2) The serum protein electrophoresis or quantitative immunodiffusion test for immunoglobulin as required by § 640.65 (b)(1).
(3) Such testing pursuant to paragraph (f) (1) and (2) of this section shall not be considered divided manufacturing, requiring two product licenses for source Plasma (Human), provided that:
(i) The results of such tests are maintained by the establishment licensed for Source Plasma (Human) whereby such results may be reviewed by a licensed physician as required in § 640.65(b)(2), and/or by authorized Food and Drug Administration inspectors.
(ii) The Source Plasma (Human) manufacturer has obtained a written agreement that the testing laboratory will permit authorized Food and Drug Administration inspectors to inspect their testing procedures and facilities during any reasonable business hours.
(iii) The testing laboratory will participate in any proficiency testing programs undertaken by the Bureau of Biologics, Food and Drug Administration.

(g) *Records.* In addition to the general recordkeeping requirements of § 600.12 of this chapter, every manufacturer of Source Plasma (Human) must keep for each donor a separate and complete record of all initial and periodic examinations, tests, laboratory data, interviews, etc., undertaken pursuant to §§ 640.63, 640.65, 640.66, and 640.67. This record must also contain the original or a clear copy of the donor's written consent for participation in the plasmapheresis program as required by § 640.61 and the certification of good health as prescribed in § 640.63(b). Each donor record must be directly cross-referenced to the unit(s) of Source Plasma (Human) associated with the donor.

§ 640.70 Modification of Source Plasma (Human).

(a) Upon approval by the Director, Bureau of Biologics, Food and Drug Administration, of an amendment to the product license for Source Plasma (Human), a manufacturer may prepare Source Plasma (Human) as a liquid product for a licensed blood derivative manufacturer who has indicated a need for a liquid product.

(b) Liquid Source Plasma (Human) shall meet all standards of the frozen Source Plasma (Human) except:

(1) Liquid Source Plasma (Human) shall be stored in nonleachable containers so that the containers and their components will not interact with the plasma contents under conditions of storage and use so as to alter the safety, quality, purity, or potency of the plasma and shall provide adequate protection against external factors that may cause deterioration or contamination.

(2) Liquid Source Plasma (Human) shall be shipped, stored and labeled for storage at a temperature of 10° C. or colder. An exception to the shipping or storage temperature shall be approved by the Director, Bureau of Biologics, Food and Drug Administration, based upon his receipt of substantial evidence to support another temperature. Such evidence may be submitted by either the product licensee of the liquid Source Plasma (Human) or the manufacturer of the final blood derivative product who has requested the liquid Source Plasma (Human).

(3) The label for the liquid Source Plasma (Human) shall be easily distinguished from that of the frozen product. Color coding shall not be used for this purpose.

(4) The label affixed to each container of liquid Source Plasma (Human) shall contain, in addition to the information required by § 640.69(e) but excluding § 640.69(e)(6) the name of the manufacturer of the final blood derivative product for whom is was prepared.

(5) Liquid Source Plasma (Human) shall be inspected immediately prior to issuance. If the color or physical appearance is abnormal, or there is any indication or suspicion of microbial contamination, the unit of liquid Source Plasma (Human) shall not be issued.

Subparts H and I—[Reserved]

Subpart J—Immune Serum Globulin (Human)

§ 640.100 Immune Serum Globulin (Human).

(a) *Proper name and definition.* The proper name of this product shall be Immune Serum Globulin (Human). The product is defined as a sterile solution containing antibodies derived from human blood.

(b) *Source material.* The source of Immune Serum Globulin (Human) shall be blood, plasma or serum from human donors determined at the time of donation to have been free of causative agents of diseases that are not destroyed or removed by the processing methods, as determined by the donor's history and from such physical examination and clinical tests as appear necessary for each donor at the time the blood was obtained. The source blood, plasma or serum shall not contain a preservative and shall be stored in a manner that will prevent contamination by microorganisms, pyrogens or other impurities.

(c) *Additives in source material.* Source blood, plasma or serum shall contain no additives other than citrate or acid citrate dextrose anticoagulant solution, unless it is shown that the processing method yields a product free of the additive to such an extent that the safety, purity and potency of the product will not be affected adversely.

§ 640.101 General requirements.

(a) *Heat stability test.* Approximately 2 ml. of completely processed material of each lot shall not show any visible sign of gelation after heating in a 12 x 75 mm. stoppered glass tube at 57° C. for 4 hours.

(b) *Hydrogen ion concentration.* The pH of final container material shall be 6.8±0.4 when measured in a solution diluted to 1 percent protein with 0.15 molar sodium chloride.

(c) *Turbidity.* The product shall be free of turbidity as determined by visual inspection of final containers.

(d) *Date of manufacture.* The date of manufacture is the date of initiating the last valid measles or poliomyelitis antibody test (§ 640.104(b) (2) and (3)) whichever date is earlier.

(e) *Labeling.* In addition to complying with all applicable labeling required in this subchapter, labeling shall indicate that:

(1) There is no prescribed potency for viral hepatitis antibodies.
(2) The product is not recommended for intravenous administration.
(3) The lot is or is not suitable for use with Measles Virus Vaccine, Live, Attenuated.
(4) The lot is or is not recommended for poliomyelitis.

(f) *Samples and protocols.* For each lot of Immune Serum Globulin (Human) the following material shall be submitted to the Director, Bureau of Biologics, Food and Drug Administration, Building 29A, 9000 Rockville Pike, Bethesda, MD 20014:

(1) A 50 ml. sample of the final product.
(2) All protocols relating to the history of each lot and all results of all tests prescribed in these additional standards.

§ 640.102 Manufacture of Immune Serum Globulin (Human).

(a) *Processing method.* The processing method shall be one that has been shown: (1) To be capable of concentrating tenfold from source material at

least two different antibodies; (2) not to affect the integrity of the globulins; (3) to consistently yield a product which is safe for subcutaneous and intramuscular injection and (4) not to transmit viral hepatitis.

(b) *Microbial contamination.* Low temperatures or aseptic techniques shall be used to minimize contamination by microorganisms. Preservatives to inhibit growth of microorganisms shall not be used during processing.

(c) *Bulk storage.* The globulin fraction may be stored in bulk prior to further processing provided it is stored in clearly identified hermetically closed vessels. Globulin as either a liquid concentrate or a solid and containing alcohol or more than 5 percent moisture shall be stored at a temperature of −10° C. or lower. Globulin as a solid free from alcohol and containing less than 5 percent moisture, shall be stored at a temperature of 0° C. or lower.

(d) *Determination of the lot.* Each lot of Immune Serum Globulin (Human) shall represent a pooling of approximately equal amounts of material from not less than 1,000 donors.

(e) *Sterilization and heating.* The final product shall be sterilized promptly after solution. At no time during processing shall the product be exposed to temperatures above 45° C. and after sterilization the product shall not be exposed to temperatures above 30° to 32° C. for more than 72 hours.

§ 640.103 The final product.

(a) *Final solution.* The final product shall be a 16.5±1.5 percent solution of globulin containing 0.3 molar glycine and a preservative.

(b) *Protein composition.* At least 90 percent of the globulin shall have an electrophoretic mobility not faster than -2.8×10^{-5} centimeters^2 per volt per second, when measured at a 1 percent protein concentration in sodium diethylbarbiturate buffer at pH 8.6 and 0.1 ionic strength.

§ 640.104 Potency.

(a) *Antibody levels and tests.* Each lot of final product shall contain at least the minimum levels of antibodies for diphtheria, measles, and for at least one type of poliomyelitis. In the event the final bulk solution is stored at a temperature above 5° C. the antibody level tests shall be performed after such storage with a sample of the stored material.

(b) *Minimum levels.* The minimum antibody levels are as follows:

(1) No less than 2 units of diphtheria antitoxin per ml.

(2) A measles neutralizing antibody level of no less than 0.25 times the level of the reference measles serum, except that when recommended for use with Measles Virus Vaccine, Live, Attenuated, the measles antibody level shall be as prescribed in § 640.114.

(3) A poliomyelitis neutralizing antibody level of no less than 1.0 for Type 1, 1.0 for Type 2, and 2.5 for Type 3, times the antibody level of the reference poliomyelitis immune globulin.

(c) *Reference materials.* The following reference materials shall be obtained from the Bureau of Biologics:

(1) U.S. reference measles serum for correlation of measles antibody titers.

(2) U.S. reference poliomyelitis immune globulin for correlation of poliomyelitis antibody titers, Types 1, 2, and 3.

Subpart K—Measles Immune Globulin (Human)

§ 640.110 Measles Immune Globulin (Human).

(a) *Proper name and definition.* The proper name of the product shall be Measles Immune Globulin (Human). It shall consist of a sterile solution of 10 to 18 percent globulin derived from human blood, having a measles antibody level of 0.5 times the level of the U.S. measles reference serum. Measles Immune Globulin shall be made from a sterile 16.5±1.5 percent solution of human globulin.

(b) *Source material.* The source of Measles Immune Globulin (Human) shall be blood, plasma or serum from human donors determined at the time of donation to have been free of causative agents of diseases that are not destroyed or removed by the processing method, as determined by the donor's history and from such physical examination and clinical tests as appear necessary for each donor at the time the blood was obtained. The source blood, plasma or serum shall not contain a preservative and shall be stored in a manner that will prevent contamination by microorganisms, pyrogens or other impurities.

(c) *Additives in source material.* Source blood, plasma or serum shall contain no additives other than citrate or acid citrate dextrose anticoagulant solution, unless it is shown that the processing method yields a product free of the additive to such an extent that the safety, purity and potency of the product will not be affected adversely.

§ 640.111 General requirements.

(a) *Heat stability test.* Approximately 2 ml of final container material of each lot shall not show any visible sign of gelation after heating in a 12 x 75 mm. stoppered glass tube at 57° C. for four hours.

(b) *Hydrogen ion concentration.* The pH of final container material shall be 6.8±0.4 when measured in a solution diluted to 1 percent protein with 0.15 molar sodium chloride.

(c) *Turbidity.* The product shall be free of turbidity as determined by visual inspection of final containers.

(d) *Date of manufacture.* The date of manufacture is the date of initiating the last valid measles antibody test as required in § 640.114.

(e) [Reserved]

(f) [Reserved]

(g) *Samples and protocols.* For each lot of globulin, the following materials shall be submitted to the Director, Bureau of Biologics, Food and Drug Administration, Building 29A, 9000 Rockville Pike, Bethesda, MD 20014.

(1) 30 ml of final product.

(2) All protocols relating to the history of the manufacture of each lot and all results of all tests prescribed in these additional standards.

§ 640.112 Manufacture of Measles Immune Globulin (Human).

(a) *Processing method.* The globulin shall be prepared by a processing method that (1) has been shown to be capable of concentrating tenfold from source material at least two different antibodies, (2) does not affect the integrity of the globulins and is capable of consistently yielding a product which is safe for subcutaneous and intramuscular injection and (3) will not transmit viral hepatitis.

(b) *Reference materials.* The following reference material shall be obtained from the Bureau of Biologics: U.S. reference measles serum for correlation of measles antibody titers with globulin products.

(c) *Microbial contamination.* Low temperatures or aseptic techniques shall be used to minimize contamination by microorganisms. Preservatives to inhibit growth of microorganisms shall not be used during processing.

(d) *Bulk storage.* The globulin fraction may be stored in bulk prior to further processing provided it is stored in well-marked hermetically closed vessels. Purified globulin as either a liquid concentrate or a solid and containing alcohol or more than 5 percent moisture shall be stored at a temperature not to exceed −10° C. Purified globulin as a solid free from alcohol and containing less than 5 percent moisture, shall be stored at temperatures not to exceed 0° C.

(e) *Determination of the lot.* Each lot of Measles Immune Globulin (Human) shall represent a pooling of material from not less than 1,000 donors.

(f) *Sterilization and dilution.* The product shall be prepared initially as a 16.5 percent solution and this preparation shall be sterilized promptly after solution. After sterilization the product shall not be exposed to temperatures above 45° C. for more than a total of 72 hours. Dilution of this sterile globulin solution shall be made only to adjust the required measles antibody level.

§ 640.113 The final product.

(a) *Final solution.* The final product shall be a 10 to 18 percent solution of globulin containing 0.3 molar glycine and a preservative.

(b) *Protein composition.* No less than 90 percent of the globulin shall have an electrophoretic mobility not faster than -2.8×10^{-5} centimeters^2 per volt per second, when measured at a 1 percent protein concentration in sodium diethylbarbiturate at pH 8.6 and 0.1 ionic strength.

§ 640.114 Potency.

Antibody levels and tests. Each lot of final product shall contain no less than the minimum levels of antibodies for diphtheria and measles as follows:

(a) The product shall contain no less than 2 units of diphtheria antitoxin per ml, adjusted for dilution from the 16.5 percent solution.

