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Highlights

3562 **Taxes** Treasury/IRS proposes rules on limitation of benefits in event of early termination of certain tax qualified retirement plans.

3558 Treasury/IRS proposes rules on imposition of excise taxes on undistributed income of private foundations.

3559 Treasury/IRS proposes rules on reduction of business energy credits by subsidized borrowings.

3541 **Consumer Leasing** FHLBB authorizes federally-chartered savings and loan associations and savings banks to engage in personal property leasing.

3543 **Federal Home Loan Banks** FHLBB amends reserve and net worth requirements.

3539 **Child Care Food Program** USDA/FNS changes maximum allowable reimbursement rates for sponsors of day care homes.

3545, 3546 **Employment Taxes** Treasury/IRS issues rules on voluntary withholding from annuity payments and submission of certain withholding certificates. (2 documents)

3551 **Health Systems Agencies** HHS/PHS amends rules on designation and funding.

CONTINUED INSIDE

Highlights

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Questions and requests for specific information may be directed to the telephone numbers listed under INFORMATION AND ASSISTANCE in the READER AIDS section of this issue.

3694 **Medical Devices** HHS/FDA proposes general rules on classification of all ophthalmic devices. (Part II of this issue)

3752 **Prisons** Justice/PB proposes rules on management of Youth Corrections Act Institutions, Adult Basic Education Program and Suicide Prevention Program. (Part III of this issue)

3555 **Banks and Banking** Treasury/Comptroller proposes to amend rules on disposition of credit life insurance income.

3613 **Oil and Gas Leasing** Interior/BLM requests comments on outer continental shelf bidding systems.

3554, 3555 **Loans—Rural Areas** USDA/REA proposes to amend bulletin on supplemental financing for electrical facilities. (2 documents)

3574 **Railroads** ICC invites comments on maintenance of demurrage and detention records for freight cars and trailers.

3566 **Occupational Safety and Health** Labor/OSHA seeks comments on occupational exposure to ethylene oxide.

Antidumping Commerce/ITA issues notices on:

3577 Spun acrylic yarn from Japan.

3579 Unrefined montan wax from German Democratic Republic.

3577 **Cheese** Commerce/ITA publishes annual list of foreign government subsidies on articles of quota cheese.

3576 **Privacy Act Documents** ACTION

3672 **Sunshine Act Meetings**

Separate Parts of This Issue

3694 **Part II, HHS/FDA**
3752 **Part III, Justice/PB**

Contents

Federal Register
Vol. 47, No. 17
Tuesday, January 26, 1982

ACTION
RULES
3553 Reporting and recordkeeping requirements
NOTICES
3576 Privacy Act; systems of records

Agricultural Stabilization and Conservation Service
NOTICES
Marketing quotas and acreage allotments:
3576 Peanuts; 1982 national poundage quota and 1982–1985 national poundage quota referendum period, etc.; correction

Agriculture Department
See Agricultural Stabilization and Conservation Service; Food and Nutrition Service; Rural Electrification Administration.

Air Force Department
NOTICES
Meetings:
3581 Scientific Advisory Board

Alcohol, Tobacco and Firearms Bureau
PROPOSED RULES
Alcohol; viticultural area designations:
3564 Madera, Calif.

Civil Rights Commission
NOTICES
Meetings; State advisory committees:
3576 Connecticut
3577 Hawaii

Commerce Department
See International Trade Administration; National Bureau of Standards.

Comptroller of Currency
PROPOSED RULES
3555 Credit life insurance income; disposition

Consumer Product Safety Commission
NOTICES
3672 Meetings; Sunshine Act

Defense Department
See Air Force Department.

Economic Regulatory Administration
NOTICES
Powerplant and industrial fuel use; prohibition orders, exemption requests, etc.:
3581 Federal Paper Board Co.

Employment and Training Administration
NOTICES
Adjustment assistance:
3647 Allegheny Ludlum et al.
3647 Merck & Co., Inc., and Calgon Corp.
3648 Reid Stevens
3646 Washington Stove Works et al.

Energy Department
See Economic Regulatory Administration; Federal Energy Regulatory Commission; Hearings and Appeals Office, Energy Department.

Environmental Protection Agency
RULES
Air quality implementation plans; approval and promulgation; various States, etc.:
3548–3550 California (3 documents)

Hazardous waste programs; interim authorizations; various States:
3551 Arizona; comment period opened and review period recommenced
NOTICES
Motor vehicle fuel economy, evaluation of retrofit devices:
3596 Fuel Maximiser
Pesticide registration, cancellation, etc.:
3596 2-Chlorotoluene
Toxic and hazardous substances control:
3591, 3592 Premanufacture notices receipts (2 documents)
3596 Premanufacture notification requirements; test marketing exemption applications

Federal Aviation Administration
RULES
Airworthiness directives:
3544 McDonnell Douglas

Federal Communications Commission
PROPOSED RULES
Common carrier services:
3573 Domestic fixed-satellite service; space stations licensing; extension of time
NOTICES
Meetings:
3598 National Industry Advisory Committee (2 documents)
3672 Meetings; Sunshine Act (2 documents)
3597 Public broadcasting; alternative financing for public telecommunications entities; inquiry
3597 Rulemaking proceedings filed, granted, denied, etc.; petitions by various companies; correction

Federal Energy Regulatory Commission
NOTICES
Hearings, etc.:
3583 Bonneville Power Administration
3585 Grisdale Hill Co.
3586 Johnson, Michael E.
3588 Jordon-Reiwerts
3586 Marr, Douglas S.
3587 Modesto Irrigation District
3584 Mono, Calif.
3588 Tuolumne Regional Water District
3589 Waltham Hydroelectric Power Co.
3590 Woods Creek, Inc. (2 documents)

Federal Home Loan Bank Board
RULES
Federal Savings and Loan Insurance Corporation:
3543 Reserve and net worth requirements
Federal savings and loan system, etc.:
3541 Consumer leasing; authorization

Federal Mine Safety and Health Review Commission
NOTICES
3673 Meetings; Sunshine Act

Federal Reserve System
NOTICES
Bank holding companies; proposed de novo nonbank activities:
3598 Citicorp et al.
3600 Philadelphia National Corp. et al.
Federal Open Market Committee:
3599 Domestic open market operations, authorization
3599 Domestic policy directives

Food and Drug Administration
PROPOSED RULES
Medical devices:
3694 Ophthalmic devices; general provisions and classification

Food and Nutrition Service
RULES
Child nutrition programs:
3539 Child care food program; reimbursement rates for day care homes sponsors; interim rule and request for comments

General Services Administration
NOTICES
Procurement:
3601 Bidders mailing list; addresses of government entities

Geological Survey
NOTICES
Outer Continental Shelf; oil, gas, and sulphur operations; development and production plans:
3622 Aminoil U.S.A., Inc.
3622 Exxon Co., U.S.A.
3622 Shell Oil Co.

Health and Human Services Department
See also Food and Drug Administration; Public Health Service.
NOTICES
Organization, functions, and authority delegations:
3608 Office of Regional Director

Hearings and appeals Office, Energy Department
NOTICES
Applications for exception:
3591 Cases filed

Interior Department
See Geological Survey; Land Management Bureau; National Park Service; Reclamation Bureau; Surface Mining Reclamation and Enforcement Office.

Internal Revenue Service
RULES
Employment taxes:
3545 Annuity payments; voluntary withholding of income tax
3546 Withholding exemption certificates (Form W-4)
PROPOSED RULES
Excise taxes:
3558 Private foundations; minimum investment return
Income taxes:
3559 Business energy credits; reduction by subsidized borrowings
3562 Employee retirement plans, qualified; early termination

International Trade Administration
NOTICES
Antidumping:
3577 Spun acrylic yarn from Japan
3579 Unrefined montan wax from East Germany
3577 Cheese, quota; foreign government subsidies, annual list

Interstate Commerce Commission
RULES
Motor carriers:
3553 Household goods transportation; revision of operational regulations; availability of corrected copies of Form OCP-100
PROPOSED RULES
Rail carriers:
3574 Demurrage and detention records, etc.; maintenance
NOTICES
3630, 3631 Long and short haul applications for relief (2 documents)
Motor carriers:
3626 Compensated intercorporate hauling operations; intent to engage in
3628, 3631 Finance applications (2 documents)
3632, 3636 Permanent authority applications (2 documents)
3627 Permanent authority applications; correction
3630 Permanent authority applications; operating rights authority; republications
3634 Permanent authority applications; restriction removals
Railroad operation, acquisition, construction, etc.:
3646 Continental Group, Inc.
3645 TeCe Corp.

Justice Department
See Prisons Bureau.

Labor Department
See Employment and Training Administration; Occupation Safety and Health Administration; Pension and Welfare Benefit Programs Office.

Land Management Bureau
NOTICES
Environmental statements; availability, etc.:
3624 Twin Falls livestock grazing management program, Idaho
Meetings:
3624 Outer Continental Shelf Advisory Board
Opening of public lands:
3622 Arizona

Outer Continental Shelf; oil and gas lease sales:
3613 Bidding systems; inquiry
Survey plat filings:
3624 Montana (2 documents)
Withdrawal and reservation of lands, proposed, etc.:
3623 Arizona (2 documents)

National Bureau of Standards
NOTICES
Information processing standards, Federal:
3581 Interface standards exclusion list; additions
3580 Interface standards exclusion list; proposed changes; inquiry
Senior Executive Service:
3580 Performance Review Board; membership

National Park Service
NOTICES
3625 Cape Cod National Seashore; water resources management alternatives analysis; availability and inquiry
Historic Places National Register; pending nominations:
3625 Alabama et al.

Nuclear Regulatory Commission
NOTICES
Applications, etc.:
3650 Boston Edison Co.
3651, 3655 Carolina Power & Light Co. (2 documents)
3652, 3653 Commonwealth Edison Co. (2 documents)
3654, 3655 Commonwealth Edison Co. et al. (2 documents)
3656 GPU Nuclear Corp. et al.
3657 Iowa Electric Light & Power Co. et al.
3658 Niagara Mohawk Power Corp.
3659 Northeast Nuclear Energy Co. et al.
3660 Northern States Power Co.
3661 Philadelphia Electric Co. et al.
3661 Power Authority of State of New York
3662–3664 Tennessee Valley Authority (3 documents)
Meetings:
3650 Reactor Safeguards Advisory Committee
3662 Regulatory guides; issuance and availability

Occupational Safety and Health Administration
PROPOSED RULES
Health and safety standards:
3566 Ethylene oxide; occupational exposure standards; advance notice

Pension and Welfare Benefit Programs Office
NOTICES
Employee benefit plans; prohibited transaction exemptions:
3648 Kennedy Associated, Inc.

Prisons Bureau
PROPOSED RULES
Inmate control, custody, care, treatment, and instruction:
3752 Youth Corrections Act institutions, adult basic education program, and suicide prevention program

Public Health Service
RULES
3551 Health systems agencies; elimination of reviews, etc.
NOTICES
Organization, functions, and authority delegations:
3603–3608 Food and Drug Administration (4 documents)

Reclamation Bureau
NOTICES
Environmental statements; availability, etc.:
3626 Chikaskia project, Kans. and Okla.; extension of time

Rural Electrification Administration
PROPOSED RULES
Electric borrowers:
3554 Supplemental financing for loans (Bulletin 20–14, Attachment A)
3555 Supplemental financing for loans (Bulletin 20–14, Attachment C)

Securities and Exchange Commission
NOTICES
Hearings, etc.:
3667 Narragansett Capital Corp. et al.
Self-regulatory organizations; proposed rule changes:
3665 Boston Stock Exchange, Inc.
3666 Chicago Board Options Exchange, Inc.
3666 Cincinnati Stock Exchange
3667 Philadelphia Stock Exchange, Inc.
Self-regulatory organizations; unlisted trading privileges:
3666 Cincinnati Stock Exchange
3666 Midwest Stock Exchange, Inc.

Small Business Administration
NOTICES
Applications, etc.:
3671 Faulkner Investment Co.
3671 International Paper Capital Formation, Inc.
3671 Vadus Capital Corp.

Surface Mining Reclamation and Enforcement Office
PROPOSED RULES
Permanent program submission; various States:
3571 Ohio; hearing

Transportation Department
See Federal Aviation Administration.

Treasury Department
See Alcohol, Tobacco and Firearms Bureau; Comptroller of Currency; Internal Revenue Service.

MEETINGS ANNOUNCED IN THIS ISSUE

CIVIL RIGHTS COMMISSION
3576 Connecticut Advisory Committee, Cromwell, Conn. (open), 2–18–82
3577 Hawaii Advisory Committee, Honolulu, Hi. (open), 2–20–82

DEFENSE DEPARTMENT
Air Force Department—
3581 USAF Scientific Advisory Board, Scott Air Force Base, Ill. (closed), 2–11–82

FEDERAL COMMUNICATIONS COMMISSION
3598 National Industry Advisory Committee: Executive Committee, Washington, D.C. (open), 2–16–82; Broadcast Services Subcommittee, Washington, D.C. (open), 2–16–82

INTERIOR DEPARTMENT
Land Management Bureau—
3624 Outer Continental Shelf Advisory Board, Scientific Committee, Washington, D.C. (open), 2–22 through 2–24–82

NUCLEAR REGULATORY COMMISSION
3650 Reactor Safeguards Advisory Committee, Qualification Program for Safety Related Equipment Subcommittee, Washington, D.C. (open), 2–10–82

HEARINGS

INTERIOR DEPARTMENT
Land Management Bureau—
3624 Twin Falls livestock grazing management program, draft environmental impact statement, Twin Falls, Idaho, 2–25–82
Office of Surface Mining Reclamation and Enforcement—
3571 Ohio Permanent Regulatory Program, Columbus, Ohio, 2–20–82

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

7 CFR
226 3539
Proposed Rules:
1701 (2 documents) 3554, 3555

12 CFR
541 3541
545 3541
561 3541
563 3543
Proposed Rules:
2 3555

14 CFR
39 3544

21 CFR
Proposed Rules:
886 3694

26 CFR
31 (2 documents) 3445, 3546
32 3545
37 3546
Proposed Rules:
1 (2 documents) 3559, 3562
53 3558

27 CFR
Proposed Rules:
9 3564

28 CFR
Proposed Rules:
524 3752
544 3752
549 3752

29 CFR
Proposed Rules:
1910 3566

30 CFR
Proposed Rules:
Ch. VII 3571

40 CFR
52 (3 documents) 3548–3550
123 3551

42 CFR
122 3551

45 CFR
Ch. XII 3553

47 CFR
Proposed Rules:
25 3573

49 CFR
1056 3553
Proposed Rules:
1033 3574
1254 3574

Rules and Regulations

Federal Register
Vol. 47, No. 17
Tuesday, January 26, 1982

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.
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DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 226

Child Care Food Program; Reimbursement Rates for Sponsors of Day Care Homes

AGENCY: Food and Nutrition Service, USDA.

ACTION: Interim rule with request for comments.

SUMMARY: As mandated by Pub. L. 97–35, the Omnibus Reconciliation Act of 1981, this interim rule alters the number of tiers and adjusts the base rates which determine maximum allowable reimbursement for administrative expenses incurred by sponsors of day care homes in the Child Care Food Program (CCFP).

DATES: The interim rule is effective January 1, 1982, except § 226.16(d)(4)(ii) which contains information collection requirements which are subject to review by OMB. The Department is establishing a 60-day comment period. Comments must be received on or before March 29, 1982 to be assured of consideration for the final rule.

ADDRESS: Written comments should be sent to Beverly Walstrom, Chief, Policy and Program Development Branch, Child Care and Summer Programs Division, Food and Nutrition Service, U.S. Department of Agriculture, Alexandria, Virginia 22302.

FOR FURTHER INFORMATION CONTACT: Beverly Walstrom at the above address or by telephone at (703) 756–3888. Copies of all written comments will be available for review during business hours at Room 416, 3101 Park Center Drive, Alexandria, Virginia 22302.

SUPPLEMENTARY INFORMATION: Classification: This rulemaking has been reviewed in accordance with Executive Order 12291 and has not been classified as major because it will not have an annual effect on the economy of $100 million, will not cause a major increase in costs or prices, and will not have a significant economic impact on competition, employment, investment, productivity, innovation or on the ability of U.S. enterprises to compete. This rule has also been reviewed with regard to the requirements of Pub. L. 96–354. David B. Alspach, Acting Administrator of the Food and Nutrition Service, has certified that this rule does not have a significant economic impact on a substantial number of small entities.

The Child Care Food Program (CCFP) is authorized by Section 17 of The National School Lunch Act, which was amended on August 13, 1981, by Pub. L. 97–35, The Omnibus Reconciliation Act of 1981. Among the provisions of Pub. L. 97–35 is a mandate to "adjust the maximum allowable levels for administrative expense payments (for organizations which sponsor day care homes) . . . so as to achieve a 10 percent reduction in the total amount of reimbursement provided to institutions for such administrative expenses."—Pub. L. 97–35, (Section 810(c) (August 13, 1981). The Department has determined that in order to comply with this provision, it will be necessary to cut actual expenditures approximately $1.8 million. To make this adjustment, moreover, Congress directed the Department to "increase the economy of scale factors used to distinguish institutions that sponsor a greater number of family or group day care homes from those which sponsor a lesser number of such homes."

Currently, the maximum allowable levels are as follows:

	Per home
First 25 homes	$53
26–75 homes	41
Each home over 75	35

This reimbursement structure was originally developed for the January 22, 1980, CCFP regulations by taking into account factors which indicated that certain economies of scale occur at 25 homes and 75 homes. Since it was assumed that most day care homes would participate in the CCFP under the auspices of moderately sized sponsoring organizations, the Department did not establish larger tiers to reflect the existence of further economies of scale.

However, over the last several years, sponsoring organizations have grown rapidly to enrollments far exceeding 75 homes. A review of available data now shows that over 20 percent of current sponsoring organizations operate more than 75 homes. These organizations, moreover, account for over 75 percent of all homes participating in the Program. Information available to the Department from a representative sample of sponsoring organizations further indicates that economies of scale which include, among other things, savings on overhead and savings resulting from more sophisticated recordkeeping occur at the levels of 50 homes and 200 homes. Based on experience, the Department also believes that a third level of 1,000 homes is reasonable. Therefore, the Department is replacing the current three-tiered structure used to determine maximum reimbursement with a four-tiered structure which recognizes economies of scale at 50 homes, 200 homes, and 1,000 homes. The Department believes this structure establishes economy of scale factors at more realistic levels for sponsoring organizations with large numbers of day care homes.

After creating a four tier system, the Department next determined reimbursement rates for each tier which would be equivalent to the rates paid to sponsoring organizations under the three tier structure. The Department then calculated the relative impact of the proposed rate changes on various size sponsors. In the case of the third and fourth tiers (201–1,000 homes and each home over 1,000, respectively), the rates would be the same under both the former structure and the new structure. Tier One went from 1–25 homes to 1–50, and Tier Two went from 26–75 homes to 51–200. The new tiers overlap the old tiers for sponsors which fall into the 26–50 home range and the 75–200 home range. For that reason, the Department had to recalculate rates.

The information on sponsors necessary to make these calculations was developed by Abt Associates as part of its nationwide study of administrative costs for sponsors of family day care homes. Of 492 sponsors with 1–50 homes, 346 have 1–25 homes and 146 have 26–50 homes. Abt weighted these sponsors according to

the number of sponsors in each of these two categories and determined that the weighted average at present reimbursement levels for each of the first 50 homes is $49. This rate, therefore, is transposed to the 1–50 tier.

The same procedure was followed to calculate the current rate for each of the next 150 homes. The 54 sponsors with 51–75 homes and the 76 sponsors with 76–200 homes were weighed to arrive at the current rate of $37 for each of the 150 homes in the second tier.

In accordance with this method, the current rates for the new tiers are as follows:

	Per home
First 50 homes	$49
51–200 homes	37
201–1,000 homes	35
Each home over 1,000	35

In adjusting these rates, the Department was guided by estimates of administrative costs of $18.3 million that would occur in Fiscal Year 1982 if neither the tiers nor the rates were modified. According to this information, in order to achieve the legislative mandate, the adjusted rates must ensure a savings in this area of at least $1.8 million. To achieve the goal of a 10 percent reduction in total amount of reimbursement provided to institutions for administration, the Department must first account for the fact that actual expenditures for organizations' administrative costs amount to only slightly more than 80 percent of the maximum reimbursement available under the current rate structure. Consequently, in order to comply with the mandate of the law, the Department first had to adjust the current rates to account for the fact that a portion of the reimbursement presently available to sponsoring organizations is not claimed. Therefore, the Department adjusted the rates for all tiers by 15 percent. The Department decided on this percentage rather than 20 percent to account for any possibility that subsequent claims might increase the portion of maximum reimbursement actually paid. The Department emphasizes that this adjustment does not, itselt, represent a reduction in expenditures. Rather, it merely recognizes that actual reimbursement is below the maximum levels and that a rate reduction must be made before the rates can be further adjusted to achieve the required reduction in the Department's expenditures.

After making a 15 percent reduction in the rates in all four tiers, the Department considered a variety of options for accomplishing the 10 percent reduction in total reimbursements, as the law directs. In reviewing these options, the Department employed the following criteria. First, because the Department believes the proposed rate structure must offer reasonable assurance of achieving a 10 percent reduction in expenditures, the actual reduction in rates should result in a total projected expenditure reduction of slightly more than 10 percent. Secondly, the law directs the Department to make greater reductions in the rates for large organizations than in the rates for smaller ones in order to reflect existing economies of scale. Finally, the Department noted the possible effects which each option might be expected to have on each size of sponsoring organization. In particular, the Department was concerned that reductions in the administrative rates might affect the ability of organizations of certain sizes to continue operating the Program. If large sponsoring organizations, for example, were forced to cease operations due to insufficient administrative reimbursement, it is possible that Program benefits might be denied to many children currently being served.

For the reasons outlined above, the Department did not adopt a rate structure based on an across-the-board reduction in the rates for sponsoring organizations in all tiers. Such a rate structure would require small organizations to adjust as much as larger ones, even though the former have much less capacity than the latter to absorb reductions. The Department, therefore, has determined that a reduction in rates only for larger organizations serves the best interests of all participants in the program. Consequently, after the 15 percent adjustment in all tiers to account for the available reimbursement not presently paid, the Department made no further reduction in the first two tiers and reduced the third tier by 16 percent and the fourth tier by 26 percent. The new rates for all tiers are as follows:

	Per home
First 50 homes	$42
51–200 homes	32
201–1,000 homes	25
Each home over 1,000	22

A review of information projected by Abt Associates indicates that these rates would enable the Department to make the reduction in administrative reimbursement required by law. On the other hand, this structure does not make a precipitous reduction in overall expenditures. Moreover, smaller organizations would be less affected by the new rates than larger ones with greater economies of scale. Finally, the Department believes that this structure would allow the mandate of the law to be achieved without serious disruption to any group of sponsoring organizations. For these reasons, the Department is adopting this rate structure.

The Department emphasizes that there is no intention to reduce the ability of sponsoring organizations to operate in the Child Care Food Program. This rate structure recognizes both the fact that organizations' actual claims for reimbursement have generally been lower than the maximum available under the rates and the fact that Congress has mandated a reduction in *actual* administrative expenditures as part of a general effort to reduce spending by the Federal government. The Department also realizes that reductions in administrative reimbursement need to be accompanied by corresponding modifications to the administrative responsibilities which sponsoring organizations must discharge. For this reason, this regulation also reduces from four to three the minimum number of annual visits which sponsoring organizations must make to each of their homes. The sponsoring organization monitoring requirement is one of the more costly activities for which organizations are responsible. This reduction in monitoring, therefore, will assist sponsoring organizations in their adjustment to the new reimbursement levels. The Department is also prepared to consider reductions in other administrative responsibilities currently fulfilled by sponsoring organizations. The Department, therefore, requests commenters to recommend other areas in which administrative duties can be modified without adverse consequences.

Since the effective date of this change is January 1, 1982, it is impracticable for there to be prior notice and public comment thereon. However, subsequent comments will be received and considered.

The reporting and recordkeeping requirements contained in this regulation are subject to review by OMB under the Paperwork Reduction Act and are not effective until approved by OMB.

PART 226—CHILD CARE FOOD PROGRAM

Accordingly, 7 CFR Part 226 is amended as follows:

1. By amending § 226.12(a) to revise (a)(3) (i), (ii) and (iii) and add (iv) to read as follows:

§ 226.12 Administrative payments to sponsoring organizations for day care homes.

(a) * * *

(3) * * *

(i) Initial 50 day care homes by 42 dollars;

(ii) Next 150 day care homes by 32 dollars;

(iii) Next 800 day care homes by 25 dollars; and

(iv) Additional day care homes by 22 dollars. During any fiscal year, administrative payments to a sponsoring organization may not exceed 30 percent of the total amount of administrative payments and food service payments for day care home operations.

* * * * *

2. By revising § 226.16(d)(4)(ii) to read as follows:

§ 226.16 Sponsoring organization provisions.

* * * * *

(d) * * *

(4) * * *

(ii) Three times each year at each day care home, provided at least one review is made during each day care home's first four weeks of Program operations and not more than six months elapse between reviews;

* * * * *

(Sec. 810 and 820, Pub. L. 97-35, Omnibus Reconciliation Act of 1981; Sec. 2, Pub. L. 95-627, 92 Stat. 3603 [42 U.S.C. 1766]; Sec. 10, Pub. L. 89-642, 80 Stat., 889 [42 U.S.C. 1779])

Dated: January 19, 1982.

David B. Alspach,

Acting Administrator, Food and Nutrition Service.

[FR Doc. 82-1818 Filed 1-25-82; 8:45 am]

BILLING CODE 3410-30-M

FEDERAL HOME LOAN BANK BOARD

12 CFR Parts 541, 545 and 561

[No. 82-21]

Consumer Leasing

Dated: January 14, 1982.

AGENCY: Federal Home Loan Bank Board.

ACTION: Final rules.

SUMMARY: The Federal Home Loan Bank Board has adopted regulations to authorize federally-chartered savings and loan associations and federally-chartered mutual savings banks to engage in personal property leasing that may be considered the functional equivalent of lending that Federal associations are otherwise permitted to do. The regulation will enable Federal associations to more fully utilize their lending powers.

EFFECTIVE DATE: February 14, 1982.

FOR FURTHER INFORMATION CONTACT: James C. Stewart, ([202) 377-6457), Office of General Counsel, Federal Home Loan Bank Board, 1700 G Street, NW., Washington, D.C. 20552.

SUPPLEMENTARY INFORMATION: By Resolution No. 81-584, the Federal Home Loan Bank Board proposed regulations to allow federally-chartered savings and loan associations and federally-chartered mutual savings banks to engage in certain forms of leasing that are the functional equivalent of consumer lending. 46 FR 49135 (Oct. 6, 1981). The Board has determined that Federal associations have the power to engage in lease financing under the consumer lending authority created in Section 401 of the Depository Institutions Deregulation and Monetary Control Act of 1980, Pub. L. No. 96-221, 94 Stat. 153, 12 U.S.C. 1464(c)(2) (Supp. IV 1980).

The proposed regulation closely followed those governing the leasing activities of national banks and bank holding company subsidiaries, 12 CFR 7.3400 and 225.4(a)(6) (1981), and incorporated the legal restrictions on permissible lease financing described in M&M Leasing Corp. v. Seattle First National Bank, 563 F.2d 1377 (9th Cir. 1977), cert. denied, 436 U.S. 956 (1978). Under the proposal, Federal associations would be permitted to enter into full payout, net leases. A net lease places all the burdens of ownership on the lessee who would be responsible for maintenance and repair of the leased property. The full payout requirement means that over the term of the lease the lessor must recoup its entire investment in the leased property plus the cost of financing. The lessor's return would come from the monthly payments made by the lessee, estimated tax benefits, and the estimated residual value of the property. Following the example of the Office of the Comptroller of the Currency (OCC), the Board proposed placing a limit of 25 percent of the original cost of the leased item on residual value estimates. Higher estimates would be allowed if the residual value were guaranteed by a financially capable party. The Board specifically asked for comment on the suitability of the 25 percent limit as well as for comment on the tax, accounting, and usury aspects of consumer leasing for Federal associations.

The Board received 15 comment letters on the consumer leasing proposal: 12 from savings and loan associations; two from state savings and loan leagues, and one from a certified public accountant. All commenters favored the proposal. Several felt that the proposed authority was too limited and should be extended to include commercial leasing. Other commenters sought some affirmative statement that indirect leasing is permissible. Several commenters found the net lease and full payout restrictions too inflexible.

With respect to the areas in which the Board specifically sought comment, respondents indicated no objection to the 25 percent limitation on unguaranteed residual values. It was noted that this figure does not place Federal associations at a disadvantage to national banks and in any event may be exceeded by merely obtaining a guaranty of the residual value. Regarding usury, commenters urged the Board to take the same position as OCC that leases are not subject to usury laws. Several suggested that the Board incorporate specific preemptive language in the final regulation. Concerning the tax aspects of leasing, two commenters noted that savings and loan associations would only receive half of any investment tax credit attributable to the purchase of leased property. *See* I.R.C. section 46(e). These commenters suggested that, for this reason, Federal associations may find it more advantageous to conduct their leasing activities through a service corporation and recommended that the Board authorize consumer leasing as a preapproved activity under 12 CFR 545.9-1(c) (1981). In the only comment offered on the accounting aspects of leasing, it was suggested that these issues were adequately covered in Accounting for Leases published by the Financial Accounting Standards Board.

Based on the comments received, the Board has determined that few changes should be made to the proposed regulation. Since commenters found the residual value estimate limits acceptable, the Board will retain the proposed formula in the final rule. The Board adheres to the position taken in the preamble to the proposed regulation that state usury laws would not apply to a consumer lease entered into by a federal association.

In the Board's view, it would be undesirable to delete the full payout and net lease requirements of the proposal at this time, in view of the present powers of federally-chartered savings and loans and savings banks, and the current state of the law. The limitations of full payout

and net leases were both cited by the Ninth Circuit as important indicia of a permissible leasing transaction for banks. See M&M Leasing Corp. v. Seattle First National Bank, 563 F. 2d 1377, 1380 (9th Cir. 1977), cert. denied, 436 U.S. 956 (1978). Accordingly, these restrictions are being affirmatively adopted by the Board at this time. However, if after federally-chartered associations have exercised the leasing authority provided in this rule, either the powers of such associations or applicable laws evolve further, the Board will reevaluate the restrictions imposed herein.

Certain questions have arisen with respect to the authority of federals to engage in indirect leasing transactions (*i.e.*, the purchase of a lease and the leased property after the lease has been executed between a dealer and the customer). It was the Board's intent in 12 CFR 5457–10a(a)(2) of the proposal that federal associations be permitted to engage in indirect consumer leasing to the same extent that they may engage in indirect consumer lending. Consequently, a federal association may purchase a consumer lease meeting the requirements of the regulation just as it might purchase a consumer loan. Such authority can be found in the Board's own regulations and the relevant case law as set forth in the preamble to the proposal.

Consumer leasing as approved today, may only be engaged in by federals as an incident to the consumer lending authority; federal associations may not directly engage in commercial leasing. However, Board staff will consider whether certain forms of commercial leasing could be offered by a service corporation and make appropriate recommendations to the Board.

The Board is aware that a significant percentage of automobile leasing is to small businessmen and professionals who use leased automobiles for both business and personal activities. Partial business use of the leased property may raise questions whether the lease may be considered a consumer lease for the purposes of this rule. In the Board's view, however, a lease to a natural person of personal property which will be put to some personal use should be presumed to be a consumer lease.

Leasing as a pre-approved service corporation activity is currently under study by the Board's staff. Accordingly, no amendment to that regulation will be made at this time. The Board is of the view, however, that leasing of the type described in this regulation is the functional equivalent of consumer lending and is authorized to service corporations as an incident to their consumer lending authority under 12 CFR 545.9–1(c)(1)(vi).

Accordingly, the Federal Home Loan Bank Board hereby amends Parts 541 and 545 of Subchapter C and Part 561 of Subchapter D, Chapter V of Title 12, Code of Federal Regulations, as set forth below.

SUBCHAPTER C—FEDERAL SAVINGS AND LOAN SYSTEM

PART 541—DEFINITIONS

1. Amend § 541.25 by adding after the word "loan" in the first line:

§ 541.25 Consumer loan.

* * * (or a lease meeting the requirements of § 545.7–10a of this subchapter) * * *

PART 545—OPERATIONS

2. Add a new § 545.7–10a, to read as follows:

§ 545.7–10a Consumer leasing.

(1) Become the legal or beneficial owner and lessor of specific personal property or otherwise acquire such property at the request of the lessee who wishes to lease it from the association; or

(a) *General.* Within the limitations of § 545.7–10, a Federal association may:

(1) Become the owner and lessor of personal property by purchasing the property from another lessor in connection with its purchase of the related lease; and

(3) Incur obligations incidental to its position as the legal or beneficial owner and lessor of the leased property, if the lease is a net, full-payout lease representing a noncancelable obligation of the lessee, notwithstanding the possible early termination of that lease, and at the expiration of the lease all interest in the property shall be either liquidated or released on a net basis as soon as practicable.

(b) *Definitions.* For the purposes of this section:

(1) A "net lease" is a lease under which the association will not, directly or indirectly, provide or be obligated to provide for:

(i) The servicing, repair or maintenance of the leased property during the lease term;

(ii) the purchasing of parts and accessories for the leased property; *Provided, however,* That improvements and additions to the leased property may be leased to the lessee upon its request in accordance with the full-payout requirements of this section;

(iii) The loan of replacement or substitute property while the leased property is being serviced;

(iv) The purchasing of insurance for the lessee, except where the lessee has failed in its contractual obligation to purchase or maintain the required insurance;

(v) The renewal of any license or registration for the property unless such action by the association is necessary to protect its interest as an owner or financer of the property.

(2) A "full-payout" lease is one from which the lessor can reasonably expect to realize a return of its full investment in the leased property plus the estimated cost of financing the property over the term of the lease derived from:

(i) Rentals;

(ii) Estimated tax benefits; and

(iii) The estimated residual value of the property at the expiration of the initial term of the lease, which shall not exceed 25 percent of the acquisition cost of the property to the lessor unless the estimated residual value is guaranteed by a manufacturer, the lessee, or a third party not an affiliate of the association and the association makes the determination that the guarantor has the resources to meet the guarantee. In all cases, however, both the estimated residual value of the property and that portion of the estimated residual value relied upon by the lessor to satisfy the requirements of a full-payout lease must be reasonable in light of the nature of the leased property and all relevant circumstances so that realization of the lessor's full investment plus the cost of financing the property primarily depends on the creditworthiness of the lessee and any guarantor of the residual value, and not on the residual market value of the leased item.

(c) *Salvage powers.* if, in good faith, an association believes that there has been an unanticipated change in conditions which threatens its financial position by significantly increasing its exposure to loss, the provisions of paragraphs (a) and (b) of this section shall not prevent the association:

(1) As the owner and lessor under a net, full-payout lease, from taking reasonable and appropriate action to salvage or protect the value of the property or its interests arising under the lease; or

(2) As the assignee of a lessor's interest in a lease, from becoming the owner and lessor of the leased property pursuant to its contractual right, or from taking any reasonable and appropriate action to salvage or protect the value of the property or its interests arising under the lease.

(3) Additional terms. The provisions of paragraphs (a) and (b) of this section do not prohibit an association from

including any provisions in a lease, or from making any additional agreements, to protect ints financial position or investment in the circumstances set forth in subparagraphs (1) and (2) of this paragraph (c).

SUBCHAPTER D—FEDERAL SAVINGS AND LOAN INSURANCE CORPORATION

PART 561—DEFINITIONS

3. Amend § 561.38 by adding the following language to the first sentence after the word "mobile homes" and before the first colon:

§ 561.38 Consumer credit.

* * * and leases of personal property to consumers that may be considered the functional equivalent of loans on personal security * * *

(Sec. 401 of the Depository Institutions Deregulation and Monetary Control Act, Pub. L. No. 96-221, 94 Stat 151, (12 U.S.C. 1464(d)); secs. 402, 403, 407, National Housing Act, (12 U.S.C. 1725, 1726, and 1730). Reorg. Plan No. 3 of 1947, 3 CFR 1071 (1943–48 Comp.))

By the Federal Home Loan Bank Board.

James J. McCarthy,

Acting Secretary.

[FR Doc. 82-1923 Filed 1-25-82; 8:45 am]

BILLING CODE 6720-01-M

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12 CFR Part 563

[No. 82-19]

Net Worth Amendment

AGENCY: Federal Home Loan Bank Board.

ACTION: Final rule.

SUMMARY: The Federal Home Loan Bank Board has amended the reserve and net-worth requirements to reflect the latitude suggested by the National Housing Act which requires institutions whose accounts are insured by the Federal Savings and Loan Insurance Corporation ("FSLIC") to maintain reserves of between three and six percent of insured accounts as the Board may determine. This action is taken pursuant to the Board's discretionary authority under section 403(b) of the National Housing Act and serves to increase lending funds avilability.

EFFECTIVE DATE: December 31, 1980.

FOR FURTHER INFORMATION CONTACT: James C. Stewart, Office of General Counsel (telephone number: (202) 377-6457), Federal Home Loan Bank Board, 1700 G Street, NW., Washington, D.C. 20552.

SUPPLEMENTARY INFORMATION: The Federal Home Loan Bank Board is amending its regulations pertaining to net-worth and reserve requirements to reflect the latitude suggested by the National Housing Act. Currently, the Board's regulations require insured institutions to maintain reserves at four percent of insured accounts and net worth at four percent of liabilities. 12 CFR 563.13 (1981). Under section 403(b) of the National Housing Act, insured institutions are required to maintain reserves of between three and six percent of insured accounts, as the Board may determine. 12 U.S.C. 1726(b) (Supp. IV 1980). In addition to this statutory reserve requirement, the Board requires insured institutions to maintain net worth at a specified percentage of liabilities as a measure of capital adequacy. 12 CFR 563.13(b) (1981).

In Section 409 of the Depository Institutions Deregulation and Monetary Control Act, Congress conferred discretionary authority on the Board to set the statutory insurance reserve requirement between three and six percent. Pub. L. No. 96-221, 94 Stat. 160 (1980) (codified at 12 U.S.C. 1726(b)). Pursuant to that authority, the Board lowered the reserve requirement from five to four percent. *See Net Worth Amendments,* 45 FR 76111 (Nov. 5, 1980).

The Board remains of the view that it is essential for insured institutions to maintain adequate capital to ensure their contained viability and to provide some cushion of protection to the FSLIC. However, the Board also believes that in the present economic environment, it is both unnecessary and unrealistic to retain the present basic statutory reserve and regulatory net worth requirements at four percent of insured accounts and four percent of liabilities, respectively. Such retention is unnecessary because the Board's supervisory staff is able to resolve situations involving troubled institutions successfully where the net worth of the institution is substantially below the four percent level. Such retention is unrealistic because many institutions are facing operating losses resulting almost exclusively from the disparity between the relatively low return received on their asset portfolios and the considerably higher return paid on their liabilites. Such losses are therefore largely beyond the current control of the institution.

The Board is of the opinion that when Congress conferred on the Board discretionary authority to adjust the statutory reserve requirement between three and six percent, it was the intent of Congress that the Board take circumstances such as the foregoing into account in setting the required statutory reserve and regulatory net-worth levels. Since the Board is of the view that a reserve and net-worth level of three percent still provides protection to the FSLIC and accountholders, the Board has therefore determined to amend the net-worth and reserve requirements to reflect the maximum flexibility suggested by the statute. The amendments provide that the percentage requirements will return to four percent on December 31, 1983.

The Board has determined that the public interest would be served by retroactive implementation to cover insured institutions whose fiscal years began on or after December 3, 1980, and therefore neither the notice and public procedure provisions of 5 U.S.C. 553(b) and 12 CFR 508.12 nor the 30-day delayed effective date provisions of 5 U.S.C. 553(d) and 12 CFR 508.14 will be observed.

Accordingly, the Board hereby amends Part 563, Subchapter D, Chapter V of Title 12, Code of Federal Regulations, as set forth Below.

SUBCHAPTER D—FEDERAL SAVINGS AND LOAN INSURANCE CORPORATION

PART 563—OPERATIONS

§ 563.13 Reserve accounts

1. Amend paragraphs (a)(2) and (b)(2) of § 563.13 by substituting the phrase "three percent" for the phrase "four percent" wherever it occurs.

2. Amend paragraph (b)(4) of § 563.13 by adding the following sentence thereto at the end:

(b) *Net-worth requirements.* * * *

(4) *Qualifying balance deduction.* * * * The authority granted by this paragraph shall not be used to reduce the institution's statutory reserve to less than the amount specified in paragraph (a). of this section.

(Sec. 409, 94 Stat. 160. Secs. 402, 403, 407, 48 Stat. 1256, 1257, 1260, as amended (12 U.S.C. 1725, 1726, 1730). Sec. 5A, 47 Stat. 727, as amended by sec. 1, 64 Stat. 256, as amended, sec. 17, 47 Stat. 736, as amended (12 U.S.C. 1425a, 1437). Sec. 5, 48 Stat. 132, as amended (12 U.S.C. 1464. Reorg. Plan No. 3 of 1947, 12 FR 4891 3 CFR, 1943–48 Comp., p. 1071))

Dated: January 14, 1982.

By the Federal Home Loan Bank Board.

James J. McCarthy,

Acting Secretary.

