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# federal register

MONDAY, APRIL 5, 1976




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Ten agencies have agreed to a six-month trial period based on the assignment of two days a week beginning February 9 and ending August 6 (See 41 FR 5453). The participating agencies and the days assigned are as follows:

| Monday | Tuesday | Wednesday | Thursday | Friday |
|---|---|---|---|---|
| NRC | USDA/ASCS | | NRC | USDA/ASCS |
| DOT/COAST GUARD | USDA/APHIS | | DOT/COAST GUARD | USDA/APHIS |
| DOT/NHTSA | USDA/FNS | | DOT/NHTSA | USDA/FNS |
| DOT/FAA | USDA/REA | | DOT/FAA | USDA/REA |
| | CSC | | | CSC |
| | LABOR | | | LABOR |

Documents normally scheduled on a day that will be a Federal holiday will be published the next work day following the holiday.

Comments on this trial program are invited and will be received through May 7, 1976. Comments should be submitted to the Director of the Federal Register, National Archives and Records Service, General Services Administration, Washington, D.C. 20408.

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## Title 3—The President

PROCLAMATION 4425

# National Rural Health Week, 1976

*By the President of the United States of America*

### A Proclamation

There is a serious and growing disparity between the health of the 56 million Americans who live in rural America and that of the general population. Physician and dentist shortages are more acute in rural America, emergency medical services are less available, occupational injury and accident rates are far higher and comprehensive health and public health services are less available.

For far too long rural health problems have been ignored. Rural health care was lost sight of in the general breakdown of all rural services resulting from the great migration of our population from farm to city during the first half of this century. In the last decade this migration came to a halt and to some extent was reversed. From 1970–1973, the growth rate for rural areas actually exceeded the growth rate for metropolitan areas, thus compounding the problem.

The Secretary of Health, Education, and Welfare has designated 1,400 counties and regions as critical health manpower shortage areas where there are too few doctors, dentists, nurses and other health professionals to properly serve the population. Most of these are in rural areas.

Let me affirm, in our Nation's Bicentennial year—which celebrates to such a great extent the positive values of our rural heritage—that we shall make a major commitment to the improvement of health care in our rural communities.

I call upon all our people, rural and urban alike, to support the goal of improving the quality of rural life through better health.

NOW, THEREFORE, I, GERALD R. FORD, President of the United States of America, to draw attention to these facts and to encourage solutions to the health problems of rural America, do hereby designate the week beginning April 4, 1976, as National Rural Health Week.

IN WITNESS WHEREOF, I have hereunto set my hand this second day of April, in the year of our Lord nineteen hundred and seventy-six, and of the Independence of the United States of America the two hundredth.

Gerald R. Ford

[FR Doc.76-9897 Filed 4-2-76;11:35 am]

# rules and regulations

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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

## Title 14—Aeronautics and Space

### CHAPTER I—FEDERAL AVIATION ADMINISTRATION, DEPARTMENT OF TRANSPORTATION

[Docket No. 75-NW-34-AD; Amendment 39-2569]

### PART 39—AIRWORTHINESS DIRECTIVES

#### Boeing Model 727 Series Airplanes

A proposal to amend Part 39 of the Federal Aviation Regulations to include an airworthiness directive requiring an ultrasonic or magnetic particle inspection of all critical areas of the nose landing gear release mechanism torsion shafts, reworked or nonreworked, until replacement with the new improved shaft and installation of the lubrication provisions are accomplished on Boeing Model 727 series airplanes was published in 40 F.R. 53269.

Interested persons have been afforded an opportunity to participate in the making of the amendment. Several comments were received from the Air Transport Association of America. One comment was that the new improved P/N 65-86496-1 shaft should not be included in the AD inspection since it has a stress level less than one-half of the P/N 65-18949-1 shaft and is well below the stress corrosion threshold. Also, the commentator stated that they were not aware of any failures of the newer shaft. Another comment was that incorporation of the lubrication provisions is strictly a product improvement to reduce friction in the mechanism, improve corrosion resistance, and facilitate disassembly. The commentator stated that they were not aware of any instances where insufficient lubrication prevented proper operation of the nose landing gear. Upon further consideration and review of the service performance of the new shaft, the FAA believes that installation of the lubrication provisions is not essential to provide the required level of safety. Also, the FAA believes that the performance of the new shaft is such to consider it as terminating action.

Another comment by the ATA was that since shaft failures are caused by stress corrosion, total time on the part is irrelevant and the proposed 8,000 landing threshold should apply from the time the shaft was new or reworked. The FAA agrees. Failures have occurred on shafts with less than 8,000 landings after rework; however, those particular shafts were found to be improperly reworked and are the subject of AD 73-26-6. For this reason, AD 73-26-6 should not be superseded by the proposal which deals with P/N 65-18949-1 shafts which have either never been reworked or reworked in accordance with approved procedures.

The last comment was that the AD should allow the magnetic particle inspection of the shaft to be conducted at 2,400 landing intervals instead of the 1,500 landing intervals. Justification given for this comment was that the magnetic particle method is the most sensitive for detecting cracks in high strength steel and that a more thorough inspection for corrosion would be conducted since the shaft would be removed, cleaned, and inspected on the bench. The FAA concurs with this comment and the AD incorporates this alternate interval.

In consideration of the foregoing, and pursuant to the authority delegated to me by the Administrator (31 FR 13697), § 39.13 of the Federal Aviation Regulations is amended by adding the following new airworthiness directive:

BOEING: Applies to all Boeing Model 727 series airplanes, certificated in all categories, which are equipped with Boeing P/N 65-18949-1 nose landing gear release mechanism torsion shafts not affected by AD 73-26-6. Compliance required as indicated.

To prevent failure of the nose landing gear release mechanism torsion shaft and a resulting possible gear-up landing, accomplish the following:

A. Within the next 750 landings after the effective date of this AD, unless accomplished within the last 750 landings, and thereafter at intervals not to exceed 1,500 landings for shafts inspected in accordance with the ultrasonic inspection procedures or 2,400 landings for shafts inspected in accordance with the magnetic particle inspection procedures, inspect the P/N 65-18949-1 shafts, reworked and nonreworked, which have accumulated 8,000 or more landings since reworked or new, respectively, on or after the effective date of this AD, per paragraph B below until the shaft is replaced per paragraph C.

B. Inspect the torsion shaft bearing surface in accordance with the ultrasonic or magnetic particle inspection procedures specified in paragraph III of Boeing Service Bulletin No. 727-32-238, or later FAA approved revisions, or inspect in a manner tion approved by the Chief, Engineering and Manufacturing Branch, FAA Northwest Region. Shafts found cracked must be replaced prior to further flight, per paragraph C or with either one of the following:

1. A nonreworked P/N 65-18949-1 shaft which has accumulated less than 8,000 landings. (Upon accumulation of 8,000 landings the inspection requirements of paragraph A above apply); or

2. An uncracked shaft, P/N 65-18949-1, which has been reworked once in accordance with Boeing Service Bulletin No. 727-32-203, Revision 3, or later FAA approved revisions, or in a manner approved by the Chief, Engineering and Manufacturing Branch, FAA Northwest Region. These shafts are subject to the inspection provisions of paragraph A upon accumulation of 8,000 landings after initial rework. Additional rework will not thereafter exempt the shaft from the inspection requirements.

C. Installation of a new improved shaft, P/N 65-86496-1, and associated parts in accordance with Boeing Service Bulletin Nos. 727-32-205, or 727-32-223, or later FAA approved revisions, or an equivalent installation approved by the Chief, Engineering and Manufacturing Branch, FAA Northwest Region, constitutes terminating action of this AD.

D. For the purpose of this AD, when conclusive records are not available to show the number of landings accumulated by a particular shaft, the number of landings may be computed by dividing the airplane time in service since the shaft was installed in the airplane by the operator's fleet average time per flight for his Model 727 airplanes.

The manufacturer's specifications and procedures identified and described in this directive are incorporated herein and made a part hereof pursuant to 5 U.S.C. 552(a)(1).

All persons affected by this directive, who have not already received these documents from the manufacturer, may obtain copies upon request to Boeing Commercial Airplane Company, P.O. Box 3707, Seattle, Washington 98124. The documents may also be examined at FAA Northwest Region, 9010 East Marginal Way South, Seattle, Washington 98124. The documents may also be examined at FAA Northwest Region, 9010 East Marginal Way South, Seattle, Washington.

This amendment becomes effective May 11, 1976.

This amendment is made under the authority of Sections 313(a), 601, and 603 of the Federal Aviation Act of 1958 (49 U.S.C. 1354(a), 1421, and 1423) and of Section 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).

Issued in Seattle, Washington March 26, 1976.

J. H. TANNER,
*Acting Director,*
*Northwest Region.*

NOTE: The incorporation by reference provisions in the document were approved by the Director of the Federal Register on June 19, 1967.

[FR Doc.76-9436 Filed 4-1-76;8:45 am]

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[FR Doc.76-9436 Filed 4-2-76;8:45 am]

### PART 39—AIRWORTHINESS DIRECTIVES

#### DeHavilland Aircraft

The Federal Aviation Administration is amending section 39.13 of Part 39 of the Federal Aviation Regulations so as to issue an airworthiness directive applicable to DeHavilland DHC-6 type airplanes.

There have been reports that water is inadvertently entering the floats of subject aircraft, which are used for water bombing operations. The aircraft, on such operations, is operated by one crewmember (occupant) since another occupant would exceed the maximum-authorized takeoff weight. Thus the deficiency, until rectified, precludes the use

of the aircraft in other types of operations involving the carriage of cargo or another occupant.

Since this deficiency can exist or develop on aircraft of similar-type design, an airworthiness directive is being issued which will require placarding against other than a single occupant.

In view of the foregoing and because the deficiency is one which affects air safety, notice and public procedure hereon are impractical and good cause exists for making the amendment effective in less than 30 days.

In consideration of the foregoing and pursuant to the authority delegated to me by the Administrator, 14 CFR 11.89 [31 F.R. 13697] § 39.13 of Part 39 of the Federal Aviation Regulations is amended by issuing a new airworthiness directive, as follows:

DEHAVILLAND: Applies to all DHC-6 aircraft fitted with Canadian Aircraft Products float models 12000, 12000A or 12000B modified for water bombing operation in accordance with Field Aviation Company, Ltd. Drawing Number 84193.

It has been found that water has been inadvertently entering the water compartments of the aforementioned CAP float models and creating a hazardous condition by exceeding the maximum allowable gross weight with passengers on board.

Compliance required prior to next flight. All aircraft affected by this Airworthiness Directive are no longer eligible for the carriage of passengers or cargo.

Post on the dashboard in full view of the pilot a placard reading "Aircraft Restricted to One Crew Member and Cargo (water) Only in Floats."

The restriction imposed by this Airworthiness Directive may be removed by the incorporation of an acceptable modification approved by the Chief, Engineering and Manufacturing Branch, FAA, Eastern Region.

This amendment is effective April 12, 1976.

This amendment is made under the authority of sections 313(a), 601 and 603 of the Federal Aviation Act of 1958 [49 U.S.C. 1354(a), 1421 and 1423], and section 6(c) of the Department of Transportation Act [49 U.S.C. 1655(c)].

Issued in Jamaica, N.Y., on March 26, 1976.

L. J. CARDINALI,
*Acting Director,*
*Eastern Region.*

[FR Doc.76-9568 Filed 4-2-76;8:45 am]

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[Airworthiness Docket No. 76-WE-3-AD; Amdt. 39-2567]

## PART 39—AIRWORTHINESS DIRECTIVES

### McDonnell Douglas DC-10 Series Airplanes

Pursuant to the authority delegated to me by the Administrator (31 F.R. 13697), an emergency airworthiness directive was adopted on March 15, 1976, and made effective immediately by individual telegrams, dated March 16, 1976, to all known United States operators of McDonnell Douglas DC-10 Series airplanes, certificated in all categories. The airworthiness directives was required because there was one incident wherein the ground spoilers deployed on take-off roll. The spoilers were disarmed automatically because the No. two throttle was advanced. During cold temperature take-offs the No. two engine throttle may not be advanced sufficiently to automatically disarm the spoilers. The operating temperatures above which the spoilers may be armed for take-off varies with engine type and thrust used. The agency encourages arming of the spoilers for take-off, however, the agency has determined that (1) the spoiler automatic disarming feature (throttle) must be in a position to disarm the spoilers or the spoiler handle must not be armed for take-off, or (2) the auto spoilers must be deactivated. The airworthiness directive requires installation of a placard pending incorporation of an Airplane Flight Manual Limitation, or deactivation of the auto spoilers, or equivalent changes approved by the Chief, Aircraft Engineering Division, FAA Western Region.

Since it was found that immediate corrective action was required, notice and public procedure thereon was impracticable and contrary to the public interest and good cause existed for making the airworthiness directive effective immediately as to all known U.S. operators of McDonnell Douglas DC-10 Series airplanes, by individual telegrams dated March 16, 1976. These conditions still exist and the airworthiness directive is hereby published in the Federal Register as an amendment to § 39.13 of Part 39 of the Federal Aviation Regulations to make it effective as to all persons.

MCDONNELL DOUGLAS. Applies to DC-10-10, -10F, -30, -30F and -40 Series airplanes, certificated in all categories.

To assure automatic disarming in the event of inadvertent deployment of the spoilers during take-off, accomplish either (a) and (b), or (c) below:

(a) Within seven days after effective date of this AD, unless already accomplished, install an appropriate placard, as indicated below, in plain view of the pilots:

(1) For airplanes equipped with CF6-6D or CF6-6D1 engines: "Do not arm spoilers for take-off if outside air temperature is below -13°C (For derated thrust take-off) or below -28°C (For full thrust take-off)."

(2) For airplanes equipped with CF6-50A, CF6-50C or CF6-50H engines: "Do not arm spoilers for take-off if outside air temperature is below -25°C (For derated thrust take-off) or below -31°C (For full thrust take-off)."

(3) For airplanes equipped with JT9D-20 engines: "Do not arm spoilers for take-off if outside air temperature is below +5°C (For derated thrust take-off) or below -11°C (For full thrust take-off)."

Above required placard may be removed when "(b)" below is accomplished.

(b) Within sixty days after the effective date of this AD, if autospoilers are not deactivated per (c) below, incorporate the following limitations in the appropriate FAA Approved Airplane Flight Manual (AFM), under the heading *Ground spoilers:*

(1) In AFM Limitations Section, Report No. MDC-J1010: "Do not arm spoilers for take-off if outside air temperature is below -13°C (For derated thrust take-off), or below -28°C (For full thrust take-off)."

(2) In AFM Limitations Section, Report No. MDC-J1030 and MDC-J5830: "Do not arm spoilers for take-off if outside air temperature is below -25°C (For derated thrust take-off) or below -31°C (For full thrust take-off)."

(3) In AFM Limitations Section, Report No. MDC-J1040: "Do not arm spoilers for take-off if outside air temperature is below +5°C (For derated thrust take-off) or below -11°C (For full thrust take-off)."

(c) Within seven days after the effective date of this AD, deactivate and placard the auto-spoilers inoperative per McDonnell Douglas AOL 10-108 Rev. "C", or later FAA-approved revision.

Equivalent placards, modifications, or AFM pages may be approved by the Chief, Aircraft Engineering Division, FAA Western Region.

This amendment is effective April 10, 1976 for all persons except those to whom it was made effective by telegrams, dated March 16, 1976, which contained this amendment.

This amendment is made under the authority of Sections 313(a), 601, and 603 of the Federal Aviation Act of 1958 (49 U.S.C. 1354(a), 1421 and 1423) and of Section 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).

Issued in Los Angeles, California on March 25, 1976.

ROBERT H. STANTON,
*Director, FAA Western Region.*

[FR Doc.76-9569 Filed 4-2-76;8:45 am]

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[Airspace Docket No. 76-SO-27]

## PART 73—SPECIAL USE AIRSPACE

### Change of Using Agency for R-2908

The purpose of this amendment to Part 73 of the Federal Aviation Regulations is to change the using agency for Restricted Area R-2908 to reflect the correct identity of the military organization using the restricted area.

Since designation of a different using agency is a minor amendment in which the public is not particularly interested, notice and public procedure thereon are unnecessary. However, as it is essential that the current using agency of the restricted area be identified, good cause exists for making this amendment effective immediately.

In consideration of the foregoing, Part 73 of the Federal Aviation Regulations is amended, effective upon publication of this amendment in the FEDERAL REGISTER, as hereinafter set forth.

In § 73.29 (41 FR 664) the using agency in R-2908 is amended to read: "Commander, Training Air Wing SIX, Naval Air Station, Pensacola, Fla. 32508."

This amendment is made under the authority of Sec. 307(a) of the Federal Aviation Act of 1958 (49 U.S.C. 1348(a)) and Sec. 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).

Issued in Washington, D.C., on March 30, 1976.

WILLIAM E. BROADWATER,
*Chief, Airspace and Air*
*Traffic Rules Division.*

[FR Doc.76-9567 Filed 4-2-76;8:45 am]

## CHAPTER II—CIVIL AERONAUTICS BOARD

[Reg. ER-951, Amdt. 8]

## PART 234—FLIGHT SCHEDULES OF CERTIFICATED AIR CARRIERS; REALISTIC SCHEDULING REQUIRED

### Expansion of Designated Domestic Passenger Flights Reported on CAB Form 438

*Correction*

In FR Doc. 76-8960 appearing in the issue of Tuesday, March 30, 1976 on page 13332 make the following change:

In the second paragraph of the first column, the last line should have read "top 200 city pairs, and (2) eliminate the exclusion of the reporting of city pairs less than 200 miles apart."

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## Title 16—Commercial Practices

## CHAPTER I—FEDERAL TRADE COMMISSION

[Docket C-2792]

## PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS

### Bill J. Robertson, et al.; Correction

In FR Doc. 76-7991 appearing on page 11815 of the issue for Monday, March 22, 1976, the following correction is made:

On page 11816, order paragraph II. 8, last line of the middle column, should read:

"all disclosures required by Paragraph 5"

CHARLES A. TOBIN,
*Secretary.*

[FR Doc.76-9632 Filed 4-2-76;8:45 am]

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## Title 21—Food and Drugs

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

## PART 510—NEW ANIMAL DRUGS

## PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

### Zinc Bacitracin

The Commissioner of Food and Drugs has evaluated a new animal drug application (98-452V) filed by Thompson-Hayward Chemical Co., P.O. Box 2383, Kansas City, KS 66110, proposing safe and effective use of a zinc bacitracin premix for the manufacture of poultry feed. The application is approved, effective April 5, 1976.

The Commissioner is amending Parts 510 and 558 (21 CFR Parts 510 and 588) to reflect this approval.

In accordance with § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)) of the animal drug regulations, a summary of the safety and effectiveness data and information submitted to support the approval of this application is released publicly. The summary is available for public examination at the office of the Hearing Clerk, Rm. 4-65, 5600 Fishers Lane, Rockville MD 20852, Monday through Friday from 9 a.m. to 4 p.m., except on Federal legal holidays.

Therefore, under 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), Parts 510 and 558 are amended as follows:

1. In Part 510, § 510.600(c) is amended by adding a new sponsor alphabetically to paragraph (c)(1) and numerically to paragraph (c)(2) to read as follows:

**§ 510.600 Names, addresses, and code numbers of sponsors of approved applications.**

* * * * *

(c) * * *

(1) * * *

| Firm name and address | *Drug listing No.* |
|---|---|
| * * * * * | |
| Thompson - Hayward Chemical Co., P.O. Box 2383, Kansas City, Kans. 66110 | 011721 |
| * * * * * | |

(2) * * *

| *Drug listing No.* | *Firm name and address* |
|---|---|
| * * * * * | |
| 011721 | Thompson - Hayward Chemical Co., P.O. Box 2383, Kansas City, Kans. 66110. |
| * * * * * | |

2. In Part 558, § 558.78 is amended by adding paragraph (a), and by revising paragraph (e)(1) (i) and (ii) to read as follows:

**§ 558.78 Bacitracin, zinc.**

(a) *Approvals.* (1) Premix level of 50 grams bacitracin per pound granted to No. 011721 in § 510.600(c) of this chapter.

(2) [Reserved]

* * * * *

(e) * * *

(1) * * *

| Bacitracin, zinc in grams per ton | Combination (grams per ton) | Indications for use | Limitations | Sponsor |
|---|---|---|---|---|
| (i) 4-50 | | 1. Chickens, turkeys, and pheasants; growth promotion and feed efficiency. | | |
| | | 2. Chickens, turkeys, and pheasants; for increased rate of weight gain and improved feed efficiency. | Growing chickens, turkeys, and pheasants. | 011721 |
| (ii) 5-20 | | 1. Quail; growth promotion and feed efficiency. | In quail not over 5 weeks of age | |
| | | 2. Quail; for increased rate of weight gain and improved feed efficiency. | Growing quail; feed as the complete feed to starting quail through 5 weeks of age. | 011721 |

* * * * *

*Effective date.* This regulation shall be effective April 5, 1976.

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

Dated: March 30, 1976.

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

[FR Doc.76-9583 Filed 4-2-76;8:45 am]

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[Recodification Docket No. 12]

[Docket No. 76N-0082]

## PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

### Reorganization and Republication

*Correction*

In FR Doc. 76-7091 appearing at page 10984 of the issue for Monday, March 15, 1976, make the following corrections:

1. In the table in § 558.55(e)(2), page 10989, the fifth line in the "Indications for use" column, reading "As bacitracin zinc", should read "do".

2. In the table in § 558.58(e)(1):

a. On page 10990, in the ninth line of the "Limitations" column, "0000 9" should read "000039".

b. On page 10990, in the 13th line of the "Limitations" column, the semicolon following "monohydrate" should be a colon.

c. On page 10990, in the 17th line of the "Limitations" column, the comma following "monohydrate" should be a semicolon.

d. On page 10991, the first two lines in the "Combination in grams per ton" column, reading "Bambermycins 2 to plus roxar-", should read "Bambermycins 2 to 3 plus roxar-".

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[Docket No. 75N-0366]

## PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

### Source Plasma (Human); Correction

In FR Doc. 76-6899, published at page 10762 in the FEDERAL REGISTER of March 12, 1976, § 640.69 in the third column of page 10769 is corrected in the fourth line of paragraph (b) by changing "20° C." to read "−20° C."

Dated: March 29, 1976.

WILLIAM F. RANDOLPH,
*Acting Associate Commissioner for Compliance.*

[FR Doc.76-9584 Filed 4-2-76;8:45 am]

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## Title 24—Housing and Urban Development

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

[Docket No. R-76-336]

## PART 275—LOW RENT PUBLIC HOUSING PROTOTYPE COST LIMITS

### Pine Ridge, S.D.; Deletion

In the FEDERAL REGISTER issued June 10, 1975, (40 FR 24818), prototype per unit cost schedules were published pursuant to Section 15(5) of the United States Housing Act of 1937. Consideration of subsequent factual project cost data and

other information received from the Denver, Colorado Regional Office indicates that the prototype cost limits for Pine Ridge, South Dakota are superfluous and accordingly, should be deleted from the FEDERAL REGISTER.

Written data, views or statements should be filed with the Director, Office of Underwriting Standards, HUD Central Office, Room 6156, 451—7th Street, SW., Washington, D.C. 20410, and a copy should be sent to the local HUD Area Office. The offices were listed in our publication of June 10, 1975.

Accordingly, 24 CFR, Part 275 is amended as follows:

On Page 40 FR 24871, delete the existing prototype per unit cost schedule for Pine Ridge, South Dakota.

(Sec. 7(d) of Dept. of HUD Act, 42 U.S.C. 3535(d)).

*Effective date.* This amendment is effective on April 5, 1976.

DAVID S. COOK,
*Assistant Secretary for Housing Production and Mortgage Credit, Federal Housing Commissioner.*

[FR Doc.76-9602 Filed 4-2-76;8:45 am]

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

## PART 1916—CONSULTATION WITH LOCAL OFFICIALS

### Changes Made in Determinations of the Village of Jean Lafitte, Louisiana, Base Flood Elevations

On July 11, 1970, at 35 FR 11182, the Federal Insurance Administrator published a list of communities with Special Flood Hazard Areas. The list included Flood Insurance Rate Maps for portions of Jefferson Parish, Louisiana, Unincorporated Areas, a portion of which is now the incorporated Village of Jean Lafitte, Louisiana.

The Federal Insurance Administration, after consultation with the Chief Executive Officer of the community, has determined that it is appropriate to modify the base (100-year) flood elevations of some locations in the Village of Jean Lafitte, Louisiana. These modified elevations are currently in effect and amend the Flood Insurance Rate Map, which was in effect prior to this determination. A revised rate map will be published as soon as possible. The modifications are made pursuant to Section 206 of the Flood Disaster Protection Act of 1973 (P.L. 93-234) and are in accordance with the National Flood Insurance Act of 1968, as amended, (Title XIII of the Housing and Urban Development Act of 1968, P.L. 90-448) 42 U.S.C. 4001-4128, and 24 CFR Part 1916.

For rating purposes, the new community number is 220371A, and must be used for all new policies and renewals.

Under the above-mentioned Acts of 1968 and 1973, the Administrator must develop criteria for flood plain management. In order for the community to continue participation in the National Flood Insurance Program, the community must use the modified elevations to carry out the flood plain management measures of the Program. These modified elevations will also be used to calculate the appropriate flood insurance premium rates for new buildings and their contents and for the second layer of insurance on existing buildings and contents.

From the date of this notice, any person has 90 days in which he can request through the community that the Federal Insurance Administrator reconsider the changes. Any request for reconsideration must be based on knowledge of changed conditions or new scientific or technical data. All interested parties are on notice that until the 90-day period elapses, the Administrator's new determination of elevations may itself be changed.

Any persons having knowledge or wishing to comment on these changes should immediately notify:

The Honorable Leo E. Kerner, Jr., Mayor,
Village of Jean Lafitte,
P.O. Box 501,
Lafitte, Louisiana 70067.

Also, at this location is the map showing the new base flood elevations. This map is a copy of the one that will be printed. The numerous changes made in the base flood elevations on the Jean Lafitte Flood Insurance Rate Map make it administratively infeasible to publish in this notice all of the base flood elevation changes contained on the Jean Lafitte map.

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 F.R. 17804, November 28, 1968), as amended; 42 U.S.C. 4001-4128; and Secretary's delegation of authority to Federal Insurance Administrator 34 F.R. 2680, February 27, 1969, as amended by 39 F.R. 2787, January 24, 1974.)

Issued: March 24, 1976.

J. ROBERT HUNTER,
*Acting Federal Insurance Administrator.*

[FR Doc.76-9649 Filed 4-2-76;8:45 am]

## Title 26—Internal Revenue

## CHAPTER I—INTERNAL REVENUE SERVICE, DEPARTMENT OF THE TREASURY

[T.D. 7415]

## PART 1—INCOME TAX; TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1953

## PART 301—PROCEDURE AND ADMINISTRATION

### Refund of 1975 Individual Income Taxes and Tax Credit for Certain Personal Exemptions

PREAMBLE

By a notice of proposed rule making appearing in the FEDERAL REGISTER for November 25, 1975 (40 F.R. 54583), amendments to the Income Tax Regulations (26 CFR Part 1) under sections 42 and 6428 of the Internal Revenue Code of 1954 and to the Regulations on Procedure and Administration (26 CFR Part 301) under sections 6096(b) and 6611(e) of the Code were proposed in order to conform such regulations to sections 101 and 203 of the Tax Reduction Act of 1975 (89 Stat. 27, 29) (hereinafter referred to as "the Act"). This document adopts the amendments as proposed without change.

Section 101(a) of the Act adds to the Code a new section 6428 which provides for refund of a specified portion of the individual taxpayer's income tax for 1974. Section 101(b) of the Act extends the 45 day period under section 6611(e), relating to interest on overpayments of tax, to 60 days for taxable years beginning in 1974.

Section 203(a) of the Act adds to the Code a new section 42 which allows as a credit against the tax imposed by chapter 1 for the taxable year an amount equal to $30 multiplied by the total number of deductions for personal exemptions to which the individual taxpayer is entitled for the taxable year under section 151 (b) and (e). The additional personal exemptions to which the taxpayer (or his spouse) may be entitled based upon age of 65 or more or blindness are not to be included in computing the taxpayer's total number of deductions for personal exemptions. The maximum credit for personal exemptions may not exceed the tax imposed by chapter 1 for the taxable year. Section 42 further provides that, in computing the credits allowed under section 33 (relating to foreign tax credit), section 37 (relating to retirement income), section 38 (relating to investment in certain depreciable property), section 40 (relating to expenses of work incentive programs), and section 41 (relating to contributions to candidates for public office), the tax imposed by chapter 1 for the taxable year shall first be reduced (before any other reduction) by the credit for personal exemptions.

Section 203(b)(4) of the Act amends section 6096(b) of the Code (relating to designation of income tax payments to Presidential Election Campaign Fund) by adding the credit for personal exemptions to the list of credits in that section.

The amendment to the regulations under section 6428 is effective only with respect to an individual's first taxable year beginning in 1974; the amendment to the regulations under section 6611(e) is effective only with respect to taxable years beginning in 1974; and the amendments to the regulations under sections 42 and 6096(b) are effective only with respect to taxable years ending in 1975.

This document does not conform the regulations under section 42 of the Code to section 3 of the Revenue Adjustment Act of 1975 (89 Stat. 972).

ADOPTION OF AMENDMENTS TO THE REGULATIONS

On November 25, 1975, a notice of proposed rule making was published in the FEDERAL REGISTER (40 F.R. 54583) in order to conform the Income Tax Regulations (26 CFR Part 1) to sections 42 and 6428 of the Internal Revenue Code of 1954 and the Regulations on Pro-

cedure and Administration (26 CFR Part 301) to sections 6096(b) and 6611 (e) of the Code, as added or amended by sections 101 and 203 of the Tax Reduction Act of 1975 (89 Stat. 27, 29). The amendments of the Income Tax Regulations (26 CFR Part 1) and the Regulations on Procedure and Administration (26 CFR Part 301) are hereby adopted as proposed.

(Sec. 7805, Internal Revenue Code of 1954 (68A Stat. 917; 26 U.S.C. 7805))

DONALD C. ALEXANDER,
*Commissioner of Internal Revenue.*

Approved: March 30, 1976.

CHARLES M. WALKER,
*Assistant Secretary of the Treasury.*

Parts 1 and 301 of 26 CFR Chapter I are amended as follows:

INCOME TAX REGULATIONS

**§ 1.42 [Redesignated and amended]**

PARAGRAPH 1. Section 1.42 is amended as follows:

1. Section 1.42 is redesignated as § 1.45.

2. The first line of the statutory provision is amended by striking out "Sec. 42." and inserting in lieu thereof "Sec. 45.".

3. The historical note is revised to read as follows:

[Sec. 45 as renumbered by secs. 203 (a), 204 (a), 208 (a), Tax Reduction Act 1975 (89 Stat. 29, 30, 32); as previously renumbered as sec. 39 by sec. 2 (a), Rev. Act 1962 (76 Stat. 926); as previously renumbered as sec. 40 by sec. 809 (c), Excise Tax Reduction Act 1965 (79 Stat. 167); and as previously renumbered as sec. 42 by sec. 601 (a), Rev. Act 1971 (85 Stat. 553)]

PAR. 2. The following new sections are added immediately after § 1.40–1.

**§ 1.42 Statutory provisions; tax credit for personal exemptions for taxable years ending in 1975.**

Sec. 42. *Credit for personal exemptions*—(a) *General rule.* In the case of an individual, there shall be allowed as a credit against the tax imposed by this chapter for the taxable year $30, multiplied by each exemption for which the taxpayer is entitled for the taxable year under subsection (b) or (e) of section 151.

(b) *Application with other credits.* The credit allowed by subsection (a) shall not exceed the amount of the tax imposed by this chapter for the taxable year. In determining the credits allowed under—

(1) Section 33 (relating to foreign tax credit),

(2) Section 37 (relating to retirement income),

(3) Section 38 (relating to investment in certain depreciable property),

(4) Section 40 (relating to expenses of work incentive programs), and

(5) Section 41 (relating to contributions to candidates for public office),

the tax imposed by this chapter shall (before any other reductions) be reduced by the credit allowed by this section.

[Sec. 42 as added by sec. 203(a), Tax Reduction Act 1975 (89 Stat. 29)]

**§ 1.42–1 Credit for personal exemptions.**

(a) *Allowance of credit.* Subject to the limitation of paragraph (b) of this section, in the case of an individual, there shall be allowed as a credit against the tax imposed by chapter 1 for the taxable year, an amount equal to $30 multiplied by the total number of deductions for personal exemptions to which the individual is entitled for the taxable year under section 151 (b) and (e) and the regulations thereunder (relating to allowance of deductions for personal exemptions with respect to the taxpayer, his spouse, and dependents). For purposes of applying the preceding sentence, the total number of deductions for personal exemptions shall not include any additional exemptions to which the individual or his spouse may be entitled based upon age of 65 or more or blindness under section 151 (c) or (d) and the regulations thereunder.

(b) *Limitation.* The credit allowed by section 42 and paragraph (a) of this section shall not exceed the amount of tax imposed by chapter 1 for the taxable year.

(c) *Application with other credits.* In determining the credits allowed under—

(1) Section 33 (relating to foreign tax credit),

(2) Section 37 (relating to retirement income),

(3) Section 38 (relating to investment in certain depreciable property),

(4) Section 40 (relating to expenses of work incentive programs), and

(5) Section 41 (relating to contributions to candidates for public office),

the tax imposed by chapter 1 for the taxable year shall first be reduced (before any other reduction) by the credit allowed by section 42 and paragraph (a) of this section for the taxable year.

(d) *Effective dates.* The credit allowed by section 42 and paragraph (a) of this section shall apply only for taxable years ending after December 31, 1974, and before January 1, 1976.

PAR. 3. The following new section is added immediately after § 1.6425–3.

**§ 1.6428 Statutory provisions; refund of 1974 individual income taxes.**

Sec. 6428. *Refund of 1974 individual income taxes*—(a) *General rule.* Except as otherwise provided in this section, each individual shall be treated as having made a payment against the tax imposed by chapter 1 for his first taxable year beginning in 1974 in an amount equal to 10 percent of the amount of his liability for tax for such taxable year.

(b) *Minimum payment.* The amount treated as paid by reason of this section shall not be less than the lesser of—

(1) The amount of the taxpayer's liability for tax for his first taxable year beginning in 1974, or

(2) $100 ($50 in the case of a married individual filing a separate return).

(c) *Maximum payment*—(1) *In general.* The amount treated as paid by reason of this section shall not exceed $200 ($100 in the case of a married individual filing a separate return).

(2) *Limitation based on adjusted gross income.* The excess (if any) of—

(A) The amount which would (but for this paragraph) be treated as paid by reason of this section, over

(B) The applicable minimum payment provided by subsection (b),

shall be reduced (but not below zero) by an amount which bears the same ratio to such excess as the adjusted gross income for the taxable year in excess of $20,000 bears to $10,000. In the case of a married individual filing a separate return, the preceding sentence shall be applied by substituting "$10,000" for "$20,000" and by substituting "$5,000" for "$10,000".

(d) *Liability for tax.* For purposes of this section, the liability for tax for the taxable year shall be the sum of—

(1) The tax imposed by chapter 1 for such year, reduced by the sum of the credits allowable under—

(A) Section 33 (relating to foreign tax credit),

(B) Section 37 (relating to retirement income),

(C) Section 38 (relating to investment in certain depreciable property),

(D) Section 40 (relating to expenses of work incentive programs), and

(E) Section 41 (relating to contributions to candidates for public office), plus

(2) The tax on amounts described in section 3102 (c) or 3202 (c) which are required to be shown on the taxpayer's return of the chapter 1 tax for the taxable year.

(e) *Date payment deemed made.* The payment provided by this section shall be deemed made on whichever of the following dates is the later:

(1) The date prescribed by law (determined without extensions) for filing the return of tax under chapter 1 for the taxable year, or

(2) The date on which the taxpayer files his return of tax under chapter 1 for the taxable year.

(f) *Joint return.* For purposes of this section, in the case of a joint return under section 6013 both spouses shall be treated as one individual.

(g) *Marital status.* The determination of marital status for purposes of this section shall be made under section 143.

(h) *Certain persons not eligible.* This section shall not apply to any estate or trust, nor shall it apply to any nonresident alien individual.

[Sec. 6428 as added by sec. 101(a), Tax Reduction Act 1975 (89 Stat. 27)]

REGULATIONS ON PROCEDURE AND ADMINISTRATION

**§ 301.6096 [Amended]**

PAR. 4. Section 301.6096 is amended as follows:

1. Subsection (b) is amended by striking out "and 41." and inserting in lieu thereof ", 41, and 42.".

2. The historical note is revised to read as follows:

[Sec. 6096 added by sec. 302, Foreign Investors Tax Act 1966 (80 Stat. 1587); amended by sec. 802 (a) and (b)(2), Rev. Act 1971 (85 Stat. 573); by sec. 6(a) of the Act of July 1, 1973 (87 Stat. 135); and by sec. 203(b)(4), Tax Reduction Act 1975 (87 Stat. 30)]

**§ 301.6096–1 [Amended]**

PAR. 5. Paragraph (b) of § 301.6096–1 is amended by striking out "and 41." and inserting in lieu thereof ", 41 and 42.".

PAR. 6. Paragraph (j) of § 301.6611–1 is amended to read as follows:

**§ 301.6611–1 Interest on overpayments.**

* * * * *

(j) *Refund of overpayment.* No interest shall be allowed on any overpayment of tax imposed by subtitle A of the Code if such overpayment is refunded—

(1) In the case of a return filed on or before the last date prescribed for filing the return of such tax (determined with-

out regard to any extension of time for filing such return), within 45 days after such last date, or

(2) After December 17, 1966, in the case of a return filed after the last day prescribed for filing the return, within 45 days after the date on which the return is filed.

However, in the case of any overpayment of tax by an individual (other than an estate or trust and other than a nonresident alien individual) for a taxable year beginning in 1974, "60 days" shall be substituted for "45 days" each place it appears in this paragraph.

[FR Doc.76-9658 Filed 4-2-76;8:45 am]

## Title 43—Public Lands: Interior

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

### APPENDIX—PUBLIC LAND ORDERS

[Public Land Order 5579]

[CA-2403]

### CALIFORNIA

### Partial Revocation of Reclamation Project Withdrawal

By virtue of the authority contained in section 3 of the Act of June 17, 1902, as amended and supplemented, 43 U.S.C. 416, it is ordered as follows:

1. The order of the Bureau of Reclamation dated February 19, 1952, concurred in by the Bureau of Land Management February 26, 1952, withdrawing lands for the American River Division of the Central Valley Project, is hereby revoked so far as it affects the following described lands:

TAHOE NATIONAL FOREST

MOUNT DIABLO MERIDIAN

T. 16 N., R. 14 E.,
Sec. 14, NW¼SW¼;
Sec. 22, E½E½.

The areas described aggregate 200 acres in Placer County.

2. At 10 a.m. on May 4, 1976, the lands shall be open to such forms of disposition as may by law be made of national forest lands.

JACK O. HORTON,
*Assistant Secretary of the Interior.*

MARCH 29, 1976.

[FR Doc.76-9593 Filed 4-2-76;8:45 am]

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[Public Land Order 5580]

[S-5132]

### CALIFORNIA

### Withdrawal for National Forest Recreation Sites

By virtue of the authority vested in the President and pursuant to Executive Order No. 10355 of May 26, 1952 (17 F.R. 4831), it is ordered as follows:

1. Subject to valid existing rights the following described national forest lands are hereby withdrawn from appropriation under the mining laws, 30 U.S.C., Ch. 2, but not from leasing under the mineral leasing laws, in aid of programs of the Department of Agriculture for recreation sites:

SIERRA NATIONAL FOREST

MOUNT DIABLO MERIDIAN

*Lower Chiquito Recreation Area*

T. 6 S., R. 24 E.,
Sec. 18, N½NW¼NE¼NE¼.

*Mile High Vista Point Recreation Area*

T. 7 S., R. 24 E.,
Sec. 16, N½NW¼SE¼, except for a 200 foot strip on each side of forest highway No. 100 which has been previously withdrawn as a roadside zone.

The areas described aggregate 25 acres in Madera County.

2. The withdrawal made by this order does not alter the applicability of those public land laws governing the use of the national forest lands under lease, license, or permit, or governing the disposal of the mineral or vegetative resources other than under the mining laws.

JACK O. HORTON,
*Assistant Secretary of the Interior.*

MARCH 29, 1976.

[FR Doc.76-9594 Filed 4-2-76;8:45 am]

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## Title 45—Public Welfare

## CHAPTER X—COMMUNITY SERVICES ADMINISTRATION

[CSA Instruction 600-11]

## PART 1060—GENERAL CHARACTERISTICS OF COMMUNITY ACTION PROGRAMS

### Subpart—CSA Income Poverty Guidelines

In order that the level of poverty which is used to determine program eligibility does not change as a result of substantial increases in the cost of living as measured by the Consumer Price Index, CSA by authority of Section 625 of the Community Services Act revises, from time to time, its income guidelines in order to reflect such increases.

This amendment to § 1060.2 revises the guidelines previously published in June 1975 (CSA Instruction 9004-1h) to reflect the percentage change in the Consumer Price Index from 1974 to 1975 as set forth in the Economic Report of the President, January 1976. The text defining "Income" and "A Farm Residence" remains unchanged.

CSA welcomes comments and will consider all comments received prior to May 5, 1976. Please address all comments to: Mr. Angel Rivera, Associate Director for Operations, Community Services Administration, 1200-19th Street, N.W., Washington, D.C. 20506.

Effective: May 5, 1976.

BERT A. GALLEGOS,
*Director.*

In 45 CFR Chapter X, the Subpart—CSA Income Poverty Guidelines (§§ 1060.2-1 through 1060.2-4) is revised to read as follows:

### Subpart—CSA Income Poverty Guidelines

Sec.

1060.2-1 Applicability.
1060.2-2 Policy.

### Subpart—CSA Income Poverty Guidelines

AUTHORITY: Sec. 602, 78 Stat. 530 (42 U.S.C. 2942).

### § 1060.2-1 Applicability.

This subpart applies to all grants financially assisted under Titles II, III-B and VII of the Community Services Act of 1974, if such assistance is administered by the Community Services Administration.

### § 1060.2-2 Policy.

(a) The attached income guidelines are to be used for all those CSA-funded programs, whether administered by a grantee or delegate agency, which use CSA poverty income guidelines as admission standards. These guidelines do not supersede alternative standards of eligibility approved by CSA, such as Emergency Food and Medical Services Standards used in programs offered by the Department of Agriculture.

(b) The guidelines are also to be used in certain other instances where required by CSA as a definition of poverty, e.g., for purposes of data collection and for defining eligibility for allowances and reimbursements to board members. Agencies may wish to use these guidelines for other administrative and statistical purposes as appropriate.

(c) The attached guidelines are based upon Table A-3, Characteristics of the Population Below the Poverty Level: 1974, Bureau of the Census, *Current Population Reports*, P-60, No. 102, January 1976, page 146 and the percentage change in the Consumer Price Index from 1974 to 1975 as set forth in Table B-2, page 220 of the Economic Report of the President, January 1976.

(d) The following definitions, from *Current Population Reports*, P-60, No. 91, Bureau of the Census, December 1973, have been adopted by CSA for use with the attached poverty guidelines.

(1) *Income.* Refers to total cash receipts before taxes from all sources. These include money wages and salaries before any deductions, but not including food or rent in lieu of wages. They include receipts from self-employment or from own farm or business after deductions for business or farm expenses. They include regular payments from public assistance, social security, unemployment and workmen's compensation, strike benefits from union funds, veterans benefits, training stipends, alimony, child support and military family allotments or other regular support from an absent family member or someone not living in the household; government employee pensions, private pensions and regular insurance or annuity payments; and income from dividends, interest, rents, royalties, or income from estates and trusts. For eligibility purposes, income does not refer to the following money receipts: any assets drawn down as withdrawals from a bank, sale of property, house or car, tax refunds, gifts, one-time insurance payments or compensation for injury; also to be disregarded is noncash income, such as the bonus value of food and fuel produced and consumed on farms and the imputed value of rent

from owner-occupied farm or non-farm housing.

(2) *A Farm Residence.* Is defined as any dwelling on a place of 10 acres or more with $50 or more annual sales of farm products raised there; or any place less than 10 acres having product sales of $250 or more.

ATTACHMENT A.—*CSA poverty guidelines*

| Family size | Nonfarm family | Farm family |
|---|---|---|
| **For all States except Alaska and Hawaii [1]** | | |
| 1 | $2,800 | $2,400 |
| 2 | 3,700 | 3,160 |
| 3 | 4,600 | 3,920 |
| 4 | 5,500 | 4,680 |
| 5 | 6,400 | 5,440 |
| 6 | 7,300 | 6,200 |
| **CSA income poverty guidelines for Alaska [2]** | | |
| 1 | $3,520 | $3,000 |
| 2 | 4,640 | 3,950 |
| 3 | 5,760 | 4,900 |
| 4 | 6,880 | 5,850 |
| 5 | 8,000 | 6,800 |
| 6 | 9,120 | 7,750 |
| **CSA income poverty guidelines for Hawaii [3]** | | |
| 1 | $3,240 | $2,780 |
| 2 | 4,270 | 3,650 |
| 3 | 5,300 | 4,520 |
| 4 | 6,330 | 5,390 |
| 5 | 7,360 | 6,260 |
| 6 | 8,390 | 7,130 |

[1] For family units with more than 6 members, add $900 for each additional member in a nonfarm family and $760 for each additional member in a farm family.
[2] For family units with more than 6 members, add $1,120 for each additional member in a nonfarm family and $950 for each additional member in a farm family.
[3] For family units with more than 6 members, add $1,030 for each additional member in a nonfarm family and $870 for each additional member in a farm family.

[FR Doc.76-9600 Filed 4-2-76;8:45 am]

[CSA Instruction 6802-4]

## PART 1068—COMMUNITY ACTION PROGRAM GRANTEE FINANCIAL MANAGEMENT

### Subpart—Additional Communities Eligible for Waivers of Non-Federal Share Requirement (Puerto Rico, Trust Territories, the Virgin Islands, and Indian Tribes on Reservations)

Section 225(c) of the Community Services Act, which requires a non-Federal share contribution for grants made under certain sections of Title II, also provides that the Director may approve assistance in excess of the legislatively-required contribution if he determines, in accordance with regulations establishing objective criteria, that such action is required in furtherance of the purpose of Title II. CSA has previously published (see § 1068.20) eligibility criteria for organizations and agencies located in the fifty States who are required, either by legislative requirement or administrative regulation, to provide non-Federal share. The objective of these criteria is to assure that the poorest areas in the Nation are able to participate in community action programs despite their lack of economic resources and grants eligibility for waivers of the non-Federal share to counties with 24.5% or more families poor. However, the geographic coverage of that subpart, based as it is on the poor population of counties, does not deal with those areas, such as Indian Reservations, that do not fall under the county system of government, or those areas which are not one of the fifty States.

The purpose of this subpart is to extend coverage of waiver eligibility to geographic areas (see § 1068.21-1) that meet the population poor criteria established in § 1068.20 but do not fall under the county system of government or are not one of the fifty States. CSA welcomes comments and suggested changes and will revise its regulations in light of the comments received if warranted. CSA will consider comments received prior to May 5, 1976. Please address all comments to Mr. Angel Rivera, Associate Director for Operations, Community Services Administration, 1200-19th Street, NW., Washington, D.C. 20506.

Effective: May 5, 1976.

BERT A. GALLEGOS,
*Director.*

45 CFR Chapter 10 is amended by adding a new subpart 1068.21 reading as follows:

**Subpart—Additional Communities Eligible for Waivers of Non-Federal Share Requirement (Puerto Rico, Trust Territories, the Virgin Islands and Indian Tribes on Reservations)**

Sec.
1068.21-1 Applicability.
1068.21-2 Policy.
1068.21-3 Procedures.

### Subpart—Additional Communities Eligible for Waivers of Non-Federal Share Requirement (Puerto Rico, Trust Territories, the Virgin Islands and Indian Tribes on Reservations)

AUTHORITY: Sec. 602, 78 Stat. 530; 42 U.S.C. 2942.

### § 1068.21-1 Applicability.

This subpart applies to grants to organizations and agencies in Puerto Rico, the Trust Territories and the Virgin Islands, and to Federally-recognized Indian Tribes on Reservations made under sections 221, 222(a), and 231 of the Community Services Act of 1974 when such funds are administered by the Community Services Administration.

### § 1068.21-2 Policy.

Because of the high incidences of poverty on Indian Reservations [1] and in Puerto Rico,[2] the Trust Territories,[3] and the Virgin Islands,[4] any Federally-recognized Indian Tribe on a Reservation, or any organization or agency in these areas applying for funds under sections 221, 222(a), and 231 of the Community Services Act is eligible for a waiver of a portion or all of the non-Federal share requirement.

This policy is retroactive for all grants made with FY 1976 funds. All other provisions of § 1068.10 and § 1068.20 continue to apply.

### § 1068.21-3 Procedures.

A request for waiver should be in the form of a letter accompanying each request for *program year* funding and should be addressed to the Community Services office which administers grants for that particular area. (NOTE.—Waiver requests for FY 1976 grants may be submitted at any time.) The letter shall state (1) the period for which the waiver is being requested, (2) the amount of the non-Federal share which the community can provide, and (3) that the applicant has made a reasonable effort to raise the required percentage of non-Federal share and has been unsuccessful. CSA may require that additional evidence be submitted in support of these representations.

[FR Doc.76-9601 Filed 4-2-76;8:45 am]

[1] The percentage of families poor on all Reservations exceed 38% of the population with the exception of one reservation with 24.4% of its families poor. (SOURCE: Table 14, Family Income, Poverty Status, Weeks Worked and Occupation of the Indian Population . . . Reservations and Tribes, 1970, U.S. Bureau of the Census, Census of Population: 1970, Subject Reports, Final Reports PC(2)-1F, American Indians, pp. 171-173.)

[2] Puerto Rico=59.6% of families below poverty level. Municipio San Juan=43.2% of families below poverty level. City of San Juan=42.8% of families below poverty level. (SOURCE: U.S. Bureau of Census, Census of Population: 1970, General Social and Economic Characteristics, Final Report PC(1)-C53 Puerto Rico.)

[3] 91.7% of the families have an annual income of less than $5999. (SOURCE: Table 1344, Families and Unrelated Individuals, By Size of Income, By Areas: 1969, U.S. Bureau of the Census, *Statistical Abstract of the United States:* 1974, Washington, D.C. 1974, p. 807.) (NOTE.—No Census data available on families poor.)

[4] 45.8% of the families have an annual income of less than $5999. (SOURCE: Table 1344, *Statistical Abstract of the U.S.* 1974, p. 807.) (NOTE.—No Census data available on families poor.)

## Title 49—Transportation

## CHAPTER X—INTERSTATE COMMERCE COMMISSION

[Sixth Revised S.O. No. 1043-A]

## PART 1033—CAR SERVICE

### Regulations for Return of Hopper Cars

At a Session of the Interstate Commerce Commission, Railroad Service Board, held in Washington, D.C., on the 30th day of March 1976.

Upon further consideration of Sixth Revised Service Order No. 1043, (40 FR 4), and good cause appearing therefor:

*It is ordered,* That: § 1033.1043 *Sixth Revised Service Order 1043* (Regulations for return of hopper cars), be, and it is hereby, vacated and set aside.

(Secs. 1, 12, 15, and 17(2), 24 Stat. 379, 383, 384, as amended; 49 U.S.C. 1, 12, 15, and 17(2). Interprets or applies Secs. 1(10-17), 15(4) and 17(2), 40 Stat. 101, as amended, 54 Stat. 911; 49 U.S.C. 1(10-17), 15(4), and 17(2))

*It is further ordered,* That this order shall become effective at 12:01 a.m.,

April 1, 1976; that copies of this order and direction shall be served upon the Association of American Railroads, Car Service Division, as agent of the railroads subscribing to the car service and car hire agreement under the terms of that agreement, and upon the American Short Line Railroad Association; and that notice of this order shall be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing it with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board, members Lewis R. Teeple, Thomas J. Byrne. Member William J. Love not participating.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[FR Doc.76-9637 Filed 4-2-76;8:45 am]

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[S.O. No. 1237]

## PART 1033—CAR SERVICE

### Regulations for Return of Hopper Cars

At a Session of the Interstate Commerce Commission, Railroad Service Board, held in Washington, D.C., on the 30th day of March 1976.

*It appearing,* That an acute shortage of hopper cars exists in certain sections of the country; that shippers are being deprived of hopper cars required for loading coal, resulting in an emergency, forcing curtailment of their operations, and thus creating great economic loss and reduced employment of their personnel; that coal stockpiles of several utility companies are being depleted; that hopper cars, after being unloaded, are being appropriated and being retained in services for which they have not been designated by the car owners; that present regulations and practices with respect to the use, supply, control, movement, distribution, exchange, interchange, and return of hopper cars are ineffective. It is the opinion of the Commission that an emergency exists requiring immediate action to promote car service in the interest of the public and the commerce of the people. Accordingly, the commission finds that notice and public procedure are impracticable and contrary to the public interest, and that good cause exists for making this order effective upon less than thirty days' notice.

*It is ordered,* That:

**§ 1033.1237 Service Order No. 1237.**

(a) *Regulations for return of hopper cars.* Each common carrier by railroad subject to the Interstate Commerce Act shall observe, enforce, and obey the following rules, regulations, and practices with respect to its car service:

(1) Exclude from all loading and return to owner empty, either via the reverse of the service route or direct, as agreed to by the owner, all hopper cars owned by the following railroads:

The Baltimore and Ohio Railroad Company, Reporting Marks: B&O.
Bessemer and Lake Erie Railroad Company, Reporting Marks: B&LE.
The Chesapeake and Ohio Railway Company, Reporting Marks: C&O.
Consolidated Rail Corporation, Reporting Marks: BA-BWC-CNJ-DL&W-EL-ERIE-LV-NH-NYC-PC-P&E-PRR-RDG-TOC.
Louisville and Nashville Railroad Company, Reporting Marks: L&N-NC-MON.
Norfolk and Western Railway Company, Reporting Marks: N&W-NKP-P&WV-VGN-WAB.
The Pittsburgh and Lake Erie Railroad Company, Reporting Marks: P&LE.

(2) Carriers named in paragraph (1) above are prohibited from loading all hopper cars foreign to their lines and must return such cars to the owner, either via the reverse of the service route or direct, as agreed to by the owner.

(b) For the purpose of improving car utilization and the efficiency of railroad operations, or alleviating inequities or hardships, modifications may be authorized by the Chief Transportation Officer of the car owner, or by the Director or Assistant to the Director, Bureau of Operations, Interstate Commerce Commission. Modifications authorized by the car owner must be confirmed in writing to W. H. Van Slyke, Chairman, Car Service Division, Association of American Railroads, Washington, D.C., for submission to, and approval by the Director or Assistant to the Director.

(c) No common carrier by railroad subject to the Interstate Commerce Act shall accept from shipper any loaded hopper car, described in this order, contrary to the provisions of the order.

(d) The term hopper cars, as used in this order, means freight cars having a mechanical designation listed under the heading "Class 'H'–Hopper Car Type" in the Official Railway Equipment Register, I.C.C.–R.E.R. No. 398 issued by W. J. Trezise, or reissues thereof.

(e) *Application.* The provisions of this order shall apply to intrastate, interstate, and foreign commerce.

(f) *Effective date.* This order shall become effective at 12:01 am, April 1, 1976.

(g) *Expiration date.* The provisions of this order shall expire at 11:59 pm, June 30, 1976, unless otherwise modified, changed or suspended by order of this Commission.

(Secs. 1, 12, 15, and 17(2), 24 Stat. 379, 383, 384, as amended; 49 U.S.C. 1, 12, 15 and 17(2). Interprets or applies Secs. 1 (10–17), 15(4), and 17(2), 40 Stat. 101, as amended, 54 Stat. 911; 49 U.S.C. 1(10–17), 15(4), and 17(2).)

*It is further ordered,* That a copy of this order and direction shall be served upon the Association of American Railroads, Car Service Division, as agent of all railroads subscribing to the car service and car hire agreement under the terms of that agreement, and upon the American Short Line Railroad Association; and that notice of this order be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing it with the Director, Office of the FEDERAL REGISTER.

By the Commission, Railroad Service Board, members Lewis R. Teeple, Thomas J. Byrne. Member William J. Love not participating.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[FR Doc.76-9638 Filed 4-2-76;8:45 am]

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## Title 50—Wildlife and Fisheries

## CHAPTER I—UNITED STATES FISH AND WILDLIFE SERVICE, DEPARTMENT OF THE INTERIOR

## PART 18—MARINE MAMMALS

### Subpart H—Waiver of Moratorium on Taking and Importation of Individual Marine Mammal Species

Section 101 of the Marine Mammal Protection Act of 1972 (16 USC 1371) establishes a moratorium on the taking and importing of marine mammals. Under certain conditions, which are set out in section 101(a)(3(A), the moratorium can be waived for any given species of marine mammal. The waiver is to be accompanied by regulations for the conservation of the species in question, issued pursuant to section 103 of the Act.

Section 109 of the Act preempts State laws and regulations relating to the taking of marine mammals within the State's jurisdiction. That section also provides for the reinstatement of State laws and regulations which provide for the conservation of marine mammals consistent with the Act and any applicable regulations.

On February 13, 1975, a document was published in the FEDERAL REGISTER (40 FR 6664) proposing to amend Part 18, Subchapter B of Chapter I, Title 50 of the Code of Federal Regulations, by (1) the addition of a new subpart F to the table of sections, (2) the addition of a new § 18.32 entitled "Waiver of the Moratorium," (3) the addition of a new subpart F entitled "Waiver of the Moratorium; State Laws and Regulations," and (4) the amendment of § 18.23 entitled "Native exceptions."

The proposal contained a detailed description of the proposed amendments, gave notice of the availability of the State of Alaska's regulations concerning Pacific walrus and the statements required by section 103(d)(1)–(4) of the Act, set forth a concise summary of procedural regulations which would be applicable to a hearing concerning the proposal, and gave notice of the times and places where a prehearing conference and subsequent hearing would be held if requested, as well as the name and address of the Presiding Officer and the means by which participation in a hearing could be secured.

At the request of interested parties, a hearing was held in two stages. The first stage was held in Anchorage, Alaska, on March 18–22, 1975, at which the proponents presented their case in support of the proposed cooperative State/Federal conservation program. At the second stage held in Arlington, Virginia, on April 8 and 9, 1975, the opponents and the Marine Mammal Commission were afforded an opportunity to voice their objections and to make their suggestions for changes, additions, and modifications

to the proposal. Forty-five documentary exhibits and the testimony of fourteen witnesses were received in evidence; a total of 1,152 pages of transcript were amassed. Six parties proponent, three parties opponent supported by a number of affiliated groups, and one non-aligned party, the Marine Mammal Commission, actually participated in the proceeding.

Presiding Officer Joseph B. Kennedy, in a recommended decision issued on July 10, 1975, found that waiver of the moratorium on the taking of Pacific walrus was appropriate and that, subject to suggested changes in the proposed regulations and the State's management program, the cooperative State/Federal management program for Pacific walrus should be promulgated. [In Re: Waiver of the Moratorium on Walrus Under Regulations for a Cooperative State/Federal Conservation Program, Docket No. Wash. 75–1, July 10, 1975.] The recommended decision included the suggestion that the scope and nature of the waiver as it applies to walrus be more specifically delineated in a new subpart H.

On December 24, 1975, the Director of the U.S. Fish and Wildlife Service published a final decision in the proceeding concerning waiver of the moratorium on the taking of Pacific walrus (40 FR 59459). Simultaneously published were subpart F regulations as revised in accordance with the Director's decision and those portions of the Presiding Officer's recommendations accepted by the Director (40 FR 59442). As part of the Director's decision, a draft of subpart H was published for use by the Service as a guide in the development of regulations to implement the Presiding Officer's recommendation for a new subpart specifically limiting the taking and importation of Pacific walrus.

The Director's decision provided that final regulations for subpart H would be promulgated upon approval by the Director of the revised management program to be submitted by the State of Alaska. That program has been submitted and is hereby certified to be in compliance with the requirements of the Director's decision and those portions of the Presiding Officer's recommended decision adopted by the Director. Accordingly, Part 18 of Title 50, CFR, is amended as set forth below.

This rulemaking is limited to Pacific walrus. It is the intention of the Service to publish similar regulations in the near future applicable to other species of marine mammals for which the moratorium may be waived.

It is determined that immediate implementation of State regulations controlling the flow of raw ivory is essential to the proposed walrus management scheme. Consequently, for good cause found, it is determined that this amendment is to be effective April 5, 1976.

Dated: March 31, 1976.

GEORGE W. MILIAS,
*Acting Director,*
*U.S. Fish and Wildlife Service.*

In consideration of the foregoing, Part 18 of Subchapter B Chapter I of Title 50, Code of Federal Regulations, is amended as follows:

1. In the table of sections, a new subpart H is added reading:

**Subpart H—Waiver of Moratorium on Taking and Importation of Individual Marine Mammal Species**

Sec.
18.92 Purpose of regulations.
18.93 Scope of regulations.
18.94 Pacific walrus (Alaska).

2. A new subpart H is added, reading as follows:

## Subpart H—Waiver of Moratorium on Taking and Importation of Individual Marine Mammal Species

### § 18.92 Purpose of regulations.

The regulations contained in this subpart fulfill the requirements of section 103 of the Act for regulations to govern the taking and importation of each species of marine mammal for which the moratorium imposed by section 101 has been waived.

### § 18.93 Scope of regulations.

(a) The provisions in this subpart apply only after (1) the Director has made a decision to waive a moratorium pursuant to section 101(a)(3)(A) of the Act, (2) the opportunity for a hearing required by section 103(d) of the Act has been provided, and (3) the Director has made a determination, in the case of State laws and regulations, to approve such State laws and regulations pursuant to section 109(a)(2) of the Act and subpart F of this part.

(b) The provisions of this subpart, unless specifically stated, apply to all taking and/or importation of each species of marine mammal for which the moratorium has been waived other than takings for scientific research or public display, which are governed by section 18.31, of this part, or takings incidental to commercial fishing operations which are governed by § 18.24.

### § 18.94 Pacific walrus (Alaska).

(a) Pursuant to sections 101(a)(3)(A) 103, and 109 of the Marine Mammal Protection Act of 1972, the moratorium on the hunting and killing of Pacific walrus (*Odobenus rosmarus*) in waters or on lands subject to the jurisdiction of the State of Alaska, the United States, or on the high seas by any person, vessel, or conveyance subject to the jurisdiction of the State of Alaska or the United States, is waived, effective with publication of a notice of approval of the laws and regulations of the State of Alaska, subject to the following terms and conditions:

(1) The exemption for hunting and killing of Pacific walrus by Alaskan natives under section 101(b) of the Act is rescinded and superseded by the regulations relating to the hunting and killing of Pacific walrus as set forth in this section.

(2) Hunting and killing of Pacific walrus by Alaskan natives will be accomplished in the manner and in accordance with the limitations set forth in this section.

(3) Sport hunting of Pacific walrus by licensed sport hunters will be accomplished in the manner and in accordance with the limitations set forth in this section.

(4) Officers, employees or agents of the State of Alaska may take Pacific walrus in accordance with a State research or conservation program approved by the Director in connection with the approval of the State's laws and regulations pursuant to subpart F of these regulations.

(5) Importation of Pacific walrus taken on the high seas will be permitted only when imported into the State of Alaska, and when taken in accordance with the limitations of this section.

(6) No part or product of a Pacific walrus taken under the provisions of this section may be shipped on interstate or foreign commerce unless it is marked, tagged, or otherwise identified as required by State law or regulation and such mark, tag, or other identification remains on the part or product until the final stages of processing.

(7) The taking or importation of Pacific walrus by all other persons, vessels, or other conveyances remains subject to the moratorium and the prohibitions set forth in the Marine Mammal Protection Act and subpart B of these regulations.

(8) Whenever retrieved takings exceed 3,000 walrus in any regulatory year, or the walrus herds diminish below the range of optimum sustainable population, the moratorium on the taking of walrus provided for in section 101(a) of the Marine Mammal Protection Act, 16 U.S.C. section 1371(a) will automatically be reimposed.

(b) All activities conducted pursuant to a waiver of the moratorium, including those carried out on the high seas adjacent to the coast of the State of Alaska must be in accordance with title 16 of the Alaska Statutes and the approved regulations promulgated thereunder.

(c) A violation of the provisions of the preceding subsection which occurs beyond the jurisdiction of the State of Alaska shall be punishable in accordance with section 105 of the Act.

3. Section 18.58 is revised to read as follows:

### § 18.58 List of waivers and States approved.

The following is a list of States whose laws and regulations have been approved by the Director pursuant to § 18.54 and the species of marine mammals for which the moratorium has been waived in each State:

| State | Common name | Scientific name |
|---|---|---|
| Alaska | Pacific walrus | *Odobenus rosmarus.* |

[FR Doc.76-9608 Filed 4-2-76;8:45 am]

## PART 33—SPORT FISHING

### National Elk Refuge, Wyo.

The following special regulation is issued and is effective on April 5, 1976.

**33.5 Special regulations; sport fishing: for individual wildlife refuge areas.**

WYOMING

NATIONAL ELK REFUGE

Sport fishing on the National Elk Refuge, Wyoming is permitted only on the areas designated by State fishing orders as open to fishing. These open areas, comprising 327 acres, are delineated on maps available at refuge headquarters, Jackson, Wyoming and from the Area Manager, U.S. Fish and Wildlife Service, 711 Central Avenue, Billings, Montana 59102. Sport fishing shall be in accordance with all applicable State regulations subject to the following special conditions:

(1) Use of boats or other floating devices is not permitted.

The provisions of this special regulation supplement the regulations which govern fishing on wildlife refuge areas generally which are set forth in Title 50, Code of Federal Regulations, Part 33, and are effective through October 31, 1976.

DON E. REDFEARN,
*Refuge Manager, National Elk Refuge, Jackson, Wyoming.*

MARCH 29, 1976.

[FR Doc.76-9595 Filed 4-2-76;8:45 am]

# proposed rules

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

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

### [ 43 CFR Parts 3103, 3130 ]

### OIL AND GAS EXPLORATION

### Fractional Present Interest

● The purpose of this amendment to the regulation is to permit the government to lease competitively or noncompetitively for oil and gas exploration and development that portion of lands in which the United States owns an undivided fractional oil and gas interest regardless of the percentage amount of that fraction. ●

Under the authority contained in the Mineral Leasing Act of 1920, 41 Stat. 437 as amended, 30 U.S.C. 181–263; Mineral Leasing Act for Acquired Lands of 1947, 61 Stat. 913, 30 U.S.C. 351–359; and the policy expressed in the Mining and Minerals Policy Act of 1970, 84 Stat. 1876, 30 U.S.C. 21a, this amendment would:

(1) Require that rentals and minimum royalties received for fractional mineral interest leases be at the same rate as for mineral leases in which the entire mineral interest is owned by the United States, and (2) provide that royalties on production remain as that proportion of royalties as the undivided fractional interest of the United States in the oil and gas underlying the leased lands is to the full mineral interest, and (3) eliminate the requirement that an offeror for a fractional interest noncompetitive lease show the extent of his ownership of operating rights to the fractional mineral interest not owned by the United States in each tract covered by the offer to lease, and (4) eliminate the presumption that issuance of a lease to one who would own less than 50 percent of the operating rights to any tract covered by such lease is contrary to the public interest.

Experience by Bureau of Land Management field offices show that this requirement serves no useful purpose. First, in the vast majority of cases, the government owns 50 percent or more of the mineral rights in any given tract. Secondly, private owners usually will lease their interest in these lands even when the government has refused to lease its interest because of the 50 percent limitation. When operations commence, the government then is obligated to petition the courts for a cease and desist order or sue for a proportionate share of the revenues. The public interest can be better served by issuing a lease for the government's fractional interest in mineral rights to a qualified applicant.

In accordance with the Department's policy on public participation in rule-making (36 FR 8336) interested parties may submit written comments, suggestions, or objections with respect to the proposed rules to the Director (210), Bureau of Land Management, Washington, D.C. 20240 until May 4, 1976.

It is hereby determined that the publication of the proposed rulemaking with respect to 43 CFR Part 3130 is not a major Federal action significantly affecting the quality of the human environment and that no detailed statement pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969 (43 U.S.C. 4332(2)(C)) is required. This is merely a change in administrative procedure.

Copies of comments, suggestions, or objections made pursuant to this notice will be available for public inspection in the Division of Legislation and Regulatory Management (210), Bureau of Land Management, Room 5555, Interior Building, Washington, D.C., during regular business hours (7:45 a.m. to 4:15 p.m.).

It is proposed to amend 43 CFR Parts 3103 and 3130 as follows:

1. Section 3103.3–3 is amended as follows:

**§ 3103.3–3 Fractional interests.**

Rentals, minimum royalties and royalties payable for lands in which the United States owns an undivided fractional interest shall be payable as provided in subpart 3130.

2. The table of sections for part 3130 is amended as follows:

### PART 3130—FRACTIONAL OR FUTURE INTEREST LEASES AND PERMITS

### Subpart 3130—Fractional or Future Interest Leases and Permits

Sec.


3130.1 Competitive and noncompetitive.
3130.2 Rental and royalties.
3130.2–1 Rental.
3130.2–2 Royalties and minimum royalties.
3130.3 Public domain.
3130.3–1 Fractional interest offers.
3130.4 Acquired lands.
3130.4–1 General statement.
3130.4–2 Consent of agency and stipulations required.
3130.4–3 Forms.
3130.4–4 Fractional present interests.
3130.4–5 Future and fractional interest offers.


3. Section 3130.2 is revised as follows:

**§ 3130.2 Rental and royalties.**

**§ 3130.2–1 Rental.**

Rental shall not be prorated for any lands in which the United States owns an undivided fractional interest but shall be payable at the same rate as provided in subpart 3103 for the full acreage in such lands.

**§ 3130.2–2 Royalties and minimum royalties.**

Minimum royalties shall not be prorated for any lands in which the United States owns an undivided fractional interest but shall be payable at the same rate as provided in subpart 3103.3–5 for the full acreage in such lands. Royalty on production shall be payable in the same proportion to royalties provided in subpart 3103 as the undivided fractional interest of the United States in the oil and gas underlying the leased lands is to the full mineral interest.

4. Section 3130.3 is amended as follows:

**§ 3130.3 Public domain.**

**§ 3130.3–1 Fractional interest offers.**

An offer for a fractional present interest noncompetitive oil and gas lease must be filed on a form approved by the Director in accordance with subpart 3111.

5. Section 3130.4 is amended as follows:

**§ 3130.4 Acquired lands.**

**§ 3130.4–4 Fractional present interest.**

An offer for a fractional present interest noncompetitive lease must be filed on a form approved by the Director in accordance with subpart 3111.

JACK O. HORTON,
*Assistant Secretary of the Interior.*

[FR Doc.76–9596 Filed 4–2–76;8:45 am]

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

### [ 7 CFR Part 917 ]

[Docket No. AO 90–A6]

### FRESH PEARS, PLUMS, AND PEACHES GROWN IN CALIFORNIA

### Decision on Proposed Further Amendment of the Marketing Agreement and Order

A public hearing was held upon proposed further amendment of the marketing agreement, as amended, and Order No. 917, as amended (7 CFR Part 917), (hereinafter referred to collectively as the "order") regulating the handling of fresh pears, plums and peaches grown in California. The hearing was held, pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 *et seq.*), and the applicable rules of practice (7 CFR Part 900), at Fresno, California, pursuant to notice thereof issued on November 19, 1975, and corrected on November 28, 1975.

Upon the basis of the evidence introduced at the hearing and the record thereof, the Administrator, on February 18, 1976, filed with the Hearing Clerk, United States Department of Agriculture, his recommended decision containing notice of the opportunity to file written exceptions thereto. Two exceptions were filed. One was filed by L. T. Wallace, Director, California Department of Food and Agriculture. It indicated support for consolidation of the State and federal marketing orders as contemplated by the proposed amendment. It also expressed interest in order provisions to facilitate direct marketing programs which may require regulations somewhat different from those established for regular commercial shipments. The provisions of § 917.43 of the order contain provisions under which the respective commodity committees may recommend and the Secretary grant exceptions which would enable direct marketing programs as appropriate and justified. Hence, no change in the order is necessary to provide authority for such exception.

The other exception was filed by Roy Alper, Director, California Citizen Action Group. The exception maintained that adequate notice of hearing was not given. However, as stated in the record, notice of the hearing was published in the November 19, 1975, issue of the FEDERAL REGISTER, and therefore legal notice was given as required in § 900.4(b)(1)(i) of the Rules of Practice and Procedure Governing Proceedings to Formulate Marketing Agreements and Marketing Orders (7 CFR Part 900). Moreover, notice of the hearing was published in newspapers of general circulation in the production area, and a copy of the notice was mailed to the governors of California, Washington, and Oregon and to all known interested persons. The exception expressed views in opposition to promotional authority, the provision for members represent the public on the committees and the need for changes in the order, as contemplated by the proposed amendment. These subjects and the issues involved were covered at the hearing. The evidence in the record of the hearing supports each proposal as set forth in the recommended decision.

*Rulings on exceptions.* In arriving at the findings and conclusions, and the regulatory provisions of this decision, each of the exceptions to the recommended decision was carefully and fully considered in conjunction with the record evidence. To the extent that the findings and conclusions, and the regulatory provisions of this decision are at variance with any of the exceptions, such exceptions are hereby denied for the reasons previously stated in this decision.

The material issues, findings and conclusions, rulings, and general findings of the recommended decision are hereby approved and adopted and are set forth in full herein.

*Material issues.* The material issues of record are as follows:

1. Authorize the regulation of intrastate shipments of fresh pears and peaches.

2. Authorize marketing promotion projects, including paid advertising, for fresh pears and peaches.

3. Authorize the commodity committee for each fruit to make recommendations to the Secretary of Agriculture with respect to its expenses and the rate of assessment needed to provide funds for these expenses and to maintain an operating monetary reserve.

4. Enlarge the Pear Commodity Committee by one member.

5. Authorize each commodity committee to recommend redefinition of the production districts and realignment of district representation on the committee.

6. Authorize the appointment of one public member on each commodiy committee and public representaion on the Control Committee.

7. Delete the section pertaining to exemptions.

8. Make conforming changes.

*Findings and conclusions.* The following findings and conclusions on the material issues are based on the record of the hearing:

(1) The order should be amended to make intrastate shipments of peaches and pears subject to regulation thereunder. This should be effected as a revision of the term "handle" as hereinafter set forth. All handling of peaches and pears gown in the production area is in the current of interstate or foreign commerce or directly burdens, obstructs, or affects such commerce.

California is an important market for peaches and pears. Los Angeles far outranks other principal markets for California peaches. In 1974, 1,156 carlot equivalents of peaches were unloaded in Los Angeles and 506 carlots were unloaded in the San Francisco-Oakland area, commonly referred to as the Bay area, the second ranking market. During that year these two markets accounted for nearly 43 percent of total unloads of California peaches in 46 specified market areas. The Minneapolis-St. Paul market ranked third with 283 carlots of peaches. Likewise, the markets within the State constitute substantial outlets for fresh pears even during years of low pear production. During the 5-year period 1969–73 annual intrastate shipments of California pears were approximately 25 percent of total fresh shipments.

Moreover, Los Angeles, San Francisco, Oakland, and other intrastate markets are major points for the transshipment of peaches and pears to markets outside the State. Handlers of such fruits do not consider California markets and those outside as separate market areas. Each handler's objective is to secure the highest possible returns for his fruit. He surveys all available markets; and if a market within the State offers the best opportunity for the sale of peaches or pears, he ships to this point. If markets outside are reflecting higher returns, shipments are diverted to those markets. Hence, it is evident that prices for peaches and pears in all markets are interrelated and if any particular market either in or outside the State offers greater returns than those elsewhere, supplies are diverted to the most advantageous market.

The movement and sale of peaches and pears from the production area to markets within the State are intermingled with the movement and sale of peaches and pears from such area to interstate markets and thus affect interstate commerce and the regulation thereof. Currently, intrastate shipments of peaches and pears are subject to regulation under California marketing orders. Regulation of such shipments under the order would facilitate more efficient administration, reduce costs and assure regulations uniformly applicable to intrastate and interstate shipments of peaches and pears and promote orderly marketing for all shipments of such fruits.

The term "handle" with respect to peaches and pears should be defined to include all phases of selling and transporting which place peaches and pears in the channels of commerce within the production area or from the production area to any point outside thereof. The handling of peaches and pears begins at the time the fruit is picked from the trees and includes each of the successive selling and transporting activities until the fruit reaches its final destination. The performance of any one or more of these activities such as selling, consigning, delivering, or transporting within or from the production area by any person, either directly or through others, should constitute handling. In order to effectuate the declared policy of the act, each handler should be required, except as provided in the order, to limit the handling of peaches and pears to fruit which conforms to the applicable regulations prescribed by or under the order.

The order should be amended as hereinafter set forth to redefine the term "grower", as it applies to pears, to mean any person who produces pears for market in fresh form and who has a proprietary interest therein. The term "grower" is defined in the order to identify the persons who are eligible to vote as "growers" in referenda in connection with the order, to vote for nominees to fill positions on the respective committees under the order and to serve in such positions. Currently, "grower" is defined with respect to pears as any person who produces pears for market in fresh form in the current of interstate or foreign commerce, and who has a proprietary interest therein. This amended definition would make all growers of pears eligible to vote for nominees to fill positions on the Pear Commodity Committee, irrespective of the markets (intrastate or interstate), to which their pears are shipped. This is appropriate since, as heretofore concluded, all shipments of pears should be subject to regulation under the order. Hence, all growers of pears should be eligible to vote in referenda, for nominees to fill committee positions, and to serve in such positions.

(2) Promotional activities for peaches and pears are presently conducted under State marketing orders. The record shows a wide consensus among the peach and pear industries that promotional activi-

ties have been beneficial in increasing demand and should be continued. The evidence indicates that economies could be effected and that it would otherwise be advantageous to the peach and pear industries if such activities were carried out under the order. Current promotional activities have focused on the "California Summer Fruits" theme covering peaches, pears, plums and nectarines. The sharing of overhead and administrative costs reduces the costs of promotional activities for each fruit. The evidence indicates that provisions for paid advertising activities for peaches and pears and vesting authority therefor in the Peach and Pear Commodity Committees would place the peach and pear industries in a better position to advance the interests of growers, and this would tend to effectuate provisions of the act and the order. Therefore, the order should be amended as hereinafter set forth to authorize any form of marketing promotion for peaches and pears permitted by the act, including paid advertising.

Major promotional effort may appropriately be directed to the following objectives: (1) To make prospective consumers aware of the products' availability, their characteristics and uses, (2) to encourage in-store promotional activity, and (3) to foster improved handling of fruit at wholesale and retail levels. However, such objectives should not be considered all inclusive, and the committees should be authorized to pursue such other objectives as may be determined to be appropriate and authorized by the act.

The following promotional and advertising techniques were cited as examples of techniques which may be employed:

Trade contact is widely regarded as a basic component of promotional activity. Contact is made through field representatives assigned to the various marketing areas where activities are to be concentrated. The duties of field representatives could include the dissemination of supply information, including when peak volume is available for market and information concerning varieties, the distribution of point-of-sale material and other aids, merchandising media programs to the trade, and arranging for and supervising retail contests.

Publicity education is a good promotional technique. Food page publicity which makes available recipes, serving suggestions, selection and ripening tips will generally be given newspaper editorial space. The food pages of newspapers and magazines, radio and TV programs and local extension home economists are valuable sources for guidance in meal planning. Consumers readily accept suggestions from these sources as reliable and acceptable information. The proposed authority for market promotion, including paid advertising, would enable the committee to supply peach and pear information and publicity materials to food news editors and similar persons for appropriate distribution. Funds may also be used to carry out studies and research in promotion-related activities. An example of this type of activity is the development of a relatively inexpensive ripening bowl which would be used by consumers in handling and ripening fresh fruits at home.

Another technique is paid advertising, often referred to as "media." Media generally is expensive but some things can be done selectively in this field that are inexpensive and yet create an impact on the buying trade as well as the consuming public. Trade paper ads, particularly at the beginning of the season, together with the editorial support which trade papers are willing to accord an advertiser are helpful in launching a program for seasonal fruits such as peaches and pears. Spot radio or TV commercials in the principal markets during peak movement periods have proved to be successful. It has been found in many fresh promotional programs that spot announcements, particularly when developed with a "dealer tag" at the end of each spot, have considerable influence in triggering retail promotions. "Dealer tags" are blank spots at the end of the announcements in which the announcer refers to a local retailer as a good place to purchase the product. These spots can be mechandised in such a way as to secure extra display space and promotional price and tie-in advertising financed by the retailer.

The Peach and Pear Commodity Committees should have the responsibility of developing and carrying out each season's advertising and promotional program. In developing recommendations for such program, the respective committees, prior to initiation of any such program, should submit their recommendations and plans to the Secretary for approval.

(3) The order currently provides that the Control Committee recommend to the Secretary a budget of expenses and an assessment rate for each fruit. In actual practice each commodity committee has developed its respective portion of the budget and appropriate rate of assessment and forwarded the proposals to the Control Committee, which in turn has made its recommendation to the Secretary. The order should be amended, as hereinafter set forth, to empower each commodity committee to recommend to the Secretary its budget of expenses and rate of assessment.

Recommendations with respect to the budget and assessment rates depend to a high degree upon anticipated production of the regulated fruits. The Control Committee in the past has submitted a recommended assessment rate for each fruit and a report on the budget as early in the shipping season as practical. However, the initial shipment dates of the fruits vary considerably, and a reasonable estimate of the production of each fruit cannot be made until just prior to the beginning of shipments. The recommended amendment would allow each commodity committee to submit to the Secretary its budget and recommended rate of assessment together with the information considered by the committee in arriving at the budget and recommendation when sufficient information is available to estimate crop size and evaluate activities for the coming season.