(b) Each lot of final product shall contain a measles antibody level of 0.5 times the level of the U.S. reference measles serum. The measles antibody potency shall be determined by simultaneous determinations of the neutralizing antibody titers of the globulin on tests and of a reference preparation against 100 $TCID_{50}$ (50–500 $TCID_{50}$ when based upon a single test) of measles virus in a tissue culture system. The potency test shall also include a determination of virus titer and controls for globulin toxicity and cell culture viability. Twofold serial dilutions of the globulin under test and of the reference preparation shall be employed in this determination. In applying these requirements a plus or minus variation of one twofold dilution is acceptable.

PART 650—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR DERMAL TESTS

Subpart A—Diphtheria Toxin for Schick Test

Sec.

Subpart B—Tuberculin

AUTHORITY: Sec. 215, 58 Stat. 690, as amended; 42 U.S.C. 216. Sec. 351, 58 Stat. 702, as amended; 42 U.S.C. 262, unless otherwise noted.

CROSS REFERENCES.—For U.S. Customs Service regulations relating to viruses, serums, and toxins, see 19 CFR 12.21–12.23. For U.S. Postal Service regulations relating to the admissibility to the United States mails see 39 CFR Parts 124 and 125, esp. § 125.2.

Subpart A—Diphtheria Toxin for Shick Test

§ 650.1 Diphtheria Toxin for Shick Test.

The proper name of this product shall be Diphtheria Toxin for Schick Test, which shall be a preparation of a diphtheria toxin obtained from the growth of *Corynebacterium diphtheriae*.

§ 650.2 U.S. Standard preparation.

The U.S. Standard Diphtheria Toxin for Schick Test shall be used to determine the Schick test dose of the product. The Schick test dose of the standard is that amount of the standard, when mixed with 0.001 unit of the U.S. Standard Diphtheria Antitoxin and injected intradermally in a guinea pig, will induce an erythematous reaction of 10 mm. in diameter.

§ 650.3 Manufacture of Diphtheria Toxin for Shick Test.

(a) *Propagation of bacteria.* The culture medium for propagation of the *Corynebacterium diphtheriae* for preparation of the parent toxin shall not contain ingredients known to be capable of producing allergenic effects in human subjects.

(b) *The parent toxin.* Diphtheria Toxin for Schick Test shall be prepared from a parent toxin which has been demonstrated to be stable and which contains no less than 400 minimum lethal doses per milliliter or 400,000 minimum reaction doses per milliliter. A minimum lethal dose is the smallest amount of toxin that will kill a guinea pig weighing approximately 250 gm. on the fourth day after its subcutaneous injection. A minimum reaction dose is that amount of toxin which when injected intradermally into a guinea pig induces an erythematous reaction 10 mm. in diameter.

§ 650.4 Potency test.

The dermal reactivity of each lot of the product shall be determined from the results of simultaneous guinea pig intradermal potency tests of the product under test and of the standard. The test shall be performed as follows:

(a) *Guinea pigs.* At least four healthy female guinea pigs shall be used, all of the same strain and each of a size that will permit a random distribution of eight intradermal injections. The hair shall be removed from the back and both sides of each guinea pig without producing abrasions of the skin. The denuded skin of each animal shall be sectioned into four equal areas at right angles to the vertebral column to provide two injection sites in each of the four areas, one on each side of the vertebra. The test is not valid if the guinea pigs do not show a graded response to the graded dilutions of the Schick test dose of the standard toxin.

(b) *Preparation of the test doses.* Four dilutions, two of the product under test and two of the U.S. Standard Diphtheria Toxin for Schick Test, shall be prepared in sterile buffered saline pH 7.4 containing 0.2 percent gelatin. The low and high dilutions of the standard shall be those amounts of a Schick test dose of the standard which in a dose of 0.1 ml. are capable of eliciting graded erythematous dermal reactions between 10 mm. and 20 mm. in diameter. The low and high dilutions of the Schick test dose of the toxin under test shall be the same as those of the standard toxin and estimated to have the same dermal reactivity.

(c) *Inoculation.* The low and high dilutions of the product (chart designation P_L and P_H) and the low and high dilutions of the standard (chart designations S_L and S_H) shall be injected intradermally in a volume of 0.1 ml. into each of the four guinea pigs according to either the following scheme, or in another scheme, provided it will permit comparable randomization of injection sites:

Area	Guinea Pig Number							
	1		2		3		4	
	Left	Right	Left	Right	Left	Right	Left	Right
A	S_L	S_L	S_H	S_H	P_L	P_L	P_H	P_H
B	S_H	S_H	S_L	S_L	P_H	P_H	P_L	P_L
C	P_L	P_L	P_H	P_H	S_L	S_L	S_H	S_H
D	P_H	P_H	P_L	P_L	S_H	S_H	S_L	S_L

(d) *Calculation of test results.* Between 40 and 66 hours following injection, a diameter of the reaction for each injection site shall be calculated by averaging two diameters of the reaction measured at right angles to each other. The average reaction for each dilution for each animal shall be determined, then the average diameters of the reactions of all of the guinea pigs for each dilution shall be calculated. The ratios of the reactions are determined by dividing the average diameter of the low dilution of the product under test by the average diameter of the low dilution of the standard and by dividing the average diameter of the high dilution of the product by the average diameter of the high dilution of the standard.

(e) *Potency requirement.* The potency of the product under test is satisfactory if each calculated ratio of the reactions of the product under test and of the standard is 1.0. The potency of the lot under test is considered to be equal to that of the standard if the ratios are not lower than 0.77 or higher than 1.30, provided that in a single test the ratios are substantially the same.

§ 650.5 Stability test.

A sample of each lot of the product shall be held at 37° C. for not less than 24 hours and then tested for potency as prescribed in § 650.4. The stability of the product is satisfactory if test results of the sample meet the potency requirement prescribed in § 650.4(e).

§ 650.6 Samples; protocols; official release.

For each lot of the product, the following material shall be submitted to the Director, Bureau of Biologics:

(a) A protocol which consists of a summary of the history of manufacture of each lot including all results of all tests for which test results are requested by the Director, Bureau of Biologics.

(b) A sample of no less than 20 ml. of the product.

No lot of the product shall be issued by the manufacturer until notification of official release is received from the Director, Bureau of Biologics.

§ 650.7 Equivalent methods.

Modification of any particular manufacturing method or process or the conditions under which it is conducted as set forth in the additional standards relating to Diphtheria Toxin for Schick Test, shall be permitted whenever the manufacturer presents evidence that demonstrates the modification will provide assurances of the safety, purity, and potency of the product that are equal to or greater than the assurances provided by such standards, and the Commissioner of Food and Drugs so finds and makes such findings a matter of official record.

Subpart B—Tuberculin

§ 650.10 Tuberculin.

The proper name of this product shall be Tuberculin, which shall be a preparation derived from *Mycobacterium tuberculosis* or *M. Bovis*.

§ 650.11 General requirements.

(a) *General safety.* Each lot of Tuberculin shall be tested for safety as prescribed in § 610.11 of this chapter, except that the sample of tuberculin from multiple puncture devices shall be obtained by removing the tuberculin in a manner that will permit the injection of material from at least five devices into each of two guinea pigs and from at least two devices into each of two mice.

(b) *Labeling.* In addition to complying with all other applicable labeling provisions of this subchapter, the package label shall state the following:

(1) For Tuberculin for Mantoux testing, the number of U.S. units (TU) per dose.

(2) For Tuberculin for multiple puncture testing, a statement indicating that the activity per test is comparable to a stated number of U.S. units (TU) administered by the Mantoux method.

(3) The applicable type of Tuberculin placed immediately following and of no less prominence than the proper name, as follows:

(i) "Old," or

(ii) "Purified Protein Derivative" or "PPD."

(c) *Samples; protocols; official release.* For each lot of Tuberculin the following shall be submitted to the Director, Bureau of Biologics, Food and Drug Administration, Building 29A, 9000 Rockville Pike, Bethesda, MD 20014:

(1) A protocol which consists of a summary of the history of manufacture of each lot including all results of each test for which test results are requested by the Director, Bureau of Biologics.

(2) Tuberculin distributed on a multiple puncture device, as follows:

(i) A total of no less than 100 devices,

(ii) A total of no less than 20 ml. of bulk tuberculin.

(3) A total of no less than 20 ml. of liquid tuberculin.

(4) Sufficient dried tuberculin in final containers so that upon reconstitution as recommended in labeling it will yield at least 20 ml.

The product shall not be issued by the manufacturer until notification of official release of the lot is received from the Director, Bureau of Biologics.

§ 650.12 U.S. Standard preparations.

(a) The U.S. Standard Tuberculin, Old, shall be used for determining the potency of nonfractionated tuberculins, as prescribed in § 650.14. One U.S. Tuberculin unit is 0.1 ml. of a 1:10,000 dilution of this standard.

(b) The U.S. Standard Tuberculin, Purified Protein Derivative, shall be used in determining the potency of tuberculins made from protein fractions, as prescribed in § 650.14. One U.S. Tuberculin unit is 0.1 ml. of a 1: 5,000 dilution of this standard.

§ 650.13 Production.

(a) *Propagation of mycobacteria.* The medium used for production of mycobacteria shall not contain ingredients known to be capable of producing allergenic effects in human subjects.

(b) *Tests for viable mycobacteria.* The culture filtrate from each strain in its most concentrated form shall be shown to be free of viable mycobacteria by the following tests:

(1) *Animal test.* A 1.0 ml. sample of the filtrate shall be injected intraperitoneally into each of at least three healthy guinea pigs weighing between 300 and 400 gm. At least two-thirds of the animals must survive an observation period of at least 6 weeks and must show a normal weight gain. After the observation period the animals shall be necropsied and examined for signs indicative of tuberculosis except that animals that die during the observation period shall be necropsied and examined as soon as feasible after death. The filtrate is satisfactory for Tuberculin manufacture if none of the animals in the test show evidence of tuberculosis infection.

(2) *Culture test.* A 2.0 ml. sample of the filtrate shall be inoculated onto Löwenstein-Jensen's egg medium or other media demonstrated to be equally capable of supporting growth. A control test on the culture medium shall be conducted simultaneously with the sample under test and shall be shown to be capable of supporting the growth of small numbers of the production strain(s). All the test vessels shall be incubated at a suitable temperature for a period of 6 weeks under conditions that will prevent drying of the medium, after which the cultures shall be examined for evidence of mycobacterial colonies. The filtrate is satisfactory for Tuberculin manufacture if the test shows no evidence of mycobacteria.

§ 650.14 Potency test.

The potency of each lot of Tuberculin shall be estimated from a comparison of the responses obtained by the intradermal injection into sensitized guinea pigs weighing over 500 gm. of a sample of the lot under test and of the appropriate standard preparation. The U.S. Standard Tuberculin, Old, shall be used in determining the potency of tuberculins made from the concentrated filtrate of the soluble products of the growth of the mycobacteria. The U.S. Standard Tuberculin, Purified Protein Derivative, shall be used in determining the potency of tuberculins made from protein fraction of the soluble products of the growth of the mycobacteria. The test shall be performed as follows:

(a) *Sensitization of test animals.* At least four white guinea pigs shall be sensitized with *M. tuberculosis* or *M. bovis*. The degree of sensitivity shall be such that an intradermal injection of one U.S. unit of the appropriate standard preparation will produce in each test animal an erythematous reaction approximately 100 mm^2 within 18–24 hours.

(b) *Test Procedure.* The hair shall be removed from both sides of the sensitized test animals without producing abrasions of the skin. Dilutions of the standard containing 0.5, 1, 2, and 4 U.S. units in the test dose of 0.1 ml. and four comparable levels of activity of the lot under test shall be injected intradermally into opposite and parallel sites of each animal. Only three dilutions need be used when the initial concentration of the lot under test does not contain four units in 0.1 ml. Within 18–24 hours following injection, measurements of the greater and lesser diameters of erythema measured to the closest millimeter shall be made at each site. The mean value of the product of the diameters for each dilution shall be calculated. The number of U.S. units in the lot under test shall be estimated from its relationship to the reactivity of the appropriate standard preparation.

(c) *Potency.* The potency of the lot is satisfactory if the test results are within limits, as follows:

(1) *Products for Mantoux testing.* ±20 percent of the labeled U.S. units.

(2) *Liquid products for multiple puncture testing.* ±20 percent of the U.S. units claimed by the manufacturer in the license application.

(3) *Products dried on multiple puncture devices.* ±50 percent of the U.S. units claimed by the manufacturer in the license application.

§ 650.15 Equivalent methods.

Modification of any particular method or process or the conditions under which it is conducted as set forth in the additional standards relating to Tuberculin, shall be permitted whenever the manufacturer presents evidence that demonstrates the modification will provide assurances of the safety, purity, and potency of the product that are equal to or greater than the assurances provided by such standards, and the Commissioner of Food and Drugs, so finds and makes such finding a matter of official record.

PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

Subpart A—Hepatitis Associated Antibody (Anti-Australia Antigen)

AUTHORITY: Sec. 215, 58 Stat. 690, as amended; 42 U.S.C. 216. Sec. 351, 58 Stat. 702, as amended; 42 U.S.C. 262, unless otherwise noted.

CROSS REFERENCES: For U.S. Customs Service regulations relating to viruses, serums, and toxins, see 19 CFR 12.21–12.23. For U.S. Postal Service regulations relating to the admissibility to the United States mails see 39 CFR Parts 124 and 125, esp. § 125.2.

Subpart A—Hepatitis Associated Antibody (Anti-Australia Antigen)

§ 660.1 Hepatitis Associated Antibody (Anti-Australia Antigen).

(a) *Proper name and definition.* The proper name of this product shall be Hepatitis Associated Antibody (Anti-Australia Antigen) which shall consist of a preparation of serum containing the hepatitis associated antibody.

(b) *Source.* The source of this product shall be plasma or blood, obtained aseptically from animals immunized with hepatitis associated (Australia) antigen which have met the applicable requirements of § 600.11 of this chapter or from human donors whose blood is positive for hepatitis associated antibody.

§ 660.2 General requirements.

(a) *Processing.* The processing method shall be one that has been shown to consistently yield a specific and potent final product free of properties which would adversely affect the test results when the product is tested by the methods recommended by the manufacturer in the package enclosure.

(b) *Ancillary reagents and materials.* All ancillary reagents and materials supplied in the package with the product shall meet generally accepted standards of purity and quality and shall be effectively segregated and otherwise manufactured in a manner (such as heating at 60° C. for 10 hours) that will reduce the risk of contaminating the product and other biological products. Ancillary reagents and materials accompanying the product which are used in the performance of the test as described by the manufacturer's recommended test procedures shall have been shown not to adversely affect the product within the prescribed dating period.

(c) *Labeling.* In addition to the items required by other applicable labeling provisions of this subchapter, the following shall also be included:

(1) Indication of the source of the product immediately following the proper name on both the final container and package label, e.g., human, guinea pig.

(2) Name of the test method(s) recommended for the product on the package label and on the final container label when capable of bearing a full label (see § 610.60(a) of this chapter).

(3) A warning on the package label and on the final container label if capable of bearing a full label (see § 610.60 (a) of this chapter) indicating that the product and antigen if supplied, shall be handled as if capable of transmitting hepatitis.

(4) If the product is dried, the final container label shall indicate "Reconstitution date: _____" and a statement indicating the period within which the product may be used after reconstitution.

(5) The package shall include a package enclosure providing (i) adequate instructions for use, (ii) a description of all recommended test methods, and (iii) warnings as to possible hazards, including hepatitis, in handling the product and any ancillary reagents and materials accompanying the product.

(d) *Final container.* Final containers shall be sterile, colorless, and transparent.

(e) *Date of manufacture.* The date of manufacture of Hepatitis Associated Antibody (Anti-Australia Antigen) that has been iodinated with radioactive iodine (I^{125}) shall be the day of labeling the antibody with the radionuclide.

(f) *Samples; protocols; official release*—(1) *Hepatitis Associated Antibody (Anti-Australia Antigen).* Except as provided otherwise in this paragraph, the following material for each filling of the product shall be submitted to the Director, Bureau of Biologics:

(i) A sample of each filling packaged as for distribution including all ancillary reagents and materials.

(ii) A protocol which consists of a summary of the history of manufacture of each filling, including all results of each test for which test results are requested by the Director, Bureau of Biologics.

(iii) No filling of the product shall be issued by the manufacturer until notification of official release of the filling is received from the Director, Bureau of Biologics.

(2) *Hepatitis Associated Antibody (Anti-Australia Antigen) iodinated with ^{125}I.* Hepatitis Associated Antibody (Anti-Australia Antigent) that has been iodinated with radioactive iodine (^{125}I) may be released by the manufacturer pursuant to the requirements of § 610.1 of this chapter without obtaining an official release from the Director, Bureau of Biologics provided:

(i) The manufacturer submits to the Bureau of Biologics a protocol of each master lot along with one sample of the lot, such material to be postmarked no more than 1 day following the manufacturer's release date.

(ii) At least two complete kits of each released lot will be retained as retention samples for no less than 90 days from the date of manufacture.

§ 660.3 Reference panel.

A Reference Hepatitis Associated Antigen (Australia Antigen) Panel shall be obtained from the Bureau of Biologics and shall be used for determining the potency and specificity of Hepatitis Associated Antibody (Anti-Australia Antigen).

§ 660.4 Potency test.

To be satisfactory for release each filling of Hepatitis Associated Antibody (Anti-Australia Antigen) shall be tested against the Reference Hepatitis Associated Antigen (Australia Antigen) Panel and shall be sufficiently potent to be able to detect the antigen in the appropriate sera of the reference panel by all test methods recommended by the manufacturer in the package enclosure.

§ 660.5 Specificity.

Each filling of the product shall be specific for hepatitis associated antibody as determined by specificity tests found acceptable to the Director, Bureau of Biologics.

Subpart B—Leukocyte Typing Serum

§ 660.10 Leukocyte Typing Serum.

(a) *Proper name and definition.* The proper name of this product shall be Leukocyte Typing Serum which shall consist of a preparation of serum containing an antibody or antibodies for identification of leukocyte antigens.

(b) *Source.* The source of this product shall be plasma or blood obtained aseptically from animals which have met the applicable requirements of § 600.11 of this chapter, or from human donors.

§ 660.11 Potency tests.

(a) *Test according to manufacturer's directions.* Each lot of the product intended for cytotoxicity testing shall produce an 80 percent or greater cell death with at least 85 percent of the positively reacting cell samples, and a 60 percent or greater cell death with the remaining 15 percent of the positvely reacting cell samples when tested by all methods recommended in the manufacturer's package enclosure against the manufacturer's panel of cells which shall have been approved by the Director, Bureau of Biologics, Food and Drug Administration. The antiserum shall maintain such level of reactivity throughout the dating period. The approved composition of the cell panel may be obtained from the Director, Bureau of Biologics, Food and Drug Administration, HFB–1, 5600 Fishers Lane, Rockville, MD 20852.

(b) *Test with diluted serum.* Each lot of the product, at a dilution of at least 1:2, shall produce a strong positive reaction of 80 percent or greater cell death for cytotoxic typing serums when tested with appropriate leukocytes by all methods recommended in the manufacturer's package enclosure.

(c) *Last valid potency test.* For purposes of determining the date of manufacture, the date of the last valid potency test shall be the date of initiation by the manufacturer of the test in paragraph (b) of this section.

§ 660.12 Specificity test.

Each lot of the product shall be specific for the antibody or antibodies indicated on the label when tested by all methods recommended in the manufacturer's package enclosure.

§ 660.13 Processing.

(a) *Method.* The processing method shall be one that has been shown to consistently yield a specific and potent final product free of properties which would adversely affect the product for its intended use.

(b) *Ancillary reagents and materials.* Ancillary reagents and materials accompanying the product, which are used in the performance of the test as described by the manufacturer's recommended test procedures, shall have been shown not to adversely affect the product within the prescribed dating period.

(c) *Color coding.* Color coding of labels, containers, or droppers supplied with the product shall not be used. The addition of coloring agents or dyes to the product or ancillary reagents to differentiate leukocyte antibodies is not permitted. A container of a vital stain for purposes of facilitating the reading of the test may be included in the testing kit.

(d) *Final containers.* Final containers shall be colorless, transparent, and shall have been sterilized and filled by aseptic procedures.

§ 660.14 Labeling.

In addition to the applicable requirements of §§ 610.60, 610.61, and 610.62 of this chapter, the following information shall be included in the labeling:

(a) The source of the product, if other than human, immediately following the proper name on both the final container and package label;

(b) The name of the specific antibody or antibodies present in the product immediately following the source when specified, or the proper name when the source is not specified. The antibody designation shall be of no less prominence than the proper name on all labeling;

(c) The name of the test method or methods recommended for the product on the package label and on the final container label when capable of bearing a full label;

(d) A package enclosure providing adequate instructions for use including:

(1) A description of all recommended test methods;

(2) A description of all supplementary reagents including a description of a suitable complement source;

(3) Necessary precautions, including a warning, against exposure to carbon dioxide;

(4) A caution to use more than one antiserum for each specificity;

(5) A caution not to dilute the antiserum;

(6) A caution that cross-reacting antigens exists.

(e) The package enclosure shall contain adequate directions for reconstitution which shall include the following instructions:

(1) Do not reconstitute with more than the recommended volume of diluent;

(2) Place the reconstituted material in small aliquots so that the product will undergo no more than two freeze-thaw cycles;

(3) Store all unused aliquots at −65° C. or colder within 8 hours of reconstitution;

(4) A statement that the frozen aliquots must be used within one year of reconstitution or prior to the expiration date appearing on the label of the product, whichever is earlier;

(5) A statement instructing the user to record the expiration date and the reconstitution date of the serum on the label of each multi-use aliquot stored in a small test tube, and to maintain similar information for the material stored in typing trays.

§ 660.15 Samples, protocols, official release.

(a) *Definition of a lot.* For release purposes, a lot is defined as uniform final container material identified by the manufacturer as having been thoroughly mixed in a single vessel and which has been dried in a single run. A lot may be retested upon expiration and assigned a new lot number provided all tests required of the initial lot are performed and a protocol of such tests and samples are submitted to the Bureau of Biologics, Food and Drug Administration, for release purposes. The protocol shall include identification of the lot number under which it was previously released and the date of release.

(b) *Sample size.* For each lot of product, four final containers packaged as for distribution shall be sent to the Director, Bureau of Biologics, Food and Drug Administration, Bldg. 29–A, 9000 Rockville Pike, Bethesda, MD 20014, for testing and release by the Bureau. In addition, 300 milligrams shall be submitted for a test to determine moisture content. Samples for moisture testing may be either (1) Final container material of the product, or (2) Dummy samples of material with the same protein concentration as the product, filled in the same size vials, with the same volume as the product. Such dummy samples shall be appropriately labeled and placed in random locations throughout the drying oven.

(c) *Protocols and release.* A protocol which consists of a summary of the history of manufacture of each lot, including all results of all tests required by regulations, shall be submitted for each lot of product to be released. The product shall not be issued by the manufacturer until notification of official release of the lot is received from the Director, Bureau of Biologics, Food and Drug Administration.

PART 680—ADDITIONAL STANDARDS FOR MISCELLANEOUS PRODUCTS

Subpart A—Allergenic Products

Subpart B—Trivalent Organic Arsenicals

AUTHORITY: Sec. 215, 58 Stat. 690, as amended; 42 U.S.C. 216. Sec. 351, 58 Stat. 702, as amended; 42 U.S.C. 262, unless otherwise noted.

CROSS REFERENCES: For U.S. Customs Service regulations relating to viruses, serums, and toxins, see 19 CFR 12.21–12.23. For U.S. Postal Service regulations relating to the admissibility to the United States mails see 39 CFR Parts 124 and 125, esp. § 125.2.

Subpart A—Allergenic Products

§ 680.1 Allergenic Products.

(a) *Definition.* Allergenic Products are products that are administered to man for the diagnosis, prevention or treatment of allergies.

(b) *Criteria for source material.* Only specifically identified allergenic source materials which contain no more than 1 percent of detectable foreign materials, shall be used in the manufacture of an Allergenic Product. Source materials such as feathers, hairs, and danders shall be free from blood and serum.

§ 680.2 Manufacture of Allergenic Products.

(a) *Extraneous allergenic substances.* All manufacturing steps shall be performed so as to insure that the product will contain only the allergenic and other substances intended to be included in the final product.

(b) *Cultures derived from microorganisms.* Culture media into which organisms are inoculated for the manufacture of Allergenic Products shall contain no allergenic substances other than those necessary as a growth requirement. Neither horse protein nor any allergenic derivative of horse protein shall be used in culture media.

(c) *Liquid products for oral administration.* Liquid products intended for oral administration that are filled in multiple dose final containers shall contain a preservative in a concentration adequate to inhibit microbial growth.

(d) *Residual pyridine.* Products for which pyridine is used in manufacturing shall have no more residual pyridine in the final product than 25 micrograms per milliliter.

§ 680.3 Tests.

(a) *Identity.* When a specific identity test meeting the provisions of § 610.14 of this chapter cannot be performed, the manufacture of each lot shall be separated from the manufacture of other products in a manner that will preclude adulteration, and records made in the course of manufacture shall be in sufficient detail to verify the identity of the product.

(b) *Safety.* A safety test shall be performed on the contents of a final container of each lot of each product as prescribed in § 610.11 of this chapter, except for the following:

(1) For lots consisting of no more than 20 final containers or 20 sets of individual dilutions, or where the final container contains no more than one intended human dose, the safety test need

not be performed on the contents of a final container provided the safety test is performed on each lot of stock concentrate and on each lot of diluent contained in the final product. Only stock concentrates and diluents which have passed the general safety test shall be kept in the work areas used for the manufacture of Allergenic Products. A stock concentrate is an extract derived from a single allergenic source and used in the manufacture of more than one lot of product, and from which final dilutions or mixtures are prepared directly.