[FR Doc. 82-1922 Filed 1-25-82; 8:45 am]

BILLING CODE 6720-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 82-NM-03-AD; Amdt. 39-4306]

Airworthiness Directives: McDonnell Douglas Model DC-10 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adds a new Airworthiness Directive (AD) that would require modification of the wing leading edge slat control system on McDonnell Douglas Model DC-10 series airplanes. The modification would consist of the installation of two balance spring assemblies on the slat control mechanism for the left and right outboard slat control valves as well as installation of balanced pressure relief valves in hydraulic systems No. 1 and No. 3 slat extend lines of the left and right outboard slat control systems. This AD will improve the capability of these airplanes to continue safe flight and landing by assuring that uncommanded outboard slat retraction does not occur as a result of a failure event during critical flight phases.

DATE: Effective date February 25, 1982. Compliance schedule as prescribed in the body of the AD, unless already accomplished.

ADDRESSES: The applicable service information may be obtained from: McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Director, Publications and Training, C1-750 (54-60). This information also may be examined at FAA Northwest Mountain Region, 9010 East Marginal Way South, Seattle, Washington 98108, or 4344 Donald Douglas Drive, Long Beach, California 90808.

FOR FURTHER INFORMATION CONTACT: Gilbert L. Thompson, Aerospace Engineer, Systems and Equipment Branch, ANM-130L, Federal Aviation Administration, Northwest Mountain Region, Los Angeles Area Aircraft Certification Office, 4344 Donald Douglas Drive, Long Beach, California 90808, telephone (213) 548-2833.

SUPPLEMENTARY INFORMATION: On September 22, 1981, a DC-10-30F airplane experienced a failure of the No. 3 engine during takeoff resulting in subsequent rejection of the takeoff with no injuries to passengers or crew. During the investigation of this incident by the FAA, it was learned that uncontained failure of the No. 3 engine first stage low pressure turbine disk resulted in uncommanded retraction of the right wing outboard slats due to failure of the associated outboard slat follow-up cable. It was further learned during this investigation that a similar No. 3 engine failure in 1977 on a foreign-operated DC-10-30 may have also resulted in uncommanded retraction of the right hand outboard slats. In the latter case, the engine failure occurred at approximately 400-600 feet altitude with subsequent execution of a safe landing. These events prompted a re-evaluation by the FAA of the ability of the DC-10 airplane to be capable of continued safe flight and landing after the occurrence of a critical engine failure combined with outboard slat retraction, considering such occurrence as a single event. This re-evaluation centered around an analysis of the probability of occurrence of such an event during critical phases of flight in conjunction with a controllability analysis of the airplane under these conditions.

The results of analytical determination of the probability of occurrence of a critical engine failure combined with slat retraction during critical phases of flight (including takeoff and landing) show that the occurrence of such an event is considered extremely improbable (a likelihood of occurrence of less than one in a billion). Though such analysis may be used as evidence to indicate that a specific failure event is extremely improbable and, therefore, not warranting further consideration, it is the FAA's position that probability analyses alone do not determine acceptability of a given design. As with most probability analyses, certain assumptions must be made, based upon historical data were possible, which structure the bounds within which the results remain meaningful. In determining the probability of the event noted, sufficient room for judgment exists in establishing the bounds for some of the assumptions therein postulated to preclude acceptability of the design based on probability analyses alone.

Having considered the DC-10 service experience to date, the existing data concerning turbine engine failures, and the results of the above noted probability analysis, it is FAA's determination that sufficient area exists for judgment in the interpretation of this data to warrant a determination that design changes should be incorporated to improve safety.

Since this condition is likely to exist or develop in other airplanes of the same type design, an Airworthiness Directive is being issued which requires modifications to the DC-10 slat control systems which would assure that the wing slats remain extended even if the systems that actuate them sustain severe damage. This action is in full accord with FAA policy to utilize AD procedures to make changes to the approved type design when appropriate in the interest of aviation safety.

It is expected that kit parts for the above modifications will be obtainable beginning April 1982 with worldwide DC-10 fleet parts availability completed by October 1982.

Since a situation exists that requires immediate adoption of this regulation, it is found that notice and public procedure herein are impracticable and good cause exists for making this amendment effective in less than 30 days.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) is amended by adding the following new Airworthiness Directive:

McDonnell Douglas: Applies to McDonnell Douglas Model DC-10-10, -10F, -15, -30, -30F, and -40 series airplanes certificated in all categories.

To assure that the DC-10 wing slats remain extended even if the slat control system sustains severe damage, accomplish the following:

Unless already accomplished compliance is required with paragraphs A and B on or before January 31, 1983, or in accordance with a schedule of accomplishment approved by the Chief, Los Angeles Area Aircraft Certification Office, FAA Northwest Mountain Region.

A. Modify the leading edge slat servo system and replace the outboard slat system follow-up cables as outlined in the Accomplishment Instructions of McDonnell Douglas DC-10 Service Bulletin 27-187, original issue, or later revisions approved by the Chief, Los Angeles Area Aircraft Certification Office, FAA Northwest Mountain Region.

B. Install balanced pressure relief valves in hydraulic systems No. 1 and No. 3 slat extend lines, left and right wing, as outlined in the Accomplishment Instructions of McDonnell Douglas DC-10 Service Bulletin 27-189, original issue, or later revisions approved by the Chief, Los Angeles Area Aircraft Certification Office, FAA Northwest Mountain Region.

C. Within the next 2000 flight hours after accomplishment of the modifications noted in paragraph A above, and at intervals not to exceed 4000 flight hours thereafter, visually inspect the balance spring assemblies and outboard slat follow-up cables, left and right wing, for integrity of installation.

D. Within the next 4,000 flight hours after accomplishment of the modifications noted in paragraph B above, and at intervals not to exceed 4,000 flight hours thereafter, functionally check for proper operation of the outboard slat relief valves as outlined in the Accomplishment Instructions, paragraph (E) of McDonnell Douglas DC-10 Service Bulletin 27-189, original issue, or later revisions approved by the Chief, Los Angeles Area Aircraft Certification Office, FAA Northwest Mountain Region.

E. Upon the request of an operator, an FAA maintenance inspector, subject to prior approval by the Chief, Los Angeles Area Aircraft Certification Office, FAA Northwest Mountain Region, may adjust the repetitive intervals specified in paragraphs C and D of this AD to permit compliance at an established inspection period of that operator if the request contains substantiating data to justify the change for that operator.

F. Alternate means of compliance with this AD which provide an equivalent level of safety may be used when approved by the Chief, Los Angeles Area Aircraft Certification Office, FAA Northwest Mountain Region.

G. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

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 the McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Director, Publications and Training, C1-750 (54-60). These documents also may be examined at FAA Northwest Mountain Region, 9010 East Marginal Way South, Seattle, Washington 98108, or 4344 Donald Douglas Drive, Long Beach, California 90808.

This amendment becomes effective February 25, 1982.

(Secs. 313(a), 601, and 603 Federal Aviation Act of 1958, as amended (49 U.S.C. 1354(a), 1421, and 1423); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)); and 14 CFR 11.89)

Note.— The FAA has determined that this regulation is an emergency regulation that is not major under Executive Order 12291. It has been further determined that this document involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If this action is subsequently determined to involve a significant regulation, a final regulatory evaluation or analysis, as appropriate, will be prepared and placed in the regulatory docket (otherwise, an evaluation is not required). A copy of it, when filed, may be obtained by contacting the person identified under the caption "**FOR FURTHER INFORMATION CONTACT.**"

This rule is a final order of the Administrator. Under Section 1006(a) of the Federal Aviation Act of 1958, as amended, (49 U.S.C. 1486(a)), it is subject to review by the courts of appeals of the United States, or the United States Court of Appeals for the District of Columbia.

Issued in Seattle, Wash., on January 21, 1982.

Charles R. Foster,

Director, Northwest Mountain Region.

[FR Doc. 82-1999 Filed 1-25-82; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 31 and 32

[T.D. 7804]

Employment Taxes; Applicable on or After January 1, 1955; and Temporary Employment Tax Regulations Under the Tax Reform Act of 1969; Voluntary Withholding From Annuity Payments

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations.

SUMMARY: This document provides final Employment Tax Regulations (26 CFR Part 31) relating to voluntary withholding of income tax from annuity payments. Changes to the applicable tax law were made by the Tax Reform Act of 1969 and the Act of December 24, 1980 (Pub. L. 96-601). The regulations provide guidance to payors and payees of annuities with respect to such withholding.

DATES: The regulations are effective for payments of annuities made after December 31, 1970.

FOR FURTHER INFORMATION CONTACT: Barry L. Wold of the Legislation and Regulations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, N.W., Washington, D.C. 20224 (Attention: CC:LR:T) (202-566-3828).

SUPPLEMENTARY INFORMATION:

Background

On May 19, 1981, the **Federal Register** published proposed amendments to the Employment Tax Regulations (26 CFR Part 31) under section 3402 (o) of the Internal Revenue Code of 1954 (46 FR 27357). The regulations were proposed to conform the existing regulations to section 805 (g) and (h)(3) of the Tax Reform Act of 1969 (83 Stat. 708, 709) and to the portions relating to annuities of section 4 of the Act of December 24, 1980 (Pub. L. 96-601; 94 Stat. 3495). The content of the proposed regulations, except for technical changes in titles, was identical to that of the Temporary Employment Tax Regulations under the Tax Reform Act of 1969 (26 CFR Part 32). Accordingly, 26 CFR Part 32 is deleted by this Treasury decision. A public hearing was not held, since one was not requested. After consideration of all comments regarding the proposed amendments, those amendments are adopted without change by this Treasury decision.

Response to Comments

Two comments relating to the notice of proposed rulemaking were received. One comment proposed that the minimum amount of tax to be withheld from a monthly annuity payment and the net amount of the annuity payment received by the payee below which tax may not be withheld both be increased ten-fold. This suggestion has not been adopted since such high minimums would eliminate the flexibility that the present regulations provide.

The other comment opposed the concept of withholding from annuities. These regulations, however, merely implement the clear mechanism that the Code provides for withholding from annuities. Congress has mandated withholding from annuities where the payee requests withholding, and the Service must implement that requirement.

Evaluation of the effectiveness of these regulations will be based on comments received from offices within the Treasury and the Internal Revenue Service, other governmental agencies, and the public. These regulations will impose no new reporting or recordkeeping requirements.

Drafting Information

The principal author of these regulations is Barry L. Wold of the Legislation and Regulations Division of the Office of Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulations, on matters of both substance and style.

Adoption of Amendments to the Regulations

Accordingly, the regulations proposed to be prescribed as final Employment Tax Regulations (26 CFR Part 31) published as a notice of proposed rulemaking in the Federal Register for May 19, 1981 (46 FR 27357), are hereby adopted as proposed. In addition, 26 CFR Part 32 is deleted.

(Secs. 3402(o) (3) and (4) and 7805 of the Internal Revenue Code of 1954 (26 U.S.C. 3402(o) (3) and (4), 94 Stat. 3495; 26 U.S.C. 7805, 68A Stat. 917))

Roscoe L. Egger, Jr.,

Commissioner of Internal Revenue.

Approved: January 15, 1982.

John E. Chapoton,

Assistant Secretary of the Treasury.

PART 31—EMPLOYMENT TAXES: APPLICABLE ON AND AFTER JANUARY 1, 1955

Par. 1. Section 31.3402(o)–1 (relating to extension of withholding to certain payments other than wages) is amended by revising the caption for the section and for paragraph (a), to read as follows:

§ 31.3402(o)–1 Extension of withholding to supplemental unemployment compensation benefits.

(a) *In general.* * * *

* * * * *

PART 32—TEMPORARY EMPLOYMENT TAX REGULATIONS UNDER THE TAX REFORM ACT OF 1969

§ 32.1 [Redesignated as § 31.3402(o)–2]

Par. 2. Section 32.1 (relating to extension of withholding of income tax at source on wages to annuity payments if requested by payee) is redesignated as § 31.3402(o)–2, and such redesignated section is inserted after § 31.3402(o)–1. Section 31.3402(o)–2 as so redesignated is amended by removing the word "payer" and inserting the word "payor" in every place where the word "payer" appears, and by revising the caption for the section to read as follows:

§ 31.3402(o)–2 Extension of withholding to annuity payments if requested by payee.

* * * * *

PART 32—[Removed]

Par. 3. Part 32 is removed in its entirety.

[FR Doc. 82–1873 Filed 1–21–82; 4:21 pm]

BILLING CODE 4830–01–M

26 CFR Parts 31 and 37

[T.D. 7803]

Employment Taxes; Applicable on or After January 1, 1955; Temporary Employment Tax Regulations for Withholding Exemption Certificates; Submission of Certain Withholding Certificates

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations.

SUMMARY: This document provides final Employment Tax Regulations (26 CFR Part 31) relating to the submission of certain withholding exemption certificates (Forms W–4). The regulations provide guidance to employers and employees with respect to the furnishing and honoring of employee withholding exemption certificates.

DATE: This document is effective with respect to withholding exemption certificates furnished by employees to employers on or after February 25, 1982.

FOR FURTHER INFORMATION CONTACT: Legislation and Regulations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, N.W., Washington, D.C. 20224 (Attention: CC:LR:T) (202–566–3829).

SUPPLEMENTARY INFORMATION:

Background

On March 19, 1981, the Federal Register published proposed amendments to the Employment Tax Regulations (26 CFR Part 31) under sections 3401 and 3402 of the Internal Revenue Code of 1954 (46 FR 17566). On the same date, the Federal Register also published Temporary Employment Tax Regulations for Withholding Exemption Certificates (26 CFR Part 37) under section 3402 of the Internal Revenue Code of 1954 (46 FR 17547). A public hearing was held on June 2, 1981. After consideration of all comments regarding the proposed amendments, those amendments are adopted as revised by this Treasury decision.

Issues

Comments received from employers dealt with several issues. Some employers were concerned that § 37.3402–1(e)(4) of the temporary regulations, relating to the requirement that an employer submit to the Service any new Form W–4 and supporting statement that makes a claim inconsistent with the Service's prior notice to the employer, unnecessarily interposed the employer in the middle of a dispute between the employee and the Service. These employers suggested that the regulations be changed to require the employee to submit this form and statement directly to the Service. The final regulations have been modified to permit the employee to submit a new Form W–4 (with supporting statement) that makes a claim inconsistent with the notice furnished by the Service to the employer either (1) directly to the Service or (2) to the employer who must then forward it to the Service.

Several employers were concerned about the length of time the Service may take to review some W–4 certificates. The Service has developed new internal administrative measures to provide for monthly processing in order to reduce the period of any employer or employee uncertainty over the validity of the employee's claims.

Several employers expressed concern about recordkeeping burdens imposed on them by the regulations. Because the Code assigns to the employer the responsibility for collecting income taxes at the source on wages, it is impossible to eliminate this burden. Several other employers expressed appreciation for the provisions that based the employer's responsibility to submit Forms W–4 upon an objective numerical standard, rather than upon a subjective, case-by-case standard. The final regulations have been modified to require that employers submit to the Service copies of Forms W–4 that claim more than 14 exemptions, rather than more than 9 exemptions. This change will decrease the paperwork burden on employers. The submission requirements for Forms W–4 that claim exempt status are unchanged.

Comments received from certain individuals expressed the view that income tax withholding from wages constitutes a violation of one or more provisions of the United States Constitution. For example, the provisions forbidding unlawful seizures and deprivations of property under the Fourth and Fifth Amendments to the United States Constitution were cited.

The Federal withholding system does not violate any rights of taxpayers under the Constitution. The Supreme Court has denied a constitutional challenge to the withholding system in a case where the taxpayers sought to enjoin withholding from their wages. *United States v. American Friends Service Committee, et al.*, 419 U.S. 7 (1974). Also, the United States Court of Appeals for the Tenth Circuit has specifically held that federal income tax withholding does not result in the taking of property without due process. *Campbell v. Amax Coal Co.*, 610 F. 2d 701 (10th Cir. 1979). This

holding was based on an earlier decision in which the Supreme Court refused to grant the petitioner a writ of certiorari. *United States v. Smith*, 484 F. 2d. 8 (10th Cir. 1973); cert. denied, 415 U.S. 978.

Drafting Information

The principal author of these final regulations is Charles C. Saverude of the Legislation and Regulations Division, Office of Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulations, both on matters of substance and style.

Adoption of Amendments to the Regulations

Accordingly, the following amendments are made to the Employment Tax Regulations (26 CFR Part 31), and the Temporary Employment Tax Regulations for Withholding Exemption Certificates (26 CFR Part 37) are deleted from the Code of Federal Regulations.

PART 31—EMPLOYMENT TAXES; APPLICABLE ON OR AFTER JANUARY 1, 1955

Paragraph 1. The last sentence of paragraph (b) of § 31.3401(e)–1 is amended by removing "§ 37.3402–1" and inserting in lieu thereof "§ 31.3402(f)(2)–1(g)".

Par. 2. The last sentence preceding Example (1) of § 31.3402(n)–1 is amended by removing "§ 37.3402–1" and inserting in lieu thereof "§ 31.3402(f)(2)–1(g)".

Par. 3. Section 31.3402(f)(2)–1 is amended by the addition of a new paragraph (g) thereto to read as follows:

§ 31.3402(f)(2)–1 Withholding exemption certificates.

* * * * *

(g) *Submission of certain withholding certificates*—(1) *General rule.* An employer shall submit, in accordance with paragraph (g)(3) of this section, a copy of any withholding exemption certificate, together with a copy of any written statement received from the employee in support of the claims made on the certificate, which is received from the employee during the reporting period (even if not in effect at the end of the quarter) if the employee is employed by that employer on the last day of the reporting period and if—

(i) The total number of withholding exemptions (within the meaning of section 3402(f)(1) and the regulations thereunder) claimed on the certificate exceeds 14, or

(ii) The certificate indicates that the employee claims a status exempting the employee from withholding, and the exemption provided by paragraph (g)(2) of this section does not apply.

(2) *Exception.* A copy of the certificate shall not be submitted under paragraph (g)(1)(ii) of this section if the employer reasonably expects, at the time the certificate is received, that the employee's wages (under chapter 24 of the Code) from that employer shall not then usually exceed $200 per week.

(3) *Rules for submission*—(i) *In general.* The reporting period is a calendar quarter. Copies required to be submitted under paragraph (g)(1) of this section shall be submitted at the time and place of filing Form 941 or 941E for the reporting period, or Form 941–M for the last month of the reporting period. Form 941, 941E or 941–M shall be used, in accordance with the instructions for the form, to transmit the copies.

(ii) *Option.* At the choice of the employer, copies required to be submitted under paragraph (g)(1) of this section may be submitted earlier and for shorter reporting periods than a calendar quarter. In such case, the employer shall submit the copies to the service center where the employer would file a Form 941 or 941E and shall include with the submission a statement showing the employer's name, address, employer identification number, and the number of copies of withholding exemption certificates submitted. However, in no event shall a copy be submitted later than the time for filing the report required to be submitted for the calendar quarter reporting period under subdivision (i) of this paragraph (g)(3).

(iii) *First report.* The first submission of copies shall include a copy of any certificate required to be submitted under paragraph (g)(1) of this section which is received by the employer on or after April 1, 1980.

(4) *Other withholding exemption certificates.* An employer shall also submit a copy of any currently effective withholding exemption certificate (or make the original certificate available for inspection), together with a copy of any written statement received from the employee in support of the claims made on the certificate, upon written request of the Internal Revenue Service. This request of the Service may relate either to one or more named employees or to one or more reasonably segregable units of the employer. In this regard, the Service may, by written notice, advise the employer that a copy of each new withholding exemption certificate received from one or more named employees, or from one or more reasonably segregable units of the employer, which is required, under this paragraph (g) to be submitted to the Service is to be submitted to the District Director. The employer shall then submit to the District Director a copy of each such new certificate of each such employee immediately after the employer receives the new certificate from the named employee.

(5) *Computation of withholding.* (i) Until receipt of written notice from the Internal Revenue Service that a certificate, a copy of which was submitted under this section, is defective, that certificate is effective and the employer shall withhold on the basis of the statements made in that certificate, unless that certificate must be disregarded under the provisions of subdivision (vi) of this paragraph (g)(5).

(ii) The Internal Revenue Service may find that a copy of a withholding exemption certificate submitted contains a materially incorrect statement or it may determine, after written request to the employee for verification of the statements on the certificate, that it lacks sufficient information to determine if the certificate is correct. If the Internal Revenue Service so finds or determines and notifies the employer in writing that the certificate is defective, the employer shall then consider the certificate to be defective for purposes of computing amounts of withholding.

(iii) If the Internal Revenue Service notifies the employer that the certificate is defective, the Internal Revenue Service will, based upon its findings, advise the employer that the employee either is not entitled to claim a status exempting the employee from withholding or is not entitled to claim a total number of withholding exemptions in excess of a number specified by the Internal Revenue Service in the notice, or both. The Internal Revenue Service will also specify the Internal Revenue Service office to be contacted for further information.

(iv) The Internal Revenue Service will provide the employer with a copy for the employee of each notice it furnishes to the employer under this paragraph (g)(5) in addition to the notice furnished to the employer for his own use. The Internal Revenue Service will also mail a similar notice to the employee at the address of the employee as shown on the certificate under review. The employer shall promptly furnish the employee who filed the defective certificate, if still in his employ, with a copy of the written notice of the Internal Revenue Service with respect to the certificate and may request another withholding exemption

certificate from the employee. The employer shall withhold amounts from the employee on the basis of the maximum number specified in the written notice received from the Service.

(v) * * *

(vi) If and when the employee does file any new certificate (after an earlier certificate of the employee was considered to be defective), the employer shall withhold on the basis of that new certificate (whenever filed) as currently effective only if the new certificate does not make a claim of exempt status or of a number of withholding exemptions which claim is inconsistent with the advice earlier furnished by the Internal Revenue Service in its written notice to the employer. If any new certificate does make a claim which is inconsistent with the advice contained in the Service's written notice to the employer, then the employer shall disregard the new certificate, shall not submit that new certificate to the Service, and shall continue to withhold amounts from the employee on the basis of the maximum number specified in the written notice received from the Service.

(vii) If the employee makes a claim on any new certificate that is inconsistent with the advice in the Service's written notice to the employer, the employee may specify on such new certificate, or by a written statement attached to that certificate, any circumstances of the employee which have changed since the date of the Service's earlier written notice, or any other circumstances or reasons, as justification or support for the claims made by the employee on the new certificate. The employee may then submit that new certificate and written statement either to (A) the Internal Revenue Service office specified in the notice earlier funished to the employer under this paragraph (g)(5), or to (B) the employer, who must then submit a copy of that new certificate and the employee's written statement (if any) to the Internal Revenue Service office specified in the notice earlier furnished to the employer. The employer shall continue to disregard that new certificate and shall continue to withhold amounts from the employee on the basis of the maximum number specified in the written notice received from the Service unless and until the Internal Revenue Service by written notice (under subdivision (iii) of this paragraph (g)(5)) advises the employer to withhold on the basis of that new certificate and revokes its earlier written notice.

(6) *Definition of employer.* For purposes of this paragraph (g), the term "employer" includes any individual authorized by the employer to receive withholding exemption certificates, to make withholding computations, or to make payroll distributions.

PART 37—TEMPORARY EMPLOYMENT TAX REGULATIONS FOR WITHHOLDING EXEMPTION CERTIFICATES [REMOVED]

Par. 4. The Temporary Employment Tax Regulations for Withholding Exemption Certificates, 26 CFR Part 37, are hereby removed.

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

Roscoe L. Egger, Jr.,

Commissioner of Internal Revenue.

Approved: January 18, 1982.

John E. Chapoton,

Assistant Secretary of the Treasury.

[FR Doc. 82-1874 Filed 1-21-82; 4:22 pm]

BILLING CODE 4830-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[A-9-FRL—2020-4]

Imperial and Monterey Areas; State of California; Approval and Promulgation of Implementation Plans

AGENCY: Environmental Protection Agency.

ACTION: Final rulemaking.

SUMMARY: Today's action approves cutbacks in asphalt rules submitted by the State of California for the Imperial County Air Pollution Control District and the Monterey Bay Unified Air Pollution Control District. These rules will reduce hydrocarbon emissions and meet requirements of the Clean Air Act.

EFFECTIVE DATE: This action is effective on February 25, 1982.

ADDRESS: A copy of the State submittals is located at: The Office of the Federal Register, 1100 "L" Street, NW., Room 8401, Washington, D.C. 20408.

FOR FURTHER INFORMATION CONTACT: Louise P. Giersch, Director, Air and Hazardous Materials Division, Environmental Protection Agency, Region 9, 215 Fremont Street, San Francisco, CA 94105; Attn: Douglas Grano (415) 974-8222.

SUPPLEMENTARY INFORMATION: On November 10 and December 4, 1980 (45 FR 74480 and 80279), EPA approved with conditions the Imperial County and the North Central Coast (Monterey) Nonattainment Area Plans (NAP), with regard to Part D. The reader is referred to those **Federal Register** notices for a detailed discussion of EPA's findings. Today's notice discusses one condition of EPA's approval of the NAPs which required the State to submit cutback asphalt rules reflecting reasonably available control technology (RACT).

In response to the condition, the State submitted Rule 418.1, "Cutback Asphalt," for Imperial County and Rule 425, "Cutback Asphalt," for the Monterey Bay Unified Air Pollution Control District (MBUAPCD) on March 30, 1981. In addition, EPA received a letter dated April 2, 1981 from the MBUAPCD which provided data to justify an exemption contained in their rule.

On July 23, 1981 (45 FR 37911) EPA proposed to approve the two cutback rules. No comments were received. Therefore, EPA is taking final action under Part D of the Clean Air Act to approve the two rules and remove a condition of approval of the Imperial and Monterey NAPs.

Conditional approval of the overall NAPs will be continued until EPA publishes in the **Federal Register** final approval or disapproval of all the conditional approval items for the Imperial County and Monterey Bay Area NAPs.

Under Executive Order 12291, EPA must judge whether a rulemaking action is "major." Further, under the Regulatory Flexibility Act, EPA must assess the effect of the rulemaking action on "small entities." This regulation is not "major" because it approves state and local actions and imposes no new requirements. I hereby certify that the action will not have a significant economic impact on a substantial number of small entities.

Incorporation by reference of the State Implementation Plan for the State of California was approved by the Director of the Federal Register on July 1, 1981.

(Secs. 110, 129, 171 to 178, and 301(a) of the Clean Air Act, as amended (42 U.S.C. 7410, 7429, 7501 to 7508, and 7601(a)))

Dated: January 18, 1982.

Anne M. Gorsuch,

Administrator.

Subpart F of Part 52 Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

Subpart F—California

1. Section 52.220 is amended by adding paragraphs (c)(89) (iii) and (iv) as follows:

§ 52.220 **Identification of plan.**

* * * * *

(c) * * *

(89) * * *

(iii) Imperial

(A) New Rule 418.1.

(iv) Monterey

(A) New Rule 425.

* * * * *

[FR Doc. 82-1848 Filed 1-25-82; 8:45 am]

BILLING CODE 6560-38-M

40 CFR Part 52

[A-9-FRL—2019-8]

California State Implementation Plan Revision; Approval and Promulgation of Implementation Plans

AGENCY: Environmental Protection Agency.

ACTION: Final rulemaking.

SUMMARY: Revisions to rules of the Butte County, Glenn County, Siskiyou County, and Yolo-Solano Air Pollution Control Districts (APCDs) were forwarded to EPA by the California Air Resources Board. These revisions generally are administrative and retain equivalent emission control requirements. EPA reviewed these rules with respect to the Clean Air Act and determined that they should be approved. This action will be effective on March 29, 1982, unless someone submits adverse or critical comments to EPA on or before February 25, 1982.

EFFECTIVE DATE: March 29, 1982.

ADDRESSES: Copies of the revisions are available for public inspection during normal business hours at the following locations:

Public Information Reference Unit, Environmental Protection Agency, Library, 401 "M" Street, S.W., Room 2404, Washington, D.C. 20460

Library, Office of the Federal Register, 1100 "L" Street, N.W., Room 8401, Washington, D.C. 20408

California Air Resources Board, 1102 "Q" Street, Sacramento, CA 95812

Butte County Air Pollution Control District, 316 Nelson Avenue, Oroville, CA 95965

Glenn County Air Pollution Control District, 720 North Colusa Street, Willows, CA 95988

Siskiyou County Air Pollution Control District, 525 South Foothill Drive, Yreka, CA 96097

Yolo-Solano Air Pollution Control District, 323 First Street, Suite 5, Woodland, CA 95695

FOR FURTHER INFORMATION CONTACT: Douglas Grano, Chief, State Implementation Plan Section, Air and Hazardous Materials Division, Environmental Protection Agency, Region 9, 215 Fremont St., San Francisco, CA 94105 (415) 974-8222.

SUPPLEMENTARY INFORMATION: The California Air Resources Board submitted the following rules and regulations on the indicated dates:

Butte County

November 3, 1980

Rule

1 Definitions (Agricultural Burning, Agricultural Waste, No Burn Day, and Burn Day)
3-1 Orchard Heaters
3-2 Permit Required
3-6 Prohibition of Agricultural Burning on No Burn Days
3-11 Drying Period Required
3-11.2 Rice Straw Burning
3-11.3 Field Crop Ignition
3-12 Ignition Hours
3-12.1 Restricted Burning
3-12.2 Field Crops Harvested Prior to September 10
3-14 Exceptions (From Agricultural Burning Rules)
3-15 Special Permit
3-16 Restricted Burning
3-16.1 Range Improvement Burning

Glenn County

November 3, 1980

Rule

2 Definitions (Agricultural Burning, Brush Treated, Garbage, and Bulk Storage Plant)
3 Enforcement
11 Reporting—Recording
11.1 Agricultural Waste Burning Restrictions
11.2 No title (Specifies Burning Period)
13 No-Burn Days
13.1 Restricted Burn and Quota Burn Day
14 Preparation of Material to be Burned
14.1 Range Improvement Burning
14.2 Forest Management Burning
14.3 Rice Straw Burning
15 Acreage Limitation
16 Exceptions (From Agricultural Burning Rules)
19 Burning on No Burn Days
21 Fire Permit Districts
21.1 No title (Certification of Permitters)
22 Permit Form
75 Prohibition Under State Law
81 Exceptions (From Open Burning Rules)
83 Petroleum Storage and Dispensing
83.1 Service Stations and Bulk Storage Plants
83.2 Petroleum Solvents
96 Variances
110 Applicable Articles of the Health and Safety Code
112 Contents of Petitions

Siskiyou County

January 28, 1981

Rule

(No Number) General Provisions
Article I Definitions
Article II Notification of Burning Conditions
Article III Exceptions
Article IV Enforcement
Article V-5.1 Prohibitions—General
Article V-5.2 Prohibitions—Range Improvement Burning
Article VI Burning Permits
Article VII Agricultural Burning Reports

Yolo-Solano

November 3, 1980

Rule

1.2 Definitions (Agricultural Burning for Agricultural Operations and Range Improvement, and No Burn Day)
6.1 Prohibitions
6.3 Special Permits

Under Section 110 of the Clean Air Act as amended, and 40 CFR Part 51, the Administrator is required to approve or disapprove these regulations as State Implementation Plan (SIP) revisions. All the rules listed above have been evaluated and found in accordance with EPA policy and 40 CFR Part 51.

This notice approves all the rule revisions listed above and incorporates them into the California SIP. EPA's approval of the above revisions to the California SIP is being done without prior proposal because the revisions are not controversial. The public is advised that this approval action will be effective March 29, 1982. However, if notice is received by EPA within 30 days that someone wishes to submit adverse or critical comments, the approval action will be withdrawn and a subsequent notice will be published before the effective date. The subsequent notice will indefinitely postpone the effective date, modify the final action to a proposed action, and establish a comment period.

Under Executive Order 12291, EPA must judge whether a rulemaking action is "major." Further, under the Regulatory Flexibility Act, EPA must assess the effect of the rulemaking action on "small entities." This regulation is not "major" because it approves state and local actions and imposes no new requirements. I hereby

certify that the action will not have a significant economic impact on a substantial number of small entities.

Incorporation by reference of the State Implementation Plan for the State of California was approved by the Director of the Federal Register on July 1, 1981.

(Secs. 110, and 301(a) of the Clean Air Act, as amended (42 U.S.C. 7410 and 7601(a)))

Dated: January 18, 1982.

Anne M. Gorsuch,

Administrator.

Subpart F of part 52 of Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

Subpart F—California

1. Section 52.220 is amended by adding paragraphs (c)(96) (ii)–(iv) and (c)(98)(ii) as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(96) * * *

(ii) Butte County APCD.

(A) New or amended rules 1–8, 1–8.1, 1–10, 1–13, 1–14, 3–1, 3–2, 3–6, 3–11, 3–11.2, 3–11.3, 3–12, 3–12.1, 3–12.2, 3–14, 3–15, 3–16, and 3–16.1.

(iii) Glenn County APCD.

(A) New or amended rules 2 (a,i,v, and aa), 3, 11, 11.1, 11.2, 13, 13.1, 14, 14.1, 14.2, 14.3, 15, 16, 19, 21, 21.1, 22, 75, 81, 83, 83.1, 83.2, 96, 110, and 112.

(iv) Yolo-Solano APCD.

(A) New or amended rules 1.2 (a and g), 6.1 and 6.3.

* * * * *

(98) * * *

(ii) Siskiyou County APCD.

(A) New or amended agricultural burning regulations consisting of "General Provisions" and Articles I–VII.

* * * * *

2. Section 52.255 is amended by adding paragraph (b)(3)(xiv) as follows:

§ 52.255 Gasoline transfer vapor control.

* * * * *

(b) * * *

(3) * * *

(xiv) Glenn County APCD.

* * * * *

[FR Doc. 82-1849 Filed 1-25-82; 8:45 am]

BILLING CODE 6560-38-M

40 CFR Part 52

[A-9-FRL—2020-1]

California Rule Revisions for Six Sacramento Valley Air Pollution Control Districts; Approval and Promulgation of Implementation Plan

AGENCY: Environmental Protection Agency.

ACTION: Final rulemaking.

SUMMARY: On December 22, 1980, EPA proposed to take action on revisions to the rules of the Butte County, Sacramento County, Shasta County, Sutter County, Yuba County, and Yolo-Solano Air Pollution Control Districts (APCDs) in California's Sacramento Valley. Comments were received which caused EPA to reevaluate certain rules. EPA is today approving under the Clean Air Act rule revisions for the above six APCDs.

EFFECTIVE DATE: February 25, 1982.

ADDRESS: A copy of the revisions is located at: The Office of the Federal Register, 1100 "L" Street, NW., Washington, D.C. 20005.

FOR FURTHER INFORMATION CONTACT: Louise P. Giersch, Director, Air & Hazardous Materials Division, Environmental Protection Agency, Region 9, 215 Fremont Street, San Francisco, CA 94105; Attn: Douglas Grano (415) 974–8222.

SUPPLEMENTARY INFORMATION: From October 15, 1979 through April 2, 1980, the California Air Resources Board (ARB) submitted to EPA revisions to the rules of six Sacramento Valley APCDs for inclusion into the California State Implementation Plan. The majority of rules submitted make minor administrative revisions to previously approved rules. New rules considered in today's notice concern volatile organic compounds, agricultural burning, and emergency variances.

Comments were received on the December 22, 1980 (45 FR 84096) proposal from the ARB and the Sacramento and Yuba County APCDs. The comments concerned the proposed disapproval of Sacramento County Rules 7 (*Ringelmann Chart*), 24 (Specific *Contaminants*), and 30 (*Exception*), and Yuba County Rules 2.1(j) (*Exceptions to Rule 2.0*) and 2.4(g) (Exception to Rule 2.3). The above rules were reevaluated by EPA and are being approved in today's notice because EPA now agrees that the rules will not interfere with maintenance of the National Ambient Air Quality Standards in the affected areas. Comments received are identified and responded to in EPA's "Public Comment Technical Support Document for the Sacramento Valley, Six Districts," which is available at the EPA Library in Washington, D.C. and the Region 9 Office.

This notice takes final action to approve those rules proposed for approval on December 22, 1980, with the exception of a number of rules which have been superseded by recent rule revisions. Also approved today are the rules listed above on which public comments were received. All of the rules approved in this notice have been evaluated and found consistent with the Clean Air Act and 40 CFR Part 51 requirements.

Under Executive Order 12291, EPA must judge whether a rulemaking action is "major." Further, under the Regulatory Flexibility Act, EPA must assess the effect of the rulemaking action on "small entities." This regulation is not "major" because it approves state and local actions and imposes no new requirements. I hereby certify that the action will not have a significant economic impact on a substantial number of small entities.

Incorporation by reference of the State Implementation Plan for the State of California was approved by the Director of the Federal Register on July 1, 1981.

(Secs. 110 and 301(a) of the Clean Air Act as amended (42 U.S.C. 7410 and 7601(a)))

Dated: January 18, 1982.

Anne M. Gorsuch,

Administrator.

Subpart F of Part 52 of Chapter I, Title 40, of the Code of Federal regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

Subpart F—California

1. Section 52.220, paragraphs (c)(51)(xvi), (51)(xvii), (52) (xvi), (xviii), and (xix), (54) (iv), (vi), (vii), and (viii), (58) (vi), and (vii), (67)(iv), (70)(iii), and (79)(vi) are added as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(51) * * *

(xvi) Sacramento County APCD.

(A) Amended Rule 71.

* * * * *

(xvii) Shasta County APCD.

(A) Amended Rule 3.4.

* * * * *

(52) * * *

(xvi) Yuba County APCD.

(A) New or amended Rules 1, Section 1 (except Silviculture Deletion), 1.1

(except PM), 2.0–2.2, 2.4 except (a), 2.5–2.12, 2.15–2.20, 2.22–2.24, 2.27, 2.30, Section 5 (Deletion), 5.0–5.3, 5.5–5.19, 6.1–6.7, 7, 7.1 and 8.1.

* * * * *

(xviii) Shasta County APCD.

(A) New or amended Rules 1.1, 1.2, 2.11, 2.12, and 3.2 (except rows (vi) and (vii)).

(xix) Yolo—Solano APCD.

(A) New or amended Rules 4.1–4.3.

* * * * *

(54) * * *

(iv) Yolo—Solano APCD.

(A) Amended Rule 5.4.

* * * * *

(vi) Sutter County APCD.

(A) New or amended Rules 1.4, 2.8.1 (Deletion), 2.17, and 2.82.

(vii) Yuba County APCD.

(A) Amended Rule 2.26.

(viii) Butte County APCD.

(A) New Rule 2–12.e.

(58) * * *

(vi) Shasta County APCD.

(A) New or amended Rules 1.2, 3.14, and 3.15.

(vii) Yolo—Solano APCD.

(A) Amended Rules 2.8 and 6.6.

(67) * * *

(iv) Sacramento County APCD.

(A) New or amended Rules 7, 24, 25, 28, 30, and 53.

* * * * *

(70) * * *

(iii) Shasta County APCD.

(A) Amended Rule 3.3.

* * * * *

(79) * * *

(vi) Shasta County APCD.

(A) New Rule 3.17.

* * * * *

[FR Doc. 82-1853 Filed 1-25-82; 8:45 am]

BILLING CODE 6560-38-M

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40 CFR Part 123

[SW-9-FRL-2035-1]

Arizona Application for Interim Authorization, Phase I, Hazardous Waste Management Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public comment period and recommencement of review period.

SUMMARY: EPA regulations to protect human health and the environment from improper management of hazardous waste were published in the **Federal Register** on May 19, 1980 (40 FR 33063).

These regulations include provisions for authorization of State programs to operate in lieu of the Federal program. On November 3, 1980, the State of Arizona applied for Phase I Interim Authorization. Today EPA is announcing the availability for public review of additional material submitted by the State in support of its application, and is giving notice that the review period for the Arizona application is being recommended.

DATE: Written comments on the additional material submitted by Arizona must be received by February 25, 1982.

ADDRESSES: Copies of the material under review are available at the following addresses for inspection and copying by the public:

1. Arizona Department of Health Services, Bureau of Waste Control, 1740 West Adams Street, Phoenix, AZ 85007, (602) 255–1164.

2. The State depositories in each Arizona county. Please call the number above for specific references.

3. Environmental Protection Agency, Region 9, Library, 6th Floor, 215 Fremont Street, San Francisco, CA 94105, (415) 974–8076.

Comments and/or requests for a hearing should be sent to: Alexis Strauss, Hazardous Materials Branch, Environmental Protection Agency, Region 9, 215 Fremont Street, San Francisco, CA 94105, (415) 974–8245.

FOR FURTHER INFORMATION CONTACT: Alexis Strauss, (415) 974–8245.

SUPPLEMENTARY INFORMATION: In the May 19, 1980 **Federal Register** (45 FR 33063) the Environmental Protection Agency promulgated Phase I of its regulations pursuant to Subtitle C of the Resource Conservation and Recovery Act of 1976 (as amended), to protect human health and the environment from the improper management of hazardous waste. EPA's Phase I regulations establish, among other things: The identification and listing of hazardous waste; the standards applicable to generators and transporters of hazardous wastes, including a manifest system; and the "interim status" standards applicable to existing hazardous waste management facilities before they receive permits.