Under the revised procedure handlers may continue to make advance payments of their proportionate share of the operating cost of the program in any given year. Evidence indicates that it would be economically advantageous to have a single agency collect assessments from handlers. The Control Committee has functioned in this capacity in the past and should continue to do so.

The interrelationship of the commodities under the order requires that expenses of the Control Committee must be shared by the three commodities. The record indicates that the allocation of shared expenses should continue to be computed by the Control Committee which has as members representatives of each of these commodity committees. It is appropriate that the Control Committee provide each commodity committee information as to its proportionate share of expenses and that such amount be reflected in each commodity committee's proposed budget.

The order should be amended to revise provisions relating to the financial reserve. In the operation of the order, the Control Committee currently maintains separate reserve accounts for the three commodities to cover any expenses authorized under the order. The source of funds in reserve has been from excess assessments of the respective committee. The reserve is limited to an amount approximately equal to the expenses of a fiscal period. Currently, the reserve equals about 40 percent of the average expense of a fiscal period. Since the reserve funds are maintained for the respective commodity committees, and such committees should be given primary budgetary and assessment authority, it would be appropriate and consistent with the expanded fiscal responsibilities of each commodity committee to confer the authority to accumulate and maintain a financial reserve upon each commodity committee. Therefore, it is concluded that the order should be amended to so confer such authority.

(4) The order should be amended to increase the membership of the Pear Commodity Committee from twelve to thirteen members and to allocate the enlarged membership of the committee among such areas as hereinafter specified. Such action is necessary to provide appropriate representation for all pear-producing districts. Representation on the Pear Commodity Committee is allocated among representation areas principally on the basis of the relative volume of production as set forth in § 917.21. The most recent reapportionment of representation on the Pear Commodity Committee was effected on February 28, 1975, and set forth in § 917.121 of the order under Subpart—Rules and Regulations. The provisions of § 917.21 should be amended to reflect the allocation set forth in § 917.121 and further amended, as hereinafter set forth, to place the Stanislaus district with the districts of the same geographical area, delineate the El Dorado District from the

balance of the production area, and designate such district as a separate representation area. Such representation area should be represented by the member currently representing the El Dorado District and the balance of the production area. It is appropriate and in accordance with provisions of the order that a member and alternate member to represent the balance of the production area, mostly centered in Tehachapi-Littlerock area, be selected by the Secretary from nominations or from other qualified individuals.

Additionally, the order should be amended, as hereinafter set forth in § 917.23, to reflect the allocation of representation to the Plum Commodity Committee. Such amendment is necessary to simplify current languge and to incorporate changes previously made effective in the administrative rules and regulations established under the order.

(5) The order currently contains authority for the Control Committee, with the Secretary's approval, to redefine the districts and to reapportion membership among districts. Under the order, changes in the number of members from each representation area shall be based, insofar as practicable, upon the proportionate quantity of the respective fruit shipped from the respective representation area during the preceding three fiscal periods. Information on shipments of the particular fruit is available from records of the particular commodity committee. Moreover, each commodity committee has the knowledge to determine if equitable representation is being given to the various areas of the production area. In practice, the commodity committees have originated proposals with respect to redefinition of districts and realocation of membership and forwarded them to the Control Committee. Under such circumstances the order should be amended to vest authority in the respective commodity committees for redistricting and reapportionment of membership.

The authority with respect to redefinition of districts and reallocation of representation on commodity committees should be revised to establish the principle that in effecting any such redefinition and reallocation, consideration shall be given to assigning a member position on the Peach Commodity Committee to any representation area which originated 5 percent of regulated shipments during the previous 3-year period. This principle is currently applied in assigning members to the Pear and Plum Commodity Committees. Evidence indicates that volume of shipments is primarily important; however, consideration should also be given to such factors as geographical location and isolation from the main areas of production.

(6) Sections 917.16, 917.18, and 917.19 as such sections relate to designation, nomination and selection of grower members of the Control Committee should be amended, as hereinafter set forth, to conform such sections to the amendment of § 917.20, as hereinafter discussed, to authorize public member and alternate member positions on each commodity committee. Section 917.16 should be amended to substitute the term "commodity committee" members for the term "grower" members in the designation of the Control Committee. The order provides that the Pear, Peach and Plum Commodity Committees nominate, pursuant to a prescribed allocation, the grower members of the Control Committee. Any member or alternate member of a commodity committee is eligible for nomination by such commodity committee to the Control Committee. Under the recommended authorization, any pubilc representative selected to serve as member or alternate member on any commodity committee would likewise be a prospective nominee for membership on the Control Committee. Inasmuch as public representatives may be nominated by their respective commodity committees to serve on the Control Committee, it would be appropriate to designate said 13 members of the Control Committee as "commodity committee" members rather than "grower" members.

Likewise, §§ 917.18 and 917.19 should be amended to provide that the nomination and selection processes currently applicable to "grower" members of the Control Committee would instead be applicable to "commodity committee" members of the Control Committee. Taking into account the fact that public members may also serve on the Control Committee, it is no longer appropriate to require that a member of the Control Committee be a person who produced fruit during the previous season, and the order should be so amended.

The other should be amended to authorize each commodity committee to nominate an additional member and alternate member to represent the public. Evidence indicates that public representation on commodity committees could improve the exchange of information and viewpoints between the committees and the public. Also, the participation of a public member during the committee's discussions and recommendations would supplement the opportunity for expression of public opinion afforded in meetings of the committees which are open to the public. Public members on California Advisory Boards under State authority have proved to be effective participants and contributors, and the record indicates that comparably qualified persons should prove equally as effective on commodity committees and the Control Committee.

Any individual selected from the public to serve on a commodity committee should meet specified requirements. For example, it would be appropriate that public member and alternate member nominees not have a direct financial interest nor be closely associated with the production, processing, financing or marketing of agricultural commodities. Also, such nominees should be able to devote sufficient time and express a willingness to attend committee activities regularly and to familiarize themselves with the background and economics of the industry. The evidence further indicates that consideration should be given to selecting nominees under such authorization who are residents of the area in which the fruit is produced.

It is impractial, however, to specify detailed qualification requirements for public member and alternate member in the order and it would be appropriate to adopt such by means of rules and regulations recommended by the Control Committee as a need for different qualifications may become apparent as experience is gained. The Control Committee should submit such rules and regulations to the Secretary for his approval. The Control Committee should have the further duty of recommending for the Secretary's approval procedures to be followed by the commodity committees in nominating the public member and alternate member. As previously discussed, any public member or alternate member, by virtue of appointment to a commodity committee, should be eligible for nomination and selection to the Control Committee.

(7) Exemption provisions in § 917.44 should be deleted. Exemption procedure therein specified has been effective under rules and regulations since 1951. Since that date very few growers have applied for exemption. Exemption provisions were designed to deal with the situation in which a grower, due to conditions beyond his control, was prevented by regulation from shipping a percentage of his fruit equal to the average that could be shipped from his district. Conditions beyond the grower's control could include adverse climatic conditions and other unforseen factors affecting the quality of the crop. In recent years growers have adopted cultural practices which tend to offset such factors, and regulations issued under the order have provided tolerances to permit shipment of some such affected fruit. However, it is recognized that with ample quantities of good quality fruit available, there is not apt to be a market for seriously damaged fruit.

The authority for the establishment of a Sales Managers' Committee for each of the regulated fruits should be deleted. Sales Managers' Committees, each comprised of 7 shipper members, were originally provided to meet with the respective commodity committees and to advise them as to regulations that should be recommended to the Secretary. In recent years an increasing number of members of commodity committees have been growers who ship their own fruit and who may ship the fruit of other growers. Moreover, meetings of the committees are open and shippers are free to attend and express their suggestions as to regulations. In view of this and the fact grower-shipper members now serve on the committees, the need for establishing Sales Managers' Committees as a device for keeping the committees apprised of shipper views has ended. Due to such changes and other circumstances Sales Managers' Committees have not functioned since 1972.

The provisions for "elective bodies" as a method of nominating the 12 shipper members of the Control Committee should be deleted. Under such method

any shipper or group of shippers who shipped at least one-third of the total tonnage of fruit shipped during the preceding season may form an elective body and nominate four members. Testimony indicates that the provision of elective bodies was thought necessary to assure equitable representation on the Control Committee. However, no shipper or group of shippers have exercised the prerogative of forming an elective body.

The procedure currently being used to nominate shipper membership of the Control Committee is the procedure provided in the order as an alternative to nominations by elective bodies. Such procedure provides that the Control Committee convene a meeting of shippers of regulated fruits by February 1 of each year. At such meeting shippers select a nominee for each of the 12 shipper member positions on the Control Committee. This procedure has proved to be satisfactory and appropriate. Therefore, provisions of the order pertaining to nomination of shipper members of the Control Committee should be revised as hereinafter set forth.

Currently, based on a twelve-member committee, the quorum requirement for the Pear Commodity Committee is eight members. The order should be amended to increase the quorum requirement for the Pear Commodity Committee to nine members. Such increased requirement is consistent with the increased size of such committee, which would be effected by this amendment. The order now requires a vote equal to the quorum requirement to sustain an action pursuant to § 917.39 or recommendations for regulation of shipments pursuant to §§ 917.40 through 917.43. This has proved to be satisfactory and should be continued. Therefore, the order should be amended, as hereinafter set forth, to increase the quorum requirement for the Pear Commodity Committee to 9 members and to require an affirmative vote by 9 members for the approval of actions and recommendations pursuant to the specified sections.

The date in the order by which nominations to fill positions on the Peach, Pear and Plum Commodity Committees shall be made, should be changed from February 15 of each year to February 15 of each odd-numbered year. The revised date for designating nominees of the commodity committees would conform with current order provisions requiring that members of said committees be selected biennially for a term ending on the last day of February of odd-numbered years. The 2-year term of office of commodity committee members was effected in an amendment of the order in 1971. Previous to that, members were selected to a 1-year term of office, and nominations were made by February 15 of each year. Through oversight the provision for nomination on the basis of a two-year term was not changed.

Paragraph (b) of § 917.22 contains references to the appointment of the Peach Commodity Committee for the term ending the last day of February 1972. Such references are obsolete, and the entire text of paragraph (b) should be deleted.

Testimony indicates that all the provisions of the order that are not proposed to be amended which are currently in effect for interstate shipments of pears and peaches should be retained in their present form. All of such provisions should be applicable to the intrastate shipments of pears and peaches in the same manner as they are applicable to such shipments of plums.

(8) The amendment heretofore recommended will make it necessary to make certain conforming changes in sections not specifically discussed in connection therewith. All such changes should be incorporated in the order as hereinafter set forth.

*Marketing agreement and order.* Annexed hereto and made a part hereof are two documents entitled, respectively, "Marketing Agreement, as Further Amended, Regulating the Handling of Fresh Pears, Plums and Peaches Grown in California", and "Order Amending the Order, as Amended, Regulating the Handling of Fresh Pears, Plums and Peaches Grown in California", which have been decided upon as the detailed and appropriate means of effectuating the foregoing conclusions.

*It is hereby ordered,* That this entire decision, except the annexed marketing agreement, be published in the FEDERAL REGISTER. The regulatory provisions of the marketing agreement are identical with those contained in the order as hereby proposed to be amended by the annexed order which is published with this decision.

*Referendum order.* It is hereby directed that a referendum be conducted in accordance with the procedure for the conduct of referenda (7 CFR 900.400 *et seq.*), to determine whether the issuance of the annexed order as amended and as hereby proposed to be amended, regulating the handling of fresh pears, plums, and peaches grown in California is approved or favored by producers, as defined under the terms of the order, who during the representative period were engaged in the production area in the production of the regulated commodities for market.

The representative period for the conduct of such referendum is hereby determined to be March 1, 1975, through October 31, 1975.

The agents of the Secretary to conduct such referendum, jointly or severally, are hereby designated to be W. B. Blackburn and G. P. Muck, Fruit and Vegetable Division, Agricultural Marketing Service, United States Department of Agriculture, 2800 Cottage Way, Room E-2713, Sacramento, California 95825.

Signed at Washington, D.C. on: March 29, 1976.

RICHARD L. FELTNER,
*Assistant Secretary.*

ORDER[1] AMENDING THE ORDER, AS AMENDED, REGULATING THE HANDLING OF FRESH PEARS, PLUMS AND PEACHES GROWN IN CALIFORNIA

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

(a) *Findings upon the basis of the hearing record.* Pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 *et seq.*), and the applicable rules of practice and procedure governing the formulation of marketing agreements and orders (7 CFR Part 900), a public hearing was held upon proposed amendment of the marketing agreement, as amended, and Order No. 917, as amended (7 CFR Part 917), regulating the handling of fresh pears, plums and peaches grown in California.

Upon the basis of the record it is found that:

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

(2) The order, as amended, and as further amended, regulates the handling of fresh pears, plums and peaches grown in the production area in the same manner as, and is applicable only to persons in the respective classes of commercial and industrial activity specified in, the marketing agreement and order upon which hearings have been held;

(3) The order, as amended, and a further amended, is limited in its application to the smallest regional production area which is practicable, consistently with carrying out the declared policy of the act, and the issuance of several orders applicable to subdivisions of the production area would not effectively carry out the declared policy of the act;

(4) The order prescribes, so far as practicable, such different terms applicable to different parts of the production area as are necessary to give due recognition to the differences in the production and marketing of fresh pears, plums and peaches grown in the production area; and

[1] This order shall not become effective unless and until the requirements of § 900.14 of the rules of practice and procedure governing proceedings to formulate marketing agreements and marketing orders have been met.

(5) All handling of fresh pears, plums and peaches grown in the production area is in the current of interstate or foreign commerce or directly burdens, obstructs, or affects such commerce.

ORDER RELATIVE TO HANDLING

*It is therefore ordered*, That on and after the effective date hereof the handling of fresh pears, plums and peaches grown in the production area shall be in conformity to and in compliance with the terms and conditions of the order, as hereby amended, as follows:

The provisions of the proposed marketing agreement and order, amending the order, contained in the recommended decision issued by the Administrator on February 18, 1976, and published in the FEDERAL REGISTER on February 23, 1976 (F.R. Doc. 76-5085), and corrected on March 9, 1976 (41 F.R. 10231), shall be and are the terms and provisions of this order, amending the order, and are set forth in full herein.

1. Section 917.5 *Grower* is revised to read as follows:

**§ 917.5 Grower.**

"Grower" is synonymous with producer and means any person who produces fruit for market in fresh form, and who has a proprietary interest therein.

2. Section 917.6 *Handle* is revised to read as follows:

**§ 917.6 Handle.**

"Handle" and ship are synonymous and mean to sell, consign, deliver or transport fruit or to cause fruit to be sold, consigned, delivered or transported between the production area and any point outside thereof, or within the production area: *Provided*, That the term handle shall not include the sale of fruit on the tree, the transportation within the production area of fruit from the orchard where grown to a packing facility located within such area for preparation for market, or the delivery of such fruit to such packing facility for such preparation.

2a. Section 917.15 *Representation area* is revised to read as follows:

**§ 917.15 Representation area.**

"Representation area" means any one of the districts or groups of districts which are designated for nominating members and alternate members to the commodity committees under §§ 917.21 through 917.23 or as changed pursuant to § 917.35(g).

3. § 917.16 *Designation of Control Committee* is revised by deleting the word "grower" in the first sentence and substituting therefor the words "commodity committee members." After such revision § 917.16 reads as follows:

**§ 917.16 Designation of Control Committee.**

A Control Committee is hereby established consisting of 12 shipper members and 13 commodity committee members, and the members shall be selected in accordance with the provisions of § 917.17 through § 917.19. The members shall be selected annually for a term ending on the last day of February, and said members shall serve until their respective successors are selected and have qualified.

4. Section 917.17 *Nomination of shipper members of the Control Committee* is revised by deleting paragraphs (a) and (b), adding a new paragraph (a), and redesignating paragraph (c) as paragraph (b). As revised, § 917.17 reads as follows:

**§ 917.17 Nomination of shipper members of the Control Committee.**

Nominations for the 12 members of the Control Committee to represent shippers shall be made in the following manner:

(a) By February 1 of each year the Control Committee shall announce a time and place for a meeting of all shippers of fruit and shall conduct the election of nominees at such meeting. At said election meeting, the shippers present shall select a nominee for each of the shipper member positions on the Control Committee. Each shipper shall cast only one vote.

(b) No shipper shall be entitled to participate in the nomination of members of the Control Committee, or be eligible for membership on such committee, if such shipper has failed to pay the assessments, due to be paid by him pursuant to the provisions of § 917.37.

5. Section 917.18 *Nomination of grower members of the Control Committee* is revised by:

(1) Revising the title thereof;

(2) Deleting the first paragraph and substituting a new paragraph:

(3) Deleting the words "to represent growers" in the second sentence of paragraph (a);

(4) Deleting the phrase "who produced fruit during the previous season, and" in the first sentence of paragraph (b); and

(5) Deleting the second sentence in paragraph (b). As amended, § 917.18 reads as follows:

**§ 917.18 Nomination of commodity committee members of the Control Committee.**

Nominations for the 13 members of the Control Committee to represent the commodity committees shall be made in the following manner:

(a) A nomination for one member shall be made by each commodity committee selected pursuant to § 917.25. Nominations for the remaining members shall be made by the respective commodity committees as provided in this section. The number of remaining members which each respective commodity committee shall be entitled to nominate shall be based upon the proportion that the previous three fiscal periods' shipments of the respective fruit is of the total shipments of all fruit to which this part is applicable during such periods. In the event provisions of this part are terminated as to any one fruit, nominations of members to the Control Committee shall be composed of representatives of the remaining two fruits. The apportionment shall be determined as aforesaid. In the event provisions of this part are terminated as to any two fruits, the members of the commodity committee of the remaining fruit shall have all of the powers, duties, and functions given to the Control Committee under this part and sections of this part pertaining to the designation of the Control Committee shall be terminated.

(b) A person nominated by any commodity committee for membership on the Control Committee shall be an individual person who is a member or alternate member of the commodity committee which nominates him. Each member of each commodity committee shall have only one vote in the selection of nominees for membership on the Control Committee.

6. Section 917.19 *Selection of members of the Control Committee* is revised by deleting the word "grower" in the second sentence and substituting the words "commodity committee." As revised, § 917.19 reads as follows:

**§ 917.19 Selection of members of the Control Committee.**

From the nominations made pursuant to § 917.17, or from other persons, the Secretary shall select the shipper members of the Control Committee. From the nominations made pursuant to § 917.18, or from other persons, the Secretary shall select the commodity committee members of the Control Committee. Any person selected as member of the Control Committee shall qualify by filing with the Secretary a written acceptance of the appointment.

7. Section 917.20 *Designation of members of commodity committees* is revised by deleting the first sentence and substituting the following. As revised, § 917.20 reads as follows:

**§ 917.20 Designation of members of commodity committees.**

There are hereby established a Pear Commodity Committee and a Peach Commodity Committee each consisting of 13 members and a Plum Commodity Committee consisting of 12 members. Each commodity committee may be increased by one public member nominated by the respective commodity committee and selected by the Secretary. The members of each said committees shall be selected biennially for a term ending on the last day of February of odd-numbered years, and such members shall serve until their respective successors are selected and have qualified. The members of each commodity committee shall be selected in accordance with the provisions of § 917.25.

8. Section 917.21 *Nomination of Pear Commodity Committee Members* is revised by amending paragraphs (b) and (f) thereof and adding a new paragraph (g). As revised, paragraphs (b), (f), and (g) of § 917.21 read as follows:

**§ 917.21 Nomination of Pear Commodity Committee members.**

(b) Sacramento River District, Stockton District, Stanislaus District, Contra Costa District, Santa Clara District, and Solano District four nominees.

* * * * *

(f) El Dorado District one nominee.

(g) All of the production area not included in paragraphs (a) through (f) of this section one nominee.

§ 917.22 [Amended]

* * * * *

9. Section 917.22 *Nomination of Peach Commodity Committee members* is amended by deleting paragraph (b).

(10) Section 917.23 *Nomination of Plum Commodity Committee members* is revised to read as follows:

**§ 917.23 Nomination of Plum Commodity Committee members.**

Nominations for membership on the Plum Commodity Committee shall be made by the growers of plums in the respective representation areas as follows:

(a) Kern District, Tehachapi District, South Coast District, and Southern California District one nominee.

(b) Tulare District two nominees.

(c) Fresno District six nominees.

(d) Placer-Colfax District one nominee.

(e) North Sacramento Valley District and Central Sacramento Valley District one nominee.

(f) All of the production area not included in paragraphs (a) through (e) of this section one nominee.

11. Paragraph (a) of § 917.24 *Procedure for nominating members of various commodity committees* is revised by deleting from the first sentence the word "year" and substituting "odd-numbered year." As revised, paragraph (a) reads as follows:

**§ 917.24 Procedure for nominating members of various commodity committees.**

(a) The Control Committee shall hold or cause to be held not later than February 15 of each odd-numbered year a meeting or meetings of the growers of the fruits in each representation area set forth in §§ 917.21, 917.22, and 917.23 for the purpose of designating nominees of the commodity committees. These meetings shall be supervised by the Control Committee, which shall prescribe such procedure as shall be reasonable and fair to all persons concerned.

* * * * *

12. Paragraph (b) of § 917.29 *Organization of committees* is revised to read as follows:

**§ 917.29 Organization of committees.**

* * * * *

(b) A quorum of the Pear Commodity Committee and of the Peach Commodity Committee shall each consist of nine members and a quorum of the Plum Commodity Committee shall consist of eight members.

* * * * *

§ 917.34 [Amended]

13. Section 917.34 *Duties of Control Committee* is revised as follows:

(1) Paragraph (e) is revised to read as follows:

(e) To develop and provide the commodity committees data on shared expenses to facilitate equitable apportionment of such expenses in the development of budgets.

(2) Paragraph (g) is revised to read as follows:

(g) With the approval of the Secretary estalbish procedures for the selection and appointment of a public member and alternate to each of the commodity committees.

(3) Paragraph (l) is deleted; and

(4) Paragraphs (j), (k), and (l) are redesignated as (l), (j), and (k), respectively.

14. Section 917.35 is amended by revising paragraph (a), and by adding paragraphs (f) and (g) to read as follows:

**§ 917.35 Powers and duties of each commodity committee.**

* * * * *

(a) With regard to the respective fruit for which it was established, to establish production research and marketing research and development projects as authorized under § 917.39, to recommend to the Secretary regulation of shipments pursuant to the provisions of this part, and to possess such other powers and exercise such other duties as will properly effectuate the purpose of this part: *Provided, however,* That the Peach and Pear Commodity Committees shall each approve actions under § 917.39 and make said recommendations pursuant t o § 917.40 through § 917.43 only upon the affirmative vote of not less than nine members of each said committee: *Provided further,* That the Plum Commodity Committee shall approve such actions pursuant to § 917.39 or make said recommendations pusruant to § 917.40 through § 917.43 only upon the affirmative vote of not less than eight members of said committee.

* * * * *

(f) To submit as soon as practicable after the beginning of each fiscal year to the Secretary, for his approval, a budget of its expenses for such fiscal period, including its proportional share of the expenses of the Control Committee and an explanation of the items therein, and a recommendation as to the rate of assessment for the respective fruit for which the commodity committee was established.

(g) With the approval of the Secretary, to redefine the Districts into which the State of California has been divided under § 917.14 or change the representation of any representation area affecting the respective commodity committee: *Provided, however,* That if any such changes are made, representation on any such committee from the various representation areas shall be based, so far as practicable, upon the proportionate quantity of the respective fruit shipped from the respective representation area during the preceding three fiscal periods: *Provided further,* That the commodity committees shall follow the principle, so far as practicable, of assigning a member position on the commodity committees to any representation area from which five percent of regulated shipments have originated during such periods.

15. Section 917.36 *Expenses* is revised to read as follows:

**§ 917.36 Expenses.**

Each commodity committee is authorized to incur such expenses as the Secretary finds are reasonable and are likely to be incurred by the said commodity committee during each fiscal period for the maintenance and functioning of such committee, including its proportionate share of the expenses of the Control Committee; and for such research and service activities relating to handling of the fruit for which the commodity committee was established as the Secretary may determine to be appropriate. The funds to cover such expenses shall be acquired by the levying of assessments as provided in § 917.37.

16. Paragraphs (a) and (c) of § 917.37 *Assessments* are revised by amending the first sentence of each paragraph. After such revision paragraphs (a) and (c) read as follows:

**§ 917.37 Assessments.**

(a) As his pro rata share of the expenses which the Secretary finds are reasonable and are likely to be incurred by the commodity committees during a fiscal period, each handler shall pay to the Control Committee, upon demand, assessments on all fruit handled by him. The payment of assessments for the maintenance and functioning of the committees may be required under this part throughout the period it is in effect irrespective of whether particular provisions thereof are suspended or become inoperative.

* * * * *

(c) In order to provide funds to carry out the functions of the commodity committee prior to commencement of shipments in any season, shippers may make advance payments of assessments, which advance payments shall be credited to such shippers and the assessments of such shippers shall be adjusted so that such assessments are based on the quantity of fruit shipped by such shippers during such season. Any shipper who ships fruit for the account of a grower may deduct, from the account of sale covering such shipment or shipments, the amount of assessments levied on said fruit shipped for the account of such grower.

17. The first sentence of § 917.38 *Accounting* is revised by deleting the words "the Control Committee" and substituting therefor the words "each commodity committee." After such revision the first sentence to the colon of § 917.38 reads as follows:

**§ 917.38 Accounting.**

If, at the end of a fiscal period, the assessments collected are in excess of expenses incurred, each commodity committee, with the approval of the Secretary, may carry over such excess into subsequent fiscal periods as a reserve: * * *

18. Section 917.39 *Market research and development* is revised to read as follows:

**§ 917.39 Market research and development.**

The committees, with the approval of the Secretary, may establish or provide for the establishment of production research, marketing research, and development projects designed to assist, improve, or promote the marketing, distribution, and consumption or efficient production of fruit. Such projects may provide for any form of marketing promotion including paid advertising. The expenses of such projects shall be paid from funds collected pursuant to § 917.37.

19. Paragraph (a) of § 917.43 *Special purpose shipments* is revised by deleting "917.44" from the first sentence. As revised, paragraph (a) of § 917.43 reads as follows:

**§ 917.43 Special purpose shipments.**

(a) Except as otherwise provided in this section, any person may, without regard to the provisions of §§ 917.37, 917.41, and 917.42, and the regulations issued thereunder, handle fruit (1) for consumption by charitable institutions; (2) for distribution by relief agencies; or (3) for commercial processing into products.

* * * * *

**§ 917.44 [Removed]**

20. Section 917.44. *Exemptions* is deleted.

UNITED STATES DEPARTMENT OF AGRICULTURE, AGRICULTURAL MARKETING SERVICE

MARKETING AGREEMENT, AS FURTHER AMENDED, REGULATING THE HANDLING OF FRESH PEARS, PLUMS AND PEACHES GROWN IN CALIFORNIA

The parties hereto, in order to effectuate the declared policy of the Agricultural Marketing Agreement Act of 1937, as amended (Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674), and in accordance with the applicable rules of practice and procedure effective thereunder (7 CFR Part 900) desire to enter into this agreement further amending the marketing agreement regulating the handling of fresh pears, plums and peaches grown in California; and each party hereto agrees that such handling shall, from the effective date of this marketing agreement, be in conformity to, and in compliance with, the provisions of said marketing agreement as hereby further amended:

The provisions of §§ 917.1 to 917.69, inclusive, of the order as amended and as further amended by the order annexed to and made a part of the decision of the Secretary of Agriculture with respect to a proposed marketing agreement and order regulating the handling of fresh pears, plums and peaches grown in California, plus the following additional provisions shall be, and the same hereby are, the terms and conditions hereof; and the specified provisions of said annexed order are hereby incorporated into this marketing agreement as if set forth in full herein:

**§ 917.70 Counterparts.**

This agreement may be executed in multiple counterparts and when one counterpart is signed by the Secretary, all such counterparts shall constitute, when taken together, one and the same instrument as if all signatures were contained in one original.

**§ 917.71 Additional parties.**

After the effective date hereof, any handler may become a party to this agreement if a counterpart is executed by him and delivered to the Secretary. This agreement shall take effect as to such new contracting party at the time such counterpart is delivered to the Secretary, and the benefits, privileges, and immunities conferred by this agreement shall then be effective as to such new contracting party.

**§ 917.72 Order with marketing agreement.**

(a) Each signatory handler requests the Secretary to issue, pursuant to the act, an order providing for regulating the handling of fruit by all handlers in the same manner as is provided for in this agreement.

(b) The undersigned hereby authorizes the Director, or Acting Director, Fruit and Vegetable Division, Agricultural Marketing Service, United States Department of Agriculture, to correct any typographical errors which may have been made in this marketing agreement.

In witness whereof, the contracting parties, acting under the provisions of the act, for the purpose and subject to the limitations therein contained, and not otherwise, have hereto set their respective signatures and seals.

---------- By: ----------[1]
(Firm Name) (Signature)

---------- ----------
(Mailing Address) (Title)

(Corporate Seal; if none, so state) ---------- (Date of Execution)

[FR Doc.76-9590 Filed 4-2-76;8:45 am]

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## DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

### Food and Drug Administration

### [ 21 CFR Part 1 ]

[Docket No. 76P-0111]

### BEVERAGES IN GLASS AND PLASTIC CONTAINERS; TYPE SIZE EXEMPTION FOR CONTAINER CLOSURE LABELS

### Withdrawal of Proposal, Denial of Petition, and Termination of Rule Making Proceeding

The Food and Drug Administration (FDA) is withdrawing the proposal for type size exemption for container closure labels of beverages in glass and plastic containers (published in the FEDERAL REGISTER of March 14, 1975 (40 FR 11882)), denying the petition upon which the proposal was based, and terminating the rule making proceeding in that matter.

The proposed amendment, if adopted, would have exempted labels on the closures of glass or plastic containers of certain beverages from the 1/16-inch minimum type size requirements of § 1.8d(c) (21 CFR 1.8d(c)) when: (1) The label information on the closure included nutrition labeling and a full list of ingredients pursuant to § 1.10 (21 CFR 1.10) and the policy expressed in § 3.88 (21 CFR 3.88 and appeared in at least 1/32-inch type size, and (2) the closure had less than 2 square inches of available labeling surface on its top and bore all labeling appearing on the package (except that the quantity of contents statement could be placed on the container pursuant to specified regulations). The proposal was published in response to a petition submitted on behalf of Dairy Cap Corp., Jamaica, New York.

A total of 657 comments were received in response to the proposal. Of these, 255 consisted of duplicate copies of comments which had been sent by the authors to other persons (e.g., members of Congress) in addition to FDA and then forwarded by those persons to FDA, or were not directly applicable to the proposal. Of the remaining 402 comments, 349 were received from consumers, consumer organizations, and state or city governments and 53 were received from industry or industry representatives. Twenty-seven comments favored the proposal, 374 comments opposed it, and 1 comment sought clarification. All of the comments received from consumers and consumer organizations opposed the proposed exemption.

A discussion of the comments received and the Commissioner's conclusions thereon follow:

1. A large majority of the comments opposed the proposal on the ground that 1/32-inch type is not sufficiently prominent for the presentation of required labeling information to the consumer. Several comments stated that crowding all mandatory information onto a container closure with less than 2 square inches of available label space may result in an unreadable label even when presented in 1/32-inch type size. Many comments claimed that current closure labeling is already too difficult to read. Several comments stated that current retail practices often result in information on the closure being obliterated by the price stamp or tag of the item. One comment presented survey data purporting to show that 99 percent of the consumers relied upon the container, not the closure, for information concerning the contents of a food package.

The Commissioner received specimens and copies of closure labels in response to the proposal. The legibility of these labels varies with the color contrasts and overall design of the labels. These labels also confirm that at times retail pricing practices obliterate a portion of

[1] If one of the contracting parties to this agreement is a corporation my signature constitutes certification that I have the power granted to me by the Board of Directors to bind this corporation to the marketing agreement.

the required label information. The Commissioner notes that the numerous consumer comments were opposed to granting the proposed exemption and that consumer survey data submitted in comments on the proposal indicate consumer preference for more legible nutrition information. The Commissioner is of the opinion that there are unusual cases where it is appropriate to permit the use of 1/32-inch type for labeling purposes, and he has already established a few exemptions in 21 CFR Part 1 for the use of such type size for small packages (§ 1.8d(c)(2) and (3)). He concludes, however, that in this case the proposed exemption to permit use of 1/32-inch type should not be granted because: (1) Other panels in addition to the surface of the closure are available to provide mandatory label information in larger type complying with the standard minimum type size requirements of § 1.8d(c); (2) considerable consumer opposition was expressed in response to the proposal; (3) it appears that small closures printed with mandatory label information in 1/32-inch type may often be difficult to read; and (4) retail pricing practices may obliterate label information on the closure.

2. One of the reasons given by the petitioner in requesting the proposed exemption was that alternative labeling processes were too costly and that these additional costs would needlessly be passed on to consumers. Several comments addressed these cost issues. Comments in favor of the proposed exemption maintained that alternative labeling methods would increase costs and listed several ways in which continued use of closure labeling would be more economical. However, only one of these comments provided actual cost data. This comment stated that side panel labeling would increase the cost of milk products by 2 to 3 cents per gallon container. Comments opposing the proposed exemption stated that nutrition labeling required capital expenditures for all packaged food required to bear such labeling and that the cost of compliance for glass and plastic beverage containers was not significantly different from the cost for other types of packaging. Several of these comments provided estimates of cost increases ranging from 0.002 to 1 cent per container.

The Commissioner recognizes that the nutrition labeling regulations impose some additional costs on manufacturers regardless of the kind of packaging used and that, in most cases, these additional costs are passed on to the consumer. However, based upon the extraordinary interest in the proposal manifested by consumers and their opposition to it, and the absence of convincing data to establish that the cost of compliance with the standard requirements is unreasonable for the subject beverage containers, the Commissioner concludes that, in this case, the cost factor is not an adequate basis for adopting the proposal.

3. A number of comments opposed the proposal because a significant part of the industry has invested both time and money in an effort to comply with existing nutrition labeling regulations and is currently providing adequate nutrition information for the consumer. Some of these comments viewed the proposed exemption as discriminating against one segment of the industry in favor of those that chose not to invest in a compliance effort. Other comments simply stated that since certain segments of the industry have already demonstrated an ability to provide nutrition information in accordance with current regulations, all segments of the industry should be able (and should be required) to comply.

The Commissioner agrees that, in the interest of equity, labeling requirements should be applied uniformly except under unusual circumstances where this is clearly not feasible. He has concluded that such unusual circumstances have not been demonstrated here.

4. Many comments stated that there was sufficient area on most glass bottles and plastic containers to bear labeling which meets the requirements of existing regulations and that technology currently exists to provide adequate side panel labeling. Examples of current side panel labeling were provided by those commenting.

A few comments suggested alternative methods of providing the required labeling informtion, such as use of hang tags.

The Commissioner issued in the FEDERAL REGISTER of May 2, 1974 (39 FR 15268) a final regulation which provides certain exemptions from the type size requirements of § 1.8d for small food packages. In that document he stated that there is no justification for granting exemptions because of small label size when available container or package surface area has not been fully utilized. Since the petitioner acknowledges that some plastic containers currently bear a preprinted applied label on the container sidewall, and some manufacturers have requested that side panels be permitted to bear nonmandatory labeling including a universal product code (UPC) symbol, it is clear that manufacturers have the capability to use the side panel for label information. (A manufacturer may petition for the use of other labeling methods such as hang tags or information pads provided these labeling methods furnish the consumer with the same required label information in a reasonable format.)

5. One comment objected to the Commissioner's statement in the proposal that "efforts by various manufacturers to print the nutrition information in 1/16 inch type size on the grooved and crimped sides of screw-on bottle closures have not been successful, since the information printed on the side of the closure is often inconspicuous and illegible." This comment was accompanied by a specimen of a screw cap closure with information printed on its crimped and grooved surface. The Comment claimed that the Commissioner's statement has led to some confusion and misunderstanding and requested that the Commissioner confirm the availability of the side of a bottle closure as an information panel provided that the information appears in not less than 1/16 inch type size.

The Commissioner advises that § 1.8d (a)(3) (21 CFR 1.8d(a)(3)) provides that, if the top of the container is the principal display panel and the container has no alternative principal display panel, the information panel is any panel adjacent to the principal display panel. Section 1.8d(a)(1) also provides that if the space immediately contiguous and to the right of the principal display panel is too small or is otherwise unusable, e.g., folded flaps or can ends, the panel immediately contiguous and to the right of this part of the label may be used as the information panel. Functional distortions of packages may render certain package areas unusable for labeling. The specimen cap accompanying the comment clearly illustrates this fact in that the nutrition information printed on the crimped and grooved surface of the closure is distorted and difficult to read. The Commissioner advises that the grooved and crimped surfaces of screw cap closures are not appropriate information panels, except under extraordinary and restricted circumstances where the Commissioner by regulation has specifically allowed these surfaces to be used.

6. One comment stated that FDA suggested in the proposal that "the ecological advantages of reusable containers" provides a valid basis for the proposed exemption. This comment asserted that FDA is legally precluded from taking or refraining from taking any action based upon an adverse environmental impact and instead is limited to the statutory grounds for such action established by the specific laws it administers.

Environmental impact was only part of the Commissioner's consideration in proposing this exemption. The Commissioner's primary concern was to avoid needless cost increases to consumers if alternate labeling methods were satisfactory to meet consumer needs. In the FEDERAL REGISTER of April 14, 1975 (40 FR 16662), the Commissioner issued a notice concerning the legal effect of the National Environmental Policy Act (NEPA) on agency action. In that notice, the Commissioner acknowledged that he may take or refrain from taking action on the basis of a determination of an adverse environmental impact only to the extent that such action is independently authorized by the laws he administers. That notice was challenged in a suit brought by an environmental group and was declared invalid by the United States District Court for the District of Columbia in Environmental Defense Fund, Inc. v. Mathews, Civ. No. 75-1811, March 26, 1976. Even under the policy enunciated in the April 1975 notice, the Commissioner concludes that he has the authority to consider relevant environmental factors in ruling upon a proposal for an exemption from labeling requirements pursuant to section 403 of the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. 343).

7. Several comments suggested that the proposed exemption was justified on ecological grounds because side panel labeling on plastic containers and glass bottles would interfere with reclamation and recycling systems. Other comments stated that this was not a valid reason for granting an exemption since less than 1 percent of the total packaged fluid milk sold in the United States is in returnable plastic containers.

The Commissioner does not agree that side panel labeling would necessarily interfere with reclamation or recycling systems. Sticker type side panel labeling is only one labeling method available to manufacturers. A manufacturer is free to choose a labeling system that is compatible with a recycling or returnable container system such as silkscreening, provided it also meets current labeling requirements.

In addition, the use of hang tags and information pads may be compatible with a reclamation system. If members of industry find that these or other methods are compatible with their container systems, they may petition for use of these methods as stated in paragraph 4 above.

Having considered the information contained in Dairy Cap Corp.'s petition, and the comments submitted in response to the propsed amendment to § 1.8d published in the FEDERAL REGISTER of March 14, 1975 (40 FR 11882), the Commissioner concludes that the proposed exemption is not in the public interest and shall not be adopted.

In a letter dated March 14, 1975, however, FDA gave notice that regulatory action would not be taken against any product labeled in accordance with the proposed exemption pending publication of a final ruling on the proposal. The Commissioner recognizes that a number of manufacturers are currently utilizing closure labeling which does not comply with current regulations but which does conform to the proposed exemption. The Commissioner also recognizes that in many cases new labeling equipment and label designs will be required to make the necessary labeling changes. Therefore, until April 1, 1977, FDA will take no action against products which have been labeled in compliance with the proposed exemption, in order to furnish manufacturers an opportunity to utilize existing stocks of labels and to obtain adequate substitute labeling systems. All products initially introduced into interstate commerce on or after April 1, 1977 shall comply with current regulations.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 403, 701(a), 52 Stat. 1040–1042 as amended, 1047–1048 as amended, 1055 (21 U.S.C. 321, 343, 371(a))) and under authority delegated to him (21 CFR 2.120), the Commissioner hereby denies Dairy Cap Corp.'s petition, withdraws the proposed amendment to § 1.8d published in the FEDERAL REGISTER of March 14, 1975 (40 FR 11882), and terminates the rule making proceeding initiated by that proposal.

Dated: March 31, 1976.

A. M. SCHMIDT,
*Commissioner of Food and Drugs.*

[FR Doc.76-9781 Filed 4-2-76;8:45 am]

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**[ 21 CFR Parts 430, 436 and 440 ]**

[Docket No. 75N-0020]

## PENICILLIN

### Updating and Technical Changes to Antibiotic Drugs

*Correction*

In FR Doc. 76-8019 appearing at page 11533–11553 in the issue of Friday, March 19, 1976, the following corrections should be made.

1. On page 11533, paragraph designated as 1, line 9, should read "440.155b, 440.160, 440.166, 440.174, 440.-"

2. On page 11536, in the table in § 436.-33(b), under the column entitled *Antibiotic Drug*, the forty-second line should read, "Doxycycline hyclate for injection".

3. On page 11537, § 436.205(c), the ninth entry in the table under the heading in the *Antibiotic Column*, should read "Cephapirin sodium".

4. On page 11538, § 436.316 (a)(1), the first line should read "(1) *Amyl acetate (iso-amyl acetate)*".

5. On page 11538, 3rd column, the 8th line from the end of § 436.16(b) should read "tone solution adding the latter by means".

6. On page 11541, third column, the first line of the paragraph designated 28 should read: "Section 440.81 *Buffered crystal–*".

7. On page 11544, § 440.171a, the first word of the 3rd line now reading *"equality"* should read *"quality"*.

8. On page 11546, § 440.180a (a), the 14th line should read as follows: "than 90 percent and not more than 120".

9. On page 11547, § 440.180g (a)(3), the first line following paragraph (*b*)(2) should read, "(ii) Samples required (*a*) The penicil-".

10. On page 11550, § 440.274a (a)(1), line 23 should read, "is not more than one-tenth of 1 percent".

11. On page 11550, under § 440.274a (a)(3), line 3 should read, "requirements of § 431.1 of this chapter.".

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**Office of Education**

**[ 45 CFR Part 196 ]**

## DOMESTIC MINING AND MINERAL AND MINERAL FUEL CONSERVATION FELLOWSHIPS

### Notice of Proposed Rulemaking

Pursuant to the authority contained in Title IX, Part D, of the Higher Education Act of 1965, as amended (20 U.S.C. 1134n et seq.), notice is hereby given that the Commissioner of Education, with the approval of the Secretary of Health, Education, and Welfare, proposes to issue the rules and regulations set forth below for the Domestic Mining and Mineral Fuel Conservation Fellowship Program.

Section 961(a)(1) of Part D of Title IX authorizes a fellowship program "to assist graduate students of exceptional ability who demonstrate a financial need for advanced study in domestic mining and mineral and mineral fuel conservation including oil, gas, oil shale, and uranium."

Fellowships will be allocated to institutions of higher education on the basis of the criteria set forth in Section 196.12. These institutions in turn will recommend eligible students to the Commissioner for his selection. Three specific types of fellowships will be allocated and awarded: (1) continuation fellowships for graduate or professional study leading to an advanced degree, (2) new fellowships for graduate or professional study leading to an advanced degree, and (3) fellowships for research incident to the presentation of a doctoral dissertation. The latter type of fellowship will be awarded to students who have completed all course work required for granting a doctoral or equivalent degree and comprehensive examinations where appropriate, and whose doctoral dissertation proposal has been approved. An institution of higher education may apply for an allocation of any or all of these three types of fellowships.

Interested persons are invited to submit written comments, suggestions, or objections regarding these regulations to the Division of Training and Facilities, Bureau of Postsecondary Education, Room 3060, Regional Office Building Three, 7th and D Streets SW., Washington, D.C. 20202. Comments received in response to this notice will be available for public inspection at the above office on Mondays through Fridays between 8:30 a.m. and 4:30 p.m. All relevant material must be received not later than May 5, 1976.

(Catalog of Federal Domestic Assistance Programs: 13.567 Domestic Mining and Mineral and Mineral Fuel Conservation Fellowships)

Dated: February 13, 1976.

T. H. BELL,
*U.S. Commissioner of Education.*

Approved: March 22, 1976.

MARJORIE LYNCH,
*Acting Secretary of Health, Education, and Welfare.*

Title 45 of the Code of Federal Regulations is amended by adding a new Part 196, to read as follows:

Sec.

196.1 Definitions.
196.2 General provisions regulations.
196.3 Purpose.
196.4 Award procedure.
196.5 Types of fellowships.
196.6 Eligibility for fellowships.
196.7 Fellowship conditions.
196.8 Stipend.
196.9 Dependency allowance.
196.10 Travel allowance.
196.11 Institutional allowance.
196.12 Criteria for allocating fellowships to institutions of higher education.

Sec.
196.13 Reaward of vacated fellowships.
196.14 Payment procedures.
196.15 Criteria for determining financial need.
196.16 Records and reports.

AUTHORITY: Title IX, Part D, sections 961–965 of Pub. L. 89–329, as amended (20 U.S.C. 1134n–1134r), unless otherwise noted.

### § 196.1 Definitions.

As used in this part:

(a) "Act" means the Higher Education Act of 1965, as amended.

(20 U.S.C. 1134n et seq.)

(b) "Domestic Mining" is defined as the means by which mineral and mineral fuel resources of the United States are extracted from the earth.

(c) "Fellow" means a person to whom the Commissioner awards a fellowship under this Part.

(d) "Fellowship" means an award by the Commissioner under this Part.

(e) "Institution of higher education" is defined in Section 1201(a) of the Higher Education Act of 1965, as amended.

(20 U.S.C. 1141(a))

(f) "Mineral and Mineral Fuel Conservation" is defined as the means by which an adequate supply of the Nation's non-renewable resources is maintained, either through exploration for new sources, more efficient extraction of existing reserves, or better utilization of already processed minerals and mineral fuel.

(20 U.S.C. 1134n)

### § 196.2 General provisions regulations.

Assistance under Title IX, Part D of the Act is subject to the applicable provisions contained in Subchapter A of this chapter (relating to fiscal, administrative, property management, and other matters).

(20 U.S.C. 1134n)

### § 196.3 Purpose.

It is the purpose of this program to provide fellowships to assist graduate students of exceptional ability who demonstrate a financial need for advanced study in domestic mining and mineral and mineral fuel conservation including oil, gas, coal, oil shale and uranium.

(20 U.S.C. 1134n(a))

### § 196.4 Award procedures.

Fellowships will be allocated to institutions of higher education which apply for a fellowship allocation and which offer a graduate program leading to an advanced or professional degree in the field of domestic mining or mineral and mineral fuel conservation on the basis of the criteria set forth in § 196.12. Institutions receiving such an allocation shall recommend eligible students to the Commissioner for his selection.

(20 U.S.C. 1134n(b)(1); 1134(c))

### § 196.5 Types of fellowships.

The types of fellowships that will be awarded under this Part are as follows:

(a) Fellowships for individuals for graduate study leading to an advanced or professional degree in a field of domestic mining or mineral and mineral fuel conservation.

(1) These fellowships will be awarded to individuals who have been accepted for graduate study at an institution of higher education that has received a fellowship allocation under this Part.

(2) The fellowships will be allocated each year to institutions of higher education and will consist of two categories: new fellowships and continuation fellowships. Continuation fellowships will only be awarded to individuals who previously received an award under this Part and who are continuing their study leading to an advanced or professional degree.

(3) In no case may an individual receive assistance under this Part for a period in excess of three years.

(b) Doctoral dissertation fellowships. These fellowships are one-year fellowships for persons who have completed all course work required for granting a doctoral degree or an equivalent degree (except such course work credited on the dissertation) and comprehensive examinations where appropriate, and whose doctoral dissertation (or other equivalent dissertation) proposal has been approved by appropriate officials of an institution of higher education that has received a fellowship allocation for this purpose.

(20 U.S.C. 1134n(c); 1134o)

### § 196.6 Eligibility for fellowships.

Recipients of fellowships under this Part must:

(a) Be of exceptional ability, as determined by the institution of higher education;

(b) Demonstrate financial need, as determined by the institution of higher education under the criteria set forth in § 196.15; and

(c) Be a national of the United States or be in the United States for other than a temporary purpose and intend to become a permanent resident thereof, or be a permanent resident of the Trust Territory of the Pacific Islands.

(20 U.S.C. 1134n(a)(1))

### § 196.7 Fellowship conditions.

In order to continue receiving payments under the provisions of this Part, a fellow must:

(a) Maintain satisfactory proficiency in the approved program in which he or she is registered;

(b) Continue to devote full-time to study or research in the field in which the fellowship was awarded; and

(c) Not engage in gainful employment during the period of the fellowship tenure, except in an internship or research activity under faculty supervision in the filed in which he or she is studying.

(20 U.S.C. 1134q(a))

### § 196.8 Stipend.

(a) The stipend to which a fellow is entitled will be $3000 for an academic year consisting of twelve months.

(b) A fellow who is enrolled in the program of study for less than twelve months shall only be entitled to receive a pro rata share of the annual entitlement. For purposes of this section, a fellow who is enrolled in the program for the entire academic year (including summer sessions) at an institution of higher education shall be considered to be enrolled in the program for the full twelve months.

(20 U.S.C. 1134p(a))

### § 196.9 Dependency allowance.

A fellow shall also be entitled to receive $300 per twelve month academic year for each of his or her dependents. The allowance for dependents shall not exceed $1500 per academic year.

(20 U.S.C. 1134p(a))

### § 196.10 Travel allowance.

(a) A fellow is entitled to reimbursement for actual and necessary traveling expenses for himself and his dependents from his ordinary place of residence to the institution of higher education, library, archive, or other research center where he will pursue his studies under the fellowship, and to return to such residence.

(b) The travel allowance shall be limited to reimbursement for one round trip during each 12 month fellowship period.

(c) In no case shall this amount exceed the cost of such travel by common carrier.

(d) The travel allowance shall not include reimbursement for the difference in cost between first-class accommodations and less-than-first-class accommodations, except when less than first-class accommodations are not reasonably available.

(20 U.S.C. 1134p(c))

### § 196.11 Institutional allowance.

The institution of higher education at which the fellow is pursuing his course of study will be paid 150 percent of the amount paid to the fellow (not including any amounts paid for dependents). This allowance is intended to cover tuition normally charged to individuals enrolled at that institution, and the allowance shall be reduced by any amount charged to the fellow for tuition.

(20 U.S.C. 1134p(b))

### § 196.12 Criteria for allocating fellowships to institutions of higher education.

The allocation of fellowships among institutions of higher education which apply for participation in this program and which offer a graduate program leading to an advanced or professional degree in the field of domestic mining or mineral and mineral fuel conservation will be based on the following criteria:

(a) Highest priority will be given to allocate fellowships to institutions of higher education where the fellowships will be used to support fellows currently receiving assistance under this Part who are not continuing their graduate studies, provided there is evidence that the individuals are making satisfactory progress

toward completing the course of study in which they are enrolled.

(b) The remaining fellowships will be allocated among institutions of higher education based on the degree to which there is demonstrated evidence that the educational program at that institution:

(1) Is designed to address one or both of the following national needs:

(i) The need for trained individuals to improve the technologies for the efficient extraction and processing of nonrenewable mineral and mineral fuels including the development of improved systems of underground, underwater, and surface mining techniques, improved methods to protect the health and safety of people working in extraction and processing operations, and improved methods to protect and restore the environment in extraction and processing operations;

(ii) The need for training individuals to develop ways to ensure the availability of non-renewable minerals and mineral fuels through improved exploration or discovery techniques, optimum recovery of existing mineral and mineral fuel reserves, improved utilization of processed minerals and mineral fuels through recycling technology, and improved understanding of mineral economics;

(2) Is of high quality in terms of course offerings;

(3) Leads to immediate career opportunities in domestic mining and mineral and mineral fuels industries, including careers in teaching in those subject areas at institutions of higher education;

(4) Offers an opportunity for relevant supervised practical, internship, or field experience;

(5) Has a program director and teaching staff which have the education, background, research interests, and experience to plan and implement a successful program of domestic mining and mineral and mineral fuel conservation education;

(6) Has the necessary institutional resources (facilities, equipment, library, etc.) to meet program objectives; and

(7) Has developed procedures to measure the effectiveness of the program.

(20 U.S.C. 1134n(c))

**§ 196.13 Reaward of vacated fellowships.**

If a fellowship is vacated prior to the end of a period for which it was awarded, the institution to which the fellowship is allocated may recommend to the Commissioner another individual to receive the fellowship. This individual must meet all the eligibility requirements set forth in § 196.6. The duration of a reawarded fellowship shall be for a period of graduate or professional work or research not in excess of the remainder of the period for which the fellowship is replaces was awarded.

(20 U.S.C. 1134n(b)(2))

**§ 196.14 Payment procedures.**

(a) The Commissioner will pay to the appproved institution of higher education the stipend, dependency allowance, travel allowance, and institutional allowance (calculated pursuant to §§ 196.8, 196.9, 196.10, and 196.11) for each fellowship allocated to that institution. The institution of higher education is responsible for disbursing all funds due the recipient.

(b) The timing of payments to fellows will be left to the discretion of each institution of higher education, although no fewer than two payments a year shall be made. Institutions are responsible for recovery of excess payments made to students who, for any reason, fail to complete the academic year for which they are registered.

(20 U.S.C. 1134p)

**§ 196.15 Criteria for determining financial need.**

In determining whether a student has financial need for the purposes of this fellowship program, the institution must consider the student's projected costs for the year including tuition, fees, books, materials, and supplies, plus other reasonable costs that a student might have for room and board in comparison with the student's resources (including available income and contribution from available assets).

(20 U.S.C. 1134n(a))

**§ 196.16 Records and reports.**

Each institution of higher education which receives an allocation of fellowships under this part, and each individual who is awarded a fellowship shall keep such records and submit such reports as are required by the Commissioner. Such reports shall include a certificate from an appropriate official at the institution of higher education, library, archive, or other research center approved by the Commissioner, stating that the fellow is making satisfactory progress in and is devoting essentially full time to the program for which the fellowship was awarded.

(20 U.S.C. 1134q(b))

[FR Doc.76-9610 Filed 4-2-76;8:45 am]

## DEPARTMENT OF TRANSPORTATION

### Coast Guard

### [ 46 CFR Parts 35, 58, 78, 97, 111, 112, 196 ]

[CGD 75-001]

### ELEVATORS AND DUMBWAITERS

### Adoption of ANSI Requirements With Modifications

The Coast Guard is considering amending its Marine Engineering regulations by adding design and construction requirements for elevators and dumbwaiters. The proposal would adopt the American National Standard Safety Code for Elevators, Dumbwaiters, Escalators, and Moving Walks (ANSI A17.1) with certain modifications necessary for vessel installations. The proposal also contains requirements for maintenance, testing, and inspection of elevators and dumbwaiters.

Interested persons may participate in this proposed rule making by submitting written data, views, or arguments to the Executive Secretary, Marine Safety Council (G-CMC/81), U.S. Coast Guard, Washington, D.C. 20590. Each person submitting a comment should include his name and address, identify the notice (75-001), and give reasons for any recommendations. Comments received before May 21, 1976, will be considered before final action is taken on this proposal. Copies of all written comments received will be available for examination by interested persons in room 8117, Department of Transportation, 400 Seventh Street SW., Washington, D.C. The proposal may be changed in light of comments received.

No hearing is contemplated but one may be held at a time and place set in a later notice in the FEDERAL REGISTER if requested by an interested person raising a genuine issue and desiring an opportunity to comment orally at a public hearing.

Current Coast Guard regulations do not contain extensive safety requirements for elevators and dumbwaiters. The regulations that specifically address these installations are limited to the following:

(a) 46 CFR 32.57-10(d)(2) (structural fire protection of hoistways).

(b) 46 CFR 72.05-10(d)-(g) (structural fire protection of hoistways).

(c) 46 CFR 92.07-10(d)(2) (structural fire protection of hoistways).

(d) 46 CFR 111.60-5(b) (elevator cable).

(e) 46 CFR 111.80-35 (control circuits and switches).

(f) 46 CFR 190.07-10(d)(2) (structural fire protection of hoistways).

Elevators and dumbwaiters are being installed on an increasing number of vessels and additional regulations are necessary to provide for the safety of these installations. Elevator and dumbwaiter installations on a vessel can pose a significant safety hazard to the vessel and its personnel if not properly designed, constructed, and maintained. This notice proposes to adopt most of the rules in ANSI A17.1 because of the excellent safety record of installations designed, constructed, and maintained in accordance with these rules.

The proposed design and construction regulations would apply to each elevator and dumbwaiter installation contracted for on or after the effective date of the regulations. The proposed regulations for inspection, maintenance, and testing, the regulations concerning ignition safety in § 58.60-31, and the rules in Parts I, II, III, and VII of ANSI A17.1 for hoistway and car door locks and for electric contacts, undercar safeties, and terminal stopping devices would also apply to existing elevators and dumbwaiters on vessels. The preface to ANSI A17.1 recommends that its rules for hoistway and car door locks and electric contacts, undercar safeties, and terminal stopping de-

vices be made applicable to existing elevators and dumbwaiters.

A discussion of the proposed design and construction rules follows:

1. Section 58.60–3(a) excludes the application of Rule 211.3 in ANSI A17.1, which requires emergency signal devices and certain other equipment for operation of elevators under emergency conditions. Most of these requirements have application only to buildings and are not suitable for shipboard installations. However, proposed § 58.60–11(d) requires that an elevator on a vessel have an emergency signal device that sounds in the vessel's main machinery control station and in the pilothouse.

2. Section 58.60–7 requires in part that each elevator and dumbwaiter have a certification from the manufacturer that the design and factory construction of the equipment comply with the proposed regulations. Adherence to the regulations during design and factory construction, as evidenced by the certification, should minimize or eliminate the need for making corrections during the Coast Guard's plan review process.

3. Section 58.60–9 in part requires each elevator, if its primary purpose is personnel transportation, to be a passenger elevator of the type described in ANSI A17.1. Passenger elevators are necessary on vessels because they provide a greater degree of safety to persons than freight elevators can provide.

4. Section 58.60–11(a) requires in part that each emergency exit from an elevator car have a means to open it from both inside and outside the car. The purpose of the rule is to allow vessel personnel to exit from the elevator if it stops because of a power failure on the vessel. The rule modifies ANSI A17.1 Rule 204.1e (item 3) which requires in part that the emergency exit be arranged so that it can be opened only from outside the car.

5. Section 58.60–11(b) provides in part that the emergency exit of an elevator must have a stop switch and that closing the exit must not be a means to reset the stop switch. These requirements are necessary to prevent renewed movement of the elevator after its occupants leave by the emergency exit.

6. Section 58.60–13 requires that each elevator have a loadweighing device that prevents movement of the elevator when the load exceeds 125 percent of its rated load. The purpose of the rule is to prevent an overload from occurring when transporting large pieces of machinery.

7. Section 58.60–15(a) requires that the control system for an elevator or dumbwaiter be designed to operate under specified conditions of voltage variation, frequency variation, and vibration. The specified conditions are the same as those contained in the American Bureau of Shipping Rules for Automatic and Remote Control Systems.

8. Section 58.60–15(b) prohibits the use of touch type (capacitive type) operating devices at elevator and dumbwaiter landings. The purpose of this prohibition is to prevent a car from being called to a landing by a fire in that location.

9. Sections 58.60–19 and –21 require each counterweight to have at least one counterweight safety and each elevator car and elevator counterweight to have at least one buffer. The requirement in ANSI A17.1 Rule 109.1 to have counterweight safeties and buffers applies only to certain elevators. However, these devices are necessary for each shipboard installation to prevent defective operation resulting in structural damage to the vessel.

10. The following list contains ANSI A17.1 rules that are affected by the proposed regulations:

(a) Rule 100.1(a)–(c) (deleted; see § 58.60–3(d) and § 58.60–5(a)).

(b) Rule 102.1a (deleted; see § 58.60–3(b)).

(c) Rule 109.1 (modified by § 58.60–19 and § 58.60–21).

(d) Rule 204.1e (item 3) (modified by § 58.60–11(a)).

(e) Rule 204.7(a) (modified by § 58.60–33(c)).

(f) Rule 205 (modified by § 58.60–33(b)).

(g) Rule 210.4 (deleted; see proposed replacement § 58.60–3(c) and § 58.60–5(b)).

(h) Rule 211.3 (deleted; see § 58.60–3(a) and § 58.60–11(d)).

This proposal is issued under the authority of 46 U.S.C. 375, 391a, 416, 481; 49 U.S.C. 1655(b); 49 CFR 1.46.

In consideration of the foregoing, it is proposed to amend Chapter I of Title 46, Code of Federal Regulations, as follows:

## PART 35—OPERATIONS

1. By adding a new § 35.01–55 to read as follows:

**§ 35.01–55 Maintenance, inspection, and tests of elevators and dumbwaiters. TB/ALL**

The master or person in charge of a vessel shall ensure that—

(a) The maintenance, tests, and inspections recommended by the American National Standard Safety Code for Elevators, Dumbwaiters, Escalators, and Moving Walks (ANSI A17.1) are performed on each elevator and dumbwaiter; and

(b) Records of all maintenance, inspection, and tests of each elevator and dumbwaiter—

(1) Are maintained;

(2) Show the dates of and the name(s) of the person(s) or company conducting the maintenance, inspection, and tests; and

(3) Are available to the marine inspector and are retained for the period of the current certificate of inspection of the vessel.

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## PART 58—MAIN AND AUXILIARY MACHINERY AND RELATED SYSTEMS

2. By adding a new Subpart 58.60 to reads as follows:

### Subpart 58.60—Elevators and Dumbwaiters

Sec.

58.60–1 Scope.
58.60–3 ANSI A17.1 Requirements.
58.60–5 Applicable requirements in other subparts.
58.60–7 Certification and plan submittal.
58.60–9 Elevators primarily used for personnel transportation.
58.60–11 Emergency exit, stop switch, lighting, and signal.
58.60–13 Load-weighing devices.
58.60–15 Control systems.
58.60–17 Hoistway door restraints.
58.60–19 Counterweight safeties.
58.60–21 Buffers.

ADDITIONAL REQUIREMENTS FOR CARGO HANDLING ROOM REQUIREMENTS

58.60–31 Ignition safety.
58.60–33 Miscellaneous.

**§ 58.60–1 Scope.**

(a) This subpart contains design and construction requirements for elevators and dumbwaiters on vessels.

(b) The regulations apply to each vessel elevator and dumbwaiter contracted for on or after [the effective date of these regulations]. Section 58.60–31 and the rules in Parts I, II, II, and VII of the American National Safety Code for Elevators, Dumbwaiters, Escalators, and Moving Walks (which is incorporated by reference in this subpart at § 58.60–3) pertaining to hoistway and car door locks and electric contacts, undercar safeties, and terminal stopping devices also apply to each elevator and dumbwaiter installed on a vessel or contracted for before [the effective date of these regulations].

**§ 58.60–3 ANSI A17.1 requirements.**

The design and construction of each elevator and dumbwaiter must comply with the American National Standard Safety Code for Elevators, Dumbwaiters, Escalators, and Moving Walks (ANSI A17.1) to the extent that it is consistent with this subpart, except the following requirements:

(a) Equipment requirements for operation of elevators and dumbwaiters under emergency conditions (ANSI A17.1 Rule 211.3).

(b) Prohibition concerning use of hoistways for wiring, raceways, and cables (ANSI A17.1 Rule 102.1a).

(c) Electrical equipment and wiring requirements (ANSI A17.1 Rule 210.4).

(d) Structural fire protection requirements (ANSI A17.1 Rule 100.1(a)–(c)).

**§ 58.60–5 Applicable requirements in other subparts.**

(a) Subchapters D, H, I, and U of this Chapter contain requirements pertaining to structural fire protection construction of elevators and dumbwaiters.

(b) Subchapter J (Electrical Engineering) of this Chapter contains design, construction, and installation requirements for elevators and dumbwaiters including requirements for the following components:

(1) Door locking devices and contacts.
(2) Emergency power supply.
(3) Motor controllers.
(4) Traveling cables.

**§ 58.60–7 Certification and plan submittal.**

(a) Each elevator and dumbwaiter must have a certification from the manufacturer that the design and factory construction of the equipment, including

all components, comply with this subpart.

(b) Details plans showing the design and construction of each elevator and dumbwaiter must be submitted for approval in accordance with the procedures in Subpart 50.20 of this subchapter. A copy of the manufacturer's certification must also be submitted. The plans must include hoistway and car construction plans that show the locations of safety devices, electrical schematics, electrical arrangement drawings, and hydraulic system plans. Each set of plans and drawings, except electrical schematics, must contain a bill of materials.

**§ 58.60–9 Elevators primarily used for personnel transportation.**

Each elevator, if its primary purpose is personnel transportation, must be a passenger elevator that is automatic and power operated. ("Passenger elevator" is defined in section 3 of the Introduction of ANSI A17.1.)

**§ 58.60–11 Emergency exit, stop switch, lighting, and signal.**

(a) Each emergency exit from an elevator car must have a means to open it from both inside and outside the car. The inside of each car must have a means to enable a person to pass through the emergency exit.

(b) Each elevator must have a stop switch that is activated by opening the emergency exit. The stop switch must prevent movement of the elevator until reset. Closing the emergency exit must not be a means to reset the stop switch.

(c) Each elevator car, except a cargo handling room elevator car that does not have lighting fixtures, and each hoistway must have emergency lighting.

(d) Each elevator must have an emergency signal device that can be activated from inside the elevator car. The signal device must be an alarm that is powered from the vessel's emergency power system. The alarm must sound in both the vessel's main machinery control station and in the pilothouse.

**§ 58.60–13 Load-weighing devices.**

Each elevator must have a load-weighing device that prevents movement of the elevator when its load exceeds 125 percent of its rated load.

**§ 58.60–15 Control systems.**

(a) Each control system of an elevator or dumbwaiter must be designed to operate under the following conditions:

(1) Voltage variations of plus or minus 10 percent of the system's power supply.

(2) Frequency variations of plus or minus 5 percent of the system's power supply.

(3) Vibratory frequencies of 5 to 15 Hz with single amplitudes of 0.7mm (0.030 in.) and frequencies of 15 to 25 Hz with single amplitudes of 0.5mm (0.020 in.).

(b) Operating controls of an elevator or dumbwaiter that are installed on a landing must not be touch type (capacitive type).

**§ 58.60–17 Hoistway door restraints.**

Each hoistway door of an elevator or dumbwaiter must have means to prevent movement, except when opening or closing in response to control signals, when the vessel is simultaneously in a 30 degree roll and a 10 degree pitch.

**§ 58.60–19 Counterweight safeties.**

Each counterweight of an elevator or dumbwaiter must have at least one counterweight safety.

**§ 58.60–21 Buffers.**

Each elevator car and each counterweight of an elevator must have at least one buffer.

ADDITIONAL REQUIREMENTS FOR CARGO HANDLING ROOM ELEVATORS

**§ 58.60–31 Ignition safety.**

(a) This section applies only to elevators in cargo handling rooms.

(b) Electrical circuitry of an elevator must be intrinsically safe. The term "intrinsically safe" is defined in Part 110 of this Chapter.

(c) Each metal to metal contact for an elevator must be nonsparking construction, except that a gate may have steel to steel contact. Plating must not be used to provide nonsparking construction.

(d) Each elevator component that can accumulate static charge must be grounded.

(e) Operation of an elevator car safety or counterweight safety must not increase temperatures in the cargo handling room to or above the lowest cargo ignition temperature of the cargoes that the vessel is certificated to carry.

(f) The driving motor shaft of an elevator must be encased at its point of entry into the cargo handling room by an oil reservoir gland seal.

(g) Each hoistway and each elevator car side and top must be made of expanded metal.

**§ 58.60–33 Miscellaneous.**

(a) An elevator hoistway in a cargo handling room must not be the only means of exit from the room.

(b) A type A safety of a cargo handling room elevator, when activated, must stop the elevator instantaneously or within a stopping distance that is not greater than the maximum stopping distance prescribed for a type B safety in Table 205.3 of ANSI A17.1.

(c) Each cargo handling room elevator car must have lighting fixtures unless the room lights provide lighting in the car.

## PART 78—OPERATIONS

3. By adding a new § 78.17–90 to read as follows:

**§ 78.17–90 Maintenance, inspection, and tests of elevators and dumbwaiters.**

The master or person in charge of a vessel shall ensure that—

(a) The maintenance, tests, and inspections recommended by the American National Standard Safety Code for Elevators, Dumbwaiters, Escalators, and Moving Walks (ANSI A17.1) are performed on each elevator and dumbwaiter; and

(b) Records of all maintenance, inspections, and tests of each elevator and dumbwaiter—

(1) Are maintained;

(2) Show the dates of and the name(s) of the person(s) or company conducting the maintenance, inspection, and tests; and

(3) Are available to the marine inspector and are retained for the period of the current certificate of inspection of the vessel.

## PART 97—OPERATIONS

4. By adding a new § 97.15–70 to read as follows:

**§ 97.15–70 Maintenance, inspection, and tests of elevators and dumbwaiters.**

The master or person in charge of a vessel shall ensure that—

(a) The maintenance, tests, and inspections recommended by the American National Standard Safety Code for Elevators, Dumbwaiters, Escalators, and Moving Walks (ANSI A17.1) are performed on each elevator and dumbwaiter; and

(b) Records of all maintenance, inspections, and tests of each elevator and dumbwaiter—

(1) Are maintained;

(2) Show the dates of and the name(s) of the person(s) or company conducting the maintenance, inspections, and tests; and

(3) Are available to the marine inspector and are retained for the period of the current certificate of inspection of the vessel.

## PART 111—ELECTRICAL SYSTEM—GENERAL REQUIREMENTS

5. By revising the second sentence of § 111.70–20(n) to read as follows:

**§ 111.70–20 Motor controllers, general requirements.**

* * * * *

(n) *Protection against low voltage.* * * * Each controller for an elevator motor and each conrtoller for an auxiliary that is vital to the operation of propulsion machinery and that does not pose a hazard upon automatic restart must have low voltage release. * * *

* * * * *

## PART 112—EMERGENCY LIGHTING AND POWER SYSTEM

6. By adding a new § 112.15–5(c) to read as follows:

**§ 112.15–5 Final emergency source loads.**

* * * * *

(c) Each elevator in a passenger vessel.

* * * * *

## PART 196—OPERATIONS

7. By adding a new § 196.15–70 to read as follows:

**§ 196.15–70 Maintenance, inspection, and tests of elevators and dumbwaiters.**

The master or person in charge of a vessel shall ensure that—

(a) The maintenance, tests, and inspections recommended by the American National Standard Safety Code for Elevators, Dumbwaiters, Escalators, and Moving Walks (ANSI A17.1) are performed on each elevator and dumbwaiter; and

(b) Records of all maintenance, inspections, and tests of each elevator and dumbwaiter—

(1) Are maintained;

(2) Show the dates of and the name(s) of the person(s) or company conducting the maintenance, inspections, and tests; and

(3) Are available to the marine inspector and are retained for the period of the current certificate of inspection of the vessel.

Dated: March 29, 1976.

W. M. BENKERT,
*Rear Admiral, U.S. Coast Guard, Chief, Office of Merchant Marine Safety.*

[FR Doc.76-9617 Filed 4-2-76;8:45 am]

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**[46 CFR Part 164]**

**[CGD 74-129]**

## NONCOMBUSTIBLE MATERIALS FOR MERCHANT VESSELS

### Procedures for Approval

The Coast Guard is considering amending the approval requirements for noncombustible materials used in merchant vessel construction to conform to Resolution A.270(VIII) of the Intergovernmental Maritime Consultative Organization (IMCO) adopted by IMCO on November 20, 1973.

Interested persons are invited to participate in this proposed rule making by submitting written views, data, or arguments to the Executive Secretary, Marine Safety Council (G-CMC/81), U.S. Coast Guard, Washington, D.C. 20590. Each person submitting a comment should include his name and address, identify this notice (CGD 74-129) and the specific section of the proposal to which his comment applies, and give the reasons for his comments. The proposal may be changed in light of the comments received.

All comments received before May 21, 1976, will be considered before final action is taken on the proposal. Copies of all written comments received will be available for examination by interested persons in Room 8117, Nassif Building, 400 Seventh Street SW., Washington, D.C. 20590.

No public hearing is planned but one may be held at a time and place to be set in a later notice in the Federal Register if requested in writing by an interested person raising a genuine issue, and desiring to comment orally at a public hearing.

The Coast Guard has participated in IMCO working sessions to develop an internationally acceptable test method for measuring the noncombustibility of merchant vessel construction materials. As a result of these efforts, IMCO has adopted Resolution A.270(VIII) which recommends a uniform procedure for testing materials.

This notice proposes to replace the test described in Subpart 164.009 with the uniform test developed by IMCO. Adoption of the IMCO test will facilitate the process of obtaining Coast Guard approval of noncombustible materials used in construction of foreign built vessels that are registered in the United States. The manufacturer in a country that adopts the IMCO test will be able to submit a material for Coast Guard approval with assurance that the tests and measurements performed are the same as those performed in his country.

Use of the IMCO test should not place a burden on manufacturers of noncombustible materials that currently have certificates of approval. Each of these materials should be able to qualify for renewal of its approval certificate under the proposed regulations. Mineral wool is the only known material which in general cannot pass the current test for approval but which will pass the IMCO test. The increase in internal temperature of mineral wool upon testing, as measured by the specimen thermocouple of the test furnace, is in most cases in excess of the 20° C limit specified in the current § 164.009–3(d)(5)(iii). However, the Coast Guard considers mineral wool to be acceptable for use in merchant vessel construction and there are several mineral wools that are presently approved by the Coast Guard.

Several amendments to the current test for approval in Subpart 164.009 are necessary to implement the IMCO resolution. The proposed revisions are as follows:

1. Change units of measurement and weight to the metric system.

2. Delete the reheating test in § 164.009–3(e) of the current regulations. The results of several years of testing show that materials that have passed the basic test have also passed the reheating test; accordingly, the second test is unnecessary.

3. Replace the existing specifications for the test furnace with specifications that conform to the IMCO recommendations. The IMCO specifications are an improvement over current specifications. The IMCO specifications add a specimen insertion device to ensure accurate positioning of the specimen in the furnace tube, and they add temperature control coils to provide a means to control energy input to the furnace.

4. Increase the number of specimens to be tested from 3 to 5 and change their dimensions and shape from a rectangle of 1½ x 1½ x 2 inches to a cylinder with a 45 mm diameter and a height of 50 mm.

5. Increase the length of time that specimens of a sample are conditioned before testing from 4 hours to 20 hours and reduce the conditioning temperature from 105° C to 60° C. The new conditioning times and temperatures will allow removal of excess moisture without significantly affecting the properties of the sample.

6. Modify the test procedure as follows:

a. Delete the airflow and vapor ignition requirements in § 164.009–3(d)(3) and (d)(4) of the current regulations. The revised furnace design makes these requirements unnecessary.

b. Extend the duration of heating from 15 minutes to 20 minutes.

c. Require that thermocouple readings be recorded at intervals of 10 seconds or less.

d. Require a periodic temperature calibration of the furnace.

7. Revise the pass/fail testing criteria as follows:

a. Delete the specimen thermocouple reading as a criterion for approval. However, the data will be compiled for use in determining whether materials tested in the future will have abnormally high internal temperatures during testing. If high temperatures that pose a safety hazard do occur, necessary amendments to the testing procedure will be made. Compilation of the data for observation purposes will not increase the cost of testing to the manufacturer.

b. Change the allowable temperature rise above the initial stabilized temperature measured by each thermocouple from 20° C to 50° C.

c. Replace the current flame emission requirements in § 164.009–3(d)(5)(i) (which provides that a specimen cannot flame during the test except for painted or paper coated surfaces during the first two minutes of the test) with a requirement that flaming during the test not exceed 10 seconds.

d. Delete the requirements concerning glow and flammable vapor emission in § 164.009–3(d)(5) of the current regulations.

8. Add a listing of the contents of the laboratory test report.

9. Delete the existing provisions in § 164.009–4 permitting a manufacturer to perform the test at a laboratory of his selection in lieu of a designated laboratory.

It should be noted that the description of the approval procedure in the proposed § 164.009–9 supplements the general approval procedures in Subpart 2.75 of Title 46, Code of Federal Regulations.

This proposal also contains several editorial changes made for purposes of clarification of Subpart 164.009 provisions.

This amendment is proposed under the authority of 46 USC 375, 390b, 391a, 416, and 481; 49 USC 1655(b)(1); E.O. 11239; E.O. 11382; 49 CFR 1.4(b) and 1.46.

In consideration of the foregoing, the Coast Guard proposes to amend Part 164 of Title 46, Code of Federal Regulations, by revising Subpart 164.009 to read as follows:

**Subpart 164.009—Noncombustible Materials for Merchant Vessels**


Sec.
164.009–1 General.
164.009–3 Applicable Documents.
164.009–5 Noncombustible materials not requiring specific approval.
164.009–7 Contents of application.
164.009–9 Procedure for approval.
164.009–11 Test apparatus.
164.009–13 Furnace calibration.
164.009–15 Test procedure.
164.009–17 Density measurement.
164.009–19 Measurement of moisture and volatile matter content.
164.009–21 Test report.
164.009–23 Factory inspection.
164.009–25 Marking.


AUTHORITY: R.S. 4405, as amended (46 USC 375), sec. 3, 70 Stat. 152 (46 USC 390b), R.S. 4417a, as amended (46 USC 391a), R.S. 4462, as amended (46 USC 416), R.S. 4488, as amended (46 USC 481), sec. 6(b)(1), 80 Stat. 937 (49 USC 1655(b)(1)); E.O. 11239, 30 FR 9671; E.O. 11382, 32 FR 16247; 49 CFR 1.4(b) and 1.46.

### § 164.009–1 General.

(a) This subpart contains—

(1) procedures for approval of noncombustible materials used in merchant vessel construction;

(2) the test and measurements required for approval of materials; and

(3) a list of noncombustible materials for which specific approval under this subpart is not required.

(b) The test and measurements described in this subpart are conducted by a laboratory designated by the Commandant. The laboratory designated for this purpose is the National Bureau of Standards, Washington, D.C. 20234.

### § 164.009–3 Applicable documents.

(a) References to the following documents are made in this subpart:

(1) *Federal Specification:* HH–M–351D Millboard, Asbestos, dated November 18, 1968, as amended on April 27, 1972.

(2) *ASTM Standard:* D–1571–73, Specification for Woven Asbestos Cloth, published in August, 1973.

(b) Federal Specification HH–M–351D may be purchased from the Business Service Center, General Services Administration, Washington, D.C. 20407. ASTM Standard D–1571–73 may be purchased from the American Society for Testing Materials, 1916 Race Street, Philadelphia, Pennsylvania 19103.

### § 164.009–5 Noncombustible materials not requiring specific approval.

The following noncombustible materials may be used in merchant vessel construction though not specifically approved under this subpart:

(a) Sheet glass, block glass, clay, ceramics ,and uncoated glass fibers.

(b) All metals, except magnesium and magnesium alloys.

(c) Portland cement, gypsum, and magnesite concretes having aggregates of sand, gravel, asbestos fibers, expanded vermiculite, expanded or vesicular slags, diatomaceous silica, perlite, or pumice.

(d) Asbestos millboard meeting the requirements of Federal Specification HH–M–351D.

(e) Woven asbestos cloth meeting the requirements for Grade AAA or AAAA asbestos in ASTM Standard D–1571–73.

(f) Woven, knitted, or needle punched glass fabric containing not more than 2.5 percent lubricant.

### § 164.009–7 Contents of application.

An application for approval of a material under this subpart must contain the following:

(a) The trade name of the material.

(b) The thickness or density, or both, of the material, or the range of thicknesses or densities, or both, of the material as manufactured.

(c) The composition of the material.

(d) The density and percentage of moisture and volatile matter of each component of the material.

(e) The address of the factory manufacturing the material.

(f) A sample representative of the material that is 305 mm long and 305 mm wide and that has a height equal to the largest thickness of the material as manufactured.

(g) If the applicant intends to observe the test and measurements of the sample, a statement to that effect.

(h) A commitment by the applicant to pay for the cost of the test and measurements when billed by the designated laboratory.

### § 164.009–9 Procedure for approval.

(a) An application for approval of a material under this subpart must be sent to the Chief, Merchant Marine Technical Division, whose address is Commandant (G–MMT–3/83), U.S. Coast Guard, Washington, D.C. 20590.

(b) The application is examined by the Coast Guard to determine the probability that the material meets the requirements for approval. The Coast Guard notifies the applicant of the results of the examination and of the sample size necessary for submission to the designated laboratory.

(c) The designated laboratory notifies the applicant of the time and place for submission and testing of the sample.

(d) The designated laboratory conducts the tests and measurements of the sample in accordance with the procedures in this subpart, prepares a test report, and sends four copies of the report to the Chief, Merchant Marine Technical Division. The applicant may observe the test and measurements.

(e) The Chief, Merchant Marine Technical Division, sends a copy of the test report to the applicant and advises him whether the material is approved. If the material is approved, an approval certificate is sent to the applicant.

### § 164.009–11 Furnace apparatus.

(a) The test furnace apparatus consists of a furnace tube, stabilizer, draft shield, furnace stand, temperature coil controls with a voltage stabilizer, specimen holder, specimen insertion device, and three thermocouples (a furnace thermocouple to measure furnace temperature, a surface thermocouple to measure temperature at the surface of a specimen, and a specimen thermocouple to measure temperature at the center of a specimen). A detailed plan of the construction and arrangement of the furnace apparatus may be obtained from the Chief, Merchant Marine Technical Division.

(b) Temperatures measured by the thermocouples are recorded by an instrument having a measuring range that corresponds to the temperature changes that occur during a furnace calibration or test. The temperature recording equipment is accurate to within at least 0.5 percent of temperatures recorded during a test.