(2) For powders for scratch tests, a sample shall be suspended in a suitable diluent and injected into each animal, and the sample size shall be the single human dose recommended.

(c) *Sterility.* A sterility test shall be performed on each lot of each Allergenic Product as prescribed in § 610.12 of this chapter, with the following exceptions:

(1) When bulk material is not prepared, the sterility test prescribed for bulk material shall be performed on each container of each stock concentrate at the time a stock concentrate is prepared, and the test sample shall be no less than 1 ml. from each stock concentrate container.

(2) For lots consisting of no more than 5 final containers, the final container test shall be performed in accordance with § 610.12(f)(7) of this chapter using the sample therein prescribed or using a sample of no less than 0.25 ml. of product from each final container, divided in approximately equal proportions for testing in Fluid Thioglycollate and Fluid Sabouraud's media. The test sample in the latter alternative method may be an overfill in the final container.

(3) For products prepared in sets of individual dilution series, a test sample of 0.25 ml. shall be taken from a final container of each dilution, which samples may be pooled and one half of the pooled material used for the test with fluid Thioglycollate medium and one-half used for the test with fluid Sabouraud's medium.

(4) Tablets and capsules need not be tested for sterility provided aseptic techniques are employed in their manufacture.

Subpart B—Trivalent Organic Arsenicals

§ 680.10 Tests prior to release.

Tests required to be made, prior to the release of each lot of a licensed product, shall be supplemented in the case of the trivalent organic arsenicals by tests for:

(a) Stability,
(b) Solubility,
(c) Arsenic content,
(d) Moisture,
(e) Relative nontoxicity.

§ 680.11 Pretesting by Bureau; sample of each lot.

Prior to the release of any lot of the product, the manufacturer shall forward to the Director, Bureau of Biologics, no less than 15 ampoules of the largest single-dose size in such lot, together with protocols showing the results of each test required prior to release.

§ 680.12 Expiration date.

Notification from the Director, Bureau of Biologics, that lot samples forwarded in accordance with § 680.11 have satisfactorily passed prescribed tests shall indicate a date which may be taken as the date of manufacture for the purpose of fixing the expiration date. The date of issue shall be the same as the date of manufacture.

§ 680.13 Composition of product.

Solutions or solutions of mixtures in the concentrations recommended for clinical administration shall be of such hydrogen ion value and tonicity as to be physiologically compatible with human blood.

§ 680.14 Container.

The product shall be hermetically sealed under vacuum or under a dry nonoxidizing gas in glass ampoules. The contents of any final container shall not exceed 10 maximum human doses.

§ 680.15 Final container label.

In addition to the labeling requirements stated in § 610.60 of this chapter, the final container label of the trivalent organic arsenicals shall bear the statements required in § 680.16 (b) and (c) and an additional statement giving the amount of the drug contained in the ampoule.

§ 680.16 Outside label.

The outside label, in addition to the complete proper name and all other items required for products generally shall show conspicuously: (a) If the product is dispensed as a mixture or solution, the name of all admixed substances,

(b) If the ampoule is a multiple dose container, the fact that it is a multiple dose container.

(c) Specific method of preparation, if any, required prior to administration, as, for example alkalinization.

NOTE.—Incorporation by reference provisions approved by the Director of the FEDERAL REGISTER, December 12, 1972.

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PART III

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

REORGANIZATION AND REPUBLICATION

Title 21—Food and Drugs

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

[Recodification Docket No. 3]

SUBCHAPTER L—REGULATIONS UNDER CERTAIN OTHER ACTS ADMINISTERED BY THE FOOD AND DRUG ADMINISTRATION

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 third document in a series of recodification documents that will eventually include all regulations administered by the Food and Drug Administration.

Since the publication of the new Subchapter J—Radiological Health in the FEDERAL REGISTER of October 15, 1973 (38 FR 28623), and the establishment of the revised Subchapter F—Biologics elsewhere in this issue of the FEDERAL REGISTER, the three remaining parts of former Subchapter F, i.e., Part 281—Enforcement of the Tea Importation Act, Part 285—Regulations under the Federal Caustic Poison Act, and Part 290—Regulations for the enforcement of the Federal Import Milk Act, have been reorganized into a new Subchapter L in an effort to provide greater clarity and adequate space for the development of future regulations.

The following table shows the relationship of these regulations in Subchapter F prior to this republication and the redesignations reflected in the new Subchapter L:

Old part	New part
281	1220
285	1230
290	1210

The changes being made are nonsubstantive in nature and for this reason notice and public procedure are not prerequisites to this promulgation. Therefore, 21 CFR Chapter I is amended by redesignating Parts 281, 285, and 290 of Subchapter F as Subchapter L, Parts 1220, 1230, and 1210 respectively, to read as set forth below.

Dated Nov. 13, 1973.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

PART 1210—REGULATIONS UNDER THE FEDERAL IMPORT MILK ACT

Subpart A—General Provisions

Sec.
1210.1 Authority.
1210.2 Scope of act.
1210.3 Definitions.

Subpart B—Inspection and Testing

1210.10 Availability for examination and inspection.
1210.11 Sanitary inspection of dairy farms.
1210.12 Physical examination of cows.
1210.13 Tuberculin test.
1210.14 Sanitary inspection of plants.
1210.15 Pasteurization; equipment and methods.
1210.16 Methods of bacterial count.
1210.17 Authority to sample and inspect.
1210.18 Scoring.

Subpart C—Permit Control

1210.20 Application for permit.
1210.21 Permit number.
1210.22 Form of tag.
1210.23 Permits granted on certificates.
1210.24 Temporary permits.
1210.25 Permits for pasteurized milk or cream.
1210.26 Permits for raw milk or cream.
1210.27 Permits waiving clauses 2 and 5, section 2 of the Federal Import Milk Act.
1210.28 Permits waiving clause 4, section 2 of the Federal Import Milk Act.

Subpart D—Permit Suspension and Revocation

1210.30 Suspension and revocation of permit.
1210.31 Order to show cause why permit should not be revoked; temporary suspension of permit pending hearing.
1210.32 Docket or file number.
1210.33 Service of order to show cause.

Subpart E—Hearing Procedures

1210.40 Time and place of hearing.
1210.41 Designation of examiner.
1210.42 Appearance of respondent.
1210.43 Attorney representing the Department of Health, Education, and Welfare.
1210.44 Testimony of witnesses.

Subpart F—Evidence

1210.50 Form of introduction of evidence.
1210.51 Depositions.
1210.52 Affidavits.
1210.53 Hearsay evidence.
1210.54 Admissibility of records.
1210.55 Copies of exhibits.
1210.56 Judicial notice.
1210.57 Objection to evidence.
1210.58 Filing of briefs.
1210.59 Tentative findings of fact.

Subpart G—Appeals Procedures

1210.60 Exceptions by the respondent.
1210.61 Oral argument before the Secretary.
1210.62 Issuance of final order.
1210.63 Hearing before prosecution.

AUTHORITY.—Secs. 2, 3, 44 Stat. 1101, 1102, as amended; 21 U.S.C. 142, 143.

CROSS REFERENCES: For Animal and Plant Health Inspection Service regulations concerning tubercular cattle, see 9 CFR Parts 51 and 77. For Animal and Plant Health Inspection Service regulations, see 9 CFR Chapter I. For customs regulations concerning importation of milk and cream, see 19 CFR 12.7. For regulations of the Agricultural Marketing Service (Marketing Agreements and Orders) covering marketing areas for milk, see 7 CFR Chapter X.

Subpart A—General Provisions

§ 1210.1 Authority.

For the purposes of the regulations in this part the act (44 Stat. 1101; 21 U.S.C. 141–149) "To regulate the importation of milk and cream into the United States for the purpose of promoting the dairy industry of the United States and protecting the public health" shall be known and referred to as "the Federal Import Milk Act."

§ 1210.2 Scope of act.

The provisions of the act apply to all milk and cream offered for import into the continental United States.

§ 1210.3 Definitions.

(a) *Secretary.* Secretary means the Secretary of Health, Education, and Welfare.

(b) *Commissioner.* Commissioner means the Commissioner of Food and Drugs.

(c) *Milk.* For the purposes of the act and of the regulations in this part:

Milk is the whole, fresh, clean, lacteal secretion obtained by the complete milking of one or more healthy cows, properly fed and kept, excluding that obtained within 15 days before and 5 days after calving, or such longer period as may be necessary to render the milk practically colostrum free.

(d) *Condensed milk.* Condensed milk, as the term is used in section 3, paragraph 2, of the Federal Import Milk Act, includes evaporated milk in the manufacture of which sterilization of the milk and cream is a necessary and usual process; it includes sweetened condensed milk only if it is prepared by a process which insures sterilization of the milk and cream. Condensed milk, as the term is used in section 3, paragraph 3, of the Federal Import Milk Act, means sweetened condensed milk.

(e) *Sweetened condensed milk.* Sweetened condensed milk conforms to the definition and standard of identity for such food as set out in § 18.530 of this chapter.

(f) *Evaporated milk.* Evaporated milk conforms to the definition and standard of identity for such food as set out in § 18.520 of this chapter.

(g) *Cream.* Cream is that portion of the milk, rich in milk fat, which rises to the surface of milk on standing or is separated from it by centrifugal force. (See §§ 18.500 to 18.515 of this chapter).

(h) *Pasteurization.* Pasteurization is the process of heating every particle of milk or cream to at least 143° F., and holding it at such temperature continuously for at least 30 minutes, or to at least 161° F., and holding it at such temperature continuously for at least 15 seconds.

(i) *Shipper.* A shipper is anyone, other than a common carrier, who ships, transports, or causes to be shipped or transported into the United States milk or cream owned by him.

Subpart B—Inspection and Testing

§ 1210.10 Availability for examination and inspection.

Dairy farms and plants from which milk or cream is shipped or transported into the United States shall be open at all reasonable times to authorized agents for necessary examinations and inspections. Failure to permit such examinations and inspections may be considered cause for the suspension or revocation of the permit.

§ 1210.11 Sanitary inspection of dairy farms.

The sanitary conditions of any dairy farm producing milk or cream to be shipped or transported into the United States or to a plant from which milk or cream is to be shipped or transported into the United States must score at least 50 points out of 100 points, according to the methods for scoring as provided by the score card for sanitary inspection of dairy farms in the form prescribed by the Secretary.

§ 1210.12 Physical examination of cows.

(a) Physical examination of any and all cows in herds producing milk or cream which is to be shipped or transported into the United States shall be made by an authorized veterinarian of the United States or of any State or municipality thereof or of the country in which such milk or cream is produced to determine whether such cow or cows are in a healthy condition. Such examination shall be made as often as the Secretary may deem necessary and, in any event, shall have been made within one year previous to the time of the importation.

(b) The result of the physical examination shall be set forth in the form prescribed by the Secretary.

§ 1210.13 Tuberculin test.

(a) Except as provided in § 1210.27 any and all animals in herds producing milk or cream which is to be shipped or transported raw into the United States shall be free from tuberculosis, as determined by a tuberculin test applied by an official veterinarian of the United States or of any State or municipality thereof or of the country in which such milk or cream is produced. Such test shall be made as often as the Secretary may deem necessary and, in any event, shall have been made within 1 year previous to the time of the importation. All animals showing positive or suspicious reactions to the tuberculin test must be permanently removed from the herd.

(b) The results of the tuberculin test and all facts concerning the disposal of reacting or suspected animals shall be set forth in the form prescribed by the Secretary.

§ 1210.14 Sanitary inspection of plants.

The sanitary conditions of any plant handling milk or cream any part of which is to be shipped or transported into the United States shall score at least 50 points out of 100 points according to the methods for scoring as provided by the score card for sanitary inspection of such plants in the form prescribed by the Secretary.

§ 1210.15 Pasteurization; equipment and methods.

All dairy farms and plants at which any milk or cream is pasteurized for shipment or transportation into the United States shall employ adequate pasteurization machinery of a type easily cleaned and of sanitary construction capable of holding every portion of the milk or cream at the required temperature for the required time. Such pasteurizing machinery shall be properly equipped with accurate time and temperature recording devices, which shall be kept at all times in good working order. The temperature at the time of heating and holding must invariably be recorded on thermograph charts, initialed, numbered, and dated by the official having jurisdiction over such farms and plants. All thermograph charts shall be held for a period of 2 years unless within that period they have been examined and released by such authorized agents as are designated by the Secretary.

§ 1210.16 Method of bacterial count.

The bacterial count of milk and cream refers to the number of viable bacteria as determined by the standard plate method of the American Public Health Association in use at the time of the examination.

§ 1210.17 Authority to sample and inspect.

Inspectors engaged in the enforcement of the Federal Import Milk Act are empowered to test for temperature, to take samples of milk or cream, and to use such means as may be necessary for these purposes.