The May 19 regulations also include provisions under which EPA can authorize qualified State hazardous waste management programs to operate in lieu of the Federal program. The regulations provide for a transition period in which qualified State programs can be granted Interim Authorization. The Interim Authorization program is being implemented in two phases, corresponding to the two phases in which the underlying Federal program will take effect. In order to qualify for Interim Authorization, the State hazardous waste program must, among other things:

(1) Have been in existence prior to August 17, 1980, and

(2) Be "substantially equivalent" to the Federal program.

A full description of the requirements and procedures for State Interim Authorization is included in 40 CFR Part 123 Subpart F, (45 FR 33479).

On November 3, 1980 the State of Arizona applied to EPA for Phase I interim authorization of its hazardous waste management program. On November 7, 1980, EPA issued a notice of a public hearing and comment period on the State's application in the **Federal Register.** The public hearing was held in Phoenix on December 11, 1980, and the comment period remained open until the close of the hearing. In order to meet the requirements of interim authorization, the State issued emergency amendments to the original (May 2, 1980) regulations on October 23, 1980. Final regulations, addressing several concerns raised by the regulated community, were adopted on October 14, 1981. These regulations were based on broad and various State statutory provisions, which provide the requisite legal basis for their promulgations, as certified by the Arizona Attorney General.

As the final regulatory amendments had not been adopted when the emergency regulations expired, Arizona requested an extended consideration of the application by EPA. The formal review period for the interim authorization application is hereby recommended. Those portions of the application which have been changed since the previous public notice are now available for public review and comment. EPA will make a final determination on the application within 90 days of the date of this notice.

Sonia F. Crow,

Regional Administrator.

[FR Doc. 82-1924 Filed 1-25-82; 8:45 am]

BILLING CODE 6560-38-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 122

Health Systems Agencies

AGENCY: Public Health Service.

ACTION: Amendment to final rule.

SUMMARY: This regulation amends the Department's regulation governing the designation and funding of health

systems agencies (HSAs) to provide that HSAs will no longer be required to conduct appropriateness reviews, conduct reviews of the proposed uses of Federal funds, or collect, and make available to the public, the rates charged for each of the twenty-five most frequently used hospital services in their States. The intended effect of this regulation is to reduce the functional burden on HSAs during a period of reduced funding.

EFFECTIVE DATE: The amendment made by this regulation shall take effect October 1, 1981.

FOR FURTHER INFORMATION CONTACT: Libby Merrill, Director, Policy Coordination Staff, Bureau of Health Planning, Room 6–22, 3700 East-West Highway, Hyattsville, Maryland 20782, (301) 436–6870.

SUPPLEMENTARY INFORMATION:

Regulatory Flexibility Act and Executive Order 12291

The Department of Health and Human Services has determined that this final rule will not significantly impact on small business and therefore does not require preparation of a Regulatory Flexibility Analysis under the Regulatory Flexibility Act, Pub. L. 96–354.

The Department also has determined that this final rule is not a "major rule" under Executive Order 12291. Thus, a regulatory impact analysis is not required because it will not:

(1) Have an annual effect on the economy of $100 million or more;

(2) Impose a major increase in costs or prices for consumers; individual industries; Federal, State or local government agencies; or geographic regions; or

(3) Result in significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

General

The Omnibus Budget Reconciliation Act of 1981, Pub. L. 97–35, contains a number of amendments to Title XV of the Public Health Service Act. Section 934(b) of the Reconciliation Act allows the Secretary to waive any or all of the requirements for HSAs to conduct appropriateness reviews, conduct reviews of the proposed uses of Federal funds, and/or collect and make available to the public rates charged for each of the twenty-five most frequently used hospital services in their States. The waiver can be made either on a case by case basis for each HSA, or for all HSAs by regulation if the Secretary determines that there are not sufficient funds for HSAs to meet these requirements.

The Secretary has determined that because of the reduced level of funding authorized for HSAs in FY 1982, HSAs will not have sufficient funds to conduct these three required activities. Thus, under the amended regulations set forth below, the Secretary has waived the requirements to perform the three functions by providing each HSA with the discretion to determine which, if any, of the three functions it has sufficient resources to perform. However, if, in exercising this discretion, an HSA elects to perform either or both of the review functions, it must do so in accordance with the regulations, 42 CFR Part 122, Subparts E and/or G. If an HSA elects to collect and make available hospital rates, it should follow the Departmental guidance (Program Policy Notice 80–19, dated May 9, 1980). In addition, each HSA that elects to perform any or all of these functions should notify its HHS Regional Office and the general public within its health service area of its decision.

Other Amendments

Public Law 97–35 also amends Title XV in these respects: reduces the total authorizations for the health planning program; delays by 12 months the penalty provision applicable to States that do not have a fully designated State health planning and development agency (SHPDA) by a certain date; extends the allowable time a SHPDA can be conditionally designated; raises the Federally required minimum thresholds for certificate of need reviews; allows chief executive officers of States and Territories to apply to the Secretary for designation under section 1536 of the Public Health Service Act; reduces the minimum Federal grants that HSAs can receive; allows HSAs to receive contributions from health insurers; and modifies the HMO exemption criteria (effective October 1, 1982) in the certificate of need program. Pub. L. 97–35 also deletes Title V funds from the funds that can be withheld under Section 1122 of the Social Security Act, for health institutions' capital expenditures that were not approved. These amendments, as well as amendments contained in the Health Planning and Resources Development Amendments of 1979, Pub. L. 96–79, and the Health Programs Extension Act of 1980, Pub. L. 96–538, will be incorporated as appropriate in program regulations as the Department completes its current program of reviewing, revising and streamlining the health planning regulations.

Comments

The Secretary has determined that for this regulation public participation in rulemaking would be impractical and contrary to the public interest and that good cause exists for making this regulation effective on October 1, 1981. Publishing these final rules at the earliest date will afford HSAs the opportunity to eliminate immediately their expenditures for these functions, and channel their remaining funds into the functions having the greatest effect on the health systems in their areas.

Accordingly, Subpart B of 42 CFR Part 122 is amended as set forth below.

Dated: November 17, 1981.

Edward N. Brandt, Jr.,

Assistant Secretary for Health.

Approved: January 5, 1982.

Richard S. Schweiker,

Secretary.

PART 122—HEALTH SYSTEMS AGENCIES

Title 42 is amended in § 122.107 by revising paragraphs (c)(15) and (c)(17) and by adding a new paragraph (c)(19).

1. In § 122.107, paragraphs (c)(15) and (c)(17) are revised and a new paragraph (c)(19) is added as follows:

§ 122.107 Full designation agreements.

* * * * *

(c) * * *

(15) The agency may review on a periodic basis in accordance with procedures and criteria established pursuant to section 1532 of the Act and applicable regulations of the Secretary (42 CFR Part 122, Subpart G), at least those institutional and home health services which are offered in the health service area of the agency and with respect to which goals have been established in the State health plan and shall make recommendations to the State Agency for each State in which the agency's health service area is located respecting the appropriateness in the area of such services.

* * * * *

(17) The agency may review and approve or disapprove, or may review and comment upon, as appropriate, in accordance with procedures and criteria established pursuant to section 1532 of the Act and applicable regulations of the Secretary (42 CFR Part 122, Subpart E) each specified proposed use within its health service area of Federal funds in accordance with section 1513(e) of the

Act and applicable regulations of the Secretary.

* * * * *

(19)(i) The agency may collect annually on a form developed in consultation with the State Agency (or agencies) the rates charged for each of the twenty-five most frequently used hospital services in the State (or States) including the average semiprivate and private room rates.

(ii) Each health systems agency shall make available to the public for inspection and copying (at a reasonable expense to the public) any information supplied to the health systems agency pursuant to this subparagraph in readily understandable language and in a manner designed to facilitate comparisons among the hospitals in the health systems agency's health service area.

* * * * *

[FR Doc. 82-1929 Filed 1-25-82; 8:45 am]

BILLING CODE 4160-15-M

ACTION

45 CFR Ch. XII

Listing of OMB Control Numbers in Action Regulations

AGENCY: Action.

ACTION: Technical amendments.

SUMMARY: This document amends ACTION's regulations to include OMB control numbers in the specific regulations where current information collection requirements are described.

EFFECTIVE DATE: January 26, 1982.

FOR FURTHER INFORMATION CONTACT: Arthur F. Fergenson, General Counsel, ACTION, 806 Connecticut Avenue, N.W., Washington, D.C. 20525, 202-254-3116.

SUPPLEMENTARY INFORMATION: In accordance with the provisions of the public protection clause (Section 3512) of the Paperwork Reduction Act of 1980, Pub. L. 96-511, ACTION published in 47 FR 63, January 4, 1982, a notice listing the existing recordkeeping requirements, showing regulatory citations, sections containing the requirements, and current OMB numbers.

Following the text of each paragraph cited in the list, add parenthetically the OMB number provided:

CFR section	OMB No.
45 CFR 1203.5(a)(1)	3001-0016
45 CFR 1207.2-2	116-R0351
45 CFR 1208.2-2	116-R0351
45 CFR 1209.2-2(a)	116-R0351

Dated in Washington D.C., on January 15, 1982.

Thomas W. Pauken,

Director, ACTION.

[FR Doc. 82-1851 Filed 1-25-82; 8:45 am]

BILLING CODE 6050-01-M

INTERSTATE COMMERCE COMMISSION

49 CFR Part 1056

[Ex Parte No. MC-19 (Sub-No. 36)]

Household Goods Carriers Operational Practices

AGENCY: Interstate Commerce Commission.

ACTION: Notice of availability of corrected copies of modified form OCP-100.

SUMMARY: The Commission's Office of Compliance and Consumer Assistance is making available to the public corrected copies of Form OCP-100, Your Rights and Responsibilities When You Move. The text of the publication contains recent modifications and corrections of certain typographical errors which appeared in the most recent publication of this document. This action is intended to facilitate compliance by household goods carriers with that part of the operational rules which requires that this publication be furnished by such carriers to all prospective individual shippers.

ADDRESS: Corrected Form OCP-100 may be obtained from the Office of Compliance and Consumer Assistance, Room 7205, Interstate Commerce Commission, Washington, D.C. 20423.

FOR FURTHER INFORMATION CONTACT: Ray G. Atherton, Jr., (202) 275-7844 or Patricia M. Schulze, (202) 275-7841.

Dated: January 19, 1982.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-1926 Filed 1-25-82; 8:45 am]

BILLING CODE 7035-01-M

Proposed Rules

Federal Register
Vol. 47, No. 17
Tuesday, January 26, 1982

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 AGRICULTURE

Rural Electrification Administration

7 CFR Part 1701

Proposed Revision of Attachment A to REA Bulletin 20–14, Supplemental Financing for Loans Considered Under Section 4 of the Rural Electrification Act

AGENCY: Rural Electrification Administration, USDA.

ACTION: Proposed rule.

SUMMARY: REA proposes to revise Attachment A to REA Bulletin 20–14, Supplemental Financing for Loans Considered Under Section 4 of the Rural Electrification Act. This bulletin is used in determining the REA/supplemental loan percentages for concurrent loans. As a result of the recent amendment to the RE Act, and in accordance with existing REA policy, 140 borrowers which had been eligible to receive 100 percent of their financing needs from REA at a 2 percent interest rate will be required to obtain up to 30 percent of their financing needs from non-REA sources. The remaining portion of their financing needs would be provided by an REA insured loan at a 5 percent interest rate. This proposed action will amend the REA/supplemental lending ratios for those former statutory 2 percent borrowers (those with two or fewer consumers per mile or an average adjusted plant revenue ratio of over 9.0 as of December 31, 1980) to allow them to obtain 90 percent of their financing needs from an REA insured loan at a 5 percent interest rate and the remaining 10 percent from non-REA lenders. It will apply to loan requests received by REA after July 24, 1981. All other REA borrowers will be unaffected by this change.

DATE: Public comments must be received by REA no later than March 29, 1982.

ADDRESS: Submit written comments to Charles R. Weaver, Director, Electric Loans and Management Division, Rural Electrification Administration, Room 3342, South Building, U.S. Department of Agriculture, Washington, D.C. 20250.

FOR FURTHER INFORMATION CONTACT: Milton E. Wright, Borrowers Management Branch—Electric Loans and Management Division, Room 3338, South Building, U.S. Department of Agriculture, Washington, D.C. 20250, Telephone (202) 382–1936.

The Draft Regulatory Impact Analysis describing the options considered in developing this proposed rule and the impact of implementing each option is available on request to the above address.

SUPPLEMENTARY INFORMATION: Pursuant to the Rural Electrification Act, as amended, (7 U.S.C. 901 et seq.), REA proposes to amend Appendix A–REA Bulletins by revising the first page of Attachment A of REA Bulletin 20.14, Supplemental Financing for Loans Considered Under Section 4 of the Rural Electrification Act, as follows:

Attachment A—Supplemental Loan Criteria for Electric Distribution Borrowers

I. *Borrower Eligibility for Supplemental Financing:* Borrowers in either of the following two categories will be expected, unless there are exceptional circumstances as determined by the Administrator, to obtain a portion of their long-term loan funds from a supplemental financing source:

A. Borrowers which have not previously received a concurrent REA and non-REA loan and which have a:

1. Times Interest Earned Ratio (TIER) (average of highest two ratios in last three years) of 1.5 or more, and

2. Debt Service Coverage (DSC) (average of highest two of last three years) of 1.25 or more.

B. Borrowers which have received one or more concurrent REA and non-REA loans.

II. *Loan Proportions for Concurrent Loans:*

A. The loan proportions for concurrent loans to borrowers, who are eligible for supplemental financing as set forth above, with an average consumer density (DENSITY) of two or fewer per mile or an average adjusted plant revenue ratio (APRR) of over 9.0 as of December 31, 1980, will be 90 percent from REA and 10 percent from supplemental sources.

B. The loan proportions for concurrent loans to all other borrowers, who are eligible for supplemental financing as set forth above, will be based on the borrower's plant revenue ratio (PRR) as follows:

PRR	REA percentage	Supplemental lender percentage
9.01 and above	90	10
8.01 to 9.0	80	20
8.00 and below	70	30

This proposed action has been issued in conformance with Executive Order 12291, Federal Regulation, and has been determined to be "not major." A Regulatory Flexibility Analysis is not required, and an OBM Circular A–95 review is not applicable to this action.

REA is initiating rulemaking procedures for a complete review and possible revision of REA Bulletin 20–14. The action proposed in this notice should be viewed as a temporary policy.

Among the various options which REA considered was allowing former statutory 2 percent borrowers to obtain 100 percent of their financing needs from REA at a 5 percent interest rate. This option would not encourage the use of non-REA financing, and it would increase the demand for REA insured loan funds. REA also considered taking no action. This option would create a hardship for some borrowers in terms of both the impact of increased interest costs and the impact of establishing new financing arrangements with non-REA lenders.

The primary objective of the action selected is to ease for certain borrowers the transition from 100 percent REA financing to partial supplemental financing and the resulting increase in interest costs. As a result of the proposed action, these borrowers will be required to establish and use supplemental lending sources. This action is also consistent with previous REA policy. When borrowers were first required to use outside lending sources REA used a transition period to ease the impact on the borrowers of going to partial supplemental financing.

All written submissions made pursuant to this action will be made available for public inspection during regular business hours from the above office. This program is listed in the Catalog of Federal Domestic Assistance as 10.850—Rural Electrification Loans and Loan Guarantees.

Dated: January 18, 1982.
Jack Van Mark,
Acting Administrator.
[FR Doc. 82-1875 Filed 1-25-82; 8:45 am]
BILLING CODE 3410-15-M

7 CFR Part 1701

Proposed Attachment C to REA Bulletin 20-14, Supplemental Financing for Loans Under Sections 4 and 305 of the Rural Electrification Act

AGENCY: Rural Electrification Administration, USDA.

ACTION: Proposed rule.

SUMMARY: REA proposes to add an Attachment C to REA Bulletin 20-14, Supplemental Financing for Loans Considered Under Section 4 of the Rural Electrification Act. This attachment will amend this bulletin and all bulletins inconsistent herewith to provide that distribution and subtransmission purposes will be given priority in the making of loans under Sections 4 and 305 of the Rural Electrification Act. Generally generation and bulk transmission facilities, headquarters facilities, acquisitions, general plant equipment and other purposes will be financed by the borrower from non-REA loans or general funds, subject to approval requirements set forth in REA Bulletin 103-2. Attachment C also sets forth a procedure for determining the supplemental proportions for concurrent loans to power supply borrowers.

The proposed Attachment C will ensure that all distribution and power supply borrowers are treated consistently in the financing of subtransmission facilities and enable REA to make optimum use of available REA loan funds.

DATE: Public comments must be received by REA no later than March 29, 1982.

ADDRESS: Submit written comments to Charles R. Weaver, Director, Electric Loans and Management Division, Rural Electrification Administration, Room 3342, South Building, U.S. Department of Agriculture, Washington, D.C. 20250.

FOR FURTHER INFORMATION CONTACT: Milton E. Wright's Borrowers' Management Branch, Electric Loan and Management Division, Room 3338, South Building, U.S. Department of Agriculture, Washington, D.C. 20250, telephone (202) 382-1936.

All written submission made pursuant to this action will be available in Room 3342, South Building, U.S. Department of Agriculture, Washington, D.C. This program is listed in the Catalog of Federal Domestic Assistance as 10.850—Rural Electrification Loans and Loan Guarantees.

The Draft Regulatory Impact Analysis describing the options considered in developing this proposed rule and the impact of implementing each option is available on request to the above address.

SUPPLEMENTARY INFORMATION: Pursuant to the Rural Electrification Act, as amended (7 U.S.C. 901 et seq.), REA proposes to amend REA Bulletin 20-14, Supplemental Financing for Loans Under sections 4 and 305 of the Rural Electrification Act, by adding an Attachment C, Loans for Electric Facilities, to the bulletin.

This proposed action has been issued in conformance with Executive Order 12291, Federal Regulation, and has been determined to be "not major." A Regulatory Flexibility Analysis is not required, and an OMB Circular A-95 review is not applicable to this action.

REA is also initiating rulemaking procedures for a complete review and possible revision of REA Bulletin 20-14.

Among the various options which REA considered was revising Bulletin 20-14 to specify that REA loans would be limited to distribution *facilities* only. REA also considered apportioning available loans to distribution *borrowers* only. These options would not ensure that all borrowers would be treated consistently for financing of facilities most closely related to electric distribution. In addition, the option selected makes optimum use of available REA electric loans for distribution and subtransmission facilities. The text of Attachment C follows:

Attachment C—Financing for Electric Facilities

I. *Priorities for REA Loans:* To make optimum use of available REA loan funds and to ensure that borrowers are treated consistently in the financing of different types of facilities, priority will be given to REA loans for the following purposes:

A. Distribution facilities.

B. Subtransmission facilities—those between (1) the high side voltage level of transformation to the applicable primary distribution voltage and (2) the low side of the next higher voltage transformation.

Except as otherwise determined by the Administrator, borrowers should use general funds or non-REA loans for other purposes. REA will consider accommodating the lien of its mortgage to facilitate financing from other lenders for such purposes. Loan guarantees will be available for bulk transmission and generation facilities in accordance with REA Bulletin 20-22 and for such other purposes as the Administrator may determine on a case-by-case basis.

II. *Supplemental Loan Proportions:*

A. *Distribution Borrowers:* Supplemental loan proportions for distribution borrowers are specified in Attachment A (or revisions thereof) of this bulletin.

B. *Power Supply Borrowers:* When a power supply borrower requests an REA loan, it will be required, unless otherwise determined by the Administrator, to obtain a supplemental loan. The supplemental loan proporition for a power supply system will be the arithmetic mean of the supplemental loan proportions for which its distribution system members would qualify.

Example—A power supply borrower with four members with supplemental loan proportions as follows would have a supplemental loan proportion of 22.5%:

	REA proportion (percent)	Supplemental proportion (percent)
Member A	70	30
Member B	70	30
Member C	80	20
Member D	90	10
		*90

*90 divided by 4 equal 22.5 percent.

Dated: January 18, 1982.
Jack Van Mark,
Acting Administrator.
[FR Doc. 82-1866 Filed 1-25-82; 8:45 am]
BILLING CODE 3410-15-M

DEPARTMENT OF THE TREASURY

Comptroller of the Currency

12 CFR Part 2

[Docket No. 82-1]

Disposition of Credit Life Insurance Income

AGENCY: Comptroller of the Currency (OCC), Treasury.

ACTION: Proposed rule.

SUMMARY: OCC proposes to amend an existing regulation, 12 CFR Part 2, to reflect recommendations of the Federal Financial Institutions Examination Council. Among other things, the proposed amendments will permit limited bonuses and incentives to bank employees for credit life insurance sales and will define the compensation to be

paid to a national bank by an affiliate to which credit life insurance income is credited. OCC also proposes the repeal of certain provisions in 12 CFR Part 2 thought to be unnecessary.

DATE: Comments must be received by March 10, 1982.

ADDRESS: Send comments to Docket No. 82-1, Communications Division, Third Floor, Office of the Comptroller of the Currency, Washington, D.C. 20219, Attention: Marie Giblin. Telephone (202) 447-1800. Comments will be available for public inspection and photocopying.

FOR FURTHER INFORMATION CONTACT: Ford Barrett, Assistant Chief Counsel, Comptroller of the Currency, Washington, D.C. 20219, telephone 202/447-1896.

SUPPLEMENTARY INFORMATION:

Special Studies

The Secretary of the Treasury has certified that the proposed amendments do not require a regulatory flexbility analysis on the ground that the amendments will have no significant economic impact. As proposed, the amendments will change several minor details of a long standing OCC regulation and bring it into conformity with a policy statement recommended by the Federal Financial Institutions Examination Council. In addition, the amendments will permit OCC to delete several provisions in the existing regulation that are thought to be unnecessary.

The amendments proposed below do not constitute a major rule under section 3 of Executive Order 12291, and therefore no regulatory impact analysis is necessary. The Federal Financial Institutions Examination Council concluded that its recommended policy statement, from which the proposed amendments are drawn, will have a beneficial impact on financial institutions. The effect on bank holding companies and individuals was assessed as immaterial and minor, respectively. Since OCC's regulation has been in effect for more than three years, the impact of the proposed amendments should not differ from the Council's assessment. In view of the proposed deletion of provisions relating to minority shareholders and board of director approvals, the impact of the proposed amendments should be even more favorable.

Background

In 1978 OCC promulgated a regulation, 12 CFR Part 2, prohibiting individual bank employees, officers, directors and principal shareholders from retaining for their own personal benefit commissions from the sale of credit life, health and accident insurance ("credit life insurance") to loan customers. Three years later, on December 31, 1980, the Federal Financial Institutions Examination Council ("Council") adopted, after soliciting public comments (45 FR 1152), a policy statement on the same subject with the same thrust, and recommended it to its member agencies. The Council's policy statement and the OCC regulation have the same overall purpose and effect, but differences exist in certain details. Moreover, as a result of the Council's action, OCC believes portions of its regulation are no longer necessary. Accordingly, OCC now proposes to amend 12 CFR Part 2 to achieve consistency with the Council's policy statement and to delete unnecessary provisions.[1]

Specifically, the following additions and deletions are proposed:

(1) The citations to OCC's rulemaking authority in 12 CFR 2.1 will be amended to include 12 U.S.C. 93a and 12 U.S.C. 1818(n). The former is OCC's general rulemaking authority and the latter is the rulemaking provision in the Financial Institutions Supervisory Act of 1966, 80 Stat. 1046, 1052-1053, as amended. The reference in the existing regulation to 12 U.S.C. 1818(b) will be deleted.

(2) The definition of "credit life insurance" in 12 CFR 2.3(e) will be expanded to include mortgage life and disability insurance. The term "mortgage life and disability insurance" is intended to cover any insurance designed to repay a mortgage loan on the death or disability of the borrower.

(3) A new sentence will be added to 12 CFR 2.4(a) to clarify that bank employees and officers may receive bonuses or incentives based on credit life insurance sales. Bonuses must be paid out of the bank's funds and may not be given more frequently than quarterly. The aggregate value of the bonuses and incentives in any one year may not exceed 5 percent of the recipient's annual salary. Alternatively, bonuses paid to any one individual during the year may not exceed 5 percent of the average salary of all loan officers participating in the plan.

According to the Council, "Allowing limited bonuses will respond to the comment voiced by many financial institutions that an incentive is required to motivate a loan officer to sell credit life insurance, while still reducing the potential for abusive sales practices." Moreover, OCC has previously interpreted 12 CFR Part 2 as permitting limited bonuses based on credit life insurance sales. See Interpretive Letters No. 26, 45 and 86 published at CCH Fed. Banking L. Rep. ¶85,101, ¶85,120 and ¶85,161, respectively.

(4) 12 CFR 2.4(b) will be amended to reflect the Council's recommendation that credit life income should be credited to the income accounts of the bank (or its operating subsidiary) and not to the bank's individual employees, officers, directors, principal shareholders, their interests, or other affiliates. However, such income may be credited to an affiliate operating under the Bank Holding Company Act or to a trust for the benefit of all shareholders, provided the bank receives reasonable compensation for use of bank personnel, premises and good will in the sale of the insurance. As a general rule, "reasonable compensation" means an amount equivalent to at least 20 percent of the affiliate's net income attributable to the financial institution's credit life insurance sales.

OCC has long held the view that the bank is the proper place to credit all income from the sale of credit life insurance on bank loans. See, e.g., 42 FR 48518, 48521 (1977). However, OCC recognizes that the Board of Governors of the Federal Reserve System has approved numerous applications under the Bank Holding Company Act on the assumption that this income would be credited directly to the holding company for use in servicing its debt. Accordingly, 12 CFR Part 2 currently permits this income to be credited to affiliates. OCC continues to believe this procedure is acceptable provided that reasonable compensation is paid to the bank. As the Council stated in the commentary accompanying its recommended policy statement, the reasonable compensation requirement "recognizes both the role of the financial institution in generating credit life insurance sales and the rights of any minority stockholders to share in the benefits of such plans."

Under the Council's recommended policy statement "income" includes commissions and experience rating credits (sometimes referred to as retrospective rate credits); it does not refer to that portion of the premium required to cover the underwriting risk.

The reasonable compensation requirement is intended to work as follows. Where a bank holding company operates an insurance agency selling credit life insurance to both the bank's customers and to customers of the

[1] The Board of Governors of the Federal Reserve System has adopted the Council's recommended policy statement. 46 FR 24690 (May 1, 1981).

holding company's finance company subsidiary, the minimum reasonable compensation to the bank would be 20 percent of the net income from credit life sales made by the bank. Where the entire credit life premium is credited to the holding company's reinsurance company subsidiary, there are two choices for satisfying the reasonable compensation requirement. Under the first, the bank would be paid an amount equivalent to 20 percent of the reinsurance company's net income attributable to the bank's credit life sales. Under the second, the bank would be paid 20 percent of the net income of a pro forma insurance agency affiliate receiving the ongoing rate of commission. Thus, if the standard rate of commission were 30 percent of the premium and the agency on a pro forma basis grossed 30 percent of all premiums paid by bank loan customers, the reinsurance affiliate would pay the bank approximately 20 percent of the 30 percent gross. (A small allowance could be made for the pro forma agency's expenses so that the 20 percent factor would be applied to a net figure.)

OCC understands that some states have placed limitations on the compensation a bank may receive from an insurer, including a bank holding company's reinsurance company subsidiary. For example, § 185.9 (a) and (c) of Regulation No. 27–A issued by the State of New York Insurance Department appears to place some limitations on compensation.[2] However, the limitations do not appear necessarily to conflict with the 20 percent of net income approach recommended by the Council and described above. Moreover, since § 185.9(c) allows the Superintendent of Insurance to approve compensation arrangements on a case-by-case basis, the Comptroller's requirement may be found to be acceptable. Finally, even if a direct conflict exists, the Comptroller's reasonable compensation requirement may supercede contrary state regulations since the sale of credit life insurance through a national bank may constitute the business of banking subject to the Comptroller's exclusive supervision under 12 U.S.C. 481 and 484 and not the business of insurance within the meaning of the McCarran-Ferguson Act, 15 U.S.C. 1011, *et seq.*

(5) The provision in 12 CFR 2.4(b) guaranteeing minority stockholders of a national bank their pro rata share of the credit life insurance income generated by the bank will be deleted. This action is proposed because it seems unusually burdensome to require both the payment of reasonable compensation and the reservation of the minority stockholders' share in all instances in which the credit life income is credited to a holding company or non-banking affiliate owning less than 100 percent of the bank's stock. Second, the minority shareholders will benefit, if only indirectly, from the requirement that the bank be paid reasonable compensation for use of its personnel, premises and good will. Finally, the Council's recommended policy statement contains no special provision for minority shareholders.

(6) 12 CFR 2.4(c) will be deleted in its entirety. The provisions in (c) either conflict with the amendments proposed to subsection (b) or are not consistent with the Council's recommendations. Subsection (d) will be renumbered as subsection (c).

(7) 12 CFR 2.5(a), which requires action by a national bank's board of directors in certain instances, will be deleted as no longer necessary. Subsections (a) and (b) were originally intended to make the board aware of the method used to distribute credit life insurance income. Since compliance with 12 CFR Part 2 has been good overall, this subsection can be deleted. Subsection (b) will be retained in slightly modified form.

(8) OCC proposes that the amendments will be effective 30 days after publication in final form in the **Federal Register**, except that the effective date of the reasonable compensation requirement in 12 CFR 2.4(b) will be May 1, 1983. Under the terms of the Council's policy statement, OCC is not required to delay the effective date of the reasonable compensation requirement for national banks. OCC proposes to do so nevertheless, since multi-bank holding companies with both national and state bank subsidiaries will find it easier to implement if the effective date is the same for both types of banks. National banks that elect to wait until May 1, 1983, to implement the reasonable compensation requirement must continue to adhere to the minority shareholder provision in the existing 12 CFR 2.4(b) until that date.

Alternatives

As noted above, OCC proposes to adopt the Council's position of allowing credit life insurance income to be credited to a non-bank affiliate of the holding company provided that reasonable compensation is paid to the bank for use of its premises, personnel and good will. Comment is also requested on alternative approaches, which include:

1. OCC would make no changes in 12 CFR Part 2 on this subject. The effect would be to continue to allow the credit life income to flow to a holding company affiliate, with no requirement for compensation to the bank. The existing proviso in 12 CFR 2.4(b) that the minority shareholders' proportionate share be placed in trust would be retained.

2. OCC would delete the proviso in 12 CFR 2.4(b) relating to the minority stockholders' proportionate share and monitor on a bank by bank basis the adequacy of the compensation paid by the holding company affiliate to the bank, subject to a guideline that, as a general rule, reasonable compensation means an amount equivalent to at least 20 percent of the affiliate's net income attributable to the bank's credit life insurance sales.

3. OCC would amend 12 CFR Part 2 to require that all income generated from credit life insurance sales be credited solely to the bank. This alternative is similar to the proposal on which the Federal Financial Institutions Examination Council sought comment, 45 FR 1152.

Comments should consider what impact, if any, OCC's proposal and the alternatives thereto will have on a national bank.

PART 2—DISPOSITION OF CREDIT LIFE INSURANCE INCOME

Accordingly, OCC proposes to amend 12 CFR 2 to read as follows:

Section 2–1 is revised to read as follows:

§ 2.1 Authority.

This part is issued by the Comptroller of the Currency under the general authority of the national banking laws, 12 U.S.C. 1 *et seq.*, and under the specific authority of 12 U.S.C. 24 (Seventh), 60, 73, 92, 93a and 1818(n).

2. Section 2.3(e) is revised to read as follows:

§ 2.3 Definitions.

* * * * *

(e) The term "credit life insurance" means credit life, health and accident insurance, sometimes referred to as credit life and disability insurance, and mortgage life and disability insurance.

3. Section 2.4 is revised to read as follows:

§ 2.4 Distribution of credit life insurance income.

(a) No bank employee, officer, director or principal shareholder may retain

[2] In addition, § 185.10 appears to prohibit the payment of retrospective rate credits to banks selling group credit insurance.

commissions or other income from the sale of credit life insurance in connection with any loan made by the bank. Except as provided in paragraph (b) of this section, retention of credit life insurance income by such persons or by corporations, partnerships, associations or other entities in which such persons have an interest of more than 5 percent is an unsafe and unsound banking practice. Notwithstanding this prohibition, bank employees and officers may participate in a bonus or incentive plan under which payments based on credit life insurance sales are made in cash or in kind out of the bank's funds not more frequently than quarterly and in an amount not exceeding in any one year 5 percent of the recipient's annual salary. Alternatively, bonuses paid to any one individual during the year for credit life sales may not exceed 5 percent of the average salary of all loan officers participating in the bank's plan.

(b) As an accounting and operations matter, income derived from credit life insurance sales to loan customers shall be credited to the income accounts of the bank and not to the bank's individual employees, officers, directors, principal shareholders, their interests or other affiliates. However, such income may be credited to an affiliate operating under the Bank Holding Company Act or to a trust for the benefit of all shareholders; *Provided,* That the bank receives reasonable compensation in recognition of the role played by its personnel, premises and good will in credit life insurance sales. As a general rule, "reasonable compensation" means an amount equivalent to at least 20 percent of the affiliate's net income attributable to the bank's credit life insurance sales.

(c) Nothing in this section shall be construed to prohibit a bank employee, officer, director, or principal shareholder who holds an insurance agent's license from agreeing to compensate the bank for the use of its premises, employees, and good will; *Provided,* That all income received by said employee, officer, director, or principal shareholder from this activity is turned over to the bank as compensation.

4. Section 2.5 is revised to read as follows:

§ 2.5 Responsibilities of directors.

Directors shall observe the rules in § 2.4 and shall be mindful of their duty under both the common law and 12 U.S.C. 73 to promote and advance the interests of the bank over their own personal interests.

Dated: December 9, 1981.

Charles E. Lord,

Acting Comptroller of the Currency.

[FR Doc. 82-1860 Filed 1-25-82; 8:45 am]

BILLING CODE 4810-33-M

Internal Revenue Service

26 CFR Part 53

[EE-69-80]

Minimum Investment Return of Private Foundations

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed clarifying amendments to regulations relating to the excise tax imposed by section 4942 on the undistributed income of a private foundation. The existing regulations do not deal explicitly with future interests created by the private foundation. The proposed regulations will provide guidance to foundations that may be subject to this tax.

DATES: Written comments and requests for a public hearing must be delivered or mailed by March 29, 1982. The amendments are proposed to be effective for taxable years beginning after December 31, 1969.

ADDRESS: Send comments and requests for a public hearing to: Commissioner of Internal Revenue, Attention: CC:LR:T:EE-69-80, Washington, D.C. 20224.

FOR FURTHER INFORMATION CONTACT: George B. Baker of the Employee Plans and Exempt Organizations Division, Office of the Chief Counsel, Internal Revenue Service, 111 Constitution Avenue, NW., Washington, D.C. 20224, Attention: CC:LR:T:EE-69-80, 202-566-3422 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

Background

This document contains proposed amendments to the Foundation and Similar Excise Taxes (26 CFR Part 53) under section 4942 of the Internal Revenue Code of 1954. The amendments are to be issued under the authority contained in section 7805 of the Internal Revenue Code of 1954 (68A Stat. 917, 26 U.S.C. 7805).

Proposed Amendments

In determining whether a private foundation has undistributed income for a taxable year, the private foundation's minimum investment return must be computed. This involves multiplying the fair market value of the assets of the foundation, excluding certain assets, by the applicable percentage. For this computation, the regulations provide that future interests are excluded from the foundation's assets until all intervening interests have expired. The amendment clarifies that the exclusion is not available to any future interest created by the private foundation after December 31, 1969. An additional amendment deletes a cross reference in § 53.4942(a)-3(d)(2) to § 1.9100-1 of the regulations. The cross reference is inappropriate because § 1.9100-1, by its terms, is not applicable to the private foundation excise taxes in Subtitle D of the Code.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted, consideration will be given to any written comments that are submitted (preferably six copies) to the Commissioner of Internal Revenue. All comments will be available for public inspection and copying. If a public hearing is held, notice of the time and place will be published in the **Federal Register.**

Regulatory Flexibility Act

Although this document is a notice of proposed rulemaking which solicits public comment, the Internal Revenue Service has concluded that the regulations proposed herein are interpretative and that the notice and public procedure requirements of 5 U.S.C. 553 do not apply. Accordingly, these proposed regulations do not constitute regulations subject to the Regulatory Flexibility Act (5 U.S.C. chapter 6).

Drafting Information

The principal author of these proposed regulations was George B. Baker of the Employee Plans and Exempt Organizations Division of the Office of Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulations, both on matters of substance and style.

Proposed Amendment to the Regulations

Amendments to 26 CFR Part 53 are proposed as follows:

PART 53—FOUNDATION AND SIMILAR EXCISE TAXES

Paragraph 1. Section 53.4942(a)–2 (c)(2)(i) is revised to read as follows:

§ 53.4942 (a)–2 Computation of undistributed income.

* * * * *

(c) *Minimum investment return.* * * *

(2) *Certain assets excluded.* * * *

(i) Any future interest (such as a vested or contingent remainder, whether legal or equitable) of a foundation in the income or corpus of any real or personal property, other than a future interest created by the private foundation, after December 31, 1969, until all intervening interests in, and rights to the actual possession or enjoyment of, such property have expired, or, although not actually reduced to the foundation's possession, until such future interest has been constructively received by the foundation, as where it has been credited to the foundation's account, set apart for the foundation, or otherwise made available so that the foundation may acquire it at any time or could have acquired it if notice of intention to acquire had been given;

* * * * *

§ 53.4942 [Amended]

Para. 2. The last sentence of paragraph (2) of § 53.4942 (a)–3 (d) is removed.

Roscoe L. Egger, Jr.,

Commissioner of Internal Revenue.

[FR Doc. 82–1884 Filed 1–25–82; 8:45 am]

BILLING CODE 4830–01–M

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26 CFR Part 1

[LR–176–80]

Income Tax; Subsidized Borrowings Reduce Business Energy Credits

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations relating to the rule which reduces the energy credit where energy property is financed by subsidized energy financing or tax exempt industrial development bonds. Changes to the applicable tax law were make by the Energy Tax Act of 1978 and the Crude Oil Windfall Profit Tax Act of 1980. These regulations will provide the public with the guidance needed to comply with the law.

DATES: Written comments and requests for a public hearing must be delivered or mailed by March 29, 1982. This amendment is proposed to be effective for certain periods after October 1, 1978.

ADDRESS: Send comments and requests for a public hearing to: Commissioner of Internal Revenue, Attn: CC:LR:T (LR–176–80) Washington, D.C. 20224.

FOR FURTHER INFORMATION CONTACT: Mary Frances Pearson of the Legislation and Regulations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, D.C. 20224 (Attn: CC:LR:T) (202–566–3458; not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains a proposed amendment to the Income Tax Regulations (26 CFR Part 1) under section 48 of the Internal Revenue Code of 1954. This amendment is proposed to conform the regulations to changes make by section 301(b) of the Energy Tax Act of 1978 (Pub. L. 95–618, 92 Stat. 3195) and sections 221(b)(2) and 223(c) of the Crude Oil Windfall Profit Tax Act of 1980 (Pub. L. 96–223, 94 Stat 229). The proposed regulations are to be issued under the authority contained in Code sections 7805 (68A Stat. 917, 26 U.S.C. 7805) and 38(b) (76 Stat. 962, 26 U.S.C. 38).

Explanation of Provisions

In general, the energy percentage, as determined under section 46 (a)(2)(C), is applied to the total amount of qualified investment in energy property to establish the amount of credit allowed. Section 301(b) of the Energy Tax Act of 1978 added section 48 (l)(11) to the Code. This provision in effect reduces the energy credit percentage by one–half if the energy property is financed in whole or in part with the proceeds of tax-exempt industrial development bonds within the meaning of section 103(b)(2) (exempt IDB's). Sections 221 (b)(2) and 223(c) of the Crude Oil Windfall Profit Tax Act of 1980 amended section 48(l)(11) to reduce the qualified investment in energy property by the amount of financing attributable to the proceeds of exempt IDB's and subsidized energy financing.

The 1980 Act amendments apply for the period after December 31, 1979, in the case of property qualifying under the 1980 Act as energy property for the first time. This property is called "early application property" and is described in § 1.48–9(o)(9) of the proposed amendments to the regulations. For all other energy property, the 1980 Act amendments apply for the period after December 31, 1982.

For example, assume a taxpayer acquires and places in service recycling equipment (which is not early application property) and finances the acquisition in part with exempt IDB's. If the equipment is acquired and placed in service before January 1, 1983, then to determine the credit for energy property, the energy percentage is reduced by one-half and then is multiplied against the total qualified investment in that property. If the equipment is acquired and placed in service after December 31, 1982, the qualified investment is reduced by the amount of the financing attributable to the exempt IDB's and the full energy credit is multiplied against the reduced qualified investment.

Subsidized Energy Financing

Section 48(l)(11), as amended by section 223(c) of the Crude Oil Windfall Profit Tax Act, defines subsidized energy financing as financing provided under a Federal, State, or local program a principal purpose of which is to provide subsidized financing for projects designed to conserve or produce energy.