### § 164.009–13 Furnace calibration.

A calibration is performed on each new furnace and on each existing furnace as often as necessary to ensure that the furnace is in good working order. In each calibration the energy input to the furnace is adjusted so that the furnace thermocouple gives a steady reading of 750±10° C. The wall temperature of the furnace tube is then measured by an optical micro-pyrometer at intervals of 10 mm on 3 equally spaced vertical axes. The furnace is correctly calibrated if the temperature of the furnace tube wall is between 825 and 875° C 50 mm above and below the midline of the wall and if the average wall temperature is approximately 850° C.

### § 164.009–15 Test procedure.

(a) *Preparation of specimens.* (1) The designated laboratory prepares 5 cylindrical specimens representative of the properties of the sample submitted for testing. The dimensions of each specimen are as follows:

| | |
|---|---|
| diameter: | $45^{+2}_{-0}$ mm |
| height: | 50±3 mm |
| volume: | 80±5 cm³ |

(2) If the height of the sample, except a composite material, is less than 47 mm, the specimens prepared consist of layers of the sample.

(3) If the sample is a composite material and has a height that is not 50±3 mm, the layers of the specimen prepared are proportional in thickness to the layers of the sample.

(4) The top and bottom faces of each specimen prepared are the faces of the material as manufactured.

(5) If it is not practicable to prepare a specimen by the procedures described in paragraphs (a)(2) through (a)(4) of this section, the test is performed on five specimens of each component of the sample made to the dimensions prescribed in paragraph (a)(1) of this section.

(b) *Conditioning of specimen.* Each specimen is conditioned for at least 20 hours in a ventilated oven maintained at 60±5° C and is then cooled to room temperature in a desiccator.

(c) *Weight of specimen.* The weight of each conditioned specimen after cooling is determined before it is tested.

(d) *Placement of specimen in holder.* After a specimen is conditioned and weighed, it is placed in the specimen holder. A specimen that is made of layers

of a composite material is held firmly together in the specimen holder.

(e) *Attachment of thermocouples.* After the specimen is placed in the specimen holder, the thermocouples are attached to the specimen as follows: A vertical hole with a diameter of 2 mm and a depth that is half the height of the specimen is made in the center of the top of the specimen. The specimen thermocouple is then inserted into the hole so that its hot junction is at the center of the specimen. The surface thermocouple is put in contact with the surface of the specimen at its mid-height.

(f) *Preparation of the apparatus.* The apparatus is examined to determine whether it is in good working order and to ensure that the equipment is protected against drafts and is not exposed to direct sunlight or artificial illumination. The furnace temperature is stabilized at 750° C±10° C and kept at that temperature for the duration of the test. The furnace temperature is stabilized when no adjustments are needed in the energy input to the furnace to keep the temperature constant.

(g) *Insertion of specimen.* After the furnace temperature is stabilized for at least 10 minutes, the specimen is inserted into the furnace. The insertion is completed within 5 seconds. The specimen is positioned so that the hot junction of the surface thermocouple is diametrically opposite the hot junction of the furnace thermocouple.

(h) *Heating period.* The heating period begins upon insertion of the specimen into the furnace and continues for 20 minutes, or until peak temperatures have passed.

(i) *Test observations.* Temperature measurements at each thermocopule are made at intervals of not more than 10 seconds during the heating period, and note is taken of the occurrence and duration of any flaming. At the end of the heating period, the specimen is removed from the furnace and weighed while still hot.

(j) *Test results.* Material is approved under this subpart if the test results of the sample submitted are within the following limits:

(1) The highest temperature recorded for each specimen during the test by the furnace thermocouple, when averaged with the highest temperatures recorded for the other specimens, is not more than 50° C above the stabilized furnace temperature.

(2) The highest temperature recorded for each specimen during the test by the surface thermocouple, when averaged with the highest temperatures recorded for the other specimens, is not more than 50° C above the stabilized furnace temperature.

(3) The duration of flaming of each specimen during the test, when averaged with duration of flaming recorded for the other specimens, is not more than 10 seconds.

(4) The average weight loss of the specimens after heating is not more than 50 percent of their average weight after conditioning.

**§ 164.009–17 Density measurement.**

(a) The measurements described in this section are made to determine the density of a sample.

(b) If the sample is a solid material, a specimen that has a length of 305 mm, a width of 305 mm, and thickness equal to that of the sample is prepared. The length and width are measured to the nearest 0.80 mm and the thickness to the nearest 0.25 mm. Allowance is made for any irregularity in the surfaces of the specimen. The average of at least four measurements of each dimension is determined.

(c) If the sample is fibrous insulation, a specimen is prepared from sheets of the sample submitted. The sample is a cube and each dimension is 305 mm±1.60 mm. The average of at least four measurements of each dimension is determined.

(d) The weight of a specimen is determined with a sensitive balance scale accurate to at least 0.5 percent of the weight of the specimen.

(e) The dimension and weight measurements of a specimen are made after it has been conditioned for at least one week, and for any additional time needed for the specimen to reach a constant weight, in an atmosphere that is 22.8°±2° C and 50 percent ±5 percent relative humidity.

**§ 164.009–19 Measurement of moisture and volatile matter content.**

(a) The measurements described in this section are made to determine the moisture and volatile matter content of a sample.

(b) A specimen cut from the density specimen of a sample is conditioned for at least one week, and for any additional time needed for the specimen to reach a constant weight, in an atmosphere that is 22.8° C±2° C, and 50 percent ±5 percent relative humidity. The conditioned specimen is then weighed and transferred to a previously weighed wide mouth weighing bottle that has a glass stopper. With the stopper removed, the bottle, stopper, and specimen are heated at 105°±5° C for four hours. After four hours, the stopper is inserted in the bottle and the bottle and sample are cooled and weighed.

(c) The content of moisture and volatile matter is the difference between the two weighings and is reported as a percentage of the weight of the conditioned specimen.

**§ 164.009–21 Laboratory report.**

The laboratory report of the test and measurements of a material contains the following:

(a) Name of the designated laboratory.

(b) Name of manufacturer of the material.

(c) Date of receipt of the material and dates of the test and measurements.

(d) Trade name of the material.

(e) Description of the material.

(f) Density of the sample.

(g) Percentage of moisture and volatile matter in the sample.

(h) Description of the specimens tested if the specimens are prepared from composite material.

(i) If the test was done on individual components of the sample, a description of the components.

(j) Test results including the following:

(1) Complete time and temperature data for each thermocouple.

(2) Each observation of flame emission and the time and duration of each emission.

**§ 164.009–23 Factory inspection.**

(a) The Coast Guard does not inspect noncombustible materials approved under this subpart on a regular schedule. However, the Commander of the Coast Guard District in which a factory is located may detail a marine inspector at any time to visit a factory where a noncombustible material is manufactured to conduct an inspection of the manufacturing and quality control procedures and to select representative samples of the material for examination or tests to verify that the material is as stated in the original application for approval. The manufacturer is advised in advance of the time of testing samples selected and may witness the tests upon request.

**§ 164.009–25 Marking.**

The manufacturer must mark each shipping container for an approved noncombustible material with the approval number and date of approval of the material.

Dated: March 29, 1976.

W. M. BENKERT,
*Rear Admiral, U.S. Coast Guard, Chief, Office of Merchant Marine Safety.*

[FR Doc.76–9618 Filed 4–2–76;8:45 am]

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**[ 33 CFR Part 166 ]**

[CGD 75–208]

## VAPOR RECOVERY SYSTEMS IN CARGO TRANSFER OPERATIONS

### Advance Notice of Proposed Rule Making

The Coast Guard is considering adding regulations to the Ports and Waterways Safety Regulations in Subchapter P of Title 33 of the Code of Federal Regulations. The amendments would establish a new Part 166 containing safety equipment requirements for vapor recovery systems (VRS) and operational requirements concerning the use of VRS equipment during vessel cargo loading and unloading operations at waterfront facilities.

Interested persons are invited to participate in this advance notice of proposed rule making by submitting comments in writing to the Executive Secretary, Marine Safety Council (G-CMC/81), U.S. Coast Guard, Washington, DC 20590. Each person submitting a comment should include his name and address, identify this notice (CGD 75–208) and specific subject matter in this notice to which his comment refers, and

give reasons in support of his comments. All comments received before May 21, 1976, will be considered before taking further action on this proposal. Copies of all written comments received will be available for examination by interested persons in Room 8117, Nassif Building, 400 Seventh Street, SW., Washington, D.C. If the Coast Guard determines after evaluation of comments received that it is in the public interest to proceed further with this rule making, a notice of proposed rule making will be issued.

Oral inquiries and communications concerning this advance notice may be directed to LTJG Woodrow Vaughn, U.S. Coast Guard Headquarters, Merchant Marine Technical Division of the Office of Merchant Marine Safety, Washington, D.C. 20590 (Telephone number: (202) 426-2160).

The Coast Guard has authority under Section 101 (6) and (7) and Section 104 of Title I of the Ports and Waterways Safety Act of 1972 (33 U.S.C. 1221, 1224) to establish safety equipment requirements and operational requirements for VRS at waterfront facilities. If as a result of this advance notice of proposed rule making the Coast Guard determines that VRS requirements applicable to vessels should be proposed in addition to requirements applicable to waterfront facilities, the vessel requirements would be issued under the authority of 46 U.S.C. 170, 375, 391a, and 416 and would be published in Title 46, Code of Federal Regulations.

This advance notice of proposed rule making is being issued to provide an early opportunity for public participation in the formulation of VRS rules. Comments and information obtained from this notice will supplement inquiries that have been made by the Coast Guard concerning VRS and will be helpful in identifying and selecting proposed VRS rules.

The Coast Guard has consulted with the Environmental Protection Agency and the Maritime Administration of the Department of Commerce concerning the issuance of this proposal. EPA has issued regulations concerning VRS that apply to the Houston-Galveston Intrastate Air Quality Control Region. The regulations are contained in 40 CFR 52.2287 and are currently under revision (see the FEDERAL REGISTER of October 10, 1975, at page 47765).

Comments on this notice are requested concerning the use of VRS, safety features of the equipment, hazards associated with the equipment and its use, and the requirements that should be imposed concerning the equipment, its use at waterfront facilities, and the hazards involved. Commenters should describe in their replies the type of system or systems to which their remarks are addressed.

The following subjects are of specific concern to the Coast Guard in this rule making:

a. Existing and contemplated equipment or measures needed to provide protection against static electrical discharges and other sources that could cause ignition of vapors in VRS.

b. Existing and contemplated VRS that can be used at waterfront facilities. (Please describe the equipment, operational procedures used and associated hazards, and specify whether the vapors that the system recovers are flammable, non-flammable, or inert vapors.)

c. Vessel to VRS couplings.

d. Monitoring equipment necessary for detecing VRS malfunctions such as escape of hazardous vapors and overpressurization of vessel cargo tanks during cargo transfer operations, and shutdown equipment necessary if the malfunction occurs.

e. Changes in cargo transfer operations that may be necessary to accommodate VRS such as restrictions on cargo transfer rates, pressures, and temperatures necessary to ensure safe operation and to prevent spills.

The Coast Guard welcomes any additional relevant suggestions on matters brought to its attention in this rule making.

(46 U.S.C. 170, 375, 391a, and 416; 33 U.S.C 1224; 49 CFR 1.46.)

W. M. BENKERT,
*Rear Admiral, U.S. Coast Guard, Chief, Office of Merchant Marine Safety.*

MARCH 30, 1976.

[FR Doc.76-9619 Filed 4-2-76;8:45 am]

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## Federal Aviation Administration

## [ 14 CFR Part 21 ]

[Docket No. 15532; Notice 76-8]

## ISSUANCE OF SPECIAL FLIGHT PERMITS WITH A CONTINUING AUTHORIZATION TO AIR TAXI OPERATORS OF LARGE AIRCRAFT

### Notice of Proposed Rule Making

The Federal Aviation Administration is considering amending § 21.197(c) of the Federal Aviation Regulations to permit air taxi operators of large aircraft to obtain a special flight permit with a continuing authorization for the purpose of flying their large aircraft that might not meet applicable airworthiness requirements, but are capable of safe flight, to a base where maintenance or alterations are to be performed.

Interested persons are invited to participate in this proposed rule-making by submitting such written data, views, or arguments as they may desire. Comunications should identify the FAA regulatory docket or notice number and be submitted in duplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attention: Rules Docket, AGC-24, 800 Independence Avenue, S.W., Washington, D.C. 20591. All comments received on or before June 4, 1976, will be considered by the Administrator before taking action on the proposed rule. The proposal contained in this notice may be changed in the light of comments received. All comments submitted will be available in the Rules Docket, both before and after the closing date for comments, for examination by interested persons.

Section 21.197(a) provides for the issuance of a special flight permit for an aircraft that might not meet applicable airworthiness requirements, but is capable of safe flight, for the purpose of flying the aircraft to a base where maintenance or alterations are to be performed. Section 21.197(c) provides, in pertinent part, for the issuance of a special flight permit with a continuing authorization to Part 121 and 127 certificate holders. These continuing authorizations eliminate the need for the certificate holders to apply for each special flight permit, individually. Authorizations issued pursuant to § 21.197(c), including any conditions and limitations associated with the authorization, are set forth in the certificate holder's operations specifications.

The purpose of § 21.197(c) is to eliminate the unnecessary burden, on Part 121 and 127 certificate holders and the FAA, of individually dealing with each of the relatively large number of special flight permits that those operators need for ferrying aircraft to bases where maintenance can be performed. By virtue of the continuous air-worthiness maintenance program used by these operators and their operations specifications, procedures can be established to provide for the issuance of special flight permits with continuing authorizations for such ferry flights while ensuring that the flights are conducted safely.

It has been brought to the attention of the FAA that certain air taxi operators of large aircraft also desire to obtain special flight permits with continuing authorizations. Under § 135.2, these operators must comply with the certification and operation requirements for supplemental air carriers as set forth in Part 121 unless compliance with the Part 121 rules applicable to domestic or flag air carriers is required under specified circumstances. In any event, large aircraft operated under the provision of § 135.2 must be maintained under a continuous airworthiness maintenance program and the operations conducted under § 135.2 must be covered in the certificate holder's operations specifications as provided in Part 121. Therefore, the reasons for providing for the issuance of special flight permits with continuing authorizations to Part 121 and 127 certificate holders are equally applicable to air taxi operators operating under the provisions of § 135.2 with respect to their large aircraft. Accordingly, it is proposed herein to amend § 21.197(c) to provide for the issuance of special flight permits with continuing authorizations to air taxi operators of large aircraft.

These amendments are proposed under the authority of sections 313(a), 601, 603, and 604 of the Federal Aviation Act of 1958 (49 U.S.C. 1354(a), 1421, 1423, and 1424) and Section 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).

In consideration of the foregoing, it is proposed to amend Part 21 of the Fed-

eral Aviation Regulations by revising § 21.197(c) to read as follows:

**§ 21.197 Special flight permits.**

* * * * *

(c) Upon application, as prescribed in § 121.79 or § 127.27 of this chapter, a special flight permit with a continuing authorization may be issued, for aircraft that may not meet applicable airworthiness requirements but are capable of safe flight, for the purpose of flying aircraft to a base where maintenance or alterations are to be performed. The permit issued under this paragraph may be issued to—

(1) Part 121 or 127 certificate holders; or

(2) Air taxi operators conducting operations with large aircraft under the provisions of § 135.2 of this chapter, for the aircraft used in those operations.

The permit issued under this paragraph is an authorization, including any conditions and limitations for flight, which is set forth in the certificate holder's operations specifications.

Issued in Washington, D.C. on March 26, 1976.

J. A. FERRARESE,
*Acting Director,*
*Flight Standards Service.*

[FR Doc.76-9440 Filed 4-2-76;8:45 am]

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## [ 14 CFR Parts 25, 91, 121 ]

[Docket No. 15534; Notice 76-9]

## IN-FLIGHT OVERBOARD LEAKAGE OF FLUIDS SUBJECT TO FREEZING

### Advance Notice of Proposed Rule Making

The FAA is considering rule making to establish type certification, maintenance, and equipment standards to prevent the occurrence of in-flight overboard leakage of fluids subject to freezing on transport category airplanes.

This advance notice of proposed rule making is being issued in accordance with the FAA's policy for the early institution of public proceedings in actions related to rule making. An "advance" notice is issued to invite early public participation in the identification and selection of a course or alternate courses of action with respect to a particular rule-making problem.

Interested persons are invited to participate in the rule making by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket or notice number and be submitted in duplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attention: Rules Docket, AGC-24, 800 Independence Avenue, S.W., Washington, D.C. 20591. Communications should be received on or before June 4, 1976, to assure proper consideration. All comments submitted will be available in the Rules Docket, both before and after the closing date for comments, for examination by interested persons. If it is determined to be in the public interest to proceed further, after consideration of the available data and comments received in response to this notice, a notice of proposed rule making will be issued.

A number of incidents have been reported of ice damage caused by the leakage of fluids subject to freezing from lavatory and potable water fill/drain systems. A number of these incidents have resulted in minor damage to the airplane or engines. Several incidents of damage to ground structures have also been reported. It is suspected that one incident resulted in the complete separation of an engine from an airplane.

The FAA has surveyed the existing air carrier maintenance programs with respect to lavatory and potable water fill/drain systems for adequacy and encouraged operators to develop and expand inspections of these systems. The survey included a review of lavatory and potable water ground handling systems, airplane equipment associated with the fill/drain systems, the personnel associated with system servicing, air carrier servicing procedures, and system seal replacement frequencies. The survey was conducted taking into consideration the kinds of overboard leakage of fluids known to have occurred in service.

The survey indicated that many operators had instituted corrective action by establishing programs for periodic inspections of fill/drain systems susceptible to leakage. Also, some operators have established new or revised training programs for their servicing personnel. However, there exists no uniformity in the application of corrective measures, and the problem continues to exist. Therefore, the agency believes that rule making is necessary to prevent the recurrence of ice formation and ice damage resulting from in-flight overboard leakage of fluids subject to freezing on transport category airplanes.

The FAA desires to review the technical and cost situations before making any specific rule-making proposals and believes it important in this regard to have available all relevant information that can be provided by the public. To this end, the FAA welcomes the participation of aircraft manufacturers, operators, and other interested persons and, by means of this advance notice, solicits the views of all interested persons on the following questions:

1. What incidents of ice damage caused by the leakage of fluids subject to freezing from airplane lavatory and potable water fill/drain systems are known to have occurred? Information relating to the causes of the leakage and the type and extent of ice damage should be submitted to aid in the evaluation of the incident.

2. What additional type certification standards are necessary to assure that future transport category airplanes are free of the problem of the leakage of fluids subject to freezing?

3. What modifications are necessary for the existing lavatory and potable water fill/drain airplane and ground support system to prevent in-flight leakage? Are the modifications necessary for only particular airplane types or for particular kinds of ground equipment?

4. What servicing procedures are needed to maintain the integrity of current systems? What compliance standards and inspection intervals would be necessary to ensure adequate system servicing?

5. What period of time should be permitted for accomplishing necessary modifications? Data substantiating the reasonableness of suggested time periods is solicited.

6. What cost/benefit considerations would be involved in accomplishing necessary corrective actions?

This advance notice of proposed rule making is issued under the authority of sections 313(a), 601, 603, and 604 of the Federal Aviation Act of 1958 (49 U.S.C. 1354(a), 1421, 1423, and 1424), and section 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).

Issued in Washington, D.C. on March 29, 1976.

J. A. FERRARESE,
*Acting Director,*
*Flight Standards Service.*

[FR Doc.76-9566 Filed 4-2-76;8:45 am]

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## [ 14 CFR Part 71 ]

[Airspace Docket No. 76-GL-7]

## FEDERAL AIRWAY

### Proposed Alteration

The Federal Aviation Administration (FAA) is considering an amendment to Part 71 of the Federal Aviation Regulations that would cap a segment of Federal Airway V-450 at 10,000 feet MSL only during those times that a Military Operations Area (MOA) southeast of Manitowoc, Wis., is in use.

Interested persons may participate in the proposed rule making by submitting such written data, views or arguments as they may desire. Communications should identify the airspace docket number and be submitted in triplicate to the Director, Great Lakes Region, Attention: Chief, Air Traffic Division, Federal Aviation Administration, 2300 East Devon, Des Plaines, Ill. 60018. All communications received on or before May 5, 1976 will be considered before action is taken on the proposed amendment. The proposal contained in this notice may be changed in the light of comments received.

An official docket will be available for examination by interested persons at the Federal Aviation Administration, Office of the Chief Counsel, Attention: Rules Docket, AGC-24, 800 Independence Avenue, S.W., Washington, D.C. 20591. An informal docket also will be available for examination at the office of the Regional Air Traffic Division Chief.

Request for copies of this Notice of Proposed Rule Making should be addressed to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Information Center, APA-230, 800 Independence Avenue, S.W., Washington, D.C. 20591.

The proposed action would amend V-450 to exclude the airspace above 10,000 feet MSL from 35 NM southeast of Green Bay, Wis., to 33 NM northwest of

Muskegon, Mich., only during the time that the Minnow MOA is in use (activated by NOTAM).

The Minnow MOA would be established as follows:

Boundary. Beginning at Lat. 44°13'00" N., Long. 87°29'00" W. to Lat. 44°01'00" N., Long. 86°56'00" W. to Lat. 43°41'00" N., Long. 86°38'00" W. to Lat. 43°17'00" N., Long. 86°44'00" W. to Lat. 43°14'00" N., Long. 87°36'00" W. to Lat. 43°24'00" N., Long. 87°40'00" W. to the point of beginning.

Altitudes. 10,000 feet MSL to but not including FL 180.

Time of use. Intermittent by NOTAM (normally daylight hours).

Controlling agency. Federal Aviation Administration, Chicago ARTC Center.

Scheduling agency. 128th TAC Control Sq. (ANG), General Mitchell Field, Milwaukee, Wis.

The proposed amendment to V-450 would provide airspace for a type of training that is not permitted in airways. MOAs are established and charted to identify portions of airspace which are used by the military for various flight training activities and to alert nonparticipating pilots to such activities. They do not impose any flight restrictions or communication requirements on Visual Flight Rule (VFR) flight operations. Instrument Flight Rule (IFR) flights will continue to be separated procedurally. The Minnow MOA will be used for combat maneuvers, aerobatics and intercepter training.

This amendment is proposed under the authority of Sec. 307(a) of the Federal Aviation Act of 1958 (49 U.S.C. 1348(a)) and Sec. 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).

Issued in Washington, D.C., on March 29, 1976.

WILLIAM E. BROADWATER,
*Chief, Airspace and Air Traffic Rules Division.*

[FR Doc.76-9565 Filed 4-2-76;8:45 am]

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## [14 CFR Part 71]

[Airspace Docket No. 76-SO-30]

### TRANSITION AREA

### Proposed Designation

The Federal Aviation Administration is considering an amendment to Part 71 of the Federal Aviation Regulations that would designate the Whiteville, N.C., transition area.

Interested persons may submit such written data, views or arguments as they may desire. Communications should be submitted in triplicate to the Federal Aviation Administration, Southern Region, Air Traffic Division, P.O. Box 20636, Atlanta, Ga. 30320. All communications received on or before May 5, 1976 will be considered before action is taken on the proposed amendment. No hearing is contemplated at this time, but arrangements for informal conferences with Federal Aviation Administration officials may be made by contacting the Chief, Airspace and Procedures Branch. Any data, views or arguments presented during such conferences must also be submitted in writing in accordance with this notice in order to become part of the record for consideration. The proposal contained in this notice may be changed in light of comments received.

The official docket will be available for examination by interested persons at the Federal Aviation Administration, Southern Region, Room 645, 3400 Whipple Street, East Point, Ga.

The Whiteville transition area would be designated as:

That airspace extending upwards from 700 feet above the surface within a 6.5-mile radius of Columbus County Municipal Airport (latitude 34°16'23" N., longitude 78°42'52" W.); within 3 miles each side of the 051° bearing from the Camp RBN (latitude 34°16'29" N., longitude 78°42'41" W.), extending from the 6.5-mile radius area to 8.5 miles northeast of the RBN.

The proposed designation is required to provide controlled airspace protection for IFR operations at Columbus County Municipal Airport. A prescribed instrument approach procedure to the airport, utilizing the Myrtle Beach VORTAC is proposed in conjunction with the designation of this transition area. In addition, a nonfederal nondirectional radio beacon is to be installed on the airport.

This amendment is proposed under the authority of Sec. 307(a) of the Federal Aviation Act of 1958 (49 U.S.C. 1348(a)) and of Sec. 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).

Issued in East Point, Ga., on March 23, 1976.

PHILLIP M. SWATEK,
*Director, Southern Region.*

[FR Doc.76-9437 Filed 4-2-76;8:45 am]

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## [14 CFR Part 71]

[Airspace Docket No. 76-SO-31]

### TRANSITION AREA

### Proposed Alteration

The Federal Aviation Administration is considering an amendment to Part 71 of the Federal Aviation Regulations that would alter the Brunswick, Ga., transition area.

Interested persons may submit such written data, views or arguments as they may desire. Communications should be submitted in triplicate to the Federal Aviation Administration, Southern Region, Air Traffic Division, P.O. Box 20636, Atlanta, Ga. 30320. All communications received on or before May 5, 1976 will be considered before action is taken on the proposed amendment. No hearing is contemplated at this time, but arrangements for informal conferences with Federal Aviation Administration officials may be made by contacting the Chief, Airspace and Procedures Branch. Any data, views or arguments, presented during such conferences must also be submitted in writing in accordance with this notice in order to become part of the record for consideration. The proposal contained in this notice may be changed in light of comments received.

The official docket will be available for examination by interested persons at the Federal Aviation Administration, Southern Region, Room 645, 3400 Whipple Street, East Point, Ga.

The Brunswick transition area described in § 71.181 (41 F.R. 440) would be amended as follows: "* * * long. 81°27'59" W.) * * *" would be deleted and "* * * long. 81°27'59" W.); within 3 miles each side of the Golden Isle localizer west course, extending from the 8.5-mile radius area to 8.5 miles west of the LOM * * *" would be substituted therefor.

The proposed alteration is required to provide controlled airspace protection of IFR aircraft executing the proposed ILS RWY 7 instrument approach procedure to Brunswick-Golden Isles Municipal Airport.

This amendment is proposed under the authority of Sec. 307(a) of the Federal Aviation Act of 1958 (49 U.S.C. 1348(a)) and of Sec. 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).

Issued in East Point, Ga., on March 23, 1976.

PHILLIP M. SWATEK,
*Director, Southern Region.*

[FR Doc.76-9438 Filed 4-2-76;8:45 am]

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## [14 CFR Part 73]

[Airspace Docket No. 76-SO-28]

### TEMPORARY RESTRICTED AREAS

### Proposed Designation

The Federal Aviation Administration (FAA) is considering an amendment to Part 73 of the Federal Aviation Regulations that would designate temporary restricted areas in the vicinity of Valparaiso, Fla. These temporary restricted areas would be used to encompass a portion of a joint military exercise "Brave Shield XV" to be conducted from October 11 through October 17, 1976.

Interested persons may participate in the proposed rule making by submitting such writen data, views or arguments as they may desire. Communications should identify the airspace docket number and be submitted in triplicate to the Director, Southern Region, Attention: Chief, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Ga. 30320. All communications received on or before May 5, 1976 will be considered before action is taken on the proposed amendment. The proposal contained in this notice may be changed in the light of comments received.

An official docket will be available for examination by interested persons at the Federal Aviation Administration, Office of the Chief Counsel, Attention: Rules Docket, AGC-24, 800 Independence Avenue, SW., Washington, D.C. 20591. An informal docket also will be available for examination at the office of the Regional Air Traffic Division Chief.

Request for copies of this Notice of Proposed Rule Making should be addressed to the Federal Aviation Administration, Office of Public Affairs, Atten-

tion: Public Information Center, APA-230, 800 Independence Avenue, S.W., Washington, D.C. 20591.

The United States Air Force has requested establishment of temporary restricted areas for Brave Shield XV which is a Joint Readiness Exercise (JRX) formulated to provide training for active and reserve component forces in all phases of joint ground and air operations through the complete spectrum of warfare. Blank small arms ammunition will be used throughout the exercise, which is scheduled from October 11 through October 17, 1976, at the Eglin Air Force Base Range Complex, Valparaiso, Fla. The exercise will be contained almost completely within existing special use airspace, but two small restricted areas will be required for expected spillouts of aircraft intending to operate within existing restricted areas. R-2911A would be designated contiguous to and north of existing R-2915A from 500' AGL to 3,000' AGL, and its size would be from 2 to 4 miles wide and 13 miles long. R-2911B would be triangular in shape and designated contiguous to and east of existing R-2914A from 1,000' AGL to 3,000' AGL. It's size would be an average of 6 miles wide and 16 miles long.

There will be approximately 132 tactical fighter aircraft, 10 reconaissance, 34 airlift, 90 rotary wing, and 38 other fixed-wing aircraft involved in this United States Readiness Command (USREDCOM) joint exercise. Participating aircraft would be conducting turn operations within R-2911A and R-2911B in order to gain more effective training in the existing restricted areas. Total air sorties are not expected to exceed 400 per day which will be mostly concentrated within the existing restricted areas. The two proposed additional restricted areas would be joint use and would provide an additional safety margin for exercise and non-participating aircraft.

A Tactical Air Control System (TACs) will be established for the control of exercise aircraft within designated airspace. While the TACs will control only participating aircraft, procedures can be established to accommodate to the maximum extent possible civil aviation interests so as not to cause undue hardships. Leased lines of communications will be utilized to accomplish the orderly and safe ingress/egress of both exercise air traffic and coordinated movement in and out of the exercise areas. No preplanned missions or operations will be conducted solely in the proposed R-2911A and R-2911B. Flight operations conducted outside the exercise area will continue to conform to established enroute procedures and control authority. The USAF Readiness Command is planning to meet with nonexercise aviation interests/agencies to discuss use of the proposed areas so as to allay possible objection and to solicit local support of the excercise.

The USAF has advised that this exercise would be in compliance with the National Environmental Policy Act of 1969. The military flight operations would be required to conform to the minimum safe altitudes as prescribed in Federal Aviation Regulations Part 91 with respect to providing altitude/distance separation from persons, assemblies, and property on the ground.

The proposed amendment would designate the following temporary restricted areas:

R-2911A

Boundaries. Beginning at Lat. 30°39'00" N., Long. 86°55'00" W., to Lat. 30°44'00" N., Long. 86°52'00" W., to Lat. 30°45'00" N., Long. 86°38'00" W., to Lat. 30°43'00" N., Long. 86°38'00" W., thence west along the northern boundary of Restricted Area R-2915A to point of beginning.

Designated altitudes. 500 to 3000 feet AGL.

Time of designation. 0600 to 1900 local time, daily, October 11-17, 1976.

Controlling agency. Federal Aviation Administration, Jacksonville ARTC Center.

Using agency. US Air Force Tactical Air Command/USAF Readiness Command (TAC/USAFRED), Langley AFB, Virginia.

R-2911B

Boundaries. Beginning at Lat. 30°41'00" N., Long. 86°05'00" W., to Lat. 30°41'00" N., Long. 85°56'00" W., to Lat 30°24'00" N., Long. 85°56'00" W., thence northwest along the eastern boundary of Restricted Area R-2914 to point of beginning.

Designated altitudes. 1000 to 3000 feet AGL.

Time of designation. 1201 through 2359 local time, daily, October 11-17, 1976.

Controlling agency. Federal Aviation Administration, Jacksonville ARTC Center.

Using agency. US Air Force Tactical Air Command/USAF Readiness Command (TAC/USAFRED), Langley AFB, Virginia.

This amendment is proposed under the authority of Sec. 307(a) of the Federal Aviation Act of 1958 (49 U.S.C. 1348(a)) and Sec. 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).

Issued in Washington, D.C., on March 30, 1976.

WILLIAM E. BROADWATER,
*Chief, Airspace and Air Traffic Rules Division.*

[FR Doc. 76-9564 Filed 4-2-76;8:45 am]

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## [ 14 CFR Part 75 ]

[Airspace Docket No. 76-SO-20]

## JET ROUTES

### Establishment and Alteration

The Federal Aviation Administration (FAA) is considering an amendment to Part 75 of the Federal Aviation Regulations that would designate J-99 from Augusta, Ga., to Louisville, Ky., via Knoxville, Tenn., and realign a segment of J-73 to extend from Tallahassee, Fla., to Nashville. Tenn., via LaGrange, Ga.

Interested persons may participate in the proposed rule making by submitting such written data, views or arguments as they may desire. Communications should identify the airspace docket number and be submitted in triplicate to the Director, Southern Region, Attention: Chief, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Ga. 30320. All communications received on or before May 5, 1976 will be considered before action is taken on the proposed amendment. The proposal contained in this notice may be changed in the light of comments received.

An official docket will be available for examination by interested persons at the Federal Aviation Administration, Office of the Chief Counsel, Attention: Rules Docket, AGC-24, 800 Independence Avenue, S.W., Washington, D.C. 20591. An informal docket also will be available for examination at the office of the Regional Air Traffic Division Chief. Request for copies of this Notice of Proposed Rule Making should be addressed to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Information Center, APA-230, 800 Independence Avenue, S.W., Washington, D.C. 20591.

The proposed amendment would designate J-99 to extend from Augusta to Louisville via Knoxville and redesignate a segment of J-73 to extend from Tallahassee via LaGrange and Nashville.

Although operational requirements are expected to limit the use of these routes to FL-330 and above for the foreseeable future, they would improve the north/south flow of traffic in this area. The high altitude route distances between northern and southern terminals would be reduced also.

This amendment is proposed under the authority of Sec. 307(a) of the Federal Aviation Act of 1958 (49 U.S.C. 1348(a)) and Sec. 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).

Issued in Washington, D.C., on March 26, 1976.

WILLIAM E. BROADWATER,
*Chief, Airspace and Air Traffic Rules Division.*

[FR Doc.76-9439 Filed 4-2-76;8:45 am]

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# FEDERAL DEPOSIT INSURANCE CORPORATION

## [ 12 CFR Part 329 ]

## INTEREST ON DEPOSITS

### Extension of Comment Period

This notice extends the period for comments in connection with the notice, published in the FEDERAL REGISTER on March 8, 1976 (41 FR 9896), proposing a rule restricting the payment of negotiated rates of interest on pooled time deposits of $100,000 or more. That notice stated that comments would be accepted until April 16, 1976.

The comment period in connection with the proposed rule is hereby extended to May 10, 1976.

By order of the Board of Directors, dated March 30, 1976.

FEDERAL DEPOSIT INSURANCE CORPORATION,
[SEAL] ALAN R. MILLER,
*Executive Secretary.*

[FR Doc.76-9581 Filed 4-2-76;8:45 am]

## VETERANS ADMINISTRATION

### [ 38 CFR Part 21 ]

### VETERANS EDUCATION

### Measurement of Courses; Other Technical Changes

The following regulatory changes are made in Part 21, Title 38, Code of Federal Regulations to clarify and update existing provisions.

Section 21.3041 is amended to clarify those situations when the ending date of a child's period of eligibility for educational assistance under chapter 35 may be extended by the time of Veterans Administration processing of an application.

Section 21.4131 is amended to accord the chapter 35 claimant full rights under 38 U.S.C., section 1712. An ambiguity in paragraph (d) of this section created by a recent change is also corrected.

Section 21.4203(f) is amended to clarify semantics and to demonstrate who is required to file quarterly certifications of attendance.

Section 21.4233(c)(1) is broadened to allow nonundergraduate course training in part by open circuit TV subject to certain limitations.

Section 21.4235(e) is changed to redesignate a job title.

Section 21.4271 is amended to differentiate between clock hours of attendance and clock hours of net instruction in accordance with 38 U.S.C. 1788.

Section 21.4272 is amended to provide that students receiving equal training receive equal benefits. It also provides that only fully accredited schools certify transferability of credit for "three letter schools."

Section 21.4274 is amended to clarify the degree referred to in the section.

Section 21.4279 is amended to correct the entitlement charge.

Section 21.4280 is amended to update the list of groups authorized to accredit schools per the Office of Education, Department of Health, Education, and Welfare.

In addition editorial changes are made to reflect that these provisions apply equally to male and female beneficiaries.

Interested persons are invited to submit written comments, suggestions or objections regarding the proposal to the Administrator of Veterans Affairs (271A), Veterans Administration, 810 Vermont Avenue, NW., Washington, DC 20420. All relevant material received before May 5, 1976 will be considered. All written comments received will be available for public inspection at the above address only between the hours of 8 a.m. and 4:30 p.m. Monday through Friday (except holidays), during the mentioned 30-day period and for 10 days thereafter. Any person visiting Central Office for the purpose of inspecting any such comments will be received by the Central Office Veterans Assistance Unit in room 132. Such visitors to any VA field station will be informed that records are available for inspection only in Central Office and furnished the address and the above room number.

Notice is also given that it is proposed to make these changes effective date of final approval.

1. In § 21.3041, paragraph (e)(2) is revised to read as follows:

**§ 21.3041 Periods of eligibility; child.**

* * * * *

(e) * * *

(2) Processing time: Extended by length of processing time, but not beyond age 31, § 21.3040(d). "Processing time" means the period of time which elapses between the eligible person's 18th birthday or the date of receipt of the application, whichever is later, and the date on which the program of education is approved. Such an extension shall only be made if Veterans Administration processing time has shortened the eligible person's period of eligibility or reduced the benefits otherwise payable.

* * * * *

2. In § 21.3042, paragraphs (a), (b) and (d) are revised to read as follows:

**§ 21.3042 Service with Armed Forces.**

(a) No educational assistance under chapter 35 may be provided an otherwise eligible person during any period he or she is on duty with the Armed Forces. See § 21.3021 (a) and (f). This does not apply to brief periods of active duty for training. See § 21.4135(n). (38 U.S.C. 1701(d)) For chapter 34 benefits see § 21.4235.

(b) If the eligible person served with the Armed Forces, his or her discharge or release from each period of service must have been under conditions other than dishonorable. (38 U.S.C. 1701(d))

* * * * *

(d) For the eligible child called to active duty after July 30, 1961, and before August 1, 1962, by (1) an order issued to him or her as a Reserve or (2) an extension of an enlistment, appointment or period of duty pursuant to section 2 of Public Law 87–117, 75 Stat. 242 ("Berlin Crisis"), the extended period under § 21.3041 will be further extended by the number of months and days served during such period.

3. Section 21.3043 is revised to read as follows:

**§ 21.3043 Suspension of program; child.**

For an eligible person who suspends his or her program due to conditions determined by the Veterans Administration to have been beyond his or her control the period of eligibility may, upon request, be extended by the number of months and days intervening the date the suspension began and the date the reason for suspension ceased to exist. The burden of proof is on the eligible person to establish that suspension of a program was due to conditions beyond his or her control. The period of suspension shall be conisdered to have ended as of the date of the person's first available opportunity to resume training after the condition which caused it ceased to exist. The following circumstances may be considered as beyond the eligible person's control:

(a) While in active pursuant of a program of education he or she is appointed by the responsible governing body of an established church, officially charged with the selection and designation of missionary representatives, in keeping with its traditional practice, to serve the church in an official missionary capacity and is thereby prevented from pursuit of his or her program of studies.

(b) Immediate family or financial obligations beyond his or her control require the eligible person to take employment, or otherwise preclude pursuit of his or her program.

(c) Unavoidable conditions arising in connection with the eligible person's employment which preclude pursuit of his or her program.

(d) Pursuit of his or her program is precluded because of the eligible person's own illness or illness or death in his or her immediate family.

(e) Active duty, including active duty for training in the Armed Forces.

4. In § 21.3044, paragraphs (b) and (c)(1) are revised:

**§ 21.3044 Entitlement.**

* * * * *

(b) The 36-month period of entitlement is any 36 months within the period of eligibility. The eligible person is not required to pursue his or her program in the period of 36 consecutive months.

(c) The 36-months limitation may be exceeded only in the following cases:

(1) Where no charge against entitlement is made based on a course or courses pursued by a wife, husband, widow, or widower under the Special Assistance for the Educationally Disadvantaged program. (See § 21.4237); or

* * * * *

5. In § 21.4131, paragraphs (a)(2) and (d) are revised to read as follows:

**§ 21.4131 Commencing dates.**

The commencing date of an award or increased award of educational assistance allowance will be determined under this section.

(a) * * *

(2) Date 1 year prior to date of receipt of the application or enrollment certification, whichever is later. (See §§ 21.1032 and 21.3032.)

* * * * *

(d) *Reopened application after abandment* (*§§ 21.1032 and 21.3032*). The date of receipt of application or enrollment certification, whichever is later, if pursuing an approved course.

* * * * *

6. In § 21.4203, paragraphs (e) and (f)(1) are revised to read as follows:

**§ 21.4203 Reports by schools; requirements.**

* * * * *

(e) *Correspondence courses.* Where the course in which a veteran is enrolled under 38 U.S.C. ch. 34 or a wife, husband, or widow or widower is enrolled under 38

U.S.C. ch. 35 is pursued exclusively by correspondence, the school will report by an endorsement on the veteran's or eligible wife's, husband's, widow's or widower's certification the number of lessons completed by the veteran, wife, husband, widow or widower and serviced by the school. Such reports will be submitted quarterly. (38 U.S.C. 1780)

(f) *Certification—(1) Courses not leading to a standard college degree.* A certification must be submitted quarterly for each veteran and eligible person enrolled in a course not leading to a standard college degree, even if the course is pursued on a quarter, semester or term basis or even if the course is measured on a credit-hour basis, except for those courses pursued on less than one-half time basis or by servicemen or servicewomen while on active duty, and except as provided in paragraphs (e) and (g) of this section. (See § 21.4204.) A report also will be required before release of the final allowance check. The report will consist of a certification containing the information required for release of payment, signed by the veteran or eligible person and the school on or after the final date of the reporting period. The date on which each person signed must be clearly shown. The only exception to the requirement of two signatures is a certification of interruption of training when the veteran or eligible person is not available for signature.

* * * * *

7. In § 21.4204, paragraph (a) is revised to read as follows:

**§ 21.4204 Periodic certifications.**

* * * * *

(a) *Reports by schools, veterans and eligible persons.* For a veteran or eligible person enrolled in a course which leads to a standard college degree, excepting those on active duty and veterans or eligible persons pursuing the course on a less than half-time basis there must be verification of continued enrollment in and pursuit of the course for the entire enrollment period. Verification of continued enrollment will be made by a Veterans Administration representative in direct contact with the school at least once a year and in the last month of enrollment if the enrollment period ends more than 3 months after the last verification. In the case of a veteran or eligible person who completed, interrupted or terminated his or her course, any communication from the student or other authorized person notifying the Veterans Administration of the veterans' or eligible person's completion of course as scheduled or earlier termination date, will be accepted to terminate payments accordingly. Reports by other veterans and eligible persons will be submitted in accordance with § 21.4203 (e), (f) and (g).

* * * * *

8. In § 21.4233, paragraph (c)(1) (introduction) is revised to read as follows:

**§ 21.4233 Combination.**

* * * * *

(c) *Television—(1) Open circuit telecast.* A program may be pursued in part by open circuit telecast when:

* * * * *

9. In § 21.4235, paragraph (e) is revised to read as follows:

**§ 21.4235 Predischarge Education Program (PREP) and Special Assistance for Educationally Disadvantaged Veterans; chapter 34.**

* * * * *

(e) *Certifications.* Certifications as to the serviceman's or servicewoman's need for deficiency and/or remedial courses in basic English language skills and mathematic skills under paragraph (a)(1) of this section may be made by either the service education officer, by a Veterans Administration counseling psychologist or by the educational institution administering the course or to which the student has made application for admission. Certifications as to the veteran's need for deficiency and/or remedial courses in basic English language skills under paragraph (a)(2) and (3) of this section may be made by a Veterans Administration counseling psychologist or by the educational institution administering the course or to which the student has made application for admission. Certifications as to need for other refresher, remedial and/or deficiency course requirements under paragraph (a)(1), (2) and (3) of this section are to be made by the educational institution administering the course which the student is preparing to enter, or to which the student has made application for admission.

* * * * *

10. In § 21.4271, paragraphs (a) and (b) are revised to read as follows:

**§ 21.4271 Trade or technical; high schools.**

(a) *Shop practice predominates.* Trade or technical courses, which include shop practice as an integral part of the course, will be measured on a basis of clock hours of attendance per week. This includes such courses under the supervision of a college or university where credit is not given towards a standard college degree.

(b) *Theoretical or classroom instruction predominates.* A technical course in which theoretical or classroom instruction constitutes more than 50 percent of the required hours per week, will be measured on the basis of clock hours of net instruction per week. This includes such courses given by a college or university for which credit is not granted towards a standard college degree.

* * * * *

11. In § 21.4272, the introductory portion preceding paragraph (a), paragraphs (a) through (e) and (f)(2) are revised to read as follows:

**§ 21.4272 Collegiate undergraduate; credit-hour basis.**

An undergraduate college level course in an institution of higher learning will be measured on a credit-hour basis provided all the conditions under paragraphs (a), (b), (c)(1) or (c)(2) of this section are met.

(a) *Degree courses; accredited or candidate.* The course is offered by a college or university and is accredited by a nationally recognized association for degree level programs or is offered by a college or university which is accredited or a "candidate for accreditation" by one of the nationally recognized regional accrediting associations.

(1) The course is offered on a semester- or quarter-hour basis, and

(2) The course leads to an associate, baccalaureate, or higher degree which is granted by the school offering the course.

(b) *Degree courses; nonaccredited.* The course is not accredited at a college degree level by a recognized accrediting association and is offered by a college or university which is not accredited or a recognized candidate for accreditation by one of the national recognized regional accrediting associations.

(1) The course is offered on a semester- or quarter-hour basis, and,

(2) The course leads to an associate, baccalaureate, or higher degree, which is granted by the school offering the degree under authority specifically conferred by a State education agency, and

(3) The school will furnish a letter from a State university or letters from three schools that are full members of a nationally recognized accrediting association certifying that credits have been accepted on transfer at full value without reservations, in partial fulfillment of the requirements for a baccalaureate or higher degree for at least three students within the last 5 years, and at least 40 percent of the subjects within each curriculum, desired to be measured on a credit-hour basis, shall have been so accepted by the certifying State university or each of the three accredited schools.

(c) *Nondegree courses—(1) Accredited school.* The nondegree course is offered by a degree granting college or university which is accredited as a degree granting school by a nationally recognized accrediting association, and

(i) The course is offered on a semester- or quarter-hour basis, and

(ii) The course requires not less than high school graduation or equivalent for admission, and

(iii) The school certifies that credit for the subjects within the curriculum, desired to be measured on a credit-hour basis, is granted upon transfer to the element of the school which offers an associate or higher degree, and credit is award at full value, i.e., credit hour for credit hour toward partial fulfillment of the requirements for an associate or higher degree, or

(2) *Nonaccredited school.* The nondegree course is offered by a degree grant-

ing college or university which is not accredited as a degree granting institution, and the school meets the conditions of paragraph (c)(1) (i), (ii) and (iii) of this section and furnishes proper certification for its degree courses to which the credits transfer as provided in paragraph (b)(3) of this section.

(d) *Courses; measurement equivalency.* Where a term is not a standard semester or quarter as defined in § 21.4200(b), the equivalent for full-time training will be measured by multiplying the credits to be earned in the session by 18 if credit is granted in semester hours, or by 12 if credit is granted in quarters, and dividing the product by the number of whole weeks in the session. The resulting quotient will be the semester hours on which educational assistance allowance will be computed using the criteria of § 21.4270 proper or the criteria of footnote 3 to that section, whichever is appropriate. In determining whole weeks for this formula, 3 days or less will be disregarded and 4 days or more will be considered a full week. In no case will a course be measured as full-time when less than 14 standard class sessions per week (or 12 standard class sessions if 12 credit hours is full time at the school) are required.

(e) *Credit courses; special.* Where the course is acceptable for credit but credit may not be awarded to the veteran or eligible person because he or she has not met college entrance requirements or for some other valid reason, the course will be measured the same as if it were pursued for credit provided the veteran or eligible person performs all of the work prescribed for other students who are enrolled for credit.

(f) *Noncredit deficiency courses.* * * *

(2) *Entitlement charge.* For awards to eligible children under chapter 35, the entitlement charge will be made on the same basis as measurement for payment purposes. For awards (under chapter 34 and for wives, husbands, widows and widowers under chapter 35, no entitlement charge will be made for any noncredit deficiency course on a secondary school level.

* * * * *

12. In § 21.4274, paragraph (b) is revised to read as follows:

**§ 21.4274 Law courses.**

* * * * *

(b) *Nonaccredited.* A law course leading to a professional law degree, completion of which will satisfy State educational requirements for admission to legal practice, pursued in a nonaccredited law school which requires for admission to the course at least 60 standard semester units of credit or the equivalent in quarter units of credit, will be assessed on the basis of 12 class sessions per week for full-time attendance. If the course does not meet these requirements it will be assessed on the basis of clock hours of attendance per week.

13. In § 21.4279, paragraph (b)(1) is revised to read as follows:

**§ 21.4279 Combination correspondence-residence program.**

* * * * *

(b) The rate of educational assistance allowance payable shall be computed as set forth in §§ 21.4270 and 21.4136(a).

(1) The changes for that portion of the program pursued exclusively by correspondence will be in accordance with § 21.4136(a) with 1 month of entitlement charged for each $270 of cost reimbursed.

* * * * *

14. In § 21.4280, paragraph (a)(1) is revised to read as follows:

**§ 21.4280 Independent study leading to a standard college degree.**

(a) An eligible veteran or person may receive an educational assistance allowance for pursuit of an independent study course under the following conditions:

(1) The course is offered by a college or university which is fully accredited by one of the regional accrediting agencies;

* * * * *

Approved: March 30, 1976.

By direction of the Administrator.

[SEAL] ODELL W. VAUGHN,
*Deputy Administrator.*

[FR Doc.76-9677 Filed 4-2-76;8:45 am]

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### [ 21 CFR Parts 1303 and 1304 ]

### QUOTAS

### Certification of Procurement of Quota

In recent months, the Drug Enforcement Administration has discovered a number of instances in which manufacturers who procure and use a basic class of a Schedule II bulk chemical for the purpose of manufacturing such chemical into dosage forms or other substances, have procured such Schedule II controlled substance without having been assigned a procurement quota authorizing them to do so.

Manufacturing quotas assigned to manufacturers of bulk chemicals in each class are directly related to the needs of the firms to which procurement quotas have been issued. Thus, if numerous firms (each without having applied for or having received a procurement quota) were to purchase small quantities of a particular basic class of Schedule II controlled substances in bulk, or if one firm (also without quota) were to purchase a large quantity of that same basic class in bulk, it is likely that the needs of those firms which have applied for and have been issued procurement quotas for that basic class might not be met from the remaining quantities of the substance which could be made available from bulk manufacturers and other legitimate sources. This would serve to frustrate the intent of Congress in enacting 21 U.S.C. 826, and would create the potential for unnecessary disturbances within the pharmaceutical manufacturing industry.

The United States is obligated to provide to the United Nations certain data which can be derived only from holders of individual manufacturing quotas and procurement quotas. If a firm has not applied for, or been issued, a procurement quota for a particular basic class of Schedule II substance, it is unlikely that DEA could otherwise obtain the required data on that basic class from that firm. Obviously, if DEA does not have this data, the data could not be officially reported to the United Nations, and the intent of the agreements creating these reporting obligations would be frustrated.

In an effort to encourage all legitimate manufacturers of dosage forms to comply with the requirements of the regulations pertaining to procurement quotas, DEA publishes this Notice of Proposed Rulemaking. The amendment proposed herein is designed to develop consistency within the industry and to further the intent of Congress in fairly and efficiently administering the quota system.

Therefore, pursuant to Section 306 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 826) and under the authority vested in the Attorney General by Sections 301 and 501(d) of the Act (21 U.S.C. 821 and 871(b)), and delegated to the Administrator of the Drug Enforcement Administration by Section 0.100 of Title 28, Code of Federal Regulations, the Administrator proposes regulations amending Parts 1303 and 1304 of Title 21 of the Code of Federal Regulations, as follows:

### PART 1303—QUOTAS

1. Section 1303.12 of Title 21, Code of Federal Regulations, is amended by the addition of a new paragraph (f) to read as follows:

**§ 1303.12 Procurement quotas.**

* * * * *

(f) Any person to whom a procurement quota has been issued, authorizing that person to procure and use a quantity of a basic class of controlled substances listed in Schedules I or II during the current calendar year, shall, at or before the time of giving an order to another manufacturer requiring the distribution of a quantity of such basic class, certify in writing to such other manufacturer that the quantity of such basic class ordered does not exceed the person's unused and available procurement quota of such basic class for the current calendar year. The written certification shall be executed by the same individual who signed the DEA (or BND) Form 222c transmitting the order. Manufacturers shall not fill an order from persons required to apply for a procurement quota under subsection (b) of this section unless the order is accompanied by a certification as required under this subsection. The certification re-

quired by this subsection shall be in the following form:

CERTIFICATION OF AVAILABLE PROCUREMENT QUOTA

.....
(Date)

.....

.....

.....
(Name and address of bulk manufacturer)

Re: Order Form No. .....
(Number of DEA (or BND) Form 222c)

DEAR SIR: The undersigned certifies that .....
(Name of person giving the order) is the holder of a procurement quota for calendar year .....
(Current year) for basic class .....
(Name of basic class), a basic class of controlled substance, in Schedule .....
(Appropriate schedule) and that the quantity of .....
(Name of basic class), in the amount of .....
(Amount expressed in grams), specified in the above-referenced order form does not exceed the unused and available procurement quota for .....
(Name of basic class) issued to .....
(Name of person giving the order) for .....
(Current year)

Sincerely,

.....
(Signature of person or attorney-in-fact)

* * * * *

## PART 1304—RECORDS AND REPORTS OF REGISTRANTS

2. Section 1304.22 of Title 21, Code of Federal Regulations, is amended by adding a new paragraph (a)(10) to read as follows:

**§ 1304.22 Records for manufacturers.**

* * * * *

(a) * * *

(10) The originals of all written certifications of available procurement quotas submitted by other persons (as required by § 1303.12(f) of this chapter) relating to each order requiring the distribution of a basic class of controlled substance listed in Schedule I or II.

* * * * *

All interested persons are invited to submit their comments and objections in writing regarding this proposal not later than May 10, 1976.

These comments or objections should state with particularity the issues concerning which the person desires to be heard. A person may object or comment on the proposals relating to either or both of the above amendments. Comments and objections should be submitted in quintuplicate to the DEA Federal Register Representative, Office of Chief Counsel, Drug Enforcement Administration, Room 1203, 1405 Eye Street NW., Washington, D.C. 20537.

In the event that comments or objections to these proposals raise one or more issues which the Administrator finds, in his sole discretion, to warrant a full adversary-type hearing, the Administrator shall order a public hearing in the FEDERAL REGISTER summarizing the issues to be heard and setting the time for the hearing.

Dated: March 30, 1976.

PETER B. BENSINGER,
*Administrator,*
*Drug Enforcement Administration.*

[FR Doc.76-9665 Filed 4-2-76;8:45 am]

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## [ 21 CFR Part 1311 ]

## CONTROLLED SUBSTANCES

### Registration of Importers and Exporters

The Drug Enforcement Administration (DEA), after due consideration, seeks the adoption of proposed regulations relating to the registration of importers and exporters under the Controlled Substances Import and Export Act. This Notice of Proposed Rulemaking is published to allow concerned parties to make comments and recommendations concerning this subject matter.

The existing regulations on this subject, especially as relating to controlled substances in scheduled III, IV, and V, have not addressed certain statutory requirements which are now included in the additions and amendments proposed in this Notice. The changes are designed to develop consistency between statutory sections and the corresponding implementing regulations, and to further the intent of Congress.

Applicants under the Import-Export Act's registration section pertaining to importers of controlled substances in schedules III, IV, and V (21 U.S.C. 958(c)) must generally satisfy the same requirements for registration that apply to domestic manufacturers (21 U.S.C. 823(d)). Under the authority of the Import-Export Act (21 U.S.C. 958(e)), DEA may promulgate regulations specifically relating to the registration of importers under 21 U.S.C. 958(c), and these regulations should, inter alia, serve to define and clarify the concept of "public interest" (21 U.S.C. 823(d)), especially in order to take into account factors uniquely relevant to the importation of narcotic drugs in schedules III, IV, and V.

It is clear that Congress intended to insure that any DEA-regulated domestic bulk manufacturer of a particular basic class of narcotic controlled substance in schedule I or II (which is contained in material, compounds, mixtures or preparations of narcotic controlled substances in schedules III, IV, or V) would not be placed at an unjust competitive disadvantage by having to compete with an influx of cheap and/or inferior imported narcotic drugs manufactured by foreign companies which are unencumbered by the security, recordkeeping, and quota requirements of the Controlled Substances Act (CSA). Congress, by including narcotic drugs in schedules III, IV, and V in the same category as controlled substances in schedules I and II for purposes of regulating the actual importation of such drugs (21 U.S.C. 952(a)(2)), implicitly recognized that the United States Government (through DEA) should consider, pursuant to 21 U.S.C. 823(d), the costs imposed by the CSA on a domestic manufacturer of a bulk chemical used in the manufacture of narcotic drugs listed in schedules III, IV, and V, as well as other cost-related factors (such as the existence of competitive restraints upon the bulk manufacturer as the general result of governmental regulations), prior to the authorization of registrations to import these drugs under 21 U.S.C. 958(c). The proposed regulations are consistent in this respect with the intent of Congress.

Generally, in the absence of proof that a person is the authorized holder of a registration under the CSA, the statutory burden of going forward with evidence with respect to such registration is on the applicant for such registration, 21 U.S.C. 885(b). By regulation, this burden has been made applicable only in cases involving application to be registered to manufacture, import or export controlled substances in schedule I or II; 21 CFR § 1301.55(a) and 21 CFR 1311.53(a). Likewise by regulation, in any other hearing for denial of a registration, the burden of proving that the requirements of the applicable statutory section are not satisfied falls upon DEA; 21 CFR § 1301.55(b) and 21 CFR 1311.53(b). It is now DEA's position that the existing regulation concerning burden of proof in a hearing on the denial of an application for registration to import or export narcotic drugs in schedules III, IV, and V (21 CFR 1311.53(b)) should be amended in order that it conform to the general statutory requirement. The proposed regulations do so.

Therefore, pursuant to Sections 303(d), 515(b), 1002(a)(2) and (b), and 1008(c) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 823(d), 21 U.S.C. 885(b), 21 U.S.C. 952(a)(2) and (b), and 21 U.S.C. 958(c)) and under the authority vested in the Attorney General by Sections 301, 501(b), 1008(e) and 1015 of the Act (21 U.S.C. 821, 871(b), 958(e) and 965), and delegated to the Administrator of the Drug Enforcement Administration by Section 0.100 of Title 28, Code of Federal Regulations, the Administrator proposes regulations amending Part 1311 of Title 21 of the Code of Federal Regulations as follows:

## PART 1311—REGISTRATION OF IMPORTERS AND EXPORTERS OF CONTROLLED SUBSTANCES

1. Section 1311.42 is amended by amending its section subtitle; redesignating paragraph (e) as paragraph (g); redesignating paragraph (f) as paragraph (h); amending the present paragraph (c) and redesignating the amended paragraph as paragraph (e); amending the present paragraph (d) and redesignating the amended paragraph as paragraph (f); and by adding two new paragraphs (c) and (d), as follows:

**§ 1311.42 Application for importation of controlled substances in schedules I and II; narcotic drugs in schedules III, IV and V; and nonnarcotic controlled substances in schedules III, IV and V.**

* * * * *

(c) The Administrator shall register an applicant to import narcotic drugs in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determinnig the public interest, the following factors shall be considered:

(1) Maintenance of effective controls against diversion of particular controlled substances and any narcotic drug in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) Compliance with applicable State and local law;

(3) Promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) Prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) Past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion;

(6) That the applicant will be permitted to import only:

(i) Such amounts of any narcotic drug listed in schedule III, IV, or V as the Administrator shall find to be necessary to provide for the medical, scientific, or other legitimate needs of the United States during an emergency in which domestic supplies of the basic class of narcotic controlled substance in schedule I or II contained in the material, compound, mixture or preparation sought to be imported are found by the Administrator to be inadequate; or

(ii) Such amounts of any narcotic drug listed in schedule III, IV, or V as the Administrator shall find to be necessary to provide for the medical, scientific, or other legitimate needs of the United States in any case in which the Administrator finds that competition among domestic manufacturers of the basic class of narcotic controlled substance in schedule I or II contained in the material, compound, mixture or preparation sought to be imported is inadequate and will not be rendered adequate by the registration of additional manufacturers under Section 303 of the Act (21 U.S.C. 823); or

(iii) Such amounts of any narcotic drug listed in schedule III, IV, or V as the Administrator shall find to be necessary to provide for ballistics and other analytical or scientific purposes; and

(7) Such other factors as may be relevant to and consistent with the public health and safety.

(d) The Administrator shall register an applicant to import non-narcotic controlled substances in schedule III, IV or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) Maintenance of effective controls against diversion of particular controlled substances and any non-narcotic controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) Compliance with applicable State and local law;

(3) Promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) Prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) Past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion;

(6) Such other factors as may be relevant to and consistent with the public health and safety.

(e) In determining whether the applicant can and will maintain effective controls against diversion within the meaning of paragraphs (b), (c), and (d), the Administrator shall consider among other factors:

(1) Compliance with the security requirements set forth in §§ 1301.71–1301.76 of this chapter; and

(2) Employment of security procedures to guard against in-transit losses within and without the jurisdiction of the United States.

(f) In determining whether competition among the domestic manufacturers of a controlled substance in schedule I or II, including a basic class of narcotic drug contained in any material, compound, mixture, or preparation in schedules III, IV, and V for which importation is requested, is adequate within the meaning of paragraphs (b) (1) and (6) (iii) and (c) (ii) of this section, as well as Section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)), the Administrator shall consider:

(1) The extent of price rigidity in the light of changes in (i) raw materials and other costs and (ii) conditions of supply and demand;

(2) The extent of service and quality competition among the domestic manufacturers for shares of the domestic market including (i) shifts in market shares and (ii) shifts in individual customers among domestic manufacturers;

(3) The existence of substantial differentials between (i) domestic prices and (ii) the higher of prices generally prevailing in foreign markets or the prices at which the applicant for registration to import is committed to undertake to provide such products in the domestic market in conformity with the Act. In determining the existence of substantial differentials hereunder, appropriate consideration should be given to any additional costs imposed on domestic manufacturers by the requirements of the Act and such other cost-related and other factors as the Administrator may deem relevant. In no event shall an importer's offering prices in the United States be considered if they are lower than those prevailing in the foreign market or markets from which the importer is obtaining his supply;

(4) The existence of competitive restraints imposed upon domestic manufacturers by governmental regulations; and

(5) Such other factors as may be relevant to the determinations required under this paragraph.

* * * * *

2. Section 1311.53 is amended by adding two new paragraphs (b) and (c) and by amending the present paragraph (c) and redesignating the amended paragraph as paragraph (d), as follows:

**§ 1311.53 Burden of proof.**

* * * * *

(b) At any hearing on the granting or denial of an applicant to be registered to import any narcotic drug listed in schedule III, IV, or V, or to export any narcotic drug in schedule III or IV, the applicant shall have the burden of proving that the requirements for each registration pursuant to Section 1008(c) of the Act (21 U.S.C. 958(c)) are satisfied.

(c) At any hearing on the granting or denial of an applicant to be registered to import or export any non-narcotic controlled substance in schedule III, IV, or V, the Administration shall have the burden of proving that the requirements for such registration pursuant to Section 1008(c) of the Act (21 U.S.C. 958(c)) are not satisfied.

(d) At any hearing for the revocation or suspension of a registration, the Administration shall have the burden of proving that the requirements for such revocation or suspension pursuant to section 304(a) of the Act (21 U.S.C. 824(a)) are satisfied.

* * * * *

All interested persons are invited to submit their comments and objections in writing regarding this proposal not later than May 10, 1976. These comments or objections should state with particularity the issues concerning which the person desires to be heard. A person may object or comment on the proposals relating to either or both of the above amendments. Comments and objections should be submitted in quintuplicate to the DEA Federal Register Representative, Office of Chief Counsel, Drug Enforcement Administration, Room 1203, 1405 Eye Street, N.W., Washington, D.C. 20537.

In the event that comments or objections to these proposals raise one or more issues which the Administrator finds, in his sole discretion, to warrant a full adversary-type hearing, the Administrator shall order a public hearing in the FEDERAL REGISTER summarizing the issues to be heard and setting the time for the hearing.

Dated: March 31, 1976.

PETER B. BENSINGER,
*Administrator,*
*Drug Enforcement Administration.*

[FR Doc.76-9664 Filed 4-2-76;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 COMMERCE

### National Oceanic and Atmospheric Administration

### PORPOISE

### Marine Mammals; Incidental Take

On December 5, 1975, the Director, National Marine Fisheries Service (NMFS), published notice (40 FR 56899) that after review of all materials submitted, and considering all arguments made on his proposal to reissue permits in certain commercial fishing operations to allow the incidental take of marine mammals in 1976, the NMFS would modify its original proposal (40 FR 41531, 9/8/75).

The decision was that a quota would not be imposed on January 1, 1976; however, a quota would be imposed later in 1976 if during the first part of the fishing season porpoise mortality, occurring in connection with U.S. tuna purse seine fishing, was projected to exceed 70 percent of the final estimated 1975 U.S. kill. Subsequent to that decision, at a public meeting, NMFS scientists discussed with representatives of the Marine Mammal Commission and others the methodology which would be used to compare the 1976 porpoise mortality with the 1975 mortality, in order to reach a decision regarding the quota. On the basis of such discussion, NMFS concluded that the comparison would be made on the basis of total U.S. incidental porpoise mortality estimated from observer data collected on fishing trips from January 1 through April 14 of each year (1975 and 1976). Data on porpoise mortality from observed fishing trips will be stratified by vessel classes and trip types. The estimates will be calculated on a kill-per-trip basis for completed trips and on a kill-per-day at sea basis for incomplete trips in order to provide the most accurate comparison between the two years.

Where data are missing, the kill-per-day at sea will be estimated on the basis of generally accepted statistical methodology. In order to meet the required reduction, porpoise mortality in 1976 must be equal to or less than 70 percent of the 1975 mortality calculated in the same manner. The estimated incidental porpoise mortality for 1975 through April 14 for U.S. flag purse seine vessels is 74,352. Therefore, the estimated porpoise mortality through April 14, 1976, must be equal to or less than 52,046 (70% of 74,352).

The following statement of methodology, which includes definitions, assumptions and the mathematical formulae, will be used to determine whether the stated reduction in porpoise mortality has been achieved during the first part of 1976, in order to determine whether or not a quota will be imposed.

I. *Definitions.* The following definitions are for terminology used in the methodology:

*Area Under Consideration*—The estimate is to be based on porpoise kill and tuna fishing only for the area bounded by 40° N latitude, 40° S latitude, 160° W longitude and the coastline of the North and South American continents.

*Days at Sea*—Days at sea are defined as the sum of the day of departure (or January 1 if departure occurred prior to that date), day of return and days in between minus any days spent in foreign ports, due to seizure by a foreign country. In the case of a vessel that is forced to spend time in a foreign port, the day that vessel was brought into the port and the day that it left are counted as days at sea.

*Vessel Trips*—A completed trip is any trip which departed on or after January 1, returned to port prior to April 15, and off-loaded any part of its catch. An incomplete trip is any other trip including those which had fish aboard as of January 1, those that were seized by a foreign country, those that remained at sea after April 14, or where the observer did not remain aboard the entire trip. In addition, a U.S. vessel is on an open season trip if it departed prior to closure of the open tuna season as defined by IATTC. In 1975, the season closed at 0001 on March 13. A U.S. vessel is on the last free trip if it was in port prior to the closure of the open season and left port within 30 days of the closure. A U.S. vessel is on a regulated inside trip if it is fishing inside the IATTC regulatory area (CYRA) after closure of the open season and does not qualify for a last free trip. A U.S. vessel is on a regulated outside trip if it is fishing west of the CYRA after closure of the open season.

II. *Data Sources.* Data on number of trips and days at sea for the U.S. purse seine fleet will be compiled from records maintained by the Southwest Regional Office of the National Marine Fisheries Service.

Data on porpoise kill per trip for completed trips and kill per day at sea, classified as either "prior to season closure" or "subsequent to season closure," for incomplete trips will be obtained from NMFS observer reports. For 1976, data from incomplete trips will be obtained through voluntary radio reporting from vessels with observers aboard.

Porpoises of "unknown" status will be prorated on a species basis to the categories of live, dead, and injured based on the proportions of these categories amongst animals of known status as in the past, for all trips in 1975, and for those trips in 1976, which are completed. For incomplete trips in 1976, only data involving known dead will be obtained by radio. A correction factor will be determined by the ratio-of-averages method from the data of completed trips in 1976, and applied to the data from incomplete trips in 1976.

Only data on dead animals (known dead and prorated to dead from unknown status) will be used (i.e., not including injured animals). As long as the same procedure is followed each year, this should have no effect on the comparison. Deletion of the estimated injured animals should improve the precision of the comparison.

III. *Inherent Assumptions.* Observer data are random and unbiased in that: Trip sampling is random, Sampling does not affect bahevior of sampled vessels relative to the fleet, Observer observations are reliable, and Unknown mortality rate due to injury remains constant for the 2 years under consideration.

IV. *Statistical Methodology.* The mathematical treatment of the data involves several formulae because data are obtained both from complete and incomplete trips at sea. Also, historical data reflect seasonal fishing variations as well as differences between vessel classes. Therefore, in order to make a valid comparison between the two periods, 1975 and 1976, a complex statistical treatment will be used as follows.

The data will be stratified into three vessel size classes and three trip types. If any of these nine cells are blank when all data are collected, appropriated ratios based on the average kill per day from adjacent cells will be used to fill the blank cells. If there is a missing complete trip cell, then the calculation of mortality will be based on kill per day rather than kill per trip for that cell. An example of filling missing cells is:

(a) given

| | | |
|---|---|---|
| $X_{11}$ | | $X_{13}$ |
| | $X_{22}$ | $X_{23}$ |
| $X_{31}$ | $X_{32}$ | $X_{33}$ |

where $X_{21}$ and $X_{12}$ are missing.

(b) $$\hat{X}_{21}=(X_{11}+X_{31}+X_{22}+X_{23})/4$$

(c) $$\hat{X}_{12}=(X_{22}+X_{32})\ (X_{11}+X_{13})/(\hat{X}_{21}+X_{31}+X_{23}+X_{33})$$

(d) $$\hat{X}_{21}=(X_{22}+X_{23})\ (X_{11}+X_{21})/(\hat{X}_{12}+X_{32}+X_{13}+X_{33})$$

(e) repeat (c) and (d) until $\hat{X}_{12}$ and $\hat{X}_{21}$ converge to stable values.

1. *Notation*

Let $i$=observed vessel trip,

$i=\begin{cases}1 \text{ for vessels} \leq 400 \text{ tons carrying capacity (Class I)}\\ 2 \text{ for vessels} > 400 \text{ tons, built before 1961 (Class II)}\\ 3 \text{ for vessels} > 400 \text{ tons, built after 1960 (Class III)}\end{cases}$

$k=\begin{cases}1 \text{ for complete trips (Trip type I)}\\ 2 \text{ for incomplete trips days at sea prior to season closure (Trip type II)}\\ 3 \text{ for incomplete trip days at sea from season closure through April 14. (Trip type III)}\end{cases}$

$l=\begin{cases}1 \text{ for 1975}\\ 2 \text{ for 1976,}\end{cases}$

$m_{ijkl}$=total deaths (known and prorated from unknown) porpoise of the $i$-th vessel-trip in the $j$-th vessel-class of the $k$-th trip type in the $l$-th year,

$m'_{ijkl}$=*known* porpoise deaths in $i$, $j$, $k$ and $l$,

$t_{jkl}$=number of observed vessel-trips in $j$, $k$, and $l$,

$T_{jkl}$=total number of complete vessel-trips by U.S.-flag purse seiners in $j$ and $l$,

$d_{ijkl}$=number of days at sea by the $i$-th vessel on an incomplete trip in $j$, $k$, and $l$,

$D_{jkl}$=number of days at sea by all U.S.-flag purse seiners on incomplete trips in $j$, $k$, and $l$,

$M_l$=estimated total incidental porpoise mortality on complete trips in year $l$,

$M^*_l$=estimated total incidental porpoise mortality on incomplete trips in year $l$,

$r$=ratio of total porpoise deaths (known and prorated from unknown status) to known porpoise mortality for complete trips in 1976.

2. *Calculation for Complete Trips*

$$\overline{m}_{ijkl}=\sum_i m_{ijkl}/t_{jkl}$$

$$M_l=\sum_j T_{jkl}\cdot\overline{m}_{jkl}$$

3. *Calculation for Incomplete Trips*

$$\overline{m}_{jkl}=\sum_i (m_{ijkl}/d_{ijkl})/t_{jkl}$$

$$\overline{m}'_{jkl}=\sum_i (m_{ijkl}/d_{ijkl})/t_{jkl}$$

$$M^*_l=\sum_k \sum_j (D_{jkl}\cdot\overline{m}_{jkl}$$

$$r=\sum_i \sum_j m_{ijkl}\Big/\sum_i \sum_j m'_{ijkl}$$

$$M^*_2=r\sum_k \sum_j (D_{jkl}\cdot\overline{m}'_{jkl})$$

4. *Comparison.* Mortality in 1976 to April 15 is represented by $(M_2+M^*_2)$. Mortality in 1976 must be equal to o less than 70 percent of the 1975 mortality $(M_1+M^*_1)$ therefore, the mathematical equation is:

$$(M_2+M^*_2)\leq 0.7\ (M_1+M^*_1)$$

5. *Mortality Estimate for 1975 through April 14.* The basic data for 1975 are given in the following tables:

TABLE 1.—*Data obtained from the 1975 observer program*

| Vessel class | Completed trips | | | | | Incomplete trips | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Kill per trip | | | Kill per day | | Jan. 1 to Mar. 12 | | | Mar. 13 to Apr. 14 | |
| | Observed vessels | Average | Coef. of variation | Average | Coef. of variation | Vessels | Kill per day, average | Coef. of variation | Vessels | Kill per day, average | Coef. of variation |
| I | 3 | 83.33 | 0.75 | 1.41 | 0.70 | 0 | | | 1 | 0 | |
| II | 0 | | | | | 1 | 4.55 | | 2 | 8.23 | 0.33 |
| III | 14 | 682.36 | .11 | 12.53 | .13 | 4 | 5.39 | 0.41 | 10 | 3.21 | .34 |

TABLE 2.—*Data on fishing trips by the U.S. fleet in early 1975* [1]

| Vessel class | Complete trips | Incomplete trips | | | |
|---|---|---|---|---|---|
| | | Jan. 1 to Mar. 12 | | Mar. 13 to Apr. 14 | |
| | | Trips | Days | Trips | Days |
| I | 20 | 3 | 50 | 17 | 249 |
| II | 14 | 4 | 182 | 18 | 329 |
| III | 64 | 22 | 753 | 75 | 1,591 |

[1] Source: Trip records of NMFS, Southwest Regional Office.

Six Class III vessels and one Class II vessel in the incomplete category were held in port by Ecuador. The days spent in port for this reason have been subtracted from the days at sea. We did not obtain observer estimates of kill per trip for complete trips of Class II vessels or kill per day for incomplete trips of Class I vessels during January 1 through March 12. We estimated the missing values as documented above. Kill per day for complete trips of Class II vessels is estimated to be 19.97. Kill per day for incomplete trips of Class I vessels during January 1 to March 12 is estimated to be 0.32. The total number of days at sea for Class II U.S. vessels on complete trips was 816.

An estimate of the porpoise mortality for each vessel class and "trip type" is obtained by multiplying the average kill rate (Table 1) by the total trips or days (Table 2) for the appropriate vessel class and trip type. For example, the 1975 estimated mortality of Class I vessels for complete trips is 1,667 (83.33 from Table 1×20 from Table 2), and the mortality of Class III vessels for incomplete trips (3/13–4/14) is 5,107 (3.21 from Table 1×1591 from Table 2). The results of all nine calculations are given in Table 3. The total estimated incidental porpoise mortality from January 1, 1975, through April 14, 1975, is 74,352 animals.

TABLE 3.—*Estimates of incidental porpoise mortality for 1975 through Apr. 14 for U.S.-flag purse seine vessels*

| Vessel class | Complete trips | Incomplete trips | | Total (Jan. 1 to Apr. 14) |
|---|---|---|---|---|
| | | Jan. 1 to Mar. 12 | Mar. 13 to Apr. 14 | |
| I | 1,667 | 16 | 0 | 1,683 |
| II | 16,296 | 828 | 2,708 | 19,832 |
| III | 43,671 | 4,059 | 5,107 | 52,837 |
| Total (Jan. 1 to Apr. 14) | 61,634 | 4,903 | 7,815 | 74,352 |

V. *Failure-to-Report Methodology.* The methodology is based upon voluntary radio reporting of observers at sea as of April 15 on incomplete trips. If any vessel fails to report, its kill per day will be

estimated by the previously discussed method for filling blank cells (Section IV). The estimated kill per day will be averaged with those of vessels which do report to determine the mean kill per day for the affected cell.

The procedures to be used to determine the level of a quota, if one is to be imposed, will be published in a separate FEDERAL REGISTER notice not later than May 1, 1976. The procedure to be used to determine the date when porpoise sets will be prohibited in connection with a quota also will be published at this time.

Dated: March 30, 1976.

ROBERT W. SCHONING,
*Director,*
*National Marine Fisheries Service.*

[FR Doc.76-9493 Filed 4-2-76;8:45 am]

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## Office of the Secretary

## VOLUNTARY LABELING PROGRAM FOR HOUSEHOLD APPLIANCES AND EQUIPMENT TO EFFECT ENERGY CONSERVATION AND VOLUNTARY PROGRAM FOR APPLIANCE EFFICIENCY

### Status of These Programs in View of the Energy Policy and Conservation Act

The purpose of this notice is to announce the status of the Voluntary Labeling Program for Household Appliances and Equipment to Effect Energy Conservation and the intentions of the Department of Commerce with respect thereto, and to announce the rescission of the Voluntary Program for Appliance Efficiency.

The Department of Commerce has been operating two voluntary energy conservation programs, the Voluntary Labeling Program for Household Appliances and Equipment to Effect Energy Conservation (15 CFR Part 9) and the Voluntary Program for Appliance Efficiency (40 FR 8846, March 3, 1975). Sections 321 to 339 of the Energy Policy and Conservation Act (P.L. 94-163) (the Act) mandate energy conservation programs in these same two areas and assign responsibility for their implementation to the Federal Energy Administration (FEA) and the Federal Trade Commission (FTC).

It is the position of the Department of Commerce, after consultation with the FEA and FTC, that the enactment of this legislation will operate to supplant the Department's two voluntary programs at such times as labeling rules and energy efficiency improvement targets are prescribed for similar products in accordance with the provisions of section 324 and section 325 of the Act. In view of this and certain new responsibilities given the Department's National Bureau of Standards (NBS) under section 323 of the Act, it is the determination of the Department that, to avoid confusion within industry and to direct the efforts of NBS in line with its new responsibilities, further efforts toward the development of final specifications and programs under the two voluntary programs shall hereby cease.

At the same time, it is the determination of the Department that it should continue to maintain and service the four specifications which have to date been issued in final under the Voluntary Labeling Program for Household Appliances and Equipment to Effect Energy Conservation. These four specifications cover room air conditioners, refrigerators, combination refrigerator-freezers, and freezers. These four specifications will remain in operation until supplanted by the prescription of labeling rules covering like appliances by the Federal Trade Commission, and manufacturers may continue to participate under these specifications until such time.

In accordance with the foregoing determination, the Department has published in the FEDERAL REGISTER on this date the updated Appendix A to Voluntary Energy Conservation Specification No. 1-74 for Room Air Conditioners, which contains values for cooling capacity ranges and energy efficiency ratio (EER) ranges for use on room air conditioner labels. The notice of the updated Appendix A appears immediately following this notice.

No programs had been issued in final under the Voluntary Program for Appliance Efficiency by the date of enactment of the Energy Policy and Conservation Act, and, accordingly, that program is hereby rescinded, effective immediately.

Issued: March 30, 1976.

BETSY ANCKER-JOHNSON, Ph.D.,
*Assistant Secretary for*
*Science and Technology.*

[FR Doc.76-9579 Filed 3-31-76;11:19 am]

## VOLUNTARY LABELING PROGRAM FOR HOUSEHOLD APPLIANCES AND EQUIPMENT TO EFFECT ENERGY CONSERVATION

### Room Air Conditioners Efficiency Ranges for Voluntary Energy Conservation Specification No. 1-74

On this date, the Department of Commerce has published in the FEDERAL REGISTER its determination that specifications which have previously been issued in final under the Voluntary Labeling Program for Household Applicances and Equipment to Effect Energy Conservation (15 CFR Part 9) will continue to be maintained and serviced until supplanted by the prescription of labeling rules covering like appliances by the Federal Trade Commission in accordance with section 324 of the Energy Policy and Conservation Act (P.L. 94-163). The notice of this determination appears immediately preceding this notice. The following information is therefore provided in accordance with the foregoing determination.

By notice published in the FEDERAL REGISTER May 1, 1974 (39 FR 15196), the Department announced the issuance of Voluntary Energy Conservation Specification No. 1-74, for Room Air Conditioners, under the Voluntary Labeling Program for Household Appliances and Equipmnt to Effect Energy Conservation.

In Voluntary Energy Conservation Specification No. 1-74, section 2.3 requires that Appendix A to that Specification, containing values for cooling capacity ranges and energy efficiency ratio (EER) ranges for use on labels, be updated on an annual basis. Section 10.0 of the Specification provides that Appendix A may be updated and published without first publishing notice of the proposed change in the FEDERAL REGISTER.

Accordingly, the updated Appendix A to Voluntary Energy Conservation Specification No. 1-74 is hereby issued. The new room air conditioner EER range values shall be utilized as prescribed in section 4.4.1 of that Specification.