§ 1210.18 Scoring.

Scoring of sanitary conditions required by §§ 1210.11, 1210.14 shall be done by an official inspector of the United States or of any State or municipality thereof or of the country in which the dairy farm or plant is located.

Subpart C—Permit Control

§ 1210.20 Application for permit.

Application for a permit to ship or transport milk or cream into the United States shall be made by the actual shipper upon forms prescribed by the Secretary. The request for forms of applications for permits should be addressed to Commissioner of Foods and Drugs, Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20852.

§ 1210.21 Permit number.

Each permit issued under the Federal Import Milk Act, including each temporary permit, shall bear an individual number. The right to the use of such number is restricted solely to the permittee.

§ 1210.22 Form of tag.

Each container of milk or cream shipped or transported into the United States by such permittee shall have firmly attached thereto a tag in the following form, bearing the required information in clear and legible type:

Product.....
(State whether raw milk, pasteurized milk, raw cream, or pasteurized cream.)
Permit number.....
Federal Import Milk Act.
Department of Health, Education, and Welfare.
Shipper.....
Address of shipper.....

Provided, That in case of unit shipments consisting of milk only or cream only under one permit number, in lieu of each container being so marked, the vehicle of transportation, if sealed, may be tagged with the above tag, which should, in addition, show the number of containers and quantity of contents of each.

§ 1210.23 Permits granted on certificates.

In the discretion of the Secretary, a permit may be granted on a duly certified statement signed by a duly accredited official of an authoried department of any foreign government or of any State of the United States or any municipality thereof. Such statement shall be in the form of a certificate prescribed by the Secretary, and shall have attached thereto, as a part thereof, signed copies of reports prescribed by §§ 1210.12, 1230.13, and also by §§ 1210.11, 1210.14, as applicable. The necessary inspections and examinations upon which the reports are based shall be made by persons who are acting under the direct supervision of the certifying official.

§ 1210.24 Temporary permits.

A temporary permit will be granted only upon a satisfactory showing that the applicant therefor has been unable to obtain the necessary inspections required by the applicable provisions of section 2 of the Federal Import Milk Act. Temporary permits shall be valid until the Secretary shall provide for inspection to ascertain that clauses 1, 2, and 3 of section 2 of the Federal Import Milk Act have been complied with.

§ 1210.25 Permits for pasteurized milk or cream.

Permits to ship or transport pasteurized milk or cream into the United States will be granted only upon compliance with the requirements of clauses 1 and 3 of section 2 of the Federal Import Milk Act, §§ 1210.11, 1210.12, 1210.14, as applicable.

§ 1210.26 Permits for raw milk or cream.

Except as provided in § 1210.27, permits to ship or transport raw milk or cream into the United States will be granted only when the milk or cream comes from dairy farms or plants where pasteurization is not carried on and then only upon compliance with the requirements of clauses 1, 2, and 3 of section 2 of the Federal Import Milk Act, §§ 1210.11 to 1210.14 as applicable.

§ 1210.27 Permits waiving clauses 2 and 5, section 2 of the Federal Import Milk Act.

A permit to ship or transport raw milk into the United States will contain a waiver of clauses 2 and 5 of section 2 of the Federal Import Milk Act when the shipper is an operator of a creamery or condensery, or is a producer shipping or transporting to a creamery or condensery and the creamery or condensery is located in the United States within a radius of 20 miles of the point of production of such milk, and the milk, prior

to its sale, use, or disposal, is pasteurized, condensed, or evaporated.

§ 1210.28 Permits waiving clause 4, section 2 of the Federal Import Milk Act.

The Secretary, in his discretion, will issue to a shipper who is an operator of a condensery a permit waiving the requirements of clause 4, of section 2 of the Federal Import Milk Act and allowing milk and cream containing not to exceed 1,200,000 bacteria per cubic centimeter to be shipped or transported into the United States if the condensery is located within a radius of 15 miles of the point of production of the milk and cream and such milk and cream are to be sterilized in the manufacture of condensed milk.

Subpart D—Permit Suspension and Revocation

§ 1210.30 Suspension and revocation of permit.

A permit to ship or transport milk or cream into the United States may be suspended for cause at any time. A permit may be revoked for cause after opportunity to be heard has been accorded the permittee, who may appear in person, by attorney, or by letter and show cause why the permit should not be revoked.

§ 1210.31 Order to show cause why permit should not be revoked; temporary suspension of permit pending hearing.

When the Secretary has reason to believe that the holder of any permit for the shipment of milk or cream into the United States has failed to comply with the provisions of or has violated sections 141–149 of Title 21, United States Code, or any of the regulations in this part, or that the milk or cream shipped by the holder of the permit into the United States is not produced and handled in conformity with, or that the quality thereof does not conform to, all of the provisions of section 142 of Title 21, United States Code, the Secretary shall serve upon the permittee an order to show cause why such permit should not be revoked, and, pending the hearing upon such order, the Secretary may temporarily suspend such permit.

§ 1210.32 Docket or file number.

The order to show cause shall be assigned a docket or file number and the proceedings had thereunder shall thereafter be referred to by such number.

§ 1210.33 Service of order to show cause.

The order to show cause shall be addressed to the permittee, who shall be designated as the respondent, and shall be served upon the permittee by an employee of the Department of Health, Education, and Welfare or by registered mail, return receipt requested. If the respondent is a corporation, service shall be had upon the president, secretary, treasurer or statutory agent of the corporation.

Subpart E—Hearing Procedures

§ 1210.40 Time and place of hearing.

The Secretary shall set a time and place for a hearing upon the order to show cause.

§ 1210.41 Designation of examiner.

The Secretary shall designate an employee of the Department of Health, Education, and Welfare as examiner to conduct the hearing, and such examiner may, in accordance with the rules of evidence applicable to administrative proceedings, admit or exclude any evidence presented and may limit the scope of any evidence admitted.

§ 1210.42 Appearance of respondent.

The respondent may appear in person or by counsel. All persons who appear at the hearing must conform to the standards of ethical conduct required of practitioners before the courts of the United States.

§ 1210.43 Attorney representing the Department of Health, Education, and Welfare.

At the hearing, the Secretary shall be represented by an attorney designated by the General Counsel of the Department of Health, Education, and Welfare.

§ 1210.44 Testimony of witnesses.

The testimony of witnesses at the hearing shall be upon oath or affirmation administered by the examiner.

Subpart F—Evidence

§ 1210.50 Form of introduction of evidence.

The form of the introduction of evidence shall not be a ground for objecting to such evidence.

§ 1210.51 Depositions.

The deposition of any witness, taken after reasonable notice to the opposite party and at a time and place and before a person designated for the purpose by the Secretary, shall be admitted if the evidence is otherwise admissible.

§ 1210.52 Affidavits.

Affidavit, if relevant and material may, in the discretion of the examiner, be admitted, but the Secretary will consider the lack of opportunity for cross-examination in determining the weight that shall be given to such evidence.

§ 1210.53 Hearsay evidence.

Hearsay evidence may, in the discretion of the examiner, be admitted even though it does not come within any well recognized exception to the hearsay rule, but the Secretary will determine what weight shall be given to such evidence.

§ 1210.54 Admissibility of records.

Copies of the records of the Department of Health, Education, and Welfare, certified under the seal of the Department, shall be admissible to the same extent that the original records would be admissible.

§ 1210.55 Copies of exhibits.

When practicable to do so, a copy of each exhibit shall be furnished to the opposing party either before or at the time of its introduction.

§ 1210.56 Judicial notice.

Judicial notice, on request, will be taken of such matters as are noticed by the courts of the United States.

§ 1210.57 Objection to evidence.

If the respondent objects to the admission of any evidence offered against him or the rejection of any evidence offered by him, or to the limitation of the scope of any evidence introduced by him, he shall state the grounds of such objection. If the objection is overruled, he may take an exception.

§ 1210.58 Filing of briefs.

At the conclusion of the hearing, the examiner shall announce the period of time within which briefs may be filed following the receipt by the respondent of the tentative findings of fact and the tentative order, as set out in § 1210.59.

§ 1210.59 Tentative findings of fact.

The examiner, within a reasonable time after the conclusion of the hearing, shall prepare tentative findings of fact and a tentative order, which shall be served upon the respondent or sent to him be registered mail.

Subpart G—Appeals Procedures

§ 1210.60 Exceptions by the respondent.

Within 20 days after the receipt of the tentative findings of fact and the tentative order, the respondent, if he wishes to take exceptions to any matters set out therein, shall transmit such exceptions to the General Counsel of the Department of Health, Education, and Welfare. At the same time, the respondent shall transmit a brief statement concerning each of the exceptions to the actions of the examiner at the hearing, as set out in §§ 1210.41, 1210.42, 1210.44, and 1210.50–1210.57, upon which he wishes to rely. If exception is taken to any proposed finding 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 respondent, if he files exceptions, shall state in writing whether he desires to make an oral argument on the exceptions before the Secretary.

§ 1210.61 Oral argument before the Secretary.

In the event that an oral argument before the Secretary is requested, a date for such argument shall be fixed by the Secretary or by the Under Secretary, if designated to act in his stead.

§ 1210.62 Issuance of final order.

If oral argument is heard in any proceeding by the Secretary or Under Secretary, the final order in the proceeding shall be issued by the person who heard the argument.

§ 1210.63 Hearing before prosecution.

Before violation of the act is referred to the Department of Justice for prosecution under section 5 of the Federal Import Milk Act, an opportunity to be heard will be given to the party against whom prosecution is under consideration. The hearing will be private and confined to questions of fact. The party notified may present evidence, either oral or written, in person or by attorney, to show cause why he should not be prosecuted. After a hearing is held, if it appears that the law has been violated, the facts will be reported to the Department of Justice.

PART 1220—REGULATIONS UNDER THE TEA IMPORTATION ACT

Subpart A—General Provisions

Subpart B—Shipment and Storage

Subpart C—Customs Requirements

Subpart D—Sampling Procedures

Subpart E—Establishment of Standards

Subpart F—Individual Standards

Subpart G—Inspection, Testing, and Grounds for Rejection

Subpart H—Administrative Procedures Based on Examination

AUTHORITY.—Secs. 1, 10, 29 Stat. 604, 607; 21 U.S.C. 41, 50, unless otherwise noted.

CROSS REFERENCE: For Bureau of Customs regulations governing importation of tea, see 19 CFR 12.33.

Subpart A—General Provisions

§ 1220.5 Importation of inferior goods prohibited.

The importation of any merchandise as tea which is inferior in purity, quality, and fitness for consumption to the standards fixed and established by the Secretary of Health, Education, and Welfare, in accordance with section 3 of the Tea Importation Act (29 Stat. 605; 21 U.S.C. 43), is prohibited.

§ 1220.6 Importation without appraisement.

Importations of tea may be entered for consumption, for transit to foreign countries, or for immediate transportation without appraisement. All entries must be on the regular forms, and the regular serial numbers, for both bonds and entries should be used.

§ 1220.7 Bonding of tea for consumption.

Tea entered for consumption must be stored as provided in § 1220.15, pending examination, and bond must be taken by the District Director of Customs, as provided in section 4 of the Tea Importation Act (29 Stat. 605; 21 U.S.C. 44), on Customs Form No. 7551 or 7553. This bond shall be canceled upon the issuance of a permit for release, as the consumption entry bond includes provisions for the redelivery, the exportation, the destruction, and the holding of the merchandise for customs examination.

§ 1220.8 Tea packages and contents shall constitute a unit.

Tea packages and contents shall be treated as a unit, and no separation of tea from its covering can be allowed, for either exportation or destruction, except under the two following conditions:

(a) In cases of importations of tea containing an excessive quantity of dust and siftings, the tea may be sifted and admitted to entry if found up to the standard, and the dust and siftings may also be admitted if found up to the standard or, if no standard exists, if found up to the respective leaf standard. If not up to the standard, or respective leaf standard when no standard exists, the dust and siftings must be exported or destroyed under Government supervision.

(b) If, by reason of damage, a tea otherwise equal in quality to the standard has been rejected, the damaged portion may be removed and exported or destroyed under custom's supervision, and the sound remainder resubmitted for examination and admitted to entry if found up to the standard.

§ 1220.9 Duties of supervising tea examiner.

(a) The supervising tea examiner is charged with the immediate supervision of all matters relating to the enforcement of the Tea Importation Act, and particularly the securing of uniformity in the treatment of imported teas at all the points of examination. He is also to perform such duties in connection with tea under the Federal Food, Drug, and Cosmetic Act as may be assigned to him.

(b) For the purpose of securing uniformity in the treatment of teas each tea examiner will send to the supervising tea examiner one-half pound samples of the teas rejected by him, also such other samples of teas as the supervising tea examiner may direct. To each sample a label (T. I. S. Cat. No. 2) shall be affixed.