The proposed regulations follow the Conference Report, which indicates that loan guarantees, credits against State and local income taxes, and taxable grants are not subsidized energy financing. *See,* H.R. Rep. No. 96–817, 96th Cong. 2d Sess. 136–137 (1980) (Conference Report). (For an example of a taxable energy grant, *see,* Rev. Rul. 79–356, 1979–2 C.B. 28). Non-taxable government grants also are not included within the definition of subsidized energy financing for purposes of the rule in section 48(l)(11). However, the same result is achieved for purposes of the energy credit since the basis of the property is determined with reference to cost under section 1012 and the amount of a non-taxable grant will not be taken into account in determining basis. Also, price guarantees and purchase commitments are not considered subsidized financing since these type of arrangements confer only a contingent benefit. However, if funds are advanced under a price guarantee or a purchase commitment agreement which, in effect, results in a loan (for example, where payments under the agreement are made before the project becomes operational), these advances are considered to be subsidized energy financing. The proposed regulations incorporate the substance of a colloquy between Senators Baker and Long on the Senate floor that subsidized energy financing does not include funds received by government owned utilities if the source of the funds is from rate-payers from the sale of services and no tax revenues are

involved. *See*, 126 Cong. Rec. S. 3052 (daily ed. March 26, 1980); Rev. Rul. 81–52, 1981–7 I.R.B. 9.

Allocation

The statutory rule under section 48(l)(11) multiples qualified investment by a fraction to determine the amount of qualified investment taken into account for the energy credit. The fraction is one minus another fraction the numerator of which is the portion of qualified investment in the property which is allocable to subsidized financing or proceeds of exempt IDB's and the denominator of which is the total qualified investment in the property before the application of this rule. The proposed regulations achieve the same result as the statute by simply reducing qualified investment for the energy credit by the portion attributable to the energy financing of proceeds.

The proposed regulations allocate the proceeds according to the type of borrowings used to finance the energy property. Borrowings attributable to subsidized energy financing are directly applied to reduce the qualified investment in energy property. The reason is that subsidized energy loans, *e.g.*, loans granted pursuant to the Energy Security Act (Pub. L. 96–294, 94 Stat. 611), have legal restraints on the use of loans by taxpayers. For example, under section 509(a)(1)(B)(ii) of that Act, proceeds must be used to acquire a specific type of energy property, *i.e.*, solar energy systems. On the other hand, the proceeds of exempt IDB's are ratably allocated between energy property and other property and then, once the allocation is made, the qualified investment in the energy property is reduced by the portion of exempt IDB financing attributed to the energy property.

The reason for this ratable allocation approach is to prevent tax avoidance. In general, proceeds from exempt IDB's can be applied to all property in a facility regardless of the mix of energy property or other property. In the absence of a ratable allocation rule, taxpayers in order to preserve the energy credit might attempt to allocate the proceeds first to non-energy property and only then, if any proceeds remain, to energy property.

Comments and Requests For a Public Hearing

Before adopting these proposed regulations, consideration will be given to any written comments that are submitted (preferably six copies) to the Commissioner of Internal Revenue. All comments will be available for public inspection and copying. A public hearing will be held upon written request to the Commissioner by any person who has submitted written comments. If a public hearing is held, notice of the time and place will be published in the **Federal Register.**

Regulatory Flexibility Act

Although this document is a notice of proposed rulemaking which solicits public comment, the Internal Revenue Service has concluded that the regulations proposed herein are interpretative and that the notice and public procedure requirements of 5 U.S.C. 553 do not apply. Accordingly, these proposed regulations do not constitute regulations subject to the Regulatory Flexibility Act (5 U.S.C. chapter 6).

Drafting Information

The principal author of these proposed regulations is Mary Frances Pearson of the Legislation and Regulations Division of the Office of Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulations, both on matters of substance and style.

Proposed Amendments to the Regulations

The proposed amendments to the Income Tax Regulations (26 CFR Part 1) are as follows:

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

§ 1.48–9 [Amended]

Section 1.48–9 is amended by adding a new paragraph (o) to read as follows:

* * * * * * *

(o) *Energy property financed by subsidized energy financing or industrial development bonds*—(1) *In general.* (i) This paragraph (o) prescribes rules—

(A) for reducing the qualified investment for purposes of the energy credit. See section 48 (l)(11) as amended by section 223(c)(1) of the Crude Oil Windfall Profit Tax Act of 1980 (Pub. L. 96–223) and paragraph (o)(2) of this section.

(B) For reducing the energy credit percentage. See section 48(l)(11) as amended by section 221(b)(2) of that Act and paragraph (o)(6) of this section.

(ii) For effective dates, see paragraph (o)(8) of this section.

(2) *General rule.* For purposes of the energy credit, qualified investment in any energy property (determined without this paragraph (o)) is reduced by the amount of subsidized borrowed funds used to finance in whole or in part the energy property. Funds borrowed are subsidized if they are directly or indirectly attributable to the proceeds of exempt IDB's or subsidized energy financing.

(3) *Exempt IDB defined.* For purposes of this paragraph (c), an exempt IDB is an industrial development bond (within the meaning of section 103(b)(2)) with respect to which the interest paid is excluded from gross income under section 103.

(4) *Subsidized energy financing.* (i) Funds are attributable to subsidized energy financing if the source of the funds for financing (other than exempt IDB's) is provided directly or indirectly (such as in association with, or through the facilities of, a bank or other lender) by, or through, a government agency under a program a principal purpose of which is to provide (or assist in providing) financing for projects designed to conserve or produce energy. For purposes of this paragraph (o), a government agency is a State or local governmental unit referred to in § 1.103–1(a) or the Federal government.

(ii) Subsidized energy financing does not include a grant includible in gross income under section 61, a nontaxable government grant, or a credit against State or local taxes. Loan guarantees, price guarantees, purchase commitments, price support loans, and similar arrangements are not considered subsidized energy financing unless the arrangement is essentially subsidized borrowing under paragraph (o)(4)(i) of this section.

(iii) The following examples illustrate this paragraph (o)(4).

Example (1). A law in State A requires, as part of its State-wide energy program, that public utilities in the State provide low-interest loans to business enterprises for the purchase of energy property. The utilities are able to make these low-interest loans available to the enterprises by charging a 2 percent surcharge on each utility service bill. The funds from the surcharge are kept separate in an escrow account. This type of low interest loan is not subsidized energy financing and will not reduce the qualified investment of any energy property purchased with these funds.

Example (2). Assume the same facts as in example (1) except that, in lieu of the surcharge, the utilities receive money from the State for the express purpose of providing energy loans. Any low-interest loans made from these funds will be considered subsidized energy financing.

Example (3). State B allows a tax credit to a financial institution which makes low interest loans to corporations for the purpose of acquiring energy devices. The financial

institution receives a credit each year in the amount of the excess of the interest that would have been paid at market rates and the actual interest paid on such loans. The State B tax credit arrangement is an interest subsidy. Thus, any low-interest loans pursuant to this credit arrangement is considered subsidized energy financing.

Example (4). State C wishes to encourage the production of synthetic fuels. As an inducement to Corporation X to build a synthetic fuel production plant, C enters into a contract with X guaranteeing X a certain price for the first 1,000 barrels of daily production. Before the plant is operational and pursuant to the price guarantee commitment, X receives an interest free advance of $10,000. Since the advance of funds is essentially a subsidized energy loan, it is considered to be subsidized energy financing.

(5) *Allocation of proceeds.* (i) For purposes of the general rule, this paragraph (o)(5) sets forth the manner of determining the amount of subsidized borrowed funds that are considered used to finance energy property.

(ii) If borrowings attributable to subsidized energy financing are used to finance a facility, the entire amount of the borrowings are considered used to finance the energy property included in that facility and thus is applied directly to reduce the qualified investment in the energy property.

(iii)(A) If borrowings attributable to the proceeds of exempt IDB's are used to finance a facility, the borrowings reduce the qualified investment in that energy property. The amount of those borrowings considered used to finance energy property included in that facility equals to the amount of the borrowings multiplied by a fraction. The numerator of the fraction is the qualified investment in the energy property before the reduction and the denominator is the total cost of that facility.

(B) If borrowings are attributable to the proceeds of exempt IDB's the exempt status of which is derived solely under section 103(b)(4), and the proceeds of such borrowings are used solely to finance the type of property or facility described in section 103(b)(4) from which the issue derives its tax-exempt status, then the facility referred to in paragraph (o)(5)(iii)(A) of this section is the property or facility from which the issue derives its tax-exempt status.

(iv) If both borrowings attributable to subsidized energy financing and borrowings attributable to exempt IDB financing are used to finance a facility, the total amount of subsidized energy financing is first applied directly to reduce the qualified investment (determined without this subdivision (iv)) in the energy property included in the facility. Then, paragraph (o)(5)(iii) of this section is applied to the exempt IDB financing by reducing both the numerator and the denominator of the fraction by the same total amount.

(v) The following examples illustrate this paragraph (o)(5).

Example (1). In 1983, Corporation X builds a facility costing $10,000. The facility includes energy property having a useful life of 7 years and the qualified investment (before reduction) is $8,000. X receives in 1983 a $6,000 energy loan from the Department of Energy for this facility at a subsidized rate of interest. The qualified investment for the energy property is reduced by $6,000 to $2,000. See paragraph (o)(5)(ii) of this section.

Example (2). Assume the same facts as in example (1) except that the $6,000 is borrowed from a fund established by a local government unit from the proceeds of exempt IDB's. The qualified investment in the energy property is reduced by $4,800 (*i.e.*, $6,000 x $8,000/$10,000). Thus, the qualified investment is reduced from $8,000 to $3,200. See paragraph (o)(5)(iii)(A) of this section.

Example (3). Assume the same facts as in example (1) except that the total $6,000 borrowed to finance the property is from two sources. $2,000 is a subsidized energy loan and $4,000 is attributable to the proceeds of exempt IDB's. First, the qualified investment in the energy property of $8,000 is reduced by the subsidized energy loan of $2,000 to $6,000. For purposes of allocating the proceeds from exempt IDB's, the numerator and denominator of the fraction in example (2) are both reduced by this $2,000 from $8,000/$10,000 to $6,000/$8,000. Thus, the amount attributed to the proceeds of exempt IDB's is $3,000 (*i.e.*, $4,000 x $6,000/$8,000), and the qualified investment for the energy property is $3,000, *i.e.*, $6,000–$3,000. See paragraph (o)(5)(iv) of this section.

Example (4). (a) In 1983, Corporation Y constructs a coal gasification project having an estimated useful life of 20 years and consisting of a gasifier and air pollution control equipment. The total cost of the project is $60 million, allocable to various types of property as follows:

($000,000 omitted)

	Gasifier	Pollution control equipment
Energy property	$30	$10
Other	10	10
	40	20

(b) Y finances construction of the project with subsidized financing ($10 million) and conventional financing ($36 million). Y also receives proceeds of $14 million from an issue of exempt IDB's, the exempt status of which is derived solely under section 103(b)(4)(F). Y uses the proceeds of the exempt IDB's solely to provide the pollution control equipment.

(c) Qualified investment for the energy credit is determined as follows:

	Energy property	
	Gasifier	Pollution control equipment
1. Cost	$30	$10
2. Allocation of subsidized energy financing ($10) to energy property:		
(a) $10 x 30/40	7.5	
(b) $10 x 10/40		2.5
3. Remainder after applying paragraph (o)(5)(ii) of this section	$22.5	$7.5
4. Allocation of proceeds ($14) of IDB exempt solely under section 103(b)(4):		
(a) Fraction of cost of pollution control equipment that is energy property		10/20
(b) Reduce numerator and denominator of fraction by line 2(b)		7.5/17.5
(c) Multiply by proceeds		$14
(d) Allocated proceeds (line (b) x (c))		$6
5. Qualified investment for energy credit after applying paragrapn (o)(5)(i)–(iv) of this section (line 3–line 4(d))	$22.5	$1.5

(6) *One-half exempt IDB rule for certain periods.* For periods beginning on or after October 1, 1978, to which the general rule of paragraph (o)(2) of this section does not apply, the energy percentage for property is one-half of the energy percentage determined under section 46(a)(2)(C) if any funds borrowed to finance the facility of which the energy property is a part are directly or indirectly attributable to the proceeds of exempt IDB's. For explanation of the effective date of this paragraph (o)(6), see paragraph (o)(8) of this section.

(7) *Add-on equipment rule.* (i) Energy property is not considered to be financed with subsidized borrowings solely because it is installed in an existing facility which has been previously so financed.

(ii) The facts and circumstances determine if energy property installed in connection with existing property is a separate unit or installed pursuant to a design, plan, or as a component of a larger property (such as a project or facility).

(iii) The following example illustrates this paragraph (o)(7).

Example. In 1981, Corporation X finances its energy facility with the proceeds of exempt IDB's. The facility meets all air pollution laws and regulations in existence, or anticipated, when it is placed in service. In 1982, a new State reglation requires the installation of additional air pollution control equipment which is alternative energy property under section 48(f)(3)(A)(vi). X receives subsidized energy financing and installs the added equipment pursuant to the new regulation. The added air pollution control equipment is a separate unit.

Therefore, the subsidized energy loan for the facility is not imputed to the qualified investment in this new separate unit.

(8) *Effective dates.* (i) The general rule in paragraph (o)(2) of this section applies to early application property for periods after December 31, 1979. Early application property is defined in paragraph (o)(9) of this section. For other property, it applies to periods after December 31, 1982.

(ii) Notwithstanding paragraph (o)(8)(i) of this section, funds attributable under paragraph (o)(4) of this section to subsidized energy financing made before January 1, 1980, shall not be taken into account for purposes of reducing qualified investment under the general rule of paragraph (o)(2) of this section. See section 223(c)(2)(D) of Pub. L. 96–223. Subsidized energy financing is considered made before January 1, 1980, if it meets the requirements of § 1.167(j)–4(c) (applied without reference to any dates therein).

(iii) The one-half-exempt IDB rule in paragraph (o)(6) of this section applied for periods beginning after October 1, 1978, to which the general rule of paragraph (o)(2) of this section does not apply.

(iv) For purposes of this subparagraph (8), whether qualified investment (without any reduction under this paragraph (o)) falls within a period is determinied under section 48(m). If under section 48(m) this qualified investment for energy property is allocable to more than one period, the portion of subsidized borrowings used to finance the property (as determined under paragraph (o)(5) of this section) is ratably apportioned to this qualified investment for each period in proportion to this qualified investment for each period.

(v) The following examples illustrate this paragraph (o)(8).

Example (1). (a) Corporation Z begins building on February 1, 1980, a facility costing $100,000, $75,000 of which is solar energy property which generates electricity. The energy property has a useful life of seven years. The facility is completed in 1983. Z spent $45,000 for the energy property for the period ending on December 31, 1982, and $30,000 for periods after that date. In connection with this facility, Z receives a loan of $10,000 attributable to subsidized energy financing made in January 1980.

(b) The subsidized energy financing is allocated between the two periods in proportion to the amount of basis of energy property attributable to each period. Thus, $6,000 of the subsidized financing is allocated to the period before 1983 (*i.e.*, $10,000 x $45,000/$75,000) and $4,000 is allocated to the period after 1982 (*i.e.*, $10,000 x $30,000/$75,000). See paragraph (o)(8)(iv) of this section.

(c) The $6,000 of subsidized energy financing attributable to the period before 1983 does not reduce qualified investment in energy property (other than early application property) because the general rule in paragraph (o)(2) of this section does not apply. However, the qualified investment of $30,000 for the period after 1982 is reduced by $4,000 to $26,000.

Example (2). Assume the same facts as in example (1) except that the energy property is early application property. The general rule in paragraph (o)(2) of this section applies and the total amount of subsidized energy financing ($10,000) is subtracted from the total qualified investment. Thus, the qualified investment for the energy credit is reduced from $75,000 to $65,000.

Example (3). (a) Assume the same facts as in example (1) except that the $10,000 loan was attributable to the proceeds of exempt IDB financing. Exempt IDB financing allocated to pre-1983 periods does not reduce the qualified investment. Instead, the energy percentage is reduced by one-half from 15 percent to 7½ percent and applied against the qualified investment allocable to such periods, *i.e.*, $45,000. See section 46(a)(2)(C).

(b) The amount of exempt IDB financing attributable to qualified investment in energy property is $7,500 (*i.e.*, $10,000 x $75,000/$100,000). The portion of that amount attributable to periods after 1982 is $3,000 (*i.e.*, $7,500 x $30,000/$75,000). Accordingly, the qualified investment for the energy property attributable to periods after 1982 is reduced from $30,000 by $3,000 to $27,000. See paragraph (o)(8)(iv) of this section.

Example (4). Assume the same facts in example (3) except that the energy property is early application property. The general rule in paragraph (o)(2) of this section applies to the entire energy property, and the total amount of the proceeds of exempt IDB's is multiplied by the fraction in paragraph (o)(50(iii) of this section. Thus, the qualified investment of $75,000 is reduced by $7,500 (*i.e.*, $10,000 x $75,000/$100,000) by $67,500.

(9) *Early application property.* (i) Early application property is—

(A) Qualified hydroelectric generating property (described in section 48(l)(2)(A)(vii)),

(B) Cogeneration equipment (described in section 48(l)(2)(A)(viii)),

(C) Qualified intercity buses (described in section 48(l)(2)(A)(ix)),

(D) Ocean thermal property (described in section 48 (l)(3)(A)(ix)), or

(E) Expanded energy property.

(ii) Expanded energy property is—

(A) Property that is included for the first time as alternative energy property under clause (iii) or (v) of section 48 (l)(3)(A) by reason of the amendments thereto by section 222(b) (1) and (2) of the Crude Oil Windfall Profit Tax Act of 1980 (Pub. L. 96–223, 94 Stat. 229),

(B) Solar or wind energy property that provides solar process heat referred to in section 48(l)(4)(C),

(C) Modifications to alumina electrolyte cells referred to in section 48(l)(5)(L), and

(D) Property described in the last sentence of section 48(l)(3)(A) (relating to storage equipment for refuse-derived fuel).

Roscoe L. Egger, Jr.,

Commissioner of Internal Revenue.

[FR Doc. 82-1683 Filed 1-25-82; 8:45 am]

BILLING CODE 4830-01-M

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26 CFR Part 1

[EE-11-78]

Income Tax; Early Termination of Qualified Plans

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations relating to the limitation of benefits in the event of the early termination of certain tax qualified retirement plans providing defined benefits for employees. Changes in the applicable law were made by the Employee Retirement Income Security Act of 1974. The regulations would provide the public with additional guidance needed to comply with that Act and would affect employers maintaining such plans and employees covered by such plans subject to Title IV of that Act.

DATES: Written comments and requests for a public hearing must be delivered or mailed by March 29, 1982. In general, the amendments are proposed to be effective for plan terminations occurring on or after 60 days after the date final regulations are published in the **Federal Register**.

ADDRESS: Send comments and requests for a public hearing to: Commissioner of Internal Revenue, Attention: CC:LR:T (EE–11–78), Washington, D.C. 20224.

FOR FURTHER INFORMATION CONTACT: Marjorie Hoffman of the Employee Plans and Exempt Organizations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, D.C. 20224 (Attention: CC:LR:T) (202)–566–3430) (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains proposed amendments to the Income Tax Regulations (26 CFR Part 1) under section 401 of the Internal Revenue Code of 1954. The amendments reflect certain provisions of Title IV of the

Employee Retirement Income Security Act of 1974 (88 Stat. 1003) related to plan termination insurance. These amendments are to be issued under the authority contained in sections 411(d) (2) and (3) and 7805 of the Internal Revenue Code of 1954 (68A Stat. 917, 88 Stat. 912; 26 U.S.C. 411(d) (2) (3) and 7805). The proposed amendments contain references to certain vesting regulations (section 411 of the Code and Income Tax Regulations § 1.411(d)–2 (26 CFR Part 1)).

Statutory Provisions

Section 401(a)(4) of the Code prescribes certain discrimination standards which are qualification requirements for employee retirement plans (and related trusts) described in sections 401(a), 403(a), and 405 of the Code. Section 411 (d)(2) and (d)(3) of the Code prescribe additional vesting-discrimination standards which are also qualification standards for these retirement plans.

Specific Rules Concerning Plan Provisions

Prior to the enactment of ERISA, a qualified plan could provide either for termination at will by the employer or discontinuance of contributions thereunder, and yet limit the likelihood that the plan would result in discrimination prohibited by section 401 (a)(4) and (a)(7). The plan did this by satisfying certain conditions, including the incorporation of provisions which complied with the restrictions contained in paragraph (c)(2) of § 1.401–4.

Because of various provisions added by ERISA, that regulation is proposed to be amended. In general, the amendment which is applicable to certain retirement plans covered by section 4021(a) of ERISA would raise the limit of employer contributions for the benefit of the 25 highest paid employees without violating the provisions of section 401(a)(4) of the Code. The additional employer contributions allowed as a result of this change will, as a result of the interaction of sections 401(a) and 411 of the Code, be mandatory. The increased amount available to substantial owners is equal to the present value of the benefit guaranteed for substantial owners under section 4022 of ERISA, or if the plan has not terminated, the present value of the benefit that would be guaranteed if the plan terminated on the date the benefit commenced. The increased amount available to employees other than substantial owners is equal to the present value of the benefit guaranteed under section 4022(b)(3)(B) of ERISA.

Under these regulations a plan would be required to apply the new dollar limits in order to continue to satisfy the vesting requirements of section 411. However, a plan amendment incorporating the higher limits would not be required to be adopted until 1984, unless the plan were terminated prior to that time. It is anticipated that, if this regulation is adopted, the Service will provide further guidance regarding plan amendments to raise the "high 25" limits.

In this connection it should be noted that nonforfeitable benefits for purposes of Title IV of ERISA are determined under the definition of that term in Title IV and implementing Pension Benefit Guaranty Corporation regulations.

Regulatory Flexibility Act

Although this document is a notice of proposed rulemaking which solicits public comment, the Internal Revenue Service has concluded that the regulations proposed herein are interpretative and that the notice and public procedure requirements of 5 U.S.C. 553 do not apply. Accordingly, these proposed regulations do not constitute regulations subject to the Regulatory Flexibility Act (5 U.S.C. chapter 6).

Comments and Requests for a Public Hearing

Before adopting these proposed regulations, consideration will be given to any written comments that are submitted (preferably eight copies) to the Commissioner of Internal Revenue. All comments will be available for public inspection and copying. A public hearing will be held upon written request to the Commissioner by any person who has submitted written comments. If a public hearing is held, notice of the time and place will be published in the **Federal Register.**

Drafting Information

The principal authors of these proposed regulations were Richard J. Wickersham and Leonard S. Hirsh of the Employee Plans and Exempt Organizations Division of the Office of Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulation, both on matters of substance and style.

Proposed Amendments to the Regulations

The proposed amendments to 26 CFR Part 1 are as follows:

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

Section 1.401–4 is amended by adding three new sentences at the end of paragraph (c)(1) and by adding a new paragraph (c)(7). These added provisions read as follows:

§ 1.401–4 Discrimination as to contributions or benefits.

* * * * *

(c)(1) * * * Any pension plan containing a provision described in this paragraph shall not fail to satisfy section 411(a), (d)(2) and (d)(3) merely by reason of such a plan provision. Paragraph (c)(7) of this section sets forth special early termination rules applicable to certain qualified defined benefit plans for plan years affected by the Employee Retirement Income Security Act of 1974 ("ERISA"). Paragraph (c)(7) of this section does not contain all the rules required by the enactment of ERISA.

* * * * *

(7)(i) A qualified defined benefit plan subject to section 412 (without regard to section 412(h)(2)) shall not be required to contain the restriction described in paragraph (c)(2)(ii)(*c*) of this section applicable to an employee in a plan whose full current costs for the first 10 years have not been funded.

(ii) A qualified defined benefit plan covered by section 4021(a) of ERISA ("qualified Title IV plan") shall satisfy the restrictions in paragraph (c)(2) of this section only if the plan satisfies this paragraph (c)(7). A plan satisfies this paragraph (c)(7) by providing that employer contributions which may be used for the benefit of an employee described in paragraph (c)(2) of this section who is a substantial owner, as defined in section 4022(b)(5) of ERISA, shall not exceed the greater of the dollar amount described in paragraph (c)(2)(iii) of this section or a dollar amount which equals the present value of the benefit guaranteed for such employee under section 4022 of ERISA, or if the plan has not terminated, the present value of the benefit that would be guaranteed if the plan terminated on the date the benefit commences, determined in accordance with regulations of the Pension Benefit Guaranty Corporation ("PBGC").

(iii) A plan satisfies this paragraph (c)(7) by providing that employer contributions which may be used for the benefit of all employees described in paragraph (c)(2) of this section (other than an employee who is a substantial owner as defined in section 4022(b)(5) of ERISA) shall not exceed the greater of

the dollar amount described in paragraph (c)(2)(iii) of this section or a dollar amount which equals the present value of the maximum benefit described in section 4022(b)(3)(B) of ERISA (determined on the date the plan terminates or on the date benefits commence, whichever is earlier) without regard to any other limitations in section 4022 of ERISA.

(iv) A plan provision satisfying this paragraph (c)(7) may be adopted by amendment or by incorporation at the time of establishment. Any allocation of assets attributable to employer contributions to an employee which exceeds the dollar limitation in this paragraph (c)(7) may be reallocated to prevent prohibited discrimination.

(v) the early termination rules in the proceding subparagraphs (1) through (6) apply to a qualified Title IV plan except where such rules are determined by the Commissioner to be inconsistent with the rules of this paragraph (c)(7), § 1.411(d)–2, and section 4044(b)(4) of ERISA. The early termination rules of this paragraph (c)(7) contain some of the rules under section 401(a)(4) and (a)(7), as in effect on September 2, 1974, and section 411(d)(2) and (3). Section 1.411(d)–2 also contains certain discrimination and vesting rules which are applicable to plan terminations.

(vi) Paragraph (c)(7) of this section shall apply to a qualified Title IV plan which is considered terminated within the meaning of § 1.411(d)–2 (c)(2) on or after (60 days after the date final regulations are published in the **Federal Register**).

Roscoe L. Egger, Jr.,

Commissioner of Internal Revenue.

[FR Doc. 82–1885 Filed 1–25–82; 8:45 am]

BILLING CODE 4830–01–M

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 9

[Notice No. 405]

Madera Viticultural Area

AGENCY: Bureau of Alcohol, Tobacco and Firearms, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Bureau of Alcohol, Tobacco and Firearms (AFT) is considering the establishment of a viticultural area in the state of California to be known as "Madera." This proposal is the result of a petition submitted by Mr. David B. Ficklin, president, Ficklin Vineyards. ATF feels that the establishment of viticultural areas and the subsequent use of viticultural area names as appellations of origin will help wineries better designate the specific grape-growing area where their wines come from and will help wine consumers better identify the wine they purchase.

DATE: Written comments must be received by March 12, 1982.

ADDRESS: Send written comments to: Chief, Regulations and Procedures Division, Bureau of Alcohol, Tobacco and Firearms, P.O. Box 385, Washington, DC 20044–0385, Attn.: Notice No. 405.

Copies of the petition, the proposed regulations, the appropriate maps, and written comments will be available for public inspection during normal business hours at: ATF Reading Room, Room 4405, Federal Building, 12th and Pennsylvania Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Norman P. Blake, Research and Regulations Branch, Bureau of Alcohol, Tobacco and Firearms, Washington, DC (202–566–7626).

SUPPLEMENTARY INFORMATION:

Background

On August 23, 1978, ATF published Treasury Decision ATF–53 (43 FR 37672, 54624) revising regulations in 27 CFR Part 4. These regulations allow the establishment of definite viticultural areas. The regulations also allow the name of an approved viticultural area to be used as an appellation of origin on wine labels and in wine advertisements.

On October 2, 1979, ATF published Treasury Decision AFT–60 (44 FR 56692) which added a new Part 9 to 27 CFR for the listing of approved viticultural areas.

Section 9.11, Title 27, CFR, defines an American viticultural area as a delimited grape-growing region distinguishable by geographical features. Section 4.25a(e)(2) outlines the procedures for proposing an American viticultural area. Any interested person may petition ATF to establish a grape-growing region as a viticultural area. The petition should include:

(a) Evidence that the name of the proposed viticultural area is locally and/or nationally known as referring to the area specified in the petition;

(b) Historical or current evidence that the boundaries of the viticultural area are as specified in the petition;

(c) Evidence relating to the geographical characteristics (climate, soil, elevation, physical features, etc.), which distinguish the viticultural features of the proposed area from surrounding areas;

(d) A description of the specific boundaries of the viticultural area, based on features which can be found on United States Geological Survey (U.S.G.S.) maps of the largest applicable scale; and

(e) A copy of the appropriate U.S.G.S. maps with the boundaries prominently marked.

Proposed Regulations

This notice of proposed rulemaking is intended to solicit comments from interested parties concerning establishment of the Madera viticultural area. While ATF feels that the evidence submitted in the petition may warrant the designation of a viticultural area, it is not convinced that the petitioned area is geographically or viticulturally distinct from surrounding areas, or that the name "Madera" is historically associated with the entire area. Therefore, ATF is not proposing any specific regulatory language. However, on the basis of written comments received in response to this notice, testimony received at possible future public hearings, and its own research, ATF may issue a final rule establishing "Madera" as a viticultural area without further notice.

Madera Viticultural Area-Petition

The proposed Madera viticultural area is located in portions of Madera and Fresno Counties within the eastern section of the Central San Joaquin Valley. This area consists of approximately 230,000 acres between the natural boundaries of the Chowchilla River on the north and the San Joaquin river on the south.

The petitioner states that the proposed area has a history relating to wine grapes and wine dating back to the 1870's. Presently there are six wineries within the proposed area. Two of these wineries label their wines utilizing "Madera" as an appellation of origin. Within the last six years, wines bearing the appellation "Madera" have received numerous national and international awards. Over the last 15 years, wine grape acreage has increased from 6,500 to over 30,000 acres.

The California Crop and Livestock Reporting Service, in its publication *1980 California Grape Acreage*, lists 33 separate varieties of wine grapes grown in Madera County. The grape growing area of Madera County is located within the proposed boundaries. Within California Madera County ranks fifth in acres of wine grapes, and third in total acres of grapes with over 68,000 acres. Due to the characteristics hot and dry climate of this area, grape growers rely

solely on irrigation water from the Sierra Nevada Mountains to the east. Because of the climate, and the availability of irrigation water, grape yield per acre in the proposed area is much larger than in the coastal regions of California. Fourteen of the 33 varieties of wine grapes grown in this area rank third or higher in acreage within the State. Some of these varieties include: *Grenache, Muscat Hamburg, Royalty* and *Tinta, Mederia* which all rank first in acreage within California. The area also includes significant plantings of *Barbera, Carignane, Chenin Blanc, French Colombard, Rubired* and *Ruby Cabernet* wine grapes.

The petitioner states that the soils are comprised of three major alluvial soil associations; San Joaquin-Madera, Cometa-Whitney and Hanford-Tujunga. These soil associations are all derived primarily from granitic sediments and are moderate to well-drained.

The elevation of the proposed area ranges from 190 feet above sea level on the western edge, in Madera County, and, after gently sloping for 30 miles, to 390 feet above sea level in the extreme eastern section located in Fresno County.

The six U.S.G.S. quadrangle maps, 15 minutes series, which show the boundaries of the proposed area are: "Clovis"; "Herndon"; "Madera"; "Firebaugh"; "Le Grand"; and "Chowchilla."

The boundaries of the petitioned area are as follows:

Beginning at the most northwestern point, located on the Madera-Merced County line, the interesection of Road (RD) 15 and the Chowchilla River; south along RD 15 for 11 miles to the intersection of Avenue (AVE) 17; east along AVE 17 for four miles to RD 19; south along RD 19 for five miles to AVE 12 (Firebaugh Road); east on AVE 12 (Firebaugh Road) for three miles to RD 22; south along RD 22 and a line extending RD 22 for a total of eight and one-half miles to the San Joaquin River. The boundary then runs easterly to northeasterly along the course of the San Joaquin River (Madera-Fresno County line) for approximately 23 miles to the point where a line extending Shepherd Avenue intersects; east, in Fresno County, along the line extending Shepherd Avenue and along Shepherd Avenue for a total of six miles to Sunnyside Avenue; north on Sunnyside Avenue and a line extending Sunnyside Avenue for a total of seven miles to a point where a line extending AVE 15 intersects; west along the line extending AVE 15, crossing the San Joaquin River into Madera County, and along Avenue 15 for approximately 17.5 miles to the Atchison, Topeka and Santa Fe (A.T.&S.F.) railroad tracks; northwest along the A.T.&S.F. railroad tracks approximately five miles to the intersection of RD 26; north along RD 26 for 11 miles to the Chowchilla River; west along the course of the Chowchilla River (Madera/Merced County line) for approximately 12 miles to the beginning point.

Compliance With Executive Order 12291

In compliance with Executive Order 12291, ATF has determined that this proposal is not a major rule since it will not result in—

(a) An annual effect on the economy of $100 million or more;

(b) A major increase in cost or prices for consumers, individual industries, Federal, State, or local government agencies, or geographical regions; or

(c) Significant adverse effects on competition, employment, investment, productivity, or on the ability of United States-based enterprise to compete with foreign-based enterprises in domestic or export markets.

Regulatory Flexibility Act

The provisions of the Regulatory Flexibility Act relating to an initial and final regulatory flexibility analysis (5 U.S.C. 603, 604) are not expected to apply to this proposal because the notice of proposed rulemaking, if promulgated as a final rule, would not have a significant economic impact on a substantial number of small entities. This proposal is not expected to have significant secondary or incidental effects on a substantial number of small entities; or impose, or otherwise cause, a significant increase in the reporting, recordkeeping, or other compliance burdens on a substantial number of small entities.

ATF has previously approved the use of "Madera County (Madera)" as a county appellation of origin. This proposed viticultural area is smaller than the county appellation and the boundaries extend into the northeast portion of Fresno County. However, available information indicates that the wineries and vineyards which currently benefit from the use of the county appellation are located within the proposed viticultural area.

Therefore, ATF believes that this notice of proposed rulemaking, if promulgated as a final rule, would not have a significant economic impact on a substantial number of small entities.

Public Participation—Written Comments

ATF requests comments from all interested persons concerning this proposed viticultural area. ATF particularly requests comments and information concerning: Possible alternative boundaries; viticultural and geographical evidence which may distinguish the proposed area from surrounding areas; and historical and current evidence that the name "Madera" is known as referring to or associated with the entire area specified in the petition.

All comments received before the closing date will be carefully considered. Comments received after the closing date and too late for consideration will be treated as possible suggestions for future ATF action.

ATF will not recognize any material and comments as confidential. Comments may be disclosed to the public. Any material which the commenter considers to be confidential or inappropriate for disclosure to the public should not be included in the comment. The name of any person submitting a comment is not exempt from disclosure.

Any interested person who desired an opportunity to comment orally at a public hearing on this proposed regulation should submit a request, in writing, to the Director within the 45-day comment period (March 12, 1982). The Director, however, reserves the right to determine, in light of all circumstances, whether a public hearing should be held.

Drafting Information

The principal author of this document is Norman P. Blake, Specialist, Research and Regulations Branch, Bureau of Alcohol, Tobacco and Firearms.

Authority

This viticultural area is proposed under the authority of 27 U.S.C. 205.

Signed: December 9, 1981.

G. R. Dickerson,

Director.

Approved: January 8, 1982.

John P. Simpson,

Acting Assistant Secretary (Enforcement and Operations).

[FR Doc. 82-1808 Filed 1-25-82; 8:45 am]

BILLING CODE 4810-31-M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. H-200]

Occupational Exposure to Ethylene Oxide

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: Notice is given that OSHA is undertaking, through rulemaking procedures under section 6(b) of the Occupational Safety and Health Act of 1970 (the Act), 29 U.S.C. 655(b), a reevaluation of the current occupational health standard regulating employee exposure to ethylene oxide (EtO), 29 CFR 1910.1000, Table Z-1. This notice summarizes the information currently available to OSHA concerning the production and use of EtO, estimates of employee exposure, and the potential health effects of employee exposure to EtO. The notice also invites interested parties to submit data, views and comments regarding the development of a new standard for EtO and the appropriate scope of coverage.

DATE: Comments in response to this Advance Notice should be submitted by March 31, 1982.

ADDRESS: Comments should be submitted to the Docket Officer, Occupational Safety and Health Administration, Docket No. H-200, Room S-6212, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

FOR FURTHER INFORMATION CONTACT: Dr. Robert P. Beliles, Occupational Safety and Health Administration, Room N3718, U.S. Department of Labor, Washington, D.C. 20210, Telephone (202) 523-7081.

SUPPLEMENTARY INFORMATION:

1. Introduction

The present OSHA standard for EtO (CAS Registry No. 75-21-8) requires employers to assure that employee exposure to EtO does not exceed 50 parts per million parts of air (50 ppm), determined as an 8-hour time weighted average (TWA) (*1*). This standard was adopted in 1971 from the existing Walsh-Healey Federal standard pursuant to section 6(a) of the Act. The source for the Walsh-Healey standard was the Threshold Limit Value (TLV) recommended in 1968 by the American Conference of Governmental Industrial Hygienists (ACGIH) (*2*).

The ACGIH documentation for this exposure level consisted of limited data on 6 month studies in animals which showed no adverse effects below 50 ppm and one study of workers exposed to EtO at 5 to 10 pmm for more than 10 years with no reported effects (*3*). Studies demonstrating carcinogenicity were not available when this TLV was adopted by the ACGIH. In the past 4 years, however, a substantial number of studies have become available that shed significant new light on the nature and extent of potential health effects related to EtO exposures.

In 1977, the National Institute of Occupational Safety and Health (NIOSH) issued a "Special Occupational Hazard Review" on EtO (*4*). NIOSH recommended that occupational exposure be limited to a ceiling concentration of 75 ppm determined during a 15-minute sampling period (which had been recommended as a Short Term Exposure Limit (STEL) by ACGIH in 1977) (*5*) in addition to the OSHA standard of 50 ppm as a TWA. NIOSH also concluded that occupational exposure to EtO may increase the frequency of mutations in human populations. This conclusion was based on observations of (1) changes in the genetic material of cells in at least 13 biological species following exposure to EtO, and (2) covalent chemical bonding between EtO and deoxryibonucleic acid (DNA), a major constitutent of genetic material. While these observations raised concern about the potential carcinogenicity of EtO, there were no epidemiologic studies or long-term carcinogenesis assays available at the time to assess carcinogenic potential for humans.

In 1979, ACGIH published a Notice of Intended Change for EtO to 10 ppm as a TWA concentration with no STEL (*6*), and adopted this change in 1981 (*7*). ACGIH based this action on a number of short-term *in vitro* studies which resulted in positive mutagenic responses to EtO and a 1979 study by Hogstedt et al. (*8*), documenting the occurrence of 3 cases of leukemia in a group of 230 workers (more fully discussed below). ACGIH's 1981 TLV publication also includes a Notice of Intended Change to further lower the EtO limit from 10 ppm to 5 ppm based on the positive carcinogenicity bioassay results in a study on rats conducted by the Bushy Run Research Center (*9*) (discussed below).

On May 22, 1981, NIOSH issued a "Current Intelligence Bulletin" on EtO (*10*) to inform employees and employers about the potential carcinogenic hazard of EtO to workers. Based on recent scientific data, NIOSH recommended that EtO be regarded as a potential occupational carcinogen and that OSHA's present exposure limit of 50 ppm be reexamined since the establishment of this limit preceded the recognition of the carcinogenic potential of EtO and was based only on consideration of acute and chronic nonmalignant health effects.

2. Petition for Emergency Temporary Standard (ETS)

On August 13, 1981, the Public Citizen Health Research Group and the American Federation of State, County and Municipal Employees (AFSCME) petitioned the Agency to issue an emergency temporary standard under section 6(c) of the Act lowering the current OSHA PEL from 50 ppm to 1 ppm as an 8-hour time-weighted-average with a maximum peak exposure of 5 ppm (15 minutes) (*11*). After reviewing the petition and available data, OSHA has determined that current conditions involving EtO do not warrant the issuance of an ETS under section 6(c) of the Act. The petition, therefore, has been denied (*12*).

3. Production and Use

EtO is also known as 1,2-epoxyethane, oxirane, and dimethylene oxide. At room temperature and atmospheric pressure, EtO is a colorless gas; at higher pressures it may be a volatile liquid. It has a characteristic ether-like odor with a widely variable odor threshold in humans; the mean detectable concentration in air is about 700 ppm (1260 mg/m^3) (*13*). It is completely miscible with water, alcohol, acetone, benzene, ether, carbon tetrachloride, and most organic solvents. Ethylene oxide is highly reactive and potentially explosive in the presence of alkali metal hydroxides and highly active catalytic surfaces, or when heated. EtO is relatively stable in aqueous solutions, or when diluted with carbon dioxide (CO_2) or halocarbons. In order to reduce explosion hazards when EtO is used as a fumigant or sterilant it is often used in gaseous mixtures (such as 10% EtO and 90% CO_2, or 12% EtO and 88% halocarbon).

Ethylene oxide is a major industrial chemical and is one of the 25 chemicals of highest production volume in the United States. Current production capacity in the United States is about 6.7 billion pounds per year. In 1980, the industrial consumption of EtO was about 5.3 billion pounds (*14*).

EtO is primarily used as an intermediate in the production of several industrial products. The largest consumption of EtO is in the production

of ethylene glycol for automotive antifreeze and as an intermediate chemical in the production of polyester fibers, films, and bottles. The second largest consumption is in production of nonionic surface-active agents for industrial applications and for heavy-duty home laundry detergents and dishwashing formulations. Production of glycol ethers (e.g., solvents for surface coatings) and ethanolamines (used in production of soaps, detergents, and textile chemicals) constitute the third and fourth largest uses, respectively.