Issued: March 30, 1976.

BETSY ANCKER-JOHNSON, Ph.D.,
*Assistant Secretary for*
*Science and Technology.*

The following is the revised Appendix A:

VOLUNTARY ENERGY CONSERVATION SPECIFICATION NO. 1-74, FOR ROOM AIR CONDITIONERS

APPENDIX A: COOLING CAPACITY RANGES AND EER RANGES FOR USE ON LABELS AND IN CATALOGS

REVISED JANUARY 1976

| RATED COOLING CAPACITY OF MODEL TO BE LABELED OR LISTED IN CATALOG, Btu PER HOUR | COOLING CAPACITY RANGE FOR USE ON LABEL OR IN CATALOG, Btu PER HOUR | EER RANGE FOR USE ON LABEL OR IN CATALOG, Btu PER WATT-HOUR | | | |
|---|---|---|---|---|---|
| | | WINDOW MODELS* | | THROUGH-WALL MODELS** | |
| | | 115 VOLT MODELS | HIGHER VOLTAGE MODELS | 115 VOLT MODELS | HIGHER VOLTAGE MODELS |
| UP TO 4799 | UP TO 5000 | 5.4 TO 8.8 | --- | 6.5 TO 6.5 | --- |
| 4 800 TO 5 199 | 4 500 TO 5 500 | 5.4 TO 8.8 | --- | 6.5 TO 6.5 | --- |
| 5 200 TO 5 799 | 5 000 TO 6 000 | 5.6 TO 8.8 | --- | 6.0 TO 7.0 | --- |
| 5 800 TO 6 199 | 5 500 TO 6 500 | 5.6 TO 9.3 | --- | 6.0 TO 7.7 | --- |
| 6 200 TO 6 799 | 6 000 TO 7 000 | 5.6 TO 10.5 | --- | 6.0 TO 10.5 | --- |
| 6 800 TO 7 199 | 6 500 TO 7 500 | 5.5 TO 10.5 | --- | 5.7 TO 10.5 | --- |
| 7 200 TO 7 799 | 7 000 TO 8 000 | 5.5 TO 9.5 | --- | 5.7 TO 9.3 | 5.3 TO 5.3 |
| 7 800 TO 8 199 | 7 500 TO 8 500 | 5.5 TO 9.9 | 5.6 TO 6.5 | 5.7 TO 9.5 | 5.3 TO 7.3 |
| 8 200 TO 8 799 | 8 000 TO 9 000 | 5.9 TO 10.5 | 5.6 TO 6.9 | 6.0 TO 9.5 | 5.1 TO 7.7 |
| 8 800 TO 9 199 | 8 500 TO 9 500 | 6.6 TO 10.7 | 5.6 TO 6.9 | 6.4 TO 10.7 | 5.1 TO 7.7 |
| 9 200 TO 9 799 | 9 000 TO 10 000 | 6.6 TO 11.6 | 5.6 TO 7.1 | 6.4 TO 11.5 | 5.1 TO 7.7 |
| 9 800 TO 10 199 | 9 500 TO 10 500 | 7.0 TO 11.6 | 5.6 TO 7.9 | 7.8 TO 11.5 | 5.4 TO 7.9 |
| 10 200 TO 10 799 | 10 000 TO 11 000 | 7.2 TO 11.6 | 5.6 TO 8.0 | 7.8 TO 7.8 | 5.5 TO 8.0 |
| 10 800 TO 11 199 | 10 500 TO 11 500 | 7.6 TO 8.5 | 5.8 TO 8.0 | --- | 5.5 TO 8.0 |
| 11 200 TO 11 799 | 11 000 TO 12 000 | 8.0 TO 8.8 | 5.7 TO 8.2 | --- | 5.5 TO 6.9 |
| 11 800 TO 12 199 | 11 500 TO 12 500 | 8.3 TO 9.1 | 5.0 TO 8.2 | 9.1 TO 9.1 | 5.5 TO 7.8 |
| 12 200 TO 12 799 | 12 000 TO 13 000 | 8.7 TO 9.6 | 5.0 TO 8.2 | 9.1 TO 9.1 | 5.7 TO 8.2 |
| 12 800 TO 13 199 | 12 500 TO 13 500 | 9.5 TO 10.0 | 5.0 TO 8.5 | 9.6 TO 9.6 | 4.8 TO 8.5 |
| 13 200 TO 13 799 | 13 000 TO 14 000 | 9.5 TO 10.2 | 5.1 TO 8.5 | 9.6 TO 10.2 | 4.8 TO 8.5 |
| 13 800 TO 14 199 | 13 500 TO 14 500 | 10.0 TO 10.2 | 5.1 TO 8.3 | 10.2 TO 10.2 | 4.8 TO 5.7 |
| 14 200 TO 14 799 | 14 000 TO 15 000 | 10.1 TO 10.2 | 5.1 TO 7.7 | 10.2 TO 10.2 | 5.1 TO 6.7 |
| 14 800 TO 15 199 | 14 500 TO 15 500 | --- | 5.4 TO 9.3 | --- | 5.1 TO 7.8 |
| 15 200 TO 15 799 | 15 000 TO 16 000 | --- | 5.4 TO 9.5 | --- | 5.4 TO 8.0 |
| 15 800 TO 16 499 | 15 500 TO 16 500 | --- | 5.8 TO 9.5 | --- | 5.5 TO 8.2 |
| 16 500 TO 17 499 | 16 200 TO 17 800 | --- | 5.8 TO 8.9 | --- | 5.8 TO 8.2 |
| 17 500 TO 18 499 | 17 200 TO 18 800 | --- | 6.0 TO 9.3 | --- | 6.5 TO 9.0 |
| 18 500 TO 19 499 | 18 200 TO 19 800 | --- | 6.0 TO 9.3 | --- | 7.1 TO 9.3 |
| 19 500 TO 20 499 | 19 200 TO 20 800 | --- | 6.2 TO 7.4 | --- | 6.3 TO 7.2 |
| 20 500 TO 21 499 | 20 200 TO 21 800 | --- | 6.4 TO 7.5 | --- | 6.7 TO 6.7 |
| 21 500 TO 22 499 | 21 200 TO 22 800 | --- | 6.3 TO 7.7 | --- | --- |
| 22 500 TO 24 499 | 22 000 TO 25 000 | --- | 6.0 TO 9.4 | --- | 6.5 TO 8.0 |
| 24 500 TO 26 499 | 24 000 TO 27 000 | --- | 5.9 TO 9.4 | --- | 6.7 TO 7.3 |
| 26 500 TO 28 499 | 26 000 TO 29 000 | --- | 5.9 TO 8.1 | --- | 6.7 TO 7.5 |
| 28 500 TO 30 499 | 28 000 TO 31 000 | --- | 6.0 TO 7.8 | --- | --- |
| 30 500 TO 33 499 | 30 000 TO 34 500 | --- | 6.0 TO 7.5 | --- | 6.2 TO 6.3 |
| 33 500 TO 36 000 | 32 500 TO 36 000 | --- | 6.2 TO 7.1 | --- | 6.2 TO 6.3 |

NOTE: Includes only units operating on 60-hertz electrical service.
*Includes EER ratings of all window models as defined in Section 3.5, Voluntary Energy Conservation Specification No. 1-74.
**Includes EER ratings of all through-wall models as defined in Section 3.6, Voluntary Energy Conservation Specification No. 1-74, plus EER ratings of window models suitable for mounting through a wall.

[FR Doc.76-9580 Filed 3-31-76;11:19 am]

## DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

### Center for Disease Control

### OCCUPATIONAL SAFETY AND HEALTH

### Request for Information on Personal Protective Equipment

Section 22(c) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 671(c)) authorizes the National Institute for Occupational Safety and Health (NIOSH) to develop and establish recommended occupational safety and health standards and to perform all functions of the Secretary of Health, Education, and Welfare under sections 20 and 21 of the Act. Section 21(a)(2) of the Act (29 U.S.C. 670(a)(2)) provides for the conduct of informational programs on the importance of and proper use of adequate safety and health equipment.

In order to carry out these mandates, the Institute has need for specific technical data regarding the performance of industrial personal protective equipment including, but not limited to the following types of equipment:

Head Protective Equipment
Eye and Face Protective Equipment
Hearing Protective Equipment
Foot and Toe Protective Equipment
Respiratory Protective Equipment
Hand Protective Equipment
Body Protective Equipment

Of particular interest is information dealing with equipment failure or defects that would indicate the need for improved standards or test procedures. Both laboratory and workplace data are needed for review and evaluation to better enable NIOSH to develop recommendations for personal protective equipment in criteria documents and to plan and conduct necessary research. Specific suggestions for improved standards or test procedures are also solicited by this request.

Any person having information or data relevant to the performance of personal protective equipment is requested to submit such information, with accompanying documentation, to the Associate Director, Appalachian Laboratory for Occupational Safety and Health, NIOSH, 944 Chestnut Ridge Road, Morgantown, WV 26505, within 60 days.

All information received in response to this request will be available for public inspection at the foregoing address during regular business hours.

Dated: March 30, 1976.

JOHN F. FINKLEA,
*Director, National Institute for Occupational Safety and Health.*

[FR Doc.76-9582 Filed 4-2-76;8:45 am]

Food and Drug Administration

[Docket No. 76N-0064]

## DRUG PRODUCTS CONTAINING PAPAVERINE OR ETHAVERINE, AND SIMILAR OR RELATED DRUGS

### Request for Data on Safety, Effectiveness, and Legal Status

Drug products containing papaverine or ethaverine have been used for many years for the relief of spasm in certain blood vessels of the body. These products have never been evaluated in accordance with the new drug provisions of the Federal Food, Drug, and Cosmetic Act. Whether there is adequate support for the claims being made for such products is open to serious question. In order to determine the scientific validity and the legality of the claims being made for such drugs and their legal status ("new drug," "not new drugs," or "grandfathered drugs") the Commissioner of Food and Drugs is requesting manufacturers to submit data to support all of the claimed uses and other pertinent information. Data are requested for all marketed dosage forms and are to be submitted by July 6, 1976.

The Food and Drug Administration has reviewed the labeling and advertising for several of these products, some of which are in controlled release dosage forms, and finds what may be unsubstantiated claims which purport that the products are effective for nearly any condition involving impaired circulation. Examples of such claims are: vascular spasm associated with acute myocardial infarction; angina pectoris; peripheral and pulmonary embolism; ureteral colic; biliary colic; gastrointestinal colic; bronchial spasm; preservation of cerebral circulation; blockage of vasospasm that can result in neurologic damage; relief of and reduction of symptoms after cerebral damage.

Some manufacturers may contend that their products are generally recognized as safe and effective within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act and therefore are not new drugs, or that they are exempt from part or all of the new drug provisions of the act pursuant to the exemption for products marketed prior to June 25, 1938, contained in section 201 (p) of the act, or pursuant to section 107(c) of the Drug Amendments of 1962 (the "grandfather" clauses). It is the manufacturer's responsibility to prove any such contention. Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645 (1973); U.S.V. Pharmaceutical Corp. v. Weinberger, 412 U.S. 655 (1973); see also 21 CFR 314.200(e) (1) and (2).

To resolve the issues of safety and effectiveness of these products and to facilitate the determination of the legal status of all such drug products under the act, the Commissioner requests manufacturers, packers, and distributors to submit to the Food and Drug Administration, on or before July 6, 1976, data that support all uses claimed for such products and protocols and expected completion dates of ongoing and planned studies as well as evidence to support any other contention.

This notice applies not only to papaverine and ethaverine, but to all drugs, not the subject of approved new drug applications, which are related or similar to papaverine or ethaverine, as defined in 21 CFR 310.6. It is the responsibility of every drug manufacturer, packer, and distributor to determine whether this notice is applicable to any drug product they manufacture, pack, or distribute. Any person may request an opinion of the applicability of this notice to a specific drug product he manufactures or distributes that may be related or similar to papaverine or ethaverine by writing to the Food and Drug Administration, Bureau of Drugs, Division of Drug Labeling Compliance (HFD-310), 5600 Fishers Lane, Rockville, MD 20852.

A submission contending that a drug product is generally recognized as safe and effective within the meaning of section 201(p) of the act must consist of the same quantity and quality of scientific evidence as is required to obtain approval of a new drug application unless a waiver has been obtained from such requirement for effectiveness (as provided in 21 CFR 314.111(a)(5)) and/or safety for good cause shown. Such submission shall be in the format and with the analyses required by 21 CFR 314.200 (d). General recognition of safety and effectiveness shall ordinarily be based upon objective and well-controlled published studies which may be corroborated by unpublished studies and other data and information.

A contention that a drug product is exempt from part or all of the new drug provisions of the act pursuant to the exemption for products marketed prior to June 25, 1938, contained in section 201 (p) of the act, or pursuant to section 107(c) of the Drug Amendments of 1962, shall be supported by submission of evidence of past and present quantitative formulas, labeling, and evidence of marketing on which reliance is made for such contention. Such formulas, labeling, and evidence of marketing shall be submitted in the format described in 21 CFR 314.200(e).

A contention that a drug product is not a new drug for any other reason must be supported by submission of such factual records, data, and information as is necessary and appropriate to support such contention. In particular, no contention that a drug product is generally recognized as effective will be acceptable unless, at a minimum, it is supported by adequate and well-controlled studies as described in section 505(d) of the act (21 U.S.C. 355(d)) and 21 CFR 314.111(a)(5). Weinberger v. Hynson, Westcott, and Dunning, 419 U.S. 609, 629 (1973).

The data and information submitted pursuant to this notice will be dealt with as follows:

1. Submissions in support of a contention of "grandfather" status will be studied, and the Commissioner's determination will be published in the FEDERAL REGISTER.

2. Data in support of a contention that a product is safe and effective, and/or is generally recognized as safe and effective will be reviewed by the Bureau of Drugs with the assistance of an Advisory Committee, as appropriate.

If it is concluded that the product is safe and effective, and/or is generally recognized as safe and effective for an indication(s), a notice stating the conditions for marketing will be published in the FEDERAL REGISTER.

If the data do not conclusively demonstrate safety and effectiveness for an indication(s), but there is reasonable likelihood that additional studies will provide such conclusive evidence, a notice will be published in the FEDERAL REGISTER stating the conditions under which the product may continue on the market while additional studies are undertaken. Such products shall then be labeled and advertised only for the indication(s), if any, for which the product is concluded to be safe and effective and the indication(s) for which additional clinical studies are undertaken. With respect to the latter indication(s), labeling and advertising shall disclose the fact that safety and effectiveness are under review.

If it is concluded that the data fail to show the product to be safe and effective for any indication(s) and it is concluded that it is unlikely that additional studies would fully support the indication(s), a notice of opportunity for hearing on the issues will be published in the FEDERAL REGISTER.

3. If no data whatever are submitted in support of a claimed indication(s), and "grandfather" status for such indication(s) has not been proved, a notice of determination of new drug status for these products will be published in the FEDERAL REGISTER.

After all issues of safety and effectiveness and "grandfather" status have been resolved for all claimed indication(s), the drug products shall be either unlawful and subject to removal from the market, subject to marketing under approved new drug applications, or subject to marketing under an old drug monograph(s).

Notwithstanding the procedures outlined above, the Commissioner shall, at any time, initiate appropriate regulatory action with respect to any advertising or labeling which subjects patients to hazards.

Submissions pursuant to this notice shall be in triplicate, directed to the attention of the Division of Cardio-Renal Drug Products (HFD-110) (Room 16B-45), and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 201 (p), 501, 502, 505, 701(a), 52 Stat. 1041-1042, 1049-1053 as amended, 1055 (21 U.S.C. 321(p), 351, 352, 355, 371(a))) and under authority delegated to the Com-

missioner of Food and Drugs (21 CFR 2.120).

Dated: March 30, 1976.

WILLIAM F. RANDOLPH,
*Acting Associate Commissioner for Compliance.*

[FR Doc.76-9586 Filed 4-2-76;8:45 am]

[Docket No. 75N-0324]

## CERTAIN DRUGS FOR USE IN PREMATURE LABOR, HABITUAL ABORTION, AND DYSMENORRHEA; LUTREXIN, TREXINEST

### Withdrawal of Approval of New Drug Application

The Food and Drug Administration (FDA) is withdrawing approval of new drug applications for Lutrexin (NDA 8-986) and Trexinest (NDA 10-144); effective April 15, 1976.

#### I. INTRODUCTION AND BACKGROUND

Lutrexin is a drug manufactured by Hynson, Westcott & Dunning, Inc. (Hynson), of Baltimore, MD. It contains lututrin, described in Lutrexin's labeling as a protein-like, water-soluble, nonsteroid uterine relaxing hormone from the ovary of a sow (R[1] 1). The labeling for Lutrexin recommends it for use in treating functional dysmenorrhea, selected cases of premature labor, second and third trimester threatened abortion, and habitual abortion (R 1).

On December 23, 1953, the Commissioner of Food and Drugs approved a new drug application (NDA) for Lutrexin (NDA 8-986). The basis for that approval was that the drug had been shown to be safe under the conditions of use prescribed, recommended, or suggested in its labeling. Subsequently, the Drug Amendments of 1962 (76 Stat. 780) added to the new drug provisions of the Federal Food, Drug, and Cosmetic Act in section 505(d) of the act (21 U.S.C. 355 (d)) the requirement that "new drugs" be shown to be effective for their intended use by "substantial evidence" consisting of "adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved * * *"

As part of the National Academy of Sciences/National Research Council (NAS/NRC) Drug Efficacy Study, the Commissioner issued a notice in the FEDERAL REGISTER of July 9, 1966 (31 FR 9426) asking each holder of an effective NDA approved from 1938 to October 10, 1962 to submit, among other things, all data and literature pertinent to the evaluation of the effectiveness of the drug or drugs covered by the NDA's for the conditions indicated in their labeling. Hynson submitted data and literature on drugs containing lututrin, including Lutrexin. On May 23, 1968, FDA notified Hynson by letter of the NAS/NRC panel's decision on drugs used in disturbances of the reproductive system, to which Hynson's submission had been referred. The panel concluded that Lutrexin was "possibly effective" for functional dysmenorrhea, citing the lack of well-controlled studies. The panel concluded that Lutrexin was "possibly effective" for premature labor, pointing out that, in its opinion, "the diagnosis of premature labor can be made only when labor has clearly started and that one cannot predict which patients will go into premature labor. Therefore, the Panel cannot evaluate the efficacy of Lutrexin Tablets in preventing the onset of premature labor, as one cannot know, with a satisfactory degree of certainty, in which patients premature labor will probably develop." The panel concluded that Lutrexin was also "possibly effective" for threatened and habitual abortion, stating that it knew of no adequate evidence to support this claim.

In an announcement in the FEDERAL REGISTER of May 24, 1968 (33 FR 7701), the Commissioner stated his agreement with the findings of the NAS/NRC panel. The Commissioner requested that within 60 days Hynson "submit adequate documentation, not previously submitted, in support of the representations made for the product." By a notice in the FEDERAL REGISTER of March 22, 1969 (34 FR 5556), under former Docket No. FDC-D-123, the Commissioner proposed to issue an order withdrawing the NDA for Lutrexin. He also proposed to withdraw the NDA for Hynson's drug Trexinest (NDA 10-144), a combination product containing lututrin; Hynson has since agreed not to contest withdrawal of the NDA for Trexinest. The Commissioner stated that "new information before the Commissioner with respect to such drugs, evaluated together with the evidence available to him when the applications were approved, shows there is a lack of substantial evidence of effectiveness of the drugs," and that Hynson had 30 days to notify FDA whether it elected to exercise its opportunity for a hearing on the proposed withdrawal pursuant to § 314.200 (21 CFR 314.200). On April 18, 1969, Hynson requested an opportunity for a hearing, but reserved the right to contest the jurisdiction of FDA in the administrative proceeding, in a judicial proceeding, or in both.

On August 19, 1968, Hynson filed a complaint for a declaratory judgment and injunctive relief in the United States District Court for the District of Maryland. *Hynson, Westcott & Dunning, Inc.* v. *Finch* (C.A. No. 21112). Hynson requested a judicial determination of the following issues: "(1) whether the drug products were generally recognized as safe on or before October 9, 1962, and if so, are they for that reason exempt from the effectiveness provisions of the 1962 Amendments under the Grandfather Clause of those Amendments; and (2) whether in any event these drugs are now generally recognized as both safe and effective and for that reason are not new drugs under the definition in Section 201(p) of the Federal Food, Drug and Cosmetic Act." The case was dismissed on September 17, 1970. The court held that Hynson had failed to exhaust its administrative remedies before FDA, and that review of final agency action was available in the court of appeals.

Prior to the district court's decision, FDA issued new regulations in the FEDERAL REGISTER of May 8, 1970 (35 FR 7520) setting forth detailed criteria for determining the existence of "substantial evidence" of effectiveness, and requiring that a request for hearing on the proposed withdrawals of an NDA set forth specific facts showing that there is a genuine and substantial issue of fact. On May 19, 1970, FDA notified Hynson that it must comply with the new regulations.

On October 16, 1970, Hynson requested an evidentiary hearing. In a notice published in the FEDERAL REGISTER of June 18, 1971 (36 FR 11763), the Commissioner denied Hynson's request for a hearing on the ground that it did not set forth specific facts showing that a genuine and substantial issue of fact was presented for resolution at a hearing, and withdrew the NDA for Lutrexin on the ground that there was a lack of substantial evidence to prove that it is effective for the indications contained in its labeling. Pursuant to 21 U.S.C. 355(h) Hynson appealed the Commissioner's order to the United States Court of Appeals for the Fourth Judicial Circuit. The court of appeals vacated the withdrawal order on May 24, 1972. *Hynson, Westcott & Dunning, Inc.* v. *Richardson*, 461 F. 2d 215 (1972). The court of appeals held that Hynson's NDA was not exempt from the Drug Amendments of 1962 on the basis of the Grandfather Clause, but that Hynson had presented sufficient evidence showing that a genuine and substantial issue of fact existed to warrant a hearing. Both sides then sought review of the court of appeals' decision in the Supreme Court. On June 18, 1973, the Supreme Court upheld the FDA summary judgment procedures and the regulations elaborating on the statutory requirement for substantial evidence of effectiveness. *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973). The Supreme Court agreed with the court of appeals that Hynson had justified a hearing on the issue of whether there is substantial evidence of the effectiveness of Lutrexin. Accordingly, in the FEDERAL REGISTER of May 2, 1974 (39 FR 15341) the Commissioner ordered a public hearing on the issue.

On June 4, 1974, a prehearing conference was held before Administrative Law Judge Irving Sommer. On June 12, Judge Sommer issued a prehearing order. In it he ruled that the issue to be resolved at the hearing was:

> Whether there exists substantial evidence of the effectiveness of Lutrexin for the conditions of use prescribed, recommended, or suggested in its labeling, *i.e.* whether there exist adequate and well-controlled clinical studies, as defined by 21 CFR 314.111(a)(5), on the basis of which it could fairly and responsibly be concluded by experts, qualified by scientific training and experience to evaluate

[1] "R" refers to exhibits introduced by Hynson.

the drug, that the drug has the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling.

Judge Sommer also ruled that Hynson "has the burden of proof with respect to said issue and shall present its evidence first." The judge, after considering prehearing memoranda on the point, reaffirmed this ruling at the commencement of the hearing (T[2] 3 and 4).

The hearing was conducted from June 17 to July 12, 1974.

At the hearing, Hynson introduced the testimony of 12 witnesses. Eight witnesses testified concerning studies they either conducted or participated in, and which related directly or indirectly to the question of Lutrexin's effectiveness: Edward H. Frieden, Ph. D. (chemistry), professor of chemistry at Kent State University; Harold H. Bryant, Ph. D. (pharmacology), formerly an assistant professor of pharmacology at the University of Maryland and once employed by Hynson; George H. Rezek, M.D., a physician specializing in obstetrics and gynecology; James J. Mulligan, M.S. (biology), a research microbiologist with Hynson; William M. Bickers, M.D., a physician specializing in obstetrics and gynecology; William F. Peterson, M.D., chairman of the Department of Obstetrics and Gynecology at the Washington Hospital Center; Richard Gratton, M.D., a physician specializing in obstetrics and gynecology; and Joseph T. Majewski, M.D., a private physician specializing in obstetrics and gynecology associated with the Veterans Administration Hospital in Tomah, WI.

The other four witnesses commented on the validity of the Lutrexin studies, or addressed the issue of whether placebo-controlled studies of Lutrexin are ethical, or both: Williard M. Allen, M.D., professor of obstetrics and gynecology at the University of Maryland, and a member of the NAS/NRC panel that reviewed the evidence of Lutrexin's effectiveness; William F. Colliton, a physician specializing in obstetrics and gynecology; Joseph F. Sadusk, Jr., a physician and formerly Director of the FDA Bureau of Medicine (now Bureau of Drugs); and John C. Krantz, Jr., Ph.D. (chemistry), emeritus professor of pharmacology at the University of Maryland.

The Government introduced the testimony of four witnesses: Fritz Fuchs, M.D., professor of obstetrics and gynecology, Cornell University Medical College; William T. Beaver, M.D., professor of pharmacology, Georgetown School of Medicine; Thomas C. Chalmers, M.D., dean and professor of medicine, Mount Sinai School of Medicine; Theodore M. King, M.D., professor and director, Department of Gynecology and Obstetrics, Johns Hopkins School of Medicine.

The parties also introduced documentary evidence, including reports of laboratory and clinical studies of Lutrexin or related pharmacological agents, medical texts and articles, and (by reference) all documents in the certified record before the court of appeals in *Hynson, Westcott & Dunning, Inc.* v. *Richard, supra.*

At the conclusion of the hearing, Hynson and the Government submitted extensive proposed findings of fact and conclusions of law, supported by posthearing memorandums and reply memordandums. On November 27, 1974, Judge Sommer, pursuant to 21 CFR 314.230, handed down his "Tenative Findings of Fact and Order." He concluded:

1. That, as a result of the absence of adequate and well-controlled clinical investigations from which experts could conclude that Lutrexin is effective for anything, there is a lack of substantial evidence of Lutrexin's effectiveness within the meaning of 21 U.S.C. 355(d).

2. That Lutrexin is a "new drug" within the meaning of the Federal Food, Drug and Cosmetic Act.

3. That the New Drug Application for Luxtrexin (NDA 8-986) and for Trexinest (NDA 10-144) should be withdrawn pursuant to 21 U.S.C. 355(d).

On December 23, 1974, Hynson, pursuant to 21 CFR 314.231, filed exceptions to the judge's "Tentative Findings of Fact and Order," together with a supporting brief. Hynson offered corrected findings of fact and conclusions of law summarizing those it had proposed to Judge Sommer; the proposed findings of fact were also incorporated by reference. (Although not incorporated in its submission to the Commissioner, Hynson's proposed conclusions of law will be considered, where relevant.) Hynson further requested the opportunity to make an oral argument before the Commissioner. In accordance with a notice published in the FEDERAL REGISTER of November 10, 1975 (40 FR 52426), oral argument was held on January 16, 1976.

Pursuant to 21 CFR 314.232, the Commissioner issues the following findings of fact, conclusions of law, and final order.

## II. LEGAL ARGUMENTS

A. *Burden of proof.* Hynson contends that the judge erred in ruling that it had the "burden of proof" to show substantial evidence of Lutrexin's effectiveness. Hynson points to section 505(e) of the act (21 U.S.C. 355(e)), which requires withdrawal of NDA approval for a drug if the Commissioner finds "on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug" is effective. Hynson argues that the Government did not meet the "new information" requirement at the hearing because it introduced no affirmative evidence that Lutrexin is not effective, and because the testimony of the Government's expert witnesses was not based on personal experience with the drug. According to Hynson, the finding of the NAS/NRC panel that Lutrexin is less than effective does not constitute "new information" within the meaning of section 505(e).

Hynson's argument confuses several issues. The statutory requirement that the Commissioner must base a decision to withdraw an NDA on "new information" does not control the determination of who bears the burden of proving the existence of substantial evidence of effectiveness at a hearing. In ruling that Hynson had the burden of proof on the substantial evidence question, the judge correctly applied the interpretation of the NDA withdrawal provision of the act set forth by the Supreme Court in *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*:

[S]ection 505(e) directs FDA to withdraw approval of an NDA if the manufacturer fails to carry the burden of showing there is "substantial evidence" respecting the efficacy of the drug.

412 U.S. at 617. The Administrative Procedure Act (5 U.S.C. 556(d)) requires that "except as otherwise provided by statute, the proponent of a rule or order has the burden of proof." The Supreme Court's construction of section 505(e) establishes that the proposed withdrawal of an NDA for lack of substantial evidence of a drug's effectiveness is such an exception to the general rule, and that the judge properly assigned the burden of proof on that issue to Hynson.

The Government was required, of course, to show that "new information" exists on the basis of which the Commissioner could find that there is a lack of substantial evidence of Lutrexin's effectiveness. To the extent that satisfaction of this statutory requirement was a predicate to proposing to withdraw Lutrexin's NDA or to triggering Hynson's burden of demonstrating the existence of substantial evidence at the hearing, the predicate was supplied by publication in the FEDERAL REGISTER of May 24, 1968 (33 FR 7701) and March 22, 1969 (34 FR 5556) of the FDA concurrence in the NAS/NRC evaluation that Lutrexin is less than effective for all of its indications and introduction of the NAS/NRC report into the hearing record (G[3] 1). Contrary to Hynson's assertion, when it is proposed to withdraw the NDA for a drug like Lutrexin, for which FDA has never made a determination of effectiveness, the NAS/NRC evaluation constitutes "new information." *Upjohn* v. *Finch*, 422 F. 2d 944, 951 (6th Cir. 1970), squarely so held, and that conclusion was implicit in the Supreme Court's approval of the NDA withdrawal procedures in *Weinberger* v. *Hynson, Westcott & Dunning, Inc., supra.* Indeed, for many drugs, the NAS/NRC evaluation was the first comprehensive analysis of available effectiveness data.

At the hearing Hynson introduced the testimony of Dr. Willard M. Allen, one of the members of the NAS/NRC panel that evaluated Lutrexin (T 46 through 53). Dr. Allen's testimony concerning the composition of the panel, the manner in which it undertook its review of the data, and its understanding of how its report would be used by FDA does not demonstrate that the panel reached the wrong scientific conclusion concerning

[3] "G" refers to exhibits introduced by the Government.

the evidence of Lutrexin's effectiveness. On cross-examination, Dr. Allen stated that all of the members of the panel were experts in evaluating drugs (T 75) and that the panel found no evidence supporting Lutrexin's effectiveness (T 73 and 75). Accordingly, Hynson's proposed findings of fact Nos. 220 through 227, corrected findings of fact No. 28, proposed conclusion of law No. 17, and corrected conclusions of law No. 12 are rejected to the extent that they state or suggest that the NAS/NRC evaluation of Lutrexin does not constitute "new information."

"New information" may also consist of a reevaluation of existing information. *Upjohn* v. *Finch, supra; Bell* v. *Goddard*, 366 F. 2d 177, 181 (7th Cir. 1966). Such a reevaluation may initiate a proposed withdrawal. It may also occur in the summary judgment context, or, as here, at an oral evidentiary hearing. Hynson's contention to the Commissioner that no "new information" was presented at the hearing completely disregards the searching inquiry that was there made into the studies introduced by Hynson. The record of that inquiry provides abundant "new information" that there is a lack of substantial evidence of Lutrexin's effectiveness.

Hynson incorrectly suggests that the Government was required to supplement the record with evidence affirmatively establishing that Lutrexin is not effective (proposed conclusion of law No. 17(3) and 17(4), corrected conclusion of law No. 12(c)). The issue at the hearing, however, was not whether Lutrexin is ineffective, but whether there is substantial evidence that it is effective. The absence of such evidence could, and did, emerge through the testimony of Hynson's witnesses on direct and cross-examination, and through evaluation of the studies submitted by Hynson as hearing exhibits. Hynson's proposed finding of fact No. 228 that the "only evidence in the record * * * on the alleged lack of substantial evidence of the effectiveness of Lutrexin, consists of the opinion testimony of the four government witnesses" erroneously implies that the studies and testimony introduced by Hynson itself were irrelevant to the issue of substantial evidence of Lutrexin's effectiveness. They were not only relevant to that issue, they were the issue.

The testimony of the Government's four expert witnesses confirmed the lack of substantial evidence of Lutrexin's effectiveness. These witnesses are recognized authorities in their respective fields, which include clinical pharmacology and obstetrics and gynecology. That the witnesses did not themselves have experience in using or testing Lutrexin in no way vitiated their demonstrated expertise in evaluating the studies of others or in assessing the kind of investigations that must be performed to provide substantial evidence of the effectiveness of a drug like Lutrexin. Hynson's statements suggesting that the Government's witnesses were not qualified (proposed finding of fact No. 229(1) and 229(2)) are wholly unpersuasive.

Hynson discounts the testimony of the Government's witnesses on a number of grounds. It states that they did not audit the testimony of Hynson's witnesses and so could not evaluate whether defects in the Lutrexin studies had been remedied by oral testimony from their authors (proposed finding of fact No. 229(3)). However, it was Hynson's obligation to introduce such remedial testimony. Its failure to do so is not mitigated by the absence of rebuttal testimony. Moreover, one of the Government's witness heard the testimony of one of Hynson's principal witnesses (T 1420), two read the transcript of the testimony of another (T 946, 1472), and all were examined by the Government with specific reference to the defects in the reports of the Luxtrexin studies, and thus provided testimony that better enabled the trier of fact to evaluate the testimony of Hynson's witnesses.

Hynson cross-examined the Government's experts with respect to a number of their own studies (T 981 through 992, 1514 through 1519, 1198 through 1201). The purpose of this was to show that the regulations of FDA on adequate and well-controlled investigations cannot be complied with in every particular (Hynson's corrected conclusion of law No. 12(d)), and possibly to impeach the criticisms leveled by the Government's witnesses against the Lutrexin studies (Hynson's proposed conclusion of law No. 17(5)). However, the issue at the hearing was not whether the reports of the clinical investigations of Lutrexin fully met every detail in the regulations, but whether they were sufficiently adequate and well-controlled to constitute substantial evidence of Lutrexin's effectiveness. Nothing in the record demonstrates that it is impossible to comply with the regulations to that extent. That the Government's experts recognized shortcomings in the reports of some of their own studies neither improves the Lutrexin studies nor discredits the experts' assessment of them.

In its prehearing memorandum to the judge (at 1 and 2), Hynson cited *Bell* v. *Goddard, supra*, as authority for requiring the Government to assume the burden of proof on the substantial evidence question. There the court held that in a proceeding to withdraw, on safety grounds, an NDA for a drug that had once been approved as safe, "the burden of proving * * * [the drug] 'unsafe' at the suspension proceeding was on the FDA." 366 F. 2d at 181. That case does not apply here. The drug in *Bell* had specifically been approved by FDA as having been shown to be safe. Lutrexin was never approved by FDA as having been shown to be effective. Also, the ground for withdrawing the NDA in *Bell* was that the drug was actually "unsafe." The issue in this hearing was not whether Lutrexin is ineffective, but whether there is substantial evidence that it is effective.

Hynson also contended to the judge that, having made a showing sufficient to justify a hearing, it had satisfied its burden of going forward at the hearing, thus casting on the Government the burden of making out a prima facie case that there are no adequate and well-controlled investigations supporting Lutrexin's effectiveness (prehearing memorandum at 3). This is like arguing that a litigant in a court case who successfully opposes a motion for summary judgment is thereby relieved of his burden of proof at the subsequent trial, which is not the rule. The "burden" of justifying a hearing should not be confused with the different "burden" of proving the facts necessary to prevail at a hearing. The court of appeals in 1972 and the Supreme Court in 1973 held only that summary disposition of Hynson's hearing request was inappropriate because Hynson's submission was sufficient to raise a genuine issue of fact concerning whether the invetigations were adequate and well-controlled. Neither court held or implied that Hynson had also satisfied its burden of proving that fact. Moreover, it is illogical for Hynson to maintain that the Government should have made out a prima facie case that the Lutrexin studies were not adequate and well-controlled before Hynson introduced live testimony of the investigators themselves for the purpose of providing additional information on the manner in which the studies were conducted.

The Commissioner notes that the phrase "burden of proof" is commonly used to refer to both the burden of producing evidence and to the burden of persuading the trier of fact. It has not always been clear in which sense the phrase has been used by the parties at various stages of this proceeding. The Commissioner concludes that Hynson had both the burden of production and the burden of persuasion on the issue of substantial evidence of Lutrexin's effectiveness.

The Commissioner further concludes that there are only two issues in this proceeding about which the record evidence leaves sufficient doubt that they could, even arguably, be affected by placing the burden of proof on the Government: whether the subsequent doses in the Bickers study (R 23, 55) were randomized (paragraph IV.A.1. of this notice), and whether Lutrexin and the Lutein used in the Falls, Rezek, Benensohn study (R 6) were the same chemical entity (paragraph IV.A.2. of this notice). A decision favorable to Hynson on either or both of these issues, however, would not change the Commissioner's conclusion that neither of those studies meets the regulatory criteria for adequate and well-controlled clinical investigations, or otherwise provides substantial evidence of the effectiveness of Lutrexin for its labeled indications. Any error in assigning the burden of proof is therefore immaterial to the Commissioner's ultimate determination. The Commissioner disagrees, however, with the Government's contention made at oral argument that he may not review the judge's decision on this point. The Administrative Procedure Act provides that, on appeal from a pre-

siding officer's decision, "the agency has all the powers which it would have in making the initial decision". (5 U.S.C. 557(b).

B. *Testimony to Remedy Deficiencies in Reports of Studies.* A controversy of uncertain dimensions appears to have arisen concerning whether it is permissible at a hearing on the issue of substantial evidence for the authors of clinical investigations to supply methodological details that do not appear in their written reports of the studies through oral testimony. In its posthearing reply memorandum (at 2), the Government quoted the following statement from *Upjohn Co.* v. *Finch, supra* at 955: "No amount of examination and cross-examination can change the scientific studies into something they are not." Hynson, in its posthearing memorandum (at 2), criticized what it felt was a "pattern * * * of statements that the Lutrexin studies speak for themselves and must stand alone as to whether they are adequate and well controlled."

Whatever may have been the Government's view, testimony by the authors of the Lutrexin studies to remedy defects and cure omissions in their written reports was offered by Hynson, received by Judge Sommer, subjected to cross-examination by the Government, and considered by both Judge Sommer and the Commissioner. The introduction of such testimony was entirely proper. While it is true that examination and cross-examination cannot supply facts about a study that do not exist, it obviously can provide facts about a study that were not included in the written report prepared by the investigator.

Omission of critical facts from the written description of a clinical investigation seriously compromises the value of the report to the scientific community. Without a clear and precise explanation of the methods used in the conduct of the investigation, those for whom the report is intended cannot evaluate it. For this reason, investigators are ordinarily scrupulous in setting forth the essential facts that establish a study as adequate and well-controlled. A report that is facially deficient in this respect, therefore, usually reflects a corresponding deficiency in the investigation itself.

However this may be, a manufacturer contesting the proposed withdrawal of approval of its NDA is entitled to remedy defects in the reports of clinical investigations through probative and relevant information (usually from the investigator himself) extrinsic to the report, as was recognized by the court of appeals in *Hynson, Westcott & Dunning, Inc.* v. *Richardson, supra* at 221 and 222. This may be done in the request for hearing or at a hearing, if one has been justified.

The Commissioner wishes to make clear that this does not mean that a manufacturer may justify a hearing pursuant to 21 CFR 314.200 by making a facially deficient submission accompanied by the assertion that defects and omissions will be cured at the hearing. The cases are clear that the submission in support of a hearing request must itself demonstrate that any effectiveness studies relied upon meet the objective criteria of the regulations to the extent of raising a genuine and substantial issue of fact; no such issue exists if a submission is deficient on its face with respect to those criteria. *Weinberger* v. *Hynson, Westcott & Dunning, Inc., supra* at 620; *Cooper Laboratories, Inc.* v. *Commissioner*, 501 F. 2d 772, 774 (D.C. Cir. 1974).

In its posthearing memorandum (at 2), Hynson makes several statements about the oral testimony of the investigators that suggest an incomplete understanding of the purpose it was intended to serve. Hynson notes that the Government's emphasis in cross-examination was on "what is *not* in the studies, with little attempt to discover, by the authors' explanations, matters concerning * * * 'whether the studies were as controlled as they might have been and whether there was a failure in the studies as published to fill in all the details the Commissioner might think appropriated.'" (Quoting the court of appeals in *Hynson, Westcott & Dunning, Inc., supra* at 221 and 222.) Eliciting remedial testimony from the investigators was Hynson's responsibility on direct examination, not the Government's on cross-examination. The purpose of the hearing was to determine whether the investigations of Lutrexin were adequate and well-controlled. Hynson cannot claim prejudice because the Government inquired into the deficiencies in the studies after Hynson introduced testimony intended to establish that they complied with the requirements of substantial evidence.

Nor did the judge "limit testimony at the hearing to opinion evidence of 'experts' who have done nothing but analyze" the reports of the Lutrexin studies (Hynson's posthearing memorandum at 2). There was testimony from expert witnesses about the reports of the studies, but there was also testimony about the studies themselves from those who conducted them. That the investigators were Hynson's witnesses rather than the Government's does not require the Commissioner to ignore those aspects of their testimony—such as failure to establish affirmatively that a deficiency in the written report did not signify a deficiency in the investigation itself—tending to prove that the investigations were not adequate and well-controlled.

It is clear from Judge Sommer's "Tentative Findings of Fact and Order" that the judge based his decision principally on the evidence introduced by Hynson (including the remedial testimony of the investigators), not on the testimony of the Government's experts. The Commissioner similarly finds that the testimony and documentary exhibits introduced by Hynson establish that the Lutrexin studies are not adequate and well-controlled.

C. *Evaluation of Lutrexin Studies Against Criteria of Adequate and Well-Controlled Investigations.* Hynson states that there is a "due process" problem in applying the criteria for "adequate and well-controlled investigations" to a drug that was "investigated adequately in terms of the principles of scientific research at the time when the majority of the Lutrexin studies were conducted" (posthearing memorandum at 7), and Hynson faults the judge for having failed to address the issue (brief to the Commissioner at 15). Judge Sommer may have felt it unnecessary to repeat the following dispositive language of the Supreme Court:

> The efficacy requirements were not designed to be prospective only. Clearly, after the initial two-year moratorium on existing drugs, FDA has the power to withdraw an application which became effective prior to the adoption of the 1962 amendments, if the applicant has not provided "substantial evidence" of the drug's efficacy. *The Act plainly contemplates that such drugs will be evaluated on the basis of adequate and well-controlled investigations.*

*Weinberger* v. *Hynson, Westcott & Dunning, Inc., supra* at 631 (emphasis added).

The "due process' problem alluded to by Hynson is derived from the concurring opinion of Justice Powell, in which he disagreed with the majority decision upholding the strict criteria for justifying a hearing, finding that they raised in his mind a troubling issue of procedural due process. Even Justice Powell, however, had no difficulty with applying the criteria for adequate and well-controlled investigations to Lutrexin in the context of an evidentiary hearing, and for that reason concurred in the Court's decision to remand the matter to the agency to hold such a hearing.

Hynson's proposed conclusion of law No. 18 and corrected conclusion of law No. 13, which state that Lutrexin was "adequately" tested when introduced, has had substantial clinical use since that time, and therefore that controlled investigations are not necessary, are accordingly rejected. Hynson's proposed finding of fact No. 230, which suggests that there is no need to conduct adequate and well-controlled studies of a drug tested in accordance with procedure prevailing when it was introduced, is similarly rejected as unsupported by the evidence and contrary to law. Dr. Sadusk testified that if a study "accords with the standards of 1955" and "if continued clinical usage * * * has demonstrated to the satisfaction of the practicing physician that the drug is effective and safe, I see no reason for redoing the clinical investigation." (T 367 and 368). Dr. Sadusk's testimony represents his personal opinion and does not accord with the statutory standard. He further fails to specify the methodological standards that would have been acceptable for scientific investigations of Lutrexin when it was first introduced. Nothing in the record establishes that any of the methods used to test Lutrexin at the time the early investigations were conducted were regarded as "adequate" by the scientific community.

Hynson suggests that the absence of any other drug known to be effective for

premature labor justifies permitting the continued marketing of Lutrexin as a "possibly effective" drug for that condition (brief to the Commissioner at 16 and 17; corrected conclusion of law No. 8; corrected finding of fact No. 14; proposed findings of fact Nos. 205, 215 through 219). The Commissioner disagrees. Assuming that there are no alternatives to Lutrexin in treating premature labor, the statute nonetheless requires that the effectiveness of Lutrexin itself be demonstrated by substantial evidence. This does not result, as Hynson implies, in depriving patients of the only known effective drug therapy for premature labor; absent scientifically reliable evidence, Lutrexin is itself not known to be effective for that purpose.

The claim that the marketing of drugs other than Lutrexin for the same indications would deny Hynson its right to equal protection in the event that Lutrexin's NDA is withdrawn is without merit (posthearing memorandum at 8). The claim is based on the factual premise that there is no more evidence for the effectiveness of those drugs than there is for that of Lutrexin, a premise not at issue in the hearing and not proven by the comments of several witnesses concerning various alternative drug therapies for premature labor (proposed findings of fact Nos. 215 through 219). In any event, the Commissioner is not required to "choose between attacking every aspect of a problem or not attacking the problem at all," *Dandridge* v. *Williams*, 397 U.S. 471, 486 and 487 (1969), and may validly apply the new drug provisions of the act on a product-by-product basis as he has done throughout the Drug Efficacy Study Implementation program, of which this proceeding is a part.

D. *Status of Lutrexin as a "New Drug."* Judge Sommer concluded as a matter of law that Lutrexin is a "new drug" within the meaning of 21 U.S.C. 321(p) ("Tentative Findings of Fact and Order" at 24). The Commissioner agrees with this conclusion.

Hynson contends that such a conclusion is improper and denies due process because no evidence that Lutrexin "is not generally recognized * * * as effective," 21 U.S.C. 321(p), was introduced at the hearing, and Hynson did not have an opportunity to submit evidence on the question (posthearing reply memorandum at 9).

The Supreme Court held that "[i]n the absence of any evidence of adequate and well-controlled investigation supporting the efficacy of Lutrexin, *a fortiori* Lutrexin would be a 'new drug' subject to the provisions of the Act * * * [A] drug can be 'generally recognized' by experts as effective for intended use within the meaning of the Act only when that expert consensus is founded upon 'substantial evidence' as defined in § 505(d) [21 U.S.C. 355(d)]." *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, *supra* at 629, 630, and 632.

Under the Court's interpretation of the act, the judge's and the Commissioner's conclusion that Lutrexin is a "new drug" as a matter of law follows inescapably from a finding that there is a lack of substantial evidence of its effectiveness; no evidence relating to the drug's reputation in the medical and scientific community is necessary to support this conclusion. Contrary to Hynson's assertion, the Court specifically defined the "quantum" of substantial evidence needed before general recognition can be said to exist: it is substantial evidence "as defined in § 505(d)," i.e., "adequate and well-controlled investigations, including clinical investigations," and an "expert consensus founded upon" that substantial evidence. 412 U.S. at 632. Judge Sommer's and the Commissioner's finding that the Lutrexin studies are not adequate and well-controlled renders it legally impossible for the drug to be considered generally recognized among experts as safe and effective under the conditions of use prescribed, recommended, and suggested in its labeling.

Hynson, citing the Court's statement that the "absence of any evidence of adequate and well-controlled investigation" means that a drug is a "new drug," argues that its "case presented at the hearing together with the testimony by Dr. Chalmers, shows the *presence* rather than the 'absence of any evidence.'" Hynson is confusing "evidence" that is introduced at a hearing and substantial "evidence" of effectiveness. Hynson introduced "evidence," but that evidence did not prove that there is "any evidence of adequate and well-controlled investigation" of Lutrexin's effectiveness.

E. *Sufficiency of the Judge's Order and Reasonable Opportunity to Take Exception.* Hynson objects to Judge Sommer's "Tentative Findings of Fact and Order" as failing to meet the requirement of the Administrative Procedure Act for a statement of "findings and conclusions, and the reasons or basis therefor, on all material issues of fact, law, or discretion presented on the record," 5 U.S.C. 557(c), and failing to meet the requirement of the Administrative Procedure Act and of FDA regulations for an opportunity to submit to the Commissioner exceptions to the judge's tentative findings and order. 5 U.S.C. 557(c)(2); 21 CFR 314.230 and 314.231. The lack of "references to the record" in Judge Sommer's decision is said by Hynson to have impaired its ability to determine "the evidentiary basis for the findings" and so deprived it of a "'reasonable opportunity' to submit exceptions."

1. Sufficiency of Judge Sommer's findings and order. The "Tentative Findings of Fact and Order" is a 24-page document setting forth the findings made by Judge Sommer on the basis of his review of the record evidence. The findings are in narrative form, and consist of a witness-by-witness, study-by-study discussion of the evidence of Lutrexin's effectiveness for dysmenorrhea, premature labor, and habitual abortion.

Judge Sommer's narrative explanation is a pointed statement and analysis of the material facts in issue at the hearing; his conclusions with respect to those issues and his reasons for reaching them are clearly apparent from the text. The Commissioner concludes that Judge Sommer's order is sufficient in all respects.

Hynson implies that the findings and order are deficient because the numbered findings of fact at the end of the narrative do not contain the evidentiary details that Hynson feels would justify the judge's ruling. Those details, however, are fully set out in the judge's narrative explanation. Stating, discussing, and resolving factual issues in narrative form rather than in numbered paragraphs is a commonly used format that has been specifically recognized as fulfilling the Administrative Procedure Act requirement of a "statement of * * * findings and conclusions * * * on all the material issues of fact, law, or discretion." 5 U.S.C. 557(c). *Gilbertville Trucking Co.* v. *United States*, 196 F. Supp. 351 (D. Mass. 1961); *State Corporation Comm.* v. *United States*, 184 F. Supp. 691 (D. Kan. 1959). "An agency which issues opinions in narrative and expository form may continue to do so without making separate findings of fact and conclusions of law." Attorney General's Memorandum on the Administrative Procedure Act 86 (1947). So too may an Administrative Law Judge.

Hynson believes that the judge's narrative is insufficient because it "does not refer to the evidence adduced at the hearing." This statement is incorrect. It is true that there are no page citations to the transcript of the oral testimony. But the judge's discussion makes clear that his analysis and findings were based on both the testimonial and documentary evidence introduced at the hearing, and his specific references to the witnesses and the studies and to the factual issues they raised make it readily apparent what evidence the judge considered.

Hynson criticizes the findings and order for dealing with the evidence in terms of defects in methodology rather than by analyzing the results of the studies and the evidence adduced at the hearing. As an example, Hynson points to the judge's failure "to refer to use of Lutrexin in management of threatened abortion." Hynson's criticism overlooks the purpose of the hearing, which was to consider whether there exists substantial evidence, consisting of adequate and well-controlled clinical investigations, of Lutrexin's effectiveness. The results of clinical investigations have no probative scientific value unless they are "adequate and well-controlled" (see testimony of Dr. Beaver, T 1060 and 1061), and so the principal issue at the hearing was the methodology used in the Lutrexin studies. The judge analyzed the methods used in the conduct of the investigations in relation to both the written reports of the studies and the testimony of their authors, where relevant. That the judge did not specifically discuss the results of the studies does not mean that he did not consider them. It means, rather, that he considered them in the light of

his finding that critical methodological defects in the studies rendered the results unreliable.

Judge Sommer's decision not to deal specifically with "threatened abortion" is entirely attributable to Hynson's failure to establish at the hearing that Lutrexin is intended to be used for that condition, or exactly what that term means in relation to Lutrexin's labeling. As discussed elsewhere in this decision, Hynson's own witness defined "threatened abortion" as a condition occurring only during the first and early part of the second trimester (T 20), while Lutrexin is recommended for "2nd and 3rd trimester threatened abortion." To the extent that the labeling indication for "threatened abortion" is the same as those for "premature labor" or "habitual abortion," Judge Sommer discussed the relevant evidence under those headings.

2. Reasonable opportunity to take exception. Hynson contends that it was deprived of an opportunity to submit exceptions by its inability to discern the "evidentiary basis" for Judge Sommer's findings. As discussed, the basis for the judge's findings is apparent from the text of his narrative explanation. That Hynson fully understood the specific grounds for the ruling is confirmed by the detailed corrected findings of fact it submitted to the Commissioner, which contain citations to record evidence that Hynson believes refutes the judge's decision.

Responsibility for the final decision in this matter resides in the Commissioner, not the Administrative Law Judge:

> The Examiner's decision is part of the record, and the record must be considered as a whole in order to see whether the result is supported by substantial evidence * * * Yet in the last analysis it is the agency's function, not the Examiner's to make the findings of fact and select the ultimate decision, and where there is substantial evidence supporting each result it is the agency's choice that governs.

*Greater Boston Television Corp.* v. *F.C.C.*, 444 F. 2d 841, 843 (D.C. Cir. 1970).

The purpose of submitting "proposed findings and conclusions" to the judge and "exceptions" to the Commissioner is the same: to make clear what the submitting party's view of the record evidence is before a final agency decision is reached. Thus, exceptions can take the form of proposed findings and conclusions (Attorney General's Memorandum, supra at 85). Here, Hynson has both submitted exceptions and corrected findings and conclusions and incorporated in them the proposed findings and conclusions submitted to Judge Sommer.

Under the regulations, the filing of exceptions brings the entire record of the proceeding before the Commissioner for review and issuance of a final order. 21 CFR 314.230 through 314.232. As part of his independent review, the Commissioner is required to evaluate the record as a whole, and has in fact done so. He has also considered Hynson's proposed findings of fact and conclusions of law, in addition to its corrected findings and conclusions, in relation to the evidence of record, as well as Judge Sommer's tentative findings and order. The Commissioner thus fully understands Hynson's interpretation of the evidentiary facts and the reasons why it disagrees with the judge's rulings on them. The Commissioner's independent evaluation of Hynson's proposed findings and conclusions eliminates any basis for contending that Hynson was inhibited by alleged deficiencies in Judge Sommer's order from making known to the Commissioner the specific grounds for its disagreement with that order through the submission of exceptions.

### III. Historical Controls in Studies of Lutrexin

Most of the clinical investigations submitted by Hynson employed a historical control. Considerable testimony was introduced at the hearing by Hynson to justify that form of control and by the Government to show that it is inappropriate. The Commissioner concludes that a historical control is not appropriate for investigations of Lutrexin for any of its indications.

The criteria for adequate and well-controlled clinical investigations include the requirement that a comparison be made between the results of treatment with the drug and results in a control. 21 CFR 314.111(a)(5)(ii)(*a*)(*4*). Of the four recognized types of control, three—no treatment, placebo, and active treatment—involve the simultaneous, usually random, assignment of subjects to a treatment group and to a control group receiving one of the regimens specified. Use of these concurrent controls assures that effects observed in the treated group can be reliably attributed, where that is the case, to the drug rather than to, for example, the natural course of the condition or the psychological response of the subject.

The fourth type of control is the historical control. Rather than comparing two groups concurrently receiving the test drug and the control regimen, respectively, a historically controlled study compares results in subjects receiving the test drug with the expected clinical outcome of the condition if left untreated or if treated by other therapy of known effectiveness. The historical control is the least reliable of the four types of control. Among other things, a study using a historical control cannot be "blinded" to eliminate or minimize subject and observer bias, and the study groups cannot be randomized to assure comparability of the subjects with respect to variables that might affect the results. Modell and Houde, "Factors Influencing Clinical Evaluation of Drugs" (G 23 at 2194); Chalmers, *Historical Versus Randomized Controls* (G 27).

The regulations permit use of a historical control in limited circumstances:

> In certain circumstances, such as those involving diseases with high and predictable mortality (acute leukemia of childhood), with signs and symptoms of predictable duration or severity (fever in certain infections), or in case of prophylaxis, where morbidity is predictable, the results of a new drug entity may be compared quantitatively with prior experience historically derived from the adequately documented natural history of the disease or condition in comparable patients or populations with no treatment or with a regimen (therapeutic, diagnostic, prophylactic) the effectiveness of which is established.

21 CFR 314.111(a)(5)(ii)(*a*)(*4*)(*iv*). Hynson contends that historical controls are "ethically necessary for an investigation of the effectiveness of Lutrexin in premature labor and habitual abortion," and that both of those conditions "meet the criteria" of the quoted provision of the regulations (proposed conclusion of law no. 10, citing proposed findings of fact 35, 37, 38, 41, 63, 74, 81, 86, 90, 128, 140, 170, 173, 177, 188 through 190, 200 through 202, 205 through 208, 210, 212, 232, and 233). Hynson makes no similar contention with respect to testing Lutrexin's effectiveness in treating dysmenorrhea, and in fact concedes that no substantial evidence exists for that indication (proposed conclusion of law No. 13, proposed finding of fact No. 85).

A thorough review of the record developed at the hearing demonstrates that neither premature labor nor habitual abortion is a condition for which a historically controlled study can qualify as adequate and well-controlled under the regulations, and that the use of historical controls in the investigation of Lutrexin's effectiveness is not "ethically necessary."

A. *Appropriateness of Historical Controls in Studies of Lutrexin.* A historically controlled clinical investigation qualifies as adequate and well-controlled only if the condition to be treated is one with "high and predictable mortality," has "signs and symptoms of predictable duration or severity" or, for prophylactic treatment, is one "where morbidity is predictable." 21 CFR 314.111(a)(5)(ii)(*a*)(*4*)(*iv*).

The strict limitations in this provision, which is one of the "well-established principles of scientific investigation" in the regulations approved by the Supreme Court in *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, *supra* at 619, are the product of the inherent unreliability of historically controlled studies (T 97 and 98, 394, 1054 through 1059, 1427 through 1436; G 23, 27). The condition to be treated must therefore be predictable in terms of its observable indicia. It is only this predictability that permits a valid comparison between the results in patients receiving the test drug and the expected outcome of the condition if left untreated or subjected to different therapy.

Hynson states that premature labor and habitual abortion "are conditions which meet the criteria laid down by the regulations." (Proposed conclusion of law No. 10.) The findings of fact and underlying record evidence cited in support of this conclusion indicate that it is based on the "high and predictable mortality" to the fetus if born prematurely or aborted (proposed findings of fact Nos. 35 through 37, 177, 206, 212), and on the supposed predictability of the "signs and

symptoms" of premature labor (proposed findings of fact Nos. 41, 90, 140, 170, 201, 208, 232) and habitual abortion (proposed findings of fact Nos. 81, 90, 173, 200, 201, 208, 232, 233).

1. "High and predictable mortality" to the fetus. There is no dispute that a fetus delivered any appreciable length of time before term has a reduced chance of survival that diminishes to nil as the period prior to term lengthens to about 25 weeks (T 225, 932, 1361; R 4 at 323). Premature labor and spontaneous abortion, i.e., any naturally occurring premature expulsion of a nonviable fetus, are serious occurrences for both the mother and the unborn child. If those events occur, adverse consequences are "predictable," including mortality to the fetus should the pregnancy have been of short enough duration.

However, it begs the question to conclude from this that the conditions for which Lutrexin is intended, or for which it was administered in the studies, have the high and predictable mortality that would justify the use of historical controls. Although it is clear from the testimony that Lutrexin's purpose is to treat premature labor and prevent premature delivery and spontaneous abortion, the physiological conditions under which it is intended to be, and was in the studies, administered are necessarily far broader and include situations in which a woman exhibits signs and symptoms, or has a past history of unsucessful pregnancies, that cause her physician to conclude that she may deliver prematurely or about the fetus. Witnesses for both sides testified that there are many uncertainties involved in diagnosing true premature labor because the symptoms associated with it are also consistent with so-called "false labor" (T 67 through 70, 248 through 250, 556 and 557, 915 through 918, 971, 1068 through 1071, 1264 through 1266, 1357 and 1358). There was also testimony that a patient's previous history of premature labor was not a reliable indicator of premature labor in the future (T 249 and 250, 1275). With respect to the condition known as "habitual abortion," the testimony established, at most, that although a history of spontaneous abortions may justify considering a patient a high risk case, it does not in itself guarantee that any particular subsequent pregnancy will terminate in an abortion (T 58 through 64, 93, 250, 583 and 584, 874, 920, 1062 through 1065, 1275).

Precautionary administration of a drug under circumstances indicating, but not conclusively demonstrating, that the result the drug is intended to prevent may, or is about to, occur is completely proper in the exercise of sound medical judgment. Indeed, because of the uncertainty in predicting, even after careful examination, whether a woman will abort or deliver prematurely, it may be impractical to test Lutrexin other than by administering it to groups of subjects that include women who the physician believes might be in danger of aborting or delivering prematurely, but who in fact are not.

Whatever may be the necessity for testing Lutrexin on subjects whose physical condition does not always lead to the consequences that Lutrexin is supposed to avert, however, the fact is that such a physical condition is not one involving the likelihood of a consequence that is "high and predictable," as required by the regulations. Hynson's position that the certainty of adverse consequences to the fetus resulting from abortion or premature delivery constitutes "high and predictable mortality" ignores the impossibility, in the current state of diagnostic science, of limiting administration of Lutrexin to those women who will definitely abort or deliver prematurely without preventive measures. The question is not whether it is likely that the fetus will be seriously endangered by abortion or premature delivery—it is—the question is whether there is a "high and predictable" likelihood that there will be abortion or premature delivery by the patients for whom Lutrexin is intended and to whom it was administered in the studies. Based on the evidence, that likelihood is not there.

2. "Signs and symptoms of predictable duration or severity" associated with premature labor and habitual abortion.

(a) "Premature labor." Lutrexin is indicated for use in "selected cases of premature labor" and in cases of second and third trimester "threatened abortion." Premature labor is commonly defined as "spontaneous labor at 36 weeks of gestation or less" (T 915). Threatened abortion is commonly defined as cramps and bleeding in the first half of pregnancy (T 20).

At the hearing, Hynson stipulated that there are no adequate and well-controlled clinical investigations demonstrating that Lutrexin is effective in treating threatened abortion (T 118 and 119, 451). Hynson subsequently explained (posthearing reply memorandum at 4 and 5, and at the oral argument) that its counsel intended the stipulation to relate only to threatened abortion in the first and early part of the second trimester of pregnancy, and that one of its studies (R 6) supports Lutrexin's effectiveness for "second and third trimester 'threatened' abortion," which is the indication appearing in the labeling for the drug (R 1). However, since Hynson's proposed finding of fact No. 38, based on testimony from one of its own witnesses, defines "threatened abortion" as consisting of "cramps or pelvic pain and bleeding in the first trimester or early into the second trimester" (T 20), the labeling for Lutrexin evidently refers to a medical condition that either does not exist or that goes by another name.

The latter appears to be the case. Although it does not emerge pointedly in the testimony, "threatened abortion" during the second half of pregnancy, i.e., the later part of the second and all of the third trimester, would seem to be indistinguishable from "premature labor" (T 401; R 8 at 995), and Hynson's counsel did not disagree with this characterization at the oral argument. Spontaneous abortion obviously occurs as the result of labor that commences prematurely, even though the term "premature labor" is generally reserved for use in connection with "premature delivery" rather than "abortion." "Abortion" is thus "threatened" if "labor" is "premature." The differences among the various terms apparently relate more to timing and to expectations about the prospects for survival of the infant, if born alive, than they do to the physiological processes that result in expulsion of the fetus from the mother's womb.

The use of the term "threatened abortion" in close connection with "habitual abortion" in the text of Lutrexin's labeling suggests the alternative, less likely possibility that Hynson regards abortion as "threatened" if the woman has a history of spontaneous abortion. Whatever ter are attributable to Hynson's failure ambiguities remain concerning this mat- at the hearing to make clear the distinction, if any, between "2nd and 3rd trimester abortion," "premature labor," and "habitual abortion," which are the terms Hynson selected for use in the labeling for Lutrexin and for the explanation of which Hynson must thus assume responsibility. Hynson's dereliction may indeed have misled the Government at one point, as will be explained in connection with the Falls, Rezek, Benenschn study in paragraph IV.A.2. of this notice.

The evidence introduced at the hearing established that it is difficult to determine with any degree of reliability that a pregnant woman exhibiting signs and symptoms suggesting early labor is in true premature labor, or is instead undergoing Braxton-Hicks contractions, or so-called false labor (T 248 through 250, 556 and 557, 916, 971, 1069 through 1071, 1265 and 1266). This uncertainty in diagnosing true premature labor is pointed up by the disagreement among the experts about what signs and symptoms accurately signal the occurrence of true labor (T 67 through 70, 915 through 918, 1068, 1264 through 1266, 1357 and 1358). Even the most reliable technique for identifying premature labor—two or more examinations of the cervix revealing progressive effacement and dilatation (T 915 through 918, 1265 and 1266, 1294, 1357 and 1358)—depends a great deal on the judgment of the physician and does not assure an accurate diagnosis of true labor (T 916).

Hynson's proposed findings of fact and supporting testimony provide no basis for concluding that true premature labor can be reliably distinguished from false labor at a stage early enough to prevent or delay delivery in the event that the labor is real, i.e., at a stage when Lutrexin or any other known therapy could prevent delivery, assuming it was effective. (There appears to be no dispute that at some point true labor does become reliably identifiable, but that at that point it is also irreversible (T 24, 917 and 918, 1352, cited in Hynson's proposed finding of fact No. 42).) Of the proposed findings of fact referenced by Hynson as relating to whether historical controls are ethically necessary or jus-

tified by the regulations, only one—No. 41—appears to concern directly the predictability of premature labor on the basis of early signs and symptoms suggesting the possibility of labor. The finding describes the various criteria used by physicians in attempting to diagnose premature labor, but does not state that they are the certain indicators of eventual delivery of the fetus that might qualify premature labor as one of those conditions involving predictable signs and symptoms that would allow use of a historical control in a study of Lutrexin.

The finding does state, however, that "By definition Braxton-Hicks contractions or false labor do not cause dilatation of the cervix." The precise import of this statement is not clear. It is probably correct that Braxton-Hicks contractions do not "cause" dilatation of the cervix (T 23). If Hynson means to suggest by this that a dilated cervix is a fool-proof criterion for identifying true premature labor, it has fallen into the logical fallacy of assuming that a condition that is not "caused" by another condition cannot be present together with that condition. One of Hynson's own witnesses, Dr. Rezek, agreed that "a woman with a cervix three centimeters dilated could well be in false labor" (T 557), and indeed Hynson's proposed finding of fact No. 168 incorporates this testimony, along with the observation that "there are many variations on this matter." In other words, a woman can be in false labor and also have a dilated cervix, even though the two conditions are not causally related. Conversely, it is possible, although not common, for true premature labor to be in progress with a closed cervix (T 1320), which Hynson also proposes as a finding of fact (No. 213). It is evident, therefore, that dilation of the cervix cannot be considered a reliable predictor of premature labor, a conclusion that is confirmed by the wide disagreement among the witnesses concerning the correct manner of diagnosing that condition, and by their numerous statements that true and false labor cannot easily be told apart.

A finding not relied upon by Hynson for the predictability of premature labor, but which obviously tends to support that position, is No. 138, which states that "If the cervix of a pregnant woman is open even slightly, then the presumption is very strong that this patient is going to go into premature labor and result in a premature delivery." In support of this, Hynson cites T 67, 225 and 932. However, the testimony from T 225 and 932, which is by Hynson's witness, Dr. Colliton, and the Government's witness, Dr. Fuchs, respectively, does not relate to Hynson's position, much less substantiate it. The testimony of Hynson's witness, Dr. Allen, from T 67 does support that thesis, but is directly contradicted by the testimony of another Hynson witness, Dr. Rezek (T 557).

Hynson's proposed findings of fact Nos. 170 and 232 could, if read liberally, relate to the predictability of premature labor. Finding No. 170 states that an earlier threatened abortion indicates that the patient "will probably have similar trouble later * * * and threaten to go into premature labor," and finding No. 232 suggests that there is a general tendency for the uterus to expel the products of conception because they are foreign to the uterus. At best, this testimony establishes that pregnancy is a condition involving the possibility of complications, and that patients who experience such complications require careful medical management. It in no way demonstrates that premature labor is predictable on the basis of obstetrical history, a point with which Hynson's witness, Dr. Colliton, agreed (T 249).

The record evidence conclusively demonstrates that premature labor cannot be reliably diagnosed on the basis of the indicia that would lead physicians to conclude that labor might be in progress and so require preventive measures such as Lutrexin, and is thus not a condition involving signs and symptoms that are predictable, as required by 21 CFR 314.-111(a)(5)(ii)(*a*)(*4*)(*iv*). Studies testing Lutrexin's effectiveness in premature labor that utilize historical controls, therefore, cannot be considered adequate and well-controlled within the meaning of 21 CFR 314.111(a)(5)(ii)(*a*). This conclusion was also reached by the Government's expert witnesses Fuchs, T 928, 980; Beaver, T 1067 through 1071; and Chalmers, T 1436; and by Judge Sommer on the basis of his evaluation of the evidence ("Tentative Findings of Fact and Order" at 14 and 15).

(b) "Habitual abortion." Although there is no universal agreement among the experts (T 580 through 582, 872 and 873), "habitual abortion" generally refers to the fact of a woman's having had three consecutive spontaneous abortions (G 12 at 509; T 20, 926, 1266). More controversial is whether "habitual abortion" as so defined relates only to a statistical fact, or whether it also relates to a physical condition involving a predisposition by the woman to spontaneous abortion (T 58 through 64, 921; G 12 at 509 and 510). The controversy is sharper still concerning the extent to which a spontaneous abortion may be predicted on the basis of a history of habitual abortion (G 12 at 509 and 510, G 18; T 58 through 64, 250, 583 and 584, 874, 920, 1062 through 1065, 1275).

Apart from the difficulty of identifying a very early spontaneous abortion as such (G 12 at 505), diagnosing "habitual abortion" presents no problems: either a patient has had three consecutive abortions or she has not. But the question remains whether "habitual abortion" is merely a historical fact or is, instead, a pathological condition that requires treatment. Only if the latter is true is it necessary to further inquire whether it is a condition with "signs and symptoms of predictable duration or severity" such that a historical control is permitted by the regulations in a study of the effectiveness of a drug for treating it.

Habitual abortion must be distinguished from threatened abortion and premature labor. Habitual abortion refers to the predisposition, if there is one, to spontaneous abortion that is inferred from a past history of abortion, without regard to current physiological events suggesting cause for concern. Threatened abortion and premature labor refer to observable signs and symptoms indicating that a woman may be commencing the termination of an existing pregnancy. Obviously, if a woman exhibits those signs and symptoms, the fact that she has also had three previous consecutive abortions, i.e., habitual abortion, although possibly relevant to the manner in which the physician exercises his judgment, no longer constitutes the "condition" that requires therapy.

The evidence establishes that habitual abortion is not a condition with signs and symptoms that are predictable as to the outcome of a pregnancy. Hynson's principal support for the predictability of a spontaneous abortion, based on a history of three consecutive previous abortions, is the work of P. Malpas and N. J. Eastman, who postulated that there is an incidence of spontaneous abortion in the total population of pregnant women that is attributable to physiological characteristics that will continue to manifest themselves in subsequent pregnancies with the same result (T 921). By analyzing the statistics applicable to a group of women with a history of abortion, Malpas and Eastman held, it is possible to arrive at a percentage figure that represents the likelihood for that group to succeed or fail in the next pregnancy.

Hynson's proposed finding of fact No. 200 reflects the Malpas-Eastman view. It states that "A patient who has lost three consecutive pregnancies probably does not stand more than perhaps a 20 to 30 percent chance at most of carrying a fourth one to term; the likelihood of the fourth pregnancy resulting in abortion is very high." Specifically, Malpas concluded that in any group of pregnant women who had had three previous consecutive abortions, 73 percent would terminate a fourth pregnancy by abortion; Eastman concluded that the percentage was 83.6. Although it is not clear whether Hynson's witness, Dr. Willard M. Allen, adopted the Malpas-Eastman view as such, his testimony was consistent with it: in his opinion, a fourth pregnancy in a woman with three previous abortions stands no more than a 10 or 20 percent chance of success (T 59). Hynson's witness, Dr. George Rezek, stated that a fourth pregnancy "would be likely" to end in abortion (T 584), and that that is "about as definite as anyone can be" (T 585).

The Malpas-Eastman hypothesis was developed several decades ago. Based on theoretical assumptions and never confirmed by experience, it has recently been challenged by experts on the basis of clinical evidence. In a text entitled "Obstetrics" (G 12), Williams summarizes the contrary position as follows: "the question remains whether there is in fact a clinical syndrome of habitual

abortion or whether the results merely reflect the laws of chance. Both laboratory and clinical experience supports the later [sic] proposition" (G 12 at 509 and 510). For example, the clinically-based work of D. Warburton and F. C. Fraser, cited in Williams' text, led them to conclude that the chances of a fourth consecutive abortion were only 25.9 percent (G 12 at 510). The Malpas-Eastman theory was similarly criticized by J. Goldzieher and B. Genigno who found, again on the basis of clinical evidence, that the likelihood of a fourth abortion was about 24 percent (G 18 at 1204). Goldzieher later commented with respect to habitual abortion that "statistical studies as well as new diagnostic techniques will be necessary if we are ever to know whether we are facing a disease or merely bucking the laws of chance." (G 14 at 654). Even Eastman, whose original hypothesis was that 83.6 percent of fourth pregnancies would abort, later revised that figure downward to 38 percent using more realistic assumptions (G 14 at 651), although even the lower figure was theoretical only.

At the hearing a number of witnesses disagreed with the Malpas-Eastman view that past obstetric l history is a valid indicator of the course of a subsequent pregnancy. Hynson's witness, Dr. William F. Colliton, stated that "you just cannot tell what the woman is going to do * * * from her past obstetrical history." (T 250). Hynson's witness, Dr. Richard R. Gratton, appeared to accept the work of Warburton-Fraser in referring to a 25.9 percent rate of abortion for fourth pregnancies (T 874). The Government's witnesses uniformly rejected the Malpas-Eastman hypothesis. Dr. Fuchs stated that "Each percentage is subject to doubt, and how they affect the individual case is the critical point." (T 921). Dr. Beaver, a clinical pharmacologist familiar with study design and its pitfalls, concluded that on the basis of his review of the literature, "there are many variables influencing the likelihood of a woman with a history of repeated abortion that are not clearly defined at the moment" (T 1064), and "these variables do not seem to have been coped with at all in the literature on the subject" (id.). Dr. King stated that, in the absence of existing physiological problems, one cannot predict the likelihood of abortion based on a history of previous abortions (T 1269), and later stated that "it is very difficult to predict" whether a pregnancy will be successfully based on past obstetrical history (T 1274 and 1275).

According to the evidence, the condition "habitual abortion" is the postulated likelihood that a woman who has had three previous consecutive abortions will abort her fourth pregnancy. The "signs and symptoms" of this condition consist of the previous history of spontaneous abortion. The evidence compels the conclusion that a previous history of abortion does not constitute "signs and symptoms" that are predictable, as required by 21 CFR 314.111(a)(5)(ii)(*a*)(*4*)(*iv*). The theoretical figures of Malpas and Eastman are not confirmed by clinical experience, which indicate, at most, that women with three previous abortions are likely to abort a fourth pregnancy about 24 to 26 percent if the time. Even these figures may represent a statistical phenomenon rather than a physiological condition. To the extent that the figures reflect a physiological condition, they are far to low to establish the predictability needed to give validity to a comparison between the results of treatment with Lutrexin and previous results in the same or other women without Lutrexin. Accordingly, the Commissioner finds that studies utilizing historical controls in testing Lutrexin's effectiveness in treating habitual abortion, i.e., in preventing spontaneous abortion thought to be possible or probable on the basis of past spontaneous abortions, cannot be considered adequate and well-controlled within the meaning of 21 CFR 314.111(a)(5)(ii)(*a*). This was the conclusion reached by Judge Sommer based on his evaluation of the evidence ("Tentative Findings of Fact and Order" at 20).

The Commissioner therefore concludes that neither premature labor nor habitual abortion is a condition with respect to which a historically controlled study qualifies as adequate and well-controlled for demonstrating the effectiveness of Lutrexin. The Commissioner further concudes, and Hynson does not dispute, that dysmenorrhea is not a condition with respect to which a historically controlled study qualifies as adequate and well-controlled for demonstrating the effectiveness of Lutrexin (T 65, 115, 527 and 528, 898, 919, 968 and 969, 1073 through 1075, 1276, 1438).

It must be emphasized that the inappropriateness of using historical controls in these circumstances is based on record evidence concerning the nature of the pathological conditions themselves. Whether, assuming that their use was justified at all, the historical controls were used properly in the studies on which Hynson relies is a distinct question that will be separately addressed where relevant.

B. *Feasibility of Contemporaneous Controls in Studies of Lutrexin.* In its posthearing reply memorandum, Hynson asserts (at 6) that if it is as difficult to identify true premature labor as the FDA contended at the hearing (and as, indeed, the evidence showed, and even as Hynson appears to concede at page 5 of the memorandum), then it follows that it is not only inappropriate to test Lutrexin using a historical control, it is also impossible to test the drug using any kind of control. Hynson argues that use of a concomitant control—active treatment or placebo—would not cure "what the government appears to be stating to be the basic defects in the Lutrexin studies, viz., the impossibility of diagnosing true labor. One, therefore, could not compare the results, for example, in the Fuchs study of a success of ethyl alcohol over the success of placebo, because some patients in both group may have been in false labor."

Hynson's reasoning is faulty, possibly, in part, because its understanding of the Government's position concerning the nature of the study defects is erroneous. None of the Government's witnesses testified, nor in any of its pleadings did Government contend, that it is impossible to diagnose true premature labor. The evidence did establish that it is difficult to determine with any degree of reliability whether a woman is in true or false labor, and that, therefore, it is impossible to accurately predict whether a woman exhibiting the signs and symptoms that suggest the advisability of therapeutic intervention will ultimately deliver without it.

It is this lack of predictability that was stressed at the hearing as the principal reason why historically controlled studies are unsatisfactory for testing a drug designed to slow or stop premature labor, not the impossibility of diagnosing the presence of premature labor at all. The evidence made clear that although existing diagnostic techniques do not permit certainty in the matter, they do allow physicians to make a valid judgment whether a patient is more or less likely to be experiencing premature labor. That the judgment will sometimes prove to be incorrect does not mean that diagnosis of premature labor is impossible, only that it is inherently uncertain.

By taking this very uncertainty into account, however, contemporaneous controls allow meaningful investigations to be conducted into the effectiveness of drugs for conditions with an unpredictable course, like premature labor. This is accomplished by utilizing criteria designed to include in a study as many suitable subjects as possible, given existing knowledge of the condition involved and how to diagnose it (21 CFR 314.111(a)(5)(ii)(*a*)(2)(*i*)); assigning those subjects to test groups in such a way as to minimize bias 21 CFR 314.111(a)(5)(ii)(*a*)(2)(*ii*)); and assuring comparability in test and control groups of pertinent variables, such as age and severity or duration of the condition (21 CFR 314.111(a)(5)(ii)(*a*)(2)(*iii*)). The purpose of these procedures was explained by the Government's witness Dr. Beaver T 1039 through 1046). Briefly, Dr. Beaver testified that the objective of a controlled investigation of a drug's effectiveness is to assure, by comparing a treated and an untreated group of subjects, that any observed effect in the treated group is due to the drug and not to other differences between the treated and untreated groups (T 1041 and 1042). The assignment of subjects to groups to "minimize bias" refers to making sure that there are as few differences as possible between the two groups with respect to variables that might influence the outcome of the test (T 1042). Known variables, such as age, are balanced between the groups by consciously distributing subjects with such possibly relevant attributes evenly between them (T 1043 and 1044). Unknown variables are balanced by the random assignment of patients between the two groups (T 1043).

As Dr. Beaver explained, the principal weakness of the historical control is that it is unable to account for unknown variables in this way because "you do not have a random development of two or more groups and comparing the test drug with something else in another group." (T 1054). It is for this reason that a historically controlled study yields reliable results only when the condition treated is one that is highly predictable, i.e., only when the ultimate outcome of the condition is known not to be strongly influenced by unknown variables (T 1054 and 1055).

Dr. Beaver applied his analysis to premature labor and habitual abortion. With respect to patients in premature labor who are not so far advanced that delivery is inevitable (and diagnosis at that point certain), he stated that the main unknown variable is the possibility that some patients may be in false labor (T 1068). With respect to habitual abortion, Dr. Beaver concluded "that there are many variables influencing the likelihood of * * * a subsequent abortion that are not clearly defined at the moment." (T 1064).

Hynson's statement that "We fail to see how the use of a concomitant control group * * * could cure * * * the basic defects in the Lutrexin studies" is made in the face of Dr. Beaver's clear-cut explanation of this point at the hearing. Specifically concerning premature labor, he stated:

> [I]f you have a concomitant control, then you can predict that randomization will distribute * * * the true and the false labor, between your two or more groups in a pattern that can be described by the laws of chance. So it may be that * * * 40 percent of the time you are wrong, that the patient was really in false labor, and 60 percent of the time she was in true labor. But on the basis of your criteria you cannot distinguish these. So all of these people come into your sample.
>
> However, when they are allocated to the control group and the treatment group at random, you are going to get patients in false labor in both groups, and patients in true labor in both groups. And if one can then use a statistical test based on the laws of chance to rule out a difference in response between the two groups as being unlikely to be due to chance differences in distributing * * * the false and the true labor between the two groups, then you can conclude that the difference is probably due to treatment. So you have some kind of a standard to measure the size of the difference against.
>
> The problem with a historical control here is that you have no standard. You can show that some other group of patients who were supposedly in premature labor had a different outcome in your treated sample, but you do not know whether this difference was due to the drug or due to the fact that, let us say, your treated sample had more patients in it with false labor.

(T 1076 and 1077). This explanation applies equally to randomization of whatever unknown variables influence habitual abortion: they can be accounted for by using a concomitant control, but not by using a historical control.