(c) The examiner of tea at each port where a qualified tea examiner is stationed shall prepare and forward to the supervising tea examiner and to the chairman of the United States Board of Tea Appeals, as soon as practicable after the close of each month, a report (T. I. S. Cat. No. 3), showing details as to every shipment of tea examined by the tea examiner. This information the tea examiner should compile from his report of "Teas Imported and Examined" (T. I. S. Cat. No. 4) which should always be kept up to date.

Subpart B—Shipment and Storage

§ 1220.10 Teas destined for interior ports.

Imported teas entered at an exterior port destined for immediate transportation to an interior port shall be forwarded without detention.

§ 1220.15 Warehouses for storage of tea.

(a) Warehouses for the storage of tea will be designated by the District Director of Customs and the proprietor thereof will be required to give a bond in the form prescribed (Customs Form No. 3581). Teas not stored in such designated warehouses will be placed in general order store or in public store pending examination and release on proper permit. In the absence of proper storage facilities at customhouses, teas may be retained in locked cars as constructive warehouses, under proper supervision, pending examination.

(b) The importer's premises may be designated as warehouses for the storage of tea on the filing of the bond provided for by the regulations in this part, but whenever, in the discretion of the District Director of Customs, it shall be considered desirable, a storekeeper shall be assigned to the supervision of such premises at the importer's expense while the teas shall remain under bond therein.

§ 1220.16 Method of storing in warehouse.

(a) When tea under examination is stored in any warehouse it must be

so placed as to be separate from other merchandise and so as to allow convenient supervision by customs officers and officers of the Department of Health, Education, and Welfare. At ports where there are no bonded warehouses, class 2 or 3, the chief customs officer of the port will, when necessary, procure suitable premises for the temporary storage of any tea reaching his port. The repacking of tea in warehouse for export purposes is not allowed.

(b) All expenses of storage, cartage, and labor must be paid by the importer.

§ 1220.17 Removal of tea from warehouse.

No tea shall be delivered to the importer or removed from warehouse for any purpose before the examination required by the Tea Importation Act.

Subpart C—Customs Requirements

§ 1220.20 Examination of packages.

Chief officers of customs may order such an examination of packages containing tea as will satisfy them that no dutiable goods are packed therein. For this purpose the customary designation should be made of packages for examination in public store.

§ 1220.21 Tea blended, mixed and repacked for export.

Tea importers desiring to import teas into the United States to be blended, mixed, and repacked for export can do so by bonding a warehouse under the provisions of section 311 of the Tariff Act of 1930 (46 Stat. 691; 19 U.S.C. 1311), upon compliance with §§ 19.13 to 19.15, inclusive, of the Customs Regulation of 1943 (19 CFR 19.13–19.15), giving bond on Customs Form No. 3583. All teas placed in bonded manufacturing warehouses must be exported.

CROSS REFERENCE: For customs regulations governing manufacturing warehouses, see 19 CFR 19.13–19.16.

§ 1220.22 Unclaimed teas.

Unclaimed teas should be taken possession of by District Directors of Customs the same as other unclaimed goods and placed in "general order", but not sold at the expiration of the year unless declared fit for consumption by a designated tea examiner.

CROSS REFERENCE: For Bureau of Customs regulations governing disposition of merchandise unclaimed or in warehouse beyond the time fixed by law, see 19 CFR Part 20.

Subpart D—Sampling Procedures

§ 1220.30 Taking of samples at ports where tea examiner is stationed.

The examination of teas at ports where a duly qualified tea examiner is stationed shall be made by means of samples drawn by the sampler from packages designated by the tea examiner. The importer, when his teas are ready for sampling, shall submit in duplicate to the tea examiner a chop list and release permit (T.I.S. Cat. No. 1) of the several lines included in the invoice, and the tea examiner shall select for examination packages representing the different lines.

§ 1220.31 Taking of samples at ports where there is no tea examiner.

(a) In case an entry of imported tea shall be made at a port or subport where no tea examiner is stationed the importer should prepare the chop list and release permit (T. I. S. Cat. No. 1) in triplicate and forward them to the chief officer of the customs at the port of entry.

(b) Samples shall be obtained by such officers, together with the original and one copy of the chop list and release permit (T. I. S. Cat. No. 1), and shall be forwarded to the nearest qualified tea examiner for his report and return. Samples sent for the purpose of examination from ports of importation to ports where tea examiners are located shall be packed in clean tin cans, free from odor, fitted with tight covers, and of a capacity to hold about 4 ounces avoirdupois of tea. Each can shall be properly labeled (T. I. S. Cat. No. 5).

§ 1220.32 Result of examination; form of report.

(a) The examination and report upon such samples shall be made in accordance with the provisions of section 7 of the Tea Importation Act (29 Stat. 606; 21 U. S. C. 46), and the result of this examination shall be noted on the invoice by the tea examiner before he returns the invoice to the collector of customs. The tea examiner at the same time should make his returns on the original copy of the chop list and release permit (T. I. S. Cat. No. 1), which, after being duly signed by him, should be forwarded by him to the importer or consignee.

(b) In case the tea coverings are dutiable and appraised at a value or rate higher than the entered value or rate, the tea examiner shall follow the same procedure as above, except that the chop list and release permit shall be returned to the District Director of Customs for such action as he sees fit to take.

(c) In case a partial release is desired the importer shall furnish an additional chop list and release permit (T. I. S. Cat. No. 1) of the goods that he desires, the original chop list and release permit being retained by the tea examiner until action on all the teas in the entry has been taken.

§ 1220.33 Chop list.

(a) In all cases the importer shall indicate on the chop list and release permit where the goods are to be sampled, whether on the dock or in warehouse. If the consular invoice has not been received the importer may prepare an additional copy of the chop list and release permit as a pro forma invoice, marking across the face thereof "Pro Forma Invoice."

(b) Importers may print their chop list and release permit forms, provided they conform strictly with the official form (T.I.S. Cat. No. 1). Otherwise, they can be obtained free from the United States tea examiner at ports where tea examiners are stationed, or from the chief officer of customs at ports, or subports, where no tea examiners are stationed.

§ 1220.34 Surplus samples.

(a) Surplus samples drawn from importations for purposes of examination, and which represent pure tea as declared by the examiner, shall be returned to the importer after examination is completed, if so requested by the importer, but if no request is made for the return of samples they shall be disposed of as provided in § 1220.43 for unused standard samples.

(b) Surplus samples representing tea which has been finally rejected should be destroyed, or, after being denatured, should be sold for manufacturing purposes under the Tea Importation Act (35 Stat. 163; 21 U.S.C. 41).

§ 1220.37 Exemption of sample packages from examination.

Where tea is put up in packages of not over 2 pounds in weight, imported by mail, express, or otherwise from the country of production, and the fact is established that the packages are samples for distribution, or for use in soliciting orders and not for sale, no examination should be made under the Tea Importation Act (29 Stat. 604; 21 U.S.C. 41–50), and they may be delivered at once to the importer.

§ 1220.38 Tea brought in by passengers.

Packages of tea not exceeding 5 pounds in weight brought by passengers may be delivered without examination under the Tea Importation Act (29 Stat. 604; 21 U. S. C. 41–50).

Subpart E—Establishment of Standards

§ 1220.40 Tea standards.

(a) Samples for standards of the following teas, prepared, identified, and submitted by the Board of Tea Experts on March 15, 1972, are hereby fixed and established as the standards of purity, quality, and fitness for consumption under the Tea Importation Act for the year beginning May 1, 1972, and ending April 30, 1973:

(1) Formosa Oolong.

(2) Ceylon-India-Indonesia Black (all black teas except Formosa Black, Japan Black, and China Mainland Black).

(3) Formosa Black (Formosa Black, Japan Black, and China Mainland Black).

(4) Green Tea.

(5) Canton Type (all Canton types including Scented Canton and Canton Oolong types).

(6) Scented Black Tea.

These standards apply to tea shipped from abroad on or after May 1, 1972. Tea shipped prior to May 1, 1972, will be governed by the standards that became effective May 1, 1971.

(b) The Board of Tea Experts shall prepare duplicate samples of the standards for teas.

§ 1220.41 Effective date of tea standards.

The standards prepared and submitted to the Secretary of Health, Edu-

cation, and Welfare by the Board of Tea Experts, appointed by him on or before February 15 of each year, shall be fixed and established as standards under the act and shall be in effect from the 1st day of May of each year until April 30, inclusive, of the following year, except that tea shipped from abroad prior to May 1 of any year shall be governed by the standards in effect at the time of shipment. Such standards for each year will be published in the FEDERAL REGISTER.

§ 1220.42 To whom standards will be furnished.

(a) A quantity of tea of the approved standards will be repacked in half-pound tin containers by competent tea packers under the constant supervision of an officer of the Food and Drug Administration and full sets will be furnished the Board of Tea Appeals, the supervising tea examiner, and the examiners of tea at all the tea examining stations.

(b) Standards will be furnished to actual importers and regular tea brokers on application to the supervising tea examiner, at the actual cost of the same.

§ 1220.43 Disposition of obsolete standards.

After standard samples have served their purpose and new season samples have been submitted, the old samples may be included in quarterly sales of unclaimed goods, and the proceeds paid into the Treasury, after deducting expenses of advertisement and sale, the designation on the packages showing such teas to have been used as Government standards to be obliterated before delivery to purchaser.

Subpart F—Individual Standards

§ 1220.50 Macao or Canton congou and brick tea standards.

Macao or Canton congou and brick tea should be compared with the standard for China congou. The mustiness or damaged flavor exhibited in certain Canton teas would be just cause for rejection.

§ 1220.51 Teas imitating China green teas.

Whenever Japans, Ceylons, Indias, or any other teas are made up to imitate the green teas of China, they are to be examined in comparison with the China green standards.

§ 1220.52 Powchong Formosa oolong teas.

All Powchong (scented) Formosa oolong teas should be examined in comparison with the Formosa standard.

Subpart G—Inspection, Testing, and Grounds for Rejection

§ 1220.60 Instructions to examiners.

(a) Examiners are instructed not to pass upon samples representing importations of tea imported separately from the importation; neither shall they give nonofficial opinions concerning samples.

(b) The examination of tea in comparison with the standards under this act shall be made according to the usages and customs of the tea trade, including the testing of an infusion in boiling water and, if necessary, chemical analysis; and examiners are advised, inasmuch as they must not under the law admit any tea inferior to the standards in purity, quality, and fitness for consumption, to employ the present methods of determining the presence of artificial coloring and other impurities. (See § 1220.64.)

§ 1220.61 Testing of teas.

(a) In comparing with standards, examiners are to test all the teas for quality, for impurity consisting of artificial coloring or facing matter, and other impurity, and for quality of infused leaf. Quality shall be ascertained by drawing, according to the custom of the tea trade, with the weight of a silver half dime to the cup. The quality must be equal to standard, but the flavor may be that of a different district, as long as it is equally fit for consumption. As an illustration, a Teenkai may be equal to a Moyune, but a distinctly smoky or rank Fychow or Wenchow of sour character is not considered equal to the first two mentioned.

(b) Tea dust, fannings, siftings, and offgrades, including broken tea (BT), broken mix (BM), and Bohea when so marked and for which there is no specific standard, should be tested for quality, purity, and fitness for consumption in comparison with their respective leaf standards.

§ 1220.62 Testing quality of infused leaf.

In order to test the quality of the infused leaf in comparison with the standard, a second drawing should be made of double weight. Before pouring off the water, examine for an excess of "floaters" (woody stems which remain floating after the leaf is thoroughly infused) to determine whether they are in sufficient quantity to reduce the quality of the infusion below that of the standard. After pouring off the water the infused leaf should be taken out so as to exhibit the lower side which rested against the cup. Should the mass show a larger quantity of exhausted or decayed leaf than the standard, it affords sufficient evidence to be judged inferior in quality and consequently to be rejected.

§ 1220.63 Test for paraffin and similar substances.

If the examiner suspects the presence of paraffin or any similar substance, he should make the following test in comparison with the standard: Spread the tea between two sheets of unglazed white paper. Place thereon a hot iron. The greasy substance, if any, will appear on the paper, and if not equal to the standard the tea would justly be rejected.

§ 1220.64 Tests for impurities.

(a) To examine for impurities the following tests may be used in comparison with the standard:

(1) Read test, with additions and modifications, and the cup test, double-weight.—Place 2 ounces of tea in a sieve 5 or 6 inches in diameter, having 60 meshes to the inch and provided with a top. Sift a small quantity of the dust onto a semiglazed white paper about 8 by 10 inches. The amount of dust placed on the paper should be approximately 1 grain. To get the requisite amount of dust it is sometimes necessary to rub the leaf gently against the bottom of the sieve, but this must not be done until the sieve has been well shaken over the test paper. Pour the dust thus collected from the paper into the scales, weigh out 1 grain, and return this quantity to the same paper, distributing it well over the surface of the paper. Then place the paper on a plain, firm surface, preferably glass or marble, and crush the dust by pushing over it, with considerable pressure, a flat steel spatula about 5 inches long. Do this repeatedly until the tea dust is ground almost to a powder and the particles of coloring matter or other impurities, if any, are spread or streaked on the paper, so as to become more apparent. Brush off the loose dust and examine the paper by means of a simple lens magnifying 7½ diameters. In distinguishing these particles and streaks bright light is essential.