Many smaller uses account for the remainder of EtO consumption. Ethylene oxide is used as a peticide fumigant (including antimicrobial sterilant). Industries and work settings where it is used as a sterilant or fumigant include: health care, diagnosis and treatment facilities; medical products manufacturing; animal and plant quarantine service at ports of entry; transportation vehicles (e.g., aircraft, buses, and railroad cars) fumigation; the food industry (spices and seasonings); clothing, furs, and furniture fumigation; research laboratories; libraries; museums; beekeeping; dairy packaging; and cosmetics manufacturing.

4. Potential for Occupational Exposure

NIOSH estimates that approximately 144,000 workers may be exposed to EtO. Since EtO is highly explosive and reactive, the process equipment containing it generally consists of tightly closed and highly automated systems. The equipment is often located outdoors, and workers spend most of their work shift inside or around control rooms, away from the equipment. Samples collected in general process areas of six plants indicated that EtO concentrations were, with few exceptions, less than 1 ppm (*15*). The greatest potential for worker exposure probably occurs during the loading or unloading of transport tanks, product sampling procedures, and equipment maintenance and repair. Exposures may be significant in operations where tightly closed and highly automated systems are not used.

In contrast to the chemical-manufacturing plants, other industries and activities may use only a very small portion of the total EtO produced, but are responsible for high occupational exposures to many workers. For example, less than 0.24% of the annual U.S. Production of EtO is consumed in the health care and medical products industries (*16*), and only about 0.02% of the production is used for sterilization in hospitals (*4*). Yet, NIOSH estimates that approximately 75,000 health care workers employed in sterilization areas are potentially exposed to EtO and that 25,000 others may be incidentally exposed. In a limited field survey of hospitals, NIOSH found that EtO concentrations near malfunctioning or improperly designed equipment may reach transitory levels of hundreds or even a few thousand ppm. TWA ambient and breathing zone concentrations were generally below the OSHA standard of 50 ppm (*4*).

It should be noted that based on recent health data (see below), several industrial users and producers have adopted internal company exposure limits well below OSHA's 50 ppm limit (for example, Exxon and the American Hospital Supply Corporation have adopted policies to limit employee exposure to EtO to 10 ppm; Shell Chemical Division, Union Carbide, and Medtronics have adopted 5 ppm limits; Dow Chemical and Celanese, 3 ppm; Texaco, 2 ppm; and Rohm & Haas and Johnson & Johnson, 1 ppm) (*17*).

5. Sterilant and Fumigant Use

The Environmental Protection Agency (EPA) has the authority to regulate the use and application of sterilants and fumigants under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended (7 U.S.C. 136 et seq.). EPA regulations on the enforcement of FIFRA are found in 40 CFR Part 162. EtO for use as a sterilant or fumigant is regulated under FIFRA, and formulations of EtO pesticides are registered with EPA. All such pesticides are required to be labelled with warning information as to their toxicity to humans, an indication of the particular hazards, the route(s) of exposure, and the precautions to be taken to avoid accident, injury, or damage. Application of these pesticides may only be performed in accordance with the precautions set forth on the label.

Section 4(b)(1) of the OSH Act (29 U.S.C. 653(b)(1)) provides that nothing in the OSH Act "shall apply to working conditions of employees with respect to which other Federal agencies * * * exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health."

Accordingly, where the working conditions of applicators of EtO have been regulated by EPA under FIFRA, section 4(b)(1) preempts OSHA coverage of these working conditions as they relate to EtO exposure.

OSHA is soliciting information as to non-users and non-applicators of EtO pesticides who may be incidentally or intermittently exposed to EtO in the workplace as a result of sterilization and fumigation procedures.

6. Health Effects

A considerable volume of new scientific information regarding the possible occupational hazards of EtO has emerged over the past few years. Significant new data regarding the chronic toxicity, carcinogenicity, mutagenicity, and possible reproductive hazards of EtO have become available. These data, together with data regarding worker exposure to EtO, are under review at OSHA. The objectives of the review are to: (1) ascertain the extent to which any of these possible hazards may exist for workers under the current permissible exposure limit of 50 ppm; (2) determine whether current risks, if they should be shown to exist, need to be reduced; and (3) estimate the effectiveness of various possible lower exposure limits in reducing risks. OSHA presents below brief summaries of recent studies that raise concerns for adverse health effects of EtO exposure. OSHA is soliciting evaluations from the public on these and on any other studies that may be available.

(a) Carcinogenicity

(1) *Evidence in Animals.* The final report on the results of the inhalation toxicity study of EtO conducted by the Bushy Run Research Center, co-sponsored by a consortium of manufacturers of ethylene oxide, was released in January 1981 (*9*). The protocol included a chronic (24 month) inhalation study in which male and female rats of the Fischer 344 strain were exposed to three concentrations of ethylene oxide (100, 33, and 10 ppm, respectively) for 6 hours a day, 5 days a week. Two groups of animals, similarly housed and maintained except that they were not exposed to ethylene oxide, served as untreated controls.

Examinations were made of all animals that died or were killed at scheduled intervals at 6, 12, 18, 24, and 25 months. Based on histologic evaluation, the researchers concluded that the incidences of mononuclear cell leukemia and peritoneal mesothelioma were significantly increased because of exposure to EtO. The incidence of mononuclear cell leukemia in female rats was dose-related, increasing linearly with increasing exposure concentrations. A statistically significant increase in mononuclear cell leukemia was observed only in the group of females exposed at 100 ppm. For females exposed at 33 ppm, the cumulative percentage incidence of leukemia was significantly higher than that for one control group and for a conbination of both control groups, but

not for the second control group. However, the incidence of mononuclear cell leukemia in female rats exposed at 33 and 10 ppm did indicate a dose response relationship. The regression analysis of leukemia incidence versus exposure concentration was significant, with a correlation coefficient of +0.99.

Peritoneal mesothelioma was reported to be treatment-related in the male rats exposed at 33 and 100 ppm. Among the males exposed at 100 ppm, the cumulative percentage developing this tumor was reported higher (statistically significant) than controls beginning with the 21st month of exposure, whereas the incidence of the tumors in males exposed at 33 ppm was not appreciably higher than in controls until the last month of the study. There peritoneal tumors originated on the testicular mesothelium and were confined to the abdominal cavity.

In addition, the researchers reported that EtO exposure was associated with a higher frequency and/or earlier observation of mononuclear cell leukemia in male rats. The researchers also reported that a mortality-adjusted trend analysis indicated that the normal occurrence of pituitary adenoma in male and female rats was significantly accelerated by exposure to EtO.

In 1979, Dunkelberg reported preliminary results of a long-term carcinogenicity assay in mice (*18*). Ethylene oxide was administered to female NMRI mice by subcutaneous injection in weekly dosages of 0.1, 0.3, or 1.0 mg per animal. Two control groups were used. The animals had been treated for 91 weeks at the time of the report. Tumors (sarcomas) appeared at the injection site in the treated groups, but not in the control groups. The first tumor appeared in the 50th week of treatment. The number of subcutaneous tumors at the injection site appeared to increase with the dose; the number of tumors at sites distant from the injection sites was not significantly greater in the treatment groups than in control groups.

Reyniers et al. (1964) (*19*) reported tumors in 63 of 83 female mice accidentally exposed to ethylene oxide-treated bedding for 150 days and then moved to untreated bedding for the rest of their lifespan. In contrast, no tumors were reported in 83 female mice that had not been exposed to the ETO-treated bedding. The most common tumors in the exposed group were ovarian, lymphoid (malignant lymphoma), and pulmonary.

Two earlier studies on carcinogenicity should also be noted. Walpole (1957) subjected 12 "stock" rats to repeated subcutaneous injections of a total dose of 1 g/kg EtO in Archis oil for 94 days (*20*). The small sample of animals was observed for their lifetime and no tumors were observed. Van Duuren et al. (1965) applied 0.1 ml of a 10% ethylene oxide solution in acetone to the dorsal skin of 30 female Swiss Millerton mice three times a week for life (*21*). No tumors were observed.

(2) *Evidence in Humans.* Hogstedt et al. (1979) reported an excess of leukemia among Swedish workers in a factory where a mixture of EtO and methyl formate had been used to sterilize hospital equipment (*8*). Three cases of leukemia occurred between 1972 and 1977 among the 230 workers, compared to 0.2 cases expected based on age and sex-specific Swedish national leukemia rates for 1972. Two of the cases (females) had been exposed to an estimated eight-hour TWA of 20 ppm EtO. The exposure in the third case (male) was not specified for EtO, but he was known to have some contact with benzene in laboratory work. The cases of leukemia were categorized as chronic myeloid leukemia and acute myelogenic leukemia for women, and as macroglobulinemia for the man.

Hogstedt et al. (*22*) also reported the results of an historical prospective mortality investigation of workers in an EtO production facility. Individuals who had been employed in 1961, had a minimum of 1 year of employment or exposure and had achieved at least a ten year latency period from the start of exposure to the beginning of the observation period, were followed through 1977.

Among the 89 full time workers in the EtO production areas, an excess of total mortality was observed (23 deaths observed, 13.5 expected, p is less than 0.05). An excess of total cancer mortality (9 observed, 3.4 expected, p is less than 0.01) and circulatory system deaths (12 observed, 6.3 expected, p is less than 0.05) was reported. Site specific excess cancer mortality was noted for leukemia (2 observed, 0.14 expected, p is less than 0.01) and stomach cancer (3 observed, 0.4 expected, p is less than 0.01). No statistically significant excess mortality was noted among the 86 maintenance workers with intermittent EtO exposure or among the 66 workers who never were in EtO production areas. One leukemia death was noted among the maintenance workers. Other potential chemical exposures among those workers included ethylene, ethylene dichloride, ethylene chlorohydrin, and bis 2-chloroethyl ether. Exposure to EtO was estimated to range up to the odor threshold of 700 ppm in the 1940's, with average exposure below 14 ppm. EtO concentrations of 6—28 ppm during the 1950's and 1960's were estimated. EtO concentrations of 0.6—6 ppm were estimated for the 1970's.

(b) Evidence of Reproductive Effects

The final report of a one-generation reproduction study in rats by the Bushy Run Research Center is also available (*23*). Both male and female rats were exposed to doses of 100, 33, or 10 ppm of ethylene oxide vapor. The major treatment-related adverse effect was that significantly fewer pups were born per litter for rats exposed to 100 ppm EtO. A dose response relationship in fertility was observed at 100 ppm and 33 ppm, while no effect occurred following exposure to 10 ppm EtO.

LaBorde and Kimmel reported evidence of a teratogenic effect of intravenous EtO in the CD–1 mouse (*24*). They found that EtO was toxic to pregnant mice at doses of 150 mg/kg when administered intravenously during days 4–6, 8–10, or 10–12 of gestation but not at days 6–8. A significant increase in the percent of malformed fetuses was found as a result of EtO administration on days 6–8 and 10–12 of gestation.

(c) Evidence of Mutagenicity

The mutagenicity of ethylene oxide has been demonstrated in a wide range of biological systems, including submammalian and mammalian species. An increased frequency of cell mutations was observed in 13 different species including *Salmonella* (*25*), *Neurospora* (*26*), barley (*27*), (*28*), (*29*), (*30*), *Tradescantia* (*31*), *Drosophila* (*32*), (*33*), *E. coli* (*34*) and, as discussed below, rat, mouse and man.

Embree et al. (1977) have shown that ethylene oxide causes mutations in Long-Evans rats in the dominant-lethal assay. Male rats were exposed to 1000 ppm of ethylene oxide for 4 hours and each male mated with 2 females each week for 10 weeks (*35*). There was a significant increase in post-implantation deaths 1, 2, 3, and 5 weeks after treatment indicating that gametes in various stages of development from spermatocyte through mature sperm were adversely affected.

Generoso et al. (1980) reported the induction of dominant-lethal effects in rats resulting from a single intraperitoneal injection of 150 mg/kg (maximum tolerated dose). In a heritable translocation assay, male rates were given intraperitoneal injections of EtO daily on weekdays for 5 weeks with 60 or 30 mg/kg body weight per day. In addition to observed dominant lethal effects, an increased frequency of heritable translocations was reported for the EtO exposed groups (*36*).

An inhalation study of EtO on mice was performed by Cumming et al.(*37*). They found that unscheduled DNA synthesis was increased after male (101×C3H)F1 hybrid mice were exposed to 300 or 500 ppm ethylene oxide in a work-week type exposure regimen. EtO at doses of 600 and 800 ppm inhibited the repair of DNA damage as measured by a reduction in unscheduled DNA synthesis after 4 hours of exposure.

Ehrenberg et al. observed an elevated frequency of chromosomal aberrations in circulating lymphocytes among 10 people exposed to high concentrations of EtO 18 months prior to blood sampling compared to 10 controls (*38*).

A company using EtO in manufacturing and distributing health care products has reported the results of a medical evaluation including cytogenetic evaluation of 75 workers with potential EtO exposure at nine facilities (Abrahams, 1980) (*39*). Workers were exposed for an average of 2.9 years. A group of 37 workers with no known EtO exposure served as a comparison group for the cytogenetic evaluation. The data indicated that the facilities had complied with the OSHA PEL of 50 ppm as an 8-hour TWA. The physical examination revealed no unusual findings among exposed persons. A statistically significant increase in the number of chromosome aberrations in peripheral lymphocytes among the exposed workers was noted when compared to the nonexposed group. Workers also had an increased incidence of sister chromatid exchanges compared to nonexposed workers. Chromosome spreads were further evaluated for the presence of quadriradial forms per 100 cells analyzed. A significantly elevated frequency of individuals with 2 of more quadriradial chromosomes, 12% (9/73), was observed among exposed persons compared to no such chromosomes reported (0/73) among non-exposed persons. Individuals in two of the nine facilities were examined a second time. Using these values, the overall frequency of inividuals with 2 or more quadriradial chromosomes per 100 cells was 20% (11/56) as compared to 0% (0/37) in the controls. Data from the sperm analysis were inconclusive.

7. *Risk Assessment.* Evaluation of the carcinogenic, mutagenic, and reproductive effects of ethylene oxide should include an estimation of health risks under current conditions of exposure. OSHA intends to perform such assessments and requests information concerning methodologies to be used for this estimation. Questions addressing these issues are presented in detail in the section on Requested Public Submissions.

8. *Feasibility.* During this rulemaking, OSHA will develop an analysis of the feasibility of any proposed EtO standard, as required by the Act. In addition, pursuant to Executive Order 12291, OSHA will determine whether this is a major action and, if so, will prepare a Regulatory Impact Analysis. Under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), if a significant impact on small entities is anticipated, a Regulatory Flexibility Analysis will also be performed. In order to provide data and information necessary to perform those required analyses. OSHA has contracted for the services of JRB Associates of McLean, Virginia. Their data collection effort will cover the industries that produce and use EtO.

As noted below, OSHA solicits all available information on current EtO exposure levels, methods of controlling exposure, and costs of compliance. OSHA requests that industry-wide feasibility studies and the collection of data relevant to assisting the Agency in complying with E.O. 12291, the Regulatory Flexibility Act, and the OSH Act be initiated by interested persons as soon as possible. In addition, any information or views on whether regulation of EtO would have a significant impact on the human environment within the meaning of the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 et seq.) and the regulations at 40 CFR Parts 1500–1508 and 29 CFR Part 11 are also invited.

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Requested Public Submissions

Public comment on the data discussed in this Advance Notice and other relevant issues is requested for the purpose of assisting OSHA in its reevaluation of the adequacy of the present EtO standard. OSHA also requests that interested parties submit any pertinent health data not discussed in this notice.

Comment is requested on the following issues relating to health effects, technological and economic feasibility, and provisions which should be considered for inclusion in a comprehensive EtO standard. Specifically, scientific and technical data and expert analysis and opinion are sought on the following issues:

1. Do the available human and experimental data indicate that the EtO standard should be revised on the basis of carcinogenic and reproductive risks?

2. Is OSHA's existing 8-hour TWA exposure limit of 50 ppm adequate to protect workers from the occurrence of adverse health effects associated with occupational exposure to EtO?

3. What is the risk of developing cancer or any other adverse health effects that might arise from exposure to EtO at OSHA's current exposure limit of 50 ppm, or from exposure to alternative limits of 0.5, 1, 5, 10 ppm and the lowest level capable of being achieved? Are these risks significant? Comment is requested specifically on the following related issues:

a. Methods for considering both cancer incidence and time-to-tumor observation data;

b. Methods for considering differences between timing, frequency, and duration of human and experimental animal exposure;

c. Models to be used for extrapolation of dose-response data and their applicability for estimating carcinogenic and reproductive risks;

d. Information that may assist in the selection of dose-response models and in comparing human and animal target organ doses in relation to inhaled doses;

e. The adequacy of the available scientific evidence for quantification of health risks associated with EtO exposure and other means the agency may rely on to assess risk, such as qualitative evidence and expert testimony.

4. What are the number of workers exposed to EtO, their current exposure levels, duration and frequency of exposure, the job being performed, and the Standard Industrial Classification (SIC) Codes for industries and processes using EtO?

5. Of those employees exposed to EtO as a result of fumigation or sterilization operations, how many are not engaged in the actual application of the EtO? Of the non-applicators who are exposed, how frequently are they exposed, and at what levels? What control methods are available for non-applicators?

6. Which of the following control methods are available to reduce exposures to EtO to alternative 8-hour TWA's of 0.5, 1, 5, or 10 ppm? Please provide a detailed discussion of the use of these controls, their application in various work settings, their efficacy, their costs, and the time necessary for implementation. Please also provide documentation with this discussion, including engineering feasibility studies and evidence concerning actual costs of control. This information will assist OSHA in evaluating the cost-effectiveness of various alternative control strategies and the feasibility of complying with alternative TWA's of 0.5, 1, 5, or 10 ppm. To what extent would these controls involve simple modifications of equipment or procedures? To what extent and in which processes would substantial changes be necessary? What is the lowest level feasible through implementation of these controls?

a. Engineering controls including: ventilation collection, isolation containment, substitution of product or process, modification of process or equipment.

b. Work practices, housekeeping and administrative controls.

7. Are there any unique conditions in work settings where EtO is produced or

used which would preclude the use of personal protective equipment, or engineering controls and work practices to reduce exposures?

8. Are there other OSHA standards that require the use of engineering controls which would also affect or be affected by a reduction in EtO exposure levels?

9. Have there been technological improvements or changes in the production or use of EtO for the purpose of improving productivity or product quality which have also resulted in reductions in EtO exposures?

10. Is a short-term or ceiling limit for EtO exposures necessary and why, and what would be the technological and economic feasibility of complying with that limit?

11. What methods are available for reducing worker exposure to EtO to 0.5, 1, 5, or 10 ppm by means other than engineering controls, work practices, and substitutes? Are negative pressure chemical cartridge respirators available for use with EtO? What other respiratory protection is available at the above levels?

12. What measurement and analytical methods are available for use in determining compliance with an EtO exposure limit of 0.5, 1, 5, or 10 ppm?

13. Is it necessary to establish provisions for medical examinations, respirators, personal protective clothing and equipment, hygiene facilities and practices, regulated areas, maintaining records, housekeeping, employee information and training, and labels and signs? What form should such provisions take in a proposed standard? To what extent are these provisions currently being employed by industry and what are their costs?

14. In order to perform an economic feasibility analysis, it is helpful to have a financial and economic profile of the industries producing and using EtO. The following information is requested to aid in the preparation of that profile. Data should be provided for the last five years.

a. What were the total annual volumes and dollar values of production, shipments, and inventories?

b. What were the total annual investments categorized as replacement, expansion, modernization, and environmental health and safety related?

c. What were the retained earnings, after tax income, total assets, stockholders' equity, net worth, depreciation charges, and debt-equity ratios?

d. What is the rate of return on assets and equity?

15. What were the total annual employment levels and labor turnover for the industries with EtO exposures for at least the last 5 years? What is the average rate of absenteeism?

16. If the Agency determines that a substantial number of small entities are affected by this rulemaking, OSHA will prepare a Regulatory Flexibility Analysis. The following information is requested to aid in this determination.

a. How many and what kind of small businesses or organizations would be affected by regulating exposures to EtO?

b. Which, if any, federal rules may duplicate, overlap, or conflict with a comprehensive OSHA regulation concerning EtO?

c. Will difficulties be encountered by small entities when attempting to comply with requirements for exposure monitoring, permissible exposure limits, medical examinations, respirators, personal protective clothing and equipment, hygiene facilities and practices, regulated areas, recordkeeping, housekeeping, employee information and training, and labels and signs? Can some of these requirements be deleted or simplified for small entities, while also achieving comparable protection of the health of employees of small entities?

d. What timetable would be optimal for allowing small entities sufficient time to comply?

17. The National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 et seq.) requires that each Federal agency consider the environmental impact of major actions significantly affecting the quality of the human environment. Any person having information, data, or comments pertaining to possible environmental impacts is invited to submit them and accompanying documentation to OSHA. Such impact might include:

a. Any positive or negative environmental effects that could result should a new standard be adopted;

b. Beneficial or adverse relationships between the local short-term uses of the human environment and enhancement of long-term productivity; and

c. Any irreversible commitments of natural resources which could be involved should a standard be implemented.

In particular, consideration should be given to the potential direct of indirect impacts of any action, or alternative actions, on water and air pollution, energy usage, solid waste disposal, or land use.

Public Participation

Interested persons are invited to submit comment on these and other pertinent issues relating to occupational exposure to EtO by March 31, 1982. Comments should be sent in quadruplicate to the Docket Officer, at the address noted above where they will be available for inspection and copying. The data received in response to this Advance Notice will be carefully reviewed and will be used by OSHA to determine whether it is necessary and appropriate to pursue further regulatory activity regarding occupational exposure to EtO.

This Advance Notice of Proposed Rulemaking was prepared under the direction of Thorne G. Auchter, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue, N.W., Washington, D.C. 20210. It is issued pursuant to section 6(b) of the Occupational Safety and Health Act (84 Stat. 1593; 29 U.S.C. 655).

Signed at Washington, D.C. this 22nd day of January 1982.

Thorne G. Auchter,

Assistant Secretary of Labor.

[FR Doc. 82-2032 Filed 1-25-82; 8:45 am]

BILLING CODE 4510-26-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Ch. VII

Public Hearing and Public Comment Period on the Resubmitted Ohio Permanent Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; notice of receipt of Ohio Permanent Program Resubmission; schedule for public hearing and public comment period.

SUMMARY: The Office of Surface Mining (OSM) is announcing procedures for the public comment period and hearing on the substantive adequacy of the proposed Ohio regulatory program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA) which has been resubmitted by the State.

This notice sets forth the times and locations that the Ohio program is available for public inspection; the date when and the location where OSM will hold a public hearing on the resubmission; the comment period during which interested persons may resubmit written comments and data on the proposed program and other information relevant to public

participation during the comment period and public hearing.

DATES: A public hearing to review the substance of the Ohio program not previously approved by the Secretary of the Interior will be held at 1:00 p.m. on February 18, 1982, at the address listed under "ADDRESSES".

Comments from members of the public must be postmarked no later than February 20, 1982, in order to be considered in the Secretary's decision the proposed Ohio program.

ADDRESSES: The public hearing will be held at the Howard Johnson Motor Lodge, 999 E. Granville Rd. at the intersection of I-71 and S.R. 161 in Columbus, Ohio. Written comments should be sent to: Office of Surface Mining, Attn: Ohio Program Review, 46 East Ohio Street, Indianapolis, Indiana 46204–1994.

Copies of the full text of the proposed program, a listing of scheduled public meetings and copies of all written comments are available for review and copying of the OSM Region III office and the office of the State Regulatory Authority listed below, Monday through Friday 8:00 a.m.–4:00 p.m., excluding holidays.

Office of Surface Mining, Region III, 46 East Ohio Street, Indianapolis, Indiana 46204–1994, Phone (317) 269–2629;

Division of Reclamation, Ohio Department of Natural Resources, Fountain Square, Building B, Columbus, Ohio 43224, Phone (614) 265–6633.

For locations where copies of the full text of the proposed program are available for inspection see "Supplementary Information".

FOR FURTHER INFORMATION CONTACT: J. M. Furman, Assistant Regional Director, State & Federal Program, Office of Surface Mining, Room 527, 46 East Ohio Street, Indianapolis, Indiana 46204–1994, Phone (317) 269–2629.

SUPPLEMENTARY INFORMATION: Copies of the full text of the proposed program are available for inspection during regular business hours at the following locations:

Office of Surface Mining, Region III, Fifth Floor, Room 511, Federal Building and U.S. Courthouse, 46 East Ohio Street, Indianapolis, Indiana 46204–1994;

Ohio Division of Reclamation, Department of Natural Resources, Fountain Square, Building B, Columbus, Ohio 43224;

Ohio Division of Reclamation, District II, 1894 East High Street, New Philadelphia, Ohio 44663;

Ohio Division of Reclamation, District III, 966 N. Market Street, Lisbon, Ohio 44432;

Ohio Division of Reclamation, District IV, Technical Building, 850 Airport Road, Route 4, Zanesville, Ohio 43701;

Ohio Division of Reclamation, District V, 46633 East Richland, St. Clairsville, Ohio 43950;

Ohio Divison of Reclamation, District VI, 10007 E. State Street, Athens, Ohio 45701;

Ohio Divison of Reclamation, District VI, 36 Portsmouth Street, Jackson, Ohio 45640;

Office of Surface Mining, District Office, 1100 Brandywine Blvd., Building D, Zanesville, Ohio 43701.

On February 29, 1980, the State of Ohio submitted to the Secretary of the Interior its proposed State regulatory program. Pursuant to the provisions of 30 CFR Part 732 (44 FR 15326–15328), the Regional Director published notification of receipt of the program in the March 7, 1980 **Federal Register** (45 FR 14883–14884) and in newspapers of general circulation within the State. In accordance with that announcement, public comments were solicited and a public review meeting regarding completeness of the submission was held in Columbus, Ohio on April 11, 1980.

On April 28, 1980, the Regional Director published notice in the **Federal Register** that he had determined the Ohio program to be incomplete (45 FR 28168–28169) as required by 30 CFR 732.11(c).

Public hearings on the adequacy of the Ohio submission were held in St. Clairsville, Ohio on July 21, 1980, and in Columbus, Ohio on July 22, 1980, by the Regional Director after due notice on June 19, 1980, in the **Federal Register** (45 FR 41456–41458) and in newspapers of general circulation within the State.

The full chronology of the events leading to the Secretary's initial decision is contained in the **Federal Register** notice (45 FR 64962–64971) published on October 1, 1980. That notice also contained the Secretary's findings, detailed explanations of those findings and the Secretary's decision, which disapproved the Ohio program.

In accordance with the procedures set forth in 30 CFR 732.13(f), the State of Ohio would have had 60 days from the date of publication of the Secretary's disapproval decision in which to resubmit its program for consideration.

The Common Pleas Court of Franklin County, Ohio issued a Temporary Restraining Order against the State of Ohio on November 24, 1980 restraining and enjoining the State from resubmitting its proposed permanent program. On November 25, 1980, the State was enjoined from resubmitting its program for a period of one year by the Common Pleas Court of Belmont County, Ohio. Based on a Motion to Dismiss filed by the State, the Franklin County case was dismissed on July 10, 1981. The Belmont County injunction terminated on November 25, 1981. The State then had 60 days within which to resubmit its program. The State resubmitted its program on January 22, 1982.

In keeping with the public participation mandate of SMCRA and 30 CFR 732.13(f), a public comment and review period is being allowed for the Ohio program resubmission. The public review and comment period for the Ohio program ends on February 20, 1982. During this period the Secretary is soliciting comments from the Administrator of the Environmental Protection Agency, the Secretary of Agriculture and the heads of other federal agencies, as well as the general public.

Subsequent to the public hearing and review of all comments, the Regional Director will transmit to the Director a recommended decision along with a record composed of the hearing transcript, written presentations, exhibits, and copies of all public comments.

Upon receipt of the Regional Director's recommendation, the Director will consider all relevant information in the record and will recommend to the Secretary that the program that was disapproved in the Secretary's initial decision now be approved, disapproved or conditionally approved. The recommendation will specify the reasons for the decision. The procedures for the recommended decisions of the Regional Director and the Director to the Secretary are established in 30 CFR 732.12(d) and (e) (44 FR 15326–15327). For further details, refer to 30 CFR 732.12 and 732.13 of the permanent regulatory program (44 FR 15326–15327) and corresponding sections of the preamble (44 FR 14959–14961).

The Secretary's decision on the program as resubmitted will constitute the final decision by the Department. If the resubmitted program is approved, the State of Ohio will have primary jurisdiction for the regulation of surface coal mining and reclamation and coal exploration on non-federal and non-Indian lands in Ohio. If the revised program is approved, the Secretary and the Governor may also enter into a

cooperative agreement governing regulation of these activities on federal lands in Ohio. Such an agreement would be the subject of a separate rulemaking and **Federal Register** notice. If the revised program is disapproved, a federal program will be implemented and OSM will have primary jurisdiction for the regulation of the above activities in Ohio. To codify decisions on state matters, OSM has established Subchapter T of 30 CFR Chapter VII.

Subchapter T will consist of Parts 900 through 950. Provisions relating to Ohio will be found in 30 CFR Part 935 after Ohio's resubmission has been approved or disapproved.

At the public hearing on February 18, 1982, parties wishing to comment on the proposed program will be asked to register for placement on the speaker's agenda. The hearing will begin at 1:00 P.M. and will continue until all persons scheduled to speak have been heard. Persons in the audience who have not been scheduled to speak and who wish to do so will be heard at the end of the scheduled speakers. Persons not scheduled to speak but wishing to do so, assume the risk of having the public hearing adjourned unless they are present in the audience at the time all scheduled speakers have been heard. Written comments, data, or other relevant information may be submitted to supplement, or in lieu of an oral presentation at the hearing. In addition, the Regional Director has prescribed the following format and rules of procedure in accordance with 30 CFR 732.12(b)(1) (44 FR 15326).

1. The hearing shall be informal and follow legislative procedures.

2. Based on the number of speakers in attendance, each participant may be limited to 10 minutes.

3. Participants will be called in the order in which they register.

Public participation in the review of state programs is a vital component in fulfilling the purposes of SMCRA. On September 19, 1979, OSM published guidelines in the **Federal Register** (44 FR 54444–54445) governing contacts between the Department of the Interior and both state officials and members of the public. It is hoped that issuance of these guidelines will encourage full cooperation by all affected persons.

Interested members of the public are encouraged to read the Secretary's disapproval of the initial Ohio program submission (45 FR 64962–64971) published on October 1, 1980. That document contains detailed findings and explanations relating to the initial submission which was disapproved.

Set forth below is a summary of the contents of the Ohio program including resubmission material.

(a) State Law and Regulations.
(b) Other Related State Laws.
(c) Attorney General's Opinion.
(d) Delegation of Regulatory Authority.
(e) Structural Organization—Staffing Functions.
(f) Supporting Agreements between Agencies.
(g) Narrative Description for:
(1) Issuing Exploration for Mining Permits.
(2) Assessing Permit Fees.
(3) Bonding—Insurance.
(4) Inspecting and Monitoring.
(5) Enforcing the Administrative, Civil and Criminal Sanctions.
(6) Administering and Enforcing Permanent Program Standards.
(7) Assessing and Collecting Civil Penalties.
(8) Issuing Public Notices and Holding Public Hearings.
(9) Coordinating with Other Agencies.
(10) Consulting with Other Agencies.
(11) Designating Lands Unsuitable for Mining.
(12) Restricting Financial Interests.
(13) Training, Examining and Certifying Blasters.
(14) Providing for Public Participation.
(15) Providing Administrative and Judicial Review.
(16) Providing a Small Operator Assistance Program (S.O.A.P.).
(h) Statistical Information.
(i) Summary of Staff with Titles, Functions, Job Experience and Training.
(j) Description of Staffing Adequacy.
(k) Projected Use of Other Professional and Technical Personnel.
(l) Budget Information.
(m) Physical Resources Information.
(n) Other Programs Administered by the Regulatory Authority.

No Environmental Impact Statement is being prepared in connection with the process leading to the approval or disapproval of the proposed Ohio program. Under Section 702(3) of SMCRA (30 U.S.C. 1292(3)) approval does not constitute a major action within the meaning of Section 102(2)(c) of the National Environmental Policy Act of 1979 (42 U.S.C. 4332).

Edgar A. Imhoff,

Regional Director.

[FR Doc. 82-1876 Filed 1-25-82; 8:45 am]

BILLING CODE 4310-05-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 25

[CC Docket No. 81-704]

Licensing of Space Stations in the Domestic Fixed-Satellite Service and Related Revisions of Part 25 of the Rules and Regulations; Order Extending Time for Filing Comments and Reply Comments

AGENCY: Federal Communications Commission.

ACTION: Notice of inquiry and proposed rule; extension of comment/reply comment period.

SUMMARY: This action extends time for filing comments and reply comments in a rulemaking involving Commission proposals to reduce spacing between domestic satellites to accommodate additional satellites in orbit and other related rules and policies governing the licensing of such radio facilities. Extension was granted because of the additional time needed by parties to perform extensive engineering analyses.

DATE: Comments must be filed on or before March 8, 1982 and reply comments on or before April 26, 1982.

ADDRESS: Submit comments to the Federal Communications Commission Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Ronald J. Lepkowski, Common Carrier Bureau, (202) 632–5930.

In the matter of Licensing of Space Stations in the Domestic Fixed-Satellite Service and related revisions of part 25 of the rules and regulations.

Adopted: January 13, 1982.

Released: January 19, 1982.

By the Common Carrier Bureau:

1. On November 18, 1981 the Commission released its *Notice of Inquiry and Proposed Rulemaking* (FCC 81–466) (46 FR 57067; November 20, 1981) initiating this Docket. The Commission requested interested parties to file their comments on or before January 25, 1982 and reply comments on or before March 1, 1982.

2. Three licensees authorized to construct and operate domestic satellites have requested that the time for filing comments be extended from January 25, 1982 until February 26 or March 31, 1982 and that the date for filing reply comments be extended until April 1 or May 5, 1982, respectively. These parties submit that the time extension is needed to prepare a response involving extensive engineering analyses and associated

projections of costs and demand with respect to the proposed reduction in orbital spacing between adjacent satellites. Also, complications resulting from heavy work schedules, including launch of new satellites in early 1982, and disruptions occasioned by the holidays in December 1981 allegedly placed further limits on the amount of time available to perform needed technical and other analyses.

3. We are aware that extensive efforts and analyses are required from interested parties to provide detailed and specific comments in the matters raised by our Notice in this proceeding. However, the Commission also has indicated its desire to reach an early decision on the question of orbital spacing. This would permit a new orbital deployment plan to be implemented prior to the launch of a significant number of new satellites and minimize disruption of service resulting from the relocation of satellites in orbit after launch. To meet this objective, a sufficient amount of time must therefore be afforded to allow the Commission's staff to review and analyze the comments and reply comments, and present its recommendations to the Commission for final decision. Based on current launch schedule information available to the staff, it would be desirable that the Commission consider this matter by the early fall of 1982. A balance must therefore be drawn between the desire of parties for additional time to prepare their comments and reply comments, and the needs of the Commission for a sufficient amount of time to analyze the record properly and to reach a timely decision within the limits of its available staff resources.

4. Accordingly, pursuant to § 0.291 of the Commission's Rules on Delegations of Authority, it is ordered that the period of time to file comments in the proceeding captioned above is extended until March 8, 1982 and the time to file reply comments is extended to April 26, 1982. We do not anticipate grant of any further extensions of time in this docket.

Federal Communications Commission.

Gary M. Epstein,

Chief, Common Carrier Bureau.

[FR Doc. 82-1812 Filed 1-25-82; 8:45 am]

BILLING CODE 6712-01-M

INTERSTATE COMMERCE COMMISSION

49 CFR Parts 1033 and 1254

[Ex Parte No. 285]

Maintenance of Records Pertaining to Demurrage, Detention, and Other Related Accessorial Charges by Rail Common Carriers of Property

AGENCY: Interstate Commerce Commission.

ACTION: Notice of proposed rules.

SUMMARY: The Commission is assessing the need to retain rules pertaining to the maintenance of demurrage and detention records applicable to both rail freight cars and freight trailers. Such a review is consistent with 49 U.S.C. 10101a. If, based on the comments received, we conclude the rules are unnecessary in any or all respects, they will be modified accordingly or repealed in full.

DATES: Comments must be received by March 12, 1982.

ADDRESS: An original and 15 copies of all comments should be sent to: Room 5340, Interstate Commerce Commission, Washington, D.C. 20423.

FOR FURTHER INFORMATION CONTACT: Jane F. Mackall, (202) 275-7656.

SUPPLEMENTARY INFORMATION: The demurrage/detention records regulations (49 CFR 1254.01-.06) were adopted in *Maintenance of Records Pertaining to Demurrage*, 352 I.C.C. 739 (1976). The purpose for establishing these regulations was to assure sufficient records for the proper assessment and collection of all applicable demurrage, detention, or other accessorial charges applicable to both rail freight cars and freight trailers. Because of subsequent legislation and rulemakings (discussed *infra*), it is appropriate to reconsider the value of these regulations.

It is also necessary to consider in this proceeding Car Service Rule 15 (49 CFR 1033.15). Although the car service rules were rescinded in Ex Parte No. 241 (Sub-No. 1), *Investigation of Adequacy of Freight Car Ownership*, 362 I.C.C. 844, 879 (1980) (45 FR 49942, July 28, 1980), Rule 15 was retained because of the reporting requirements it satisfied for the demurrage recordkeeping rules.

Recent legislation and Commission decisions have emphasized that rail operations and practices should be determined less by government regulations than by carrier management and marketplace competition. The Staggers Rail Act of 1980 enunciates this philosophy in the Rail Transportation Policy (49 U.S.C. 10101a), directing that federal regulations should be eliminated where they are unnecessary. Indeed, the legislative history, H.R. Rep. No. 96-1430, 96 Cong., 2d Sess. 80 (1980), by implication, notes the conflict between the costs of regulation and the need to achieve revenue adequacy.

We have undertaken a review of all existing regulations consistent with Executive Order No. 12291. The instant review is a part of that process.

Our recent administrative proceedings have been in keeping with these policies. (Some of the decisions preceded the 1980 legislation). Certain of these proceedings directly affect demurrage charges. See, for example, Ex Parte No. 334 (Sub-No. 4), *Order Granting Railroads Flexibility in Setting Per Diem Levels*, served August 18, 1980; Ex Parte No. 334 (Sub-No. 5) (45 FR 58259, September 2, 1980), *Zone of Reasonableness for Car Hire Charges*, notice of proposed rulemaking served October 29, 1980 (45 FR 73524, November 5, 1980); Ex Parte No. 358, *Change of Policy, Railroad Contract Rates*, served November 9, 1978, April 10, 1979, and February 21, 1980; Ex Parte No. 241 (Sub-No. 1), *supra;* and Ex Parte No. 230 (Sub-No. 5), *Improvement of TOFC/COFC Regulation*, served February 19, 1981 (46 FR 14348, February 27, 1981).[1] In all of these proceedings, an overriding concern was whether existing rules or statutory provisions continued to be necessary to implement the Interstate Commerce Act consistent with the goals of that Act. *American Trucking Assn.* v. *Atchison, T. & S.F. Ry. Co.*, 387 U.S. 397 (1967).

These actions and the requirement to reduce government regulations where appropriate, require a thorough review of the continuing need, if any, for these rules. In fact, we have recognized carrier difficulties in complying with the rules and have granted waivers of certain of them.[2] A general review of the rules to

[1] In *Improvement of TOFC/COFC Regulation, supra*, we exempted from regulation rail and truck service provided by railroads in connection with TOFC/COFC service. Because of this exemption, the demurrage recordkeeping rules for TOFC/COFC trailers (49 CFR 1254.05) no longer apply, and should be repealed.

[2] See 45 FR 81675 (December 11, 1980) and 46 FR 62196 (December 22, 1981). In these notices, we indicated our intent to review all the rules.

determine whether the benefits exceed the costs is far preferable to case-by-case waiver of them.

When the rules were first adopted, we concluded they were necessary to collection of applicable charges. We found that substantiating records were incomplete. Today, because marketplace competition is increasingly a more critical factor for rail carriers, we anticipate that carriers have sufficient self-interest to ensure accurate recordkeeping and, thus, collection of all applicable charges. In recent years, the railroads have made great strides in other related areas in recognition of the need to take all steps in their power to improve earnings. Computerization has also increased to a point where these rules may no longer be necessary. We note that the waivers we have granted have been necessary, to accommodate new computer recordkeeping.

These rules have been in operation for over 3 years. Our specific interests include: (1) The beneficial aspects of these rules; (2) the existing and anticipated burdens of compliance with the rules (the costs of compliance that will be saved); and (3) the relationship of their benefits to their costs. Comments should be in the context of actual experience with the demurrage recordkeeping rules. We also seek information as to how these rules may affect or be affected by changes (implemented or proposed) caused by the Staggers Act.

We note that, if the demurrage recordkeeping rules are rescinded, the carriers will still have the statutory obligation to collect applicable demurrage/detention charges and, correlative to that obligation, will have to maintain appropriate records to support these charges. Rescinding the regulations would in no way relieve the carriers of this duty to collect applicable charges, but instead would leave the method, format, and locations of records to management discretion.

We believe this action will not significantly affect either the quality of the human environment or conservation of energy resources. However, comments are invited.