Two of Hynson's proposed findings of fact (Nos. 202 and 206) suggest that it is not possible to conduct a study of Lutrexin for premature labor using the randomization technique. The supporting testimony reveals that the difficulty foreseen by one witness concerned ethical considerations and obtaining informed consent (T 239 through 243, 253 and 254), which is discussed later. The other witness, Dr. Majewski, was asked whether in his study he had attempted to place patients in certain groups "according to the variables." Dr. Majewski responded in the negative, and then was asked how this could be done "as a practical matter," i.e., "randomly assign patients to certain groups according to the degree of cervical dilatation, for example." Dr. Majewski responded that it could not be done (T 1365 and 1366). The question put was internally contradictory: patients cannot be "randomly" assigned on the basis of a known variable like cervical dilatation. Dr. Majewski's response was thus ambiguous. There is no self-evident reason why patients exhibiting signs and symptoms indicating the possibility of premature labor cannot be randomly assigned to treatment and control groups.

C. *Ethics of Using Contemporaneous Rather than Historical Controls.* Hynson's position that considerations of medical ethics justified the use of a historical control in most of the Lutrexin studies is purportedly set out in the 49 findings of fact that are collectively entitled "Ethics of Human Experimentation and Impropriety of Placebo Controlled Trials." (Proposed findings of fact Nos. 56 through 94.) Only one of those findings directly supports Hynson's position: finding No. 89 states that "witnesses for Respondent testified uniformly that it would be unethical to conduct a double-blind placebo study of the effectiveness of a drug such as Lutrexin or ethyl alcohol in the management of premature labor and habitual abortion."

The testimony cited to substantiate this finding, however, proves a much narrower proposition, specifically, that if a physician personally believes that Lutrexin is the only effective therapy for premature labor or habitual abortion, or if he believes Lutrexin is markedly superior to other therapy, then it would be unethical for that physician to withhold Lutrexin from a patient with either of those conditions (T 89, 258, 351 and 352, 1442 and 1443). Necessarily, however, if a physician is not convinced of Lutrexin's effectiveness, then he could ethically withhold it as part of a contemporaneously controlled study comparing Lutrexin therapy with another regimen, such as a placebo together with bed rest.

Although Hynson refers to the possibility that a physician might form a conclusion about a drug's efficacy in the early investigational stages that would ethically preclude him from withholding it as part of a subsequent controlled study (proposed finding of fact No. 87, citing T 1521), there is nothing in the record to indicate that Lutrexin is so widely accepted as effective among physicians that there would be difficulty in finding qualified medical researchers to investigate the drug in such a study (see T 1441 through 1443, 1523 and 1524). The record suggests the opposite: Lutrexin is not a part of the therapy recommended in most basic texts on obstetrics (Beaver, T 1082, 1239 and 1240; Cibils and Zuspan, G 7; Williams, G 12; Greenhill and Friedman, G 24; Allen, T 80 through 86; King, T 1304 and 1305; Fuchs, T 918; Novak, G 28; Rezek, T 533), although it is mentioned in two (Krantz, T 615). Hynson's own witnesses testified that placebo controlled studies are ethical where no other effective therapy is believed to exist (T 32 and 33, 352 through 354, 506, 1394 and 1395). Hynson cannot avoid the statutory and regulatory requirements by submitting the historically controlled studies of a few physicians whose prior belief in Lutrexin's effectiveness would have raised an ethical barrier to their conducting a contemporaneously controlled investigation, had it occurred to them to do so.

Hynson refuted its own argument concerning the impropriety of placebo controlled studies of Lutrexin when it introduced the studies and testimony of Drs. William M. Bickers (R 23, 55) and William F. Peterson (R 52, 53), both of whom carried out investigations involving administration of Lutrexin to one group of women in premature labor and of a placebo to another. The record does not reflect any ethical doubts by these physicians concerning what they did.

Further evidence that it is not per se unethical to conduct a contemporaneously controlled study of Lutrexin in cases of either premature labor or habitual abortion is supplied by the testimony of a number of witnesses for both parties (Colliton, T 227 and 228; Sadusk, T 377 through 379; Fuchs, T 934 and 935; Beaver, 1080 through 1083; King, T 1283 through 1286; Chalmers, T 1441 through 1448). Specifically, the four witnesses for the Government testified without exception that, based on what can be reliably concluded about Lutrexin's effectiveness from the available evidence, it would not be unethical to conduct such a study of the drug's effectiveness in premature labor (Fuchs, T 934 and 935; Beaver, T 1080 and 1081; King, T 1284 and 1285; Chalmers, T 1446).

Hynson's proposed finding of fact No. 77 states that Dr. Chalmers was unable to conclude whether it would be ethical to test Lutrexin against a placebo because he did not know the effectiveness of alternative forms of therapy, citing T 1441. Elsewhere, however, Dr. Chalmers stated that a placebo controlled study of Lutrexin would be ethical (T 1446). It is apparent that in his earlier statement, Dr. Chalmers was alluding to the possibility that there is effective alternative drug therapy for premature labor, and that if that is the case, an "active treatment" control should be used comparing Lutrexin with the alternative drug. Both placebo and active treatment controls are contemporaneous, however, and not historical.

The Government witnesses testified similarly in respect to the propriety of contemporaneously controlled studies of Lutrexin's effectiveness in habitual abortion (Fuchs, T 935 and 936; Beaver, T 1090; Chalmers, T 1447 and 1448). Again, Hynson mischaracterizes testimony, this time that of Dr. Beaver. According to Hynson's proposed finding of fact No. 81, Dr. Beaver stated that "controls used in the study [R 2, 50] on habitual abortion were misused, but did not state that a double-blind placebo trial was needed." What Dr. Beaver said was that the historical control was misused, and also that it was "the wrong control" (T 1090). Since the only other controls are contemporaneous controls, Dr. Beaver necessarily testified that one of them should have been used. Earlier, Dr. Beaver testified that it would be ethical ("legitimate") to test Lutrexin against a placebo for habitual abortion (T 1083).

Oddly, Hynson has submitted the following proposed finding of fact No. 101:

> It would be ethical to conduct an investigation of the effectiveness * * * of Lutrexin in the management of premature labor utilizing in the active treatment control group Lutrexin, bed rest, sedatives and other conventional therapy, and in the control group utilizing placebo, bed rest, sedatives and other conventional therapy, assuming that the investigator has, based upon experience in the past, concluded that the conventional treatment has some positive effect, and that Lutrexin together with the same conventional therapy may have a more positive effect.

The Commissioner concludes that this finding is amply supported by the record, and that it is completely contrary to Hynson's position that a placebo controlled study of Lutrexin is unethical. It is also at odds with Hynson's view, expressed in its posthearing memorandum and implied in proposed findings of fact Nos. 91 and 92, that a double-blind placebo study would conflict with proposed Department of Health, Education, and Welfare (HEW) regulations on drug experimentation published in the FEDERAL REGISTER of August 23, 1974 (39 FR 30648). The proposed regulations precluded any "activity * * * involving fetuses *in utero* or pregnant women" unless its purpose "is to benefit the particular fetus or to respond to the health needs of the mother." These proposed regulations were issued as final regulations, without substantial change, in the FEDERAL REGISTER of August 8, 1975 (40 FR 33525). According to Hynson, administration of a placebo would violate this standard because it is of no benefit to the mother or unborn child. But the regulations require that the "activity," not the drug entity, be intended to benefit the mother or the fetus; a controlled study of Lutrexin involving a placebo is an activity with just that purpose. The intent of the regulations obviously is to prohibit experimentation on pregnant women with drugs unrelated to pregnancy, not to ban reliable research on drugs specifically aimed at facilitating the birth of a healthy child.

Hynson maintains that another provision of the HEW regulations, published in the FEDERAL REGISTER of May 30, 1974 (39 FR 18917), which requires informed consent for drug experimentation, would make it impossible to conduct a contemporaneously controlled study of Lutrexin because no pregnant woman in premature labor or liable to habitual abortion would voluntarily run the risk of receiving a placebo instead of Lutrexin (proposed findings of fact Nos. 93 and 94). Two witnesses testified to this possibility (T 242 and 243, 253 and 254, 258, 265, 332, 352). Neither, however, had ever attempted to obtain informed consent, and two witnesses for the Government stated their belief that informed consent for a placebo controlled study of Lutrexin could be secured (T 1314 and 1315, 1503). Hynson's argument is speculative, and, as with other of its contentions, is based on the unsupported hypothesis that the efficacy of Lutrexin is accepted by all physicians, who would thus be obliged to inform test subjects that participation in a controlled study involved possible denial of therapy known to be effective. Since Hynson's premise is not established, its conclusion cannot be accepted.

The Commissioner finds that the record evidence cited in Hynson's proposed findings of fact Nos. 56 through 94 does not support the proposition that studies of Lutrexin using contemporaneous controls, and placebo controls in particular, are unethical, and accordingly rejects Hynson's proposed conclusions of law Nos. 7 through 10 to the extent that they either state or imply that proposition.

## IV. EVIDENCE TO ESTABLISH THE EXISTENCE OF ADEQUATE AND WELL-CONTROLLED CLINICAL INVESTIGATIONS DEMONSTRATING THE EFFECTIVENESS OF LUTREXIN FOR ITS LABELED INDICATIONS

As discussed in part III, historically controlled investigations cannot qualify as "adequate and well-controlled" within the meaning of the regulations for any of Lutrexin's labeled indications. Accordingly, they may be considered only as corroborative of studies that are adequate and well-controlled. 21 CFR 314.-111(a)(5)(ii)(c). The following analysis, therefore, will treat at greater length those few studies that utilize a contemporaneous rather than a historical control. The analysis of a historically controlled study should be understood as incorporating a finding that the study is not "adequate and well-controlled," in addition to other deficiencies noted, if any, including failure to use properly the historical control.

In its brief to the Commissioner (at 14), Hynson states that Judge Sommer erroneously equated uncontrolled and historically controlled studies. It is apparent, however, that the Judge, having concluded that the use of historical controls had not been justified, employed the term "uncontrolled" to refer to the absence of the contemporaneous controls that were in his view required to be used. There was nothing improper in this terminology.

A. *Premature Labor.* Lutrexin is indicated for both premature labor and threatened abortion. As explained in paragraph III.A.2. of this notice, the indication for "threatened abortion" is limited by Lutrexin's labeling to the second and third trimester, rendering it functionally indistinguishable from premature labor. Investigations supporting effectiveness for one indication would thus support effectiveness for the other, and there is no need for separate discussion of the evidence for both.

To the extent that Hynson regards "threatened abortion" as a condition that exists by reason of the patient's propensity for spontaneous abortion based on previous obstetrical experience, the indication is identical to "habitual abortion," and the evidence for Lutrexin's effectiveness in treating it will be discussed under that heading.

1. The Bickers study (R 23, 55). A study principally relied upon by Hynson is "Premature Labor-Lutrexin Treated," by William M. Bickers, M.D., dated June 1, 1974, which had not been submitted to, or considered by, the Food and Drug Administration in connection with any of the proceedings concerning Lutrexin that antedated the hearing. The first report of this study (R 23) was revised on the basis of new information (T 693 and 694), and a new report was prepared (R 55). Hynson also introduced the protocol of the study (R 51) and case reports on the subjects who participated (R 56), and had marked for identification a statistical analysis of the results of the study prepared by someone other than Dr. Bickers, but which apparently never became part of the record (T 693).

The purpose of the Bickers study was "to evaluate the pharmacologic properties of a water-soluble extract of the sow corpus luteum" (Lutrexin) with respect to its effect on "human myometrial activity" and "its clinical usefulness in extending and prolonging intrauterine gestation." That is, the study was designed to test Lutrexin's effectiveness in inhibiting labor contractions and delaying delivery of the fetus.

Thirty-two pregnant women exhibiting signs of premature labor were selected for the study. Premature labor was defined as regular uterine contractions at 36 weeks gestation or less. The diagnosis of true as opposed to false labor was in some cases made with the aid of an ultrasonic device to measure the fetal heart rate (T 760 and 761) on the assumption that true labor is distinguished from false labor by an expulsive contraction that reduces the fetal heart rate by reason of compression of the head of the fetus against the cervix.

The study was double-blind and used a placebo: some of the patients received an inert preparation resembling the Lutrexin received by the others, and neither the patient nor the administering physician or nurse knew which was which. Administration of the Lutrexin and placebo was by sealed, coded envelopes.

Upon commencement of medication, the ultrasonic device described above and

another device for recording uterine contractions were used to establish myometrial inhibition, which, if present, resulted in repetition of the medication every four hours until labor was arrested. In cases where no inhibition was observed, medication was terminated.

There were 18 Lutrexin and 14 placebo patients. Of the 18 Lutrexin patients, 8 showed inhibition for 24 hours or more, 6 showed inhibition for from 4 to 24 hours, and 4 showed none. Of the 14 placebo patients, 2 (or 4) showed inhibition for from 4 to 24 hours, 12 (or 10) showed none.

The above is a summary of the written report (R 55), supplemented in minor respects by Dr. Bickers' testimony. Standing alone, the results, though there were ambiguities (to be discussed later) on the face of the report, support Lutrexin's effectiveness in inhibiting uterine contractions during the first 24 hours after admission. They do not establish, however, that labor was prolonged. Dr. Bickers' testimony, moreover, raised a serious question concerning whether the results were rendered meaningless by a critical methodological error, and a number of deficiences were identified in the report of the study itself that were not remedied by Dr. Bickers.

The methodological error was the possible randomization of medication; i.e., a subject may have received either Lutrexin or the placebo rather than the same treatment on which she had been commenced. If this happened, it would make it impossible to determine which of the 32 subjects received Lutrexin and which a placebo after the first dose, and thus equally impossible to attribute to Lutrexin any effects observed after the 4 hours immediately following the first dose. In view of the controversy surrounding this point (Hynson's posthearing memorandum at 6; Government's posthearing memorandum at 29; Hynson's brief to the Commissioner at 4 through 6), and without intending to give undue emphasis to this aspect of Dr. Bickers' testimony and study to the exclusion of other points of equal or greater significance, it is appropriate to set forth without editorial change the full text of the record containing the relevant testimony. Government counsel was developing a point concerning the presence in the study of patients in false labor by cross-examining Dr. Bickers about reduced myometrial activity observed in subjects given the placebo. The following interchange took place:

Q. So, there were a few placebo group patients who received repeated medication? Would that have been repeated placebo?

A. Yes.

Q. It was?

A. Yes.

Q. And she would have gotten another 10 tablets?

A. Yes.

Q. And if she had shown——

A. In other words if they didn't get any effect, if she got a drop on the monitor, we did not know. There was a blind study. They repeat medication like the original medication. It may or may not have been.

Q. Was it coated the same way?

A. The placebo and the Lutrexin? We couldn't tell the difference.

Q. You couldn't tell the difference? How about the repeat medication? How did you know——

A. They were given both the placebo-treated patients and the Lutrexin-treated patients.

Q. How did you know what to give them on the repeat dose? Would you explain to us how the resident who was dispensing this medicine, according to your protocol, when it was time for him to give a repeat dose, how it was that he did not know whether the repeat dose was Lutrexin or placebo?

A. No, he did not know.

Q. He did not? Why did he not know?

A. Because that is a double-blind study.

Q. Well, how did he not know?

A. He would have no way. I don't understand the question.

Q. How was it blinded?

A. Because the tablets, when the envelope is opened of course, the tablets are visible for everyone to see, but they were made up by the pharmacist to resemble the Lutrexin tablets.

Q. Let us back up, Dr. Bickers, because I don't think we are getting to the point here. The patient came in. She was examined. She met the criteria for including her in the study. She was taken to the room or the suite, and then you put the monitor on her, and then you gave her the dose, right, of whatever it was? They all got 10 tablets.

A. That first dose, we did not know what it was.

Q. Right. How did you determine which one got the drug Lutrexin and which one got the placebo?

A. Because the code number on the envelope was entered on the patient's chart.

Q. All right. How did you determine which person would get a certain code number?

A. We didn't. That was pure chance, because the code numbers didn't——

Q. How did you get the number to the patient? What is the connection?

A. I am sorry. I don't understand you.

Q. Did the resident reach in a drawer?

A. Here is the nurse's desk that has got the envelopes full of the pills in it. Here is the patient.

Q. Okay, it has got envelopes. Each envelope has 10 pills?

A. That is right.

Q. Each envelope has a code number?

A. Right.

Q. And then once a patient was admitted to the study, the treating physician or the nurse would grab 10 pills with a code number? Sir, I see you nodding.

A. I am sorry. Yes, she would.

Q. She would?

A. Yes.

Q. Then she would give the 10 pills to the women?

A. Right.

Q. She would not [sic] the code number on the patient's chart?

A. Correct.

Q. And so there was no way for anybody to know whether the 10 pills which she picked out of the drawer—is that the way it was done?

A. That is right.

Q. There was no allocation of it in the drawer?

A. No.

Q. Would you describe it as being random?

A. Definitely.

Q. Definitely. All right. So, neither the nurse, nor the doctor, nor the patient knew what the 10 pills were?

A. Exactly.

Q. The only thing known to the doctor and the nurse was the code number?

A. The number on the envelope.

Q. Did the placebo look the same as the Lutrexin?

A. Yes, very well done. I could not tell the difference.

Q. All right, sir. Where did you get the Lutrexin?

A. Where did I get it or when?

Q. Where?

A. From Mr. George Whattam of the Hynson Company in Baltimore.

Q. How did you know it was Lutrexin?

A. It was labeled Lutrexin. We took it out of the labeled box and put it in the coded envelopes.

Q. It was commercially available Lutrexin?

A. Commercially available Lutrexin.

Q. 3,000 units a tablet?

A. Right.

Q. Is that correct, Doctor?

A. That is correct.

Q. All right, sir. Then after you gave the 10 tablets, an hour later you would check to see if the contractions had diminished?

A. That is right, and if they had diminished, you would give her another random dose. We did not know what that dose was either.

Q. She would get another random dose?

A. Yes, so the Lutrexin-treated patients means that the patient is Lutrexin treated if the first dose is Lutrexin. Do you see what I mean? This we knew afterwards, after the study was over.

Q. So, you don't know what she got the second time?

A. We do know, yes, from the chart. We would know from the code number.

Mr. ELDRED. Your Honor, could I request another brief recess?

Judge SOMMER. How long?

Mr. ELDRED. Say about five to 10 minutes.

Judge SOMMER. All right.

[Brief recess.]

Judge SOMMER. We are back on the record.

By Mr. ELDRED:

Q. Dr. Bickers?

A. Yes, sir.

Q. You indicated that the patients' charts would reveal which medication they received. Is that correct?

A. They would reveal a code number, yes.

Q. A code number. That is right. Are the patients' charts here?

A. No. That is one reason for our confusion, because all of this information has been gotten by satellite in the last three weeks by telephone.

(T 779 through 784). The matter was not inquired into by counsel for Hynson on redirect.

This testimony creates an implication that the medication may have been randomized after the first dose. The hospital personnel who administered the medication could not determine what was in any given envelope of pills; it could have been Lutrexin or it could have been the placebo (T 781). This, of course, is unavoidable in a double-blind study. What is not unavoidable, however, is the failure to have the envelopes arranged beforehand, by someone who knows what is in them but who will not otherwise participate in the investigation, to assure that the administering personnel give a patient the same kind of pill throughout the duration of the study. If this is done, randomization of the medication will be prevented, yet the administering personnel will remain "blind" as to what is in the pill. Dr. Bickers' testimony implies that this was not done in his study: "Q. And so there

was no way for anybody to know whether the 10 pills which she [the nurse] picked out of the drawer—is that the way it was done? A. That is right. Q. There was no allocation of it in the drawer? A. No. Q. Would you describe it as being random? A. Definitely. Q. * * * So, neither the nurse, nor the doctor, nor the patient knew what the 10 pills were? A. Exactly (T 782). Q. * * * Then after you gave the 10 tablets, an hour later you would check to see if the contractions had diminished? A. That is right, and if they had diminished, you would give her another random dose. We did not know what that dose was either" (T 783).

There is nothing in the record to dispel the implementation that doses after the first were randomized, other than Dr. Bickers' assertions that they were not. Hynson urges that these statements, combined with Dr. Bickers' professional standing, are sufficient to resolve the issue in its favor. However, Dr. Bickers' statements were undermined by his own related testimony. Thus, Dr. Bickers stated that "they repeat medication like the original medication," but immediately followed it with the statement "It may or may not have been," apparently referring to whether or not the medication was a placebo (T 779). Dr. Bickers then testified that he knew which subjects got the placebo by the code number from the envelope entered by the nurse on the subjects' charts (T 780 and 781), but he then stated that the code numbers were not used by the nurse to determine which medication to give to a subject: "Q. * * * How did you determine which person would get a certain code number? A. We didn't. That was pure chance * * *" (T 781). The code number was thus not used to assure that a subject commenced on Lutrexin remained on Lutrexin, because the code numbers were apparently not intended to guide the nurse's selection of medication. Dr. Bickers, after stating that "We did not know what that [subsequent] dose was either," stated "Yes, so the Lutrexin-treated patients means that the patient is Lutrexin treated if the first dose is Lutrexin * * *. This we knew afterwards, after the study was over * * * from the chart. * * * from the code number" (T 783). However, if the administering nurse could not have know that the medication administered the second time was the same kind of medication administered the first time, that is, if continuity had not been assured by assigning medication by code number or by segregating the envelopes into Lutrexin and placebo groups, there could not have been any way of determining post facto that a given patient had been continued on the same medication throughout the study, because she could not have been, except by accident.

To conclude that the envelopes were segregated, that there was something in the code that guided the nurses' selection, or that continuity of medication was assured in some other way, would require acceptance of a state of facts contrary to that to which Dr. Bickers testified. It is not possible, on the basis of the record, to account for Dr. Bickers' conclusion that he "knew" that a patient who received Lutrexin the first time received Lutrexin throughout the study, for, despite prolonged questioning, Dr. Bickers provided no factual basis for such knowledge, and Hynson did not provide patient records containing dispensing information sufficiently detailed to permit subsequent determination of what medication was actually given to each patient.

One may speculate that Dr. Bickers did not understand the import of the Government's line of inquiry. However, since it was clearly aimed at finding out the answer to the very elementary question of what mechanism had been used to assure continuity of medication, one may also speculate that Dr. Bickers' failure to grasp the point resulted from ignorance of basic methodology that also manifested itself during the study. Whatever the reason, Dr. Bickers' testimony on cross-examination raised the implication that the doses had been randomized, and this implication was never explained or overcome.

As mentioned, counsel for Hynson did not pursue the point on redirect. However, Hynson points to a subsequent statement made by the Government's witness, Dr. Beaver, on direct examination concerning the raw data underlying the Bickers study as establishing that the medication was not randomized (corrected finding of fact No. 17; T 1166). The raw data consisted of the case reports; an asterisk was placed by a "Lutrexin" patient. Dr. Beaver stated that "the implication is that the repeated doses were the same thing, because if they were not you have no way of knowing what they were. There is no way of knowing from this data what the second dose was, if it was not consistently the same thing as the first dose" (T 1166). Dr. Beaver did not say that he believed from the raw data that medication had not been randomized in the Bickers study; he said that there was no way to tell, but that the only correct procedure would have been to continue each subject on the same medication, and ordinarily one assumes that the correct procedure has been followed. But Dr. Bickers' testimony implies that the correct procedure was not followed in this instance (T 1166 and 1167). By contrast, the two Government witnesses who read Dr. Bickers testimony concluded that he had, in fact, randomized the doses (King, T 1298; Chalmers, T 1474). Judge Sommer came to the same conclusion, based on his review of the transcript and his observation and recall of the testimony ("Tentative Findings of Fact and Order" at 16).

The Commissioner has considered this matter very carefully. While not as confident as the Government that the doses were in fact randomized, he is unable to conclude that they were not; on balance, the testimony suggests that they were randomized. In view of the dispute between the parties on the burden of proof issue, it is appropriate to state that even if the ultimate burden of proof were placed on the Government to establish the inadequacy of the Bickers study, the Commissioner's conclusion on this point would not change. At the hearing, the Government, through its cross-examination of Dr. Bickers, clearly raised an implication that there was a serious methodological defect in the Bickers study. On the basis of Dr. Bickers' testimony at that point, the trier of fact would have been justified in concluding that randomization had taken place more probably than not, and Judge Sommer, who had the benefit of observing the witness, did so conclude. To avoid this result, it was incumbent on Hynson to do something that would explain Dr. Bickers' testimony and overcome the implication it created. Hynson did nothing. It is insufficient to point to Dr. Bickers' professional standing as negating the possibility of a serious mistake in methodology; experienced professionals are not above error.

The Bickers study was also criticized for ambiguities in the presentation of the results (T 1167 through 1169) and for using unreliable diagnostic criteria (T 938 through 941, 945 and 946, 1289 through 1297). Dr. Bickers did little to clarify the first problem, which may have involved overlapping criteria or hazy definitions (T 756 and 757). With respect to the second criticism, one Government witness stated that measurement of variations in the fetal heart rate was not an accepted diagnostic technique for premature labor (T 398 through 947, 945 and 946). Dr. Bickers testified that the ultrasonic device was used only to aid diagnosis, and that the criteria actually used included manual determination of expulsive contractions of increasing intensity and frequency (T 738, 758 through 768). These, however, are not the most reliable criteria (T 938).

Hynson's proposed finding of fact No. 123, to the extent that it suggests that Dr. Bickers may have used progressive dilation and effacement of the cervix to diagnose premature labor, is not confirmed by the cited testimony. Dr. Bickers specifically stated that, in his opinion, the status of the cervix is not normally used to diagnose premature labor (T 738), that it was measured in the subjects in his study only as part of the routine of patient management, and that it could be an aid in the diagnosis of premature labor "in some cases" (T 759). Although other witnesses testified that progressive dilation and effacement of the cervix is the best diagnostic technique for identifying premature labor (T 915 through 918, 1265 and 1266, 1294), Dr. Bickers testified that he used dilation of the cervix as a basis for excluding rather than including subjects in the study (T 759). Indeed, 24 of the 32 patients in the study had a closed cervix (R 56). Although it is possible for true premature labor to be in progress with the cervix closed, it is also uncommon (T 1295, 1320). This may account for the fact that a number of women

in the placebo group in Dr. Bickers' study delayed delivery for a substantial length of time beyond what might be expected had they been in true premature labor (T 772 through 779, 1295). Dr. Bickers conceded that some of these women could have been in false labor, and that some of the women in the Lutrexin group might also have been (T 778), a possibility that a Government witness stated was virtually a certainty (T 1296).

The testimony thus creates serious doubts about the reliability of the diagnostic criteria used in the Bickers study, the skill with which they were applied, or both. The regulations require a method of selecting subjects that "provides adequate assurance that they are suitable for the purposes of the study." (21 CFR 314.111(a)(5)(ii)(*a*)(2)(*i*). Although it is probably impossible to exclude all cases of false labor from a study of a drug's effectiveness in inhibiting true premature labor, it is nevertheless necessary to use the most accurate diagnostic techniques available to assure that as many as possible are identified and eliminated. The fact that 75 percent of the women in the study had a closed cervix strongly indicates that the diagnostic criteria that were used were either insufficiently reliable or were not correctly applied. Moreover, by excluding most patients with a dilated cervix, Dr. Bickers may have succeeded in eliminating subjects whose labor was irreversible (T 940 and 941); but by so doing he may also have significantly skewed his study population toward an even greater proportion of women in false labor (T 941), thus further undermining the validity of the results. This difficulty was aggravated by the comparatively small size of the sample (T 944 and 945).

The Commissioner therefore finds that the Bickers study does not meet the requirements of 21 CFR 314.111(a)(5)(ii)(*a*)(2)(*i*).

On cross-examination, the Government attempted to establish that the Bickers study did not comply with the requirement of 21 CFR 314.111(a)(5)(ii)(*a*)(2)(*iii*) for assuring comparability in test and control groups of pertinent variable (T 706 and 707, 741, 744, 784). Although a witness for the Government stated that there was no indication in the study that comparability of variables had been assured (T 944), another stated that he did not find "any significant differences between the two groups * * * There were trends one way and the other, and they seemed to cancel each other out" (T 1478). The Commissioner finds no failure of compliance in this respect.

Assuming, contrary to the above finding concerning suitability of the subjects selected for study, that the Bickers investigation is adequate and well-controlled for the 4 hours between administration of the first and second dosages of medication (after which all controls may have disappeared as a result of randomization of the medication), the results do suggest that Lutrexin may inhibit or arrest uterine contractions for that 4-hour period. This, however, is not a clinically significant result, i.e., prolongation of delivery for only 4 hours does not constitute "effective" treatment of premature labor, because there is no evidence that it accomplishes any therapeutic purpose beneficial to the fetus. Hynson urges that the prolongation of delivery observed in the Bickers study is clinically significant (corrected conclusion of law No. 2; corrected findings of fact Nos. 15, 17 through 19), but that assertion is based on periods longer than 4 hours.

Although there appears to be no dispute that "prolongation of intra-uterine life is critical in terms not only of the viability but also of morbidity of the fetus" (Hynson's corrected finding of fact No. 21), Hynson cites no evidence of record that a 4-hour postponement of delivery is critical. There was testimony that periods of a few weeks can be important (T 1361 and 1362), but even Hynson concedes that "preventing delivery for only three days would probably, in most cases, not be clinically significant in terms of fetal viability or morbidity" (brief to the Commissioner at 9). (This 3-day minimum, it should be noted, is longer than the maximum 24-hour period for which there were any results in the Bickers study, even disregarding the randomization problem.) Two of the Government's witnesses specifically agreed. Dr. Beaver explained that a 4-hour cessation of labor contractions is a pharmacologic, not a therapeutic, effect; i.e., it is a physiologic fact of no necessary benefit to the patient without further tests to establish that it assures a meaningful increase in the likelihood of a live birth or of survival of the infant (T 1174 and 1175). Dr. Chalmers testified similarly (T 1490). All of the Government's witnesses agreed that the Bickers study did not justify a conclusion that Lutrexin is effective in the treatment of premature labor (T 950, 1172 through 1176, 1287, 1299, 1472 through 1476, 1481 through 1490), which is the condition for which Lutrexin is indicated on its labeling. Further, although a drug can be approved on the basis of a pharmacologic effect that is thought to be associated with an important therapeutic effect, but for which conclusive evidence of causation is lacking, approval is not appropriate here: there is no evidence that a 4-hour, or even a 24-hour, prolongation of gestation is of any clinical importance in the treatment or management of premature labor, and the labeling for Lutrexin does not state that the purpose of the drug is to achieve this pharmacologic effect.

A final reason why the Bickers study cannot provide substantial evidence of the effectiveness of Lutrexin under its labeled conditions is that the drug was tested at a higher dosage level than the one recommended in its labeling (T 949 and 950, 1171 and 1172, 1475). Hynson maintains that this is a minor technicality that could be cured by amending the labeling recommendation to correspond with the higher dosage levels (brief to the Commissioner at 6 and 7). However this may be, the law is clear that the applicant must provide substantial evidence of a drug's effectiveness under its labeled conditions of use, not those under which an investigator chooses to test it. Further, Hynson underestimates the significance of a substantial upward revision in the recommended dosage in terms of the possible need for additional safety data.

The Commissioner concludes that the Bickers study is not adequate and well-controlled for any period of time, and that if it were adequate and well-controlled with respect to the first 4 hours after administration, the study would not provide evidence that Lutrexin is "effective" in premature labor because there is no evidence that a 4-hour prolongation of labor is clinically significant. The Commissioner therefore rejects Hynson's corrected and proposed conclusion of law No. 2 as contrary to the evidence of record, and any underlying corrected or proposed finding of fact inconsistent with the foregoing.

2. The Falls, Rezek, Benensohn study. Although Dr. Rezek testified at the hearing, we was not questioned in detail by either party concerning this 1942 study (R 6) in which he collaborated. However, the study was the kingpin of a complicated effort by Hynson to demonstrate by indirection that Lutrexin has been shown to be effective in inhibiting labor contractions, a demonstration that involved the testimony of a number of Hynson's witnesses.

Before analyzing this study, it is necessary to address an incident that took place on the first day of the hearing. As discussed previously, the record is not clear about Hynson's understanding of the term "threatened abortion," as mentioned in section III.A.2. of this notice. Although Lutrexin's labeling refers to second and third trimester threatened abortion, Dr. Allen, one of Hynson's own witnesses, defined threatened abortion as a condition occurring in the first and early part of the second trimester (T 20), for which Lutrexin is not indicated. At the oral argument before the Commissioner, Hynson agreed that second and third trimester threatened abortion is probably the same thing as premature labor. Perhaps with that thought in mind, but not in the record, Hynson's counsel cut off an early attempt by Government counsel to examine the basis for the threatened abortion indication by agreeing to stipulate that there are no studies supporting it (T 118 through 120). This stipulation was later raised by counsel for Hynson to curtail a similar line of inquiry (T 452). However, if Hynson's counsel meant to limit the stipulation to first trimester threatened abortion, as it has persistently claimed since the end of the hearing, it did not so advise Government counsel at the time. Nor could Hynson have reasonably assumed that Government counsel would have understood the stipulation to be limited to the first trimester: the questioning by the Government that preceded Hynson's

stipulation (T 117 through 119) was directed at "threatened abortion" without specifications as to time of occurrence, and the label indication for Lutrexin—which was directly in issue at the hearing—is for second and third trimester threatened abortion. At no time during the hearing is there any indication that Hynson apprised Government counsel or Judge Sommer that it believed "threatened abortion" to be synonymous with premature labor insofar as Lutrexin's labeling was concerned.

Although this semantic confusion could have been just that, in fact it had a practical result. The Falls, Rezek, Benensohn article contains several studies. One involves habitual abortion, another what the authors term "threatened abortion." After the hearing, Hynson relied upon this phase of the study for supporting Lutrexin's effectiveness in premature labor. During the hearing, however, Hynson introduced no substantial testimony on the study in relation to this indication even though one of its authors, Dr. Rezek, testified, nor did Government counsel question Dr. Rezek about it. At oral argument, the Government contended that its counsel would have introduced testimony about, or conducted cross-examination on the basis of, this study had it not been for Hynson's representation that "threatened abortion" was no longer in issue, combined with the fact that the stated concern of the Falls, Rezek, Benensohn study is with "threatened abortion." This contention is plausible, particularly in light of the fact that the "threatened abortion" phase of the study, unlike the habitual abortion phase, purports to utilize a contemporaneous control, one of the few such studies identified by Hynson.

Hynson maintains that the true purpose of the study, and the use to which Hynson would put it, could have been gleaned from the conclusions at the end of the article (R 6 at 10 and 11), which refer to prolongation of gestation and premature delivery. The Commissioner does not think it appropriate for Hynson to argue that the Government should have puzzled its way through the confusion sown by Hynson to reach the conclusion that this study would later be relied on by Hynson to support an indication that is not by terms mentioned in it. Hynson had every opportunity to clarify the situation when it called Dr. Rezek as a witness. Yet the record nowhere reflects any attempt to define what was intended by "threatened abortion," nor any meaningful effort to discuss the significance of the material in R 6 in terms of the labeled indications for Lutrexin. Government counsel, as indicated, did not go into the matter extensively on cross-examination; he had no reason to believe that it later would be a key element in Hynson's support for Lutrexin's effectiveness in premature labor. Consequently, there is no testimony that would assist the Commissioner in understanding or evaluating this aspect of the Falls, Rezek, Benensohn study. The Commissioner, however, has carefully reviewed the study in relation to this indication, and his analysis follows.

The Falls, Rezek, Benensohn article includes a study in which a product called Lutein was used to treat women diagnosed as having threatened abortion. Lutein, a Hynson product, was described in the study as "a water soluble corpus luteum extract," one of a variety of such preparations on the market (R 6 at 2). It was a parenteral drug to be injected intramuscularly (id. at 3). The study notes that there is "a considerable difference in the activity of these preparations in inhibiting uterine contractions" (id.). It also disclaimed any attempt "to define their chemical formula accurately since we feel that they contain the contraction inhibiting factor which this and previous studies seem to show is the factor responsible for the beneficial results obtained clinically in the treatment of human abortion" (id. at 1).

According to the report of the study, a group of 112 women with threatened abortion was given Lutein, while a concomitant control group of 44 was not given Lutein, but did receive barbiturates or morphine. Over the 3 months of the study, there were 15 failures in the Lutein group and 37 in the control group (R 6 at 4). The study report also contains graphs indicating that injection of Lutein quiets the contractions of a uterus first stimulated by pituitary extracts (R 6 at 1 through 3, figures 2 and 3).

Described by Hynson as meeting all of the regulatory criteria (corrected finding of fact No. 25; proposed finding of fact No. 97), the study contains serious methodological defects that render it less than adequate and well-controlled on its face. As noted, these defects were not cured by testimony from Dr. Rezek. The objective of the study is not clearly stated because the term "threatened abortion" is nowhere defined in the study report. As explained, there is no common understanding in this proceeding of what is meant by "threatened abortion," much less an understanding of the term that is sufficiently well-established that it can be attributed reliably to the authors of this study. A study to test a drug for treating an undefined condition cannot be said to have a scientifically evaluable purpose. 21 CFR 314.111(a)(5)(ii)(*a*)(*1*). There is no explanation of the diagnostic criteria for selecting subjects other than the statement that their condition "could be classified as threatened abortion." The study thus identifies no method that assures that the subjects were suitable for its purpose. 21 CFR 314.111(a)(5)(ii)(*a*)(2)(*i*). No explanation is provider as to how the Lutein and control groups were formed, other than that a decision was made to give Lutein to some but not to others. If a method was used to assign subjects to the two groups so as to minimize bias, it was not stated. 21 CFR 314.111(a)(5)(ii)(*a*)(2)(*ii*). This defect is compounded by the failure to explain what exclusionary criteria were used to derive from the original groups of 217 and 88 (R 6 at 3) the comparison groups of 112 and 44 that resulted in the success rates reported for the Lutein and control subjects; these criteria, too, must have been such as to minimize bias in the assignment of subjects and should have been stated. There is, further, no indication that the investigators attempted to assure comparability of pertinent variables in test and control groups, such as previous obstetrical experience or use of concomitant medication. 21 CFR 314.111-(a)(5)(ii)(*a*)(*2*)(*iii*).

For these reasons, the report of the Falls, Rezek, Benensohn study does not demonstrate that the investigation meets the regulatory standards. Hynson seems undecided about how it wants to use this study in support of its case. In its post-hearing reply memorandum (at 4 and 5), it claims that the study is an investigation supporting Lutrexin's effectiveness for second and third trimester "threatened abortion." The study report, however, does not say during what trimester the condition denoted "threatened abortion" was diagnosed and treated, only that the span of time involved was 3 months. It could have been 3 months for all patients no matter what the stage of their pregnancy; or it could have been a particular 3-month segment in the 9-month gestation period, e.g., the first trimester. The report simply does not say. An investigation can be offered as proof of drug effectiveness only for the condition specified: in this case, "threatened abortion," undefined as to nature or time of occurrence.

Perhaps recognizing this difficulty, Hynson specifically relies on the study only as evidence that Lutein "has a pharmacologic effect on the human uterus in terms of halting contractions, with resulting therapeutic benefits in terms of fetal salvage and prolongation of gestation" (corrected conclusion of law No. 3). If the pharmacologic effect referred to is inferred from the comparison between the Lutein and "control" groups, then it is invalid because the study is not adequate and well-controlled. If it is based on the data in the study concerning the "inhibition of pituitrin action by * * * lutein" (R 6 at 2), then it is totally unverifiable because the study offers no explanation of how those data were obtained other than the cursory statement that "It was also found that they [corpeus luteum extracts] produced an inhibiting effect on uterine muscle contractions *in vitro* and *in vivo* (Figs. 1 to 5)" (R 6 at 1), and the information in the captions under the figures indicating that the uterine muscle had first been stimulated to contract by the injection of posterior lobe pituitary extracts. This would not be acceptable even as corroborative evidence because the scientific details necessary to permit the reference to be evaluated are lacking. 21 CFR 314.111(a)(5)(ii)(*c*). Assuming this were not so, it would nevertheless be impossible to infer any meaningful conclusion about the effectiveness of Lutrexin in the treatment of premature labor from the action of Lutein on uterine muscle induced to contract artificially under laboratory condi-

tions. Premature labor is not artificially induced by the injection of "posterior lobe pituitary extracts," and there is no evidence that a therapeutic benefit can be inferred from this pharmacologic effect (T 1174 and 1175).

More crucially, there is no evidence that Lutein is Lutrexin. Hynson takes the position that results of Lutein therapy are applicable to Lutrexin. It states that "The active ingredient in Lutrexin is a uterine-relaxing factor extracted from sows' ovaries and the identical factor was first marketed as both a tablet and as an injectable with the name of Lutein" (corrected finding of fact No. 2; and see proposed finding of fact No. 23). The record evidence cited in support of this proposition does not bear it out. The strongest statements were those of Dr. Rezek:

A. I don't know that they [Lutein and Lutrexin] contain the same uterine relaxant factor, since I have not seen either one of them chemically isolated, but they do contain a uterine inhibiting factor.

(T 498), and Dr. Bryant:

Q. But you did find URF [uterine relaxing factor] activity in both Lutein and so-called Lutrexin, is that correct? * * *

A. Oh, yes. The assey, the material was assayed for activity, on both materials.

(T 295). Thus, Dr. Rezek explicitly declined to state that Lutein and Lutrexin are the same pharmacologic entity; he was willing to go no further than to state that both contain "a uterine inhibiting factor." Dr. Bryant could say no more than that both exhibited uterine-relaxing activity. This does not establish that Lutein and Lutrexin are identical; it establishes that Dr. Rezek and Dr. Bryant did not know whether they are or not.

Other evidence cited by Hynson to support the identity of the two substances is page 2 of the Falls, Rezek, Benensohn study. The study does not mention Lutrexin, an oral preparation, but only injectable Lutein. The study makes no attempt to differentiate chemically among the corpus luteum extracts then on the market (R 6 at 1), but, rather, notes that there was a "considerable difference" in their activity (T 6 at 2).

At the oral argument, Hynson suggested that the testimony of Dr. Frieden relates to this issue. Dr. Frieden conducted experiments comparing a substance supplied to him by Hynson and identified as a uterine-relaxing factor with a substance known as Relaxin (T 186). He concluded that the two substances were different (T 187). Nothing in Dr. Frieden's testimony establishes that the substance provided by Hynson was either Lutrexin or Lutein, much less that Lutrexin and Lutein are the same thing. Viewed in the light most favorable to Hynson, the evidence establishes only that the identity of Lutein and Lutrexin cannot be ruled out, and no more. The Commissioner therefore concludes that the relevance of the Falls, Rezek, Benensohn study to the effectiveness of Lutrexin was not established.

Assuming that Lutein and Lutrexin were the same pharmacologic entity, Hynson would nevertheless have to establish that administration of that entity by injection achieves the same therapeutic effects as oral administration. Absent such a showing, the results of a study of Lutein could not be reliably applied to Lutrexin. A Government witness testified that "you need some evidence that the drug is absorbed first, and then need some evidence it is not changed in the absorption process, to be sure it is going to have the same effect" (T 1471). Hynson cites testimony and studies to demonstrate that Lutrexin is absorbed into the bloodstream in some form—a fact not disputed (corrected findings of fact Nos. 4 through 6, 12; proposed findings of fact Nos. 24 and 25, 28, 49). Hynson also cites testimony that, although proteins are generally degraded in the human stomach, and Lutrexin is a protein-like substance, "some proteins of a lower molecular weight are absorbed unchanged from the gastrointestinal tract" (corrected finding of fact No. 7; proposed finding of fact No. 51). The implication is that Lutrexin is such a protein (proposed finding of fact No. 26, relating to Relaxin, another uterine relaxing factor), but nothing in the record demonstrates that it is. The testimony establishes, at best, that there is a possibility that Lutrexin, which is orally administered, is not altered in the gastrointestinal tract. The Commissioner concludes that even if Lutein and Lutrexin are the same pharmacologic entity, it has not been established that oral administration of that entity does not cause it to be altered before entering the bloodstream. He therefore rules that for this additional reason the relevance of the Falls, Rezek, Benensohn study to the effectiveness of Lutrexin was not established.

For the above reasons, the Commissioner rejects as contrary to the evidence of record Hynson's corrected conclusions of law Nos. 3 and 4 and proposed conclusion of law No. 4, and any underlying corrected and proposed findings of fact inconsistent with the foregoing.

3. The Majewski, Jennings study (R 3 through 5). This study consists of an early investigation of Lutrexin in premature labor (R 3), the results of which were subsequently incorporated in a more ambitious study (R 4). A statistical analysis of the results was also introduced (R 5). The study was historically controlled, and is therefore not acceptable as substantial evidence of Lutrexin's effectiveness. Moreover, Hynson concedes that, apart from use of a historical control, the Majewski study does "not meet all of the criteria for controlled studies, e.g., random assignment of patients to various groups and accounting for variables such as parity and cervical dilatation" (corrected finding of fact No. 33). Hynson offers the study only as "corroborative evidence," which is permitted under 21 CFR 314.111 (a) (5) (ii) (c). The discussion will therefore be brief.

Viewed as one study, the Majewski, Jennings investigations involved administration of Lutrexin to 79 patients diagnosed to be in premature labor on the basis of contractions and effacement of the cervix. The test for effectiveness was whether contractions were halted, which occurred in 68.4 percent (54 of 79) of the subjects. (In the statistical analysis prepared by Hynson (R 5), the success rate was 86.4 percent. Dr. Majewski stated that he could read the analysis, but he could not interpret it (T 1382). He did not know what the analysis showed (T 1381).) Historically, conventional therapy for premature labor was successful in about 50 percent of patients in the hospital in which this study was conducted.

On direct, Dr. Majewski testified concerning the diagnostic criteria employed in the study (T 1357 and 1358) and the nature of the historical control that was used (T 1358). He also stated that he did not attempt to account for variables between the Lutrexin patients and those with whom he attempted a historical comparison (T 1365 and 1366). The question was ambiguously put, but it is apparent that comparability with respect to known variables was not considered by Dr. Majewski. This is inconsistent with 21 CFR 314.111 (a) (5) (ii) *(a) (2) (iii)*, and constitutes improper use of a historical control (T 1054 through 1059).

On cross-examination Dr. Majewski confirmed that he had made no attempt to assure comparability between the Lutrexin and historical control groups (T 1391). He also suggested (T 1368) that progressive dilation and effacement of the cervix, or progressive descent of the presenting part of the fetus, was not always established, contrary to the report of the study (R 4 at 322). As in the Bickers study, patients with a closed cervix were included in the test group (T 1368 and 1369), thus confirming the possibility that unrealiable diagnostic techniques were employed and raising doubts about the suitability of the subjects for the study. 21 CFR 314.111(a) (5) (ii) *(a) (2) (i)*. Various other possible inconsistencies and methodological defects were brought out on cross-examination (T 1373, 1376, 1390 through 1394).

On the basis of the report of the study and Dr. Majewski's testimony, the Commissioner concludes that the Majewski, Jennings study is not adequate and well-controlled within the meaning of the regulations, apart from its inappropriate use of a historical control.

4. The Gratton study (R 2, 50). Dr. Richard R. Gratton testified at the hearing concerning this study in which 253 pregnant women who had experienced problems in previous pregnancies were treated with Lutrexin. The percentage of successful pregnancies in these women was then compared with the percentage of successful pregnancies they had had in the past. The figures were 79.5 percent and 43 percent, respectively.

This is a historically controlled study that is unacceptable as substantial evidence under the regulations, and is offered by Hynson only as "corroborative evidence." (Corrected finding of fact No. 33.)

Dr. Gratton's paper, which was rejected for publication by two journals by reason of methodological deficiencies (T 901), is so flawed as to be scientifically unevaluable. Dr. Gratton selected for inclusion in the study all patients who had previously experienced a problem in pregnancy without regard to what the problem was (T 860). Although Lutrexin was used to treat premature labor in these women, neither the study report nor Dr. Gratton's testimony reveals what criteria were used to diagnose it (T 876 through 878). Dr. Gratton was asked where the criteria appeared in the report; his answer attempted to state what was actually done, but provided no information about how premature labor was diagnosed. Counsel for Hynson made no effort to clarify the point on direct or redirect. There was thus a failure to comply with 21 CFR 314.111(a)(5)((ii)(*a*)(2)(*i*). Other medication was administered to the patients T 887 through 891), thereby making it impossible to evaluate the effects of Lutrexin (T 951 and 952, 1093, 1302). The data were accumulated in such a way as to be incapable of scientific interpretation because women with different conditions were evaluated together (T 952, 1088). The Gratton study was condemned by all of the Government's witnesses on numerous grounds (Fuchs, T 952 and 953; Beaver, T 1088 through 1093; King, T 1301 and 1302; Chalmers, T 1491), and by Hynson's witness Dr. Sadusk (T 420 and 421). The Commissioner concludes that it is not adequate and well-controlled, apart from its inappropriate use of a historical control.

5. Other studies. The study by Dr. William F. Peterson (R 52 and 53) is not relied upon by Hynson. It states that "Because of the small number of patients involved, no conclusions can be drawn from this study as to the effectiveness of Lutrexin in treatment of premature labor" (corrected finding of fact No. 27). This was a double-blind, placebo-controlled study of Lutrexin in premature labor. The examination and cross-examination of Dr. Peterson established a number of methodological defects, e.g., no attempt to minimize bias (T 812 and 813), as required by 21 CFR 314.111(a)(5)(ii)(*a*)(2)(*ii*), that render it less than adequate and well-controlled. The results of the study, adjusted by Dr. Peterson to exclude some cases, indicated three out of four successes for the placebo group and three out of seven for the Lutrexin group (T 836). The Commissioner concludes that the study is not adequate and well-controlled and that in any event its results do not support Lutrexin's effectiveness.

Hynson explicitly states that the studies and reports by Drs. Rezek (R 8), DiBennedeto (R 19), Rizzolo (R 20), Gray (R 10), and Trythall (R 12) do not meet the regulatory criteria for adequate and well-controlled clinical investigations (corrected finding of fact No. 34). A reading of all five studies confirms Hynson's statement in that each study utilizes either a form of historical control or no control at all. On the basis of his independent review of those studies, the testimony of the Government's witnesses, and, in the case of Dr. Rezek's study, the supportive testimony offered by Hynson, the Commissioner agrees and finds, therefore, that none of the studies constitutes substantial evidence of Lutrexin's effectiveness in treating premature labor.

For the above reasons, the Commissioner finds that there is a lack of substantial evidence that Lutrexin is effective in the treatment of premature labor (or in the treatment of second and third trimester threatened abortion, to the extent that it is the same condition as premature labor), and accordingly rejects as contrary to the evidence of record Hynson's corrected conclusions of law Nos. 1 and 7, so much of proposed conclusion of law No. 1 as relates to premature labor, and any underlying corrected and proposed finding of fact inconsistent with the foregoing.

The Commissioner does not reach the question (proposed conclusion of law No. 12, corrected conclusion of law No. 6) whether any of the studies and reports discussed above are corroborative of adequate and well-controlled studies (21 CFR 314.111(a)(5)(ii)(*c*)) because there are no such studies for them to corroborate.

B. *Habitual Abortion.* In its corrected conclusions of law, Hynson does not urge Lutrexin's effectiveness in treating habitual abortion; it concedes that "No controlled studies, within the meaning of FDA's regulations, exist with respect to the use of Lutrexin in first trimester abortion and habitual abortion" (corrected conclusion of law No. 10, supported by corrected finding of fact No. 35). At the oral argument, Hynson's counsel was unaware that these statements had been made, characterized them as mistakes, and retracted them, at least insofar as habitual abortion is concerned. However, Hynson points to no study that would belie its original statements, and the Commissioner finds none in the record.

Hynson introduced four studies or reports relating to use of Lutrexin in habitual abortion. Dr. Gratton's study (R 2, 50) has been discussed in connection with the premature labor indication. No concomitant control was utilized, and so the study cannot qualify as adequate and well-controlled, regardless of any other defects. 21 CFR 314.111(a)(5)(ii)(*a*)(*4*). The "control" that was utilized consisted of comparing the success of pregnancies during which Lutrexin was administered to the success of previous pregnancies in the same women. Since past obstetrical experience does not reliably indicate the outcome of subsequent pregnancies, this comparison does not constitute an appropriate historical control, even assuming one is permissible in a study involving this indication (T 953, 1062 through 1067, 1275, 1440). The results of Dr. Gratton's studies cannot be scientifically interpreted or evaluated because they are reported for all patients without distinction as to the condition treated (T 435, 952, 1088), contrary to 21 CFR 314.111(a)(5)(ii)(*a*)(2)(*i*). Dr. Gratton routinely administered medication other than Lutrexin to the subjects in his study (T 888 and 889). This makes it impossible to attribute the effects, if any, in the treated group to Lutrexin rather than to the concomitant medication (T 951 and 952, 1093, 1302), in violation of 21 CFR 314.111(a)(5)(ii)(*a*)(2)(*iii*). Dr. Gratton failed to state—either in his report or as part of his testimony—what selection criteria were employed; the statement of results indicates that "habitual abortion" may have included women with any number of previous abortions, from one to ten. This violated 21 CFR 314.111(a)(5)(ii)(*a*)(*1*) and (*a*)(2)(*i*). The Gratton study, therefore, does not qualify as adequate and well-controlled

The Jeremias, Trythall study (R 11) is historically controlled (T 1132, 1496 and 1497) and involved administration of medication other than Lutrexin (T 1132 and 1133), which is contrary to 21 CFR 314.111(a)(5)(ii)(*a*)(2)(*iii*), thus destroying the validity of the comparison; also the diagnostic criteria are not set forth (T 1131 through 1135), contrary to 21 CFR 314.111(a)(5)(ii)(*a*)(2)(*i*). It is not adequate and well-controlled.

The Falls, Rezek, Benensohn study (R 6), with respect to which there was no relevant testimony, does not report the use of any control group for this indication (R 6 at 5), contrary to 21 CFR 314.111(a)(5)(ii)(*a*)(*4*), and apparently any woman with a previous abortion was included even if she had only one (id.), contrary to 21 CFR 314.111(a)(5)(ii)(*a*)(2)(*i*). It is not adequate and well-controlled, nor is it a study of habitual abortion as usually understood (T 20, 926, 1266); nor, as discussed above, is it a study of Lutrexin, but of Lutein.

The case reports of Dr. Gray (R 10) do not purport to be a controlled "study," but a review of case histories (T 1129). Accordingly, the results cannot be used for evaluation in terms of the criteria for adequate and well-controlled investigations set forth in the regulations.

The Commissioner finds that there is a lack of substantial evidence that Lutrexin is effective in treating habitual abortion, and rejects any of Hynson's corrected or proposed findings of fact that are inconsistent with this finding.

C. *Dysmenorrhea.* Dysmenorrhea is the condition of "painful menses or pelvic pain during the menstrual period" (T 25). As noted previously, there is ample evidence of record that a contemporaneously controlled study is required to establish the effectiveness of a drug for treating this condition. Indeed, one of Hynson's own experts, Dr. Allen, concurred, stating that he would have to see a successful controlled study utilizing a placebo before he could determine Lutrexin's effectiveness in treating dysmenorrhea (T 116). In its corrected con-

clusions of law, Hynson states that "No controlled investigations which meet the requirements of FDA's regulations exist with respect to the efficacy of Lutrexin in the management of dysmenorrhea" (corrected conclusion of law No. 11, supported by corrected finding of fact No. 36).

The Commissioner agrees with this position, and therefore limits discussion of the record evidence for this indication to a brief summary.

Hynson introduced three studies relating to use of Lutrexin in treating dysmenorrhea. None involved use of a contemporaneous control. In Dr. Rezek's study (R 7), Lutrexin was given to 298 women, 70 percent of whom had favorable results. Dr. Rezek testified concerning the manner in which the study was conducted (T 513 through 515). However, he stated that no control was utilized, including a historical control, as a comparison with the results in the treated patients (T 547 and 548). This is inconsistent with 21 CFR 314.111(a)(5)(ii)(*a*)(*4*). Dr. Rezek administered random dosages of Lutrexin and a placebo, i.e., the same patient received either Lutrexin or a placebo indiscriminately, resulting not in a placebo-controlled investigation, but in a succession of uncontrolled investigations of no scientific validity (T 548), contrary to the same provision. Moreover, no attempt was made to assure comparability among the test patients of pertinent variables, such as the severity of dysmenorrhea (T 537 through 539). This is inconsistent with 21 CFR 314.111(a)(5)(ii)(*a*)(2)(*iii*). The Rezek study is not adequate and well-controlled.

No testimony was introduced by the authors of the Smith, Jones study (R 16) or the Jones study (R 17). The Government's witnesses testified that the former improperly used a historical control (T 1139, 1497 and 1498), 21 CFR 314.111(a)(5)(ii)(*a*)(*4*), and that the report sets forth no method assuring comparability of pertinent variables among the Lutrexin and control groups (T 1138). 21 CFR 314.111(a)(5)(ii)(*a*)(2)(*iii*). They testified that the Jones study utilized no control (T 1139, 1497 and 1498). 21 CFR 314.111(a)(5)(ii)(*a*)(*4*).

The Commissioner finds that there is a lack of substantial evidence that Lutrexin is effective in treating dysmenorrhea and rejects any of Hynson's corrected or proposed findings of fact that are inconsistent with this finding.

D. *Conclusion.* Based on the foregoing, the Commissioner finds that there is a lack of substantial evidence of the effectiveness of Lutrexin for any of its labeled indications. Accordingly, pursuant to 21 U.S.C. 355(e)(3), the NDA for Lutrexin (NDA 8–986) must be withdrawn. The Commissioner further finds that, by reason of the lack of substantial evidence for its effectiveness, Lutrexin is a "new drug" within the meaning of 21 U.S.C. 321(p).

The references cited in this notice are available for public examination at the office of the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852, Monday through Friday from 9 a.m. to 4 p.m., except on Federal legal holidays.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 505(e), 52 Stat. 1052, as amended (21 U.S.C. 355(e)), and under authority delegated to the Commissioner (21 CFR 2.120), the new drug applications (NDA 8–986, NDA 10–144) for Lutrexin and Trexinest, and all amendments and supplements thereto, are hereby withdrawn, effective April 15, 1976.

Dated: March 29, 1976.

A. M. SCHMIDT,
*Commissioner of Food and Drugs.*

[FR Doc.76–9585 Filed 4–2–76;8:45 am]

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## Health Resources Administration

### COOPERATIVE HEALTH STATISTICS ADVISORY COMMITTEE

#### Renewal

Pursuant to the Federal Advisory Committee Act, 5 U.S.C. Appendix I, the Health Resources Administration announces the renewal by the Secretary, HEW, on March 24, 1976, with the concurrence by the Office of Management and Budget Committee Management Secretariat, of the following advisory committee:

| Committee: | *Termination date* |
|---|---|
| Cooperative Health Statistics Advisory Committee. | Mar. 25, 1978. |

Authority for this committee will expire on the date indicated, unless the Secretary formally determines that continuance is in the public interest.

Dated: March 31, 1976.

JAMES A. WALSH,
*Associate Administrator for Operations and Management.*

[FR Doc.76–9606 Filed 4–2–76;8:45 am]

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## Office of Education

### DOMESTIC MINING AND MINERAL AND MINERAL FUEL CONSERVATION FELLOWSHIPS

#### Closing Date for Receipt of Applications From Institutions of Higher Education

Notice is hereby given that pursuant to the authority contained in Part D of Title IX of the Higher Education Act of 1965 (20 U.S.C. 1134n et seq.), applications for an allocation of fellowships for advanced study in domestic mining and mineral and mineral fuel conservation are being accepted from institutions of higher education.

Applications must be received by the U.S. Office of Education Application Control Center on or before May 14, 1976.

A. *Applications sent by mail.*

An application sent by mail should be addressed as follows: U.S. Office of Education, Grant and Procurement Management Division, Application Control Center, 400 Maryland Avenue, S.W., Washington, D.C. 20202, Attention: 13.567. An application sent by mail will be considered to be received on time by the Application Control Center if:

(1) The application was sent by registered or certified mail not later than May 10, 1976, 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 room in Washington, D.C. In establishing the date of receipt, the Commissioner will rely on the time-date stamp of such mailrooms or other documentary evidence of receipt maintained by the Department of Health, Education, and Welfare, or the U.S. Office of Education.

B. *Hand delivered applications.* An application to be hand delivered must be taken to the U.S. Office of Education Application Control Center, Room 5673, Regional Office Building Three, 7th and D Streets, S.W., Washington, D.C. Hand delivered applications will be accepted daily between the hours of 8:00 a.m. and 4:00 p.m. Washington, D.C. time, except Saturdays, Sundays, or Federal holidays. Applications will not be accepted after 4:00 p.m. on the closing date.

C. *Program information and forms.* Information and application forms may be obtained from the Bureau of Postsecondary Education, Division of Training and Facilities, Regional Office Building Three, 7th and D Streets, S.W., Washington, D.C. 20202.

D. *Applicable regulations.* Proposed regulations for the Domestic Mining and Mineral and Mineral Fuel Conservation Fellowship Program are published in this issue of the FEDERAL REGISTER, and will govern the award of these fellowships when they take effect after being published in final in the FEDERAL REGISTER.

(20 U.S.C. 1134n–1134r)

(Catalog of Federal Domestic Assistance Number 13.567; Mining and Mineral Fuel Conservation Fellowship Program)

Dated: March 16, 1976.

T. H. BELL,
*Commissioner of Education.*

[FR Doc.76–9611 Filed 4–2–76;8:45 am]

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# DEPARTMENT OF TRANSPORTATION

## Coast Guard

[CGD 76 058]

### EQUIPMENT, CONSTRUCTION, AND MATERIALS

#### Approval Notice

1. Certain laws and regulations (46 CFR Chapter I) require that various items of lifesaving, firefighting and miscellaneous equipment, construction, and materials used on board vessels subject to Coast Guard inspection, on certain motorboats and other recreational vessels, and on the artificial islands and fixed structures on the Outer Continental

Shelf be of types approved by the Commandant, U.S. Coast Guard. The purpose of this document is to notify all interested persons that certain approvals have been granted as herein described during the period from February 6, 1976 to February 20, 1976 (List No. 2–76). These actions were taken in accordance with the procedures set forth in 46 CFR 2.75–1 to 2.75–50.

2. The statutory authority for equipment, construction, and material approvals is generally set forth in sections 367, 375, 390b, 416, 481, 489, 526p, and 1333 of Title 46, United States Code, section 1333 of Title 43, United States Code, and section 198 of Title 50, United States Code. The Secretary of Transportation has delegated authority to the Commandant, U.S. Coast Guard with respect to these approvals (49 CFR 1.46(b)). The specifications prescribed by the Commandant, U.S. Coast Guard for certain types of equipment, construction, and materials are set forth in 46 CFR Parts 160 to 164.

3. The approvals listed in this document shall be in effect for a period of 5 years from the date of issuance, unless sooner cancelled or suspended by proper authority.

LIFE PRESERVERS, KAPOK, ADULT AND CHILD (JACKET TYPE), MODELS 3 AND 5

Approval No. 160.002/2/1, Model 3, adult kapok life preserver, U.S.C.G. Specification Subpart 160.002, and COMDT(GMMT–3/83) letter dated March 29, 1973, Type I PFD, manufactured by Campco Ventures Company, A Division of American Recreation Group, (A Limited Partnership), P.O. 49, Fairfield, California 94533, formerly Campco Ventures, Inc., effective February 18, 1976. (It supersedes Approval No. 160.002/2/1 dated May 16, 1973 to show change of name and address of manufacturer.)

Approval No. 160.002/3/1, Model 5, child kapok life preserver, U.S.C.G. Specification Subpart 160.002, and COMDT(GMMT–3/83) letter dated March 29, 1973, Type I PFD, manufactured by Campco Ventures Company, A Division of American Recreation Group, (A Limited Partnership), P.O. 49, Fairfield, California 94533, formerly Campco Ventures, Inc., effective February 18, 1976. (It supersedes Approval No. 160.002/3/1 dated May 16, 1973 to show change of name and address of manufacturer.)

LINE-THROWING APPLIANCE, SHOULDER GUN TYPE (AND EQUIPMENT), FOR MERCHANT VESSELS

Approval No. 160.031/7/1, "Safety Liner" shoulder gun type line-throwing appliance, dwg. Nos. LT–103, dated October 25, 1968 and SK–445 issue 4, dated April 10, 1969; alternate design, dwg. Nos. LT–103 revision 5, dated December 16, 1975 and SK–445 issue 5, dated April 15, 1975, projectile used with both designs, dwg. No. 2100, dated April 11, 1969, manufactured by Hall Ski-Lift Company, Inc., 753 West Main Street, Watertown, New York 13601, effective February 12, 1976. (It supersedes Approval No. 160.031/7/0 dated July 30, 1974 to show alternate design.)

LIFEBOATS

Approval No. 160.035/416/1, 30.0′ x 10.0′ x 4.33′ fibrous glass reinforced plastic (FRP), hand-propelled lifeboat, 78-person capacity, identified by construction and arrangement dwg. No. B–80289, Rev. K dated February 5, 1971, 46 CFR 160.035–13(c) Marking, Weights: Condition "A"=5,637 pounds; Condition "B"=18,507 pounds, manufactured by Lake Shore, Inc., Welin Boat & Davit Division, P.O. Box 809, Iron Mountain, Michigan 49801, formerly Lane Lifeboat Division of Lane Marine Technology, Inc., effective February 6, 1976. (It is an extension of Approval No. 160.035/416/1 dated March 5, 1971 and change of name and address of manufacturer.)

Approval No. 160.035/417/3, 30.0′ x 10.0′ x 4.33′ fibrous glass reinforced plastic (FRP), motor-propelled lifeboat without radio cabin or searchlight (Class 1) 74-person capacity, identified by construction and arrangement dwg. No. 80305, Rev. J dated February 5, 1971, 46 CFR 160.035–13(c) Marking, Weights: Condition "A"=4,955.0 pounds; Condition "B"=18,432.0 pounds, manufactured by Lake Shore, Inc., Welin Boat & Davit Division, P.O. Box 809, Iron Mountain, Michigan 49801, formerly Lane Lifeboat Division of Lane Marine Technology, Inc., effective February 6, 1976. (It is an extension of Approval No. 160.035/417/3 dated March 5, 1971 and change of name and address of manufacturer.)

BUOYS, LIFE, RING, UNICELLULAR PLASTIC

Approval No. 160.050/12/3, 30-inch unicellular plastic ring life buoy, U.S.C.G. Specification Subpart 160.050 and American Pad & Textile Co. dwgs. No. 175–LA–3 dated December 26, 1963, or No. 175–LA–4 revised June 15, 1964, Type IV PFD, buoy bodies made by B. F. Goodrich Co., Sponge Products Division, Shelton, Connecticut 06852, manufactured by Campco Ventures Company, A Division of American Recreation Group, (A Limited Partnership), P.O. 49, Fairfield, California 94533, formerly Campco Ventures, Inc., effective February 18, 1976. (It supersedes Approval No. 160.050/12/3 dated May 16, 1973 to show change of name and address of manufacturer.)

Approval No. 160.050/13/3, 24-inch unicellular plastic ring life buoy, U.S.C.G. Specification Subpart 160.050 and American Pad & Textile Co. dwgs. No. 175–LA–3 revised December 26, 1963, or No. 175–LA–4 revised June 15, 1964, Type IV PFD, buoy bodies made by B. F. Goodrich Co., Sponge Products Division, Shelton, Connecticut 06852, manufactured by Campco Ventures Company, A Division of American Recreation Group, (A Limited Partnership), P.O. 49, Fairfield, California 94533, formerly Campco Ventures, Inc., effective February 18, 1976. (It supersedes Approval No. 160.050/13/3 dated May 16, 1973 to show change of name and address of manufacturer.)

Approval No. 160.050/14/3, 20-inch unicellular plastic ring life buoy, U.S.C.G. Specification Subpart 160.050 and American Pad & Textile Co. dwgs. No. 175–LA–3 revised December 26, 1963, or No. 175–LA–4 revised June 15, 1964, Type IV PFD, buoy bodies made by B. F. Goodrich Co., Sponge Products Division, Shelton, Connecticut 06852, manufactured by Campco Ventures Company, A Division of American Recreation Group, (A Limited Partnership), P.O. 49, Fairfield, California 94533, formerly Campco Ventures, Inc., effective February 18, 1976. (It supersedes Approval No. 160.050/14/3 dated May 16, 1973 to show change of name and address of manufacturer.)

LIFE PRESERVERS, UNICELLULAR PLASTIC FOAM ADULT AND CHILD FOR MERCHANT VESSELS

Approval No. 160.055/60/0, Type IB, Model 67, child cloth covered unicellular plastic foam life preserver, U.S.C.G. Specification Subpart 160.055, U.S.C.G. Dwg. No. 160.055–IB (Sheets 3 & 4), Tapatco Dwg. Nos. C–277–1–1, C–277–2–2, and C–277–3–3, COMDT (MMT–3) letter dated December 27, 1966, and COMDT(GMMT–3/83) letter dated March 29, 1973, Type I PFD, manufactured by Campco Ventures Company, A Division of American Recreation Group, (A Limited Partnership), P.O. 49, Fairfield, California 94533, formerly Campco Ventures, Inc., effective February 18, 1976. (It supersedes Approval No. 160.055/60/0 dated May 16, 1973 to show change of name and address of manufacturer.)

Approval No. 160.055/61/0, Type IB, Model 63, adult cloth covered unicellular plastic foam life preserver, U.S.C.G. Specification Subpart 160.055, U.S.C.G. Dwg. No. 160.055–IB (Sheets 1 & 2), Tapatco Dwg. Nos. C–276–1–1, C–276–2–2, and C–276–3–3, COMDT(MMT–3) letter dated December 27, 1966, and COMDT(GMMT–3/83) letter dated March 29, 1973, Type I PFD, manufactured by Campco Ventures Company, A Division of American Recreation Group, (A Limited Partnership), P.O. 49, Fairfield, California 94533, formerly Campco Ventures, Inc., effective February 18, 1976. (It supersedes Approval No. 160.055/61/0 dated May 16, 1973 to show change of name and address of manufacturer.)

MARINE BUOYANT DEVICE

Approval No. 160.064/1065/0, child small, Model No. 505, cloth covered unicellular plastic foam "Buoyant Vest", manufactured in accordance with U.S.C.G. Specification Subpart 160.064 and UL/MD report file No. MQ 224, Type III PFD, manufactured by America's Cup, Inc., 1413 Potrero, So. El Monte, California 91733, for Maherajah Water Skis, A California Corporation, Healdsburg, California 95448, effective February 10, 1976.

Approval No. 160.064/1066/0, child medium Model No. 505, cloth covered unicellular plastic foam "Buoyant Vest", manufactured in accordance with U.S.C.G. Specification Subpart 160.064 and UL/MD report file No. MQ 224, Type III PFD, manufactured by America's Cup, Inc., 1413 Potrero, So. El Monte, California 91733, for Maherajah Water Skis, A California Corporation, Healdsburg, California 95448, effective February 10, 1976.

Approval No. 160.064/1067/0, adult, Model No. 505, cloth covered unicellular plastic foam "Buoyant Vest", manufactured in accordance with U.S.C.G. Specification Subpart 160.064 and UL/MD report file No. MQ 224, Type III PFD, manufactured by America's Cup, Inc., 1413 Potrero, So. El Monte, California 91733, for Maherajah Water Skis, A California Corporation, Healdsburg, California 95448, effective February 10, 1976.

Approval No. 160.064/1068/0, child small, Model No. NCXS–G, cloth covered unicellular plastic foam "Buoyant Vest", manufactured in accordance with U.S.C.G. Specification Subpart 160.064 and UL/MD report file No. MQ 31, Type III PFD, manufactured by America's Cup, Inc., 1413 Potrero, So. El Monte, California 91733, for Taperflex of America, 588 Library Street, San Fernando, California 91341, effective February 10, 1976.

Approval No. 160.064/1069/0, child medium, Model No. NCSS–G, cloth covered unicellular plastic foam "Buoyant Vest", manufactured in accordance with U.S.C.G. Specification Subpart 160.064 and UL/MD report file No. MQ 31, Type III PFD, manufactured by America's Cup, Inc., 1413 Potrero, So. El Monte, California 91733, for Taperflex of America, 558 Library Street, San Fernando, California 91341, effective February 10, 1976.

Approval No. 160.064/1070/0, adult, Model No. NCMS–G, cloth covered unicellular plastic foam "Buoyant Vest", manufactured in accordance with U.S.C.G. Specification Subpart 160.064 and UL/MD report file No. MQ 31, Type III PFD, manufactured by America's Cup, Inc., 1413 Cotrero, So. El Monte, California 91733, for Taperflex of America, 558 Library Street, San Fernando, California 91341, effective February 10, 1976.

Approval No. 160.064/1090/0, adult, Model No. 200–XXL, vinyl dipped unicellular plastic foam "Sail 'N' Ski Vest", manufactured in accordance with U.S.C.G. Specification Subpart 160.064 and UL/MD report file No. MQ 242, Type III PFD, manufactured by Texas Recreation Corporation, Texas Watercrafters Division, P.O. Drawer 539, Wichita Falls, Texas 76307, for Rand Manufacturing Corporation, 14615 N.E. 91st Street, Redmond, Washington 98052, effective February 10, 1976.

Approval No. 160.064/1092/0, child small, Model No. 505, cloth covered unicellular plastic foam "Buoyant Vest", manufactured in accordance with U.S.C.G. Specification Subpart 160.064 and UL/MD report file No. MQ 110, Type III PFD, manufactured by America's Cup, Inc., 1413 Potrero, So. El Monte, California 91733, for Vogue Ski Company, 9416 E. Gidley Avenue, Temple City, California 91780, effective February 10, 1976.

Approval No. 160.064/1093/0, child medium, Model No. 505, cloth covered unicellular plastic foam "Buoyant Vest", manufactured in accordance with U.S.C.G. Specification Subpart 160.064 and UL/MD report file No. MQ 110, Type III PFD, manufactured by American's Cup, Inc., 1413 Potrero, So. El Monte, California 91733, for Vogue Ski Company, 9416 E. Gidley Avenue, Temple City, California 91780, effective February 10, 1976.

Approval No. 160.064/1094/0, adult, Model No. 505, cloth covered unicellular plastic foam "Buoyant Vest", manufactured in accordance with U.S.C.G. Specification Subpart 160.064 and UL/MD report file No. MQ 110, Type III PFD, manufactured by America's Cup, Inc., 1413 Potrero, So. El Monte, California 91733, for Vogue Ski Company, 9416 E. Gidley Avenue, Temple City, California 91780, effective February 10, 1976.

BACKFIRE FLAME CONTROL GASOLINE ENGINES; FLAME ARRESTERS; FOR MERCHANT VESSELS AND MOTORBOATS

Approval No. 162.041/190/2, Barbron all brass flame arresters, Model No. suffixed by "B" Barbron all aluminum flame arresters, Model No. suffixed by "AA" Model No. indicates units size: first two digits indicate units diameter (57=5.7''): second two digits indicate element height (15=1.5'') last two digits are base code, 571501, 572001, 572201, 572501, 573001, 575001, 572002, 571003, 571503, 572003, 573003, 575003, 571004, 571204, 571304, 571504, 572004, 572005, 572006, 571507, 572007, 572008, 571509, 572009, 571510, 572010, 575010, 572011, 572012, 571112, 571212, 571512, 571513, 572013, 571113, 571213, 572014, 572015, 571516, 571317, 571517, 571518, 572018, 571519, 571520, 572020, 572520, 572022, 572522, 573022, 571721, the majority of these models were previously approved units, due to their similarities, these units are grouped together to eliminate the long list of approval numbers which now exist for Barbron Corporation.

NOTE.—Last two digits of drawing No. indicate particular base, manufactured by Barbron Corporation, 14580 Lesure Avenue, Detroit, Michigan 48227, effective February 11, 1976. (It supersedes Approval No. 162.041/190/1 dated October 2, 1975.)

Approval No. 162.041/192/0, 6½'' diameter types B175–49, B175–55, and B175–62, aluminum body and arresting element, dwg. B175.–49–2 dated September 29, 1969, dwg. B175–55–2 dated May 11, 1970 and dwg. B175–62–2 dated January 10, 1976, with or without vent tubes or mounting brackets, this approval covers those arresters formerly covered under Approval Numbers 162.041/116/0 and 162.–041/108/0, manufactured by FACET, Fuel Devices Division, Facet Enterprises Division, 696 Hart Avenue, Detroit, Michigan 48214, effective February 20, 1976.

STRUCTURAL INSULATIONS FOR MERCHANT VESSELS

Approval No. 164.007/41/0, "Spraydon Standard J" sprayed fiber type structural insulation identical to that described in Underwriters Laboratories, Inc. Report No. R3655–13, –14 dated February 18, 1971, approved for use without insulating material to meet Class A–60 requirements in an untamped thickness of 2⅛'' and a tamped thickness of 1¾'' and a density not less than 9.1 lbs. per cubic foot, manufactured for SprayDon Corporation, 5701 Bayview Drive, Fort Lauderdale, Florida 33308, by U.S. Gypsum: Plant locations: Plainfield, New Jersey, Wabash, Indiana, effective February 12, 1976. (It supersedes Approval No. 164.007/41/0 dated June 15, 1971 to show change of name and address of manufacturer and to add a new plant location.)

INCOMBUSTIBLE MATERIALS FOR MERCHANT VESSELS

Approval No. 164.009/125/1, "SprayDon" sprayed fiber type incombustible material identical to that described in Sprayon Research Corporation letter dated March 3, 1969; approved without adhesive in a density of 11 through 15 pounds per cubic foot, manufactured for SprayDon Corporation, 5701 Bayview Drive, Fort Lauderdale, Florida 33308, by U.S. Gypsum Company: Plant locations: Plainfield, New Jersey, Wabash, Indiana, effective February 12, 1976. (It supersedes Approval No. 164.009/125/1 dated April 19, 1974 to show change of name of manufacturer and delete a plant location.)

Dated: March 30, 1976.

W. M. BENKERT,
*Rear Admiral, U.S. Coast Guard, Chief, Office of Merchant Marine Safety.*

[FR Doc.76–9621 Filed 4–2–76;8:45 am]

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[CGD 76059]

## EQUIPMENT, CONSTRUCTION, AND MATERIALS

### Termination of Approval Notice

1. Certain laws and regulations (46 CFR Chapter I) require that various items of lifesaving, firefighting and miscellaneous equipment, construction, and materials used on board vessels subject to Coast Guard inspection, on certain motorboats and other recreational vessels, and on the artificial islands and fixed structures on the Outer Continental Shelf be of types approved by the Commandant, U.S. Coast Guard. The purpose of this document is to notify all interested persons that certain approvals have been terminated as herein described during the period from June 16, 1975 to February 20, 1976 (List No. 3–76). These actions were taken in accordance with the procedures set forth in 46 CFR 2.75–1 to 2.75–50.

2. The statutory authority for equipment, construction, and material approvals is generally set forth in sections 367, 375, 390b, 416, 481, 489, 526p, and 1333 of Title 46, United States Code, section 1333 of Title 43, United States Code, and section 198 of Title 50, United States Code. The Secretary of Transportation has delegated authority to the Commandant, U.S. Coast Guard with respect to these approvals (46 CFR 1.46(b)). The specifications prescribed by the Commandant, U.S. Coast Guard for certain types of equipment, construction, and materials are set forth in 46 CFR Parts 160 to 164.

3. Notwithstanding the termination of approval listed in this document, the equipment affected may be used as long as it remains in good and serviceable condition.

LIFEBOAT WINCHES FOR MERCHANT VESSELS

The Speco Division, Kelsey-Hayes Company, Springfield, Ohio 45501, Approval No. 160.015/98/1 expired and was terminated effective December 4, 1975.

DAVITS FOR MERCHANT VESSELS

The Marine Safety Equipment Corporation, Foot of Wyckoff Road, Farmingdale, New Jersey 07727, Approval No. 160.032/160/1 expired and was terminated effective January 26, 1976.

PROTECTING COVER FOR LIFEBOATS

The Gentex Corporation, Carbondale, Pennsylvania 18407, Approval No. 160.065/1/0 expired and was terminated effective December 4, 1975.

SAFETY RELIEF VALVES, LIQUEFIED COMPRESSED GAS

The Anderson Greenwood & Company, Industrial Products Division, 5425 South Rice Avenue, Houston, Texas 77036, Approval No. 162.018/57/ expired and was terminated effective June 16, 1975.

NOZZLES, FIREHOSE, COMBINATION SOLID STREAM AND WATER SPRAY (1½-INCH AND 2½-INCH) FOR MERCHANT VESSELS

The Rockwood, 80 Second Street, South Portland, Maine 04106, Approval Nos. 162.027/2/1, 162.027/3/1 and 162.027/8/0 expired and were terminated effective February 19, 1976.

FIRE EXTINGUISHING SYSTEMS, FOAM TYPE

The Rockwood, 80 Second Street, South Portland, Maine 04106, Approval Nos. 162.033/5/0 and 162.033/6/0 expired and were terminated effective February 19, 1976.

BACKFIRE FLAME CONTROL, GASOLINE ENGINES; FLAME ARRESTERS; FOR MERCHANT VESSELS AND MOTORBOATS

The Bendix Corporation, Fuel Devices Division, 696 Hart Avenue, Detroit, Michigan 48214, Approval No. 162.041/108/2 was terminated effective February 20, 1976.

The Fuel Devices Division, Facet Enterprises, Inc., 696 Hart Avenue, Detroit, Michigan 48214, Approval No. 162.041/116/0 was terminated effective February 20, 1976.

INCOMBUSTIBLE MATERIALS FOR MERCHANT VESSELS

The GAF Corporation, 114 Canal Street, South Bound Brook, New Jersey 08880, no longer manufactures certain incombustible materials and Approval No. 164.009/93/0 was therefore terminated effective January 30, 1976.

The Johns-Manville Sales Corporation, Denver, Colorado 80217, no longer manufactures certain incombustible materials and Approval No. 164.009/168/0 was therefore terminated effective February 11, 1976.

Dated: March 30, 1976.