(2) The crushed leaf in either black or green tea appears in such quantity that there is no chance of mistaking the leaf for artificial coloring, facing material, or other impurities.

(3) The test is performed in comparison with the standard, and, if the tea is clearly equal to the standard with respect to artificial coloring, facing matter, or other impurities, the operation need not be repeated. If particles of artificial coloring, facing, or other impurities are found in the sample under comparison with the standard repeat this operation a sufficient number of times to be sure whether or not the tea contains impurities in excess of the standard.

(4) Repeat the operation, using semiglazed black paper instead of the white paper. This black-paper test shows the presence of facing and other impurities, such as talc, gypsum, barium sulfate, clay, and kaolin.

(5) If the tea under examination is found, by the foregoing tests, to contain more impurities than the standard, draw samples from packages representing at least 5 percent of the line in question, and subject each sample to the tests to ascertain whether or not the majority contain impurities in excess of the standard.

(6) The foregoing tests may be applied to tea of all varieties.

(b) Should the examination of the sample by the cup test, double-weight, for scum, sediment, etc., or the Read test, or both, disclose the presence of more impurities than the standard, a pound sample should be sent to the nearest district of the Food and Drug Administration and an analysis made in comparison with the standard to determine whether it contains more impurities than the standard. If the tea in question is found to contain more impurities than

the standard, it would properly be rejected as not being equal to the standard in purity.

(c) All extraneous substances are impurities, and the presence of any may be detected in any way found efficient.

§ 1220.65 Tea dust.

Tea dust or broken leaf mixed with other teas or separate, made to imitate gunpowder or other teas, with the use of paste or gum, or any other substance, would justly be rejected.

§ 1220.66 Tolerance for fine tea particles.

Except for teas listed under § 1220.61 (b), the amount by weight of fine tea particles that will pass through a wire sieve having 30 openings per linear inch in either direction and made of wire with a diameter of 0.01 inch, must not exceed 4 percent. Before condemning any tea for fine particles in excess of 4 percent, examiners shall sieve at least 4 representative samples, each taken from a different package in a shipment containing four or more packages, or where a lesser number of packages is involved, examiners shall sieve a representative sample from each package.

§ 1220.67 Tea inferior to the standard in any requisite is justly rejected.

Should a tea prove on examination to be inferior to the standard in any one of the requisites—namely, quality, quality of infused leaf, or purity—it would justly be rejected, notwithstanding the fact that it may be superior to the standards in some of the qualifications. No consideration shall be given to the appearance or so-called style of the dry leaf.

Subpart H—Administrative Procedures Based on Examination

§ 1220.70 Action based on result of examination.

(a) If, after examination, the tea is found not be prohibited under the act, a release permit shall at once be granted to the importer, declaring that the tea is not within the prohibition of the Tea Importation Act; but if, on examination, such tea, or merchandise described as tea, is found in the opinion of the examiner, to come within the prohibitions of the law and of the regulations in this part, the importer shall be immediately notified (T.I.S. Cat. No. 6), and the tea, or merchandise described as tea, so returned, shall not be released by the customhouse authorities, unless on a reexamination called for by the importer the return of the examiner shall be found erroneous. Should a portion only of the invoice be passed by the examiner as correct, a permit of delivery shall be granted for that portion and the remainder held as provided in section 6 of the act (29 Stat. 606; 21 U. S. C. 47).

(b) In all cases of rejections by examiners, the importers should be notified of the reason for rejection; that is, whether it be on the ground of quality, character of infused leaf, dust, or admixture with foreign substance.

§ 1220.71 Procedure for protest against findings.

In case the collector of customs, importer, or consignee shall protest against the finding of the examiner, the matter in dispute shall be referred for decision to the United States Board of Tea Appeals, designated by the Secretary of Health, Education, and Welfare, and if such board shall, after due examination, find the tea in question to be equal in purity, quality, and fitness for consumption, as compared with the proper standards, a permit shall be issued by the District Director of Customs for its release and delivery to the importer; but if, upon such final re-examination by such board, the tea shall be found to be inferior in purity, quality, and fitness for consumption, as compared with the said standards, the importer or consignee shall give a bond, unless he has previously done so, with security satisfactory to the District Director of Customs, to export said tea out of the limits of the United States within a period of 6 months after such final re-examination; and if the same shall not have been exported within the time specified, the District Director of Customs, at the expiration of that time, shall cause the same to be destroyed.

§ 1220.72 Procedure by importer for review.

(a) If the importer desires teas rejected by the examiner to be reviewed by the United States Board of Tea Appeals, as provided in section 6 of the said act, he shall, within 30 days after he has been notified of such return, file a written application with the collector in the form T.I.S. Cat. No. 20. The District Director of Customs will thereupon forward such application to the United States Board of Tea Appeals, designated by the Secretary of Health, Education, and Welfare for review of the matter in dispute, and the proceedings shall be according to section 8 of the act.

(b) The re-examination of the tea samples must be restricted to the samples put up and sealed by the examiner at ports where qualified tea examiners are stationed, or by the chief officer of the customs, if there is no qualified tea examiner so stationed, in the presence of the importer or consignee, if he so desires. In either case the samples should be transmitted to the United States Board of Tea Appeals by the tea examiner, together with a copy of the finding of the examiner, setting forth the cause of condemnation.

(c) These samples for re-examination should weigh at least 1 pound, and should be put up in tins securely labeled (T. I. S. Cat. No. 21) and well wiped and seasoned. Half of such samples shall be utilized for the examination by the Board of Tea Apppeals and for return to the port of entry with the decision, as heretofore, and the remaining half pound, if the tea be rejected by said board, shall be distributed among the various examiners for their information and guidance.

(d) Teas rejected by tea examiners and rejections affirmed by the United States Board of Tea Appeals cannot be re-examined.

§ 1220.73 Rejected tea.

Rejected tea can only be released or withdrawn for exportation, for transportation and exportation, or for manufacturing purposes under the Tea Importation Act (35 Stat. 163; 21 U.S.C. 41), as the case may be.

§ 1220.74 Exportation of rejected teas.

(a) Teas to be exported for the reason that they are within the prohibition of the statute will be entered for exportation on Customs Form No. 7515, and bond on Customs Form No. 7557 shall be given for their exportation in a penal sum equal to double the value of the tea, provided consumption entry bond (Form No. 7551 or Form No. 7553) was not previously given.

(b) Whenever a bond is given to export any condemned tea in pursuance of the act, it will be canceled upon the filing of an outward bill of lading and a duly authenticated certificate of clearance from the customs officer supervising the lading thereof, as in the case of rejected foods and drugs (T. D. 28841), and all accrued charges must be paid before issuance of permit for exportation.

(c) At interior ports the export entry shall be made for transportation and immediate exportation in bond.

§ 1220.75 Reimportation of exported teas forbidden.

(a) No imported teas which have been rejected by an examiner, or by the United States Board of Tea Appeals, and exported under the provisions of this act, shall be reimported into the United States under the penalty of forfeiture for a violation of this prohibition.

(b) Customs officers will make seizure of any tea so imported.

§ 1220.76 Destruction of condemned tea.

Whenever condemned tea is to be destroyed it must be conveyed to some suitable place, and proper means, to be prescribed by the examiner, must be used for its effectual destruction, which shall be effected in the presence of an officer of customs, detailed by the District Director of Customs for the purpose. Before the tea is destroyed a particular description or statement of the same must be prepared containing the name of the importer or owner, the date of importation, the name of the vessel, and the place from which imported, with the character and quantity of the tea and the invoice value. The fact of its destruction must be certified on said statement by the officer detailed as aforesaid, which statement must be filed in the customhouse.

PART 1230—REGULATIONS UNDER THE FEDERAL CAUSTIC POISON ACT

Subpart A—General Provisions

Sec.

Subpart B—Labeling

Sec.
1230.10 Placement.
1230.11 Required wording.
1230.12 Manufacturer; distributor.
1230.13 Labeling of "poison".
1230.14 Directions for treatment.
1230.15 Responsibility for labeling directions for treatment.
1230.16 Exemption from labeling directions for treatment.

Subpart C—Guaranty

1230.20 General guaranty.
1230.21 Specific guaranty.

Subpart D—Administrative Procedures

1230.30 Collection of samples.
1230.31 Where samples may be collected.
1230.32 Analyzing of samples.
1230.33 Investigations.
1230.34 Analysis.
1230.35 Hearings.
1230.36 Hearings; when not provided for.
1230.37 Publication.

Subpart E—Imports

1230.40 Required label information.
1230.41 Delivery of containers.
1230.42 Invoices.
1230.43 Enforcement.
1230.44 Samples.
1230.45 No violation; release.
1230.46 Violation.
1230.47 Rejected containers.
1230.48 Relabeling of containers.
1230.49 Penalties.

AUTHORITY.—Sec. 9, 44 Stat. 1049, as amended; 15 U.S.C. 409.

CROSS REFERENCES: For regulations relating to invoices, entry, and assessment of duties, see 19 CFR Part 8. For regulations regarding the examination, classification, and disposition of foods, drugs, devices, cosmetics, insecticides, fungicides, and caustic or corrosive substances, see 19 CFR 12.1–12.6. For regulations relating to consular invoices, and documentation of merchandise, see 22 CFR Part 91.

Subpart A—General Provisions

§ 1230.2 Scope of the act.

The provisions of the act apply to any container which has been shipped or delivered for shipment in interstate or foreign commerce, as defined in section 2(c) of the act (44 Stat. 1407; 15 U.S.C. 402) or which has been received from shipment in such commerce for sale or exchange, or which is sold or offered for sale or held for sale or exchange in any Territory or possession or in the District of Columbia.

§ 1230.3 Definitions.

(a) The word "container" as used in the regulations in this part means a retail parcel, package, or container suitable for household use and employed exclusively to hold any dangerous caustic or corrosive substance defined in the act.

(b) The words "suitable for household use" mean and imply adaptability for ready or convenient handling in places where people dwell.

Subpart B—Labeling

§ 1230.10 Placement.

The label or sticker shall be so firmly attached to the container that it will remain thereon while the container is being used, and be so placed as readily to attract attention.

§ 1230.11 Required wording.

(a) The common name of the dangerous caustic or corrosive substance which shall appear on the label or sticker is the name given in section 2(a) of the act (44 Stat. 1406; 15 U. S. C. 402) or any other name commonly employed to designate and identify such substance.

(b) Preparations within the scope of the act bearing trade or fanciful names shall, in addition, be labeled with the common name of the dangerous caustic or corrosive substance contained therein and comply with all the other requirements of the act and of the regulations in this part.

§ 1230.12 Manufacturer; distributor.

If the name on the label or sticker is other than that of the manufacturer, it shall be qualified by such words as "packed for," "packed by," "sold by," or "distributed by," as the case may be, or by other appropriate expression.

§ 1230.13 Labeling of "poison".

The following are styles of uncondensed Gothic capital letters 24-point (type face) size:

POISON

POISON

When letters of not less than 24-point size are required on a label in stating the word "poison" they must not be smaller than those above set forth.

§ 1230.14 Directions for treatment.

Except as provided in § 1230.16, the container shall bear in all cases upon the label or sticker thereof, immediately following the word "Poison," directions for treatment in the case of internal personal injury; in addition, if the substance may cause external injury, directions for appropriate treatment shall be given. The directions shall prescribe such treatments for personal injury as are sanctioned by competent medical authority, and the materials called for by such directions shall be, whenever practicable, such as are usually available in the household.

§ 1230.15 Responsibility for labeling directions for treatment.

A person who receives from a manufacturer or wholesaler any container which under the conditions set forth in section 2(b)(4) of the act and § 1230.16 does not bear at the time of shipment directions for treatment in the case of personal injury must place such directions on the label or sticker if he offers such container for general sale or exchange.

§ 1230.16 Exemption from labeling directions for treatment.

Manufacturers and wholesalers only, at the time of shipment or delivery for shipment, are exempted from placing directions for treatment on the label or sticker of any container for other than household use, but in any event the information required by section 2 (b) (1), (2), and (3) of the act (44 Stat. 1407; 15 U. S. C. 402) and the regulations in this part shall be given.

Subpart C—Guaranty

§ 1230.20 General guaranty.

In lieu of a particular guaranty for each lot of dangerous caustic or corrosive substances, a general continuing guaranty may be furnished by the guarantor to actual or prospective purchasers. The following are forms of continuing guaranties:

(a) Substances for both household use and other than household use:

The undersigned guarantees that the retail parcels, packages, or containers of the dangerous caustic or corrosive substance or substances to be sold to _____ are not misbranded within the meaning of the Federal Caustic Poison Act.