We certify that this action will not have a significant impact on a substantial number of small entities. If the rules are repealed, the obligation to maintain records adequate to collect applicable charges remains. Moreover, the rules apply only to railroads, very few of which may qualify as small entities.

(49 U.S.C. 10101a, 10321, and 5 U.S.C. 553)

Dated: January 18, 1982.

By the Commission, Chairman Taylor, Vice-Chairman Gilliam, Commissioners Gresham and Clapp.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-1928 Filed 1-25-82; 8:45 am]

BILLING CODE 7035-01-M

Notices

Federal Register
Vol. 47, No. 17
Tuesday, January 26, 1982

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.

ACTION

Privacy Act of 1974; System of Records Amended

AGENCY: Action.

ACTION: Notice of amendment of ACTION's Privacy Act system of records entitled, ACTION Volunteer Applicant and Service Records System.

EFFECTIVE DATE: January 26, 1982.

FOR FURTHER INFORMATION CONTACT: Noel McCaman, Chief, Communications Operations Branch, Office of Recruitment and Communications, ACTION, Washington, D.C. 20525/ Telephone Number, area code 202–254–7520.

SUMMARY: This notice is published to inform the public of the establishment of records as a result of voluntary inquiries regarding ACTION/Peace Corps volunteer programs. The ACTION Volunteer Applicant and Service records System is amended to include the mention of the maintenance and use of data submitted to the agency by mail or personal contact. As a result of ACTION/Peace Corps program advertising throughout the United States, individuals interested in volunteer service contact the agency by telephone, in person or by mail, requesting program information and applications.

Whenever information/application kits are requested, a computer based record is created for the issuance of mailing labels and letters, follow-up letters and statistical studies. Such use of this date was in effect prior to the enactment of the Privacy Act. The original ACTION Privacy ACT system of record notices published in September, 1975, should have included mention of the creation and use of such records.

THEASAURUS TERMS: Volunteers, Privacy Act.

The ACTION Volunteer Applicant and Service Records System (ACTION/ 2) published in the **Federal Register**, Volume 44, dated September 26, 1979, at page 55493, is amended as follows:

The first sentence in "Categories of individuals covered by the system" is amended to read: "Current and former ACTION full-time volunteers, trainees, applicants, and individuals who request information regarding volunteer service in the Peace Corps, including Peace Corps United Nations Volunteers, or in one of ACTION's full-time Domestic Operations programs."

The first sentence of the first paragraph under "Categories of records in the system" is amended to read: "This major system covers a number of temporary and permanent records established during the interest inquiry, applicant, placement, selection and service stages."

The heading of Item (1) under "Categories of records in the system" is amended to add the interest Inquiry record and a sentence is added to explain the record: "(1) Interest inquiry Record, Volunteer Application Folder and Computer Based Record: The inquiry record is used to create a computer based record for issuing mailing labels, letters, follow-up letters and statistical data."

Paragraph (n) is added to the section on "Routine uses of records maintained in the system, including categories of users and the purpose of such uses" to read as follows:

"(n) In addition to the agency general routine uses the information furnished by mail or by personal contact is used only by the agency recruiting staff to furnish information to the individual concerning ACTION/Peace Corps volunteer programs and for the production of summary descriptive statistics and analytical studies in support of recruitment activities."

A sentence is added to the end of the "Retention and disposal" paragraph: "The inquiry records are maintained for one year. The computer based inquiry records are maintained for two years."

Under "System Manager(s) and Address" Item a. is changed to read:

"a. The ACTION Service Center Managers located in the field and the Chief, Communications Operations Branch, Office of Recruitment and Communications, located at 806 Connecticut Avenue, N.W., Washington, D.C. 20525."

This notice is issued in Washington, D.C., on January 26, 1982.

Winfred A. Pizzano,
Deputy Director, ACTION.

[FR Doc. 82–1820 Filed 1–25–82; 8:45 am]
BILLING CODE 6050–01–M

DEPARTMENT OF AGRICULTURE

Agricultural Stabilization and Conservation Service

1982-Crop Peanuts; National Poundage Quota and Poundage Quota Referendum Period for 1982-Crop Peanuts

Correction

In FR Doc. 82–1501 appearing at page 3149 in the issue of Friday, January 22, 1982, on page 3149 in the first column, the "**EFFECTIVE DATE**" now reading "January 21, 1981" should read "January 21, 1982".

BILLING CODE 1505–01–M

CIVIL RIGHTS COMMISSION

Connecticut Advisory Committee; Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the Connecticut Advisory Committee to the Commission will convene at 7:30 p.m., and will end at 9:30 p.m., on February 18, 1982, at the Lord Cromwell Inn, Exit 21, off I–91, Cromwell, Connecticut, 06416. The purpose of this meeting is to discuss the draft report, Governmental Response to Racially and Religiously Motivated Violence.

Persons desiring additional information or planning a presentation to the Committee, should contact the Chairperson, John Rose, Jr., P.O. Box 3216, Hartford, Connecticut, 06103, (203) 525–4700 or the New England Regional Office, 55 Summer Street, 8th Floor, Boston, Massachusetts, 02110, (617) 223–4671.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., January 20, 1982.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 82-1821 Filed 1-25-82; 8:45 am]

BILLING CODE 6335-01-M

Hawaii Advisory Committee; Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the Hawaii Advisory Committee to the Commission will convene at 11:00 a.m., and will end at 3:00 p.m., on February 20, 1982, at the Island Colony Hotel, 445 Seaside Avenue, Honolulu, Hawaii, 96815. The purpose of this meeting is to discuss the Hawaiian Homeland report, and program planning for fiscal year 1982.

Persons desiring additional information or planning a presentation to the Committee, should contact the Chairperson, Patricia K. Putnam, 1910 Ala Moana Boulevard, Honolulu, Hawaii, 96815, (808) 948-7355 or the Western Regional Office, 3660 Wilshire Boulevard, Suite 810, Los Angeles, California, 90010, (213) 688-3437.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., January 20, 1982.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 82-1822 Filed 1-25-82; 8:45 am]

BILLING CODE 6335-01-M

DEPARTMENT OF COMMERCE

International Trade Administration

Articles of Quota Cheese; Annual Listing of Foreign Government Subsidies

AGENCY: International Trade Administration, Commerce.

ACTION: Publication of annual list of foreign government subsidies on articles of quota cheese.

SUMMARY: The Department of Commerce, in consultation with the Secretary of Agriculture, has prepared its annual list of foreign government subsidies on articles of quota cheese. We are publishing the current listing of those subsidies that we have determined exist.

EFFECTIVE DATE: January 1, 1982.

FOR FURTHER INFORMATION CONTACT: Susan E. Silver, Office of Compliance, International Trade Administration, U.S. Department of Commerce, Washington, D.C. 20230, (202) 377-3691.

SUPPLEMENTARY INFORMATION: Section 702(a) of the Trade Agreements Act of 1979 (19 U.S.C. 1202 note) ("the TAA") requires the Department of Commerce ("the Department") to determine, in consultation with the Secretary of Agriculture, whether any foreign government is providing a subsidy with respect to any article of quota cheese, as defined in section 701(c)(1) of the TAA, and to publish an annual list and quarterly updates of the type and amount of those subsidies.

The Department has developed, in consultation with the Department of Agriculture, information on subsidies (as defined in section 702(h)(2) of the TAA) being provided either directly or indirectly on articles of quota cheese. The appendix to this notice lists the country, the subsidy program or programs, and the gross and net amount of each subsidy on which information is currently available.

The Department will incorporate any additional programs which are found to constitute subsidies, and additional information on the subsidy programs listed, as the information is developed.

The Department encourages any person having information on foreign government subsidy programs which benefit articles of quota cheese to submit such information in writing to the Deputy Assistant Secretary for Import Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230.

This determination and notice are in accordance with section 702(a) of the TAA (19 U.S.C. 1202 note).

Gary N. Horlick,

Deputy Assistant Secretary for Import Administration.

January 19, 1982.

APPENDIX.—QUOTA CHEESE SUBSIDY PROGRAMS

Country	Program(s)	Gross subsidy [1] (cents per pound)	Net subsidy [2] (cents per pound)
Belgium	European Community (EC) restitution payments.	20.8	20.8
Canada	Export assistance on certain types of cheese.	16.7	16.7
Denmark	EC restitution payments.	12.2	12.2
Finland	Export subsidy	89.8	89.8
	Indirect subsidies	20.1	20.1
		109.9	109.9
France	EC restitution payments.	11.5	11.5
Ireland	EC restitution payments.	9.7	9.7
Italy	EC restitution payments.	35.9	35.9
Luxembourg	EC restitution payments.	20.8	20.8
Netherlands	EC restitution payments.	3.1	3.1
Norway	Indirect (milk) subsidy	22.1	22.1
	Consumer subsidy	49.1	49.1
		71.2	71.2
Portugal	Direct subsidy on all sales of gouda cheese.	20.4	20.4
Switzerland	Deficiency payments	79.9	79.9
United Kindgom	EC restitution payments.	9.6	9.6
West Germany	EC restitution payments.	15.4	15.4

[1] Defined in 19 U.S.C. 1677(5).
[2] Defined in 19 U.S.C. 1677(6).

[FR Doc. 82-1793 Filed 1-25-82; 8:45 am]

BILLING CODE 3510-25-M

Spun Acrylic Yarn From Japan; Preliminary Results of Administrative Review of Antidumping Duty Order

AGENCY: International Trade Administration, Commerce.

ACTION: Notice of preliminary results of administrative review of antidumping duty order.

SUMMARY: The Department of Commerce has conducted an administrative review of the antidumping duty order on spun acrylic yarn from Japan. The review covers the four known manufacturers and nine known exporters of this merchandise to the United States and the period from April 1, 1980 through March 31, 1981. The review disclosed no shipments of spun acrylic yarn from Japan other than samples of insignificant commercial value. The Department has found these shipments of samples to be subject to assessment of antidumping duties.

The Department has also determined that yarn produced from modacrylic fiber is not of the same class or kind of merchandise as spun acrylic yarn and is clarifying the scope of the antidumping duty order accordingly.

As a result of this review, the Department has preliminarily determined to assess dumping duties on shipments of samples, produced by one manufacturer and shipped by one exporter. Interested parties are invited to comment on these preliminary results.

EFFECTIVE DATE: January 26, 1982.

FOR FURTHER INFORMATION CONTACT: Larry T. Hampel of David R. Chapman, Office of Compliance, International

Trade Administration, U.S. Department of Commerce, Washington, D.C. 20230 (202-377-3059/2657).

SUPPLEMENTARY INFORMATION:

Background

The Department of Commerce ("the Department") published in the **Federal Register** on June 25, 1981 (46 FR 32928-9) the final results of the initial administrative review of the antidumping duty order with respect to spun acrylic yarn from Japan. In that notice the Department stated its intent to conduct the next administrative review by the end of April, 1982. As required under section 751 of the Tariff Act of 1930 ("the Tariff Act"), the Department has now conducted that administrative review.

Scope of the Review

Imports covered by this review are shipments of spun acrylic plied yarn primarily for machine-knitting, currently classifiable under items 310.5015 and 310.5049 of the Tariff Schedules of the United States Annotated (TSUSA).

During the course of this review, the Japan Chemical Fibres Association ("JCFA") requested a ruling regarding the application of this order to shipments of spun, plied yarn produced from modacrylic fiber ("modacrylic yarn"). The Department considered information presented by JCFA concerning the differences in manufacturing, physical characteristics and uses of acrylic and modacrylic yarn, and comments submitted by the American Yarn Spinners Association ("AYSA") regarding the similarity of uses of the two products. After examination of this information and information available in our records, we conclude that acrylic and modacrylic fibers are recognized as distinct throughout the industry. Furthermore, the regulations that implement the Textile Fiber Products Identification Act establish separate generic names for these two fibers (16 CFR 303.7). We conclude that the class or kind of merchandise subject to this order is yarn produced from acrylic fiber, or chiefly from acrylic fiber. Although the petitioner now contends that modacrylic yarn falls within the scope of the petition and would have been explicitly included had there been significant importations at the time of the petition, we find no contemporaneous indication that the petition was intended to cover modacrylic yarn nor that the investigation addressed modacrylic yarn. Therefore, the Department has concluded that modacrylic yarn is not of the same class or kind of merchandise as that subject to this order and we are clarifying the scope of the order to exclude specifically shipments of spun, plied yarn produced from modacrylic fiber and currently classifiable under items 310.5049 or 310.5051 of the TSUSA.

This review covers the 13 known firms engaged in the manufacture and exportation of Japanese spun acrylic yarn to the United States and the period from April 1, 1980 through March 31, 1981.

Three manufacturers and eight exporters did not export spun acrylic yarn to the United States during this period. The rate for deposit of estimated duties for these firms shall be the most recent information for each firm.

One manufacturer and a related exporter stated that, while they did not sell any merchandise for exportation to the United States during the period of review, they did export five shipments of samples of yarn for purposes of testing and/or evaluation. Each of these shipments contained a small amount of yarn of insignificant commercial value.

Merchandise entered for consumption is subject to a finding of dumping whenever ownership is or has been transferred from the manufacturer or exporter to an unrelated party. Samples and other "non-commercial" disposals are no exception.

Where possible, the Department will calculate the foreign market value and U.S. price for each entry using specific price and/or cost data relating to that entry. However, where the shipments of samples involve a transfer of ownership and contain a small quantity of merchandise of insignificant commercial value, the Department may have to rely on information other than specific price or cost data. For assessment purposes, the Department will use the weighted average margin on the same manufacturer's commercial shipments of all yarn during the current review period, or if the manufacturer has no commercial shipments during that period, during the most recent review period where such shipments occurred. If there were no commercial shipments by that manufacurer during prior review periods, the Department will assess samples shipped during the current period at the highest weighted-average margin for commercial shipments of any other manufacturer during the current, or, if necessary, the most recent review period.

Samples assessed in the above manner shall not be considered shipments for purposes of possible revocation of this order under § 353.54 of the Commerce Regulations.

In this case, all five shipments were entered for consumption and ownership has been transferred to an unrelated party. Since the manufacturer and exporter had no commercial shipments during this period, nor the prior review period, the Department resorted to the manufacturer's margin calculated during the fair value investigation as the most recent information. The fair value margin for this manufacturer and exporter is 20.26%, and this shall be the estimated deposit rate for these firms.

Preliminary Results of the Review

We preliminarily determine that for the period from April 1, 1980 through March 31, 1981, the following margins exist:

Japanese exporter	Margin
Mitsui & Co., Ltd. (Mfr: Kanegafuchi Chem. Ind. Co., Ltd.)	[1] 0
Diafibers Co., Ltd.:	
(Mfr: Japan Exlan Corp.)	[2] 18.33
(Mfr: Mitsubishi Rayon Co., Ltd.)	[2] 20.26
C. Itoh & Co., Ltd.:	
(Mfr: Asahi Chem. Ind. Co., Ltd.)	[1] 29.05%
(Mfr: Mitsubishi Rayon Co., Ltd.)	[1] 20.26%
Gunze Sangyo, Inc. (Mfr: Asahi Chem. Ind. Co., Ltd.)	[1] 29.05%
Teijin Shoji Kaisha, Ltd. (Mfr: Asahi Chem. Ind. Co., Ltd.)	[1] 29.05%
Itoman & Co., Ltd. (Mfr: Japan Exlan Corp.)	[1] 18.33%
Nissho Iwai Corp. (Mfr: Mitsubishi Rayon Co., Ltd.)	[1] 20.26%
Mitsubishi Corp. (Mfr: Mitsubishi Rayon Co., Ltd.)	[1] 20.26%
Nichimen Co., Ltd.	[1] 23.19%

[1] No shipments during review period.
[2] Shipments of samples only during review period.

Interested parties may submit written comments on these preliminary results on or before February 25, 1982, and may request disclosure and/or a hearing on or before February 10, 1982. The Department will publish the final results of the administrative review including the results of its analysis of any such comments or hearing.

The Department shall determine, and the U.S. Customs Service shall assess, duties on all entries made with purchase or export dates during the period involved. The Department will issue appraisement instructions separately on each exporter directly to the Customs Service.

Further, as provided for by § 353.48(b) of the Commerce Regulations, a cash deposit based upon the margins calculated above shall be required on all shipments entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results. This deposit requirement shall remain in effect until publication of the final results of the next administrative review.

This administrative review and notice are in accordance with section 751(a)(1) of the Tariff Act (19 U.S.C. 1675(a)(1))

and § 353.53 of the Commerce Regulations (19 CFR 353.53).

Gary N. Horlick,

Deputy Assistant Secretary for Import Administration.

January 20, 1982.

[FR Doc. 82-1727 Filed 1-25-82; 8:45 am]

BILLING CODE 3510-25-M

Unrefined Montan Wax From the German Democratic Republic; Early Determination of Antidumping Duty

AGENCY: International Trade Administration, Commerce.

ACTION: Notice of early determination of antidumping duty.

SUMMARY: The Department of Commerce has conducted an early determination of the antidumping duty to be assessed upon imports of unrefined montan wax from the German Democratic Republic entered, or withdrawn from warehouse, for consumption from March 12 to August 31, 1981. This determination will also be the basis for the deposit of estimated antidumping duties on future entries of such merchandise.

EFFECTIVE DATE: January 26, 1982.

FOR FURTHER INFORMATION CONTACT: Francis R. Crowe or John P. Nolan, Office of Compliance, International Trade Administration, U.S. Department of Commerce, Washington, D.C. 20230 (202-377-3003/4347).

SUPPLEMENTARY INFORMATION:

Background

On September 10, 1981, the Department of Commerce ("the Department") published in the **Federal Register** (46 FR 45177) an antidumping duty order covering imports of unrefined montan wax from the German Democratic Republic (GDR). In accordance with the order, Customs officers were directed to require a deposit of estimated antidumping duties on the merchandise pending liquidation.

On August 18, 1981, the only manufacturer of the merchandise, VEB Braunkohlenkombinat "Gustav Sobottka" ("BKK"), requested that we waive the deposit of estimated duties and make an early determination of duty. On October 5, 1981 (46 FR 48962), we announced that, in accordance with section 736(c) of the Tariff Act of 1930 ("the Tariff Act"), we were satisfied that we would be able to determine foreign market value and United States price for all entries of this merchandise produced by BKK from the date of publication of our preliminary affirmative determination to the date of publication of the International Trade Commission's final determination. Deposit of estimated duties was waived pending the early determination of duty.

Scope of the Review

We reviewed all imports of unrefined montan wax from the GDR entered, or withdrawn from warehouse, for consumption during the period March 12, 1981 to August 31, 1981.

For the purpose of this review, the term "unrefined montan wax" applies to a nonoxidized mineral wax extracted from lignite, not advance beyond extraction or cleansing by solvent, currently classifiable under item 494.2000 of the Tariff Schedules of the United States Annotated (TSUSA).

United States Price

In calculating United States price, the Department used purchase price, as defined in section 772 of the Tariff Act, since all sales of unrefined montan wax from the GDR were to an unrelated U.S. customer and were concluded before the merchandise was imported into the United States. We calculated purchase prices on the basis of FOB prices to the unrelated U.S. purchaser, with deductions for loading charges, foreign inland freight, and export documentation.

Foreign Market Value

We decided in the final determination of the fair value investigation (46 FR 38555) that the economy of the GDR is state-controlled to the extent that we are unable to determine the foreign market value of unrefined montan wax by normal standards as described in the amended fair value final determination (46 FR 43727). We therefore constructed a value based on specific components or factors of production in the GDR, valued on the basis of prices in the Federal Republic of Germany (FRG), a non-state-controlled-economy country reasonably comparable in economic development to the GDR. For the purpose of this 736(c) review we constructed a value for unrefined montan wax, as in the amended final determination, equal to the sum of materials, fabrication costs, general expenses, profit, and the cost of packing. The amount added for general expenses constituted at least ten percent of the sum of materials and fabrication costs. Profit was calculated at eight percent of the sum of all general expenses and costs.

Analysis of Comments Received

Interested parties were given an opportunity to submit written and oral comments. At the request of the petitioner, the American Lignite Products Co., a hearing was held on November 16, 1981. Both the petitioner and BKK submitted comments.

(1) Comment: The petitioner contends the Department used an arbitrary, inconsistent, and technically incorrect basis for determining steam cost—a major cost component of the unrefined wax manufacturing process. The petitioner proposes allocating the cost of steam between that used for producing electricity and that used for industrial processes based strictly on the actual amount of heat consumed for each purpose in a given quantity of steam.

Position: The petitioner's steam allocation method would overstate actual unit costs of industrial-process steam because it does not fully take into account BKK's dual use of a given quantity of steam produced. At the BKK facility each given quantity of steam is initially used to produce electricity and then, after the optimum amount of heat contained in that given quantity of steam is consumed in the production of electricity, the same quantity of steam, but with a lower heating value, is reused for industrial processes. The Department's steam cost allocation method, which is based on the usefulness of steam in producing electricity, takes this dual use into account and assigns a greater cost per calorie to steam used in producing electricity than the cost per calorie assigned to industrial-process steam.

The Department's steam cost allocation method, used in both the amended final fair value determination and the section 736(c) determination, is technically correct, takes into account all costs incurred in the production of steam, and properly allocates them.

(2) Comment: The petitioner also contends the Department should use the value for dried, not crude, lignite as the input material to derive the cost of producing steam, because the higher-valued dried lignite is the material actually used to produce steam at BKK. The petitioner proposes using the FRG price for dried lignite or, alternatively, the cost of a unit of heat produced by fossil fuels in the FRG in order to estimate the value of the input material used to produce steam at BKK.

Position: Use of a FRG price for dried lignite, if available, or of heat produced by a combination of fossil fuels, does not approximate as closely as the Department's method the heating value of the actual input material used at the BKK facility. The heating value used for the input material in the Department's method is the verified value of the actual fuel used at the BKK facility. Any understatement of costs in the Department's steam cost figure due to

use of crude lignite as an input material is offset by the lower heating value of BKK's crude lignite as compared to that of its dried lignite. While dried lignite is more expensive than crude lignite, less dried lignite is needed to produce equal calories of steam heat.

(3) Comment: In general, the respondent objects to both the Department's choice of the FRG as a surrogate country and the Department's allocation of pre-processing costs on the basis of the value of end products (wax, briquettes, and electricity). However, for the purpose of this administrative review, the respondent accepts the choice of the FRG as a surrogate country and the Department's allocation of pre-processing costs.

Position: The respondent's comments regarding choice of surrogate country and allocation of pre-processing costs are discussed in detail in the fair value final determination (46 FR 38555).

(4) Comment: The respondent contends the use of FRG prices, rather than costs, for electric energy and FRG public rail transport rates deprives BKK of the inherent advantages of its integrated facility. Furthermore, the respondent contends the 2.5:1 ratio of fuel costs to total costs used in the calculation of steam costs should be reduced to approximately 2.2:1.

Position: In the absence of any better information, the Department maintains that the FRG price for electric energy, the FRG rail transport rates, and the 2.5:1 ratio of fuel costs to total costs constitute the best information available.

(5) Comment: The respondent contends that the use of FRG male-only labor rates in the valuation of labor costs overstates actual labor costs at BKK because the BKK facility uses substantial female labor which has a lower cost in the FRG.

Position: While the respondent's position may be valid, the Department could not use a composite of male and female FRG labor rates because the respondent did not present information on the proportion of male and female employees at BKK needed to develop such a composite. Moreover, use of a composite male/female labor rate, rather than the FRG male-only rate, would not alter the final results of this early determination.

Results for Early Determination

As a result of our analysis, we determine that no margins exist on any of the sales made during the period of review. The absence of margins is a decrease from the 13.02 percent weighted-average margin found at the time of the final determination. The decrease in the margins is due to both an increase in the U.S. price and the appreciation of the dollar in relation to the West German mark, offset slightly be an increase in the constructed value. The appreciation of the dollar in relation to the West German mark would have been sufficient of itself to eliminate the margins that had been found in the fair value investigation. In addition an 8% to 15% increase in the U.S. price (in dollar terms) raises the U.S. price even further above the constructed value. The Department shall issue appraisement instructions separately to the Customs Service. Since these last known shipments of this merchandise resulted in the assessment of no dumping duties, the Department shall not require a cash deposit of estimated dumping duties, as provided for in § 353.48(b) of the Commerce Regulations, on any shipments of unrefined monton wax from the GDR entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice. This waiver of deposit shall remain in effect until publication of the final results of the next administrative review. The Department intends to conduct the next administrative review by the end of September 1982.

This notice is published in accordance with section 736(c)(3) of the Tariff Act (19 U.S.C. 1673(c)(3)) and § 353.49 of the Commerce Regulations (19 CFR 353.49).

Gary N. Horlick,

Deputy Assistant Secretary, Import Administration.

[FR Doc. 82-1726 Filed 1-25-82; 8:45 am]

BILLING CODE 3510-25-M

National Bureau of Standards

Appointment Of Additional Member To General Performance Review Board

In a notice published in the **Federal Register** on January 4, 1982 (47 FR 68), the National Bureau of Standards (NBS) announced the names and terms of six members of the General Performance Review Board (GPRB). That notice also announced the purpose of the GPRB and stated that upon the appointment of the seventh member of the GPRB which would bring the membership to its full complement, such appointment would be announced in the **Federal Register.**

This notice announces the appointment of the seventh member to the NBS GPRB, whose name, title and term is set out below. Dr. Richard I. Shoen, Senior Staff Associate, Division of Chemistry, National Science Foundation, 1800 G Street N.W., Washington, D.C. 20550. Term—January 1, 1982–December 31, 1983.

Persons desiring further information about the GPRB or its membership may contact Mrs. Elizabeth W. Stroud, Chief, Personnel Division, National Bureau of Standards, Washington, D.C. 20234, (301) 921–3555.

Dated: January 20, 1982.

Ernest Ambler,

Director.

[FR Doc. 82-1825 Filed 1-25-82; 8:45 am]

BILLING CODE 3510-13-M

Changes Pertaining to the Interface Standards Exclusion List

In a notice published in the **Federal Register** on September 2, 1981 (46 FR 44027), the National Bureau of Standards (NBS) announced proposed changes to the exclusion list pertaining to Federal Information Processing Standards Publication 60–1, I/O Channel Interface; Federal Information Processing Standards Publication 61, Channel Lever Power Control Interface; Federal Information Processing Standards Publication 62, Operational Specifications for Magnetic Tape Subsystems; and Federal Information Processing Standards Publication 63, Operational Specifications for Rotating Mass Storage Subsystems. Interested parties were allowed until October 19, 1981, to submit written comments regarding the proposed changes to the exclusion list.

As a result of a review and analysis of comments received, NBS has made a determination that the following additions will be made to the exclusion list:

Manufacturer and Model

Formation, F4000
Modular Computer Systems, Classic 7810
Modular Computer Systems, Classic 7820
Modular Computer Systems, Classic 7830
Modular Computer Systems, Classic 7840
Modular Computer Systems, Classic 7870
Prime, 150II
Prime, 250II
Prime, 550II
Sperry-Univac, DCT–9000

Interested parties are invited to submit written comments or recommendations regarding the exclusion list to the Director, Institute for Computer Sciences and Technology, Attention: Interface Standards Exclusion List, National Bureau of Standards, Washington, D.C. 20234. Comments specifically identifying candidate systems which should be added or removed from the exclusion list are especially encouraged. Comments should also include information supporting any proposed additions (or removals) to that list

according to the criteria described in the Federal Register notice of March 19, 1979 (44 FR 16466), which announced the availability of a proposed initial exclusion list. Any comments submitted which are deemed by the sender to contain confidential or proprietary information should be appropriately designated and marked.

NBS maintains a mailing list of vendors, Federal agencies, and other interested parties to whom copies of the current exclusion list are sent on a regular basis. Parties on the mailing list will also be sent copies of the proposed changes and the announcement of the determination on the proposed changes. Those who wish to be included on the mailing list should send a written request to the address noted above for submission of comments or recommendations regarding the exclusion list.

The exclusion list will be used in conjuntion with the applicability provisions of the Federal I/O channel level interface standards. This list and the exclusion criteria are not a part of the standards themselves, but are provided for in the standards.

Dated: January 20, 1982.

Ernest Ambler,

Director.

[FR Doc. 82-1623 Filed 1-25-82; 8:45 am]

BILLING CODE 3510-CN-M

Proposed Changes Pertaining to the Interface Standards Exclusion List

In a notice published in the Federal Register on March 19, 1979 (44 FR 16466), the National Bureau of Standards (NBS) announced the establishment of exclusion criteria and procedures for developing and maintaining an exclusion list pertaining to Federal Information Processing Standards Publication 60 (which has since been redesignated as 60-1), Input/Output (I/O) Channel Interface; Federal Information Processing Standards Publication 61, Channel Level Power Control Interface; and Federal Information Processing Standards Publication 62, Operational Specifications for Magnetic Tape Subsystems. The approval of the Secretary of Commerce (Secretary) of those three Federal Information Processing Standards was previously announced in the Federal Register on February 16, 1979 (44 FR 10098-10101). The exclusion list also pertains to Federal Information Processing Standards Publication 63, Operational Specifications for Rotating Mass Storage Subsystems, approval of which by the Secretary of Commerce was announced in the Federal Register on August 27, 1979 (44 FR 50078).

The March 19, 1979, notice stated that once the exclusion list was established, interested parties could obtain a copy of that list and would be invited to submit to the Director, Institute for Computer Sciences and Technology (ICST), comments or recommendations regarding additions to or removals from that list. The notice also advised that information regarding any proposed changes in the exclusion list would be published in the Federal Register.

Announcement of the establishment of the initial exclusion list and its availability from NBS upon request appeared in the Federal Register on June 29, 1979 (44 FR 37968). Numerous changes to that exclusion list have since been made and announced in the Federal Register.

Comments from interested parties specifically identifying candidate systems which should be added to or removed from the exclusion list have been and continue to be especially encouraged.

As a result of a review and analysis of comments and recommendations received recently, NBS is proposing the following additions to the exclusion list:

Manufacturer and model

Four-Phase Systems, Inc., 311 System
Four-Phase Systems, Inc., 312 System
Zilog, System 8000

Interested parties will be allowed until March 12, 1982 to submit writtten comments regarding the proposed changes. Such written comments should be submitted to the Director, ICST, Attention: Interface Standards Exclusion List, National Bureau of Standards, Washington, D.C. 20234. Following review of comments received in response to this notice, NBS will make a determination on the proposed changes and will announce that determination in a subsequent notice published in the Federal Register.

NBS maintains a mailing list of vendors, Federal agencies, and other interested parties to whom copies of the current exclusion list are sent on a regular basis. Parties on the mailing list will also be sent copies of the proposed changes and the announcement of the determination on the proposed changes. Those who wish to be included on the mailing list should send a written request to the address noted above for submission of comments in response to this notice.

The exclusion list will be used in conjunction with the applicability provisions of the Federal I/O channel level interface standards. This list and the exclusion criteria are not a part of the standards themselves, but are provided for in the standards.

Dated: January 20, 1982.

Ernest Ambler,

Director.

[FR Doc. 82-1624 Filed 1-25-82; 8:45 am]

BILLING CODE 3510-CN-M

DEPARTMENT OF DEFENSE

Department of the Air Force

Scientific Advisory Board; Meeting

The USAF Scientific Advisory Board Ad Hoc Committee on Enhancement of Airlift in Force Projection will hold meetings on February 10, 1982, from 8:00 am to 5:00 pm, and on February 11, 1982, from 8:00 am to 5:00 pm, at Scott Air Force Base, Illinois.

The ad hoc committee will receive classified briefings and hold classified discussions on training; survivability of aircraft; command, control and communications, and sustainability issues related to enhancement of airlift in force projection.

The meetings concern matters listed in Section 552b(c), Title 5, United States Code, specifically subparagraph (1) thereof, and accordingly the meetings are closed to the public.

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

Winnidel F. Holmes,

Air Force Federal Register Liaison Officer.

[FR Doc. 82-2001 Filed 1-25-82; 8:45 am]

BILLING CODE 3910-01-M

DEPARTMENT OF ENERGY

Economic Regulatory Administration

[ERA Case No. 55069-9211-01-21; Docket No. ERA-FC-81-20]

Federal Paper Board Company, Inc.; Powerplant and Industrial Fuel Use Act; Availability of Tentative Staff Analysis

AGENCY: Economic Regulatory Administration, DOE.

ACTION: Notice of availability of Tentative Staff Analysis.

SUMMARY: On July 20, 1981, Federal Paper Board Company, Inc. (FPB) petitioned the Economic Regulatory Administration (ERA) of the Department of Energy (DOE) for a permanent cogeneration exemption and a temporary public interest exemption from the provisions of the Powerplant and Industrial Fuel Use Act of 1978, 42

U.S.C. 8301 *et seq.* (FUA or the Act), which prohibit the use of petroleum or natural gas in new powerplants.

FPB proposes to install a 20.1 megawatt (MW) gas-fired combustion turbine, and a 3.5 MW steam turbine generator to produce electricity as well as hot water and process heat for the company's production process at its Commerce, California facility.

ERA accepted the petition on August 28, 1981, and published notice of its acceptance in the **Federal Register** on September 4, 1981 (46 FR 44495). Publication of the Notice of Acceptance commenced a 45-day public comment period pursuant to section 701 of FUA. During this period, interested persons also were afforded an opportunity to request a public hearing. The comment period ended October 19, 1981. One comment was received, from the California Cogeneration Task Force, encouraging a speedy and favorable determination regarding this and all future cogeneration exemption requests in California. There were no requests that DOE convene a public hearing.

ERA's staff has reviewed the information presently contained in the record of this proceeding. A Tentative Staff Analysis has been prepared which recommends that ERA issue an order granting a permanent cogeneration exemption to permit FPB to use natural gas as a primary energy source in the cogeneration facility.

The ERA additionally recommends that no further action be taken on FPB's request for a temporary public interest exemption to use natural gas in the proposed cogeneration facility prior to the proposed granting of the permanent exemption, as the start-up date of the proposed facility is well beyond the date by which ERA would expect to finalize a permanent exemption. However, should commenters provide ERA with data that could delay these actions, ERA proposes to grant the temporary exemption a expeditiously as possible.

ERA will issue a final order granting or denying the petition for a permanent exemption from the prohibitions of the Act within six months, unless extended by ERA, after the public comment period provided for in this notice has expired. Notice of, and a statement of reasons for, any extension will be published in the **Federal Register.**

DATE: Written comments on the Tentative Staff Analysis and requests for a public hearing are due on or before February 8, 1982.

ADDRESS: Fifteen copies of written comments, and any request for a public hearing shall be submitted to: Department of Energy, Case Control Unit, Box 4629, Room 6114, 2000 M Street NW., Washington, D.C. 20461. Docket Number ERA–FC–81–21 should be printed clearly on the outside of the envelope and on the document contained therein.

FOR FURTHER INFORMATION CONTACT:

Ellen Russell, Case Manager, Office of Fuels Programs, Economic Regulatory Administration, Department of Energy, 2000 M Street NW., Room 6114, Washington, D.C. 20461, Phone (202) 653–3379

Marilyn Ross, Office of General Counsel, Department of Energy, 1000 Independence Avenue SW., Room 6B–178, Washington, D.C. 20585, Phone (202) 252–2967

The public file containing a copy of the Tentative Staff Analysis and other documents and supporting material on this proceeding is available for inspection upon request from the Case Manager at the above address.

SUPPLEMENTARY INFORMATION: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE), on May 15, 1979, and May 17, 1979, published in the **Federal Register** (44 FR 28530 and 28950), an interim rule to implement provisions of Title II of the Powerplant and Industrial Fuel Use Act of 1978, 42 U.S.C. 8301 *et seq.* (FUA or the Act). A final rule published on June 6, 1980 (45 FR 38276), became effective August 5, 1980, but those sections of the interim rule relating to the cogeneration exemption (44 FR 28994) were continued. FUA prohibits the use of natural gas or petroleum in certain new major fuel burning installations and powerplants unless an exemption for such use has been granted by ERA.

FPB plans to install a 20.1 MW gas-fired cogeneration powerplant and a 3.5 MW steam turbine generator to produce electricity and hot water heat for its Commerce, California facility. The cogeneration facility will consist of a General Electric LM 2500 gas turbine generator, the exhaust gases of which will be passed through a heat recovery steam generator. The gas turbine has a design heat input rate of 183 million Btu's. The steam turbine generator has a heat input rate of 198.5 million Btu's/hour. The dual pressure heat recovery boiler will receive no supplemental firing. All electricity produced by the cogeneration facility will be sold to Southern California Edison, while the low pressure steam and exhaust gases will be utilized by internal process equipment and for hot water heating.

Pursuant to FUA section 103(a)(7)(B)(ii), the cogeneration facility will be treated as a powerplant because more than half of its annual electric power generation will be sold. FPB estimates that the cogeneration facility will consume approximately 1667.4 million Mcf of natural gas per year, and expects that it will begin commercial operation in late 1982. In accordance with 10 CFR 503.37, FPB petitioned ERA for a permanent cogeneration exemption from the provisions of FUA to enable it to burn natural gas as a primary energy source in the facility.

Tentative Staff Analysis

On the basis of an analysis of information presented in FPB's petition, the Staff has concluded that ERA should grant the requested permanent cogeneration exemption. After reviewing present and future regional power generation, ERA's staff has concluded that the proposed cogeneration facility would provide needed additional power to the grid immediately and into the 1990's to reduce a current and projected electrical shortfall and would eliminate or reduce the need for new oil- and gas-fired peaking units. In addition ERA has calculated that there exists an oil/gas savings potential of a minimum of 15,733 barrels of oil per year.

Based upon the information provided by FPB, ERA conducted an analysis which was reviewed by DOE's Office of Environmental Programs in consultation with the Office of the General Counsel, and DOE has concluded that the granting of this exemption is not a major Federal action significantly affecting the quality of the human environment, within the meaning of the National Environmental Policy Act of 1969. Accordingly, neither an environmental impact statement nor an environmental assessment is required.

The Tentative Staff Analysis does not constitute a decision by ERA to grant the requested exemption. Such a decision shall, in accordance with 10 CFR 501.68, be based on the entire record of this proceeding, including any comments received on the Tentative Staff Analysis.

Issued in Washington, D.C., on January 18, 1982.

Rayburn Hanzlik,

Administrator, Economic Regulatory Administration.

[FR Doc. 82-1810 Filed 1-25-82; 8:45 am]

BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Docket Nos. EF81-2021 and EF81-2011]

Bonneville Power Administration; Order Directing the Submittal of Briefs on Jurisdictional and Procedural Issues

Issued: January 19, 1982.

On June 24, 1981, the Assistant Secretary for Conservation and Renewable Resources of the Department of Energy submitted to the Commission for final confirmation and approval or disapproval, various wholesale power rate schedules, transmission rate schedules and general rate schedule provisions developed by the Administrator of the Bonneville Power Administration (BPA).[1] The rate schedules and rate schedule provisions were submitted to the Commission for final confirmation and approval pursuant to the authority vested in the Commission by the Secretary of Energy under Delegation Order Number 0204–33, as amended and supplemented, and pursuant to Section 7 of the Pacific Northwest Electric Power Planning and Conservation Act (Northwest Power Act or Act).[2] These rate schedules were granted interim approval by the Assistant Secretary pursuant to Delegation Order No. 0204–33 on June 24, 1981, to have become effective on an interim basis as of July 1, 1981.[3]

Public notices of the filing were issued on July 15, 1981, and August 7, 1981,[4] respectively. Interested parties were invited to file comments with the Commission on or before August 24, 1981.[5] In response to the Commission's notices, twenty-five petitions to intervene, protests, or notices of intervention were filed by interested parties. On October 23, 1981, the parties were given the opportunity to submit cross-comments in response to previous comments filed by the parties. Cross-comments were to be received by November 21, 1981.

Subsequent to the comment date but prior to the date established for cross-comments, however, three separate motions were filed[6] requesting that the cross-comment date be suspended pending a determination as to: 1) the scope of the Commission's authority to review the rate schedules developed by the administrator and placed in effect by the Assistant Secretary for Conservation and Renewable Energy and 2) the procedures to be followed by the Commission in reviewing the BPA rates. BPA also requested that the Commission substitute a request for briefing on the jurisdictional issues for the cross-comments that were to have been submitted by November 21, 1981.

In addition to the three motions asking for deferral of the cross-comment date, the California Energy Commission Staff filed a motion requesting that the Commission expeditiously resolve the scope of its jurisdiction to review BPA's rates.[7]

On November 18, 1981, the cross-comment date was suspended in order to give the Commission the opportunity to consider the above motions prior to the closing date established for cross-comments.