W. M. BENKERT,
*Rear Admiral, U.S. Coast Guard, Chief, Office of Merchant Marine Safety.*

[FR Doc.76–9620 Filed 4–2–76;8:45 am]

## FEDERAL AVIATION ADMINISTRATION

### Aviation Review Conference

The purpose of this notice is to announce the eighth annual Aviation Review Conference. The establishment of annual consultative planning conferences was originally documented on December 24, 1968 (33 FR 19205); and procedures for the annual consultative planning cycle of the National Aviation System were announced November 19, 1970 (35 FR 17798).

The Department of Transportation announces that the eighth annual Aviation Review Conference will be held May 24–26, 1976, at the Sheraton National Motor Hotel, Arlington, Virginia. On the first day, government spokespersons will discuss current activities and future needs of the system. On the second day, two government/user panels will discuss airports and the environment and air traffic control—its limitations and potential. On the third day, a similar panel will focus on the government's role in the future of civil aviation.

It is also planned to have prominent luncheon speakers on Monday, May 24, and Tuesday, May 25, as well as a dinner speaker on Tuesday, May 25. Details will be distributed at a later date.

There will be no registration fee; however ,a charge will be estabilshed for each luncheon and the dinner.

The National Aviation System: Challenges of the Decade Ahead, 1977 to 1986, formerly the NAS Ten Year Plan, will be available at the conference for those who have not received one.

For those persons not on the FAA consultative mailing list and who would like to receive a registration card for the conference and a reservation form for the luncheons and dinner, please write to the following address giving: (1) name, (2) address, and (3) company or affiliation:

Office of Aviation System Plans, ATTN: ASP-10, Federal Aviation Administration, 800 Independence Avenue, S.W., Washington, D.C. 20591.

F. A. MEISTER,
*Acting Associate Administrator for Policy Development and Review.*

[FR Doc.76-9571 Filed 4-2-76;8:45 am]

## CITIZENS ADVISORY COMMITTEE ON AVIATION

### Notice of Meeting

Pursuant to section 10(a)(2) of Public Law 92-463, notice is hereby given that the Citizens Advisory Committee on Aviation will hold a meeting on May 2–5, 1976, at Federal Aviation Administration Southern Region Headquarters, 3400 Whipple, East Point, Georgia. The following agenda items are scheduled for the meeting:

a. Safety in aviation.

b. Aviation education.

c. The national airport system.

Persons interested in attending the meeting should contact Ms. Norma G. Senkow, Citizens Advisory Committee on Aviation, Office of Public Affairs, APA-1, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, D.C. 20591, telephone (202) 426-3485. The meeting will be open to the public. Seating will be available on the first-come, first-served basis.

Issued in Washington, D.C. on March 29, 1976.

JOSEPH LAITIN,
*Assistant Administrator Public Affairs.*

[FR Doc.76-9572 Filed 4-2-76;8:45 am]

[Docket No. 14626]

## ELIMINATION OF VFR FLIGHT PLAN SERVICE

### Notice of Withdrawal of Proposed Policy Change

The purpose of this notice is to announce that the Federal Aviation Administration (FAA) is withdrawing its proposed change in agency policy which, if adopted, would eliminate VFR (Visual Flight Rules) flight plan service, except where specifically required by the Federal Aviation Regulation (FARs) or when otherwise designated by the Administrator.

The proposal to eliminate VFR flight plan service was published in a general notice in the FEDERAL REGISTER on May 29, 1975, at 40 FR 23358. As described in the notice, the proposed change in policy was issued to assist the FAA in determining whether a suitable alternative to VFR flight planning was available to fulfill the main purpose and value of the VFR flight plan service—the initiation and conduct of search and rescue missions. While some of the comments submitted in response to the notice supported the proposal, the vast majority of the commenters were opposed, in whole or significant part, to the proposal.

After careful and thorough evaluation of the proposal and of the comments received, the FAA now believes that a reliable and acceptable alternative to VFR flight planning is not currently available that would not jeopardize the ability to initiate and conduct timely and effective search and rescue missions. For this reason, the FAA concludes that the proposal to eliminate VFR flight plan services should be withdrawn. However, this withdrawal does not preclude consideration of similar proposals in the future or commit the FAA to any particular course of action.

This notice is issued under authority of §§ 305, 306, 307, and 601(a) of the Federal Aviation Act of 1958 (49 U.S.C. §§ 1346, 1347, 1348, and 1421(a)).

In consideration of the foregoing and without prejudice to any future action, the Federal Aviation Administration hereby withdraws the proposed change in agency policy regarding the elimination of the VFR flight plan service published in the FEDERAL REGISTER on May 29, 1975, at 40 FR 23358.

Issued in Washington, D.C., on March 26, 1976.

RAYMOND G. BELANGER,
*Director, Air Traffic Service.*

[FR Doc.76-9570 Filed 4-2-76;8:45 am]

## National Highway Traffic Safety Administration

[Docket No. IP76-3; Notice 1]

## BRITISH LEYLAND UK LTD.

### Petition for Exemption From Notice and Recall for Inconsequential Noncompliance

Leyland Cars Division, British Leyland UK Ltd., Coventry, England, has petitioned to be exempted from the notification and recall requirements of the National Traffic and Motor Vehicle Safety Act (15 U.S.C. 1381 *et seq.*) for a noncompliance with 49 CFR 571.101, Motor Vehicle Safety Standard No. 101, *Control Location, Identification, and Illumination*, on the basis that the noncompliance is inconsequential as it relates to motor vehicle safety.

Petitioner manufactured 11,750 Triumph Spitfire Mark 4 passenger cars between September 1, 1974 and February 4, 1976, that it has concluded do not comply with Standard No. 101. The noncompliance is the failure to identify the lamp control with the word "lights". The control, however, was marked with the symbol that the standard allows as a supplementary means of identification. The company's arguments for inconsequentially may be summarized as follows:

1. The control is positionally isolated from other controls, thus reducing the likelihood that it would be mistaken for another control function.

2. The control is identified by the symbol which clearly indicates its function even though the wording has been omitted.

3. There have been no complaints from owners about the omission or reports of accidents to which the omission has contributed.

This notice of receipt of a petition is published under section 157 of the National Traffic and Motor Vehicle Safety Act (15 U.S.C. 1417) and does not represent any agency decision or other exercise of judgment concerning the merits of the petition.

Interested persons are invited to submit written data, views, and arguments on the petition of British Leyland UK Ltd. described above. Comments should refer to the docket number and be submitted to: Docket Section, National Highway Traffic Safety Administration, Room 5108, 400 Seventh Street, S.W., Washington, D.C. 20590. It is requested but not required that five copies be submitted.

All comments received before the close of business on the comment closing date indicated below will be considered. The application and supporting materials, and all comments received after the closing date will also be filed and will be considered to the extent possible. When the petition is granted or denied, notice will be published in the FEDERAL REGISTER pursuant to the authority indicated below.

*Comment closing date:* May 21, 1976.

(Sec. 102, Pub. L. 93-492, 88 Stat. 1470 (15 U.S.C. 1417); delegations of authority at 49 CFR 1.50 and 49 CFR 501.8.)

Issued on March 30, 1976.

ROBERT L. CARTER,
*Associate Administrator,*
*Motor Vehicle Programs.*

[FR Doc.76-9684 Filed 4-2-76;8:45 am]

## CIVIL AERONAUTICS BOARD

[Docket No. 29004]

### NORTH CANADA AIR LTD. (NORCANAIR), CANADIAN SCHEDULED PERMIT APPLICATION (REGINA-MINOT)

#### Prehearing Conference and Hearing

Notice is hereby given that a prehearing conference in the above-entitled matter is assigned to be held on April 15, 1976, at 9:30 a.m. (local time) in Room 1003, Hearing Room C, 1875 Connecticut Avenue, N.W., Washington, D.C., before Administrative Law Judge, Frank M. Whiting.

Notice is also given that the hearing may be held immediately following conclusion of the prehearing conference unless a person objects or shows reason for postponement on or before April 8, 1976.

Ordinary transcript will be adequate for the proper conduct of this proceeding.

Dated at Washington, D.C., March 30, 1976.

[SEAL] ROBERT L. PARK,
*Chief Administrative*
*Law Judge.*

[FR Doc.76-9623 Filed 4-2-76;8:45 am]

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[Docket 27813; Agreement C.A.B. 25731, R-1 through R-8; Order 76-3-184]

### INTERNATIONAL AIR TRANSPORT ASSOCIATION

#### Passenger Fares

Issued under delegated authority March 30, 1976.

An agreement has been filed with the Board pursuant to section 412(a) of the Federal Aviation Act of 1958 (the Act) and Part 261 of the Board's Economic Regulations between various air carriers, foreign air carriers, and other carriers embodied in the resolutions of Traffic Conference 3 of the International Air Transport Association (IATA). The agreement, adopted by mail vote, has been assigned the above C.A.B. agreement number.

This agreement would cancel the Australia-Fiji fares agreed to in Agreement C.A.B. 25570[1] and reinstate the previously effective fares subject to an increase of ten percent. We will approve those portions of the agreement governing fares which are combinable with fares to/from United States points and thus have indirect application in air transportation as defined by the Act, but will disclaim jurisdiction with respect to fares which are not similarly combinable.

Pursuant to authority duly delegated by the Board in the Board's Regulations 14 CFR 385.14:

1. It is not found that the following resolutions, incorporated in Agreement 25731, and which have indirect application in air transportation as defined by the Act, are adverse to the public interest or in violation of the Act:

| Agreement CAB 25731: | *IATA resolutions* |
|---|---|
| R-1 | 300(Mail 9)003. |
| R-2 | 300(Mail 9)022u. |
| R-3 | 300(Mail 9)053. |
| R-4 | 300(Mail 9)063. |

2. It is not found that the following resolutions, incorporated in Agreement 25731, affect air transportation within the meaning of the Act:

| Agreement CAB 25731: | *IATA resolutions* |
|---|---|
| R-5 | 300(Mail 9)070a. |
| R-6 | 300(Mail 9)076c. |
| R-7 | 300(Mail 9)080e. |
| R-8 | 300(Mail 9)084z. |

Accordingly, it is ordered That:

1. Those portions of Agreement C.A.B. 25731 described in finding paragraph 1 above, which have indirect application in air transportation as defined by the Act, be and hereby are approved; and

2. Jurisdiction be and hereby is disclaimed with respect to those portions of Agreement C.A.B. 25731 described in finding paragraph 2 above.

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 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] PHYLLIS T. KAYLOR,
*Acting Secretary.*

[FR Doc.76-9624 Filed 4-2-76;8:45 am]

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[Docket 26494; Agreement C.A.B. 25735; Docket 27573; Agreement C.A.B. 25744; Docket 27813; Agreement C.A.B. 25746; Order 76-3-195]

### INTERNATIONAL AIR TRANSPORT ASSOCIATION

#### Order Rlating to Passenger Fare and Cargo Rate Matters

Adopted by the Civil Aeronautics Board at its office in Washington, D.C. on the 31st day of March, 1976.

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). The agreements, adopted by mail vote, have been assigned the above-designated C.A.B. agreement numbers.

Agreement C.A.B. 25735 would amend the currency-related surcharge on North/Central Pacific passenger fares from India/Nepal to bring it into line with that applicable on fares from India/Nepal to other world areas. Agreements C.A.B. 25744 and 25746 would establish proportional fares and rates over Copenhagen for the construction of through fares and rates to/from Vaxjoe, Sweden to reflect recently inaugurated service.

The Board, acting pursuant to sections 102, 204(a), and 412 of the Act, does not find that the following resolutions, incorporated in the agreements indicated, are adverse to the public interest or in violation of the Act:

| Agreement CAB: | *IATA resolution* |
|---|---|
| 25735 | JT31 (Mail 11) 022g. |
| 25744 | 200, JT12, JT23, JT123 (Mail 8)005c. |
| 25746 | 200, JT12, JT23, JT123 (Mail 7)005c. |

Accordingly, it is ordered that:

Agreements C.A.B. 25735, C.A.B. 25744, and C.A.B. 25746 be and hereby are approved.

This order will be published in the FEDERAL REGISTER.

By the Civil Aeronautics Board:

[SEAL] PHYLLIS T. KAYLOR,
*Acting Secretary.*

[FR Doc.76-9625 Filed 4-2-76;8:45 am]

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[Docket 28356]

### SOUTHEAST AIRLINES, INC., ET AL.

#### Order Granting Approval and Exemption

Notice is hereby given, pursuant to the statutory requirements of section 408(b) of the Federal Aviation Act of 1958, as amended, that the undersigned intends to issue the attached order under delegated authority. Interested persons are hereby afforded until April 9, 1976, within which to file comments or request a hearing with respect to the action proposed in the order.

Dated at Washington, D.C., March 30, 1976.

[SEAL] BRUCE E. CUNNINGHAM,
*Director, Bureau of*
*Operating Rights.*

Issued under delegated authority.

Application of Southeast Airlines, Inc., Africair, Inc., Marvin L. Evans, Richard M. Tracy, and Robert H. Hubsch, for exemption and/or approval of control relationships resulting from the merger of Africair, Inc., into Southeast Airlines, Inc., under section 408 of the Federal Aviation Act of 1958, as amended.

Southeast Airlines, Inc. (Southeast), Africair, Inc. (Africair), Marvin L. Evans (Evans), Richard M. Tracy (Tracy), and Robert H. Hubsch (Hubsch) request approval or exemption pursuant to section 408 of the Federal Aviation Act of 1958, as amended (the Act), to the extent necessary to permit the statutory merger of Africair into Southeast and the acquisition of a minority interest in Southeast by Tracy,

[1] Agreement 25570 was approved by the Board in Order 76-3-120 (March 17, 1976).

Evans, and Hubsch as more fully described below.

Southeast is an air taxi operating pursuant to the exemption of Part 298 of the Board's Economic Regulations and is also authorized to operate large aircraft in scheduled service between Miami and Key West, Fla., as well as in off-route charter service up to 50 percent of scheduled miles flown in its Miami-Key West scheduled operation. Southeast is currently owned in equal proportions by Thomas R. Green (Green), Donald B. Sittman (Sittman), and Irving L. Jones (Jones).[1]

Africair is a holding company having complete or partial ownership of various aeronautical enterprises whose operations are primarily outside of the United States.[2] Africair is currently owned by Tracy, Evans, and Hubsch, as well as the three owners of Southeast, Green, Sittman, and Jones. Each of the six currently owns one-sixth of Africair. The six individuals are also officers and directors of Africair and/or at least one of Africair's subsidiaries.

Under the terms of the proposed merger, Southeast will acquire all assets and assume all liabilities of Africair, and Southeast will exchange shares in itself for shares of Africair in such a proportion that, following the merger, Green, Sittman, and Jones will each own approximately 17.46 percent of Southeast while Hubsch, Tracy, and Evans will each own approximately 15.87 percent. After the merger, Africair will be dissolved with the resultant transfer of Africair's subsidiaries to Southeast outlined in footnote 2, supra.

In support of the application, the applicants assert that an of Southeast's proposed owners, directors, and officers are citizens of the United States; that the operations of neither Southeast nor the subsidiaries of Africair will be altered by the proposed merger; that Southeast is, at the moment, financially weak and that the merger will give Southeast improved economic strength; that day-to-day operational control of Southeast has been exercised by either Jones or Sittman from the time Southeast was founded in 1959 and that Sittman will continue to exercise that control following the merger; and that with the exception of Green, who will become president of the merged companies, the officers and directors of the companies involved will have essentially the same functions and responsibilities as they did with respect to Southeast and Africair prior to the merger. The applicants further state that only one of the Africair subsidiaries conducts large-aircraft operations and that the merger would have been subject to exemptions found in Part 298 of the Board's Economic Regulations but for the single large-aircraft operation;[3] that, although Africair has in the past made loans to Southeast,[4] there are at present no intercompany transactions between Southeast and Africair; that the control relationships considered herein are essentially the same as those considered and approved by the Board in approving the acquisition of control of Southeast by Green, Sittman, and Jones,[5] that the aviation activities of Green and Hubsch, other than those involving Africair and Southeast, are the same as when the Board approved Green's acquisition of Southeast in 1972;[6] and that these activities with respect to Hubsch are subject to exemption and/or approval pursuant to sections 298.14 and 298.11 of the Board's Economic Regulations. (Green's involvement in aviation enterprises aside from Africair and Southeast as listed in n. 6 *supra*, have already been approved by the Board in order 72-11-85.)

No objection to this application or requests for a hearing have been received.

Notice of intent to dispose of this application without a hearing has been published in the FEDERAL REGISTER, and a copy of such notice has been furnished by the Board to the Attorney General not later than the day following the date of such publication, both in accordance with the requirements of section 408(b) of the Act.

Upon consideration of the above, it is found that Southeast is a non-certificated air carrier; that Africair's subsidiaries are persons engaged in a phase of aeronautics; and that Evans, Tracy, and Hubsch are persons within the meaning of section 408 of the Act. Accordingly, it is found that the acquisition of control of Southeast by Evans, Tracy, and Hubsch is subject to section 408(a)(5) of the Act. It is also found that the merger of Africair into Southeast will result in the acquisition of control of various phases of aeronautics by an air carrier and by Messrs. Green, Sittman, and Jones, who are persons controlling an air carrier. With the exception of Pan African, the acquisition of control of the various phases by Southeast is exempted from the requirements of section 408 of the Act by section 298.11 of the Board's Regulations. However, it is found that the acquisition of control of Pan African by Southeast and by Messrs. Green, Sittman, and Jones, through Africair, is subject to section 408(a)(6) of the Act. It is further found that to the extent the transaction being considered herein is subject to section 408(a)(5) of the Act, it should be exempted, pursuant to the proviso thereof, and that to the extent that it is subject to section 408(a)(6) of the Act, the transaction as described herein should be approved without a hearing pursuant to the provisions of the third proviso of section 408(b) of the Act. In reaching this conclusion, we note that these control relationships raise issues not dissimilar to those considered by the Board in approving the interlocking relationship between Southeast, Africair, Pan African, and Messrs. Green, Sittman, and Jones.[7] The new substantive relationships before the Board are therefore the common control of Southeast and Leasing and the acquisition of Southeast by Tracy, Evans, and Hubsch.

Regarding control of Leasing, it appears that Leasing was established primarily to finance the acquisition of a single aircraft by Southeast. According to the applicants, no further activities are contemplated for Leasing. Moreover, this control relationship is normally subject to the exemption granted by Part 298 of the Board's Regulations.[8] Hence there appears to be no reason why the control of Leasing by Southeast should bar the merger.

Regarding the acquisition of control of Southeast by Tracy, Evans, and Hubsch, Tracy and Evans are engaged in no aviation activities other than those involving Africair and its subsidiaries. Hubsch's activities aside from Africair are the same as Green's as outlined in footnote 6, supra. For the most part, Hubsch and Green have relinquished even the small percentages of ownership in these enterprises which they had in 1972, and their control over them is a result of their positions as officers and/or directors.[9] These activities are essentially the same as those which the Board approved by order 72-11-85, November 20, 1972, and do not raise any new substantive issues. Hence there appears to be no reason why they should bar the merger being considered herein.

It does not appear that the proposed merger will result in creating a monopoly or monopolies and thereby restrain competition or

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[1] These control relationships, as well as certain interlocking relationships subject to section 409 of the Act, involving Southeast, Green, Jones, Sittman, and Africair, as more fully described below, were approved by order 72-11-85, dated Nov. 20, 1972.

[2] These subsidiaries and their activities include: Pan African Airlines (Nigeria) Ltd. (Pan African), charter air transport and helicopter operator and Cessna dealer for West Africa and Nigeria; Air Togo, S.A. (Togo), scheduled air service within Nigeria; Lion Leasing, Inc. (Leasing), aircraft leasing (Leasing currently owns one Swearingen/Metro aircraft which is defined as a small aircraft within sec. 298.2 of the Board's Economic Regulations. The Metro will be leased to Southeast for an as yet undecided amount. Based upon a letter filed in this docket on Dec. 18, 1975, it was learned that Leasing was established primarily to finance the acquisition of the Metro by Southeast because Southeast was unable to finance the acquisition itself. Although Leasing might expand its operations in the future, there are currently no plans for such an expansion); Lion Enterprises Establishment (Enterprises), aircraft leasing and Bell Helicopter agent for West Africa; Lion International Sales, Ltd. (Lion), aircraft sales in Africa; Inter-American Insurance Company Inc. (Inter-American), insurance and reinsurance of non-U.S.A. risks; and Safari Air Services, Ltd. (Safari), Cessna distributor, charter air operations, aircraft maintenance, and flight instruction in various parts of Africa.

[3] Pan African operates one DC-6 aircraft which is a large aircraft within the meaning of Part 298 of the Board's Regulations.

[4] These loans were disclosed in docket 24490, in which the Board authorized the existing common control relationships involving Southeast by order 72-11-85, *supra*.

[5] See order 72-11-85, dated Nov. 20, 1972.

[6] See n. 5, *supra*. These activities include the holding of the positions as directors and officers in the following three companies which are owned 100 percent by Greyhound Corporation: Dispatch Services, ground handling and flight dispatch services at Miami International Airport (MIA); Air Agency, Inc., cargo warehousing and documentation at MIA; and Florida Aviation Fueling Co., Inc., distribution of Gulf Oil Corporation products at MIA. The activities also include one-third ownership by each individual in GHJ enterprises, a holding company with interests entirely in the Bahamas.

[7] See n. 5, supra. In order 72-11-85, the Board considered the interlocking relationships involving Africair, Southeast, Green, Jones, and Sittman, although there was not a parent-subsidiary relationship between Southeast and Africair at that time.

[8] Based on the circumstances leading to Leasing's establishment, we conclude that there will not be a significant restraint on competition as a result of Southeast's control of Leasing. Leasing does not appear to have been created for the purpose of achieving vertical integration by Southeast, but rather for the purpose of financing a single aircraft acquisition. It is apparent that neither Africair nor Southeast would have considered de novo entry into the domestic aircraft-leasing field under ordinary circumstances. It does not appear then that the merger will elimnate an entrant into the industry.

[9] The exception is GHJ enterprises in which Green and Hubsch each own a one-third interest. However, GHJ's activities are limited to the Bahamas.

jeopardize another air carrier,[10] or that, to the extent the transactions being considered herein are subject to section 408(a)(6) of the Act, the merger will affect the control of an air carrier directly engaged in the operation of aircraft in air transportation. Furthermore, no person disclosing a substantial interest in the proceeding is currently requesting a hearing, and it is concluded that the public interest does not require a hearing.

Accordingly, on the basis of the above considerations, we find that the above-described transaction is not adverse to the public interest nor will it leave the requirements of section 408 of the Act otherwise unfulfilled.

Pursuant to authority duly delegated by the Board in the Board's Economic Regulations, 14 CFR 385.3 and 385.13, it is found that the foregoing transaction, to the extent it involves the acquisition of control of Southeast by Evans, Tracy, and Hubsch, should be exempted from the provisions of section 408(a)(5) of the Act pursuant to the proviso therein, and that, to the extent it involves the acquisition of Pan African, through Africair, by Southeast and by Messrs. Green, Sittman, and Jones, the transaction should be approved, without a hearing pursuant to the third proviso of section 408(b) of the Act, and that, to the extent not granted herein, the application should be dismissed:

1. The acquisition of control of Pan African by Southeast and by Messrs. Green, Sittman, and Jones, through the merger of Africair into Southeast be and it hereby is approved, pursuant to the third proviso of section 408(b) of the Act;

2. The acquisition of control of Southeast Airlines, Inc., by Marvin L. Evans, Richard M. Tracy, and Robert H. Hubsch be and it hereby is exempted from the requirements of subsection 408(a)(5) of the Act pursuant to the proviso thereof; and

3. To the extent not specifically granted herein, the application in docket 28356 be and it hereby is dismissed.

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 10 days of 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 is filed or the Board gives notice that it will review this order on its own motion.

[SEAL] BRUCE E. CUNNINGHAM,
*Director, Bureau of Operating Rights.*

[FR Doc.76-9626 Filed 4-2-76;8:45 am]

[10] Our view of the relevant geographic markets in which Southeast and Africair effectively compete has led us to conclude that this merger will not result in any substantial lessening of competition. Southeast operates chartered and scheduled air taxi services out of the Florida area with Swearingen/Metro aircraft, which have an approximate range of 1,300 miles. With the exception of Leasing and Inter-American, Africair's activities are limited to aircraft sales and leasing and direct air service in western Africa. In its direct air service, Pan African operates DC-6 aircraft, which have an approximate range of 3,300 miles. In view of the vast distance between western Africa and Florida (approximately 4,300 miles) and the range of the respective aircraft, it is evident to us that the respective geographic markets of Africair and Southeast are clearly distinguishable. Regarding Inter-American, since its operations are outside of the United States, and the application indicates they will remain so, it appears that there will be little adverse effect on competition through vertical integration as a result of this merger. Although Leasing does operate in Florida (see n. 8, supra), as indicated, we do not believe Southeast's control of Leasing will restrain competition.

## THE COMMISSION OF FINE ARTS

### APPEARANCE OF WASHINGTON D.C.

#### Meeting

MARCH 30, 1976.

The Commission of Fine Arts will meet at 10:00 a.m. on Wednesday, April 21, 1976, in its offices at 708 Jackson Place, N.W., Washington, D.C. 20006, to discuss various projects affecting the appearance of Washington, D.C. Inquiries regarding the agenda and requests to submit written or verbal statements should be addressed to Charles H. Atherton, Secretary, Commission of Fine Arts, at the above address.

Signed,

CHARLES H. ATHERTON,
*Secretary.*

[FR Doc.76-9592 Filed 4-2-76;8:45 am]

## COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

### ADJUSTING IMPORT LIMITS FOR CERTAIN MAN-MADE FIBER TEXTILE PRODUCTS FROM MEXICO

#### Entry or Withdrawal From Warehouse for Consumption

MARCH 31, 1976.

On June 5, 1975, there was published in the FEDERAL REGISTER (40 F.R. 24230), a letter dated June 2, 1975 from the Chairman of the Committee for the Implementation of Textile Agreements to the Commissioner of Customs, implementing those provisions of the Bilateral Cotton, Wool and Man-Made Fiber Textile Agreement of May 12, 1975, between the Governments of the United States and Mexico, which establish export limitations on certain cotton, wool and man-made fiber textile products, produced or manufactured in Mexico and exported to the United States during the twelve-month period which began on May 1, 1975. As set forth in that letter, the levels of restraint are subject to adjustment pursuant to paragraph 7(a)(ii) of the agreement which provides that specific levels of restraint may exceed current year limits by up to 6 percent, but with that same amount being deducted from the applicable levels of the succeeding agreement year.

Accordingly, at the request of the Government of Mexico and pursuant to the provision of the bilateral agreement referred to above, there is published below a letter of March 31, 1976 from the Chairman of the Committee for the Implementation of Textile Agreements to the Commissioner of Customs amending the levels of restraint applicable to man-made fiber textile products in Categories 219, 225, 235, and 238 for the twelve-month period which began on May 1, 1975.

ALAN POLANSKY,
*Chairman, Committee for the Implementation of Textile Agreements, and Deputy Assistant Secretary for Resources and Trade Assistance, U.S. Department of Commerce.*

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

COMMISSIONER OF CUSTOMS,
*Department of the Treasury*
*Washington, D.C. 20229*

MARCH 31, 1976.

DEAR MR. COMMISSIONER: On June 2, 1975 the Chairman, Committee for the Implementation of Textile Agreements, directed you to prohibit entry during the twelve-month period beginning May 1, 1975 and extending through April 30, 1976 of cotton and man-made fiber textile products in certain specified categories, produced or manufactured in Mexico in excess of designated levels of restraint. The Chairman further advised you that the levels of restraint are subject to adjustment.[1]

Under the terms of the Arrangement Regarding International Trade in Textiles done at Geneva on December 20, 1973, pursuant to paragraph 7(a)(ii) of May 12, 1975, between the Governments of the United States and Mexico, and in accordance with the provisions of Executive Order 11651 of March 3, 1972, you are directed to amend, effective on March 31, 1976, the levels of restraint established for Categories 219, 225, 235, and 238 to the following amounts:

| Category: | *Amended 12-mo. level of restraint [1] (in dozens)* |
|---|---|
| 219 | 687,602 |
| 225 | 2,012,828 |
| 235 | 359,004 |
| 238 | 1,048,996 |

[1] The levels of restraint have not been adjusted to reflect any entries made after Apr. 30, 1975.

The actions taken with respect to the Government of Mexico and with respect to imports of man-made fiber textile products from Mexico have been determined by the Committee for the Implementation of Textile Agreements to involve foreign affairs functions of the United States. Therefore, the directions to the Commissioner of Customs, being necessary to the implementation of such actions, fall within the foreign affairs exception to the rule-making provisions

[1] The term "adjustment" refers to those provisions of the Bilateral Cotton, Wool, and Man-Made Fiber Textile Agreement of May 12, 1975 between the Governments of the United States and Mexico which provide, in part, that: (1) within the aggregate and applicable group limits, specific levels of restraint may be exceeded by specified percentages; (2) these levels may be increased for carryover and carryforward up to 11 percent of the applicable category limit; (3) consultation levels may be increased within the aggregate and applicable group limits upon agreement between the two governments; and (4) administrative arrangements or adjustments may be made to resolve minor problems arising in the implementation of the agreement.

of 5 U.S.C. 553. This letter will be published in the FEDERAL REGISTER.

Sincerely,

ALAN POLANSKY,
*Chairman, Committee for the Implementation of Textile Agreements, and Deputy Assistant Secretary for Resources and Trade Assistance, U.S. Department of Commerce.*

[FR Doc.76-9603 Filed 4-2-76;8:45 am]

## FEDERAL ENERGY ADMINISTRATION

### FEDERAL POLICY ON LIQUEFIED NATURAL GAS (LNG) IMPORTS

#### Notice of Public Hearing

The Federal Energy Administration (FEA), on behalf of the Energy Resources Council (ERC), hereby announces that it will conduct public hearings and receive public comments on Liquefied Natural Gas (LNG) import policy.

In his energy message of February 26, 1976, the President stated that imports of liquefied natural gas (LNG) could be expected to grow to supplement our declining domestic supply of natural gas and he directed the Energy Resources Council to establish procedures for reviewing proposed LNG projects. It is currently contemplated that each proposed new project would be evaluated on economic and national security grounds aiming toward a target import level of one trillion cubic feet (TCF) annually by 1985—a level which would be acceptable in terms of energy independence goals. In response to the Presidential directive, the ERC has created a task force to establish procedures for the consideration of such issues as pricing, government financial asistance, regional import dependence, source of supply and reassessment of target level if circumstances warrant.

In conducting its analysis, the ERC is interested in obtaining input from all interested persons. To this end the ERC and FEA are particularly interested in obtaining at the hearing, data, views and arguments on the following questions:

SOURCE OF SUPPLY

What will the international LNG trade be in 1985 and beyond; who will be the importers and exporters and what is the likely size of the trade for each of these countries; will there be a spot market; what will be its characteristics?

What factors might be appropriate to balance or counteract the problem of U.S. energy dependence on foreign LNG, e.g., economic leverage, mutuality of interests, and others?

DEPENDENCY ON IMPORTS

In determining acceptable levels of dependency, what are some key factors or criteria to consider in terms of: individual exporting countries, importing transmission pipelines, U.S. geographic regions.

What alternative energy supply sources may be available to safeguard or backstop LNG imports?

Should there be provisions for periodic adjustment of the one TCF/year target level for LNG imports and if so, what are the factors which should be considered?

PRICING AND GOVERNMENT ASSISTANCE

What are likely price levels and changes for LNG imports? What mechanisms exist to keep prices stable or held down?

Is government financial assistance an important factor with regard to LNG import ventures?

What environmental factors are the most significant?

How may approval procedures for LNG imports which meet the national security and economic criteria, be accelerated?

ROLE OF ERC IN REVIEWING PROJECTS

What criteria should be used to evaluate projects?

What should be the extent of ERC involvement, i.e., should it play a policy or direct authority role?

How may ERC assist in promoting diversification of sources of imports?

The public hearing wil be held at 9:30 a.m., on April 21, 1976 and will be continued, if necessary on April 22, 1976 in Room 2105, 2000 M Street, N.W., Washington, D.C.

Any person who has an interest in this proceeding, or who is a representative of a group or class of persons that has an interest in it may make a written request for an opportunity to make an oral presentation at the hearing. Such a request should be directed to Executive Communications, FEA, and must be received before 4:30 p.m., e.d.s.t. on April 14, 1976. Such a request may be hand delivered to Room 3309, Federal Building, 12th and Pennsylvania Avenue, N.W., Washington, D.C., between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday. The person making the request should be prepared to describe the interest concerned, if appropriate, to state why she or he is a proper representative of a group or class of persons that has such an interest, and to give a concise summary of the proposed oral presentation and a phone number where he or she may be contacted through April 16, 1976. Each person selected to be heard will be so notified by FEA before 4:30 p.m. ,e.d.s.t., April 16, 1976 and should submit 100 copies of his or her statement to Regulations Management, FEA, Rom 2214, Federal Building, Washington, D.C. 20461, before 4:30 p.m., e.d.s.t., on April 19, 1976.

FEA reserves the right to select the persons to be heard at these hearings, to schedule their respective presentations and to establish the procedures governing the conduct of the hearings. The length of each presentation may be limited, based on the number of persons requesting to be heard.

An FEA official will be designated to preside at the hearings. These will not be judicial or evidentiary-type hearings, and there will be no cross-examination of persons presently statements.

Any further procedural rules needed for the proper conduct of the hearings will be announced by the presiding officer.

A transcript of the hearings will be made and the entire record of the hearings, including the transcript, will be retained by FEA and made available for inspection at the FEA Freedom of Information Office, Room 3116, Federal Building, 12th and Pennsylvania Avenue, N.W., Washington, D.C., between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday. Any person may purchase a copy of the transcript from the reporter.

Interested persons who do not intend to participate in the hearing, or who wish to submit additional information, are invited to submit written data, views, or arguments with respect to the subject matter set forth in this notice to Executive Communications, Room 3309, Federal Energy Administration, 12th and Pennsylvania Avenue, N.W., Washington, D.C. 20461. Such written comments should specify Box GM, at the address set forth above, and should be identified on the outside of the envelope and on documents submitted with the designation, "LNG Import Policy."

Ten copies should be submitted. All comments received by April 20, 1976, and all relevant information, will be considered by the Federal Energy Administration. Any information or data considered by the person furnishing it to be confidential must be so identified and submitted in writing, one copy only. The FEA reserves the right to determine the confidential status of the information or data and to treat it according to the determination.

Issued in Washington, D.C., March 31, 1976.

MICHAEL F. BUTLER,
*General Counsel,*
*Federal Energy Administration.*

[FR Doc.76-9604 Filed 3-31-76;2:22 pm]

### ENERGY FINANCE ADVISORY COMMITTEE

#### Notice of Establishment

This notice is published in accordance with the provisions of Section 9(a)(2) of the Federal Advisory Committee Act (Public Law 92-463). Following consultation with the Office of Management and Budget, notice is hereby given that it is in the public interest, in connection with the performance of the duties imposed on the Federal Energy Administration by law. to establish the Energy Finance Advisory Committee.

A description of the nature and purpose of this Committee is contained in its Charter which is published below.

Dated: April 1, 1976.

FRANK G. ZARB,
*Administrator.*

CHARTER

ENERGY FINANCE ADVISORY COMMITTEE

A. *Establishment*

The Administrator, Federal Energy Administration (FEA), having determined, after consultation with the Director, Office of Management and Budget, that the establishment of an advisory committee to provide FEA with advice on matters in highly complex financial areas is in the public interest in connection with duties imposed on the FEA by law, hereby establishes the Energy Finance Advisory Committee pursuant to the Federal Advisory Committee Act (Public Law 92-463).

B. *Duties, Functions, and Administrative Provisions*

1. *Objective and Scope.*—The objective of the Energy Financial Advisory Committee is to provide independent advice to the Federal Energy Administration concerning the following areas: the projected capital needs of the domestic energy industries; the characteristics, conditions, and projected changes in the money and capital markets; the financial disincentives to domestic energy development; and the effectiveness of Federal financial incentive programs to enhance domestic energy supply. The Committee will help promote a mutual understanding of the role of the Federal Government and the private financial community in developing domestic energy resources.

2. *Committee Tenure.*—In view of the goals and purposes of the Committee, it will be expected to continue for the duration of the FEA.

3. *Official to Whom Committee Reports.*—The Committee shall report to the Administrator, FEA.

4. *Committee Duties.*—The duties of the Committee are solely advisory and are stated in Paragraph 1 above.

5. *Support Activities.*—Necessary support shall be furnished by the Federal Energy Administration.

6. *Estimated Annual Operating Costs.*—The estimated annual operating cost for the Committee is $33,160 and will involve approximately one-half man-year of staff support.

7. *Meetings.*—The Committee will meet approximately four times a year.

8. *Termination Date.*—The Committee will terminate on June 30, 1976, or if the Federal Energy Administration Act of 1974 is amended to extend the duration of FEA beyond that date, the Committee will terminate on such later date or two years from the date of this Charter, whichever occurs earlier.

9. *Subcommittee(s).*—To facilitate functioning of the Committee, subcommittee(s) may be formed by the Administrator. The objectives of the subcommittee(s) are to make recommendations to the parent committee with respect to matters concerning FEA plans and programs which are related to the responsibilities of the parent Committee. The subcommittee(s) shall be comprised of such members of the parent Committee as may be determined by the Chairman of the parent Committee.

All actions of the subcommittee(s) shall be consistent with the provisions of B–1 through B–12.

10. *Members.*—Committee members shall be appointed by the Administrator of the Agency and that appointment shall be subject to review every 365 days, unless earlier terminated. Members may be reappointed to an additional term following review.

11. *Committee Size.*—Membership on this Committee shall not exceed 26 members.

12. *Election of Chairman and/or Vice Chairman.*—The Chairman and/or Vice Chairman shall be annually appointed by the Administrator or, upon the Administrator's request to the Committee, elected by the Committee members, subject to the approval of the Administrator.

Dated: April 1, 1976.

FRANK G. ZARB,
*Administrator.*

[FR Doc.76-9826 Filed 4-1-76;3:43 pm]

## PETROLEUM AND NATURAL GAS EXPLORATION, DEVELOPMENT, AND PRODUCTION ADVISORY COMMITTEE

### Notice of Establishment

This notice is published in accordance with the provisions of Section 9(a)(2) of the Federal Advisory Committee Act (Public Law 92–463). Following consultation with the Office of Management and Budget, notice is hereby given that it is in the public interest, in connection with the performance of the duties imposed on the Federal Energy Administration by law, to establish the Petroleum and Natural Gas Exploration, Development, and Production Advisory Committee.

A description of the nature and purpose of this Committee is contained in its Charter which is published below.

Dated: April 1, 1976.

FRANK G. ZARB,
*Administrator.*

CHARTER

PETROLEUM AND NATURAL GAS EXPLORATION, DEVELOPMENT, AND PRODUCTION ADVISORY COMMITTEE

A. *Establishment*

The Administrator, Federal Energy Administration (FEA), having determined, after consultation with the Director, Office of Management and Budget, that the establishment of an advisory committee to provide FEA with advice and independent review on matters related to policy and implementation of programs that affect the business of exploration, development, and production of petroleum and natural gas is in the public interest in connection with duties imposed on the FEA by law, hereby establishes the Petroleum and Natural Gas Exploration, Development, and Production Advisory Committee pursuant to the Federal Advisory Committee Act (Public Law 92–463).

B. *Duties, Functions, and Administrative Provisions*

1. *Objective and Scope.*—The objective of the Petroleum and Natural Gas Exploration, Development, and Production Advisory Committee is to provide independent advice to the Federal Energy Administration with respect to the implementation of programs that affect petroleum and natural gas exploration, development, and production.

2. *Committee Tenure.*—In view of the goals and purposes of the Committee, it will be expected to continue for the duration of the FEA.

3. *Official to Whom Committee Reports.*—The Committee shall report to the Administrator, FEA.

4. *Support Activities.*—Necessary support shall be furnished by the FEA.

5. *Committee Duties.*—The duties of the Committee are solely advisory and are stated in Paragraph 1 above.

6. *Estimated Annual Operating Costs.*—The estimated annual operating cost for the Committee is $40,000 and wil involve approximately on-half man-years of staff support.

7. *Meetings.*—The Committee will meet approximately four times a year.

8. *Termination Date.*—The Committee will terminate on June 30, 1976, or if the Federal Energy Administration Act of 1974 is amended to extend the duration of FEA beyond that date, the Committee will terminate on such later date or two years from the date of this Charter, whichever occurs earlier.

9. *Subcommittee(s).*—To facilitate functioning of the Committee, subcommittee(s) may be formed by the Administrator. The objectives of the subcommittee(s) are to make recommendations to the parent Committee with respect to matters concerning FEA plans and programs which are related to the responsibilities of the parent Committee. The subcommittee(s) shall be comprised of such members of the parent Committee as may be determined by the Chairman of the parent Committee.

All actions of the subcommittee(s) shall be consistent with the provisions of B–1 through B–12.

10. *Members.*—Committee members shall be appointed by the Administrator of the Agency and that appointment shall be subject to review every 365 days, unless earlier terminated. Members may be reappointed to an additional term following review.

11. *Committee Size.*—Membership on this Committee should not exceed 30 members.

12. *Election of Chairman and/or Vice Chairman.*—The Chairman and/or Vice Chairman shall be annually appointed by the Administrator or, upon the Administrator's request to the Committee, elected by the Committee members, subject to the approval of the Administrator.

Dated: April 1, 1976.

FRANK G. ZARB,
*Administrator.*

[FR Doc.76-9825 Filed 4-1-76;3:42 pm]

## DEPARTMENT OF AGRICULTURE

### Federal Crop Insurance Corporation

[Notice No. 106]

### CORN—CHAUTAUQUA COUNTY, NEW YORK

### Closing Date Extension for Filing of Applications for the 1976 Crop Year

Pursuant to the authority contained in § 401.103 of Title 7 of the Code of Federal Regulations, the time for filing application for corn crop insurance in Chautauqua County, New York, where such insurance is otherwise authorized to be offered, is hereby extended until the close of business on May 10, 1976. Such applications received during this

period will be accepted only after it is determined that no adverse selectivity will result.

[SEAL] M. R. PETERSON,
*Manager,*
*Federal Crop Insurance Corporation.*

[FR Doc.76-9643 Filed 4-2-76;8:45 am]

[Notice No. 107]

### PEAS, CANNING AND FREEZING, IN BOX ELDER, CACHE, DAVIS, SALT LAKE, AND WEBER COUNTIES, UTAH, AND IN FRANKLIN COUNTY, IDAHO

#### Closing Date Extension for Filing of Applications for the 1976 Crop Year

Pursuant to the authority contained in § 401.103 of Title 7 of the Code of Federal Regulations, the time for filing applications for Canning and Freezing Peas in Box Elder, Cache, Davis, Salt Lake, and Weber Counties, Utah, and in Franklin County, Idaho, where such insurance is otherwise authorized to be offered, is hereby extended until the close of business on April 2, 1976. Such applications received during this period will be accepted only after it is determined that no adverse selectivity will result.

[SEAL] M. R. PETERSON,
*Manager,*
*Federal Crop Insurance Corporation.*

[FR Doc.76-9644 Filed 4-2-76;8:45 am]

## FEDERAL MARITIME COMMISSION

[No. 76-18]

### GEORGIA PORTS AUTHORITY V. INTER-AMERICAN FREIGHT CONFERENCE-SEC. A., ET AL.

#### Filing of Complaint

Notice is hereby given that a complaint filed by Georgia Ports Authority against Inter-American Freight Conference-Sec. A., et al. was served March 31, 1976. The complaint alleges that respondent conferences and their member lines have violated sections 16 and 17 of the Shipping Act, 1916 and section 205 of the Merchant Marine Act, 1936 by virtue of making certain wharfage charges at Savannah, Georgia chargeable against cargo whereas formerly they were for the account of the vessel.

Hearing in this matter shall commence on or before September 30, 1976.

JOSEPH C. POLKING,
*Assistant Secretary.*

[FR Doc.76-9630 Filed 4-2-76;8:45 am]

[Docket No. 76-16]

### MSA INTERNATIONAL VS. CHILEAN LINE

#### Filing of Complaint

MARCH 30, 1976.

Notice is hereby given that a complaint filed by MSA International against Chilean Line was served March 29, 1976. The complaint alleges that complainant has been subjected to payment to charges for transportation in excess of those lawfully applicable in violation of Section 18(b)(3) of the Shipping Act, 1916.

Hearing in this matter shall commence on or before September 29, 1976.

JOSEPH C. POLKING,
*Assistant Secretary.*

[FR Doc.76-9629 Filed 4-2-76;8:45 am]

[Docket No. 76-17]

### SOUTH CAROLINA STATE PORTS AUTHORITY V. INTER-AMERICAN FREIGHT CONFERENCE, ET AL.

#### Filing of Complaint

MARCH 30, 1976.

Notice is hereby given that a complaint filed by South Carolina State Ports Authority against Inter-American Freight Conference et al. was served March 30, 1976.

The complaint alleges that respondent conferences and their member lines have violated sections 15, 16, 17, and 18 of the Shipping Act, 1916, section 8 of the Merchant Marine Act, 1920, and section 205 of the Merchant Marine Act, 1936, by virtue of making certain wharfage charges at the Port of Charleston chargeable against cargo whereas formerly they were for the account of the vessel.

Hearing in this matter shall commence on or before September 30, 1976.

JOSEPH C. POLKING,
*Assistant Secretary.*

[FR Doc.76-9628 Filed 4-2-76;8:45 am]

[Nos. 73-28, and 73-29]

### PUBLICATION OF DISCRIMINATORY RATES IN THE U.S. WEST COAST/JAPAN TRADE AND U.S. ATLANTIC AND GULF/JAPAN TRADE

#### Extension of Alternate Procedures

These proceedings were instituted by Orders to Show Cause issued by the Commission in its attempt to rid the U.S./Japan trades of apparent inbound-outbound rate disparities. Shortly after institution of the proceedings the Commission adopted certain procedures whereby the disparity problem would be eliminated on a piecemeal basis. March 31, 1976 is the current deadline for completion of these procedures.

Hearing Counsel have now moved for a three month extension of these procedures. They point out that only thirteen of the 106 original disparate rates remain to be resolved and express confidence that these can be resolved within the additional three month period.

We are of the opinion that an extension to and including June 30, 1976 is appropriate inasmuch as these procedures have proven effective and inasmuch as it appears the proceedings can be completed by that date. It is so ordered.

By the Commission.

[SEAL] JOSEPH C. POLKING,
*Assistant Secretary.*

[FR Doc.76-9631 Filed 4-2-76;8:45 am]

## FEDERAL RESERVE SYSTEM

### EL DORADO BANCSHARES, INC.

#### Formation of Bank Holding Company

El Dorado Bancshares, Inc., Prairie Village, Kansas, has applied for the Board's approval under § 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 98 per cent or more of the voting shares of Citizens State Bank of El Dorado, El Dorado, Kansas. The factors that are considered in acting on the application are set forth in § 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 Kansas City. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 to be received no later than April 27, 1976.

Board of Governors of the Federal Reserve System, March 29, 1976.

[SEAL] J. P. GARBARINI,
*Assistant Secretary of the Board.*

[FR Doc.76-9557 Filed 4-2-76;8:45 am]

### FIRST NATIONAL INSURANCE AGENCY, INC.

#### Proposed Retention of Dinneen Insurance Agency

First National Insurance Agency, Incorporated, Exeter, Nebraska, has applied, pursuant to § 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 retain the assets of Dinneen Insurance Agency, Exeter, Nebraska, which were acquired without the prior approval of the Board. Notice of the application was published on March 11, 1976 in the Fillmore County News, a newspaper circulated in Exeter, Nebraska.

Applicant states that it will continue to engage in the activity of acting as agent for the sale of fire and casualty insurance in a community with a population not exceeding 5,000. 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 requests 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 Kansas City.

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 April 26, 1976.

Board of Governors of the Federal Reserve System, March 26, 1976.

[SEAL] J. P. GARBARINI,
*Assistant Secretary of the Board.*

[FR Doc.76-9555 Filed 4-2-76;8:45 am]

## FIRST NEW MEXICO BANKSHARE CORP.

### Order Approving Acquisition of Bank

First New Mexico Bankshare Corporation, Albuquerque, New Mexico, a bank holding company within the meaning of the Bank Holding Company Act, has applied for the Board's approval under § 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 Bank of Las Cruces, National Association, Las Cruces, New Mexico ("Bank"), a proposed new bank.

Notice of the application, affording opportunity for interested persons to submit comments and views, has been given in accordance with § 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, including those submitted on behalf of Farmers and Merchants Bank, Las Cruces, New Mexico (hereinafter referred to as "Protestant"), in light of the factors set forth in § 3(c) of the Act (12 U.S.C. 1842(c)).

Applicant, the largest banking organization in New Mexico, controls nine banks with aggregate deposits of $678 million, representing approximately 24 per cent of total deposits in commercial banks in the State. (All banking data are as of June 30, 1975, and reflect all bank holding company formations and acquisitions approved through February 29, 1976.) Since Bank is a proposed new bank, its acquisition would neither eliminate any existing competition nor immediately increase Applicant's share of commercial bank deposits.

Applicant is seeking to make its initial entry into the Las Cruces baning market (the relevant banking market).[1] There are three banks presently in the Las Cruces market, the largest bank controlling approximately 58 per cent of market deposits and the second largest bank ("Protestant") controlling approximately 33 per cent of deposits. Applicant's closest subsidiary bank is located 101 miles west of Las Cruces in a separate banking market. Consummation of the transaction would not have an adverse effect on future competition between any of Applicant's banking subsidiaries and Bank in view of the distances involved and New Mexico's restrictive branching laws. On the other hand, Applicant's acquisition of Bank should stimulate competition in the market by introducing into this heavily concentrated market an additional banking alternative without having adverse effects on any competing bank. On the basis of the facts of record, the Board concludes that the competitive considerations of the transaction are consistent with, and lend some weight toward, approval of the application.

The financial and managerial resources and prospects of Applicant and its subsidiary banks are satisfactory. As a new bank, Bank has no operating financial history; however, its proposed capitalization, management and prospects appear satisactory. These considerations relating to banking factors are consistent with approval of the application. Considerations relating to the convenience and needs of the community to be served lend weight toward approval as Bank will provide an additional source of full banking services.

During the course of its consideration of this application, the Board also considered the comments submitted on behalf of Protestant. Protestant alleges that affiliation of Applicant with Bank would contravene New Mexico law restricting branch banking (N.M. Stat. Ann. § 48-2-17 (1953)). In addition, Protestant has made several other arguments in opposition to the application, namely, that (1) Applicant's acquisition of Bank would have adverse competitive effects both within the State of New Mexico and on the three existing banks in the relevant market; (2) that the relevant banking market is not presently attractive for *de novo* entry; and (3) that there is no need for an additional bank in the market.[2]

With regard to the branching issue, the Board has stated that a State's restrictive branch banking laws are not automatically applicable to bank holding company operations. In a given case the Board examines the facts to determine whether a particular acquisition by a bank holding company would constitute an illegal branch under State law. If the Board determines that a violation of State law would result, it is required to disapprove the transaction. (Whitney National Bank v. Bank of New Orleans, 323 F. 2d 290 (D.C. Cir. 1963), rev'd on other grounds, 379 U.S. 411 (1965); Gravois Bank, et al. v. Board of Governors, 478 F. 2d 546 (8th Cir. 1973). The Board notes that the Office of the Comptroller of the Currency has granted preliminary approval for the charter of Bank, following a hearing, apparently concluding that Bank would not be an illegal branch under New Mexico law. The facts of record in this case indicate that Bank will be a separate corporation, with its own capital stock and a loan limit based on such capital stock; that Bank will have its own statutory limit on indebtedness and liability without any reference to the limits of any other banking subsidiary of Applicant; that Bank's operations will be conducted by its own officers; that Bank's board of directors will be generally separate from the boards of Applicant and of Applicant's subsidiaries and will exercise independent judgment with respect to the management of Bank; that Bank's customers will be able to deposit and withdraw their funds only with respect to accounts in Bank and will not be able to effect a deposit or withdrawal from Bank at any other subsidiary of Applicant; and that Bank's name will be completely separate and is different from the name of any other of Applicant's banking subsidiaries.

Accordingly, the Board concludes that Bank will not be operated in a unitary fashion with any banking subsidiary of Applicant and thus this proposal will not contravene New Mexico's restrictive branch banking law. Further, the Board concludes that Applicant is a "traditionally recognized bang holding company which, with its own capital, invests in or buys the stock of banks," Whitney National Bank v. Bank of New Orleans, supra.

With regard to the other issues raised by Protestant, the Board notes again that Applicant's initial entry into the Las Cruces area will be by means of a de novo acquisition which would not have any significant adverse effect on concentration or competition in New Mexico. With regard to the effect in the Las Cruces banking market, the Board notes that the market exhibits a high degree of concentration which has remained essentially unchanged over the past few years. Thus, it would appear that competition in the market would be enhanced by the entrance of a fourth banking alternative; furthermore, while approval of this proposal may moderate somewhat the rate of growth of the banks presently in the market, the Board is unable to conclude that Bank's entry into the market would have significant adverse effects on any bank therein or impair their ability to remain viable banking organizations.

In addition, Protestant contends that the Las Cruces area cannot support an additional bank. However, the Board notes that while the economic and population growth of the area for the past two years was not as dramatic as the growth experienced over the preceding two decades, the facts of record indicate that prospects for the area are favorable

[1] The Las Cruces banking market is approximated by Dona Ana County.

[2] Protestant also requested that the Board hold a hearing on the application. Under § 3(b) of the Act, the Board is required to hold a hearing only when the primary supervisor of the bank to be acquired recommends disapproval of the application (12 U.S.C. 1842(b)). In this case, the Comptroller of the Currency issued preliminary charter approval for Bank on July 15, 1975, and has recommended that the subject application be approved. Thus, there is no statutory requirement that the Board hold a hearing. Moreover, the Board is of the view that the record in this case is sufficiently complete to render a decision without the necessity for a hearing.

and that the market can support an additional banking alternative. Finally, Protestant asserts that there is no need for an additional bank in the area in that all banking needs are being served by the existing organizations. While it appears that Bank would not offer any new services to the area not currently available, consummation of the proposal would enable Bank to help satisfy the present strong market demand for Small Business Administration guaranteed loans and real estate financing. Therefore, it is the Board's judgment, upon consideration of all the facts of record, that the arguments raised by Protestant are not sufficient to warrant denial of the subject proposal.

In view of the foregoing discussion and having considered the facts of record and all the comments of Protestant in light of the statutory factors the Board must consider under § 3(c) of the Act, it is the Board's judgment that consummation of the subject proposal would be in the public interest and that the application to acquire Bank 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 that date and (c) Bank of Las Cruces, National Association, shall be opened for business not later than six months after the effective date of this Order. Each of the periods described in (b) and (c) may be extended for good cause by the Board or by the Federal Reserve Bank of Kansas City pursuant to delegated authority.

By order of the Board of Governors,[3] effective March 29, 1976.

[SEAL] J. P. GARBARINI,
*Assistant Secretary of the Board.*

[FR Doc.76-9556 Filed 4-2-76;8:45 am]

## FLORIDA BANKSHARES, INC.

### Acquisition of Bank

Florida Bankshares, Inc., Hollywood, Florida, has applied for the Board's approval under § 3(a)(3) of the Bank Holding Company Act (12 U.S.C. 1842(a)(3)) to acquire 23.8 percent of the voting shares of First National Bank of Sebring, Sebring, Florida. The factors that are considered in acting on the application are set forth in § 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 views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, to be received not later than April 27, 1976.

[3] Voting for this action: Chairman Burns and Governors Gardner, Holland, Wallich, and Coldwell. Absent and not voting: Governors Jackson and Partee.

Board of Governors of the Federal Reserve System, March 29, 1976.

[SEAL] J. P. GARBARINI,
*Assistant Secretary of the Board.*

[FR Doc.76-9558 Filed 4-2-76;8:45 am]

## ONE CORP.

### Formation of Bank Holding Company

One Corporation, New Richmond, Wisconsin, has applied for the Board's approval under § 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 37.8 per cent of the voting shares of First National Bank of New Richmond, New Richmond, Wisconsin. The factors that are considered in acting on the application are set forth in § 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 views in writing to the Reserve Bank, to be received not later than April 22, 1976.

[SEAL] J. P. GARBARINI,
*Assistant Secretary of the Board.*

[FR Doc.76-9559 Filed 4-2-76;8:45 am]

## STEPP, INC.

### Formation of Bank Holding Company

Stepp, Inc., Mission Hills, Kansas, has applied for the Board's approval under § 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 65 per cent or more of the voting shares of Quindaro Bancshares, Inc., Kansas City, Kansas, a one-bank holding company that holds 8.3 per cent of the voting shares of Arrowhead State Bank of Kansas City, Kansas City, Kansas. The factors that are considered in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. 1842(c)).

Stepp, Inc., Mission Hills, Kansas, has also applied, pursuant to § 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 retain voting shares of A. F. Stepp Investments, Inc., Kansas City, Missouri. Notice of the application was published on February 27, 1976 in The Kansas City Star, a newspaper circulated in Kansas City, Missouri.

Applicant states that the subsidiary engages in the business of underwriting and dealing in obligations of the United States, general obligations of any State and of any political subdivision thereof, and others enumerated in section 24 (Paragraph Seventh) of Title 12 of the United States Code.

Interested persons may express their views as to whether such activities are so closely related to banking or managing or controlling banks as to be a proper incident thereto. In considering this application the Board will take into account the materials submitted in response to the notice of proposed rulemaking published in the FEDERAL REGISTER (39 FR 13007), on April 10, 1974, on the general question whether engaging in such underwriting and dealing is so closely related to banking as to be a proper incident thereto.

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 Kansas City.

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 April 23, 1976.

Board of Governors of the Federal Reserve System, March 25, 1976.

[SEAL] GRIFFITH L. GARWOOD,
*Assistant Secretary of the Board.*

[FR Doc.76-9560 Filed 4-2-76;8:45 am]

## VALLEY OF VIRGINIA BANKSHARES, INC.

### Acquisition of Bank

Valley of Virginia Bankshares, Inc., Harrisonburg, Virginia, has applied for the Board's approval under § 3(a)(3) of the Bank Holding Company Act (12 U.S.C. 1842(a)(3)) to acquire 100 per cent (less directors' qualifying shares) of the voting shares of the successor by merger to The First National Bank of Troutville, Troutville, Virginia. The factors that are considered in acting on the application are set forth in § 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 views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, to be received not later than April 19, 1976.

Board of Governors of the Federal Reserve System, March 25, 1976.

[SEAL] GRIFFITH L. GARWOOD,
*Assistant Secretary of the Board.*

[FR Doc.76-9561 Filed 4-2-76;8:45 am]

## INTERNATIONAL TRADE COMMISSION

[AA1921-151]

### BUTADIENE ACRYLONITRILE RUBBER FROM JAPAN

#### Determination of No Injury or Likelihood Thereof

On December 29, 1975, the United States International Trade Commission received advice from the Department of the Treasury that butadiene acrylonitrile rubber from Japan is being, or is likely to be, sold in the United States at less than fair value within the meaning of the Antidumping Act, 1921, as amended (19 U.S.C. 160(a)). Accordingly, on January 5, 1976, the Commission instituted investigation No. AA1921-151 under section 201(a) of said act to determine whether an industry in the United States is being or is likely to be injured, or is prevented from being established, by reason of the importation of such merchandise into the United States.

Notice of the institution of the investigation and of the public hearing was published in the FEDERAL REGISTER of January 19, 1976 (41 FR 2694).

In arriving at its determination, the Commission gave due consideration to written submissions from interested parties, evidence adduced at the hearing, and all factual information obtained by the Commission's staff from questionnaires, personal interviews, and other sources.

The United States International Trade Commission has unanimously determined that an industry in the United States is not being and is not likely to be injured, and is not prevented from being established, by reason of the importation of butadiene acrylonitrile rubber from Japan that is being, or is likely to be, sold at less than fair value within the meaning of the Antidumping Act, 1921, as amended.

By order of the Commission.

Issued: March 29, 1976.

[SEAL] KENNETH R. MASON, *Secretary.*

STATEMENT OF REASONS

On December 29, 1975, the United States International Trade Commission received advice from the Department of the Treasury (Treasury) that it had determined that imports of butadiene acrylonitrile rubber from Japan are being, or are likely to be, sold at less than fair value (LTFV) within the meaning of the Antidumping Act, 1921, as amended. On January 5, 1976, the Commission instituted investigation No. AA1921-151 under said act to determine whether an industry in the United States is being or is likely to be injured, or is prevented from being established, by reason of the importation of such merchandise into the United States.

The Commission received advice from the Treasury on March 24, 1975, that an antidumping investigation was being initiated with respect to butadiene acrylonitrile rubber from Japan and that, pursuant to section 201(c) of the act, as amended by the Trade Act of 1974, information developed during the summary investigation had led to the conclusion that there was substantial doubt whether an industry in the United States was being or was likely to be injured, or was prevented from being established, by reason of the importation of such merchandise into the United States. Accordingly, on March 28, 1975, the Commission instituted its first inquiry, No. AA1921-Inq.-1, under section 201(c)(2) of the act to determine whether "there is no reasonable indication that an industry in the United States is being or is likely to be injured, or is prevented from being established, by reason of the importation of such merchandise into the United States." On the basis of its inquiry, the Commission on April 23, 1975, did not determine that there was" no reasonable indication that an industry in the United States is being or is likely to be injured, or is prevented from being established, by reason of the importation of such merchandise into the United States." The negative determination in No. AA1921-Inq.-1 permitted the Treasury proceeding to continue.[1]

On the basis of the subject investigation, we determine that an industry in the United States is not being and is not likely to be injured, and is not prevented from being established,[2] by reason of the importation of butadiene acrylonitrile rubber from Japan being sold or likely to be sold at LTFV.

*U.S. industry.* The U.S. industry most likely to be adversely affected by imports of butadiene acrylonitrile rubber sold at LTFV consists of the facilities in the United States devoted to the production of butadiene acrylonitrile rubber, a synthetic product produced by the copolymerization of butadiene and acrylonitrile, which are both derivatives of petroleum. No evidence showing that any other industry in the United States was possibly adversely affected by the subject imports was presented or discovered during the investigation. Butadiene acrylonitrile rubber (hereinafter nitrile rubber) is a special-purpose rubber. Its greatest economic significance is that the vulcanized product retains its rubberlike characteristic after sustained contact with petroleum. Nitrile rubber is produced in two basic forms, dry and latex. The dry form, which is the form in which the product is imported from Japan, is produced in the United States by five major synthetic rubber producers, four of which are among the world's largest tire producers. A sixth company produces nitrile rubber in only the latex form. The processes used in producing nitrile rubber are basically the same for the various producers.

*No injury by reason of LTFV imports. Import penetration.*—Total imports from Japan accounted for only about 1 percent of domestic consumption of nitrile rubber in each year during 1973-75. Since the Treasury found that LTFV sales existed for only 77 percent of nitrile rubber imports from Japan during the period investigated, it is clear that LTFV imports amounted to no more than 1 percent of domestic consumption. In light of such a low import penetration, it is difficult, absent unusual circumstances, to tie LTFV imports to any injury which may be occurring in the industry in question. Such circumstances are not present here.

Moreover, the import penetration occurred largely in a period of actual or threatened scarcity and allocation of sales by domestic producers. During the period of petrochemical shortages, some customers of the domestic industry sought alternate suppliers, including foreign sources, in an effort to assure themselves of a continuous source of supply.

*Prices.*—Nippon Zeon Co., Ltd., the source of all imports of nitrile rubber from Japan during the period under investigation, undersold the comparable domestic product during 1974 and 1975 and November 1, 1974, to April 30, 1975, the period of Treasury's investigation, by average margins of 10, 10, and 13 percent, respectively. However, no price depression is apparent in the price trends for nitrile rubber, and a comparison with price trends in the overall synthetic rubber industry indicates no significant difference in the rates of price increases.

*Profitability of domestic industry.*—The nitrile rubber industry in the United States was highly profitable during the period 1971-74, with net profits ranging from 23 to 30 percent of net sales. Although the ratio of net profits to net sales declined to 5 percent in 1975, no discernible difference in the profit pattern for nitrile rubber compared with that of the overall operations of the domestic producers was observed, indicating that any injury experienced by the nitrile rubber industry was not by reason of LTFV imports but rather as a result of the general economic conditions and the sluggish demand for automobiles, the principal user of nitrile rubber.

*Employment.*—The trend in employment for the nitrile rubber industry during 1973-75 was similar to that experienced by the overall establishment operations of companies producing nitrile rubber. Thus, the decline in employment, which occurred between 1974 and 1975, could not be attributed to imports from Japan.

*Likelihood of injury.* Although the Japanese nitrile rubber industry had substantial unused capacity in 1975, there is no reason to expect a sudden increase in import penetration. The unused capacity figures for Japan are similar to those for the United States, and it is anticipated that economic recovery will result in greater utilization of capacity in both countries. There has been no indication of any plans by the Japaneses to expand capacity, and substantial lead time from instituting construction plans to actual operations is necessary in this capital-intensive industry.

Structural factors in the domestic industry indicate that imports will face difficulties in capturing a larger share of the domestic market. The domestic competitors are large corporations with long-established economic relationships with the U.S. automotive industry. In addition, the large companies maintain manufacturing divisions that use nitrile rubber as a raw material, making it difficult for the imports to compete with this vertical marketing structure.

*Conclusion.* We conclude that an industry in the United States is not being and is not likely to be injured by reason of the importation of nitrile rubber from Japan that is being, or is likely to be, sold at LTFV within the meaning of the Antidumping Act, 1921, as amended.

[FR Doc.76-9645 Filed 4-2-76;8:45 am]

[1] See "Statement of Reasons" of Chairman Bedell, Vice Chairman Parker, and Commissioner Leonard in *Butadiene Acrylonitrile Rubber from Japan * * * Inquiry No. AA1921-Inq.-1* * * * ITC Publication 727, 1975, p. 4.

[2] Prevention of the establishment of an industry is not an issue in the instant investigation and will not be discussed further.

[AA1921-153]

### CLEAR POLYMETHYL METHACRYLATE OF PELLET, POWDER FLAKE, GRANULAR OR SIMILAR FORMS

#### Investigation and Hearing

Having received advice from the Department of the Treasury on March 19,

1976, that clear polymethyl methacrylate of pellet, powder, flake, granular or similar forms, from Japan is being, or is likely to be, sold at less than fair value, the United States International Trade Commission on Mar. 30, 1976, instituted investigation No. AA1921–153 under section 201(a) of the Antidumping Act, 1921, as amended (19 U.S.C. 160(a)), to determine whether an industry in the United States is being or is likely to be injured, or is prevented from being established, by reason of the importation of such merchandise into the United States.

*Hearing.* A public hearing in connection with the investigation will be held in the Commission's Hearing Room, U.S. International Trade Commission Building, 701 E Street, N.W., Washington, D.C. 20436, beginning at 10:00 a.m., e.d.t., on Tuesday, May 11, 1976. All parties will be given an opportunity to be present, to produce evidence, and to be heard at such hearing. Requests to appear at the public hearing should be received by the Secretary of the Commission, in writing, at the Commission's office in Washington, D.C., not later than noon, Friday, May 7, 1976.

By order of the Commission.

Issued: March 31, 1976.

[SEAL] KENNETH R. MASON,
*Secretary.*

[FR Doc.76-9646 Filed 4-2-76;8:45 am]

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[337-TA-6]

### CERTAIN EYE TESTING INSTRUMENTS INCORPORATING REFRACTIVE PRINCIPLES

#### Notice and Order Concerning Commission Action Terminating Investigation

Upon consideration of the Presiding Officer's Recommendation and the record in this proceeding,

The Commission hereby orders the termination of Investigation 337-TA-6, Certain Eye Testing Instruments Incorporating Refractive Principles, based upon a finding that no violation of section 337 now exists.

Copies of the Commission Memorandum Opinion in support of the Commission action are available to the public during official working hours at the Office of the Secretary, United States International Trade Commission, 701 E Street NW., Washington, D.C. 20436.

By order of the Commission.

Issued: March 31, 1976.

[SEAL] KENNETH R. MASON,
*Secretary.*

[FR Doc.76-9648 Filed 4-2-76;8:45 am]

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[337-TA-9]

### CERTAIN HYDRAULIC TAPPETS II

#### Notice and Order Concerning Commission Action Terminating Investigation

Upon consideration of the submissions of the parties, the Presiding Officer's Recommendation, and comment by the Department of Justice in this proceeding,

The Commission hereby orders the termination of Investigation 337-TA-9, Certain Hydraulic Tappets II, based upon a finding that no violation of section 337 now exists.

Copies of the Commission Memorandum Opinion in support of the Commission action are available to the public during official working hours at the Office of the Secretary, United States International Trade Commission, 701 E Street NW., Washington, D.C. 20436.

By order of the Commission:

Issued: March 31, 1976.

[SEAL] KENNETH R. MASON,
*Secretary.*

[FR Doc.76-9647 Filed 4-2-76;8:45 am]

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## NATIONAL SCIENCE FOUNDATION

### ADVISORY GROUP ON ANTICIPATED ADVANCES IN SCIENCE AND TECHNOLOGY

#### Meeting

In accordance with the Federal Advisory Committee Act, P.L. 92-463, the National Science Foundation announces the following meeting:

Name: Advisory Group on Anticipated Advances in Science and Technology.

Date and time: April 22, 1976—9 a.m. to 4 p.m.

Place: Ames Research Center, Moffett Field, California (enter gate 18).

Type of meeting: Open.

Contact person: Mr. William Montgomery, Special Assistant to the Director of Operations, National Science Foundation, Washington, D.C. 20550. Anyone planning to attend the meeting should contact Mr. Montgomery by April 14 at 202-632-4061.

Summary minutes: May be obtained from the Committee Management Coordination Staff, Division of Personnel and Management, Rm. 248, National Science Foundation, Washington, D.C. 20550.

Purpose of Advisory Group: To provide advice and developments that may take place in science and engineering and examine the national policy implications of these developments. This group will consider subjects in a manner which will facilitate the planning for the proposed Office of Science and Technology.

AGENDA

9:00—Convene, Chairman's remarks.

9:05—Food & Nutrition—report of Subgroup.

11:00—Basic Research.

11:30—Policy Research and Role of the NAS/NAE.

12:00—Recess.

1:00—Science Indicators.

1:30—Social Sciences.

2:00—Biomedical Research.

3:00—Committee Discussion.

4:00—Adjourn.

M. REBECCA WINKLER,
*Acting Committee Management Officer.*

MARCH 31, 1976.

[FR Doc.76-9674 Filed 4-2-76;8:45 am]

### ADVISORY GROUP ON CONTRIBUTIONS OF TECHNOLOGY TO ECONOMIC STRENGTH

#### Meeting

In accordance with the Federal Advisory Committee Act, P.L. 92-463, the National Science Foundation announces the following meeting:

Name: Advisory Group on Contributions of Technology to Economic Strength.

Date and time: April 23, 1976—9 a.m. to 4 p.m.

Place: Ames Research Center, Moffett Field, California (enter gate 18).

Type of meeting: Open.

Contact person: Mr. William Montgomery, Special Assistant to the Director of Operations, National Science Foundation, Washington, D.C. 20550. Anyone planning to attend the meeting should contact Mr. Montgomery by April 14 at 202-632-4061.

Summary minutes: May be obtained from the Committee Management Coordination Staff, Division of Personnel and Management, Rm. 248, National Science Foundation, Washington, D.C. 20550.

Purpose of Advisory Group: To provide advice on issues that may lead to policy supporting an improved utilization of technology and fostering economic strength. This group will consider these subjects in a manner which will facilitate the planning for the proposed Office of Science and Technology Policy.

AGENDA

9:00—Convene, Chairman's remarks.

9:05—Food and Nutrition—report of Subgroup.

10:00—Setting National Priorities.

10:30—Science Indicators.

11:00—Improving Technology Transfer to Enhance Innovation.

12:00—Recess.

1:00—Space Program Issues.

1:45—Nuclear Waste Disposal.

2:30—Land Use and Progress Report on Regulation Subgroup.

3:00—Committee Discussion.

4:00—Adjourn.

M. REBECCA WINKLER,
*Acting Committee Management Officer.*

MARCH 31, 1976.

[FR Doc.76-9675 Filed 4-2-76;8:45 am]

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## NUCLEAR REGULATORY COMMISSION

### ADVISORY COMMITTEE ON REACTOR SAFEGUARDS; WORKING GROUP ON PEAKING FACTORS

#### Meeting

In accordance with the purposes of Sections 29 and 182 b. of the Atomic Energy Act (42 U.S.C. 2039, 2232 b.), the ACRS Working Group on Peaking Factors will hold a meeting on April 20, 1976 in Room 1046, 1717 H St., N.W., Washington, D.C. 20555. This is the first of a series of meetings to review current methods of measuring power distribution in light-water power reactors whose cores are fabricated by the various reactor vendors. This meeting will be used to consider power distribution in reactors whose cores have been fabricated by the Westinghouse Electric Corporation.

The agenda for the subject meeting shall be as follows:

*Tuesday, April 20, 1976, 8:30 a.m.* Members of the Working Group will meet in closed Executive Session, with any of their consultants who may be present, to explore their preliminary opinions regarding matters which should be considered during the open session so that the Working Group can prepare a report and recommendations to the full Committee.

*9:00 a.m. until conclusion of business.* The Working Group will meet in open session to discuss with representatives of the NRC Staff and the Westinghouse Electric Corporation current methods of measuring power distribution in nuclear reactor cores built by the Westinghouse Electric Corporation.

At the conclusion of the open session, the Working Group may caucus in a brief, closed session to determine whether the matters identified in the initial closed session have been adequately covered. During this session, Working Group members and consultants will discuss their opinions and recommendations on these matters.

In addition to these closed deliberative sessions, it may be necessary for the Working Group to hold one or more closed sessions for the purpose of exploring with the NRC Staff and representatives from other Government agencies and the nuclear industry matters involving proprietary information, particularly with regard to specific features of plant designs.

I have determined, in accordance with Subsection 10(d) of Public Law 92-463, that it is necessary to conduct the above closed sessions to protect the free interchange of internal views in the final stages of the Working Group's deliberative process (5 U.S.C. 552(b)(5)) and to protect proprietary information (5 U.S.C. 552(b)(4)). Separation of factual material from individuals' advice, opinions and recommendations while closed Executive Sessions are in progress is considered impractical.

Practical considerations may dictate alterations in the above agenda or schedule. The Chairman of the Working Group is empowered to conduct the meeting in a manner that, in his judgment, will facilitate the orderly conduct of business, including provisions to carry over an incompleted open session from one day to the next.

With respect to public participation in the open portion of the meeting, the following requirements shall apply:

(a) Persons wishing to submit written statements regarding the agenda items may do so by providing a readily reproducible copy to the Working Group at the beginning of the meeting. Comments should be limited to safety related areas within the Working Group's purview.

Persons desiring to mail written comments may do so by sending a readily reproducible copy thereof in time for consideration at this meeting. Comments postmarked no later than April 13, 1976 to Mr. T. G. McCreless, ACRS, NRC, Washington, DC 20555 will normally be received in time to be considered at this meeting.

(b) Those persons wishing to make an oral statement at the meeting should make a written request to do so, identifying the topics and desired presentation time so that appropriate arrangements can be made. The Working Group will receive oral statements on topics relevant to its purview at an appropriate time chosen by the Chairman of the Working Group.

(c) Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by a prepaid telephone call on April 19, 1976 to the Office of the Executive Director of the Committee (telephone 202/634-1374, Attn: Mr. T. G. McCreless) between 8:15 a.m. and 5:00 p.m., e.s.t.

(d) Persons with agreements or orders permitting access to proprietary information may attend portions of ACRS meetings where this material is being discussed upon confirmation that such agreements are effective and relate to the material being discussed.

The Executive Director of the ACRS should be informed of such an agreement at least three working days prior to the meeting so that the agreement can be confirmed and a determination can be made regarding the applicability of the agreement to the material that will be discussed during the meeting. Minimum information provided should include information regarding the date of the agreement, the scope of material included in the agreement, the project or projects involved, and the names and titles of the persons signing the agreement. Additional information may be requested to identify the specific agreement involved. A copy of the executed agreement should be provided to Mr. T. G. McCreless of the ACRS Office, prior to the beginning of the meeting.

(e) Questions may be propounded only by members of the Working Group and its consultants.

(f) The use of still, motion picture, and television cameras, the physical installation and presence of which will not interfere with the conduct of the meeting, will be permitted both before and after the meeting and during any recess. The use of such equipment will not, however, be allowed while the meeting is in session.

(g) A copy of the transcript of the open portion of the meeting will be available for inspection on or after April 27, 1976 at the NRC Public Document Room, 1717 H St., NW., Washington, D.C. 20555.

Copies of the minutes of the meeting will be made available for inspection at the NRC Public Document Room 1717 H St., NW., Washington, D.C. 20555 after July 20, 1976. Copies may be obtained upon payment of appropriate charges.

Dated: March 30, 1976.

JOHN C. HOYLE,
*Advisory Committee Management Officer.*

[FR Doc.76-9573 Filed 4-2-76;8:45 am]

[Docket No. 50-10]

## COMMONWEALTH EDISON CO.

### Issuance of Amendment to Facility Operating License

Notice is hereby given that the U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 15 to Facility Operating License No. DPR-2, issued to the Commonwealth Edison Company (the licensee), which revised Technical Specifications for operation of the Dresden Nuclear Power Station Unit 1 (the facility) located in Grundy County, Illinois. The amendment is effective as of its date of issuance.

The amendment incorporates increased surveillance requirements in the Technical Specifications to provide additional assurance that a high energy line failure outside of containment will not occur during the short period of time the facility will be operated prior to completing certain modifications to assure that the facility can withstand the consequences of postulated ruptures in the high energy piping outside of containment.

The application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I which are set forth in the license amendment. Notice of Proposed Issuance of Amendment to Facility Operating License in connection with this action was published in the FEDERAL REGISTER on October 30, 1974 (39 FR 38275). No request for a hearing or petition for leave to intervene was filed following notice of the proposed action.

The Commission has determined that the issuance of this amendment will not result in any significant environmental impact and that pursuant to 10 CFR § 51.5(d)(4) an environmental statement, negative declaration or environmental impact appraisal need not be prepared in connection with the issuance of this amendment.

For further details with respect to this action, see (1) the application for amendment dated January 15, 1975 and previous filings dated March 5, 1974 and December 30, 1974, (2) Amendment No. 15 to License No. DPR-2, and (3) the Commission's concurrently issued Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street N.W., Washington, D.C.

A single copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Operating Reactors.

Dated at Bethesda, Maryland, this 25th day of March, 1976.

For the Nuclear Regulatory Commission.

DENNIS L. ZIEMANN,
*Chief, Operating Reactors Branch No. 2, Division of Operating Reactors.*

[FR Doc.76-9574 Filed 4-2-76;8:45 am]

[Docket Nos. 50-269, 50-270, and 50-287]

## DUKE POWER CO.

### Issuance of Amendments to Facility Operating Licenses

Notice is hereby given that the U.S. Nuclear Regulatory Commission (the Commission) has issued Amendments No. 21, 21, and 18 to Facility Operating Licenses No. DPR-38, DPR-47, and DPR-55, respectively, issued to Duke Power Company which revised Technical Specifications for operation of the Oconee Nuclear Station, Units 1, 2, and 3, located in Oconee County, South Carolina. The amendments are effective as of the date of issuance.

These amendments allow the removal of the reactor vessel surveillance capsules from the Oconee Unit 1 reactor during Cycle 3 operation.

The application for the amendments complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendments. Prior public notice of these amendments is not required since the amendments do not involve a significant hazards consideration.

The Commission has determined that the issuance of these amendments will not result in any significant environmental impact and that pursuant to 10 CFR § 51.5(d)(4) an environmental statement, negative declaration or environmental impact appraisal need not be prepared in connection with issuance of these amendments.

For further details with respect to the action, see (1) the application for amendment dated March 16, 1976, (2) Amendments No. 21, 21, and 18 to Licenses No. DPR-38, DPR-47, and DPR-55, and (3) the Commission's related Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. 20555, and at the Oconee County Library, 201 South Spring Street, Walhalla, South Carolina 29691.

A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Operating Reactors.

Dated at Bethesda, Maryland, this 26th day of March 1976.

For the Nuclear Regulatory Commission,

ROBERT A. PURPLE,
*Chief, Operating Reactors Branch No. 1, Division of Operating Reactors.*

[FR Doc.76-9575 Filed 4-2-76;8:45 am]

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[Docket No. 50-244]

## ROCHESTER GAS AND ELECTRIC CORP.

### Issuance of Amendment to Provisional Operating License

Notice is hereby given that the U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 10, to Provisional Operating License No. DPR-18 issued to Rochester Gas and Electric Corporation (the licensee) which revised the Technical Specifications for operation of the R. E. Ginna Nuclear Power Plant located in Wayne County, New York. The amendment is effective as of its date of issuance.

The amendment changes the Technical Specifications to revise the core thermal limits curve based on the application of the approved, updated Westinghouse model for fuel densification and clad flattening, a revision in the overpower $\Delta T$ and overtemperature $\Delta T$ set points, a deletion of the allowance for relaxing end-of-life control rod insertion limits, and revised shutdown margin requirements based on a reanalysis of the main steam line break accident.

The applications for the amendment comply with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment. Notice of Proposed Issuance of Amendment to Provisional Operating License in connection with this action was published in the FEDERAL REGISTER on April 10, 1975 (40 F.R. 16249). No request for a hearing or petition for leave to intervene was filed following notice of the proposed action.

The Commission has determined that the issuance of this amendment will not result in any significant environmental impact and that pursuant to 10 CFR § 51.5(d)(4) an environmental statement, negative declaration, or environmental impact appraisal need not be prepared in connection with issuance of this amendment.