(Date) (Signature and address of guarantor)

(b) Substances for other than household use (this form may be issued only by a manufacturer or wholesaler) (§§ 1230.15, 1230.16):

The dangerous caustic or corrosive substance or substances in retail parcels, packages, or containers suitable for household use to be sold to _____ are for other than household use, and guaranteed not to be misbranded within the meaning of the Federal Caustic Poison Act.

(Date) (Signature and address of manufacturer or wholesaler)

§ 1230.21 Specific guaranty.

If a guaranty in respect to any specific lot of dangerous caustic or corrosive substances be given, it shall be incorporated in or attached to the bill of sale, invoice, or other schedule bearing the date and the name and quantity of the substance sold, and shall not appear on the label or package. The following are forms of specific guaranties:

(a) Substances for both household use and other than household use:

The undersigned guarantees that the retail parcels, packages, or containers of the dangerous caustic or corrosive substance or substances listed herein (or specifying the substances) are not misbranded within the meaning of the Federal Caustic Poison Act.

(Signature and address of guarantor)

(b) Substances for other than household use (this form may be issued only by a manufacturer or wholesaler (§§ 1230.15, 1230.16):

The dangerous caustic or corrosive substance or substances listed herein (or specifying the substances) in retail parcels, packages, or containers suitable for household use are for other than household use and are guaranteed not to be misbranded within the meaning of the Federal Caustic Poison Act.

(Name and address of manufacturer or wholesaler)

Subpart D—Administrative Procedures

§ 1230.30 Collection of samples.

Samples for examination by or under the direction and supervision of the Food

and Drug Administration shall be collected by:

(a) An authorized agent in the employ of the Department of Health, Education, and Welfare;

(b) Any officer of any State, Territory, or possession, or of the District of Columbia, authorized by the Secretary of Health, Education, and Welfare.

§ 1230.31 Where samples may be collected.

Caustic or corrosive substances within the scope of this act (44 Stat. 1406; 15 U.S.C. 401–411) may be sampled wherever found.

§ 1230.32 Analyzing of samples.

Samples collected by an authorized agent shall be analyzed at the laboratory designated by the Food and Drug Administration. Only such samples as are collected in accordance with §§ 1230.30, 1230.31 may be analyzed by or under the direction and supervision of the Food and Drug Administration. Upon request one subdivision of the sample, if available, shall be delivered to the party or parties interested.

§ 1230.33 Investigations.

Authorized agents in the employ of the Department of Health, Education, and Welfare may make investigations, including the inspection of premises where dangerous caustic and corrosive substances subject to the act are manufactured, packed, stored, or held for sale or distribution, and make examinations of freight and other transportation records.

§ 1230.34 Analysis.

(a) The methods of examination or analysis employed shall be those prescribed by the Association of Official Agricultural Chemists, when applicable, provided, however, that any method of analysis or examination satisfactory to the Food and Drug Administration may be employed.

(b) All percentages stated in the definitions in section 2(a) of the Federal Caustic Poison Act shall be determined by weight.

§ 1230.35 Hearings.

Whenever it appears from the inspection, analysis, or test of any container that the provisions of section 3 or 6 of the Federal Caustic Poison Act (44 Stat. 1407, 1409; 15 U.S.C. 403, 406) have been violated and criminal proceedings are contemplated, notice shall be given to the party or parties against whom prosecution is under consideration and to other interested parties, and a date shall be fixed at which such party or parties may be heard. The hearing shall be held at the office of the Food and Drug Administration designated in the notice and shall be private and confined to questions of fact. The parties notified may present evidence, either oral or written, in person or by attorney, to show cause why the matter should not be referred for prosecution as a violation of the Federal Caustic Poison Act.

§ 1230.36 Hearings; when not provided for.

No hearing is provided for when the health, medical, or drug officer or agent of any State, Territory, or possession, or of the District of Columbia, acts under the authority contained in section 8 of the Federal Caustic Poison Act (44 Stat. 1409; 15 U. S. C. 408) in reporting a violation direct to the United States attorney.

§ 1230.37 Publication.

(a) After judgment of the court in any proceeding under the Federal Caustic Poison Act, notice shall be given by publication. Such notice shall include the findings of the court and may include the findings of the analyst and such explanatory statements of fact as the Secretary of Health, Education, and Welfare may deem appropriate.

(b) This publication may be made in the form of a circular, notice, or bulletin, as the Secretary of Health, Education, and Welfare may direct.

(c) If an appeal be taken from the judgment of the court before such publication, that fact shall appear.

Subpart E—Imports

§ 1230.40 Required label information.

Containers which are offered for import shall in all cases bear labels or stickers having thereon the information required by section 2 (b) (1), (2), and (3) of the Federal Caustic Poison Act and the directions for treatment in the case of personal injury, except such directions need not appear on the label or sticker at the time of shipment by a wholesaler or manufacturer for other than household use.

§ 1230.41 Delivery of containers.

Containers shall not be delivered to the consignee prior to report of examination, unless a bond has been given on the appropriate form for the amount of the full invoice value of such containers, together with the duty thereon, and the refusal of the consignee to return such containers for any cause to the custody of the District Director of Customs when demanded, for the purpose of excluding them from the country or for any other purpose, the consignee shall pay an amount equal to the sum named in the bond, and such part of the duty, if any, as may be payable, as liquidated damages for failure to return to the District Director of Customs on demand all containers covered by the bond.

§ 1230.42 Invoices.

As soon as the importer makes entry, the invoices covering containers and the public stores packages shall be made available, with the least possible delay, for inspection by the representative of the district. When no sample is desired the invoice shall be stamped by the district "No sample desired, Food and Drug Administration, Department of Health, Education, and Welfare, per (initials of inspecting officer)."

§ 1230.43 Enforcement.

(a) *Enforcement agency.* The Federal Caustic Poison Act shall be enforced by the Food and Drug Administration, Department of Health, Education, and Welfare.

(b) *Enforcement of provisions.* The enforcement of the provisions of the Federal Caustic Poison Act as they relate to imported dangerous caustic or corrosive substances, will, as a general rule, be under the direction of the chief of the local inspection district of the Food and Drug Administration, Department of Health, Education, and Welfare, and District Directors of Customs acting as administrative officers in carrying out directions relative to the detention, exportation, and sale, or other disposition of such substances and action under the bond in case of noncompliance with the provisions of the Federal Caustic Poison Act.

(c) *Chief of district as customs officer.* The chief of district shall be deemed a customs officer in enforcing import regulations.

(d) *Nonlaboratory ports.* (1) At the ports of entry where there is no district of the Food and Drug Administration, the District Director of Customs or deputy, on the day when the first notice of expected shipment of containers is received, either by invoice or entry, shall notify the chief of district in whose territory the port is located.

(2) On the day of receipt of such notice the chief of district shall mail to the District Director of Customs appropriate notice, if no sample is desired. This notice serves as an equivalent to stamping the invoices at district ports with the legend "No sample desired, Food and Drug Administration, Department of Health, Education, and Welfare, per (initials of inspecting officer)."

(3) If samples are desired, the Chief of district shall immediately notify the District Director of Customs.

(4) The District Director of Customs at once shall forward samples, accompanied by description of shipment.

(5) When samples are desired from each shipment of containers, the chief of district shall furnish to District Director of Customs and deputies at ports within the district's territory a list of such containers, indicating the size of sample necessary. Samples should then be sent promptly on arrival of containers without awaiting special request.

(6) In all other particulars the procedure shall be the same at nonlaboratory ports as at laboratory ports, except that the time consumed in delivery of notices by mail shall be allowed for.

§ 1230.44 Samples.

On the same day that samples are requested by the district, the District Director of Customs or appraiser shall notify the importer that samples will be taken, that the containers must be held intact pending a notice of the result of inspection and analysis, and that in case the containers do not comply with the

requirements of the Federal Caustic Poison Act, they must be returned to the District Director of Customs for disposition. This notification may be given by the District Director of Customs or appraiser through individual notices to the importer or by suitable bulletin notices posted daily in the customhouse.

§ 1230.45 No violation; release.

As soon as examination of the samples is completed, if no violation of the act is detected, the chief of the district shall send a notice of release to the importer and a copy of this notice to the District Director of Customs for his information.

§ 1230.46 Violation.

(a) If a violation of the Federal Caustic Poison Act is disclosed, the chief of the district shall send to the importer due notice of the nature of the violation and of the time and place where evidence may be presented, showing that the containers should not be refused admission. At the same time similar notice regarding detention of the containers shall be sent to the District Director of Customs, requesting him to refuse delivery thereof or to require their return to customs custody if by any chance the containers were released without the bond referred to in § 1230.41. The time allowed the importer for representations regarding the shipment may be extended at his request for a reasonable period to permit him to secure such evidence.

(b) If the importer does not reply to the notice of hearing in person or by letter within the time allowed on the notice, a second notice, marked "second and last notice," shall be sent at once by the chief of the district, advising him that failure to reply will cause definite recommendation to the District Director of Customs that the containers be refused admission and that the containers be exported within 3 months under customs supervision.

§ 1230.47 Rejected containers.

(a) In all cases where the containers are to be refused admission, the chief of the district within 1 day after hearing, or, if the importer does not appear or reply within 3 days after second notice, shall notify the District Director of Customs in duplicate accordingly.

(b) Not later than 1 day after receipt of this notice the District Director of Customs shall sign and transmit to the importer one of the copies, which shall serve as notification to the importer that the containers must be exported under customs supervision within 3 months from such date, as provided by law; the other notice shall be retained as office record and later returned as a report to the chief of the district. In all cases the importer shall return his notice to the District Director of Customs, properly certified as to the information required, as the form provides.

§ 1230.48 Relabeling of containers.

(a) If containers are to be released after relabeling, a notice shall be sent by the chief of district direct to the importer, a carbon copy being sent to the District Director of Customs. This notice must state specifically the conditions to be performed, so as to bring the performance thereof under the provisions of the customs bonds on consumption and warehouse entries, these bonds including provisions requiring compliance with all of the requirements of the Federal Caustic Poison Act and all regulations and instructions issued thereunder. The notice will also state the officer to be notified by the importer when the containers are ready for inspection.

(b) The importer must return the notice to the District Director of Customs or chief of district, as designated, with the certificate thereon filled out, stating that he has complied with the prescribed conditions and that the containers are ready for inspection at the place named.

(c) This notice will be delivered to the inspection officer, who, after inspection, will endorse the result thereof on the back of the notice and return the same to the District Director of Customs or to the chief of district, as the case may be.

(d) When the conditions to be complied with are under the supervision of the chief of district, and these conditions have been fully met, he shall release the containers to the importer, sending a copy of the notice of release to the District Director of Customs for his information. If the containers have not been properly relabeled within the period allowed, the chief of district shall immediately give notice in duplicate to the District Director of Customs of the results of inspection. The District Director of Customs shall sign and immediately transmit one copy of the notice to the importer and proceed in the usual manner.

(e) If the containers are detained subject to relabeling to be performed under the supervision of the District Director of Customs, the District Director of Customs, as soon as relabeling is accomplished, will notify the importer that the containers are released.

(f) If the containers have not been properly relabeled within the period allowed, their sale after labeling as required by the act or other disposition must be effected by the District Director of Customs.

(g) When the final action has been taken on containers which have been refused admission, sold, or otherwise disposed of as provided for by the act or which have been relabeled under the supervision of the District Director of Customs, he shall send to the chief of district a notice of such final action, giving the date and disposition.

(h) When relabeling is allowed the importer must furnish satisfactory evidence as to the identity of the containers before release is given. The relabeling must be done at a stated place and apart from other containers of a similar nature.

(i) When containers are shipped to another port for relabeling or exportation, they must be shipped under customs carrier's manifest, in the same manner as shipments in bond.

(j) District Directors of Customs will perform the inspection service whenever containers are to be exported, sold, or otherwise disposed of, and in other cases when there is no officer of the district available.

(k) District Directors of Customs and representatives of the district will confer and arrange the apportionment of the inspection service according to local conditions. Officers of the district will, whenever feasible, perform the inspection service in connection with relabeling.

§ 1230.49 Penalties.

(a) In case of failure to comply with the instructions or recommendations of the chief of district as to conditions under which containers may be disposed of, the District Director of Customs shall notify the chief of district in all cases coming to his attention within 3 days after inspection or after the expiration of the 3 months allowed by law if no action is taken.

(b) The chief of district, upon receipt of the above-described notice, and in all cases of failure to meet the conditions imposed in order to comply with the provisions of the Federal Caustic Poison Act coming directly under his supervision, shall transmit to the District Director of Customs such evidence as he may have at hand tending to indicate the importer's liability and make a recommendation accordingly.

(c) The District Director of Customs, within 3 days of the receipt of this recommendation, whether favorable or otherwise, shall notify the importer that, the legal period of 3 months for exportation or relabeling having expired, action will be taken within 30 days to enforce the terms of the bond.

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