Discussion

The rates which are the subject of this proceeding are the wholesale and transmission rates for electric power and energy marketed primarily in the Pacific Northwest to various public and private customers. The new rates are the first to come before the Commission since the passage of the Pacific Northwest Electric Power Planning and Conservation Act on December 5, 1980. They are thus the first rates to be developed by the Administrator pursuant to procedures established in the Northwest Power Act, and will be the first rates to be confirmed and approved, or disapproved by the Commission pursuant to that Act. Prior to passage of the Northwest Power Act, the Commission's review responsibilities were conducted under the authority of the Bonneville Project Act of 1937,[8] the Flood Control Act of 1944,[9] the Federal Columbia River Transmission System Act,[10] the Department of Energy Organization Act,[11] and other statutory authorities by virtue of the Secretary of Energy's Delegation Order No. 0204–33.[12] In a Commission order issued in the previous Bonneville rate proceeding,[13] the Commission set out the standards established by these Acts which must be satisfied prior to final confirmation and approval. These statutory criteria provide that BPA rate schedules must be drawn:

1. Having regard to the recovery of the cost of generation and transmission of such electric energy;

2. So as to encourage the most widespread use of Bonneville power;

3. To provide the lowest possible rates to consumers consistent with sound business principles; and

4. In a manner which protects the interests of the United States in amortizing its investment in the projects within a reasonable period.[14]

The Commission, in its Remand Order, interpreted these standards so as to require more than merely a showing that the overall revenues to be generated by the rates would recover BPA's capital investment allocated to electric power and would appropriately amortize the Government's investment. The Commission required in addition that "the various components of BPA's overall pricing scheme meet the tests set forth in the Bonneville Power Act and the Flood Control Act."[15]

In the various pleadings and petitions to intervene filed in this docket, many parties have stated their concern over whether the Commission, in light of the Northwest Power Act, is authorized to review the rate design and interclass allocation of costs developed by the Administrator pursuant to Section 7 of the Act.

The Commission's role in the BPA ratemaking process is set forth in sections 7(a)(2) and 7(i)(6) of the Northwest Power Act which require that the rates developed by the Administrator be submitted to the Commission for confirmation and approval in order to become finally effective. Except as otherwise provided for one class of rates, all BPA rates are

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[1] See Attachment A for rate schedule designations.

[2] 16 U.S.C. 839e, 94 Stat. 2723, December 5 1980.

[3] This interim authority now resides with the FERC as a result of a Commission rulemaking established pursuant to section 7(i)(6) of the Act. *See* "Confirmation and Approval of Interim Rates of the Bonneville Power Administration," Docket No. RM82–6, issued December 4, 1981.

[4] On August 3, 1981, Bonneville had submitted a brief amendment to its original filing.

[5] The comment date was originally established as August 15, 1981, but was altered on August 7, 1981, due to Bonneville's submittal of an amendment to its original filing on August 3, 1981.

[6] The three motions were filed by the Bonneville Power Administration, eleven utilities collectively referred to as the Public Generating Pool, and six utilities known as the Intercompany Pool (ICP) and CP National Corporation, respectively. In addition to these three motions, a number of parties in their initial comments requested an early determination of the Commission's jurisdiction.

[7] In addition to the above motions which are properly before this Commission, eight related appeals have been brought before the United States Court of Appeals for the Ninth Circuit seeking in part resolution of the Commission's review authority under the rate provisions of section 7 of the Northwest Power Act. *See Central Lincoln Peoples' Utility District* v. *Johnson, et al.*, 9th Cir. Nos. 81–7622, *et al.*

[8] 16 U.S.C. 832.

[9] 16 U.S.C. 825.

[10] 16 U.S.C. 838.

[11] Pub. L. 95–91 August 4, 1977 as amended.

[12] 43 FR 60636 (Dec. 28, 1978).

[13] *U.S. Secretary of Energy, Bonneville Power Administration*, "Order Remanding Rates Without Prejudice," (Remand Order) Docket No. EF80–2011, issued November 21, 1980.

[14] 16 U.S.C. 822, 825s.

[15] Remand Order, *supra*, mimeo at 9.

to become effective on a final basis only upon a finding by the Commission that such rates:

(A) Are sufficient to assure repayment of the Federal investment in the Federal Columbia River Power System over a reasonable number of years after first meeting the Administrator's other costs,

(B) Are based upon the Administrator's total system costs, and

(C) Insofar as transmission rates are concerned, equitably allocate the costs of the Federal transmission system between Federal and non-Federal power utilizing such system.[16]

Rates for the sale of nonfirm electric power within the United States but outside the Pacific Northwest region (non-regional rates) require somewhat different findings by the Commission than the three specified above.[17]

A number of parties to this proceeding, including the Bonneville Power Administrator, have interpreted Section 7(a)(2) as limiting Commission inquiry solely to whether Bonneville's overall revenues generated by the proposed rates will recover the overall capital costs related to Bonneville's electric power and energy fuctions. This interpretation would preclude the Commission from investigating the cost-revenue relationships of rate schedules for each class of customers, except for the mandatory statutory protection provided to non-regional power customers or BPA's transmission service customers. Such an interpretation would also prohibit the Commission from reviewing BPA's rates for purposes of insuring that the Administrator has developed "the lowest possible rates to consumers consistent with sound business principles." Conversely, a number of parties have argued that the three findings which Section 7(a)(2) of the Act requires the Commission to make do not limit the scope of review which the Commission may otherwise exercise.

Because of this conflict of interpretation over the scope of the Commission's authority to review rate design and interclass cost allocations under the Regional Power Act, we believe it would be both useful and appropriate to request briefs from the parties on the extent of the Commission's review authority, Specifically, the Commission would invite the parties' attention to the following questions. With respect to rates other than non-regional rates:

(1) Is the Commission's review authority limited solely to the three findings delineated in Section 7(a)(2) of the Act?

(2) If so, does Section 7(a)(2)(A) permit a Commission inquiry into individual rate design and interclass cost allocations developed by the Administrator or is the Commission's inquiry limited to overall rates?

(3) Is the Commission still required to utilize the statutory criteria set forth in the Flood Control Act of 1944 and other pertinent statutes, in addition to the standards set forth in Section 7(A)(2), in accordance with the responsibilities assigned to the FERC by the Secretary of Energy in Delegation Order No. 0204–33?

(4) Does the finding which the Commission is required to make under Section 7(a)(2)(B) establish the Administrator's total system costs as a floor for BPA's rates, or must the Commission disapprove the rates if they exceed total system costs?

(5) Is the Commission authorized to review allegations of procedural deficiencies on the part of the Administrator, such as claims of violations of the Administrative Procedure Act or of due process?

In addition to the jurisdictional issues, a number of the parties have raised inquiries into the form and extent of the proceedings that may be conducted at the Commission in undertaking its review of the BPA rates. In the Commission's Remand Order in the prior Bonneville docket,[18] the Commission stated that it viewed its role as being essentially appellate in nature.[19] While recognizing its authority to institute a hearing, the Commission nonetheless stated that it "would expect that due process and hearing requirements would be satisfied-by the Administrator)."[20] This role has been called into question by many of the parties in light of the Northwest Power Act. Section 7(k) of the Act requires that the Commission afford an additional hearing in accordance with the procedures established for ratemaking by the Commission pursuant to the Federal Power Act. In light of the fact that no proceedings have yet been established with respect to the Section 7(k) hearing requirement, the Commission believes that it would be useful for the parties to brief and comment upon the procedures that they deem appropriate for the Commission to utilize in reaching a determination that the applicable statutory criteria have been met.

The Commission Orders

(A) All interested parties to this proceeding are hereby ordered to file briefs and comments with respect to the issues delineated in the body of this order.

(B) All briefs shall be filed with the Federal Energy Regulatory Commission within 30 days of issuance of this order. Reply briefs, if any, will be filed within 20 days of the initial briefs.

(C) The date for the submittal of cross comments is hereby stayed until reinstated by direction of the Commission.

(D) The Secretary shall promptly publish this order in the **Federal Register.**

By the Commission.

Lois D. Cashell,

Acting Secretary.

Bonneville Power Administration Rate Schedule Designations

I. System-wide Wholesale Power Rates, Docket EF81–2011.

(1) PF–1, Priority Firm Power Rate Schedule.

(2) IP–1, Wholesale Power Rate for Industrial Firm Power.

(3) MP–1, Wholesale Power Rate for Modified Firm Power.

(4) CF–1, Wholesale Firm Capacity Rate Schedule.

(5) CE–1, Emergency Capacity Rate Schedule.

(6) NR–1, New Resource Firm Power Rate Schedule.

(7) NF–1, Wholesale Nonfirm Energy Rate Schedule.

(8) RP–1, Reserve Power Rate Schedule.

(9) FE–1, Wholesale Firm Energy Rate Schedule.

(10) SI–1, Special Industrial Power Rate Schedule.

(11) General Rate Schedule Provisions.

II. System-wide Transmission Rates, Docket EF81–2021.

(1) FPT–2, Formula Power Transmission Schedule.

(2) UFT–2, Use-of-Facilities Transmission Schedule.

(3) ET–2, Energy Transmission Schedule.

(4) IR–1, Integration of Resources Schedule.

(5) General Transmission Rate Schedule Provisions.

(a) Set A.

(b) Set B.

[FR Doc. 82–1892 Filed 1–25–82; 8:45 am]

BILLING CODE 6717–01–M

[Project No. 5529–000]

County of Mono, Calif.; Application for Preliminary Permit

January 20, 1982.

Take notice that the County of Mono, California (Applicant) filed on October

[16] Section 7(a)(2) of the Northwest Power Act; 16 U.S.C. 839(a)(2).

[17] *See* Sections 7(i)(6) and 7(k) of the Act.

[18] Docket No. EF80–2011, *supra.*

[19] *Id.*, mimeo at 13.

[20] *Id.*, mimeo at pp. 17–18.

19, 1981, an application for preliminary permit [pursuant to the Federal Power Act, 16 U.S.C. 791(a)—825(r)] for Project No. 5529 to be known as the Leavitt Meadows Hydroelectric Project located on West Walker River in Mono County, California, on lands within the Toiyabe National Forest. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: Mr. Neil B. Van Winkle, County Counsel, County Courthouse, Bridgeport, California 93517.

Project Description—The proposed project would consist of: (1) a 96-foot high, 1,150-foot long dam; (2) a reservoir with 26,000 acre-feet storage at normal pool elevation 7,211 feet; (3) a 5,500-foot long pipeline; (4) a 60-inch diameter, 650-foot long penstock; (5) a powerhouse containing one or more generating units with a total capacity of 6,200 kW; and (6) a transmission line. Applicant estimates the average annual energy production to be 37 million kWh.

Proposed Scope of Studies Under Permit—A preliminary permit, if issued, does not authorize construction. Applicant seeks issuance of a preliminary permit for a period of 36 months, during which time engineering, economic and environmental feasibility studies are planned to ascertain project feasibility and to support an application for a license to construct and operate the project. Those studies would include core borings and test pits at the dam site, penstock route and powerhouse site. The Applicant has stated that new access roads are not necessary and that all disturbed lands would be restored. The estimated cost of the above activities is $200,000.

Competing Applications—This application was filed as a competing application to Eastern Sierra Energy Development and Modesto Irrigation District's applications for Project Nos. 5425 and 5493 filed on September 28, 1981, and October 13, 1981, respectively. Public notice of the filing of the initial application, which has already been given, established the due date for filing competing applications or notices of intent. In accordance with the Commission's regulations, no competing application for preliminary permit, or notices of intent to file an application for preliminary permit or license will be accepted for filing in response to this notice. Any application for license or exemption from licensing, or notice of intent to file an exemption application, must be filed in accordance with the Commission's regulations [see: 18 CFR § 4.30 et seq. or § 4.101 et seq. (1981), as appropriate].

Agency Comments—Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before March 3, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Room 208 RB at the above address. A copy of any petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Lois D. Cashell,

Acting Secretary.

[FR Doc. 82-1893 Filed 1-25-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5706-000]

Grisdale Hill Co. Application for Preliminary Permit

January 20, 1982.

Take notice that Grisdale Hill Company (Applicant) filed on December 1, 1981, an application for preliminary permit [pursuant to the Federal Power Act, 16, U.S.C. 791(a)-825(r)] for Project No. 5706 to be known as the Trout Lake Creek Project located on Trout Lake Creek, near Trout Lake, in Skamania County, Washington. The project would affect lands within Gifford Pinchot National Forest. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: Ms. Marilyn Tebor Shaw, Esq., Suite 1100, 1333 New Hampshire Avenue, NW., Washington, D.C. 20036.

Project Description—The proposed project would consist of: (1) An 8-foot high concrete diversion dam; (2) a 1.5-mile long diversion conduit; (3) a headworks; (4) a 1,000-foot long, 54-inch diameter steel penstock; (5) a powerhouse containing one generating unit rated at 3,900 kW; (6) an access road; and (7) a 16-mile long transmission line. The average annual energy generation is estimated to be 22.2 million kWh.

Proposed Scope of Studies Under Permit—A preliminary permit, if issued, does not authorize construction. Applicant seeks issuance of a preliminary permit for a period of 24 months, during which time it would conduct engineering, economic, environmental, and feasibility studies, and prepare an FERC license application. No new roads would be required to conduct the studies. Applicant proposes to make test borings at the diversion dam site and the penstock route. Each boring site will be restored. The cost of the work to be done under the preliminary permit is $125,000.

Competing Applications—Anyone desiring to file a competing application for preliminary permit must submit to the Commission, on or before March 24, 1982, the competing application itself, or a notice of intent to file such an application [see: 18 CFR 4.30 et seq. (1981); and Docket No. RM81-15, issued October 29, 1981, 46 FR 55245, November 9, 1981.]

The Commission will accept applications for license or exemption from licensing, or a notice of intent to submit such an application in response to this notice. A notice of intent to file an application for license or exemption must be submitted to the Commission on or before March 24, 1982, and should specify the type of application forthcoming. Any application for license or exemption from licensing must be filed in accordance with the Commission's regulations [see: 18 CFR 4.30 et seq. or § 4.101 et seq. (1981), as appropriate].

Submission of a timely notice of intent to file an application for preliminary permit, allows an interested person to file an acceptable competing application

for preliminary permit no later than May 24, 1982.

Agency Comments—Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 C.F.R. § 1.8 or § 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before March 24, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Lois D. Cashell,

Acting Secretary.

[FR Doc. 82-1894 Filed 1-25-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5566-000]

Michael E. Johnson; Application for Preliminary Permit

January 20, 1982.

Take notice that Michael E. Johnson (Applicant) filed on October 23, 1981, an application for preliminary permit [pursuant to the Federal Power Act, 16 U.S.C. 791(a)-825(r)] for Project No. 5566 to be known as the Smith Creek Water Power project located on Smith Creek in Boundary County, Idaho. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: Mr. Michael E. Johnson, P.O. box 82, Chattaroy, Washington 99003.

Project Description—The proposed project would consist of: (1) a 25-foot long, 8-foot high diversion structure; (2) a 660-foot long, 42-inch diameter penstock; (3) a powerhouse with a total installed capacity of 500 kW; and (4) a 4000-foot long, 7.2-kV transmission line from the powerhouse to an existing 7.2-kV transmission line. The Applicant estimates that the average annual energy production would be 2.23 million kWh. The proposed project is located on private land.

Proposed Scope of Studies Under Permit—A preliminary permit, if issued, does not authorize construction. The Applicant seeks issuance of a preliminary permit for a period of 24 months during which it would conduct the technical, environmental and economic studies, and also prepare an FERC license application. The Applicant estimates that the cost of undertaking these studies would be $6,000.

Competing Applications—Anyone desiring to file a competing application for preliminary permit must submit to the Commission, on or before March 24, 1982, the competing application itself, or a notice of intent to file such an application [see: 18 CFR 4.30 et. seq. (1981); and Docket No. RM81-15, issued October 29, 1981, 46 FR 55245, November 9, 1981.]

The Commission will accept applications for license or exemption from licensing, or a notice of intent to submit such an application in response to this notice. A notice of intent to file an application for license or exemption must be submitted to the Commission on or before March 24, 1982, and should specify the type of application forthcoming. Any application for license or exemption from licensing must be filed in accordance with the Commission's regulations [see: 18 CFR 4.30 et seq. or § 4.101 et seq. (1981), as appropriate].

Submission of a timely notice of intent to file an application for preliminary permit, allows an interested person to file an acceptable competing application for preliminary permit no later than May 24, 1982.

Agency Comments—Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before March 24, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Lois D. Cashell,

Acting Secretary.

[FR Doc. 82-1895 Filed 1-25-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5069-001]

Douglas S. Marr; Application for Exemption for Small Hydroelectric Power Project Under 5 MW Capacity

January 20, 1982.

Take notice that on November 17, 1981, Douglas S. Marr (Applicant) filed an application under Section 408 of the Energy Security Act of 1980 (Act) (16 U.S.C. 2705 and 2708 *as amended*), for exemption of a proposed hydroelectric project from licensing under Part I of the Federal Power Act. The proposed small hydroelectric project (FERC Project No. 5069) would be located on Sygitowicz Creek, near Deming, Whatcom County, Washington. Correspondence with the Applicant should be directed to: Mr.

Douglas S. Marr, 1677 Mt. Baker Highway, Bellingham, Washington 98226.

Project Description—The project would consist of: (1) A 4-foot high, 30-foot long diversion structure impounding a reservoir with a storage capacity of about 15,000 gallons and surface area of about 0.04 acres; (2) a 2,000-foot long, 12-inch diameter penstock; (3) a powerhouse with an installed capacity of 185 kW; (4) a 100-foot long transmission line which would connect the powerhouse to an existing transmission line. The Applicant estimates that the average annual energy production would be 0.887 million kWh.

Purpose of Exemption—An exemption, if issued, gives the Exemptee priority of control, development, and operation of the project under the terms of the exemption from licensing, and protects the Exemptee from permit or license applicants that would seek to take or develop the project.

Agency Comments—The U.S. Fish and Wildlife Service, The National Marine Fisheries Service, and the Washington State Department of Game and Washington State Department of Fisheries are requested, for the purposes set forth in Section 408 of the Act, to submit within 60 days from the date of issuance of this notice appropriate terms and conditions to protect any fish and wildlife resources or to otherwise carry out the provisions of the Fish and Wildlife Coordination Act. General comments concerning the project and its resources are requested; however, specific terms and conditions to be included as a condition of exemption must be clearly identified in the agency letter. If an agency does not file terms and conditions within this time period, that agency will be presumed to have none. Other Federal, State, and local agencies are requested to provide any comments they may have in accordance with their duties and responsibilities. No other formal requests for comments will be made. Comments should be confined to substantive issues relevant to the granting of an exemption. If an agency does not file comments within 60 days from the date of issuance of this notice, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Competing Applications—Any qualified license applicant desiring to file a competing application must submit to the Commission, on or before March 2, 1982 either the competing license application that proposes to develop at least 7.5 megawatts in that project, or a notice of intent to file such a license application. Submission of a timely notice of intent allows an interested person to file the competing license application no later than 120 days from the date that comments, protests, etc. are due. Applications for preliminary permit will not be accepted.

A notice of intent must conform with the requirements of 18 CFR 4.33(b) and (c) (1980). A competing license application must conform with the requirements of 18 CFR 4.33(a) and (d) (1980).

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of its Rules of Practice and procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before March 2, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB, 825 North Capitol Street, NE., Washington, D.C. 20426. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Lois D. Cashell,

Acting Secretary.

[FR Doc. 82-1896 Filed 1-25-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5808-000]

Modesto Irrigation District; Application for Preliminary Permit

January 20, 1982.

Take notice that Modesto Irrigation District (Applicant) filed on December 23, 1981, an application for preliminary permit [pursuant to the Federal Power Act, 16 U.S.C. 791(a)–825(r)] for Project No. 5808 to be known as the Daguerre Point Power Project located on the Yuba River in Yuba County, California on public lands administered by the Corps of Engineers. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: A. Lee Delano, Modesto Irrigation District, 1231–11th Street, P.O. Box 4060, Modesto, California 95352.

Project Description—The proposed project would consist of (1) An intake structure at the existing Corps of Engineers' Daguerre Point dam; (2) two 108-inch diameter, 450-foot long penstocks; (3) a powerhouse containing six generating units with a total capacity of 3600 kW and an estimated average annual energy production of 26.3 million kWh; and (4) a ¼-mile long transmission line.

Proposed Scope of Studies Under Permit—A preliminary permit, if issued, does not authorize construction. Applicant seeks issuance of a 24-month permit, during which time geological, environmental, economic and financial feasibility studies will be performed to support preparation of an environmental report, obtaining agreements with Federal, State and local agencies, and preparation of a license application. The estimated cost for the above activities is $100,000.

Competing Applications—This application was filed as a competing application to H–O–H Power's application for Project No. 5592 filed on November 2, 1981. Public notice of the filing of the initial application, which has already been given, established the due date for filing competing applications or notices of intent. In accordance with the Commission's regulations, no competing application for preliminary permit, or notices of intent to file an application for preliminary permit or license will be accepted for filing in response to this notice. Any application for license or exemption from licensing, or notice of intent to file an exemption application, must be filed in accordance with the Commission's regulations [see: 18 CFR 4.30 et seq. or § 4.101 et seq. (1981), as appropriate].

Agency Comments—Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below , it will be presumed to have no comments.

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before March 2, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Room 208 RB at the above address. A copy of any petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Lois D. Cashell,

Acting Secretary.

[FR Doc. 82-1897 Filed 1-25-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5019-000]

Jordon-Reiwerts; Application for Preliminary Permit

January 20, 1982.

Take notice that Jordon-Reiwerts (Applicant) filed on June 26, 1981, an application for preliminary permit [pursuant to the Federal Power Act, 16, U.S.C. 791(a)-825(r)] for Project No. 5019 to be known as the Aikens Creek Water Power Project located on Aikens Creek, within the Six Rivers National Forest, in Humboldt County, California. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: Oscar Larson and Associates, P.O. Box 3806, Eureka, California 95501.

Project Description—The proposed project would consist of: (1) A 5-foot high diversion structure; (2) a 2,000-foot long, 24-inch diameter, low-pressure conduit; (3) a pressure box; (4) a 1500-foot long, 20-inch diameter penstock; (5) a powerhouse with a total installed capacity of 500-kW; and (6) a 0.25-mile long, 12-kV transmission line interconnecting with an existing Pacific Gas and Electric Company transmission line. The Applicant estimates that the total annual energy production would be 3.4 million kWh.

Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The Applicant seeks issuance of a preliminary permit for 36 months during which it would conduct geological, hydrological, environmental and economic studies and prepare an FERC license application. These studies are estimated by the Applicant to cost $4,000.

Competing Applications—This application was filed as a competing application to Mac Hydro-Power's application for Project No. 4792 filed on June 3, 1981. Public notice of the filing of the initial application, which has already been given, established the due date for filing competing applications or notices of intent. In accordance with the Commission's regulations, no competing application for preliminary permit, or notices of intent to file an application for preliminary permit, or license will be accepted for filing in response to this notice. Any application for license or exemption from licensing, or notice of intent to file an exemption application, must be filed in accordance with the Commission's regulations [see: 18 CFR 4.30 et seq. or 4.101 et seq. (1981), as appropriate].

Agency Comments—Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions to Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before March 2, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Room 208 RB at the above address. A copy of any petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Lois D. Cashell,

Acting Secretary.

[FR Doc. 82-1898 Filed 1-25-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 4309-000]

Tuolumne Regional Water District; Application for License (Over 5 MW)

January 20, 1982.

Take notice that Tuolumne Regional Water District (Applicant) filed on March 10, 1981, an application for license [pursuant to the Federal Power Act, 16 U.S.C. 791(a)-825(r)] for continued operation of a water power project to be known as Phoenix Water Power Project No. 4309. The project would be located on South Fork Stanislaus River in Tuolumne County, California, within Stanislaus National Forest. Correspondence with the Applicant should be directed to: Mr. Gary Egger, General Manager/District Engineer,Tuolumne Regional Water District, 53 West Bradford Street, P.O. Box 728, Sonora, California 95370.

Project Description—The project would consist of the existing Phoenix Project and the proposed new Lyons Dam Project as described below:

(A) *Existing Phoenix Project* consists of:

(1) Lyons Reservoir with a gross storage capacity of 6,228 acre-feet and a surface area of 184 acres at elevation 4,226.6 feet; (2) Lyons Dam, a concrete arch structure with a crest length of 535 feet, a maximum height of 132 feet, and an integral spillway consisting of a 284-foot long overflow section surmounted by 4-foot flashboards and a gated section with 20-foot wide by 10-foot high radial gates; (3) a 20-foot high concrete arch division dam located approximately 80 feet downstream of Lyons Dam; (4) the Main Tuolumne Canal with a rated capacity of 52 cfs

and a length of 15.39 miles; (5) a steel penstock, about 5,611 feet long, with diameters that vary from 30 to 16 inches extending from a header box on the canal; (6) a powerhouse containing one generating unit with a rated capacity of 1.8 MW; and (7) a switchyard adjacent to the powerhouse.

(B) *Proposed Lyons Dam Project* would consist of:

(1) A 350-foot long, 48-inch diameter penstock connected to the existing 30-inch pipe at the lower sluiceway of the existing Lyons Dam;

(2) A powerhouse with a total installed capacity of 650 kW;

(3) A switchyard adjacent to the powerhouse.

The power produced by both projects would go directly into the existing 17-kV distribution system.

Purpose of Project—The Applicant estimates that the Phoenix Project would produce 13.0 million kWh annually and the Lyons Dam Project would produce 2.5 million kWh annually. All power generated from both powerhouses would be sold to the Pacific Gas and Electric Company or another electric utility.

Competing Applications—This application was filed as a competing application to Pacific Gas and Electric Company's application for Project No. 1061 filed on December 26, 1979. Public notice of the filing of the initial application, which has already been given, established the due date for filing competing applications or notices of intent. In accordance with the Commission's regulations, no competing applications for licenses or exemptions, or notices of intent to file competing applications, will be accepted for filing in response to this notice. [See: 18 CFR 4.30 et seq. or § 4.101 et seq. (1981), as appropriate].

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before March 2, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Lois D. Cashell,

Acting Secretary.

[FR Doc. 82-1899 Filed 1-25-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5636-000]

Waltham Hydroelectric Power Co.; Application for Preliminary Permits

January 20, 1982.

Take notice that Waltham Hydroelectric Power Company (Applicant) filed on November 10, 1981, an application for preliminary permit [pursuant to the Federal Power Act, 16 U.S.C. 791(a)-825(r)] for Project No. 5636 to be known as the Moody Street Water Power Project located on the Charles River in Middlesex and Norfolk Counties, Massachusetts. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: Jason M. Cortell, President, Jason M. Cortell and Associates, Inc., 284 Second Avenue, Waltham, Massachusetts 02154.

Project Description—The proposed project would consist of: (1) The existing stone block masonry Moody Street Dam, 10 feet high and 150 feet long, owned by the Metropolitan District Commission of Massachusetts; (2) an existing reservoir with a storage capacity of about 750 acre-feet at elevation 38.8 feet m.s.l.; (3) an existing fish passage facility; (4) a new intake structure; (5) a new 6-foot diameter penstock 425 feet long; (6) a new powerhouse with an installed capacity of 364 kW; (7) a new 50-foot long tailrace; (8) a new transmission line about 600 feet long; and (9) other appurtenances. Applicant estimates an annual generation of 1,818,000 kWh. Project energy would be sold to adjacent industrial or residential complexes, the Boston Edison Company, or to the City of Waltham.

Proposed Scope of Studies Under Permit—A preliminary permit, if issued, does not authorize construction. Applicant seeks issuance of a preliminary permit for a period of 24 months during which time Applicant would investigate project design alternatives, financial feasibility, environmental effects of project construction and operation, and project power potential. Depending upon the outcome of the studies, the Applicant would decide whether to proceed with an application for FERC license. Applicant estimates the cost of the studies under the permit would be $87,000.

Competing Applications—Anyone desiring to file a competing application for preliminary permit must submit to the Commission, on or before April 26, 1982, the competing application itself [see 18 CFR 4.30 et. seq. (1981)]. A notice of intent to file a competing application for preliminary permit will not be accepted for filing.

The Commission will accept applications for license or exemption from licensing, or a notice of intent to submit such an application in response to this notice. A notice of intent to file an application for license or exemption must be submitted to the Commission on or before March 24, 1982, and should specify the type of application forthcoming. Applications for licensing or exemption from licensing must be filed in accordance with the Commission's regulations [see: 18 CFR 4.30 et. seq. or 4.101 et. seq. (1981), as appropriate].

Agency Comments—Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before March 24, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE

COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Lois D. Cashell,

Acting Secretary.

[FR Doc. 82-1900 Filed 1-25-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5816-000]

Woods Creek, Inc.; Application for Preliminary Permit

January 20, 1982.

Take notice that Woods Creek, Inc. (Applicant) filed on December 24, 1981 an application for preliminary permit [pursuant to the Federal Power Act, 16 U.S.C. 791(a) 825(r)] for Project No. 5816-000 to be known as the Fourth of July Creek Hydroelectric Project located on Fourth of July Creek in Snohomish County, Washington in the Snoqualmie National Forest. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: Neil H. Macdonald, Project Manager, Woods Creek, Incorporated, 14 South Idaho Street, Seattle, Washington 98134.

Project Description—The proposed project would consist of: (1) A 6-foot high diversion weir at elevation 2320 feet; (2) a 36-inch diameter, 12,000-foot long penstock; (3) a powerhouse at elevation 1450 feet containing two generating units with a total rated capacity of 2800 kW and (4) a 7.5-mile long transmission line. The estimated average annual energy output would be 11.5 GWh.

Proposed Scope of Studies Under Permit—A preliminary permit, if issued, does not authorize construction. Applicant seeks issuance of a 24 month permit, during which time a geological, environmental and economic feasibility studies will be undertaken to support an application for license or exemption. The cost of the above activities is estimated by the Applicant to be $125,000.

Competing Applications—Anyone desiring to file a competing application for preliminary permit must submit to the Commission, on or before March 23, 1982, the competing application itself, or a notice of intent to file such an application [see: 18 CFR 4.30 et seq. (1981); and Docket No. RM81-15, issued October 29, 1981, 46 FR 55245, November 9, 1981.]

The Commission will accept applications for license or exemption from licensing, or a notice of intent to submit such an application in response to this notice. A notice of intent to file an application for license or exemption must be submitted to the Commission on or before March 23, 1982, and should specify the type of application forthcoming. Any application for license or exemption from licensing must be filed in accordance with the Commission's regulations [see: 18 CFR 4.30 et seq. or 4.101 et seq. (1981), as appropriate].

Submission of a timely notice of intent to file an application for preliminary permit, allows an interested person to file an acceptable competing application for preliminary permit no later than May 24, 1982.

Agency Comments—Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before March 23, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Lois D. Cashell,

Acting Secretary.

[FR Doc. 82-1901 Filed 1-25-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5818-000]

Woods Creek, Inc.; Application for Preliminary Permit

January 20, 1982.

Take notice that Woods Creek, Inc. (Applicant) filed on December 24, 1981, an application for preliminary permit [pursuant to the Federal Power Act, 16, U.S.C. 791(a)-825(r)] for Project No. 5818 to be known as the Eagle Creek Hydroelectric Project located on Eagle Creek in King County, Washington in the Snoqualmie National Forest. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: Mr. Neil H. Macdonald, Project Manager, Woods Creek, Incorporated, 14 South Idaho Street, Seattle, Washington 98134.

Project Description—The proposed project would consist of: (1) A 6-foot high diversion weir at elevation 2,415 feet; (2) a 36-inch diameter, 11,000-foot long penstock; (3) a powerhouse at elevation 1,015 feet containing 2 generating units with a total rated capacity of 4,700 kW and and an estimated average annual energy production of 18.9 million kWh, and (4) a 1.8 mile long transmission line.

Proposed Scope of Studies Under Permit—A preliminary permit, if issued, does not authorize construction. Applicant seeks issuance of a 24-month permit, during which time engineering, environmental, geological and economic feasibility studies will be undertaken, in addition to obtaining agreements with the U.S. Forest Service and other Federal, State and local agencies to support the application for license or exemption. The cost of these activities is estimated to be $125,000.

Competing Applications—Anyone desiring to file a competing application

for preliminary permit must submit to the Commission, on or before March 23, 1982, the competing application itself, or a notice of intent to file such an application [see: 18 CFR 4.30 et. seq. (1981); and Docket No. RM81-15, issued October 29, 1981, 46 FR 55245, November 9, 1981.]

The Commission will accept applications for license or exemption from licensing, or a notice of intent to submit such an application in response to this notice. A notice of intent to file an application for license or exemption must be submitted to the Commission on or before March 23, 1982, and should specify the type of application forthcoming. Any application for license or exemption from licensing must be filed in accordance with the Commission's regulations [see: 18 CFR 4.30 et. seq. or 4.101 et. seq. (1981), as appropriate].

Submission of a timely notice of intent to file an application for preliminary permit, allows an interested person to file an acceptable competing application for preliminary permit no later than May 24, 1982.

Agency Comments—Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 C.F.R. 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before March 23, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Lois D. Cashell,

Acting Secretary.

[FR Doc. 82-1902 Filed 1-25-82; 8:45 am]

BILLING CODE 6717-01-M

Office of Hearings and Appeals; Cases Filed

During the week of December 25, 1981 through January 1, 1982, the appeals and applications for exception or other relief listed in the Appendix to this Notice were filed with the Office of Hearings and Appeals of the Department of Energy.

Under DOE procedural regulations, 10 CFR Part 205, any person who will be aggrieved by the DOE action sought in these cases may file written comments on the application within 10 days of service of notice, as prescribed in the procedural regulations. For purposes of the regulations, the date of service of notice is deemed to be the date of publication of this Notice or the date of receipt by an aggrieved person of actual notice, whichever occur first. All such comments shall be filed with the Office of Hearings and Appeals, Department of Energy, Washington, D.C. 20461.

George B. Breznay,

Director, Office of Hearings and Appeals.

January 20, 1982.

SUBMISSION OF CASES RECEIVED BY THE OFFICE OF HEARINGS AND APPEALS

[Dec. 25, 1981 through Jan. 1, 1982]

Date	Name and Location of Applicant	Case No.	Type of Submission
Dec. 28, 1981	St. Sauver, Joseph E., Landover, Maryland	HFA-0024	Appeal of a Fee Waiver Request Denial. If Granted: Joseph E. St. Sauver would be granted a fee waiver with respect to his October 5, 1981 Freedom of Information Request.
Dec. 29, 1981	Broadway Shell (Williams), Oakland, California	HRH-0006	Request for Evidentiary Hearing. If Granted: An evidentiary hearing would be convened in connection with the Statement of Objections submitted by Raymond Williams in response to the Proposed Remedial Order issued to Broadway Shell (Williams) (Case No. BRO-1542).
Dec. 31, 1981	Dresser Industries, Inc., Washington, D.C.	HFA-0025	Appeal of an Information Request Denial. If Granted: The September 17, 1981 Information Request Denial issued by the Office of International Security Affairs would be rescinded and Dresser Industries, Inc. would receive access to certain documents related to export licenses.

[FR Doc. 82-1809 Filed 1-25-82; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[Opts-51385; TSH-FRL-2035-3]

Certain Chemicals; Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before manufacture or import commences. Statutory requirements for section 5(a)(1) premanufacture notices are discussed in EPA statements of interim policy published in the **Federal Register** of May 15, 1979 (44 FR 28558) and November 7, 1980 (45 FR 74378). This notice announces receipt of four PMNs and provides a summary of each.

DATES: Written comments by: PMN 82-28, 82-29, 82-30, & 82-31, March 19, 1982.

ADDRESS: Written comments, identified by the document control number "[OPTS-51385]" and the specific PMN number should be sent to: Document Control Officer (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-409, 401 M St., SW., Washington, D.C. 20460, (202-382-3532).

FOR FURTHER INFORMATION CONTACT: David Dull, Acting Chief, Notice Review Branch, Chemical Control Division (TS-794), Office of Toxic Substances,

Environmental Protection Agency, Rm. E-216, 401 M St., SW., Washington, D.C. 20460, (202-382-3729).

SUPPLEMENTARY INFORMATION: The following are summaries of information provided by the manufacturer on the PMNs received by EPA:

PMN 82-28

Close of Review Period. April 18, 1982.

Manufacturer's Identity. The Harshaw Chemical Corporation, 1945 E. 97th Street, Cleveland, OH 44106.

Specific Chemical Identity. Boron Trifluoride - 2,4 Dimethylaniline Complex.

Use. The manufacturer states that the PMN substance will be used as an industrial epoxy resin catalyst.

PRODUCTION ESTIMATES

	Kilograms per year	
	Minimum	Maximum
1st year	0	2,250
2d year	0	2,500
3d year	0	3,000

Physical/chemical Properties

pH—4-5
Specific gravity—9.3 lbs/gal
Flash point—205°F
Incompatible materials—Alkaline media
Extinguishing media—All types
Solubility: water—Partly soluble, hydrolizes
Color—Amber
Odor—Aniline

Toxicity Data. No data were submitted.

Exposure. The manufacturer states that during manufacture 2 workers may experience dermal and inhalation 8 hrs/day, 30 days/yr during packaging and reactor cleaning.

Environmental Release/Disposal. The manufacturer states that 10-100 kg/yr will be released to land. Disposal is to an approved landfill.

PMN 82-29

Close of Review Period. April 18, 1982.

Manufacturer's Identity. American Color and Chemical Corporation, Mt. Vernon Street, Lock Haven, PA 17745.

Specific Chemical Identity. Claimed confidential business information. Generic name provided: Naphthalenedisulfonic acid, monoazo acid dye, lithium salt.

Use. The manufacturer states that the PMN substance will be used as an industrial paper.

PRODUCTION ESTIMATES

	Kilograms per year	
	Minimum	Maximum
1st year	3,000	5,000
2d year	5,000	10,000
3d year	8,000	12,000

Physical/Chemical Properties

Appearance—Dark red solution
pH—8.0-9.0

Toxicity Data. No data were submitted.

Exposure. The manufacturer states that during manufacture 2 workers may experience cleaning and clarification press exposure 2 hrs/day, 8 days/yr.

Environmental Release/Disposal. The manufacturer states that less than 10 kg/yr will be released to air, land, and water. Disposal is to a publicly owned treatment works (POTW).

PMN 82-30

Close of Review Period. April 18, 1982.

Manufacturer's Identity. Claimed confidential business information. Organization information provided:

Manufacturing site—Middle Atlantic region.

Standard Industrial Classification Code—285;e.

Specific Chemical Identity. Claimed confidential business information. Generic name provided: Polysubstituted alkyl polamine.

Use. Claimed confidential business information. Generic use information provided: The manufacturer states that the PMN substance will be used in a destructive use.

PRODUCTION ESTIMATES

	Kilograms per year	
	Minimum	Maximum
1st year	0	6,000
2d year	3,000	12,000
3d year	6,000	18,000

Physical/Chemical Properties

Viscosity—A⁻
Color—13
% total solids—71.0

Toxicity Data. No data were submitted.

Exposure. The manufacturer states that during manufacture and processing a total of 139 workers may experience dermal and occular exposure up to 6 hrs/day, up to 6 days/yr during sampling, testing, filling, cleaning, and charging.

Environmental Release/Disposal. The manufacturer states that less than 10 kg/yr will be released to air and water and 10-100 to land. Disposal is by landfill or by incineration.

PMN 82-31

Close of Review Period. April 18, 1982.

Importer's Identity. Sandoz Colors and Chemicals, Route 10, E. Hanover, NJ 07936.

Specific Chemical Identity. Claimed confidential business information. Generic name provided: Quaternary, ammonium compound.

Use. The importer states that the PMN substance will be used as an industrial textile fiber modifier.

Import Estimates. Claimed confidential business information.

Physical/Chemical Properties

Appearance—Clear, viscous liquid
pH of 10% in water—Approximately 7.0
Ionic nature—Cationic
S. G. @ 20°C—1.003
Solubility: water—Unlimited.

Toxicity Data. No data were available on the PMN substance.

Exposure. The importer states that during processing 1 worker may experience dermal exposure 1 hr/day, 26 days/yr during transfer, padding, and printing.

Environmental Release/Disposal. The importer states that 10-100 kg/yr will be released to water. Disposal is to a POTW.

Dated: January 19, 1982.

Woodson W. Bercaw,

Acting Director, Management Support Division.

[FR Doc. 82-1826 Filed 1-25-82; 8:45 am]

BILLING CODE 6560-31-M

[OPTS-51384; TSH-FRL-2035-6]

Certain Chemicals; Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before manufacture or import commences. Statutory requirements for section 5(a)(1) premanufacture notices are discussed in EPA statements of interim policy published in the **Federal Register** of May 15, 1979 (44 FR 28558) and November 7, 1980 (45 FR 74378). This notice announces receipt of thirteen PMNs and provides a summary of each.

DATES: Written comments by: PMN 82-14, 82-15, 82-16, 82-17, 82-18, 82-19, 82-

20, 82–21, 82–22, 82–23, 82–25, 82–26, & 82–27—March 14, 1982.

ADDRESS: Written comments, identified by the document control number "[OPTS–51384]" and the specific PMN number should be sent to: Document Control Officer (TS–793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E–409, 401 M St., SW., Washington, DC 20460, (202–382–3532).

FOR FURTHER INFORMATION CONTACT: David Dull, Acting Chief, Notice Review Branch, Chemical Control Division (TS–794), Office of Toxic Substances, Environmental Protection Agency, Rm. E–216, 401 M St., SW., Washington, DC 20460, (202–426–2601).

SUPPLEMENTARY INFORMATION: The following are summaries of informtion provided by the manufacturer on the PMNs received by EPA:

PMN 82–14

Close of Review Period. April 13, 1982.

Manufacturer's Identity. Claimed confidential business information.

Specific Chemical Identity. Claimed confidential business information. Generic name provided: Reaction product of a substituted benzene, formaldehyde and inorganic acid.

Use. Claimed confidential business information. Generic use information provided: The manufacturer states that the PMN substance will be used as a lubricant additive.

Production Estimates. Claimed confidential business information.

Physical/Chemical Properties. Claimed confidential business information.

Toxicity Data. No data were submitted.