For further details with respect to this action, see (1) the applications for amendment dated March 27, and September 22, 1975, (2) Amendment No. 10 to License No. DPR-18, and (3) the Commission's related Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. 20555 and at the Lyons Public Library, 67 Canal Street, Lyons, New York 14489 and at the Rochester Public Library, 115 South Avenue, Rochester, New York 14627.

A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Operating Reactors.

Dated at Bethesda, Maryland, this 30th day of March 1976.

For the Nuclear Regulatory Commission.

ROBERT A. PURPLE,
*Chief, Operating Reactors Branch No. 1, Division of Operating Reactors.*

[FR Doc.76-9576 Filed 4-2-76;8:45 am]

## CLEVELAND ELECTRIC ILLUMINATING COMPANY, ET AL. (PERRY NUCLEAR POWER PLANT, UNITS 1 AND 2)

[Docket Nos. 50-440, 50-441]

For the Atomic Safety and Licensing Board.

Dated at Bethesda, Maryland, this 31st day of March 1976.

### Notice of Postponement of Hearing

The hearing previously scheduled for April 1, 1976, in the above-entitled proceeding has been rescheduled, by stipulation of the parties, to April 9, 1976, at 10:00 a.m., in Room 2069, Federal Building, 1240 East 9th Street, Cleveland, Ohio 44119.

JOHN M. FRYSIAK,
*Chairman.*

[FR Doc.76-9680 Filed 4-2-76;8:45 am]

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## ADVISORY COMMITTEE ON REACTOR SAFEGUARDS SUBCOMMITTEE ON WASTE MANAGEMENT

### Meeting

In accordance with the purposes of Sections 29 and 182b. of the Atomic Energy Act (42 U.S.C. 2039, 2232 b.), the ACRS Subcommittee on Waste Management will meet on April 22, 1976 in Room 1046, 1717 H Street, N.W., Washington, DC 20555. This meeting will be closed to the public.

The Subcommittee will meet in closed session with its consultants, members of the NRC Staff and NRC Staff consultants to exchange opinions and discuss preliminary views and recommendations related to the NRC Waste Management Program. In connection with this matter, the Subcommittte may hold executive sessions not open to the public or NRC Staff prior to and at the conclusion of the meeting with the NRC Staff and NRC Staff consultants to exchange opinions and formulate recommendations to the full Committee.

Persons wishing to submit written statements regarding the agenda may do so by sending a readily reproducible copy in time for consideration at this meeting. Comments postmarked no later than April 15, 1976, to Mr. R. Muller, ACRS, NRC, Washington, DC 20555 will normally be received in time to be considered at this meeting.

I have determined in accordance with Subsection 10(d) of Public Law 92-463 that it is necessary to close this meeting which will consist of an exchange of opinions and preliminary positions, the discussion of which, if written, would fall within exemption 5 of 5 U.S.C. 552(b)(5) and to protect confidential, proprietary, or plant security information (5 U.S.C. 552(b)(4)). Separation of factual material from individuals' advice, opinions, and recommendations while this meeting is in progress is considered impractical. It is essential to close this meeting to protect the free interchange of internal views and to avoid undue

interference with Subcommittee and Agency operation.

Dated: April 1, 1976.

JOHN C. HOYLE,
*Advisory Committee Management Officer.*

[FR Doc.76-9803 Filed 4-2-76;8:45 am]

[Docket Nos. 50-448; 50-449]

## POTOMAC ELECTRIC POWER CO. (DOUGLAS POINT NUCLEAR GENERATING STATION, UNITS 1 AND 2)

### Order Relative to a Prehearing Conference and Evidentiary Hearing

A prehearing conference wil be held in the Nuclear Regulatory Commission Hearing Room on the 5th floor, East West Towers Building, 4350 East West Highway, Bethesda, Maryland, at 9:30 a.m. (local time) on April 14, 1976. Appropriate matters under 10 CFR 2.752 will be considered. The public is welcome to attend. No limited appearance statements will be accepted at the prehearing conference.

This Board and the State of Maryland Public Service Commission have agreed to hold a joint evidentiary hearing in accordance with the enclosed "Joint Hearing Protocol". The hearing will be held in the East Circuit Court Room, Circuit Court for Charles County, East Charles Street, La Plata, Maryland. The proceeding will commence at 10:00 a.m. (local time) on May 17, 1976.

The public is welcome to attend. Limited appearance statements will be accepted at this evidentiary hearing. Oral statements wil be limited to five (5) minutes but written statements may be submitted without limitation on length. If here is sufficient interest, one or more evening sessions will be scheduled for limited appearance statements.

Dated at Bethesda, Maryland, this 1st day of April 1976.

It Is So Ordered.

For the Atomic Safety and Licensing Board.

ELIZABETH S. BOWERS,
*Chairman.*

JOINT HEARING PROTOCOL

I. STATEMENT OF PURPOSE

The Potomac Electric Power Company (PEPCO) has applied to the Atomic Energy Commission[1] for permits to construct the Douglas Point Nuclear Power Plant, Units 1 and 2, in Charles County, Maryland. PEPCO has also applied to the Public Service Commission of Maryland for a Certificate of Public Convenience and Necessity and to other State and local agencies for permits required under Maryland law for construction of the plant. The Sierra Club/Prince George's County Environment Coalition/Environmental Defense Fund, the Citizens Council for a Clean Potomac/Chesapeake Bay Foundation, the State of Maryland and its People's Counsel, the Commonwealth of Virginia, and Mr. Edward Wojciechowicz/D.C. Public Interest Research Group have petitioned to intervene and have been admitted as parties to proceedings before one or both of the above agencies considering the Douglas Point Nuclear Power Plant Applications.

It is in the interest of all parties involved in these proceedings that a joint hearing be held between the Nuclear Regulatory Commission (through their Atomic Safety and Licensing Board), and the Public Service Commission of Maryland to consider and take evidence on issues common to both proceedings and within the concurrent jurisdiction of both agencies. It is believed that a joint hearing would be in the public interest and would benefit all parties by expediting the decision-making processes and by reducing time, effort, and expenditures which would otherwise be incurred by the parties were separate hearings held. The joint hearing, to be held in Charles County, Maryland, would be for the purpose of simultaneously compiling two evidentiary records on the issues common to both proceedings. At the conclusion of the hearing, the Atomic Safety and Licensing Board will issue an Initial Decision in accordance with the Nuclear Regulatory Commission's Rules of Practice in 10 CFR Part 2. The Public Service Commission of Maryland will separately issue its decision in accordance with its established practice.

II. COMPOSITION OF JOINT HEARING BODIES

The hearing shall be held before an Atomic Safety and Licensing Board (ASLB) of the U.S. Nuclear Regulatory Commission, the members of the Public Service Commission (PSC) of Maryland or their designees, with the Charles County Commissioners having the right to participate. Unless otherwise provided in this protocol, each body shall be governed by its own rules and regulations.

III. PROCEDURE FOR THE HEARING

a. *Record:* A single transcript of the evidence adduced at the joint hearing shall be made for purposes of each proceeding.

b. *People's Counsel Status:* For purposes of appearance before the ASLB during the joint hearing, Maryland's People's Counsel shall be accorded all the rights and remedies of an interested State under 10 CFR § 2.715(c) of the Nuclear Regulatory Commission's Rules of Practice.

c. *Motions:* Presentation, disposition, form, content, and answers to a motion made before one body but not the other shall be ruled upon by that body. Unless made orally on the record during the hearing, joint motions made before both bodies shall be in writing, shall state with particularity the gounds and relief sought, and shall be accompanied by any affidavits or other evidence relied upon, and, as appropriate, a proposed form of order. Within ten (10) days after service of a written joint motion before both bodies, a party may file an answer in support of or in opposition to the joint motion, accompanied by affidavits or other evidence.

d. *Rulings:* The hearing bodies shall individually make necessary rulings on procedural questions. Any objection to evidentiary offerings and motions shall be heard by both bodies and individual rulings by each body shall be made thereon. Where both bodies rule that any evidentiary offering is objectionable, the offering shall not be received in evidence. Where only one body rules that an evidentiary offering is objectionable, the offering shall be received in evidence only by the non-objecting body. In such an instance, the ruling that the evidence is objectionable shall be entered into the record of the objecting body and the evidence so received shall not be part of the evidentiary record of that body.

IV. PREHEARING CONFERENCE

Both bodies may schedule one or more joint prehearing conferences prior to the evidentiary hearing for the purpose of considering the following preliminary matters, if applicable:

1. formalizing and designating contentions already proffered as matters in controversy by the parties for the purpose of ascertaining and designating those contentions which are properly the subject of a joint hearing;
2. the necessity or desirability of amending pleadings;
3. the obtaining of stipulations and admissions of fact and of the contents and authenticity of documents to avoid unnecessary proof;
4. identification of witnesses and the limitation of the number of expert witnesses, and other steps to expedite the presentation of evidence;
5. the setting of the hearing schedule;
6. setting the order in which contentions shall be heard and the order in which the parties shall present their direct evidence;
7. determining the necessity or desirability of a site visit; and
8. such other matters as may aid in the orderly disposition of the proceeding.

V. WRITTEN TESTIMONY

The parties shall submit direct testimony of witnesses in written form. Each party shall serve copies of its proposed written testimony on each other party and the hearing bodies at least ten (10) days in advance of the date set for that segment of the hearing. Proposed written testimony of an expert witness shall contain a statement of professional qualifications.

VI. SERVICE OF DOCUMENTS

Documents shall be served on all persons designated on the service list of each commission. Service may be made by

[1] Pursuant to an executive order dated January 15, 1975, the Nuclear Regulatory Commission (NRC) was activated effective January 19, 1975. NRC, under the terms of the Energy Reorganization Act of 1974 (Public Law 93-438; 88 Stat. 1233) will carry out the licensing and regulatory functions formerly assigned to the Atomic Energy Commission.

person delivery, by first-class, certified or registered mail including air mail, by telegraph, or as otherwise authorized by law.

VII. EVIDENTIARY HEARING

A. The evidentiary hearing shall commence on the date and time specified by the hearing bodies. Each body shall have the opportunity to make initial opening statements in the following order: the ASLB and then the PSC. The proceeding will be subject to control generally by the ASLB.

B. After such opening statements as members of the hearing bodies may wish to make and disposition of all preliminary matters, the boards shall hear all persons wishing to make limited appearances. For the convenience of persons wishing to make limited appearance statements, there will be one or more evening sessions.

C. Upon tentative completion of the limited appearances, opening statements of the parties will be heard in the following order:

1. Applicant
2. NRC Staff
3. People's Counsel
4. Intervenors (in alphabetical order)
5. Maryland
6. Virginia

D. Contentions shall be considered one at a time by all parties in the order determined by the joint bodies.

E. Testimony may be taken in direct and cross-examination, redirect and recross-examination, rebuttal and surrebuttal, and shall be taken in the same order specified in paragraph C above.

F. Parties may present witnesses individually or may present witnesses in a panel.

G. After all parties have completed their cases with respect to the contentions in a segment of the total evidentiary hearing, each party shall be permitted a closing argument.

H. At the conclusion of various segments of the evidentiary hearing, each body shall set a schedule for the submission of all necessary findings, conclusions, or recommendations. Each body shall issue such initial decisions, recommendations, licenses, or permits as appropriate under the rules and regulations governing their respective agencies.

VIII. EXAMINATION BY EXPERTS

A party may request the joint hearing bodies to permit a qualified individual who has scientific or technical training or experience to participate on behalf of that party in the examination and cross-examination of expert witnesses. The bodies may permit such individual to participate on behalf of the party in the examination and cross-examination of expert witnesses, where it would serve the purpose of furthering the conduct of the proceeding, upon finding (a) that the individual is qualified by scientific or technical training or experience to contribute to the development of an adequate decisional record in the proceeding by the conduct of such examination or cross-examination, (b) that the individual has read any written testimony on which he (she) intends to examine or cross-examine and any documents to be used or referred to in the course of the examination or cross-examination, and (c) that the individual has prepared himself (herself) to conduct a meaningful and expeditious examination or cross-examination. Examination or cross-examination conducted pursuant to this section shall be limited to areas within the expertise of the individual conducting the examination or cross-examination. The party on behalf of whom such examination or cross-examination is conducted and his (her) attorney shall be responsible for the conduct of examination or cross-examination by such individuals.

[FR Doc.76-9865 Filed 4-2-76;9:24 am]

## DEPARTMENT OF DEFENSE

### Office of the Secretary

### DEFENSE SCIENCE BOARD TASK FORCE ON "ELECTRONIC TEST EQUIPMENT"

### Notice of Advisory Committee Meeting

Pursuant to the provisions of Pub. L. 92-463, notice is hereby given that the Defense Science Board Task Force on Electronic Test Equipment will meet in open session on 18 and 19 May 1976 in Room 9W67, National Center Building #1, 2511 Jefferson Davis Highway, Arlington, Virginia.

The sessions will commence at 9:00 a.m. each day.

The Task Force published its final report in February 1976. This will be the first of four meetings planned to follow up on the recommendations set forth in the Task Force final report, copies of which may be obtained either through the Defense Documentation Center, Cameron Station, Alexandria, Virginia 22314, or from the U.S. Department of Commerce, National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, Virginia 22161. Ask for report No. ADA-022063.

The primary responsibility of the Task Force was to examine the greater use by the Department of Defense of privately-developed, commercially-available, off-the-shelf electronic test equipment, including modifications thereof, with the goal of achieving economy and reliability benefits for the several Armed Services and to recommend policies and procedures which will maximize these benefits.

Persons wishing to attend are advised that a reasonable quantity of seating for observers will be available on a first-come, first-seated basis. No specific arrangements or notification of desire to attend is necessary.

The Executive Secretary for the Task Force is Mr. Rudolph J. Sgro, OASD (I&L) WS, Room 2A318, Pentagon, Washington, D.C. 20301.

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

MARCH 31, 1976.

[FR Doc.76-9622 Filed 4-2-76;8:45 am]

## DEPARTMENT OF JUSTICE

### ANTITRUST DIVISION

### UNITED STATES V. HALLIBURTON CO.

### Proposed Consent Judgment and Competitive Impact Statement Thereon

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16(b) through (h), that a proposed consent judgment and a competitive impact statement as set out below have been filed with the United States District Court for the Southern District of New York in Civil Action No. 73 Civ. 1806 MEF, *United States of America* v. *Halliburton Company*. The complaint in this case alleged that the effect of the acquisition of Ebasco Services, Inc., by Halliburton Company may be substantially to lessen competition in the markets for engineering and construction of fossil and nuclear electric power generating facilities. The proposed Judgment requires Halliburton to divest Ebasco within a maximum of four years and enjoins it from acquiring any company engaged in the engineering or construction of electrical power generating facilities. Public comment is invited on or before 10:00 a.m., May 14, 1976. Such comments and responses thereto will be published in the FEDERAL REGISTER and filed with the Court. Comments should be directed to John C. Fricano, Chief, Trial Section, Antitrust Division, Department of Justice, Washington, D.C. 20530.

Dated: March 24, 1976.

CHARLES F. B. MCALEER,
*Assistant Chief, Judgments and Judgment Enforcement Section.*

UNITED STATES DISTRICT COURT, SOUTHERN DISTRICT OF NEW YORK

United States of America, Plaintiff v. Halliburton Company, Defendant. Civil Action No. 73 Civ. 1806. Filed: March 24, 1976.

*Stipulation*

It is stipulated by and between the undersigned parties, plaintiff United States of America, and defendant Halliburton Company, by their respective attorneys, that:

1. The parties consent that a final judgment in the form hereto attached may be filed and entered by the Court upon the motion of either party or upon the Court's own motion, at any time after compliance with the requirements of the Antitrust Procedures and Penalties Act (15 U.S.C. § 16) and without further notice to any party or other proceedings, provided that plaintiff has not withdrawn its consent which it may do at any time before the entry of the proposed Final Judgment by serving notice thereof on defendant and by filing that notice with the Court.

2. In the event plaintiff withdraws its consent or if the proposed Final Judgment is not entered pursuant to this Stipulation, this Stipulation shall be of no effect whatever and the making of this Stipulation shall be without prejudice to plaintiff and defendant in this or any other proceeding.

Dated: March 24, 1976.

For the plaintiff: Thomas E. Kauper, Assistant Attorney General, Baddia J. Rashid, Bernard M. Hollander, John C. Fricano, Hays Gorey, Jr., H. Arthur Rosenthal. *Attorneys, Department of Justice,* Antitrust Division, 10th & Pennsylvania Avenue, N.W., Washington, D.C. 20530.

For defendant: Jerrold G. Van Cise, Cahill Gordon & Reindel, Eighty Pine Street, New York, New York 10005.

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

United States of America, Plaintiff, v. Halliburton Company, Defendant. Civil No. 73 Civ. 1806 MEF Entered:

FINAL JUDGMENT

Plaintiff, United States of America, having filed its complaint herein on April 24, 1973, and defendant, Halliburton Company, having appeared by its attorneys and having filed its answer to said complaint, and plaintiff and defendant, by their respective attorneys, having consented to the entry of this Final Judgment without trial or adjudication of any issue of fact or law herein and without this Final Judgment constituting evidence or admission by any party with respect to any issue of fact or law herein:

NOW, THEREFORE, before the taking of any testimony and without trial or adjudication of any issue of fact or law herein, and upon consent of the parties hereto, it is hereby, ORDERED, ADJUDGED, AND DECREED:

I

This Court has jurisdiction over the subject matter of this action and of the parties hereto. The complaint states claims upon which relief may be granted against the defendant under Section 7 of the Act of Congress of October 15, 1914, as amended (15 U.S.C. § 18), commonly known as the Clayton Act.

II

As used in this Final Judgment:

(A) "Halliburton" means Halliburton Company and its subsidiaries.

(B) "Ebasco" means Ebasco Services, Inc., and its subsidiaries.

(C) "Brown & Root" means Brown & Root, Inc., and its subsidiaries.

(D) "Consulting Agreements" means the Nuclear Consulting Agreement and the Construction and Process Engineering Consulting Agreement entered into by and between Brown & Root and Ebasco, attached hereto as Exhibits A and B.

(E) "Person" means any natural person, corporation, association, firm, partnership, or other business or legal entity.

III

The provisions of this Final Judgment applicable to Halliburton shall also bind its officers, directors, agents, employees, attorneys, subsidiaries, successors, and assigns and persons acting in concert with them who have actual knowledge of this Final Judgment by reason of personal service or otherwise.

IV

(A) Halliburton is ordered and directed to divest all of its interest, direct and indirect, in Ebasco by one of the following methods:

(1) Halliburton shall divest a majority interest in Ebasco by the sale of said majority interest within one (1) year of the date of entry of this Final Judgment. Halliburton shall continue to hold title to any minority interest, subject to the provisions of this Final Judgment, for no longer than four (4) years after the date of entry of this Final Judgment. Prior to the expiration of said four (4) year period, Halliburton shall sell its entire interest in Ebasco, except Halliburton may thereafter retain a 5% non-voting and non-convertible cumulative preferred stock interest in Ebasco not to exceed $12,000,000 (twelve million) until such stock has been redeemed by Ebasco.

(2) In the event Halliburton does not elect to divest Ebasco pursuant to the method provided in Section (A)(1) hereof, Halliburton shall sell its entire interest in Ebasco within three (3) years after the entry of this Final Judgment.

(B) Halliburton shall submit, in writing, to plaintiff the complete details of any proposed divestiture plan, including the identity of the proposed purchaser(s), intended to implement the provisions of this Section. Plaintiff shall have thirty (30) days from the date of first receipt of a proposed divestiture plan in which to request additional information from Halliburton, which, in turn, shall have ten (10) days from the receipt of such request to advise plaintiff of the extent to which such information is unavailable and twenty (20) days to furnish, in writing, such additional information to the extent it is available. Plaintiff shall have thirty (30) days following the date of receipt of the requested additional information, or following the date of receipt of a written statement from Halliburton that such information is not available, in which to object, in writing, to the proposed divestiture plan or any portion thereof. If plaintiff objects to the proposed divestiture plan or any portion thereof, it shall not be consummated unless plaintiff withdraws its objection or the Court gives its consent to the plan. If no request is made for additional information, plaintiff shall advise defendant, in writing, no later than thirty (30) days after the receipt of the proposed divestiture plan whether it has any objections to the proposed plan or any portion thereof.

(C) In the event that a proposed divestiture plan for Halliburton's entire stock or other interests in Ebasco shall not have been approved by the plaintiff or the Court pursuant to subsection B of this Section prior to three (3) months before the date specified for such total divestiture under the method selected by Halliburton pursuant to subsection A of this Section or in the event total divestiture shall not have been accomplished by such specified date, the Court, upon the motion of the plaintiff, shall appoint a trustee who, at Halliburton's expense, shall sell the remaining stock or other interests of Halliburton in Ebasco at a public offering within sixty (60) days after the date specified for total divestiture under the method selected by Halliburton pursuant to subsection A of this Section.

V

(A) Until the total divestiture provided for in Section IV shall have occurred, Halliburton shall hold completely separate the assets, including personnel and business operations, of Ebasco and refrain from intermingling any personnel, whether officers, directors, or employees, including their assignments and duties, and all operations of Ebasco with Halliburton. Until Halliburton shall have divested a majority interest in Ebasco, it shall generally maintain Ebasco in its complete integrity as a separate, viable entity pending divestiture; provided, that officials of Halliburton who are not also officials of Brown & Root shall take all reasonable steps, including examination of Ebasco records and operations, to provide such financial, business promotion, and director-level management assistance to Ebasco as may reasonably be necessary to maintain and strengthen Ebasco as a separate, viable entity.

(B) Until the total divestiture provided for in Section IV shall have occurred, Halliburton shall keep all bids and proposals and similar presentations to and negotiations with electric utilities by Brown & Root and Ebasco confidential within each of those separate organizations, subject to the following provisions:

(1) Each such separate organization may communicate such information to persons not covered by this Final Judgment where such persons are requested by it to participate in such bids, proposals, presentations, and negotiations;

(2) Each such separate organization may communicate such information to electric utilities or to other customers in connection with bids, proposals, presentations or negotiations made or conducted by such organization with its customers;

(3) In the case of Brown & Root, such information may be provided to Halliburton officials; and

(4) In the case of Ebasco, such information may be provided to officials of Halliburton who are not also officials of Brown & Root solely for their use in connection with their undertaking to provide financial, business promotion and director-level management assistance to Ebasco as described in subsection A of this Section.

(C) Halliburton is enjoined and restrained, so long as it is entitled to vote any of the shares of stock of Ebasco, from:

(1) Exercising the right to vote any shares of stock of Ebasco for any purpose other than:

(a) The election or removal of directors, subject to the provisions of subparagraphs (2) and (3) of this subsection; and

(b) Such necessary business acts as, under Ebasco's certificate of incorporation, would require Halliburton to vote and are approved by plaintiff; provided, that upon disapproval by plaintiff for any reason, such vote may be exercised only if the Court shall determine that the action proposed is not inconsistent with the provisions or purposes of this Final Judgment;

(2) Exercising the right to vote any shares of stock of Ebasco for the election of any individual as a director who, after thirty (30) days notice to plaintiff shall not be approved by the plaintiff; provided, however, that once a director of Ebasco has been so elected, said director may be re-elected without recourse to the provisions of this subparagraph; and

(3) Exercising the right to vote any shares of stock of Ebasco for the removal of any director unless, after thirty (30) days notice to plaintiff, such proposed action shall be approved by the plaintiff.

(D) Until divestiture of a majority interest in Ebasco pursuant to Section IV(A)(1) or total divestiture pursuant to Section IV (A)(2) shall have been accomplished, Halliburton may have two of its officials serve on the Board of Directors of Ebasco, provided that neither of such officials shall also sit on the Board of Directors of Brown & Root. Thereafter, Halliburton is enjoined and restrained from having any officer, director, employee, or agent serve upon the Board of Directors of Ebasco, except, if divestiture of a majority interest in Ebasco pursuant to Section IV(a)(1) is by public offering, Halliburton may have two of its officials serve on the Board of Directors of Ebasco, provided that neither of such officials shall also sit on the Board of Directors of Brown & Root, for a period not to exceed eighteen (18) months following such sale.

VI

(A) Until the total divestiture provided for in Section IV shall have occurred, Halliburton shall furnish a written report to the plaintiff every three (3) months from the date of entry of this Final Judgment setting forth all specific assistance given, actions taken, and information received relating to Ebasco pursuant to Section V of this Final Judgment.

(B) Until the total divestiture provided for in Section IV shall have occurred, Halliburton shall furnish a written report to the plaintiff every three (3) months from the

date of entry of this Final Judgment setting forth the steps it has taken to accomplish the divestiture required by Section IV of this Final Judgment.

VII

It is the purpose of this Section VII to permit Ebasco and Halliburton to enter into two consulting agreements to facilitate the development of Brown & Root as an effective competitor in supplying architectural engineering services for construction of nuclear power plants and to facilitate the development of Ebasco as an effective competitor in supplying architectural engineering services for industrial process construction, while at the same time insuring that each company will be an effective, independent competitor in the markets for such services. To that end, it is of the essence that each company be enjoined from providing consulting services for one another to a greater extent than that provided for herein.

(A) Until three years after the total divestiture of Ebasco by Halliburton, Halliburton and Ebasco are enjoined from engaging in any joint venture, purchase or sale to one another of goods or services, or any other type of business relationship, except that they may carry out the provisions of the two consulting agreements attached hereto as Exhibits A and B. In all respects, Brown & Root and Ebasco shall be bound by the provisions of the consulting agreements and failure to abide by those provisions, without the prior consent of plaintiff, shall effect a cancellation of the consulting agreements and a termination of all services rendered pursuant to their terms.

(B) During the existence of the consulting agreements and the rendering of any services pursuant to their terms, Ebasco shall report annually to the plaintiff the yearly engineering man-hour capacity available to Brown & Root, by specific engineering discipline category, and Brown & Root shall report annually to the plaintiff the engineering man-hours, by specific category, actually furnished to it by Ebasco. Both Brown & Root and Ebasco shall keep complete and detailed records of the persons involved, the man-hours expended, and the nature of the assistance rendered under the consulting agreements and shall maintain such records for the length of this Final Judgment.

VIII

Halliburton is enjoined and restrained for a period of ten (10) years from the date of entry of this Final Judgment from acquiring any stock or other interest whatsoever or any assets in excess of five hundred thousand dollars ($500,000) of any person engaged in the engineering and/or engineering and construction of electrical power generating facilities without the prior approval of the plaintiff or, failing such approval, of the Court; provided, however, nothing contained herein shall require prior approval by the plaintiff or the Court for Halliburton to acquire additional or all outstanding shares of NUS Corporation.

IX

(A) For the purpose of determining or securing compliance with this Final Judgment and for no other purpose, Halliburton and Ebasco shall permit any duly authorized representative of the Department of Justice, on written request of the Attorney General or the Assistant Attorney General in charge of the Antitrust Division, and on reasonable notice to their principal offices, subject to any legally recognized privilege:

(1) To have access during normal office hours to those books, ledgers, accounts, correspondence, memoranda, and other records and documents in the possession or under the control of the companies which relate to any matters contained in this Final Judgment; and

(2) Subject to the reasonable convenience of the companies, and without restraint or interference from them, to interview their officers, directors, agents, partners, or employees regarding such matters.

(B) Upon written request of the Attorney General or the Assistant Attorney General in charge of the Antitrust Division, Halliburton and Ebasco shall submit written reports with respect to any of the matters contained in this Final Judgment.

(C) No information obtained by the means provided in this Section IX shall be divulged by any representative of the Department of Jutice to any person other than a duly authorized representative of the Executive Branch of the United States, except in the course of legal proceedings to which the United States is a party, or for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

X

Jurisdiction is retained by this Court for the purpose of enabling either of the parties to this Final Judgment to apply to this Court at any time for such further orders and directions as may be necessary or appropriate for the construction, implementation, or modification of any of the provisions of this Final Judgment, for the enforcement of compliance therewith, and for the punishment of violations thereof.

XI

This Final Judgment shall remain in full force and effect for ten (10) years, and no longer, from the date of entry hereof, except as to any provisions herein for which a shorter term is specified herein.

XII

Halliburton shall provide a copy of this Final Judgment to every officer, director, and senior employee of Halliburton and Ebasco.

XIII

Entry of this Final Judgment is in the public interest.

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United States District Judge

Dated: ----------

EXHIBIT A—NUCLEAR CONSULTING AGREEMENT

This Agreement, made as of the 22nd day of March, 1976, by and between EBASCO SERVICES INCORPORATED, a New York Corporation (hereinafter referred to as "Ebasco"), and BROWN & ROOT, INC., a Texas Corporation (hereinafter referred to as "Brown & Root")

WITNESSETH:

That, in consideration of their mutual promises and undertakings herein, the parties hereto agree as follows:

1. SCOPE OF SERVICES

A. Ebasco agrees, subject to the provisions of this Agreement to furnish as a consultant to Brown & Root nuclear design engineering services and general consulting services to assist Brown & Root in Brown & Root's performance of nuclear power plant engineering services.

B. The nuclear design engineering services to be furnished shall be jointly determined by Ebasco and Brown & Root on a project-by-project basis. This will involve identifying the nature, magnitude and duration of such services. Ebasco shall advise each Brown & Root client of Ebasco's commitment of assistance to Brown & Root on each project, which commitment shall be subject to the provisions of Section 2.B below. Such commitment shall remain in full force and effect until all of Ebasco's obligations on that project have been satisfied. The services furnished shall be in respect to Brown & Root's current South Texas Project and to no more than two additional projects awarded to Brown & Root no later than four years after the effective date of this Agreement and shall be performed in the home, branch or field offices of Ebasco or Brown & Root as mutually determined.

C. The general consulting services furnished to Brown & Root shall encompass all aspects of nuclear power plant engineering including nuclear design, engineering, interpretation of standards, administration, and attendant operations. The general consulting services shall not include services or information not generally offered to Ebasco's utility clients and shall not include the conduct of seminars or classes or the disclosure or transfer of confidential Ebasco know-how and other Ebasco proprietary information and manuals, including but not limited to computer codes, Ebasco procedure manuals, Ebasco's Quality Assurance Manual, Ebasco's Standard Nuclear Plant Design, Ebasco's Guide for the Protection of Nuclear Plants Against Industrial Sabotage and confidential material related to the Molten Salt Project, and shall not include the preparation of similar information and manuals. The general consulting services to be furnished shall terminate no later than four years after the effective date of this Agreement and shall be performed in the home or established branch offices of Ebasco or Brown & Root as mutually determined.

2. AVAILABILITY OF SERVICES

A. The total amount of services of "Key Personnel" to be furnished by Ebasco during each year of this Agreement shall not exceed 5% of Ebasco's total yearly engineering manhour capacity in the categories listed in Exhibit 1A—Key Personnel Categories. Ebasco's yearly engineering capacity for a particular year shall be deemed to be the sum total of all of the engineering manhours expended in all of these categories by Ebasco during the calendar year immediately preceding such year. The amount of services to be furnished by Ebasco other than "Key Personnel" shall be as agreed to by Ebasco.

B. The nuclear design engineering services shall be scheduled so as not to conflict with any of Ebasco's prior commitments and so as not to have any detrimental effect upon Ebasco's ability to seek additional work from other clients.

C. The general consulting services will be made available to Brown & Root subject to the condition that the performance of such services shall not conflict with any of Ebasco's prior commitments and shall not have any detrimental effect upon Ebasco's ability to seek additional work from other clients.

3. EBASCO AND BROWN & ROOT EMPLOYEES

Brown & Root will not, other than under this agreement, hire or otherwise employ the services of any key personnel of Ebasco who, at any time during the immediately preceding twenty-four month period, performed services under this Agreement.

Ebasco will not hire or otherwise employ the services of any key personnel of Brown & Root who, at any time during the immediateley preceding twenty-four month period, performed services for any project on which Ebasco shall have rendered services under this Agreement.

Key personnel as used in this Section 3 shall mean personnel of the type listed in

Exhibit I or who perform similar services or functions.

4. REIMBURSEMENT AND COMPENSATIONS

For engineering and technical services rendered, Brown & Root will compensate Ebasco on the basis of (a) reimbursement of "Salary Costs", as hereinafter defined, plus (b) reimbursement of "All other Expenses" associated with engineering and technical services, as hereinafter defined, plus (c) payment of an amount to cover overhead and profit, as follows:

A. "Salary Costs" shall include the salaries and wages of Ebasco's Home Office personnel, at their equivalent hourly rates calculated on an annual basis (in accordance with Ebasco's standard accounting practice) for the time they are engaged directly in the performance of the services hereunder (including travel time) wherever performed. It is understood that, for all services furnished hereunder, costs shall be reimbursable whether services are performed by Ebasco's employees or employees of Ebasco subsidiaries and that the same multiplier applied to Ebasco employees' Salary Costs under Section 4.C below shall be applied to the Salary Costs of employees of Ebasco subsidiaries engaged directly in the performance of services hereunder.

B. "All Other Expenses" shall include traveling and living expenses to the extent allowed to Ebasco's personnel while performing direct services away from Ebasco's offices, premium portion of overtime compensation, premium costs for insurance required to be maintained pursuant to Section 10 hereof, cost of reproductions, telegraph and telephone toll costs, costs of outside service bureau computer use, and other similar "out-of-pocket" expenses incurred by Ebasco in connection with the services. Use of Ebasco's Computer, Diagrammer, Digitizer, Plotter, Metallurgical Laboratory and related equipment, if required, will be treated as additional "out-of-pocket" expenses computed at Ebasco's customary rates.

C. To cover Ebasco's general and administrative costs of maintaining and operating its offices and as compensation for performing the services hereunder, an amount equal to 3.0 times the amounts paid under Section 4.A, "Salary Costs".

5. TERMS OF PAYMENT

Ebasco shall submit monthly invoices for the costs and related expenses incurred and compensation earned during the preceding month which invoices shall be payable upon receipt. On service assignments calling for substantial expenditures, Ebasco may require imprest fund advances under procedures mutually agreed to.

6. INSPECTION AND APPROVAL

The services performed hereunder by Ebasco shall be subject to Brown & Root's inspection and approval, but the detailed manner and method of doing same shall be under the control of Ebasco.

7. RECORDS

Ebasco and Brown & Root shall retain all pertinent records relating to services performed hereunder for a period of two (2) years after completion thereof Ebasco shall, upon written request of Brown & Root made prior to the end of such two year period, deliver to Brown & Root any such records desired by Brown & Root. Brown & Root shall have access at all reasonable times during said period to those records required for audit of reimbursable items.

8. EXTRA SERVICES

Extra services shall not be performed, nor shall the scope of services be increased or decreased, unless authorized by Brown & Root in writing and agreed to by Ebasco and unless such services and the performance thereof are in accordance with the provisions of this Agreement.

9. PROPRIETARY INFORMATION

A. Ebasco shall accept Brown & Root proprietary information in confidence in accordance with the terms set forth in the Secrecy Agreement attached hereto as Exhibit IIA.

B. Brown & Root shall accept "Ebasco Proprietary Information" in confidence in accordance with the terms set forth in the Secrecy Agreement attached hereto as Exhibit II and shall not disclose or use any of Ebasco Proprietary Information except in conjunction with projects on which, pursuant to this Agreement, the services of Ebasco personnel are employed. "Ebasco Proprietary Information" means all designs, plans, specifications, processes, formulas, patents and patent applications, inventions, trade secrets, business secrets, sales information, computer applications, and any other proprietary information and data, that are obtained by Brown & Root as a result of this Agreement, except any which

(i) Is, or shall have been, in the possession of Brown & Root prior to disclosure thereof to Brown & Root,

(ii) Is, or through no fault of Brown & Root becomes, published or otherwise available to others or the public under circumstances such that such others or the public may utilize the same without any direct or indirect obligtaion to Ebasco, or

(iii) Is, or any time may be, acquired by Brown & Root from any third party rightfully possessed of the same and having no direct or indirect obligation to Ebasco with respect to same.

10. INSURANCE

Ebasco shall be required to maintain the following insurance during the term of this Agreement: Workmen's Compensation-Statutory; Employer's Liability—$1,000,000; Comprehensive General Liability-Bodily Injury—$100/$300,000; Property Damage—$50,000; Comprehensive Automobile Liability—Bodily Injury—$100/$300,000; and Property Damage—$50,000. Upon written request of Brown & Root received within five (5) days of the acceptance hereof, Ebasco will provide additional insurance, if available, including increased coverage and/or limits, and Brown & Root will pay Ebasco the cost for such additional insurance and increased coverage. It is the expectation of Ebasco and Brown & Root that there will be included in any contract between Brown & Root and its client, in connection with which the services of Ebasco personnel shall be employed, a provision that any liabilities and costs incurred, whether or not resulting from Ebasco's failure to meet the standards specified in Section 12, in connection with personal or bodily injury, death or property damage arising out of performance of this Agreement, including damage to the project in connection with which services are furnished, shall be for the account of the client to the extent that such liabilities and costs are not recoverable from the proceeds of the insurance required to be maintained by Ebasco hereunder. In the event that such a provision acceptable to Ebasco is not in the contract with the client, Ebasco shall not be obligated to perform any services on that project.

11. CONSEQUENTIAL DAMAGES

In no event shall Ebasco be liable to Brown & Root for any indirect, special or consequential loss or damage arising out of the performance of services hereunder whether caused by negligence of Ebasco or otherwise, including, but not limited to, loss of anticipated profits, loss of use, loss of revenue, losses by reason of shutdown of a facility or operation of a facility at less than rated capacity, business interruption, cost of replacement power, pool capacity charges, cost of capital, loss of goodwill, claims of clients or similar damages. It is the expectation of both Ebasco and Brown & Root that there will be included in any contract between Brown & Root and its clients, in connection with which the services of Ebasco personnel shall be employed, a provision that neither Ebasco nor Brown & Root shall be liable to the client for any such indirect, special or consequential loss or damage. In the event that such a provision acceptable to Ebasco is not in the contract with the client, Ebasco shall not be obligated to perform any services on that project.

12. STANDARDS OF PERFORMANCE

All services hereunder are to be performed in accordance with sound and generally accepted industry practices by personnel experienced in the applicable technical fields. These services are to be performed by Ebasco for Brown & Root in consideration of the payments specified herein and with the obligation that should any of the services of Ebasco hereunder not prove satisfactory to Brown & Root, as a result of human error, omission or otherwise, Ebasco's sole obligation resulting therefrom will be to perform corrective services of the type originally undertaken by Ebasco. Ebasco will be reimbursed and compensated for such corrective services as provided in Section 4 above, except that whenever corrective services are required because of the personal failure of a corporate officer of Ebasco, or of its representative in charge of the services as a whole, to perform his supervision in a way consistent with normal engineering practice, no additional charge shall be made for such corrective services, provided such corrective services are requested of Ebasco by Brown & Root in writing within one year from the completion of the nonconforming services.

13. CONTRACTS WITH CLIENTS

Brown & Root shall cause a provision to be inserted in any contract in connection with which the services of Ebasco personnel shall be employed stating that Ebasco shall have the same protection through indemnification, limitations of liability and insurance with respect to services to be performed by Ebasco as are provided for in the contract between Brown & Root and the client. Ebasco shall be furnished a copy of the complete contract between Brown & Root and the client, and related relevant documents, prior to Ebasco becoming obligated to furnish any services on that project and if such provisions are not acceptable to Ebasco or are later changed in a material way unacceptable to Ebasco, Ebasco shall not be obligated to provide services on that project.

14. TERMINATION

Brown & Root may, at its discretion, terminate the services under this Agreement at any time by giving ten (10) days written notice. In such event, Brown & Root shall assume all obligations, commitments and claims that Ebasco may have theretofore in good faith undertaken or incurred in connection with the services, and Brown & Root shall pay Ebasco the costs, expenses and compensation provided for in this Agreement incurred or accrued by Ebasco in connection with the performance of the services and the closing out of the services, less any amount previously paid to Ebasco, plus a reasonable termination charge to be mutually agreed to between Ebasco and Brown &

Root. The obligations of the parties under Section 9, Proprietary Information, shall survive the termination of this Agreement.

15. INDEPENDENT ENTITIES

It is understood Ebasco will perform the services hereunder as a consultant to Brown & Root and that both parties to this Agreement shall be considered as independent professional engineering entities in the performance of their respective obligations undertaken hereunder. Both parties shall be free to compete with one another for the award of any contract including, with limitation, projects on which Brown & Root may have utilized or intended to utilize the services of Ebasco under this Agreement.

16. MISCELLANEOUS

A. No amendment to this Agreement shall be binding unless it is in writing and signed for Ebasco and Brown & Root by the President of each party.

B. This Agreement shall not be assignable or transferable by either party without the written consent of the other, except that Ebasco, without such consent, may subcontract performance of services to its wholly owned subsidiaries.

C. This Agreement contains the entire agreement between the parties as to the services. All previous and collateral agreements, representations, warranties, promises and conditions relating to the subject matter of this Agreement are superseded by this Agreement.

D. This Agreement shall be construed and interpreted according to the laws of the State of Texas.

E. No person or party shall have any rights or interest, direct or indirect, herein by inference or otherwise except the parties hereto.

F. Any notice or demand under or required by this Agreement shall be given in writing and shall be deemed properly given if actually received in due and timely course by the party for whom the notice was intended, or if sent by registered or certified mail, postage prepaid, to the intended party in care of the appropriate address below:

Ebasco Services Incorporated, Two Rector Street, New York, New York 10006, Attention: The president.

Brown & Root, Inc., Post Office Box Three, Houston, Texas 77001, Attention: J. G. Munisteri.

G. Should any part, term or provision of this Agreement be decided by the courts to be illegal or in conflict with any law, the validity of the remaining portions of provisions shall not be affected thereby.

H. Brown & Root agrees to execute within two months from the date of this Agreement a similar agreement with Ebasco under which Brown & Root will provide similar services to assist Ebasco in Ebasco's performance of construction and process industry engineering work for projects awarded to Ebasco on or before two years after the effective date of this Agreement. Ebasco shall not be obligated to provide services under this Agreement in the event of the failure of Brown & Root to comply with this Section 16.H.

I. The effective date of this Agreement shall be the date that the Judgment in U.S. vs Halliburton Company, 73 Civ. 1806, becomes final.

IN WITNESS WHEREOF the parties hereto have entered into this Agreement as of the day and year hereinabove first written.

EBASCO SERVICES INCORPORATED
BY R. J. SHERMAN
BROWN & ROOT, INC.
BY J. G. MUNISTERI

KEY PERSONNEL CATEGORIES

Project Manager
Project Engineer
Lead Engineers:
  Mechanical-Nuclear
  Concrete-Hydraulic
  Architectural Structural
  Electrical
  Instrumentation & Control
  HVAC
  Plumbing
  Stress Analysis
  Water Treatment
  Radwaste
  Nuclear Licensing
  Environmental Licensing
  Project QA Eng.
  Site QA Sup
  Consulting Environmental

STANDARD SECRECY AGREEMENT

This secrecy agreement entered into this 22nd day of March 1976, by and between Abasco Service, Inc., 2 Rector Street, New York, New York "Ebasco" and "Brown & Root", for the confidential handling and safeguarding of proprietary confidential information of Ebasco which is revealed to Brown & Root in reliance on this agreement.

WITNESSETH

In consideration of the promises herein contained and the disclosures by Ebasco to Brown & Root of the proprietary confidential information to which this agreement refers it is mutually agreed as follows:

1. Brown & Root promises and agrees to receive and hold in confidence Ebasco's proprietary confidential information against unauthorized publication or disclosure by the same procedures utilized by Brown & Root's in regard to its own proprietary confidential information: and agrees not to use any of Ebasco's proprietary confidential information except for such purposes as are authorized by Ebasco. Brown & Root shall use its best efforts to comply with any other specific security measures requested in writing by Ebasco. This obligation shall continue for a period of ten (10) years after the date of disclosure.

2. Ebasco's proprietary confidential information shall consist of any information, data, or theory properly identified as such in accordance with this agreement, which Ebasco claims to be his proprietary confidential information or that of another which Ebasco has received pursuant to an agreement to hold in confidence, except any which:

(A) Is, or shall have been in the possession of Brown & Root prior to disclosure thereof to Brown & Root.

(B) Is, or through no fault of Brown & Root becomes, published or otherwise available to others or the public under circumstances such that such others or the public may utilize the same without any direct or indirect obligation to Ebasco.

(C) Is, or at any time may be, acquired by Brown & Root from any third party rightfully possessed of the same and having no direct or indirect obligation to Ebasco with respect to same.

3. All of Ebasco's proprietary confidential information which is to be made subject to this agreement shall be set forth in a written document, diagram, or model, and clearly marked as Ebasco's proprietary confidential information subject to this secrecy agreement prior to its disclosure and delivery to Brown & Root. Such confidential information shall be delivered to Brown & Root through Brown & Root's security officer, 4100 Clinton Drive, Houston, Texas.

4. Brown & Root agrees that Ebasco's proprietary confidential information will be disclosed only to such of Brown & Root's employees as have a need for such information in furtherance of the purpose for which Brown & Root is authorized to use it. All of Brown & Root's personnel to which such information is disclosed shall be required to execute a written secrecy agreement on Brown & Root's standard form, prohibiting unauthorized use of disclosure of Ebasco's proprietary confidential information and such agreement shall provide that an action for any breach thereof or for enforcement thereof may be brought by Ebasco directly against the employee of Brown & Root. If Ebasco requests at the time of disclosure to Brown & Root, employees of Brown & Root will be required to execute such special form of agreement as specified by Ebasco.

5. Brown & Root will cooperate with Ebasco in the enforcement of individual secrecy agreements executed by Brown & Root's employees, but in the event of an unauthorized use or disclosure of Ebasco's proprietary confidential information by an employee or employees of Brown & Root in violation of such individual secrecy agreement, Ebasco's sole remedy shall be against the employee and Brown & Root shall have no financial liability to Ebasco for any loss resulting from such use or disclosure.

Executed the day and year above written.

BROWN & ROOT, INC.
By J. G. MUNISTERI

EBASCO
By R. J. SHERMAN

EXHIBIT IIA

STANDARD SECRECY AGREEMENT

This secrecy agreement entered into this 22nd day of March 1976, by and between Ebasco Service, Inc., 2 Rector Street, New York, New York "Ebasco" and "Brown & Root", for the confidential handling and safeguarding of proprietary confidential information of Brown & Root which is revealed to Ebasco in reliance on this agreement.

WITNESSETH

In consideration of the promises herein contained and the disclosures by Brown & Root to Ebasco of the propreitary confidential information to which this agreement refers it is mutually agreed as follows:

1. Ebasco promises and agrees to receive and hold in confidence Brown & Root's proprietary confidential information revealed to Ebasco pursuant to this agreement: agrees to protect and safeguard Brown & Root's proprietary confidential information against unauthorized publication or disclosure by the same procedures utilized by Ebasco in regard to its own proprietary confidential information: and agrees not to use any of Brown & Root's proprietary confidential information except for such purposes as are authorized by Brown & Root. Ebasco shall use its best efforts to comply with any other specific security measures requested in writing by Brown & Root. This obligation shall continue for a period of ten (10) years after the date of disclosure.

2. Brown & Root's proprietary confidential information shall consist of any information, data, or theory properly identified as such in accordance with this agreement, which Brown & Root claims to be his proprietary confidential information or that of another which Brown & Root has received pursuant to an agreement to hold in confidence, except any which:

(a) Is, or shall have been in the possession of Ebasco prior to disclosure thereof to Ebasco,

(b) Is, or through no fault of Ebasco becomes, published or otherwise available to

others or the public under circumstances such that such others or the public may utilize the same without any direct or indirect obligation to Brown & Root,

(c) Is, or at any time may be, acquired by Ebasco from any third party rightfully possessed of the same and having no direct or indirect obligation to Brown & Root with respect to same.

3. All of Brown & Root's proprietary confidential information which is to be made subject to this agreement shall be set forth in a written document, diagram, or model, and clearly marked as Brown & Root's proprietary confidential information subject to this secrecy agreement prior to its disclosure and delivery to Ebasco. Such confidential information shall be delievred to Ebasco through Ebasco's security officer, 2 Rector Street, New York, New York.

4. Ebasco agrees that Brown & Root's proprietary confidential information will be disclosed only to such of Ebasco's employees as have a need for such information in furtherance of the purpose for which Ebasco is authorized to use it. All of Ebasco's personnel to which such information is disclosed shall be required to execute a written secrecy agreement on Ebasco's standard form, prohibiting unauthorized use of disclosure of Brown & Root's proprietary confidential information and such agreement shall provide that an action for any breach thereof or for enforcement thereof may be brought by Brown & Root. If Brown & Root requests at the time of disclosure to Ebasco, employees of Ebasco will be required to execute such special form of agreement as specified by Brown & Root.

5. Ebasco will cooperate with Brown & Root in the enforcement of individual secrecy agreements exectued by Ebasco's employees, but in the event of an unauthorized use or disclosure of Brown & Root's proprietary confidential information by an employee or employees of Ebasco in violation of such individual secrecy agreement, Brown & Root's sole remedy shall be against the employee and Ebasco shall have no financial liability to Brown & Root for any loss resulting from such use or disclosure.

Executed the day and year above written.

BROWN & ROOT, INC.

BY J. G. MUNISTERI

EBASCO

BY R. J. SHERMAN

EXHIBIT B—CONSTRUCTION AND PROCESS ENGINEERING CONSULTING AGREEMENT

This Agreement, made as of the 27th day of March, 1976, by and between EBASCO SERVICES INCORPORATED, a New York Corporation (hereinafter referred to as "Ebasco"), and BROWN & ROOT, INC., a Texas Corporation (hereinafter referred to as "Brown & Root")

WITNESSETH

That, in consideration of their mutual promises and undertakings herein, the parties hereto agree as follows:

1. SCOPE OF SERVICES

A. Brown & Root agrees, subject to the provisions of this Agreement, to furnish as a consultant to Ebasco construction and process engineering services and general consulting services to assist Ebasco in Ebasco's performance of construction and process engineering services.

B. The construction and process engineering services to be furnished shall be jointly determined by Ebasco and Brown & Root on a project-by-project basis. This will involve identifying the nature, magnitude and duration of such services. Brown & Root shall advise each Ebasco client of Brown & Root's commitment of assistance to Ebasco on each project, which commitment shall be subject to the provisions of Section 2.B below. Such commitment shall remain in full force and effect until all of Brown & Root's obligations on that project have been satisfied. The services furnished shall be in respect to projects awarded to Ebasco prior to the lapse of two years from the effective date of this Agreement and shall be performed in the home, branch or field offices of Ebasco or Brown & Root as mutually determined.

C. The general consulting services furnished to Ebasco by Brown & Root shall encompass all aspects of construction and process engineering including construction procedures, process design, engineering, interpretation of standards, administration, and attendant operations. The general consulting services shall not include services or information not generally offered to Brown & Root's clients and shall not include the conduct of seminars or classes or the disclosure or transfer of confidential Brown & Root know-how and other Brown & Root proprietary information and manuals, including but not limited to computer codes, Brown & Root procedure manuals, Brown & Root's Quality Control procedures and programs, Brown & Root's Process Plant Design data and confidential material related to its properietary equipment designs and shall not include the preparation or use of similar information and manuals. The general consulting services to be furnished shall terminate no later than two years after the effective date of this Agreement and shall be performed in the home or established branch offices of Ebasco or Brown & Root as mutually determined.

2. AVAILABILITY OF SERVICES

A. The total amount of services of "Key Personnel" to be furnished by Brown & Root during each year of this Agreement shall not exceed 5% of Brown & Root's total yearly manhour capacity in the categories listed in Exhibit I—Key Personnel Categories. Brown & Root's yearly manhour capacity for a particular year shall be deemed to be the sum total of all of the engineering or home office manhours expended in all of these categories by Brown & Root personnel during the calendar year immediately preceding such year. The amount of services to be furnished by Brown & Root other than "Key Personnel" shall be as agreed to by Brown & Root.

B. The construction and process engineering services shall be scheduled so as not to conflict with any of Brown & Root's prior commitments and so as not to have any detrimental effect upon Brown & Root's ability to seek additional work from other clients.

C. The general consulting services will be made available to Ebasco subject to the condition that the performance of such services shall not conflict with any of Brown & Root's prior commitments and shall not have any detrimental effect upon Brown & Root's ability to seek additional work from other clients.

3. EBASCO AND BROWN & ROOT EMPLOYEES

Ebasco will not, other than under this Agreement, hire or otherwise employ the services of any key personnel of Brown & Root who, at any time during the immediately preceding twenty-four months period, performed services under this Agreement.

Brown & Root will not hire or otherwise employ the services of any key personnel of Ebasco who, at any time during the immediately preceding twenty-four months period, performed services for any project on which Brown & Root shall have rendered services under this Agreement.

Key personnel as used in this Section 3 shall mean personnel of the type listed in Exhibit I or who perform similar services or functions.

4. REIMBURSEMENT AND COMPENSATION

For engineering and technical services rendered, Ebasco will compensate Brown & Root on the basis of (a) reimbursement of "Salary Costs", as hereinafter defined, plus (b) reimbursement of "All Other Expenses" associated with engineering and technical services, as hereinafter defined, plus (c) payment of an amount to cover overhead and profit, as follows:

A. "Salary Costs" shall include the salaries and wages of Brown & Root's personnel in accordance with Brown & Root's standard accounting practice for the time they are engaged directly in the performance of the services hereunder (including travel time) wherever performed. It is understood that, for all services furnished hereunder, costs shall be reimbursable whether services are peformed by Brown & Root's employees or employees of Brown & Root subsidiaries and that the same multiplier applied to Brown & Root employee's Salary Costs under Section 4.C below shall be applied to the Salary Costs of employees of Brown & Root subsidiaries engaged directly in the performance of services thereunder.

B. "All Other Expenses" shall include traveling and living expenses to the extent allowed to Brown & Root's personnel while performing direct services away from their established locations, premium portion of overtime compensation, premium costs for insurance required to be maintained pursuant to Section 10 hereof, cost of reproductions, telegraph and telephone toll costs, costs of outside service bureau computer use, and other similar "out-of-pocket" expenses incurred by Brown & Root in connection with the services. Use of Brown & Root's Computer, Diagrammer, Digitizer, Plotter, Laboratory and related equipment, if required will be treated as additional "out-of-pocket" expenses computed at Brown & Root's customary rates.

C. To cover Brown & Root's general and administrative costs of maintaining and operating its offices and as compensation for performing the services hereunder, an amount equal to 3.0 times the amounts paid under Section 4.A, "Salary Costs".

5. TERMS OF PAYMENT

Brown & Root shall submit monthly invoices for the costs and related expenses incurred and compensation earned during the preceding month which invoices shall be payable upon receipt. On service assignments calling for substantial expenditures, Brown & Root may require imprest fund advances under procedures mutually agreed to.

6. INSPECTION AND APPROVAL

The services performed hereunder by Brown & Root shall be subject to Ebasco's inspection and approval, but the detailed manner and method of doing same shall be under the control of Brown & Root.

7. RECORDS

Ebasco and Brown & Root shall retain all pertinent records relating to services performed hereunder for a period of two (2) years after completion thereof. Brown & Root shall, upon written request of Ebasco made prior to the end of such two (2) year period, deliver to Ebasco any such records desired by Ebasco. Ebasco shall have access at all responsible times during said period to those record required for audit of reimbursable items.

8. EXTRA SERVICES

Extra services shall not be performed, nor shall the scope of services be increased or decreased, unless authorized by Ebasco in writing and agreed to by Brown & Root and unless such services and the performance thereof are in accordance with the provisions of this Agreement.

9. PROPRIETARY INFORMATION

A. Brown & Root shall accept Ebasco proprietary information in confidence in accordance with the terms set forth in the Secrecy Agreement attached hereto as Exhibit II.

B. Ebasco shall accept "Brown & Root Proprietary Information" in confidence in accordance with the terms set forth in the Secrecy Agreement attached hereto as Exhibit IIA and shall not disclose or use any of Brown & Root Proprietary Information except in conjunction with projects on which, pursuant to this Agreement, the services of Brown & Root personnel are employed. "Brown & Root Proprietary Information" means all designs, plans, specifications, processes, formulas, patents and patent applications, inventions, trade secrets, business secrets, sales information, computer applications, and any other proprietary information and data, that are obtained by Ebasco as a result of this Agreement, except any which

(i) is, or shall have been, in the possession of Ebasco prior to disclosure thereof to Ebasco.

(ii) is, or through no fault of Ebasco becomes, published or otherwise available to others or the public under circumstances such that such others or the public may utilize the same without any direct or indirect obligation to Brown & Root.

(iii) is, or any time may be, acquired by Ebasco from any third party rightfully possessed of the same and having no direct or indirect obligation to Brown & Root with respect to same.

10. INSURANCE

Brown & Root shall be required to maintain the following insurance during the term of this Agreement: Workmen's Compensation-Statutory; Employer's Liability—$100,000; Comprehensive General Liability—Bodily Injury—$100/$300,000; Property Damage—$50,000; Comprehensive Automobile Liability—Bodily Injury—$100/$300,000; and Property Damage—$50,000. Upon written request of Ebasco received within five (5) days of the acceptance hereof, Brown & Root will provide additional insurance, if available, including increased coverage and/or limits, and Ebasco will pay Brown & Root the cost for such additional insurance and increased coverage. It is the expectation of Ebasco and Brown & Root that there will be included in any contract between Ebasco and its client, in connection with which the services of Brown & Root personnel shall be employed, a provision that any liabilities and costs incurred, whether or not resulting from Brown & Root's failure to meet the standards specified in Section 12, in connection with personal or bodily injury, death or property damage arising out of performance of this agreement, including damage to the project in connection with which services are furnished, shall be for the account of the client to the extent that such liabilities and costs are not recoverable from the proceeds of the insurance required to be maintained by Brown & Root hereunder. In the event that such a provision acceptable to Brown & Root is not in the contract with the client, Brown & Root shall not be obligated to perform any services on that project.

11. CONSEQUENTIAL DAMAGES

In no event shall Brown & Root be liable to Ebasco for any indirect, special or consequential loss or damage arising out of the performance of services hereunder, whether caused by negligence of Brown & Root or otherwise, including, but not limited to, loss or anticipated profits, loss of use, loss of revenue, losses by reason of shutdown of a facility or operation of a facility at less than rated capacity, business interruption, cost of replacement power, pool capacity charges, cost of capital, loss of goodwill, claims of clients or similar damages. It is the expectation of both Ebasco and Brown & Root that there will be included in any contract between Ebasco and its clients, in connection with which the services of Brown & Root personnel shall be employed, a provision that neither Ebasco nor Brown & Root shall be liable to the client for any such indirect, special or consequential loss or damage. In the event that such a provision acceptable to Brown & Root is not in the contract with the client, Brown & Root shall not be obligated to perform any services on that project.

12. STANDARDS OF PERFORMANCE

All services hereunder are to be performed in accordance with sound and generally accepted industry practices by personnel experienced in the applicable technical fields. These services are to be performed by Brown & Root for Ebasco in consideration of the payments specified herein and with the obligation that should any of the services of Brown & Root hereunder not prove satisfactory to Ebasco, as a result of human error, omission or otherwise, Brown & Root's sole obligation resulting therefrom will be to perform corrective services of the type originally undertaken by Brown & Root. Brown & Root will be reimbursed and compensated for such corrective services as provided in Section 4 above, except that whenever corrective services are required because of the personal failure of a corporate officer of Brown & Root, or of its representative in charge of the services as a whole, to perform his supervision in a way consistent with normal engineering practice, no additional charge shall be made for such corrective services, provided such corrective services are requested of Brown & Root by Ebasco in writing within one (1) year from the completion of the nonconforming services.

13. CONTRACTS WITH CLIENTS

Ebasco shall cause a provision to be inserted in any contract in connection with which the services of Brown & Root personnel shall be employed stating that Brown & Root shall have the same protection through indemnification, limitations of liability and insurance with respect to services to be performed by Brown & Root as are provided for in the contract between Ebasco and the client. Brown & Root shall be furnished a copy of the complete contract between Ebasco and the client, and related relevant documents, prior to Brown & Root becoming obligated to furnish any services on that project and if such provisions are not acceptable to Brown & Root or are later changed in a material way unacceptable to Brown & Root, Brown & Root shall not be obligated to provide services on that project.

14. TERMINATION

Ebasco may, at its discretion, terminate the services under this Agreement at any time by giving ten (10) days written notice. In such event, Ebasco shall assume all obligations, commitments and claims that Brown & Root may have theretofore in good faith undertaken or incurrred in connection with the services, and Ebasco shall pay Brown & Root the costs, expenses and compensation provided for in this Agreement incurred or accrued by Brown & Root in connection with the performance of the services and the closing out of the services, less any amount previously paid to Brown & Root, plus a reasonable termination charge to be mutually agreed to between Ebasco and Brown & Root. The obligations of the parties under Section 9, Proprietary Information, shall survive the termination of this Agreement.

15. INDEPENDENT ENTITIES

It is understood Brown & Root will perform the services hereunder as a consultant to Ebasco and that both parties to this Agreement shall be considered as independent professional engineering entities in the performance of their respective obligations undertaken hereunder. Both parties shall be free to compete with one another for the award of any contract including, without limitation, projects on which Ebasco may have utilized or intended to utilize the services of Brown & Root under this Agreement.

16. MISCELLANEOUS

A. No amendment to this Agreement shall be binding unless it is in writing and signed for Ebasco and Brown & Root by the President of each party.

B. This Agreement shall not be assignable or transferable by either party without the written consent of the other, except that Brown & Root, without such consent, may subcontract performance of services to its wholly-owned subsidiaries.

C. This Agreement contains the entire agreement between the parties as the the services. All previous and collateral agreements, representations, warranties, promises and conditions relating to the subject matter of this Agreement are superseded by this Agreement.

D. This Agreement shall be construed and interpreted according to the laws of the State of Texas.

E. No person or party shall have any rights or interest, direct or indirect, herein by inference or otherwise except the parties hereto.

F. Any notice or demand under or required by this Agreement shall be given in writing and shall be deemed properly given if actually received in due and timely course by the party for whom the notice was intended, or if sent by registered or certified mail, postage prepaid, to the intended party in care of the appropriate address below:

Ebasco Services Incorporated, Two Rector Street, New York, New York 10006, Attention: The president.

Brown & Root, Inc., Post Office Box Three, Houston, Texas 77001, Attention: J. G. Munisteri.

G. Should any part, term or provision of this Agreement be decided by the courts to be illegal or in conflict with any law, the validity of the remaining portions of provisions shall not be affected thereby.

H. Ebasco agrees to execute within two (2) months from date of this Agreement a similar agreement with Brown & Root under which Ebasco will provide similar services to assist Brown & Root in Brown & Root's performance of nuclear design engineering services for Brown & Root's current South Texas Project and no more than two additional domestic projects awarded to Brown & Root no later than four years after the effective date of this Agreement. Brown & Root shall not be obligated to provide services under this Agreement in the event of the failure of Ebasco to comply with this Section 16.H.

I. The effective date of this Agreement shall be the date that the Judgment in U.S. vs. Halliburton Company, 73 Civ. 1806, becomes final.

IN WITNESS WHEREOF the parties hereto have entered into this Agreement as of the day and year hereinabove first written.

EBASCO SERVICES INCORPORATED
BY R. J. SHERMAN

BROWN & ROOT, INC.
BY J. G. MUNISTERI

KEY PERSONNEL CATEGORIES

Project Managers
Project Engineers
Lead Engineers:
  Mechanical
  Piping
  Concrete-Hydraulic
  Process Engineering
  Architectural Structural
  Electrical
  Instrumentation & Control
  HVAC
  Plumbing
  Stress Analysis
  Water Treatment
  Quality Control
  Construction Managers
  Assistant Construction Managers
  Craft Supervisors
  General Craft Foreman

STANDARD SECRECY AGREEMENT

This secrecy agreement entered into this 23rd day of March 1976, by and between Ebasco Service, Inc., 2 Rector Street, New York, New York "Ebasco" and "Brown & Root", for the confidential handling and safeguarding of proprietary confidential information of Ebasco which is revealed to Brown & Root in reliance on this agreement.

WITNESSETH

In consideration of the promises herein contained and the disclosures by Ebasco to Brown & Root of the proprietary confidential information to which this agreement refers it is mutually agreed as follows:

1. Brown & Root promises and agrees to receive and hold in confidence Ebasco's proprietary confidential informtaion against unauthorized publication or disclosure by the same procedures utilized by Brown & Root's in regard to its own proprietary confidential information: and agrees not to use any of Ebasco's proprietary confidential information except for such purposes as are authorized by Ebasco. Brown & Root shall use its best efforts to comply with any other specific security measures requested in writing by Ebasco. This obligation shall continue for a period of ten (10) years after the date of disclosure.

2. Ebasco's proprietary confidential information shall consist of any information, data, or theory properly identified as such in accordance with this agreement, which Ebasco claims to be his proprietary confidential information or that of another which Ebasco has received pursuant to an agreement to hold in confidence, except any which:

(A) is, or shall have been in the possession of Brown & Root prior to disclosure thereof to Brown & Root.

(B) is, or through no fault of Brown & Root becomes, published or otherwise available to others or the public under circumstances such that such others or the public may utilize the same without any direct or indirect obligation to Ebasco.

(C) is, or at any time may be, acquired by Brown & Root from any third party rightfully possessed of the same and having no direct or indirect obligation to Ebasco with respect to same.

3. All of Ebasco's proprietary confidential information which is to be made subject to this Agreement shall be set forth in a written document, diagram, or model, and clearly marked as Ebasco's proprietary confidential information subject to this secrecy Agreement prior to its disclosure and delivery to Brown & Root. Such confidential information shall be delivered to Brown & Root through Brown & Root's security officer, 4100 Clinton Drive, Houston, Texas.

4. Brown & Root agrees that Ebasco's proprietary confidential information will be disclosed only to such of Brown & Root's employees as have a need for such information in furtherance of the purpose for which Brown & Root is authorized to use it. All of Brown & Root's personnel to which such information is disclosed shall be required to execute a written secrecy Agreement on Brown & Root's standard form, prohibiting unauthorized use of disclosure of Ebasco's proprietary confidential information and such Agreement shall provide that an action for any breach thereof or for enforcement thereof may be brought by Ebasco directly against the employee of Brown & Root. If Ebasco requests at the time of disclosure to Brown & Root, employees of Brown & Root will be required to execute such special form of Agreement as specified by Ebasco.

5. Brown & Root will cooperate with Ebasco in the enforcement of individual secrecy agreements executed by Brown & Root's employees, but in the event of an unauthorized use or disclosure of Ebasco's proprietary confidential information by an employee or employees or Brown & Root in violation of such individual secrecy agreement, Ebasco's sole remedy shall be against the employee and Brown & Root shall have no financial liability to Ebasco for any loss resulting from such use or disclosure.

Executed the day and year above written.

BROWN & ROOT, INC.
BY J. G. MUNISTERI
Ebasco
BY R. J. SHERMAN

STANDARD SECRECY AGREEMENT

This secrecy agreement entered into this 22d day of March 1976, by and between Ebasco Service, Inc., 2 Rector Street, New York, New York "Ebasco" and "Brown & Root," for the confidential handling and safeguarding of proprietary confidential information of Brown & Root which is revealed to Ebasco in reliance on this agreement.

WITNESSETH

In consideration of the promises herein contained and the disclosures by Brown & Root to Ebasco of the proprietary confidential information to which this agreement refers it is mutually agreed as follows:

1. Ebasco promises and agrees to receive and hold in confidence Brown & Root's proprietary confidential information revealed to Ebasco pursuant to this agreement: agrees to protect and safeguard Brown & Root's proprietary confidential information against unauthorized publication or disclosure by the same procedures utilized by Ebasco in regard to its own proprietary confidential information: and agrees not to use any of Brown & Root's proprietary confidential information except for such purposes as are authorized by Brown & Root. Ebasco shall use its best efforts to comply with any other specific security measures requested in writing by Brown & Root. This obligation shall continue for a period of ten (10) years after the date of disclosure.

2. Brown & Root's proprietary confidential information shall consist of any information, data, or theory properly identified as such in accordance with this agreement, which Brown & Root claims to be his proprietary confidential information or that of another which Brown & Root has received pursuant to an agreement to hold in confidence, except any which:

(A) Is, or shall have been in the possession of Ebasco prior to disclosure thereof to Ebasco,

(B) Is, or through no fault of Ebasco becomes, published or otherwise available to others or the public under circumstances such that such others or the public may utilize the same without any direct or indirect obligation to Brown & Root,

(C) Is, or at any time may be, acquired by Ebasco from any third party rightfully possessed of the same and having no direct or indirect obligation to Brown & Root with respect to same.

3. All of Brown & Root's proprietary confidential information which is to be made subject to this agreement shall be set forth in a written document, diagram, or model, and clearly marked as Brown & Root's Proprietary Confidential Information subject to this secrecy agreement prior to its disclosure and delivery to Ebasco. Such confidential information shall be delivered to Ebasco through Ebasco's Security Officer, 2 Rector Street, New York, New York.

4. Ebasco agrees that Brown & Root's proprietary confidential information will be disclosed only to such of Ebasco's employees as have a need for such information in furtherance of the purpose for which Ebasco is authorized to use it. All of Ebasco's personnel to which such information is disclosed shall be required to execute a written secrecy agreement on Ebasco's standard form, prohibiting unauthorized use of disclosure of Brown & Root's proprietary confidential information and such agreement shall provide that an action for any breach thereof or for enforcement thereof may be brought by Brown & Root. If Brown & Root requests at the time of disclosure to Ebasco, employees of Ebasco will be required to execute such special form of agreement as specified by Brown & Root.

5. Ebasco will cooperate with Brown & Root in the enforcement of individual secrecy agreements executed by Ebasco's employees, but in the event of an unauthorized use or disclosure of Brown & Root's proprietary confidential information by an employee of Ebasco in violation of such individual secrecy agreement, Brown & Root's sole remedy shall be against the employee and Ebasco shall have no financial liability to Brown & Root for any loss resulting from such use or disclosure.

Executed the day and year above written.

BROWN & ROOT, INC.
J. G. MUNISTERI

EBASCO
R. J. SHERMAN

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

United States of America, Plaintiff, v. Halliburton Company, Defendant. Civil Action No. 73 Civ. 1806 MEF Filed:

COMPETITIVE IMPACT STATEMENT

This Statement is made pursuant to the requirements of Section 5 of the Act of Congress of October 15, 1914, as amended (15 U.S.C. § 16), commonly known as the Antitrust Procedures and Penalties Act.

I

NATURE AND PURPOSE OF THE PROCEEDING

1. On April 24, 1973 a civil action was instituted against Halliburton Company under Section 15 of the Act of Congress of October 15, 1914, as amended (15 U.S.C. § 25), commonly known as the Clayton Act.

2. The purpose of the action is to prevent and restrain the continuing violation by the defendant of Section 7 of the Clayton Act, as amended (15 U.S.C. § 18). The alleged vio-

lation arose from the acquisition by Halliburton Company ("Halliburton") of Ebasco Services, Inc. ("Ebasco") which was engaged in the engineering design and construction of fossil and nuclear fueled electric power generating facilities in actual and potential competition with Brown & Root, Inc. ("Brown & Root"), a wholly-owned Halliburton subsidiary. The action sought to require Halliburton to divest Ebasco as a viable, going concern in substantially the form with substantially the same assets and expertise as it possessed on January 22, 1973, the date upon which it was acquired by Halliburton.

II

THE EVENTS GIVING RISE TO THE ALLEGED VIOLATION

3. Halliburton is a Delaware corporation with its principal place of business in Dallas, Texas. It conducts its business through numerous subsidiaries and divisions and is engaged in selling a variety of products and services throughout the United States. It performs engineering and construction services for the petrochemical, pulp and paper and electric power industries through its wholly-owned subsidiary, Brown & Root. In 1971 Halliburton had net revenues of $1.3 billion, a net income of $55.9 million and, as of December 31, 1971, assets of $822.9 million. For the same year Brown & Root had net United States revenues of $822.9 million. Ebasco is also engaged in performing engineering and construction services throughout the United States, primarily for the electric power industry. Prior to its acquisition by Halliburton, Ebasco was owned by Boise Cascade Corporation. In 1971 Ebasco had net revenues of $173 million, a net income of $3.855 million and, as of December 31, 1971, assets of $31.6 million.

4. There are a number of kinds of electric power generating facilities. In recent years, most newly constructed electric power generating plants have been of the fossil fuel or nuclear fuel type. Future power plant construction is also expected to be predominantly nuclear or fossil. In the construction of new electric power generating facilities, engineers perform feasibility studies, design the plant, and, once the design is approved, maintain a staff to supervise construction to insure compliance with engineering specifications. Consulting engineers, sometimes called architectural or design engineers, perform these functions. The most important of these functions is the design of the generating plant. Both Brown & Root and Ebasco are consulting engineers.

5. Usually, when an electric power facility is being designed, a construction company is employed to build the facility. Some construction companies that build power plants are not consulting engineers and perform no design functions. However, some consulting engineers also perform the construction and are called engineer constructors. Both Brown & Root and Ebasco are engineer constructors. Many consulting engineers and engineer constructors in the electric power field have expertise in both the fossil and nuclear areas and are capable of designing and building either kind of power plant.

6. Ebasco is one of the major consulting engineers and engineer constructors possessing both fossil fuel and nuclear engineering capability in the electric power generating field. Brown & Root is one of the largest consulting engineers and engineer constructors serving the electric power industry and is a significant and substantial factor in the design and construction of fossil fuel electric power facilities in the United States. Unlike Ebasco, however, it does not possess substantial nuclear engineering experience. Before the filing of the complaint in this action, Brown & Root had never been engaged to design a nuclear power plant. Since that time, Brown & Root has been awarded one contract to design a nuclear power plant in South Texas.

7. At the time the complaint was filed it appeared for a variety of reasons that an increasing percentage of subsequently constructed electric power generating facilities would be of the nuclear rather than the fossil fuel type. As a result it was necessary for Brown & Root to increase its participation in this field to take advantage of the perceived trend toward nuclear power. Indeed, by April 1973 Brown & Root had begun to develop its nuclear design capability and subsequently has continued its attempt to become a recognized nuclear design firm. Since the filing of the complaint, the nature and extent of future growth in the nuclear power field has become somewhat less certain. Among the factors contributing to this development have been the increase in nuclear plant construction costs and the heightened public concern with the safety and environmental impact of nuclear power plants. Notwithstanding these factors, however, it remains clear at the present time that the long-range development of nuclear energy as an acceptable alternative to fossil fueled electric power generating facilities continues to be a priority industrial and governmental objective.

8. For the period 1968 through 1972 Ebasco accounted for approximately 14.4% and Brown & Root accounted for approximately 5.0% of design engineering, by megawattage, of new fossil and nuclear power generating plants installed in the United States. This made Ebasco and Brown & Root the second and seventh ranked firms respectively in an industry where the top eight firms accounted for about 72.4% of all such design engineering. In addition, at the time the complaint was filed Ebasco ranked first and Brown & Root ranked fifth among firms engaged in the design engineering of fossil power generating plants by accounting for 14.5% and 5.7% of the fossil power megawattage installed in the United States between 1968 and 1972. During the same period Ebasco was the third ranking designer of nuclear power generating plants and accounted for about 13.7% of the nuclear power megawattage installed in the United States.

9. The complaint charged that the effect of Halliburton's acquisition of all of Ebasco's stock from Boise Cascade Corporation substantially lessened competition by eliminating actual and potential competition between Brown & Root and Ebasco in the engineering and construction of fossil and nuclear electric power generating facilities, by lessening competition generally in the fossil and nuclear power fields and by increasing concentration in engineering design and construction in the fossil and nuclear power industries.

III

EXPLANATION OF PROPOSED FINAL JUDGMENT

A. DIVESTITURE AND OTHER TERMS

10. In broad terms the proposed Final Judgment contains three essential forms of relief. It requires the divestiture of Halliburton's entire interest in Ebasco; it contains a variety of injunctive provisions to insure that Ebasco is maintained as a viable, competitive entity pending the completion of divestiture by Halliburton; and it permits Brown & Root and Ebasco to enter into two limited engineering consulting agreements designed to permit each of the companies to increase its participation in fields where they are not presently substantial competitors.

The proposed Final Judgment requires Halliburton to divest all of its Ebasco stock in either of two ways. Under the first method, Halliburton is directed to divest a majority interest in Ebasco within one year of the entry of the Judgment and its remaining minority interest within four years of that date. If Halliburton elects not to employ the first method of divestiture, it is then required to sell its entire interest in Ebasco within three years of the Judgment's date of entry. Either method of divestiture is to be upon terms and conditions acceptable to the Antitrust Division and the Court. If Halliburton does not undertake complete divestiture within three months prior to the expiration of the prescribed period under the method it chooses, the Court, upon application of the government, will appoint a trustee to accomplish total divestiture within 60 days following the end of that period.

Pending total divestiture of its Ebasco stock the proposed Final Judgment directs Halliburton to hold the Ebasco assets and operations completely separate from Halliburton. In addition, Halliburton is affirmatively required to maintain Ebasco as a separate, viable entity during the period in which it continues to hold a majority stock interest in that firm. To accomplish this the Judgment permits Halliburton to render certain limited director-level management assistance to Ebasco pending sale of a majority interest in Ebasco. As a safeguard that Brown & Root and Ebasco remain competitively independent pending the completion of divestiture the proposed Final Judgment requires that all bids, proposals, presentations and negotiations involving Brown & Root or Ebasco and their potential electric utility customers be kept confidential within each separate organization. The Judgment permits disclosure of such data to third parties only insofar as such action may be necessary in the regular course of each firm's business activities or where disclosure of such Ebasco data to Halliburton is necessary for the defendant to fulfill its obligation to maintain Ebasco's viability pending divestiture.

To further circumscribe Halliburton's influence over Ebasco pending the completion of divestiture, the proposed Final Judgment also prohibits Halliburton from voting any of its shares of Ebasco stock except in certain limited circumstances upon approval of the Antitrust Division or the Court. Until Halliburton divests a majority interest in Ebasco, the proposed Decree permits the defendant to have two of its officials serve on Ebasco's Board of Directors. After divestiture of a majority interest, Halliburton is prohibited from having any of its officers, directors, employees or agents sit on the Ebasco board. However, in the event that such divestiture is by a public offering, the proposed Final Judgment permits Halliburton to continue limited director representation for no longer than eighteen months following such a sale.

The preceding injunctive provisions largely incorporate and expand the terms of a Preliminary Injunction Order entered by the District Court in this action on June 14, 1973. That Order required Halliburton to maintain Ebasco in its complete integrity as a separate entity pending final judgment on the merits. The proposed Final Judgment continues this obligation pending Halliburton's disposition of its Ebasco holdings. Also, the proposed Decree contains reporting provisions requiring Halliburton to make regular periodic reports to the Antitrust Division disclosing certain of its contacts with Ebasco while divestiture is pending and describing the steps it has taken to accomplish its divestiture obligations.

For a period of ten years following the entry of the proposed Final Judgment Halliburton is enjoined from acquiring any interest whatsoever or any assets in excess of $500,000

of any person engaged in the engineering or engineering and construction of electrical power generating facilities without the prior approval of the Antitrust Division or the Court. This injunction does not apply, however, to Halliburton's acquisition of an additional interest in NUS Corporation, a firm which is already 25% owned by Halliburton. The proposed Decree also provides the Antitrust Division with rights to inspect the records of Halliburton and Ebasco and to interview officers and employees of those firms to determine and secure compliance with the Final Judgment.

B. THE CONSULTING AGREEMENTS

The proposed Final Judgment permits Brown & Root and Ebasco to enter two engineering consulting agreements with each other Ebasco will render nuclear design consulting services to Brown & Root. The Judgment also permits Brown & Root to render construction and process engineering consulting services to Ebasco. Both the nuclear and the construction and process engineering consulting agreements are limited in the maximum amount of services available under their terms. They provide that the consulting services rendered are not to interfere with each company's independent competitive efforts. In addition, the agreements contain employment restrictions, reimbursement provisons, performance standards and other provision dealing with liability, proprietary information, insurance and a variety of procedural matters.

These agreements are attached to the Judgment as Exhibits A and B. In all respects, the companies are bound by the limitations contained in them. Failure to abide by their terms, without the prior consent of the Antitrust Division, will result in their automatic cancellation. Other than carrying out the terms of the consuling agreements, the proposed Final Judgment enjoins Halliburton and Ebasco from engaging in any joint venture, purchase or sale to one another of goods or services, or any other type of business relationship for a period until three years after Halliburton accomplishes divestiture of its entire common stock interest in Ebasco.

As stated in the proposed Final Judgment, the purpose of the consulting agreements is to facilitate the development of Brown & Root as an effective competitor in supplying design engineering services for the construction of nuclear power plants and to facilitate the development of Ebasco as an effective competitor in supplying construction and process engineering services. At the same time, it is important that each company be an independent competitive entity in these markets. Thus, the standards have been carefully drawn to assure that neither company is unreasonably burdened by the agreements and the accompanying injunction prohibits additional business relationships between the companies for an extended period. Also, during the term of the consulting agreements, Brown & Root and Ebasco are required to keep detailed records of the services rendered under the agreements and make annual reports to the Antitrust Division concerning the services furnished to Brown & Root by Ebasco under the nuclear consulting agreement.

11. The effect of this proposed Final Judgment is to restore Ebasco as a substantial and effective independent competitor in the engineering and construction of fossil and nuclear electric power generating facilities and to decrease concentration in that industry. In addition, the nuclear consulting agreement will possibly permit Brown & Root to more effectively increase its participation in the nuclear design field thereby increasing competition in that important and concentrated industry. Furthermore, although these fields were not subjects of this proceeding, the construction and process engineering consulting agreement will similarly create the potential for Ebasco to become a greater competitive force in markets in which it is now not even a marginal competitor.

IV

REMEDIES AVAILABLE TO POTENTIAL PRIVATE PLAINTIFFS

12. Any potential private plaintiffs who might have been damaged by the alleged violation will retain the same right to sue for monetary damages and any other legal and equitable remedies which they would have had were the proposed Final Judgment not entered. However, this Judgment may not be used as *prima facie* evidence in private litigation pursuant to Section 5(a) of the Clayton Act, as amended (15 U.S.C., § 16(a)).

V

PROCEDURES AVAILABLE FOR THE MODIFICATION OF THE PROPOSED FINAL JUDGMENT

13. Normally the Antitrust Procedures and Penalties Act provides for a public comment period of 60 days after filing of a proposed Final Judgment with the District Court. The Act, however, permits a shortening of that period if the District Court finds that the circumstances require such an action and that such a shortening is not adverse to the public interest. In this case, Halliburton has applied to the District Court for a shortening of the public comment period in order to facilitate the effectuation of a proposed plan for an early public sale of 75% of Halliburton's common stock interest in Ebasco. This plan is generally described in Section VII hereof. Pursuant to the District Court's order, written comments regarding the proposed Final Judgment may be submitted by any member of the public before 10:00 a.m., May 14, 1976. Those comments should be addressed to: John C. Fricano, Chief, Trial Section, Antitrust Division, United States Department of Justice, Washington, D.C. 20530. Such comments and the Antitrust Division's responses thereto will be filed with the District Court and published in the FEDERAL REGISTER.

14. After the entry of the proposed Final Judgment, jurisdiction is retained by the United States District Court for the Southern District of New York, New York, New York, to enable the parties to the Judgment to apply to the Court for modification of any of the provisions thereof.

VI

ALTERNATIVES TO THE PROPOSED FINAL JUDGMENT CONSIDERED BY THE UNITED STATES

15. At no time during the negotiations of the proposed Final Judgment did the Antitrust Division ever consider any primary form of relief except complete divestiture of Ebasco by Halliburton in such a manner as to restore Ebasco as an effective, independent consulting engineer and engineer constructor of fossil and nuclear electric power generating facilities. Nothing short of that basic form of relief would have accomplished the purpose of this proceeding. The proposed Final Judgment, however, permits Halliburton to retain Vernon Graphics, Inc. (Vernon), an Ebasco subsidiary which was also acquired by Halliburton at the time it purchased the Ebasco stock from Boise Cascade Corporation. Vernon is not part of Ebasco's electric power industry engineering and construction operations. Failure to include it in the divestiture package, therefore, has no impact on the independent viability of Ebasco as a designer and constructor of fossil and nuclear electric power generating facilities, the relevant market in this proceeding. Vernon is primarily engaged in the plotting and mapping of power lines and other transmission systems for the natural gas and telephone industries. These services are not normally provided by consulting engineers and constitute an independent line of business separate from the industry which was the focus of this action. Becaues of this, the Antitrust Division acceded to Halliburton's request that it be permitted to retain the Vernon subsidiary.

16. While the basic remedy of complete divestiture was a non-negotiable demand during the Antitrust Division's settlement discussions with Halliburton, considerable negotiations did occur over the length of time which Halliburton would have in order to divest its Ebasco stock. Halliburton desired as long a period as possible to accomplish this relief. The government, on the other hand, insisted that divestiture be accomplished within a three year period of the Judgment's entry. As a compromise the Antitrust Division agreed to permit Halliburton an option to the flat three year divestiture requirement. Thus, if Halliburton sold its majority control over Ebasco within one year of the Judgment's entry, the government would allow Halliburton a total period of four years to divest all of its stock. This was considered acceptable because it created an incentive for Halliburton to dispose of majority control within a very short period of time thus immediately establishing Ebasco's independent identity as a competitor. Injunctive safeguards were imposed by the government to insure that Ebasco would remain free of Halliburton influence during Halliburton's retention of a minority interest in Ebasco. This process of negotiation resulted in the dual option method of divestiture contained in the proposed Final Judgment and described above.

17. During the negotiation of this Judgment Halliburton took the position that no settlement of the case was possible unless it could be permitted to engage in a consulting arrangement with Ebasco to assist it to establish itself as a nuclear design engineer. At the time the complaint in this action was filed, Brown & Root was striving to enter the nuclear design field but had met with no success. Subsequently, it was awarded a nuclear design contract for a group of electric utilities in Texas. This is the only such project it has ever been awarded, and its efforts to receive additional contracts of this variety have been unsuccessful. Barriers to entry into the nuclear design field are substantial and reputation and prior success are important factors in this industry. The electric utility places great reliance upon a firm's reputation and past performance in deciding to whom it will award a nuclear plant contract. Ebasco, of course, was and continues to be a recognized and substantial force in this field but Brown & Root continues to have only marginal success in its entry efforts.

18. As a result of this situation, the Antitrust Division recaognized that a nuclear consulting agreement between Ebasco and Brown & Root might indeed accelerate Brown & Root's efforts to enter the nuclear field and would be pro-competitive. Effective entry by Brown & Root would decrease concentration in this important industry which is presently dominated by a handful of successful engineer constructors. Thus, while the Antitrust Division at one time considered pressing for a judgment that did not include a nuclear consulting agreement, it agreed to permit such an arrangement to become part of the settlement after carefully assessing the Halliburton proposal. It did so, however, with the commitment that the agreement necessarily would be limited in scope and carefully structured to preserve Ebasco's independence as a competitor in the nuclear industry. Furthermore, the government required that such

an agreement be totally voluntary on Ebasco's part and be acceptable as such by that company. Thus, Ebasco was independently represented during the negotiation of the nuclear consulting agreement and agreed to its terms on a voluntary basis. In return for the rendering of nuclear consulting services to Brown & Root, Ebasco is to be compensated at three times its salary costs plus all other expenses. Additionally, as part of Ebasco's compensation for the nuclear consulting agreement, the government permitted Ebasco to receive similar consulting services from Brown & Root covering construction and process engineering. Since these are fields in which Ebasco is presently an insubstantial competitor and the consulting arrangement will permit Ebasco to increase its expertise, the government also agreed to this proposal. Both consulting agreements were made a part of the proposed Final Judgment and are subject to public comment.

19. Rather extensive negotiations were conducted with Halliburton to determine the appropriate limitations on the consulting services to be permitted under its nuclear consulting agreement with Ebasco. After prolonged discussion the parties agreed to limit the maximum amount of engineering services available to Brown & Root by placing a percentage limitation on the amount of Ebasco's key personnel who would be subject to the consulting agreement. Thus, the services rendered under the agreement are limited to 5% of Ebasco's engineering manhour capacity in 17 delineated key personnel categories. Furthermore, Ebasco is free to exercise its own judgment concerning the extent of support services it will provide to Brown & Root under the agreement. In addition, the nuclear consulting agreement is further limited in time and scope. Brown & Root may draw upon Ebasco's consulting services only for a maximum of two nuclear design projects in addition to the South Texas project already awarded Brown & Root. These projects must be awarded within a period of four years from the entry date of the proposed Final Judgment, at which time the agreement terminates. These manhour and project limitations in the nuclear consulting agreement do not represent the government's initial bargaining position on these matters. They are the product of negotiation and discussion with both Brown & Root and Ebasco. After a prolonged process of analysis and discussion the Antitrust Division decided that the present terms of the nuclear consulting agreement were the most equitable and workable alternative.

20. On several occasions during the negotiation of the proposed Final Judgment Ebasco requested that the Decree be drafted to compel Halliburton to divest its Ebasco stock by public sale. Ebasco had never been a publicly-held independent company and felt that such a disposition would be the most desirable form of divestiture. While the government considered a public sale remedy to be acceptable in principle it rejected Ebasco's request to limit relief in this manner. It did so for several reasons. The timing and accomplishment of a successful public sale of Ebasco stock is dependent upon several uncertain factors, such as stock market conditions and capitilization requirements, which might unreasonably extend the divestiture period. In addition, such a divestiture limitation runs the risk of arbitrarily foreclosing other potentially desirable forms of disposition such as the sale of Ebasco stock to an acceptable third party. Since the primary purpose of relief was to accomplish the expeditious restoration of Ebasco as a viable independent competitor, it was deemed unwise to limit Halliburton's divestiture options in the manner requested by Ebasco. Thus, the government declined Ebasco's request to restrict the divestiture method in the proposed Final Judgment and settled upon the present formula requiring a sale upon acceptable terms and conditions. The option of public sale is, of course, still available under this method.

21. An alternative to the proposed Final Judgment was, of course, to proceed to a full trial on the merits. Such an alternative, however, would not have given the government anything more than it receives as a result of this Decree and would have resulted in significant delay in obtaining that relief. Additionally, there is always an element of uncertainty concerning the outcome of any antitrust litigation and there is no assurance that the Court would have ordered complete divestiture even if the government were successful in establishing liability under Section 7 of the Clayton Act. Thus, the proposed Final Judgment gives the government complete relief in a more timely fashion and also promotes the pro-competitive entry of Brown & Root into the nuclear design field.

There are no materials or documents which were determinative in formulating the proposed Final Judgment. Consequently, none are being filed by plaintiff pursuant to Section 2(b) of the Antitrust Procedures and Penalties Act (15 U.S.C. § 16(b)).

VII

PRESENT DIVESTITURE PLAN

22. At Ebasco's urging, the Antitrust Division remained open throughout the settlement negotiations to the possibility of a prompt and effective public sale of Halliburton's Ebasco stock and, as a result, engaged in extended discussions with representatives of Halliburton and Ebasco concerning the feasibility of such a sale of Ebasco's stock. At the present time Halliburton perceives an opportunity in the near future to offer 75% of Ebasco's common stock for public sale. It presently intends, subject to market conditions, to do this upon the entry of the proposed Final Judgment. Upon Halliburton's motion, and with the consent of the government, the District Court has shortened the time for public comments in order to facilitate this divestiture plan. While Halliburton at the present time cannot guarantee that it will offer the stock of Ebasco for public sale, Halliburton currently intends to file a statement necessary for the registration of the Ebasco securities with the Securities and Exchange Commission in the near future in order to enable it to offer the stock if the proposed Final Judgment is approved and entered by the Court.

23. The particulars of the proposed plan for the public sale are summarized in paragraph 24 but the financial details will be more fully set out in the registration statement which, once it becomes available, will be placed on file for inspection with the proposed Final Judgment and Competitive Impact Statement at the office of the Clerk of the United States District Court in New York and at the Department of Justice in Washington. The Department of Justice has reviewed the general outline of the plan and finds it presently acceptable. However, public comment on the plan prior to the 10:00 a.m. May 14, 1976 deadline is invited.

24. Halliburton, pursuant to its divestiture plan, presently intends to offer for sale 75% of the common stock of Ebasco and to hold the remaining 25% of the common stock subject to the term in the proposed Final Judgment which requires that Halliburton dispose of this interest within four years of the date the Judgment is entered. To accomplish the public sale, Halliburton desired to make certain modifications in Ebasco's capital structure. Therefore, simultaneous with the filing of the proposed Final Judgment, the parties moved to amend and clarify the Preliminary Injunction Order entered in this case on June 14, 1973. The Court granted this motion on March 24, 1976. This requested amendment permitted Halliburton to cause Ebasco to pay to it a dividend of $8,380,000 (which had been previously declared) and to recapitalize Ebasco through an exchange of the outstanding common stock for 120,000 shares of cumulative nonvoting and non-convertible sinking fund preferred stock in the face amount of $12,000,000. Ebasco will have no obligation to begin redemption of the preferred stock until 1979. The plan requires Ebasco, except in the event of extraordinary circumstances, to accomplish the redemption of the entire preferred stock interest of Halliburton within eight years thereafter, the first four annual sinking fund payments to be of $1,000,000 and the latter four to be of $2,000,000 each. If the contemplated divestiture plan is not accomplished, the government has specifically reserved the right to move the Court to restore Ebasco's capital position.

Dated: March 29, 1976.

HAYS GORY, JR.
JOHN L. WILSON
H. ARTHUR ROSENTHAL

Attorneys, Department of Justice, Antitrust Division, Washington, D.C. 20530, (202) 739-2434.

[FR Doc.76-9609 Filed 4-2-76;8:45 am]

## Law Enforcement Assistance Administration

## LEAA PRIVATE SECURITY ADVISORY COUNCIL

### Notice of Meeting

Notice is hereby given that the LEAA Private Security Advisory Council will meet April 21-23, 1976, in Denver Colorado. The meeting will convene at 1:00 p.m., Wednesday, April 21, in the Cripple Creek Room of the Holiday Inn, 15th and Glenarm Place in Denver. The Thursday, April 22, session will be from 9:00 a.m. to 5:00 p.m. The Friday, April 23, session will be from 9:00 a.m. to 1:00 p.m. The meeting will be open to the public.

Discussions at the meeting will focus upon the activities and reports of the Committees on Environmental Security, Law Enforcement-Private Security Relationships, Prevention of Terroristic Crimes, and Guard and Investigations.

For further information, please contact Mr. Irving Slott, Director, Program Evaluation and Monitoring Staff, Office of Regional Operations, LEAA, U.S. Department of Justice, 633 Indiana Avenue, N.W., Washington, D.C. 20531. 202/376-3830.

JAY A. BROZOST,
*Attorney-Advisor,*
*Office of General Counsel.*

[FR Doc.76-9563 Filed 4-2-76;8:45 am]

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[NM 27840]

### NEW MEXICO

### Application

MARCH 26, 1976.

Notice is hereby given that, pursuant to Section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 185), as amended by the Act of November 16, 1973 (87 Stat. 576), Southern Union Gas Company has applied for an 8-inch natural gas pipeline and a 6.66-acre well pad site right-of-way across the following land:

NEW MEXICO PRINCIPAL MERIDIAN, NEW MEXICO

T. 16 S., R. 27 E.,
Sec. 15, S½SW¼;
Sec. 21, E½NE¼, SW¼NE¼, NE¼SW¼ and NW¼SE¼;
Sec. 22, NW¼NW¼.

This pipeline will convey natural gas across 1.105 miles of national resource land in Eddy County, New Mexico.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should promptly send their name and address to the District Manager, Bureau of Land Management, P.O. Box 1397, Roswell, New Mexico 88201.

FRED E. PADILLA,
*Chief, Branch of Lands and Minerals Operations.*

[FR Doc.76-9633 Filed 4-2-76;8:45 am]

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[Utah 32459]

### UTAH

### Application

Notice is hereby given that pursuant to Section 28 of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 185), the Mountain Fuel Resources, Inc., has applied for a 20-inch natural gas injection-withdrawal pipeline right-of-way across the following lands:

SALT LAKE MERIDIAN, UTAH

T. 3 N., R. 22 E.,
Secs. 14, 15, 16, 20, 21, 23, 24 and 29.
T. 3 N., R. 23 E.,
Secs. 19, 20, 21, 22, 23 and 24.
T. 3 N., R. 24 E.,
Secs. 16, 19, 20 and 21.

The purpose of the proposed right-of-way is to provide a pipeline connecting Northwest Pipeline Corporation's transmission line with the gas storage field of Mountain Fuel Resources, Inc., to inject gas in the storage area during periods of low summer demand and withdraw gas during periods of high winter peak demand to assure maximum deliverability to Northwest Customers.

The purpose of this notice is to inform the public that the Bureau will be proceeding with the preparation of environmental and other analyses necessary for determining whether the application should be approved, and if so, under what terms and conditions.

Interested persons should express their interest and views to the Vernal District Manager, Bureau of Land Management, P.O. Box F, Vernal, Utah 84078.

Dated: March 26, 1976.

WILLIAM G. LEAVELL,
*Associate State Director.*

[FR Doc.76-9634 Filed 4-2-76;8:45 am]

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## OUTER CONTINENTAL SHELF OFF ALASKA

### Oil and Gas Lease Sale No. 39; Explanation of Lease Terms

Several questions have been asked about stipulations No. 3 and No. 4 which would be included in oil and gas leases isued for certain specified tracts included in OCS Oil and Gas Lease Sale No. 39, announced in the FEDERAL REGISTER on March 12, 1976. 41 F.R. 10971. The purpose of this notice is merely to clarify the meaning of the two stipulations; the stipulations are not amended in any way.

1. Both stipulations apply only to the emplacement of platforms and sea floor wellheads for production or storage of oil and gas, and neither stipulation is applicable to exploratory operations.

2. Stipulation No. 3 prohibits any emplacement of platforms or sea floor wellheads in an area of mass movement (slumping) of sediments, however the structure may be designed. The lessee will be given the opportunity to present evidence that a portion of the leased tract is not included in such an area of mass movement and, if the Supervisor determines that any portion of the tract is not, in fact, included in an area of mass movement of sediments, emplacement of the platform or sea floor wellhead may be permitted in that portion of the area.

3. If a tract is completely included in an area of mass movement (slumping) of sediments, a lessee subject to stipulation No. 3 will be required to install any platform or sea floor wellhead outside the leased tract. Provision for the emplacement of platforms and sea floor wellheads outside the leased tract (even in a tract subject to another lease) is included in the OCS oil and gas operating regulations, 30 CFR 250.18, particularly paragraph (b).

4. Stipulation No. 4 permits the emplacement of a platform or sea floor wellhead at a site in an area of mass movement of sediments if the lessee demonstrates to the Supervisor's satisfaction that the structure is designed to withstand the movement with safety at that site.

Dated: March 31, 1976.

ARNOLD E. PETTY,
*Acting Associate Director, Bureau of Land Management.*

Dated: April 1, 1976.

Approved:
KENT FRIZZELL,
*Under Secretary of the Interior.*

[FR Doc.76-9777 Filed 4-2-76;8:45 am]

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

### GRAIN STANDARDS

### Arizona Grain Inspection Point

Statement of considerations. Information has come to the attention of the Department that due to changes in the agricultural industry in the area of Yuma, Arizona, a trade need exists for official inspection services under the United States Grain Standards Act (7 U.S.C. 71 et seq.) at this location. At present, there is no designated official inspection agency located at Yuma, Arizona, and the only inspection services available have been provided by the Agricultural Seed Laboratories, the designated inspection agency at Phoenix, Arizona, on a submitted sample basis. Applicants in the Yuma area have also received inspection services on a submitted sample basis from the State of California at Imperial, California.

The Agricultural Seed Laboratories, Phoenix, Arizona, has indicated an interest in stationing a licensed sampler in the Yuma area. At the same time, Hutson Laboratories, Yuma, Arizona, has made application for designation in accordance with section 26.96 of the regulations (7 CFR 26.96) under the U.S. Grain Standards Act to operate as an official inspection agency at Yuma, Arizona. Neither the Agricultural Seed Laboratories' proposal nor the Huston Laboratories' application preclude other interested persons from making similar application.

NOTE: Section 7(f) of the Act (7 U.S.C. 79(f)) generally provides that not more than one inspection agency shall be operative at any one city, town, or other area.

Any interested persons who wish to submit views and comments are requested to include the name of the person or agency which they recommend to be designated to operate as an official inspection agency or provide official sampling services at Yuma, Arizona.

All such views and comments should be submitted in writing to the Hearing Clerk, U.S. Department of Agriculture, Washington, D.C. 20250. All materials submitted should be in duplicate and mailed to the Hearing Clerk not later than May 5, 1976. All materials submitted 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)). Consideration will be given to the views and comments so filed with the Hearing Clerk and to all other information available to the U.S. Department of Agriculture before final determination is made with respect to this matter.

Done in Washington, D.C. on: March 31, 1976.

WILLIAM L. MANLEY,
*Acting Administrator, Agricultural Marketing Service.*

[FR Doc.76-9591 Filed 4-2-76;8:45 am]

### Farmers Home Administration

[Notice of Designation Number A327]

### LOUISIANA

### Designation of Emergency Areas

The Secretary of Agriculture has determined that farming, ranching, or aquaculture operations have been substantially affected in certain Louisiana Parishes as a result of various adverse weather conditions shown in the following chart:

Acadia—Excessive rainfall, April 1 through July 31, 1975, caused severe damages and losses to soybeans, rice and cotton.
East Baton Rouge—Excessive rainfall, January 1 through October 30, 1975, caused severe damages and losses to hay and crops.
Grant—Excessive rainfall and flooding, March 14 through August 31, 1975, prevented the planting of approximately 2,800 acres of cotton and 2,000 acres of soybeans.
Lafourche—Excessive rainfall, May 1 through September 30, 1975, caused severe damages and losses to sugarcane, pastures and vegetables.
Natchitoches—Excessive rainfall, March 1 through July 15, 1975, caused severe damages and losses to cotton, soybeans and hay.
Rapides—Excessive rainfall, May 17 through August 31, 1975, caused severe damages and losses to cotton and soybeans.
St. Martin—Excessive rainfall, March 1 through August 29, 1975, caused severe damages and losses to sugarcane, soybeans, hay and vegetables.
Tensas—Excessive rainfall, January 1 through November 30, 1975, caused severe damages and losses to cotton and soybeans.

Therefore, the Secretary has designated these areas as eligible for emergency loans pursuant to the provisions of the Consolidated Farm and Rural Development Act, as amended by Public Law 94–68, and the provisions of 7 CFR 1832.3 (b) including the recommendation of Governor Edwin Edwards that such designation be made.

Applications for emergency loans must be received by this Department no later than May 18, 1976, for physical losses and September 20, 1976, for production losses, except that qualified borrowers who receive initial loans pursuant to this designation may be eligible for subsequent loans. The urgency of the need for loans in the designated areas makes it impracticable and contrary to the public interest to give advance notice of proposed rule making and invite public participation.

Done at Washington, D.C., this 29th day of March 1976.

FRANK B. ELLIOTT,
*Administrator,*
*Farmers Home Administration.*

[FR Doc.76–9589 Filed 4–2–76;8:45 am]

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### Forest Service

### COSSATOT-LITTLE MISSOURI UNIT

### Notice of Availability of Draft Environmental Statement

Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969, the Forest Service, Department of Agriculture, has prepared a draft environmental statement for the Cossatot-Little Missouri Planning Unit, Ouachita National Forest, Arkansas, USDA–FS–R8–DES (Adm.)–76–08.

This environmental statement concerns the proposed management direction and resource allocation for the Cossatot-Little Missouri Unit, Ouachita National Forest.

This draft environmental statement was transmitted to CEQ on March 29, 1976.

Copies are available for inspection during regular working hours at the following locations:

USDA, Forest Service, South Agriculture Bldg., Room 3230, 12th St. and Independence Ave. SW., Washington, D.C. 20250.
USDA, Forest Service 1720 Peachtree Road NW., Room 804, Atlanta, Georgia 30309.
USDA, Forest Service, Ouachita National Forest, P.O. Box 1270, Federal Building, Hot Springs, Arkansas 71901.

A limited number of single copies are available upon request to Alvis Z. Owen, Forest Supervisor, Ouachita National Forest, P.O. Box 1270, Federal Building, Hot Springs, Arkansas 71901.

Copies of the environmental statement have been sent to various Federal, State, and local agencies as outlined in the CEQ Guidelines.

Comments are invited from the public, and from State and local agencies which are authorized to developed and enforce environmental standards, and from Federal agencies having jurisdiction by law or special expertise with respect to any environmental impact involved for which comments have not been requested specifically.

Comments concerning the proposed action and requests for additional information should be addressed to Alvis Z. Owen, Forest Supervisor, Ouachita National Forest, P.O. Box 1270, Federal Building, Hot Springs, Arkansas 71901. Comments must be received by May 29, 1976 in order to be considered in the preparation of the final environmental statement.

ALVIS Z. OWEN,
*Forest Supervisor.*

MARCH 29, 1976.

[FR Doc.76–9562 Filed 4–2–76;8:45 am]

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## SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

### ALTERNATE ENERGY SYSTEMS, INC.

### Suspension of Trading

MARCH 30, 1976.

It appearing to the Securities and Exchange Commission that the summary suspension of trading in the common stock of Alternate Energy Systems, Inc. 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 12(k) of the Securities Exchange Act of 1934, trading in such securities otherwise than on a national securities exchange is suspended, for the period from 3:30 p.m. (EST) on March 30, 1976 through April 8, 1976.

By the Commission:

[SEAL] GEORGE A. FITZSIMMONS,
*Secretary.*

[FR Doc.76–9666 Filed 4–2–76;8:45 am]

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[File No. 500–1]

### ELKINS INSTITUTE, INC.

### Suspension of Trading

MARCH 30, 1976.

It appearing to the Securities and Exchange Commission that the summary suspension of trading in the common stock of Elkins Institute, Inc. 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 12(k) of the Securities Exchange Act of 1934, trading in such securities otherwise than on a national securities exchange is suspended, for the period from 3:30 p.m. (EST) on March 30, 1976 through April 8, 1976.

By the Commission.

[SEAL] GEORGE A. FITZSIMMONS,
*Secretary.*

[FR Doc.76–9667 Filed 4–2–76;8:45 am]

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[Release No. 34–12280; File No. SR–Amex–76–8]

### AMERICAN STOCK EXCHANGE, INC.

### Self-Regulatory Organizations; Rule Change

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), as amended by Pub. L. No. 94–29, 16 (June 4, 1975), notice is hereby given that on March 25, 1976, the above-mentioned self-regulatory organization filed with the Securities and Exchange Commission a proposed rule change as follows:

STATEMENT OF THE TERMS OF SUBSTANCE OF THE PROPOSED RULE CHANGE

The American Stock Exchange, Inc. ("Amex") proposes to amend Rule 393 to read as follows:

"Securities and Exchange Commission Transaction Fee

Rule 393. There shall be paid to the Exchange by each member, member firm or member corporation in such manner and at such time as the Treasurer of the Exchange shall direct, the sum of one cent for each $300 or fraction thereof of the dollar volume of the sales upon the Exchange of securities (other than bonds, debentures, and other evidences of indebtedness or any security which the Commission may, by rule, exempt from the imposition of the fee) (whether or not cleared by the American Stock Exchange Clearing Corporation) cleared by such member, member firm or member corporation. The monies so paid to the Exchange shall be paid to the Secu-

rities and Exchange Commission as the transaction fee imposed upon the Exchange by the provisions of the Securities Exchange Act of 1934."

STATEMENT OF BASIS AND PURPOSE

The basis and purpose of the foregoing proposed rule change is as follows:

The purpose of the proposed rule change is to conform Rule 393 to the provisions of Section 31 of the Securities Exchange Act of 1934 as amended by Section 22 of the Securities Acts Amendments of 1975 which became effective on January 1, 1976.

The basis under the Act is as indicated in the preceding paragraph.

On February 12, 1976, the proposed rule change was considered and approved by the Board of Governors of Amex. No additional comments were solicited or received.

The Amex has determined that the proposed amendment to Rule 393 does not put any burden on competition.

The foregoing rule change has become effective, pursuant to Section 19(b)(3) of the Securities Exchange Act of 1934. At any time within sixty days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Securities Exchange Act of 1934.

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons desiring to make written submissions should file 6 copies thereof with the Secretary of the Commission, Securities and Exchange Commission, Washington, D.C. 20549. Copies of the filing with respect to the foregoing and of all written submissions will be available for inspection and copying in the Public Reference Room, 1100 L Street, N.W., Washington, D.C. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number referenced in the caption above and should be submitted on or before May 5, 1976.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

[SEAL] GEORGE A. FITZSIMMONS,
*Secretary.*

MARCH 29, 1976.

[FR Doc.76-9669 Filed 4-2-76;8:45 am]

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[Release No. 34-12282; File No. SR-DTC-76-2]

## DEPOSITORY TRUST CO.

### Self-Regulatory Organizations; Rule Change

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), as amended by Pub. L. No. 94-29, 16 (June 4, 1975), notice is hereby given that on March 11, 1976 the above mentioned self-regulatory organization filed with the Securities and Exchange Commission a proposed rule change as follows:

STATEMENT OF THE TERMS OF SUBSTANCE OF THE PROPOSED RULE CHANGE

The proposed rule change provides for an overnight collateral loan service which gives Participants of The Depository Trust Company (DTC) the opportunity to pledge securities for an overnight bank loan while anticipating their automatic release from pledge at 9:30 A.M. New York time on the next business day of DTC in time for bookentry deliveries to other Participants, unless the Pledgee cancels the automatic release before that time. The major innovation is preauthorized release of collateral by Pledgees.

STATEMENT OF BASIS AND PURPOSE

The basis and purpose of the foregoing proposed rule change is as follows:

3. *Purpose of Proposed Rule Change*

The purpose of the proposed change in the Participants Operating Procedures (Procedures) of DTC is to give DTC's Participants the opportunity to pledge securities for an overnight bank loan while anticipating automatic release of the securities from pledge at 9:30 A.M. New York time on the next business day of DTC in time for bookentry deliveries of the securities to other Participants, unless the Pledgee cancels the automatic release before that time. The major innovation in the Procedures presented by the proposed rule change is preauthorized release of collateral by Pledgees without submission to DTC of a separate release form on the next business day of DTC. This change will provide an option for those Participants and Pledgees desiring it which will simplify the administration of their overnight pledges and loans.

4. *Basis under the Act for Proposed Rule Change*

(a) Not Applicable.

(b) The change in the Procedures relates to DTC's carrying out the purposes of Section 17A of the Securities Exchange Act of 1934 (the Act) by increasing DTC's capacity to facilitate the prompt and accurate clearance and settlement of securities transactions, in that the proposed rule change eliminates preparation and processing of separate release forms and facilities timely completion of bookentry deliveries which are dependent upon release of the pledged securities.

(c) Not Applicable.

5. *Comments Received from Members, Participants or Others on Proposed Rule Change*

DTC developed the proposed overnight collateral loan program as a result of suggestions from several Participants. Comments regarding the proposed program were solicited from DTC Participants and Pledgee Banks by articles in DTC's Newsletters of September/October 1975 and December/January 1976. Draft procedures for the proposed overnight collateral loan program, similar to the procedures set forth in Exhibit 2 hereto, were sent to Participants who asked to review draft procedures. No written comments were received. In meetings and telephone conversations with Participants and Pledgees, favorable opinions were expressed on the proposed rule change on the grounds that the proposed rule change would eliminate the need for physical delivery of collateral securities for overnight loans and would simplify DTC's procedures with respect to overnight loans by eliminating the need to submit separate release forms. Specific objections were expressed by some Participants and Pledgees on the following two points: (i) the time for automatic release of collateral, which was originally scheduled for 9:00 A.M., was too early for some Pledgees to determine whether to cancel the automatic release and contact DTC and (ii) DTC's fees for this service, which are the same as the fees in DTC's normal collateral loan program, are too high. In response to the objection as to the time for automatic release of collateral, DTC moved the release time back to 9:30 A.M. In response to the objection as to fees, DTC told Participants that it would be in future consider the question of reducing fees if operation of the proposed program justified a reduction.

6. *Burden on Competition*

None.

On or before May 10, 1976, or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the above-mentioned self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rules change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons desiring to make written submissions should file six copies thereof with the Secretary of the Commission, Securities and Exchange Commission, Washington, D.C. 20549. Copies of the complete text of the filing with respect to the foregoing and of all written submissions will be available for inspection and copying in the public reference room, 1100 L Street, N.W., Washington, D.C. Copies of such complete filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should be submitted on or before April 26, 1976.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
*Secretary.*

MARCH 30, 1976.

[FR Doc.76-9670 Filed 4-2-76;8:45 am]

[Release No. 12283; (SR-PSE-76-3)]

## PACIFIC STOCK EXCHANGE, INC.

### Order Approving Proposed Rule and Rule Changes

MARCH 30, 1976.

On January 15, 1976 the Pacific Coast Stock Exchange, Inc. ("PSE") 618 South Spring Street, Los Angeles, California, 90014, filed with the Commission, pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78(s)(b)(1), as amended by Pub. L. No. 94-29, § 16 (June 4, 1975) (the "Act"), and Rule 19b-4 thereunder, a proposed Rule VI., entitled "Exchange Options Trading," and certain changes in existing Rule I., Section 12(k), and Rule X. in order to conform such existing rules to proposed Rule VI. and to the implementation of a PSE pilot option program generally. As part of this filing, the PSE also submitted certain stated policies and practices that it has elected to treat as Rules of the Exchange for the purpose of conducting its proposed options program. This submission (the "proposal") was amended by five separate amendments submitted on February 13, 1976, February 20, 1976, March 5, 1976, March 19, 1976 and March 25, 1976, respectively.

Notice of the initial proposals together with the terms of substance thereof was given by publication of a Commission Release and publication in the FEDERAL REGISTER.[1]

#### GENERAL NATURE OF THE PROPOSAL

PSE options will generally be traded in a manner very similar to the way in which options are traded on the Chicago Board Options Exchange, Incorporated ("CBOE"). Thus, the agent (broker) and principal (dealer) functions of the traditional unitary specialist will be divided between an Order Book Official ("OBO") (agent), corresponding to CBOE's Board Broker and assigned competing market-makers (dealer).[2]

Under the terms of the proposal, which calls for the initiation of a pilot program, PSE intends initially to limit its operations to call options on twenty underlying stocks that are registered and listed on a national securities exchange.[3] The stocks (like those underlying the other exchange listed options) would be those characterized by a substantial number of outstanding shares which are widely held and actively traded.[4] As experience is gained and its system enlarged, the Exchange expects, with Commission approval, to increase the number of underlying stocks for option trading.[5]

Some of the (call) options which the PSE has proposed to list will be of the same class and expiration dates and prices as options which are presently listed on other exchanges.[6] In so doing, PSE will become the third exchange to conduct such "dual trading" in options.[7]

In general, PSE will apply clearing principles and contract standardization methods substantially identical to those currently used by other Exchanges with options programs—that is, options would be made fungible by limiting the contract variables.

#### CLEARING AND SETTLEMENT

PSE will become a one-fourth owner of the Options Clearing Corporation ("OCC"), by purchasing 25% of OCC's outstanding common shares, and OCC will provide the same services with respect to options transactions occurring on the PSE as OCC currently provides with respect to options transactions occurring on the Amex, CBOE, and PBW. Thus, clearing and settlement of options transactions occurring on the PSE will be effected through the OCC which will be the issuer of and primary obligor on all outstanding PSE options. Also, PSE options will be registered by the OCC pursuant to the Securities Act of 1933 and pursuant to Section 12(b) of the Act.[8] Because the Exchange's options will have standard terms and conditions, they will be fungible with other OCC-issued options of the same class and series; therefore, positions in Pacific's dually traded options may be closed out through transactions on another exchange on which they are listed, and positions taken in such options on other exchanges may be closed out on PSE.

#### RULES AND PROCEDURES REGULATING TRADING OF THE OPTION ON THE SAME EXCHANGE AS THE UNDERLYING SECURITY

The Exchange has constructed a separate floor for trading options, adjacent to its present San Francisco equities trading facility. Thus, PSE is the second exchange to propose trading of an option on the same exchange on which the underlying security is traded,[9] and it has taken action in two areas to lessen potential regulatory problems associated with such trading: (i) The two facilities will be separated by a wall and partitions at the end of the hall connecting the two facilities to prevent direct visual or auditory communication between the two trading areas. This action is designed primarily to bar the misuse in its options market of information obtained by floor members relating to activity in an underlying security where the information has not yet received general dissemination; (ii) it will prohibit trading in an option by a person who has obtained prior knowledge of a proposed block transaction, or one that has taken place but not been reported, in either the option or the underlying security until two minutes after the transacion is reported on the tape or otherwise disclosed.[10]

#### LAST SALE AND QUOTATIONS REPORTING

Last sale information for the Exchange's options will be reported on the separate common option tape administered by the Option Price Reporting Authority. PSE will supply option quotes from its floor to vendors so as to make them available to qualified non-members as well as members.

#### THE PSE ORDER BOOK OFFICIAL

Unlike CBOE's Board Brokers who are Exchange members, and in substance, in business for themselves, PSE's OBO's will be employees of that exchange, and PSE will charge its members a fixed fee (per transaction) for the services of the OBO in effecting such members' transactions on that exchange. In informing the Commission of the levels and structure of its proposed fees, the Exchange stated that, atlhough it has had no experience along these lines, it has attempted to project its costs and revenues associated with providing the OBO service and to set rates competitively with those of other exchanges with options programs. The Commission has examined the proposed fees and finds that consistent with the requirements of the Act, and especially Section 6(b)(4) thereunder, the Exchange should be permitted to begin its program using such fees; however, the Commission expects the Exchange to provide further data in due course to demonstrate the cost of the

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[1] Securities Exchange Act Release No. 12037, January 23, 1976 and 41 Fed. Reg. 4375, January 29, 1976.

[2] With certain modifications applicable to their floor trading systems, both the American Stock Exchange, Inc. ("Amex") and PBW Stock Exchange, Inc. ("PBW") utilize their present unitary specialist systems in their options programs.

[3] Of this number, ten will be listed for trading on the first day of operation of the PSE program and the remaining ten will be added as the Exchange deems appropriate considering such factors as the capacity of its support systems to handle such increased listings.

[4] PSE Rule VI., Sec. 12.

[5] The procedures pursuant to Rule 19b-4 under the Act relating to the adoption and alteration of rules of registered securities exchanges would be applicable to such expansion.

[6] The term "class of options" means all option contracts of the same type, i.e., put or call, covering the same underlying stock. PSE Rule VI., Sec. 1(a)(10). Trading by PSE in puts options is not a subject of this approval order.

[7] Both CBOE and PBW list options, with the same expiration dates, on the stock of Boise Cascade Corporation. The Commission does not today consider the matter of PSE's trading of options of the same class as are traded on other exchanges but with different expiration dates. The PSE has made such a proposal which is the subject of a separate Exchange filing. File No. SR-PSE-76-11.

[8] The OCC is a common clearing entity, which clears and settles all transactions in exchange listed options.

[9] PBW first proposed such trading. *See*, Securities Exchange Act Release No. 11423, May 15, 1975.

[10] PSE Rule VI., Sec. 12(k).

service provided and to justify the fees on a basis consistent with the statutory standard of reasonableness.

The Exchange will establish an error fund to compensate members for OBO mistakes. In general, the PSE Rule would limit recovery on any one member claim against the error fund and/or against the Exchange to $100,000, and the Exchange's liability for all OBO errors on a given trading day will be limited to the amount in the fund when the fund contains $200,000.[11] PSE does not seek to limit its liability for criminal, dishonest, or fraudulent acts of its OBO's, and the Rule makes clear that the Exchange's limitation of liability has no application to claims of persons other than members, e.g., customers.[12]

CONCLUSION

The Commission finds that the proposal is consistent with the requirements of the Act and the rules and regulations thereunder applicable to national securities exchanges, and in particular the requirements of Section 6 of the Act.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the provisions relating to implementation of PSE's pilot option trading program as set forth in its proposal, as amended, be, and hereby are, approved.

By the Commission.

[SEAL] GEORGE A. FITZSIMMONS,
*Secretary.*

[FR Doc.76-9668 Filed 4-2-76;8:45 am]

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[Release No. 34-12274; File Nos. 600-14, 600-15]

## CLEARING AGENCIES

### Filing of Applications for Registration

The following entities have made application to become registered clearing agencies under Section 17A of the Securities Exchange Act of 1934 (the "Act") and pursuant to subsection (c)(1) of Rule 17Ab2-1 [17 CFR 240.17Ab2-1] under the Act:

| | *File No.* |
|---|---|
| Japan Securities Clearing Corp | 600-14 |
| National Securities Clearing Corp | 600-15 |

The application of National Securities Clearing Corporation is intended to effect a proposed consolidation, in one entity, of the operations of Stock Clearing Corporation, American Stock Exchange Clearing Corporation and National Clearing Corporation, each of which is presently a registered clearing agency.

Pursuant to subsection (c)(1) of Rule 17Ab2-1 under the Act, if requested by an applicant, the Commission may grant the applicant registration as a clearing agency but exempt the applicant from one or more of the requirements as to which the Commission is directed to make a determination pursuant to subparagraphs (A)-(I) of Section 17A(b)(3) of the Act. Registration pursuant to subsection (c)(1) of Rule 17Ab2-1 shall not be effective for more than eighteen (18) months from the date on which registration is made effective by the Commission.

Subsection (c)(2) of Rule 17Ab2-1 requires that, in the case of any clearing agency registered in accordance with subsection (c)(1) of Rule 17Ab2-1, the Commission, not later than nine (9) months from the date such registration is made effective, will either grant registration without exempting the registrant from one or more of the requirements as to which the Commission is directed to make a determination pursuant to subparagraphs (A)-(I) of Section 17A(b)(3) or will institute proceedings to determine whether registration should be denied at the expiration of eighteen (18) months.

Interested persons are invited to submit written data, views and arguments concerning the foregoing applications within six weeks from the date of publication of this notice in the FEDERAL REGISTER. Such written data, views and arguments will be considered by the Commission in granting registration or instituting proceedings to determine whether registration should be denied in accordance with subsection (c)(2) of Rule 17Ab2-1. Persons desiring to make written submissions should file six copies thereof with the Secretary of the Commission, Securities and Exchange Commission, 500 North Capitol Street, Washington, D.C. 20549. Reference should be made to the appropriate file number.

Copies of the applications and of all written comments will be available for inspection at the Securities and Exchange Commission's Public Reference Room, 1100 L Street, N.W., Washington, D.C. 20006.

By the Commission.

[SEAL] GEORGE A. FITZSIMMONS,
*Secretary.*

MARCH 29, 1976.

[FR Doc.76-9671 Filed 4-2-76;8:45 am]

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[11] PSE Rule VI., Sec. 72. If the error fund has less than $200,000, the Exchange's liability for members' claims is unlimited, except for the $100,000 maximum for any one claim.

[12] No person may obtain a waiver of liability under Federal securities laws. *See*, Sec. 29 of the Act.

# SMALL BUSINESS ADMINISTRATION

## CASPER DISTRICT ADVISORY COUNCIL

### Public Meeting

The Small Business Administration Casper District Advisory Council will hold a public meeting at 9:00 a.m., Friday, April 30, 1976, in the Champagne Room of the Ramada Inn, Casper, Wyoming, to discuss such matters as may be presented by members, staff of the Small Business Administration, and others attending.

For further information, write or call Jerry S. King, District Director, U.S. Small Business Administration, P.O. Box 2839, Casper, Wyoming 82602, (307) 265-5550, extension 5266.

Dated: March 29, 1976.

MARY LOU GRIER,
*Deputy Advocate for Advisory Councils.*

[FR Doc.76-9597 Filed 4-2-76;8:45 am]

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## CLARKSBURG DISTRICT ADVISORY COUNCIL

### Public Meeting

The Small Business Administration Clarksburg District Advisory Council will hold a public meeting at 9:30 a.m., Friday, May 7, 1976, at the Holiday Inn (downtown), Huntington, West Virginia, to discuss such matters as may be presented by members, staff of the Small Business Administration, and others attending.

For further information, write or call Isaac R. Mayfield, District Director, U.S. Small Business Administration, 109 Third Street, Clarksburg, West Virginia 26301, (304) 623-3461, extension 365.

Dated: March 29, 1976.

MARY LOU GRIER,
*Deputy Advocate for Advisory Councils.*

[FR Doc.76-9598 Filed 4-2-76;8:45 am]

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## SIOUX FALLS DISTRICT ADVISORY COUNCIL

### Public Meeting

The Small Business Administration Sioux Falls District Advisory Council will hold a public meeting at 11:00 a.m., Friday, April 23, 1976, at the Kings Inn Motel, Pierre, South Dakota, to discuss such business as may be presented by members, staff of the Small Business Administration, and others attending.

For further information, call or write Chester B. Leedom, District Director, U.S. Small Business Administration, 402 National Bank of S. D. Bldg., 8th and Main Avenue, Sioux Falls, South Dakota 57102, (605) 336-2980, Ext. 231.

Dated: March 29, 1976.

MARY LOU GRIER,
*Deputy Advocate for Advisory Councils.*

[FR Doc.76-9599 Filed 4-2-76;8:45 am]

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# VETERANS ADMINISTRATION

## CENTRAL OFFICE EDUCATION AND TRAINING REVIEW PANEL

### Meeting

The Veterans Administration gives notice pursuant to Public Law 92-463 that a meeting of the Central Office Education and Training Review Panel, authorized by Section 1790(b), Title 38, United States Code, will be held in Room 119, Veterans Administration Central Office, 810 Vermont Avenue, NW., Washington, D.C. on May 18, 1976, at 10 a.m. The meeting will be held for the purpose of reviewing the February 28, 1976 deci-

sion of the Director, Veterans Administration Regional Office, Nashville, Tennessee that benefits to all eligible persons enrolled in Tennessee Barber College, 515 Jefferson Street, Nashville, Tennessee be discontinued effective February 29, 1976.

The meeting will be open to the public up to the seating capacity of the conference room. Because of the limited seating capacity, it will be necessary for those wishing to attend to contact Mr. Halsey A. Dean, Chief Field Operations, Education and Rehabilitation Service, Veterans Administration Central Office (phone 202–389–2850) prior to May 15, 1976.

Dated: March 31, 1976.

By direction of the Administrator.

[SEAL] ODELL W. VAUGHN,
*Deputy Administrator.*

[FR Doc.76–9676 Filed 4–2–76;8:45 am]

## INTERSTATE COMMERCE COMMISSION

[No. 16]

### ASSIGNMENT OF HEARINGS

MARCH 31, 1976.

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.

MC–F–12433, F-B-Truck Line Company—Purchase—Lester Smith Trucking, Inc., now assigned May 17, 1976, at Salt Lake City, Utah is canceled.

MC 125433 Sub 57, F-B Truck Line Company, now assigned May 17, 1976, at Salt Lake City, Utah is canceled and application dismissed.

MC 124878 Sub 7, Lapadula Air Freight Transfer, Inc., now assigned July 12, 1976, at Philadelphia, Pa., is canceled and application dismissed.

MC 117068 Sub 54, Midwest Specialized Transportation, Inc., now being assigned June 8, 1976 (2 days), at Chicago, Ill., in a hearing room to be later designated.

MC 126276 Sub-138 and MC 126276 Sub 143, Fast Motor Service, Inc., now being assigned June 10, 1976 (2 days), at Chicago, Ill., in a hearing room to be later designated.

MC–F 12731, American Commercial Lines, Inc.—Control—All American, Inc., And Midwest Coast Transport, Inc., now being assigned June 14, 1976 (1 week), at Chicago, Ill., in a hearing room to be later designated.

MC–F 12604, St. Johnsbury Trucking Co., Inc.—Purchase (Portion)—Lansdale Trans. Co., Inc. (Century Express Ltd. Assignor) which is now assigned April 26, 1976 for hearing is being assigned April 26, 1976 for pre-hearing conference in the Offices of the Interstate Commerce Commission, Washington, D.C.

MC 108473 (Sub 37), St. Johnsbury Trucking Co., Inc., which is now assigned April 26, 1976 for hearing is being assigned April 26, 1976 for pre-hearing conference at the Offices of the Interstate Commerce Commission in Washington, D.C.

MC–F 12234, Century Express Ltd.—Purchase—Lansdale Transportation Co., Inc. which is now assigned April 26, 1976 for hearing is being assigned April 26, 1976 for pre-hearing conference at the Offices of the Interstate Commerce Commission in Washington, D.C.

MC–F 12605, H. W. Taynton Co., Inc.—Purchase—Portion—Lansdale Trans. Co., Inc. (Century Express, Ltd, Assignor) which is now assigned April 26, 1976 for hearing is being assigned April 26, 1976 for pre-hearing conference at the Offices of the Interstate Commerce Commission in Washington, D.C.

MC 109821 (Sub 44), H. W. Taynton Co., Inc. which is now assigned April 26, 1976 for hearing is being assigned April 26, 1976 for pre-hearing conference at the Offices of the Interstate Commerce Commission in Washington, D.C.

MC–F 12633, Eagle Foods, Inc., dba Rutherford's—Purchase—Century express, Ltd. Operation of Lansdale Transportation Co., Inc. which is now assigned April 26, 1976 for hearing is being assigned April 26, 1976 for pre-hearing conference at the Offices of the Interstate Commerce Commission in Washington, D.C.

MC 107295 Sub 789, Pre-Fab Transit Co., a corporation, now being assigned May 17, 1976 (2 days), at Denver, Colo., in a hearing room to be later designated.

MC 59856 Sub 65, Salt Creek Freightways, now being assigned May 19, 1976 (3 days), at Denver, Colo., in a hearing room to be later designated.

Ex Parte No. 317, In The Matter Of Thomas A. Weir, now assigned April 6, 1976, at Buffalo, N.Y., is postponed indefinitely.

[SEAL] ROBERT L. OSWALD,
*Secretary.*

[FR Doc.76–9639 Filed 4–2–76;8:45 am]

[NO. 215]

### MOTOR CARRIER APPLICATIONS ASSIGNED FOR ORAL HEARING

The following publications include motor carrier, water carrier, broker and or freight forwarder applications which have been designated for oral hearing at a time and place to be fixed.

Each applicant (except as otherwise specifically noted) states that there will be no significant effect on the quality of the human environment resulting from approval of its application in compliance with the requirements of 49 CFR 1100.250.

Protest to the granting of the requested authority must be filed with the Commission within 30 days after the date of this Federal Register notice (unless otherwise specified). Failure seasonably to file a protest will be construed as a waiver of opposition and participation in the proceeding. A protest should comply with Section 247(d)(4) or Section 240(c)(4) as appropriate of the Commission's General Rules of Practice which requires that it set forth specifically the grounds upon which it is made, contain a detailed statement of protestant's interest in the proceeding (including a copy of the portions of its authority which protestant believes to be in conflict with that sought in the application, and a detailed description of the method—whether by joinder, interline, or other means—by which protestant would use such authority to provide all or part of the service proposed), and shall specify with particularity the facts, matters and things relied upon, but shall not include issues or allegations phrased generally. Protests not in reasonable compliance with the requirements of the rules may be rejected. The original and six (6) copies of the protest shall be filed with the Commission, and a copy shall be served concurrently upon applicant's or petitioner's representative, or applicant or petitioner if no representative is named.

No. MC–FC–75795. By order of the Commission, Motor Carrier Board, entered May 9, 1975, notice of which was published in the FEDERAL REGISTER on May 19, 1975, the application under Section 212(b) of the Interstate Commerce Act was approved and transferee, Schwerman Trucking Co. of Fla., Inc., Milwaukee, Wisconsin was authorized to acquire the operating rights of transferor, Schwerman Trucking Co., Milwaukee, Wisconsin, in Certificate No. MC–124078 (Sub-No. 386) issued to transferor on June 26, 1970, authorizing the transportation of malt beverages and related advertising matter, from Pabst, Houston County, Ga., to points in Alabama, Florida, Mississippi, North Carolina, South Carolina, and points in that part of Tennessee on and east of Interstate Highway 65; and returned shipments of the above-specified commodities, from points in the above-specified destination territory to Pabst, Houston, Ga.

By order entered March 10, 1976, Division 3 on its own motion reopened the above-entitled proceeding and assigned it for oral hearing at a time and place to be fixed for the purpose of determining, among other things, whether a transfer of stock was accomplished without prior approval from this Commission in violation of Section 5(4) of the Interstate Commerce Act. Interested parties have 30 days from the date of this publication in which to file petitions for leave to intervene. Such petitions should state the reason or reasons for the intervention, where the petitioner wishes the hearing to be held, the number of witnesses to be presented, and the estimated time required for the presentation of evidence. The Bureau of Enforcement has been directed to participate as a party in the proceeding for the purpose of presenting evidence.

No. MC–FC–75923. Authority sought by transferee, Edward D. Pohutsky, doing business as Edward Pohutsky Movers, 104 Handley St., Eynon, Pa. 18403, to acquire the operating rights of transferor, Stadium Transportation Co., Inc., 1130 Green St., Manville, N.J. 08835. Appli-

cants' representative: Edward D. Pohutsky, 104 Handley St., Eynon, Pa. 18403. Operating rights in Certificate No. MC-139414, issued September 12, 1974, sought to be transferred: Household goods as defined by the Commission, between points in Pennsylvania, on the one hand, and, on the other, points in Connecticut, Illinois, Indiana, Massachusetts, Ohio, Rhode Island, Virginia and West Virginia.

By order entered March 17, 1976, Division 3 assigned the above-entitled application under Section 212(b) of the Interstate Commerce Act for oral hearing at a time and place to be fixed on a consolidated basis with No. MC-FC-74866, Stadium Transportation Co., Inc., Manville, N.J., Transferee and Sisser Bros., Inc., New Brunswick, N.J., Transferor, which was approved by order of the Commission, Motor Carrier Board, entered January 14, 1974, notice of which was published in the FEDERAL REGISTER on January 21, 1974, and which was reopened on Division 3's own motion by order entered March 17, 1976, for the purpose of determining, among other things, whether the application is subject to handling under authority conferred by Section 212(b) of the Act. Interested parties have 30 days from the date of this publication in which to file petitions for leave to intervene. Such petitions should state the reason or reasons for the intervention, where the petitioner wishes the hearing to be held, the number of witnesses to be presented, and the estimated time required for the presentation of evidence. The Bureau of Enforcement has been directed to participate as a party in the proceeding for the purpose of presenting evidence and otherwise developing the record.

[SEAL] ROBERT L. OSWALD,
*Secretary.*

[FR Doc.76-9640 Filed 4-2-76;8:45 am]

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[No. 216]

## MOTOR CARRIER APPLICATIONS ASSIGNED FOR ORAL HEARING

The following publications include motor carrier, water carrier, broker and or freight forwarder applications which have been designated for oral hearing at a time and place to be fixed.

Each applicant (except as otherwise specifically noted) states that there will be no significant effect on the quality of the human environment resulting from approval of its application in compliance with the requirements of 49 CFR 1100.250.

Protest to the granting of the requested authority must be filed with the Commission within 30 days after the date of this Federal Register notice (unless otherwise specified). Failure seasonably to file a protest will be construed as a waiver of opposition and participation in the proceeding. A protest should comply with Section 247(d)(4) or Section 240(c)(4) as appropriate of the Commission's General Rules of Practice which requires that it set forth specifically the grounds upon which it is made, contain a detailed statement of protestant's interest in the proceeding (including a copy of the portions of its authority which protestant believes to be in conflict with that sought in the application, and a detailed description of the method—whether by joinder, interline, or other means—by which protestant would use such authority to provide all or part of the service proposed), and shall specify with particularity the facts, matters and things relied upon, but shall not include issues or allegations phrased generally. Protests not in reasonable compliance with the requirements of the rules may be rejected. The original and six (6) copies of the protest shall be filed with the Commission, and a copy shall be served concurrently upon applicant's or petitioner's representative, or applicant or petitioner if no representative is named.

No. MC-FC-76454, filed March 22, 1976. Transferee: Preston Feed & Seed Limited, P.O. Box 398, Preston-Cambridge, Ontario, Canada. Transferor: Oscar Dickey, 209 Oak St., Box 221, Stayner, Ontario, Canada. Applicant's representative: Robert D. Gunderman, Esq., Suite 710 Statler Hilton, Buffalo, New York 14202. Authority sought for purchase by transferee of the operating rights of transferor, as set forth in Certificate No. MC 135421 (Sub-No. 2), issued June 6, 1974, as follows: Grain and grain products, in bulk, over irregular routes between ports of entry on the United States-Canada Boundary line located in Michigan and New York, on the one hand, and, on the other, points in Michigan, New York, Ohio, and Pennsylvania (except flour from Scranton and Shickshinny, Pa.) subject to certain restrictions.

Transferee is presently authorized to operate as a contract carrier under Permit No. MC 127353 and subs thereafter. Application has not been filed for temporary authority under Section 210a(b).

No. MC-FC-76459, filed March 22, 1976. Transferee: M-T Express, Inc., 2700 Sterick Building, Memphis, Tenn. 38103. Transferor: Freightways Express, Inc., 2700 Sterick Building, Memphis, Tenn. 38103. Applicants' representative: James N. Clay, III, Attorney at Law, 2700 Sterick Building, Memphis, Tenn. 38103. Authority sought for purchase by transferee of the operating rights of transferor, as set forth in Certificate No. MC 105120 (Sub-No. 12), issued May 22, 1975, as follows: general commodities, with the usual exceptions, between Memphis, Tenn., and Coldwater, Miss., serving no intermediate points. Transferee holds no authority from this Commission. Application has not been filed for temporary authority under Section 210a(b).

No. MC-FC-76460, filed March 10, 1976. Transferee: John William Wallace, doing business as Angola & Buffalo Delivery, 7309 Derby Rd., Derby, N.Y. Transferor: William John Wallace, doing business as Angola & Buffalo Delivery, 53 Sunset Blvd., Angola, New York 14006. Authority sought for purchase by transferee of the operating rights of transferor, as set forth in Certificate No. MC 87984, issued September 20, 1961, as corrected December 18, 1961, as follows: General commodities, with the usual exceptions, over specified routes, between Buffalo, N.Y., and Angola, N.Y., serving no intermediate points, but serving the off-route point of Brant, N.Y. Transferee presently holds no authority from this Commission. Application has not been filed for temporary authority under Section 210a(b).

No. MC-FC-76465, filed March 11, 1976. Transferee: Packer Transportation Co., 465 South Rock Boulevard, Sparks, Nevada 89431. Transferor: Ben Packer, dba. Packer Transportation Co., 465 South Rock Boulevard, Sparks, Nevada 89431. Applicants' representative: Ben Packer, 465 South Rock Boulevard, Sparks, Nevada 89431. Authority sought for purchase by transferee of the operating rights of transferor, as set forth in Certificates No. MC 123115 (Sub-No. 1); MC 123115 (Sub-No. 3); MC 123115 (Sub-No. 4); MC 123115 (Sub-No. 7); and MC 123115 (Sub-No. 13) issued March 4, 1963, June 30, 1969, November 30, 1973, April 18, 1975, and May 12, 1975, respectively, to transport various lumber and wood products and gypsum and gypsum products and plasterboard joint treatment products from to or between points in California, Nevada, Idaho, Oregon, and Washington. Transferee presently holds no authority from this Commission. Application has not been filed for temporary authority under Section 210a(b).

No. MC-FC-76469, filed March 17, 1976. Transferee: Columbus Moving & Shipping Co., Inc., 1029 East 167th Street, Bronx, New York 10459. Transferor: Columbus Express & Shipping Co., Inc., 1029 East 167th Street, Bronx, New York 10459. Applicants' representative: Morris Honig, Attorney, 150 Broadway, New York, New York 10038. Authority sought for purchase by transferee of the operating rights of transferor, as set forth in Certificate No. MC 78926 issued November 27, 1972, as follows: Household goods, between New York, N.Y., on the one hand, and, on the other, points in Connecticut, New York, New Jersey, Pennsylvania, Massachusetts, Delaware, Maryland, Virginia, Ohio and the District of Columbia. Transferee presently holds no authority from this Commission. An application has not been filed for temporary authority under Section 210a(b).

ROBERT L. OSWALD,
*Secretary.*

[FR Doc.76-9641 Filed 4-2-76;8:45 am]

federal register

MONDAY, APRIL 5, 1976




PART II:

# FEDERAL ELECTION COMMISSION

■

Index of Notices Published in the Federal Register

## FEDERAL ELECTION COMMISSION

[Notice 1976–22]

### NOTICES PUBLISHED IN THE FEDERAL REGISTER

#### Index

Today, the Federal Election Commission publishes an index for all 1975 interim guidelines, proposed regulations, advisory opinion requests, and advisory opinions which have been published by the Commission through March 19, 1976. This index includes numerical, subject matter and publication date notation for each published item. In every case, the FEDERAL REGISTER notice number will be the common reference to each entry.

For a full text of any the entries included in this index, you may write to the Information Office, Federal Election Commission, 1325 K Street NW., Washington, D.C. 20463, or call Area code (202) 382–4733. When ordering any of these items, please specify and order only by the FEDERAL REGISTER notice number.

To follow regularly the activities of the Commission, you may refer directly to the FEDERAL REGISTER. With this index every item published by the Commission can be located by FEDERAL REGISTER notice number in the FEDERAL REGISTER for the appropriate date. The FEDERAL REGISTER is available for inspection at any Public Library which is also a Federal depository, or by subscription through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402.

This is the fourth publication of this index. It will be published monthly. Its purpose is to assist those who have a current need to be up to date on Federal election campaign laws and policies issued by the Commission. The Commission welcomes comments on the format and contents of this index, and any suggestions for change to make it more beneficial to its users.

Dated: March 30, 1976.

NEIL STAEBLER,
*Vice Chairman of the*
*Federal Election Commission.*

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FOR FEDERAL ELECTION COMMISSION
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[FR Doc.76-9672 Filed 4-2-76;8:45 am]

[Notice 1976-23]

## NOTICES PUBLISHED IN THE FEDERAL REGISTER

### Index

Today, the Federal Election Commission publishes an index for all 1976 interim guidelines, proposed regulations, advisory opinion requests, and advisory opinions which have been published by the Commission through March 19, 1976. This index includes numerical, subject matter, and publication date notation for each published item. In every case, the FEDERAL REGISTER notice number will be the common reference to each entry.

For a full text of any of the entries included in this index, you may write to the Information Office, Federal Election Commission, 1325 K Street NW., Washington, D.C. 20463, or call Area Code (202) 382-4733. When ordering any of these items, please specify and order only by the FEDERAL REGISTER notice number.

To follow regularly the activities of the Commission, you may refer directly to the FEDERAL REGISTER. With this index every item published by the Commission can be located by FEDERAL REGISTER notice number in the FEDERAL REGISTER for the appropriate date. The FEDERAL REGISTER is available for inspection at any Public Library which is also a Federal depository, or by subscription through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402.

This is the second publication of this index. It will be published monthly. Its purpose is to assist those who have a current need to be up to date on Federal election campaign laws and policies issued by the Commission. The Commission welcomes comments on the format and contents of this index, and any suggestions for change to make it more beneficial to its users.

Dated: March 30, 1976.

NEIL STAEBLER,
*Vice Chairman for the*
*Federal Election Commission.*

KEY TO DATES OF PUBLICATION IN THE FEDERAL REGISTER FOR FEDERAL ELECTION COMMISSION ADVISORY OPINIONS AND ADVISORY OPINION REQUESTS 1976

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|---|---|
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IN THE FEDERAL REGISTER
FOR FEDERAL ELECTION COMMISSION
PROPOSED REGULATIONS

| PROPOSED REGULATION | FEDERAL REGISTER DATE | NOTICE NUMBER |
|---|---|---|
| Compliance | Jan. 15, 1976 | 1976-4 |

[FR Doc.76-9673 Filed 4-2-76;8:45 am]

federal register

MONDAY, APRIL 5, 1976




PART III:

# PRIVACY ACT OF 1974

■

Various Agencies

## NATIONAL COMMISSION ON SUPPLIES AND SHORTAGES

[ 1 CFR Part 435 ]

### PRIVACY ACT OF 1974

### Proposed Regulations for Implementation

The following Proposed Regulations, drafted in accordance with Section (f) of the Privacy Act of 1974, are hereby offered for public comment. Interested parties have until April 30, 1976, to submit comments, which should be addressed to the Counsel, National Commission on Supplies and Shortages, 1750 K Street, N.W., Room 800, Washington, D.C. 20006.

Signed this 31st day of March 1976.

GEORGE C. EADS,
*Executive Director.*

It is proposed to add the following Part 435 to Title 1 of the CFR:

### PART 435—PRIVACY ACT IMPLEMENTATION

Sec.


435.1 Purpose and scope.
435.2 Definitions.
435.3 Procedures for requests pertaining to individual records in a record system.
435.4 Times, places, and requirements for the identification of the individual making a request.
435.5 Disclosure of requested information to the individual.
435.6 Request for correction or amendment to the record.
435.7 Agency review of request for correction or amendment of the record.
435.8 Appeal of an initial adverse agency determination on correction or amendment of the record.
435.9 Disclosure of record to a person other than the individual to whom the record pertains.
435.10 Fees.


AUTHORITY: Public Law 93-426, September 30, 1974.

**§ 435.1 Purpose and scope.**

The purposes of these regulations are to:

(a) Establish a procedure by which an individual can determine if the National Commission on Supplies and Shortages (hereafter known as the Commission) maintains a system of records which includes a record pertaining to the individual; and

(b) Establish a procedure by which an individual can gain access to a record pertaining to him or her for the purpose of review, amendment and/or correction.

**§ 435.2 Definitions.**

For the purpose of these regulations—

(a) The term "individual" means a citizen of the United States or an alien lawfully admitted for permanent residence;

(b) The term "maintain" includes maintain, collect, use or disseminate;

(c) The term "record" means any item, collection or grouping of information about an individual that is maintained by the Commission, including, but not limited to, his or her employment history, payroll information, and financial transactions and that contains his or her name, or the identifying number, symbol, or other identifying particular assigned to the individual, such as social security number;

(d) The term "system of records" means a group of any records under the control of the Commission from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual; and

(e) The term "routine use" means, with respect to the disclosure of a record, the use of such record for a purpose which is compatible with the purpose for which it was collected.

**§ 435.3 Procedures for requests pertaining to individual records in a record system.**

An individual shall submit a request to the Administrative Officer of the Commission to determine if a system of records named by the individual contains a record pertaining to the individual. The individual shall submit a request to the Administrative Officer of the Commission which states the individual's desire to review his or her record.

**§ 435.4 Times, places, and requirements for the identification of the individual making a request.**

An individual making a request to the Administrative Officer of the Commission pursuant to § 435.3 shall present the request at the Commission offices, Room 800, 1750 K Street, N.W., Washington, D.C. 20006, on any business day between the hours of 9 a.m. and 5 p.m. The individual submitting the request should present himself or herself at the Commission's offices with a form of identification which will permit the Commission to verify that the individual is the same individual as contained in the record requested.

**§ 435.5 Disclosure of requested information to the individual.**

Upon verification to identify the Commission shall disclose to the individual the information contained in the record which pertains to that individual.

**§ 435.6 Request for correction or amendment to the record.**

The individual should submit a request to the Administrative Officer of the Commission which states the individual's desire to correct or to amend his or her record. This request is to be made in accord with the provisions of § 435.4.

**§ 435.7 Agency review of request for correction or amendment of the record.**

Within ten working days of the receipt of the request to correct or to amend the record, the Administrative Officer of the Commission will acknowledge in writing such receipt and promptly either—

(a) Make any correction or amendment of any portion thereof which the individual believes is not accurate, relevant, timely, or complete; or

(b) Inform the individual of his or her refusal to correct or to amend the record in accordance with the request, the reason for the refusal, and the procedures established by the Commission for the individual to request a review of that refusal.

**§ 435.8 Appeal of an initial adverse agency determination on correction or amendment of the record.**

An individual who disagrees with the refusal of the Administrative Officer of the Commission to correct or to amend his or her record may submit a request for a review of such refusal to the Counsel of the National Commission on Supplies and Shortages, Room 800, 1750 K Street, NW., Washington, D.C. 20006. The Counsel will, not later than thirty working days from the date on which the individual requests such review, complete such review and make a final determination unless for good cause shown, the Counsel extends such thirty day period. If, after his or her review, the Counsel also refuses to correct or to amend the record in accordance with the request, the individual may file with the Commission a concise statement setting forth the reasons for his or her disagreement with the refusal of the Commission and may seek judicial review of the Counsel's determination under 5 U.S.C. 552a(g)(1)(A).

**§ 435.9 Disclosure of record to a person other than the individual to whom the record pertains.**

The Commission will not disclose a record to any individual other than to the individual to whom the record pertains without receiving the prior written consent of the individual to whom the record pertains, unless the disclosure has been listed as a "routine use" in the Commission's notices of its system of records.

**§ 435.10 Fees.**

If an individual requests copies of his or her record, he or she shall be charged ten cents per page, excluding the cost of any search for review of the record, in advance of receipt of the pages.

[FR Doc.76-9636 Filed 4-2-76;8:45 am]

## NATIONAL COMMISSION ON SUPPLIES AND SHORTAGES

### PRIVACY ACT OF 1974

#### Record Systems

The following Notices of Record Systems prescribed by section e(4) of the Privacy Act of 1974, and the routine uses thereof, are hereby offered for public comment. These four (4) Record Systems are the only ones in our inventory. Interested parties have until April 30, 1976, to submit comments, which should be addressed to the Counsel, National Commission on Supplies and Shortages, 1750 K Street NW., Room 800, Washington, D.C. 20006.

Signed this 31st day of March 1976.

GEORGE C. EADS,
*Executive Director.*

ALPHABETICAL LISTING OF SYSTEM NAMES

Financial Records—NCSS
Payroll Records—NCSS
Personnel Files—NCSS
Personnel Security Files—NCSS

*NCSS–1*

System name: Financial Records—NCSS.

Location: General Services Administration Central Office, 18th and F, NW., Washington, D.C. 20405; copies held by the Commission. (GSA holds records for the Commission under Memorandum of Understanding and Agreement.)

Category of individual: Commission Members and Employees; Members of Advisory Committee to the Commission.

Category of record: Official Travel Authorizations; Government Transportation Requests; Travel Vouchers; Claims for Reimbursement for Expenditures on Official Business; Vendor Register and Vendor Payment Tape.

Authority: Public Law 93–426, September 30, 1974.

Routine uses: Payment of travel claims; records are also released to GAO for audits, to the IRS for investigations, to the CSC concerning pay, benefits, retirement deductions and other information necessary for the Commission to carry out its Government-wide personnel management functions; and to private attorneys pursuant to a power of attorney. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

Record management policy and practice: Storage: Paper and tape. Retrievability: By name, manual and automated.

Safeguards: Stored in guarded building in locked files; released only to authorized personnel.

Retention and disposal: In accordance with the GSA Records Maintenance and Disposition System; Commission copies destroyed at termination of Commission, March 31, 1977.

System manager: Administrative Officer, National Commission on Supplies and Shortages, 1750 K Street NW., Room 800, Washington, D.C. 20006.

Notification: Same as above.

Access and contest: Same as above.

Sources of information: Individuals on whom records maintained.

*NCSS–2*

System name: Payroll Records—NCSS.

Location: General Services Administration Region 3, 7th and D, SW., Washington, D.C. 20407; copies held by the Commission. (GSA holds records for the Commission under Memorandum of Understanding and Agreement.)

Category of individual: Commission Members and Employees; Members of Advisory Committee to the Commission.

Category of record: Varied payroll records including time and attendance cards, payment vouchers, comprehensive listings of employees, health benefits and Government life insurance records, requests for deductions, tax forms, W–2 forms, leave data, retirement records, notification of personnel actions.

Authority: Public Law 93–426, September 30, 1974.

Routine uses: Preparation of salary checks and maintenance of leave records; records are also released to GAO for audits, to the IRS for investigations, to the CSC concerning pay, benefits, retirement deductions and other information necessary for the Commission to carry out its Government-wide personnel management functions; and to private attorneys pursuant to a power of attorney. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

Record management policy and practice: Storage: Paper and tape. Retrievability: Social Security Number. Safeguards: Stored in guarded building in locked files; released only to authorized personnel. Retention and disposal: In accordance with the GSA Records Maintenance and Disposition Systems; Commission copies destroyed at termination of Commission, March 31, 1977.

System manager: Administrative Officer, National Commission on Supplies and Shortages, 1750 K Street NW., Room 800, Washington, D.C. 20006.

Notification: Same as above.

Access and contest: Same as above.

Sources of information: Individuals on whom records maintained.

*NCSS–3*

System name: Personnel Files—NCSS.

Location: General Services Administration Central Office, 18th and F, NW., Washington, D.C. 20405; copies held by the Commission. (GSA holds records for the Commission under Memorandum of Understanding and Agreement.)

Category of individual: Commission Members and Employees; Members of Advisory Committee to the Commission.

Category of record: Standard Forms 171 (Personal Qualifications Statements) or Resumes of Educational Background and Experience; Appointment Affidavits; Tax Forms; Personnel Action Requests; Notifications of Personnel Actions; Government Life Insurance and Health Benefits Applications, Declinations or Waivers; Miscellaneous Requests for Payroll Deductions.

Authority: Public Law 93–426, September 30, 1974.

Routine uses: Official personnel actions; records are also released to GAO for audits, to the IRS for investigations, to the CSC concerning pay, benefits, retirement deductions and other information necessary for the Commission to carry out its Government-wide personnel management functions; and to private attorneys pursuant to a power of attorney. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

Record management policy and practice: Storage: Paper and tape. Retreivability: By name, manual and automated. Safeguards: Stored in guarded building in locked files; released only to authorized personnel. Retention and disposal: In accordance with the GSA Records Maintenance and Disposition System; Commisison copies destroyed at termination of Commission, March 31, 1977.

Systems manager: Administrative Officer, National Commission on Supplies and Shortages, 1750 K Street NW., Room 800, Washington, D.C. 20006.

Notification: Same as above.

Access and contest: Same as above.

Sources of information: Individuals on whom records maintained.

*NCSS–4*

System name: Personnel Security Files—NCSS.

Location: General Services Administration Central Office, 18th and F, NW., Washington, D.C. 20405; copies held by the Commission. (GSA holds records for the Commission under Memorandum of Understanding and Agreement.)

Category of individual: Commission Employees.

Category of Record: Background information for security clearances.

Authority: Public Law 93–426, September 30, 1974.

Routine uses: Issuance of security clearances; a record from this system of records may be disclosed to a Federal agency in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee to the extent that the material is relevant and necessary to the requesting agency. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

Record management policy and practice: Storage: Paper and tape. Retrievability: By name, manual and automated.

Safeguards: Stored in guarded building in locked files; released only to authorized personnel.

Retention and disposal: In accordance with the GSA Records Maintenance and Disposition System; Commission copies destroyed at termination of Commission, March 31, 1977.

System manger: Administrative Officer, National Commission on Supplies and Shortages, 1750 K Street NW., Room 800, Washington, D.C. 20006.

Notification: Same as above.

Access and contest: Same as above.

Sources of information: Individuals on whom records maintained.

[FR Doc.76–9635 Filed 4–2–76;8:45 am]

# Energy Research and Development Administration

## Privacy Act of 1974

## Proposed New System of Records

Notice is hereby given that the Energy Research and Development Administration (ERDA) is proposing a new system of records to be known as 0"ERDA-42 Document Distribution System". ERDA has submitted to the Congress and the Office of Management and Budget (OMB) a New System Report in accordance with Section (o) of the Privacy Act 5 U.S.C. 552a, and the OMB Guidelines issued thereunder. A copy of the report, including the Narrative Statement of the proposed new system is submitted to the Federal Register with this notice and although not published herewith, is on file and available for inspection at the Office of the Federal Register as well as being available at the ERDA Public Document Room, 20 Massachusetts Avenue, NW, Washington, D. C. 20545. The new system is intended to enable ERDA to compile mailing lists for the distribution of the numerous kinds of announcements and information constantly being produced in the performance of its functions.

The Description and Purpose paragraphs excerpted from the Narrative Statement of the proposed new system report and the proposed New System Notice for ERDA-42 compiled as prescribed by section (e)(4) of 5 U.S.C. 552a, are attached.

All interested persons who desire to submit written comments or suggestions for consideration in connection with the proposed notice of new system of records should send them to the Privacy Act Administration Officer, Energy Research and Development Administration, 20 Massachusetts Avenue, NW, Washington, D. C. 20545 by April 30, 1976. Comments received after the date will be given consideration to the extent practicable. Comments on the proposed document may be examined at the ERDA Public Document Room (address above).

Authority 42 U.S.C. 5815; 42 U.S.C. 2201; and 5 U.S.C. 552a.

Date March 26, 1976

Raymond G. Romatowski,
*Assistant Administrator for Administration.*

**New System Report - Privacy Act**

**Proposed New System ERDA-42 - Document Distribution System**

**Excerpts from NARRATIVE SUMMARY**

Discription of proposed new system: This system is intended to enable the Energy Research and Development Administration (ERDA) to compile mailing lists for the distribution of the numerous kinds of announcements and information constantly being produced in the performance of its functions. Under the proposed system, persons desiring to be supplied with information (or announcements of availability of information) on a continuing basis would complete a voluntary, supplementary questionnaire to identify inter alia, their occupations, fields of interest, and other related data. When information is issued, for example, in the fields indicated, or of interest to the occupation indicated, persons can be notified or supplied with appropriate announcements. Requests for a specific series of published information can be dealt with separately from general open requests for whatever may become available in designated fields of interest. An individual who does not desire to be on a mailing list for future distributions will merely specify his specific or immediate requests which will be processed on a one-time basis and will not be stored in the computer. The request of an individual will not be denied because he does not fill out the questionnaire designed by the various program divisions to elicit data about persons requesting information of interest regarding that program. The mailing lists made up therefrom and the data received will be combined with similar lists and similar data from other programs. Together these lists and this data will form ERDA's System 42.

Purpose of the System: The purpose of the system is to enable the assembly and maintenance of (a) general mailing lists, (b) particular mailing lists according to the subject matter or other indicated interests or characteristics of members of the requesting public, as appropriate, (c) to produce name/address mailing labels, and (d) to identify the interested public for the purpose of planning of information distribution.

The system will be computer based and will enable production of various mailing lists on the wide variety of subjects on which the agency is working. The distribution lists will be used either for the purpose of circulating announcements of availability of information to the interested public, or for distribution of the information publications themselves, generally or specifically, as appropriate.

**ERDA 42**

**System name:** Document Distribution System - ERDA

**System location:**

U.S. Energy Research and Development Administration (Headquarters)
Washington, D.C. 20545
U.S. Energy Research and Development Administration
Albuquerque Operations Office
P.O. Box 5400
Albuquerque, New Mexico 87115
U.S. Energy Research and Development Administration
Bartlesville Energy Research Center
Box 1398
Bartlesville, Oklahoma 74003
U.S. Energy Research and Development Administration
Chicago Operations Office
9800 South Cass Avenue
Argonne, Illinois 60439
U.S. Energy Research and Development Administration
Grand Forks Energy Research Center
University Station
Grand Forks, North Dakota 58201
U.S. Energy Research and Development Administration
Idaho Operations Office
550 2nd Street
Idaho Falls, Idaho 83401
U.S. Energy Research and Development Administration
Laramie Energy Research Center
P.O. Box 3395
University Station
Laramie, Wyoming 82070
U.S. Energy Research and Development Administration
Morgantown Energy Research Center
Box 880
Morgantown, West Virginia 26505
U.S. Energy Research and Development Administration
Nevada Operations Office
P.O. Box 14100
Las Vegas, Nevada 89114
U.S. Energy Research and Development Administration
Oak Ridge Operations Office
P.O. Box E
Oak Ridge, Tennessee 37830
U.S. Energy Research and Development Administration
Pittsburgh Energy Research Center
4800 Forbes Avenue
Pittsburgh, Pennsylvania 15213
U.S. Energy Research and Development Administration
Richland Operations Office
P.O. Box 550
Richland, Washington 99352
U.S. Energy Research and Development Administration
San Francisco Operations Office
1333 Broadway, Wells Fargo Building
Oakland, California 94616
U.S. Energy Research and Development Administration
Savannah River Operations Office
P.O. Box A
Aiken, South Carolina 29801

**Categories of individuals covered by the system:** Persons who have requested information which is distributed by ERDA on a routine basis.

**Categories of records in the system:** One record containing name and address and selection criteria.

**Authority for maintenance of the system:** PUB.L. 93-438.

**Routine uses of records maintained in the system, including categories of users and the purposes of such uses:** For additional routine uses see Appendix AA.

**Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:**

**Storage:** Paper, punched cards, magnetic tape and disk, and microfiche.

**Retrievability:** Records are retrieved by record identification code number and normally by type of information being disseminated, e.g., solar, nuclear, etc., or by the occupation, profession or other stated interest of an individual, or by selective distributions such as high schools interested in films or public interest organizations in a specific Federal Region.

**Safeguards:** Access limited to employee's with need in performance of duties. System maintained in buildings with controlled access. Computer information is controlled through established ERDA computer center procedures of personnel screening and physical security in secure building.

**Retention and disposal:** Records retention and disposal authorities are contained in ERDA, Manual Appendix 0230, "Records Disposition." Records within ERDA are destroyed by shredding, burning, or burial in a sanitary landfill as appropriate.

**System manager(s) and address:** Agency system manager -

The Director
Division of Administrative Services
Energy Research and Development Administration
Washington, D. C. 20545,

The managers and directors of field locations listed under Notification procedures below are designated system managers for their respective 0portions of this system.

**Notification procedure:** a. U.S. Energy Research and Development Administration, Privacy Act Administration Officer's Mail Addresses:

U.S. Energy Research and Development Administration (Headquarters)
Washington, D.C. 20545
U.S. Energy Research and Development Administration
Albuquerque Operations Office
P.O. Box 5400
Albuquerque, New Mexico 87115
U.S. Energy Research and Development Administrator
Bartlesville Energy Research Center
Box 1398
Bartlesville, Oklahoma 74003
U.S. Energy Research and Development Administrator
Chicago Operations Office
9800 South Cass Avenue
Argonne, Illinois 60439
U.S. Energy Research and Development Administrator
Grand Forks Energy Research Center
University Station
Grand Forks, North Dakota 58201
U.S. Energy Research and Development Administration
Idaho Operations Office
550 2nd Street
Idaho Falls, Idaho 83401
U.S. Energy Research and Development Administration
Laramie Energy Research Center
P.O. Box 3395
University Station
Laramie, Wyoming 82070
U.S. Energy Research and Development Administration
Morgantown Energy Research Center
Box 880
Morgantown, West Virginia 26505
U.S. Energy Research and Development Administration
Nevada Operations Office
P.O. Box 14100
Las Vegas, Nevada 89114
U.S. Energy Research and Development Administration
Oak Ridge Operations Office
P.O. Box E
Oak Ridge, Tennessee 37830
U.S. Energy Research and Development Administration
Pittsburgh Energy Research Center
4800 Forbes Avenue
Pittsburgh, Pennsylvania 15213
U.S. Energy Research and Development Administration
Richland Operations Office
P.O. Box 550
Richland, Washington 99352
U.S. Energy Research and Development Administration
San Francisco Operations Office
1333 Broadway, Wells Fargo Building
Oakland, California 94616
U.S. Energy Research and Development Administration
Savannah River Operations Office
P.O. Box A
Aiken, South Carolina 29801

b. Required Identifying Information: Name as it appears on the mailing label or number as it appears on the mailing label.

**Record access procedures:** Refer to Notification Procedure.

**Contesting record procedures:** Refer to Headquarters.

**Record source categories:** Self-supplied by requestors.

NOTE: There will be no new ERDA rules or changes to previously published rules resulting from the addition of this new system of records.

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