Exposure. Claimed confidential business information.

Environmental Release/Disposal. Claimed confidential business information.

PMN 82–15

Close of Review Period. April 13, 1982.

Manufacturer's Identity. Claimed confidential business information.

Organization information provided:

Manufacturing site—Middle Atlantic region.

Standard Industrial Classification Code—285 e.

Specific Chemical Identity. Claimed confidential business information. Generic name provided: Polyester from an unsaturated oil, alkane triol, carbomonocyclic anhydride and carbomonocyclic acids.

Use. Claimed confidential business information. Generic use information provided: The manufacturer states that the PMN substance will be used in a contained use.

PRODUCTION ESTIMATES

	Kilograms per year	
	Minimum	Maximum
1st year	7,000	45,000
2d year	13,200	90,000
3d year	33,000	225,000

Physical/Chemical Properties

Flash point—148° F
Viscosity—4 stokes
Acid value—13.6 mg KOH/g
Color, Gardner—8
% solids—30.0

Toxicity Data. No data were submitted.

Exposure. The manufacturer states that during manufacture, processing and use a total of 85 workers may experience dermal and occular exposure up to 6 hrs/day, up to 250 days/yr during sampling, testing, transfer, and cleaning.

Environmental Release/Disposal. The manufacturer states that less than 10 kg/yr will be released to air and water with 10–10,000 kg/yr released to land. Disposal is by distillation and incineration.

PMN 82–16

Close of Review Period. April 13, 1982.

Manufacturer's Identity. Claimed confidential business information.

Organization information provided:

Annual sales—$10,000,000 to $99,999,999.

Manufacturing site—South Atlantic region.

Standard Industrial Classification Code—286.

Specific Chemical Identity. Claimed confidential business information. Generic name provided: Substituted cyclic amide-aldehyde condensation product.

Use. The manufacturer states that the PMN substance will be used as an industrial paper coating additive.

PRODUCTION ESTIMATES

	Kilograms per year	
	Minimum	Maximum
1st year	225,000	550,000
2d year	550,000	1,100,000
3d year	1,100,000	2,200,000

Physical/Chemical Properties

pH—6.5 ± 0.5
Specific gravity, 60/60°F—1,076
Boiling point—212°F
Flash point—Above 200°F Setaflash CC
Viscosity, @ 25°C—40–60 cps
Solubility: water—Complete
Color—Amber
% solids—46.5%
Lbs/gallon—9
Odor—Mild, Indiscernible

Toxicity Data

Acute dermal toxicity LD_{50} (rat)—> 5 g/k
Skin irritation (rabbit)—Not an irritant
Eye irritation (rabbit)—Not an irritant

Environmental Test Data

COD mg/1—785 gm/l
BOD_5—185 gm/l
BOD_{11}—325 gm/l

Exposure. The manufacturer states that during manufacture 6 workers may experience dermal exposure 1 hr/day, 67 days/yr during sampling, filling, and testing.

Environmental Release/Disposal. The manufacturer states that 1,000–10,000 kg/yr will be released to land. Disposal is to a publicly owned treatment works (POTW).

PMN 82–17

Close of Review Period. April 13, 1982.

Manufacturer's Identity. American Color and Chemical Corporation, Mt. Vernon Street, Lock Haven, PA 17745.

Specific Chemical Identity. Claimed confidential business information. Generic name provided: Sulfo monoazo dye, 2,2'-iminobis ethanol salt.

Use. The manufacturer states that the PMN substance will be used as an industrial sized-pressed paper.

PRODUCTION ESTIMATES

	Kilograms per year	
	Minimum	Maximum
1st year	5,000	10,000
2d year	8,000	12,000
3d year	10,000	15,000

Physical/Chemical Properties

Appearance—Brown solution
pH—9.0–9.5

Toxicity Data. No data were submitted.

Exposure. The manufacturer states that during manufacture 2 workers may experience dermal exposure 2 hrs/day, 2 days/yr during cleaning of the clarification press.

Environmental Release/Disposal. The manufacturer states that less than 10 kg/yr will be released to air, land and water. Disposal is to a POTW.

PMN 82–18

Close of Review Period. April 13, 1982.

Manufacturer's Identity. Claimed confidential business information.

Specific Chemical Identity. Claimed confidential business information. Generic name provided: Polyurethane aqueous dispersion.

Use. Claimed confidential business information.

PRODUCTION ESTIMATES

	Kilograms per year	
	Minimum	Maximum
1st year	10,000	30,000
2d year	30,000	100,000
3d year	100,000	200,000

Physical/Chemical Properties. Claimed confidential business information.

Toxicity Data

Ames salmonella—Non-mutagenic

Exposure. The manufacturer states that during manufacture 2 workers may experience exposure during five 8 hr shifts while loading or transferring the product.

Environmental Release/Disposal. The manufacturer states that release to the environment is negligible.

PMN 82-19

Close of Review Period. April 13, 1982.

Manufacturer's Identity. Emery Industries, Inc., 4900 Este Avenue, Cincinnati, OH 45232.

Specific Chemical Identity. Pentaerythritol isostearate esters.

Use. Claimed confidential business information. Generic use information provided: The manufacturer states that the PMN substance will be used in an open use.

Production Estimates. Claimed confidential business information.

Physical/Chemical Properties

Appearance—Viscous yellow liquid, ester type odor
Specific gravity, 25/25° C—.94
Flash point ° F—500 minimum
Viscosity 100° F—248 cs
210° F—25 cs
Pour point ° F—10 maximum
Solubility: water—Negligible
Acid value—5.0 maximum
Vapor pressure—< 1 mm
Hydroxyl value—5.0 maximum

Toxicity Data

Oral toxicity LD_{50} (mouse)—25,500 mg/kg
(Guinea pig)—11,300 mg/kg
Threshold limit value (air)—10 mg/m³

Exposure. The manufacturer states that during manufacture and disposal a total of 3 workers may experience dermal exposure up to 2 hrs/day, up to 8 days/yr during sampling, cleaning, drumming, and waste disposal procedures.

Environmental Release/Disposal. The manufacturer states that 100–1,000 kg/yr will be released to land and water. Disposal is to a POTW.

PMN 82-20

Close of Review Period. April 13, 1982.

Manufacturer's Identity. Emery Industries, Inc., 4900 Este Avenue, Cincinnati OH 45232.

Specific Chemical Identity. Dipentaerythritol ester of isostearic acid.

Use. Claimed confidential business information. Generic use information provided: The manufacturer states that the PMN substance will be used in an open use.

Production Estimates. Claimed confidential business information.

Physical/Chemical Properties

Appearance—Viscous yellow liquid, ester type odor
Specific gravity 25/25° C—.94
Flash point, ° F—500 minimum
Viscosity 100° F—248 cs
210° F—25 cs
Pour point, ° F—10 maximum
Solubility: water—Nil
Vapor pressure—200° F
Evaporation rate—Nil

Toxicity Data. No data were submitted.

Exposure. The manufacturer states that during manufacture and disposal a total of 3 workers may experience dermal exposure up to 2 hrs/day, up to 3 days/yr during sampling, cleaning, drumming, and waste dispoosal procedures.

Environmental Release/Disposal. The manufacturer states that 10–1,000 kg/yr will be released to land and water. Disposal is to a POTW.

PMN 82-21

Close of Review Period. April 13, 1982.

Importer's Identity. American Orient Chemical, Inc., 121 Tyler Street, Port Newark, NJ 07114.

Specific Chemical Identity. Claimed confidential business information. Generic name provided: Hydroxynaphthoic acid metal complex.

Use. Claimed confidential business information. Generic use information provided: The importer states that the PMN substance will be used in a contained use.

IMPORT ESTIMATES

	Kilograms per year	
	Minimum	Maximum
1st year	1,000	2,000
2d year	2,000	5,000
3d year	2,000	5,000

Physical/Chemical Properties

Appearance—Yellowish green powder
Solubility:
Water, room temperature—1,000 parts per million (ppm)
80° C—2,000 ppm
Methanol—7,000 ppm
Methl ethyl ketone—200 ppm
Toluene—1,000 ppm
Density—0.3 g/cc

Toxicity Data

Ames salmonella—Not mutagenic

Exposure. The importer states at a site controlled by others that during processing, use, and disposal a total of 6 workers may experience exposure up to 1 hr/day, up to 30 days/yr packing.

Environmental Release/Disposal. The importer states that less than 10 kg/yr will be released to air 4 hrs/day, 30 days/yr. Disposal is by incineration.

PMN 82-22

Close of Review Period. April 13, 1982.

Manufacturer's Identity. Celanese Plastics and Specialties Company, P.O. Box 99038, Jeffersontown, KY 40299.

Specific Chemical Identity. Claimed confidential business information. Generic name provided: Acrylic copolymer.

Use. The manufacturer states that the PMN substance will be used as an intermediate.

PRODUCTION ESTIMATES

	Kilograms per year	
	Minimum	Maximum
1st year	0	50,000
2d year	100,000	200,000
3d year	200,000	450,000

Physical/Chemical Properties

Appearance—Clear
Flash point—95° F
Viscosity, Gardner Holdt—V-Y
Solubility:
Water—Insoluble
Ketone—Soluble
Toluene/xylene—Soluble
Butanol—Soluble
Glycol ethers—Soluble
Alkali ph >8—Soluble
Acid value—310–330 mg KOH/g
Weight/gallon—7.9–8.1 lbs.

Toxicity Data. No data were submitted,

Exposure. The manufacturer states that during manufacture, processing, and use 350 workers may experience dermal exposure 8 hrs/day, up to 200 days/yr during sampling, handling, transfer, and cleanup operations.

Environmental Release/Disposal. The manufacturer states that 100–10,000 kg/

yr will be released to land. Disposal is to an approved landfill.

PMN 82-23

Close of Review Period. April 13, 1982.
Importer's Identity. Claimed confidential business information.
Specific Chemical Identity. Claimed confidential business information. Generic name provided: Polyhalogenated aromatic alkylated hydrocarbon.
Use. Claimed confidential business information. Generic use information provided: The importer states that the PMN sustance will be used in a contained use.

IMPORT ESTIMATES

	Kilograms per year	
	Minimum	Maximum
1st year	5,000	20,000
d year	200,000	300,000
3d year	600,000	1,000,000

Physical/Chemical Properties

Appearance @ 20° C—Liquid
Specific gravity:
d^{20}_4=1.40 for the substance
1.42 for the preparation
d^{100}_4=1.34 for the latter
Boiling point @ 225° C—13 mbars
@ 380° C—1 atm
Flash point, open cup—225° C
Pour point—50° C
Explosiveness—Highly insensitive
Flammability—Incombustible
Products of pyrolysis and incineration—150° C
Solubility:
Water—Highly insoluble
Fat—Completely miscible
Organic solvents—Soluble
Color—White to pale yellow
Vapor pressure @ 20° C—0.1 mbars
@ 160° C—0.66 mbars
@ 220° C—10 mbars
@ 225° C—33 mbars approximately
Odor—Slightly aromatic
Surface tension 25° C—42.5 m/m
Water octanol distribution;
Coefficient f method—8.11
π method—7.48

Toxicity Data

Acute oral toxicity LD_{50} (rat)—Practically non-toxic
Acute dermal toxicity LD_{50} (rat)—Practically non-toxic
Skin sensitization (guinea pig)—Non-irritant
Gene mutation—None
Bioaccumulation-elimination—Very little

Environmental Test Data

Acute toxicity in fish 48 hrs—400 mg/l
Accumulated toxicity in fish—1 mg/l
Biodegradation—Appreciable
Exposure. The importer states that during processing 2 workers may experience accidental dermal exposure in case of an accident.
Environmental Release/Disposal. Disposal is by incineration

PMN 82-25

Close of Review Period. April 13, 1982.
Manufacturer's Identity. American Cyanamid, One Cyanamid Plaza, Wayne, NJ 07470.
Specific Chemical Identity. Claimed confidential business information. Generic name provided: Substituted amine polymer.
Use. Claimed confidential business information.
Production Estimates. Claimed confidential business information.
Physical/Chemical Properties. Claimed confidential business information.

Toxicity Data

Acute oral toxicity LD_{50} (rat)—2,100 mg/kg
Acute dermal toxicity LD_{50} (rat)—> 2,000 mg/kg
Primary skin irritation (rabbit)—Mildly irritating
Primary eye irritation (rabbit)—Marked irritation, without washout
Ames salmonella—Non-mutagenic
Exposure. The manufacturer states that during manufacture and use up to 80 workers may experience dermal, inhalation and ingestion exposure up to 24 hrs/day, up to 330 days/yr during drumming, sampling, and maintenance.
Environmental Release/Disposal. The manufacturer states that release to the land is negligible. Disposal is to an approved landfill.

PMN 82-26

Close of Review Period. April 13, 1982.
Manufacturer's Identity. American Cyanamid, One Cyanamid Plaza, Wayne, NJ 07470.
Specific Chemical Identity. Claimed confidential business information. Generic name provided: Substituted amine.
Use. Claimed confidential business information. Generic use information provided: The manufacturer states that the PMN substance will be used as a chemical intermediate.
Production Estimates. Claimed confidential business information.
Physical/Chemical Properties. Claimed confidential business information.

Toxicity Data

Acute oral toxicity LD_{50} (rat)—520 mg/kg
Acute dermal toxicity LD_{50} (rat)—> 2,000 mg/kg
Primary skin irritation (rabbit)—Mildly irritating
Primary eye irritation (rabbit)—Marked irritation, without washout
Ames salmonella—Non-mutagenic
Exposure. The manufacturer states that during manufacture up to 32 workers may experience dermal, inhalation, and ingestion exposure up to 24 hrs/day, up to 330 days/yr during drumming, sampling, and maintenance.
Environmental Release/Disposal. The manufacturer states that release to the land is negligible. Disposal is to an approved landfill.

PMN 82-27

Close of Review Period. April 13, 1982.
Manufacturer's Identity. American Cyanamid, One Cyanamid Plaza, Wayne, NJ 07470.
Specific Chemical Identity. Claimed confidential business information. Generic name provided: Substituted amine.
Use. Claimed confidential business information.
Production Estimates. Claimed confidential business information.
Physical/Chemical Properties. Claimed confidential business information.

Toxicity Data

Acute oral toxicity LD_{50} (rat)—8,230 mg/kg
Acute dermal toxicity LD_{50} (rat)—> 2,000 mg/kg
Primary skin irritation (rabbit)—Mildly irritating
Primary eye irritation (rabbit)—Marked irritation, without washout
Ames salmonella—Non-mutagenic
Exposure. The manufacturer states that during manufacture up to 80 workers may experience dermal, inhalation, and ingestion exposure up to 24 hrs/day, up to 330 days/yr during drumming, sampling, and maintenance.
Environmental Release/Disposal. The manufacturer states that release to the land is negligible. Disposal is to an approved landfill.

Dated: January 18, 1982.

Woodson W. Bercaw,

Acting Director, Management Support Division.

[FR Doc. 82-1829 Filed 1-25-82; 8:45 am]

BILLING CODE 6560-31-M

[Opts—42011; TSH-FRL-2035-4]

2-Chlorotoluene; Negotiated Testing Plan and Request for Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Hooker Chemicals and Plastics Corporation has submitted to the EPA a proposed testing scheme for 2-chlorotoluene (ortho-chlorotoluene), a schedule for testing, and protocols for some of the tests. The Agency is requesting public comments on these submissions, and also wishes to know if there is interest in a public meeting to discuss Hooker's proposal.

DATES: Comments on the documents should be received no later than February 22, 1982. Comments on the desirability of a public meeting, or the intent to attend if there is one, should be received no later than February 8, 1982.

ADDRESSES: Written comments and request, if any, for a public meeting, should bear the document control number 42011 and should be submitted in triplicate to: Document Control Officer (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-401, 401 M St., SW., Washington, D.C. 20460.

The material from Hooker is available for public inspection in Rm. E-107 at the above address from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays. The material may be copied for a nominal fee.

FOR FURTHER INFORMATION CONTACT: Douglas G. Bannerman, Acting Director, Industry Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-511, 401 M St., SW., Washington, D.C. 20460, Toll free: (800-424-9065), In Washington, D.C.: (554-1404), Outside the USA: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION: Hooker suggests that its voluntary testing proposal be accepted in lieu of requiring testing by rule under section 4 of the Toxic Substances Control Act. The EPA is requesting public comments on Hooker's testing scheme, schedule and protocols and on the company's proposed substitution of voluntary testing for testing required by rule.

(Sec. 4, 90 Stat. 2006, Pub. L. 94-469; (15 U.S.C. 2601))

Dated: January 13, 1982.

Don R. Clay,

Director, Office of Toxic Substances.

[FR Doc. 82-1827 Filed 1-25-82; 8:45 am]

BILLING CODE 6560-31-M

[AH-FRL-2035-8]

Fuel Economy Retrofit Devices; Announcement of Fuel Economy Retrofit Device Evaluation for "Fuel Maximiser™"

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of fuel economy retrofit device evaluation.

SUMMARY: This document announces the conclusions of the EPA evaluation of the "Fuel Maximiser™" device under provisions of Section 511 of the Motor Vehicle Information and Cost Savings Act.

BACKGROUND INFORMATION: Section 511(b)(1) and Section 511(c) of the Motor Vehicle Information and Cost Savings Act (15 U.S.C. 2011(b)) requires that:

(b)(1) Upon application of any manufacturer of a retrofit device (or prototype thereof), upon the request of the Federal Trade Commission pursuant to subsection (a), or upon his own motion, the EPA Administrator shall evaluate, in accordance with rules prescribed under subsection (d), any retrofit device to determine whether the retrofit device increases fuel economy and to determine whether the representations (if any) made with respect to such retrofit devices are accurate.

(c) The EPA Administrator shall publish in the **Federal Register** a summary of the results of all tests conducted under this section, together with the EPA Administrator's conclusions as to—

(1) The effect of any retrofit device on fuel economy;

(2) The effect of any such device on emissions of air pollutants; and

(3) Any other information which the Administrator determines to be relevant in evaluating such device.

EPA published final regulations establishing procedures for conducting fuel economy retrofit device evaluations on March 23, 1979 [44 FR 17946].

ORIGIN OF REQUEST FOR EVALUATION: On February 11, 1981, the EPA received a request from the U.S. Postal Service for evaluation of a fuel saving device termed "Fuel Maximiser™". This device consists of a small coil of copper wire in a plastic enclosure which is positioned over the negative terminal of the vehicle battery. The device allegedly creates an ion charge in the vehicle which modifies the molecular structure of the fuel, thus increasing vehicle fuel economy.

Availability of Evaluation Report: An evaluation has been made and the results are described completely in a report entitled: "EPA Evaluation of the Fuel Maximiser™ device Under Section 511 of the Motor Vehicle Information and Cost Savings Act," report number EPA-AA-TEB-511-82-1 consisting of 91 pages including all attachments.

EPA also tested the Fuel Maximiser™ device. The EPA testing is described completely in the report "EPA Testing Evaluation of the Fuel Maximiser™—A Retrofit Fuel Economy Device." EPA-AA-TEB-81-4, consisting of 41 pages. This report is contained in the preceding 511 evaluation as an attachment.

Copies of these reports may be obtained from the National Technical Information Service by using the above report numbers. Address requests to: National Technical Information Service, U.S. Department of Commerce, Springfield, VA 22161, Phone: Federal Telecommunications System (FTS) 737-4650, Commercial 703-487-4650.

Summary of Evaluation

The results of the EPA testing demonstrate that with either road or dynamometer testing procedures, the Fuel Maximiser™ failed to improve vehicle fuel economy. The two test vehicles tested are representative of domestic manufactured vehicles and should have noted an improvement if the device performed as it was claimed to do. It is concluded that the Fuel Maximiser™ has no effect on vehicle fuel economy.

FOR FURTHER INFORMATION CONTACT: Merrill W. Korth, Emission Control Technology Division, Office of Mobile Source Air Pollution Control, Environmental Protection Agency, 2565 Plymouth Road, Ann Arbor, Michigan 48105, 313-668-4299.

Dated: January 15, 1982.

Kathleen M. Bennett,

Assistant Administrator, for Air, Noise, and Radiation.

[FR Doc. 82-1833 Filed 1-25-82; 8:45 am]

BILLING CODE 6560-26-M

[OPTS-59079; TSH-FRL-2035-5]

Substituted Pyridinium Bromide Premanufacture Exemption Application

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA may upon application exempt any person from the premanufacturing notification requirements of section 5(a) or (b) of the Toxic Substances Control Act (TSCA) to permit the person to manufacture or process a chemical for test marketing purposes under section 5(h)(1) of TSCA. Requirements for test marketing exemption (TME) applications, which

must either be approved or denied within 45 days of receipt, are discussed in EPA's revised statement of interim policy published in the **Federal Register** of November 7, 1980 (45 FR 74378). This notice, issued under section 5(h)(6) of TSCA, announces receipt of one application for an exemption, provides a summary, and requests comments on the appropriateness of granting the exemption.

DATE: Written comments by: February 10, 1982.

ADDRESS: Written comments, identified by the document control number "[OPTS-59079]" and the specific TME number should be sent to: Document Control Officer (TS-793), Office of Pesticides and Toxic Substances, Management Support Division, Environmental Protection Agency, Rm. E-401, 401 M Street, SW, Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: David Dull, Acting Chief, Notice Review Branch, Chemical Control Division (TS-794), Office of Toxic Substances, Environmental Protection Agency, Rm. E-216, 401 M Street, SW, Washington, DC 20460.

SUPPLEMENTARY INFORMATION: The following is a summary of information provided by the manufacturer on the TME received by the EPA:

TME 82-2

Close of Review Period. February 27, 1982.

Manufacturer's Identity. Claimed confidential business information. Organization information provided:

Annual sales—Over $500,000,000.

Manufacturing site—Northeast region.

Specific Chemical Identity. Claimed confidential business information. Generic name provided: Substituted pyridinium bromide.

Use. Claimed confidential business information. Generic use information provided: The manufacturer states that the TME substance will be used in a way that will release less than 5 kg/yr of the substance to the environment. The use will involve exposure to chemical industry employees with potential for skin contact and inhalation exposure. The chemical will be incorporated into a consumer article. Industrial releases to the environment will be to a Publicly Owned Treatment Works (POTW) and/or to a chemical landfill.

Production Estimates

20—Maximum (kilograms per year).

Physical/Chemical Properties

Melting point—>100° C.

Solubility: water—>10 g/l at 20° C.

Toxicity Data. No data were submitted.

Exposure. The manufacturer states that a maximum of 18 workers may have dermal and inhalation exposure for 16 hrs/day, 250 days/yr during manufacture, a maximum total of 198 workers (total all shifts) may have dermal and/or inhalation exposure for 24 hrs/day, 355 days/yr during processing, and a maximum of 4 workers may have dermal exposure 24 hrs/day, 355 days/yr during disposal.

Environmental Release/Disposal. The manufacturer states that all liquid and solid wastes that will be generated by this process, apart from those wastewater streams which are approved for discharge into the POTW, will be drummed for destruction in a licensed thermal oxidizer or for disposal in a licensed chemically secure landfill, or for treatment or recovery.

Dated: January 18, 1982.

Woodson W. Bercaw,

Acting Director, Management Support Division.

[FR Doc. 82-1828 Filed 1-25-82; 8:45 am]

BILLING CODE 6560-31-M

FEDERAL COMMUNICATIONS COMMISSION

[Report No. 1326]

Petitions for Reconsideration of Actions in Rule Making Proceedings; Correction

January 20, 1982.

Report No. 1326, released January 8, 1982, inadvertently included a petition for reconsideration filed by Scott H. Robb for Catskill Communications, Inc., (WCKL) in BC Docket No. 81-322. The Catskill petition was originally listed on Report No. 1325, released December 28, 1981 and printed in the **Federal Register** on January 4, 1982, 47 FR 91. Therefore, the dates for filing oppositions and replies are January 19, 1982 and January 29, 1982, respectively.

William J. Tricarico,

Secretary, Federal Communications Commission.

[FR Doc. 82-1811 Filed 1-25-82; 8:45 am]

BILLING CODE 6712-01-M

[Special Docket No. 81-1]

Special Inquiry on Alternative Financing for Public Telecommunications; Order Extending Time for Filing Comments and Reply Comments

AGENCY: Federal Communications Commission.

ACTION: Notice of public inquiry; extension of comment/reply comment period.

SUMMARY: Action taken herein extends the due dates for filing of comments in Special Docket No. 81-1, adopted November 9, 1981. The extension will facilitate a complete public record.

DATES: Comments must be filed on or before January 22, 1982. Reply comments must be filed on or before February 22, 1982.

ADDRESS: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Judith Harman, Broadcast Bureau (202) 632-6302.

SUPPLEMENTARY INFORMATION:

In the matter of special inquiry on alternative financing for public telecommunications.

Order Extending Time

Adopted: January 11, 1982.

Released: January 19, 1982.

1. The Temporary Commission on Alternative Fimancing for Public Telecommunications ("TCAF") has before it a Motion for Extension of Time in response to the TCAF's action in the Notice of Public Inquiry, 46 FR 60270, December 9, 1981. The Motion for Extension of Time, filed on behalf of the Public Broadcasting Service, requests that the time for filing all comments in the above-captioned proceeding be extended for all parties to and including February 1, 1982 and to March 3, 1982 for all reply comments.

2. The TCAF issued the Notice of Public Inquiry to gather all relevant information on alternative revenue sources which may be available to public telecommunications entities. At present, comments are due to the TCAF on January 15, 1982 and reply comments are due on February 15, 1982. The TCAF desires to gather as thorough and meaningful a record as practicable. We are, therefore, sympathetic to petitioner's request. However, since the TCAF must submit a report to Congress on this matter by July 1, 1982, we cannot grant the full extension of time. We will, however, grant leave to file late comments in appropriate circumstances.

3. Accordingly, it is ordered, that the Motion for Extension of Time filed by petitioner is hereby granted in part. The date for filing comments in the above-captioned proceeding is extended to January 22, 1982. The date for filing reply comments is extended to February 22, 1982.

4. Authority for this inquiry is contained in Section 1232(g) of the

Public Broadcasting Amendments Act of 1981, Pub. L. 97–35.

Federal Communications Commission.

James H. Quello,

Chairman, Temporary Commission on Alternative Financing for Public Telecommunications.

[FR Doc. 82–1804 Filed 1–25–82; 8:45 am]

BILLING CODE 6712–01–M

National Industry Advisory Committee, Broadcast Services Subcommittee; Meeting

Pursuant to the provisions of Pub. L. 92–463, announcement is made of a public meeting of the Broadcast Services Subcommittee of the National Industry Advisory Committee (NIAC) to be held Tuesday, February 16, 1982. The Subcommittee will meet at the National Association of Broadcasters Board Room, 1771 N Street, NW., Washington, D.C. at 9:30 a.m.

Purpose: To consider emergency communications matters.

Agenda: As follows:

Items: 1. Opening remarks by Chairman.
2. Report of Ad Hoc Working Group re proposed nationwide test of the Emergency Broadcast System.
3. Review of impact on Presidential EBS program distribution by conversion of networks to satellite feed.
4. Recommend to Executive Committee approval of FCC, NOAA–NWS, FEMA, and NIAC Memorandum of Understanding.
5. Review of revised Standard Operating Procedures.
6. Review of draft "500" Teletypewriter Network special instruction card.
7. EBS planning program update including nuclear power plant notification requirements.
8. Other business.
9. Adjournment.

Any member of the general public may attend or file a written statement with the Committee either before or after the meeting. Any member of the public wishing to make an oral statement must consult with the Committee prior to the meeting. Those desiring more specific information about the meeting may telephone the Emergency Communications Division, FCC, (202) 632–7232.

Federal Communications Commission.

William J. Tricarico,

Secretary.

[FR Doc. 82–1805 Filed 1–25–82; 8:45 am]

BILLING CODE 6712–01–M

National Industry Advisory Committee, Executive Committee; Meeting

Pursuant to the provisions of Pub. L. 92–463, announcement is made of a public meeting of the Executive Committee of the National Industry Advisory Committee (NIAC) to be held Tuesday, February 16, 1982. The Committee will meet at the National Association of Broadcasters Board Room, 1771 N Street, NW., Washington, D.C. at 1:30 p.m.

Purpose: To consider emergency communications matters.

Agenda: As follows:

Items: 1. Opening Remarks.
2. Subcommittee Activities.
a. Aeronautical Communications Services Subcommittee.
b. Amateur Radio Service Subcommittee:
- Approval of Amateur Radio Service Subcommittee prototype plan entitled, "An Amateur Radio Service Plan for the Support of Local Government."

c. Broadcast Services Subcommittee:
- Consideration of a nationwide on-the-air test of the Emergency Broadcast System (EBS).
- NIAC approval of a Memorandum of Understanding among FEMA, FCC, NOAA, and the NIAC for developing and evaluating effective EBS plans and related capabilities of the State and local levels of EBS operations.
- Status report of new White House Statement of Requirements—Presidential Communications with the Public During Periods of National Emergency.

d. Citizens Band Radio Communications Subcommittee:
- Approval of the Citizens Band Radio Communications Subcommittee prototype plan entitled, "Citizens Band Radio Service Plan for the Support of Local Government During Emergencies."

e. Domestic & International Common Carrier Communciations Services Subcommittee.
f. Industrial Communications Services Subcommittee.
g. Maritime Communications Services Subcommittee.
3. National Security Telecommunciations Policy (PD/NSC–53):
- Consideration of government requirements to use industry private line communications that have significant capabilities (e.g., pipe line, railroad, and airline).
- Consideration of interconnection and interoperability of industry common carrier facilities.
- Consideration of NIAC responsibilities and courses of action to be taken by NIAC subcommittees in meeting the requirements of PD/NSC–53.

4. Impact of FCC Orders 80–150 and 80–581, Amendment of Part 64 of the Commission's Rules to Provide for a New Priority System for the Restoration of Common Carrier Provided Intercity Private Line Service, upon NIAC subcommittee planning.
5. Other Business.
6. Adjournment.

Any member of the general public may attend or file a written statement with the Committee either before or after the meeting. Any member of the public wishing to make an oral statement must consult with the Committee prior to the meeting. Those desiring more specific information about the meeting may telephone the Emergency Communications Division, FCC, (202) 632–7232.

Federal Communications Commission.

William J. Tricarico,

Secretary.

[FR Doc. 82–1806 Filed 1–25–82; 8:45 am]

BILLING CODE 6712–01–M

FEDERAL RESERVE SYSTEM

Bank Holding Companies; Proposed de Novo Nonbank Activities

The bank holding companies listed in this notice have applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.4(b)(1) of the Board's Regulation Y (12 CFR 225.4(b)(1)), for permission to engage *de novo* (or continue to engage in an activity earlier commenced *de novo*), directly or indirectly, solely in the activities indicated, which have been determined by the Board of Governors to be closely related to banking.

With respect to each application, 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 interest, or unsound banking practices." Any comment on an application that requests a hearing must include a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of

fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of that proposal.

Each application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank indicated for that application. Comments and requests for hearings should identify clearly the specific application to which they relate, and should be submitted in writing and received by the appropriate Federal Reserve Bank not later than February 16, 1982.

A. **Federal Reserve Bank of New York.** (A. Marshall Puckett, Vice President) 33 Liberty Street, New York, New York 10045:

1. *Citicorp,* New York, New York (financing activities; Texas, Southwestern Oklahoma): to engage through its subsidiary, Citicorp Industrial Credit, Inc. in making or acquiring, for its own accout or for the account of others, commercial loans and other extensions of credit. These activities would be conducted from an office in Dallas, Texas serving the states identified in the caption above.

2. *Citicorp,* New York, New York (credit related property and casualty insurance activities; Georgia) to expand the activities of an existing office of its subsidiary, Citicorp Person-to-Person Financial Center, Inc., located in Atlanta, Georgia. The new activity in which the office proposes to engage *de novo* is the sale of credit related property and casualty insurance protecting real and person property subject to a security agreement with Citicorp Person-to-Person Financial Center, Inc. to the extent permissible under applicable state insurance laws and regulations. The proposed service area for this activity is the entire state of Georgia.

3. *Citicorp,* New York, New York (commercial lending activities; Maryland, Delaware, Virginia, West Virginia, District of Columbia): to engage through a de novo office of Citicorp Industrial Credit, Inc. in making or acquiring, for its own account or for the account of others, commercial loans and other extensions of credit. Such activities would be conducted from an office in Towson, Maryland serving the states of Maryland, Delaware, Virginia, West Virginia, and the District of Columbia.

4. *The Hong Kong and Shanghai Banking Corporation,* Hong Kong, B.C.C., Kellett, N.V., Curacao, Netherlands Antilles, HSBC Holdings, B.V., Amsterdam, The Netherlands, and Marine Midland Banks, Inc., Buffalo, New York (financing and investment advising activities; California): to engage through their subsidiary, Marine Midland Realty Credit Corporation, in the following activities: originating, making, acquiring, and servicing, for its own account or for the account of others, loans and other extensions of credit, either unsecured or principally secured by mortgages on residential or commercial properties or lease-hold interests therein; and acting as investment or financial adviser to the extent of serving as the advisory company for a mortgage or real estate investment trust, furnishing general economic information and advice on real estate matters, and providing portfolio investment advice on real matters. These activities are to be conducted from an office located in Los Angeles, California, and will serve the entire state of California.

5. *Manufacturers Hanover Corporation,* New York, New York (relocation of office; Ohio): to continue to engage in approved activities through its subsidiary, Manufacturers Hanover Mortgage Corporation ("MHMC"), after MHMC relocates an office located in Cincinnati, Ohio to Springdale, Ohio. The new office will continue to serve customers in the same service area and will engage only in activities previously approved.

6. *Manufacturers Hanover Corporation,* New York, New York (insurance activity; United States): to engage through a de novo indirect subsidiary known as MHMC Insurance agency, Inc. in the following activities: acting as insurance agent or broker for the sale of credit life and credit accident and health insurance related to loans and other extensions of credit such as would be made by a mortgage company, that are made, acquired, or serviced by Manufacturers Hanover Mortgage Corporation, for its own account or for the account of others, Such activities will be conducted at an office located in Phoenix, Arizona, serving the entire United States.

7. *Manufacturers Hanover Corporation,* New York, New York (relocation of office and expansion of service area; South Carolina): to continue to engage through its subsidiary, Finance One of South Carolina, Inc., in comsumer finance, sales finance, home equity lending, and credit related insurance activities, after Finance One of South Carolina, Inc., relocates its office located at 281 Meeting Street, Charleston, South Carolina, to 5060 Dorchester Road, North Charleston, South Carolina, and expands the service area of the office. The application does not involve the commencement of any new activities at the new location. The office will serve customers in Charleston, eastern Colleton, southern Dorchester, and southern Berkeley Counties.

B. Other Federal Reserve Banks. None.

Board of Governors of the Federal Reserve System, January 21, 1982.

Theodore E. Downing, Jr.,

Assistant Secretary of the Board.

[FR Doc. 82-1813 Filed 1-25-82; 8:45 am]

BILLING CODE 6210-01-M

Federal Open Market Committee; Authorization for Domestic Open Market Operations

In accordance with the Committee's rules regarding availability of information, notice is given that on December 4, 1981, paragraph 1(a) of the Committee's authorization for domestic open market operations was amended to raise from $3 billion to $4 billion the limit on changes between Committee meetings in System Account holdings of U.S. government and federal agency securities, effective immediately, for the period ending with the close of business on December 22, 1981.

Note.—For paragraph 1(a) of the authorization, see 36 FR 22697.

By order of the Federal Open Market Committee, January 4, 1982.

Murray Altmann,

Secretary.

[FR Doc. 82-1814 Filed 1-25-82; 8:45 am]

BILLING CODE 6210-01-M

Federal Open Market Committee; Domestic Policy Directive of November 17, 1981

In accordance with § 217.5 of its rules regarding availability of information, there is set forth below the Committee's Domestic Policy Directive issued at its meeting held on November 17, 1981.[1]

"The information reviewed at this meeting suggests that real GNP is declining appreciably in the current quarter and that prices on the average are rising somewhat less rapidly than over the first three quarters of the year. In October the nominal value of total retail sales dropped; industrial production fell more than in September; and nonfarm payroll employment, especially in manufacturing, declined sharply. The unemployment rate rose from 7.5 percent to 8.0 percent. Housing

[1] The Record of Policy Actions of the Committee for the meeting of November 17, 1981, is filed as part of the original document. Copies are available upon request to The Board of Governors of the Federal Reserve System, Washington, D.C. 20551.

starts edged down in September from an already depressed level. Over the first 10 months of 1981, the rise in the index of average hourly earnings was less rapid than during 1980.

The weighted average value of the dollar against major foreign currencies has declined only a little since early October, although U.S. short-term interest rates have declined more than foreign rates. A reduced U.S. foreign trade deficit in September brought the deficit for the third quarter close to the second-quarter rate.

The M1–B (adjusted for estimated shifts into NOW accounts) expanded in October almost as much as it had declined in September, and growth of M2 picked up. The level of adjusted M1–B remained well below the lower end of the Committee's range for growth over the year from the fourth quarter of 1980 to the fourth quarter of 1981; the level of M2 was at the upper end of its range for the year. Short-term market interest rates have declined substantially since the end of September, and bond yields have also dropped from the peaks generally reached about then. On October 30 the Board of Governors announced a reduction in Federal Reserve basic discount rates from 14 to 13 percent. The surcharge on frequent borrowings of large depository institutions had been reduced from 3 to 2 percentage points on October 9, and on November 16 the Board removed the remaining 2 percentage points.

The Federal Open Market Committee seeks to foster monetary and financial conditions that will help to reduce inflation, promote a resumption of growth in output on a sustainable basis, and contribute to a sustainable pattern of international transactions. At its meeting in early July, the Committee agreed that its objectives would be furthered by reaffirming the monetary growth ranges for the period from the fourth quarter of 1980 to the fourth quarter of 1981 that it had set at the February meeting. These ranges included growth of 3½ to 6 percent for M1–B, abstracting from the impact of flows into NOW accounts on a nationwide basis, and growth of 6 to 9 percent and 6½ to 9½ percent for M2 and M3 respectively. The Committee recognized that the shortfall in M1–B growth in the first half of the year partly reflected a shift in public preferences toward other highly liquid assets and that growth in the broader aggregates had been running at about or somewhat above the upper end of their ranges. In light of its desire to maintain moderate growth in money over the balance of the year, the Committee expected that growth in M1–B for the year would be near the lower end of its range. At the same time, growth in the broader aggregates might be high in their ranges. The associated range for bank credit was 6 to 9 percent. The Committee also tentatively agreed that for the period from the fourth quarter of 1981 to the fourth quarter of 1982 growth of M1, M2, and M3 within ranges of 2½ to 5½ percent, 6 to 9 percent, and 6½ to 9½ percent respectively would be appropriate. These ranges will be reconsidered as warranted to take account of developing experience with public preferences for NOW and similar accounts as well as changing economic and financial conditions.

The Committee, after noting a moderate shortfall in growth of M1–B in October from the target path set at the last meeting, seeks behavior of reserve aggregates consistent with growth of M1–B from October to December at an annual rate of about 7 percent (after allowance for the impact of flows into NOW accounts) and with growth of M2 at an annual rate around 11 percent. The Chairman may call for Committee consultation if it appears to the Manager for Domestic Operations that pursuit of the monetary objectives and related reserve paths during the period before the next meeting is likely to be associated with a federal funds rate persistently outside a range of 11 to 15 percent."

By order of the Federal Open Market Committee, January 5, 1982.

Murray Altmann,

Secretary.

[FR Doc. 82-1815 Filed 1-25-82; 8:45 am]

BILLING CODE 6210-01-M

Bank Holding Company; Proposed De Novo Nonbank Activities

The bank holding company listed in this notice has applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.4(b)(1) of the Board's Regulation Y (12 CFR 225.4(b)(1)), for permission to engage *de novo* (or continue to engage in an activity earlier commenced *de novo*), directly or indirectly, solely in the activities indicated, which have been determined by the Board of Governors to be closely related to banking.

With respect to the application, 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 interest, or unsound banking practices." Any comment on the application that requests a hearing must include a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of that proposal.

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank indicated for the application. Comments and requests for hearings should identify clearly the specific application to which they relate, and should be submitted in writing and received by the appropriate Federal Reserve Bank not later than February 12, 1982.

A. **Federal Reserve Bank of Philadelphia** (Thomas K. Desch, Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105:

Philadelphia National Corp., Philadelphia, Pennsylvania (mortgage lending activities; Colorado): to engage, through its subsidiary, Colonial Mortgage Service Company Associated, Inc., in the origination of FHA, VA, and conventional residential mortgage loans and second mortgage loans. These activities would be conducted from a proposed new office in Denver, Colorado, serving the state of Colorado and adjoining areas of adjacent states.

B. **Federal Reserve Bank of Chicago** (Franklin D. Dreyer, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

American Fletcher Corp., Indianapolis, Indiana, (mortgage banking and related lending activities; Florida): to engage through its subsidiary, American Fletcher Mortgage Company, Inc., in making for its own account, or for the account of others, and selling in the secondary market, loans secured by real estate, including, but not limited to, mortgage loans secured by mortgages on one-four family residential properties, condominiums, multi-family residential income properties, commercial income properties, and properties under development or construction. These activities will be conducted from an office in Deerfield Beach, Florida, serving the state of Florida.

NBD Bancorp, Inc., Detroit, Michigan (trust company activities; Florida): to engage through its subsidiary, NBD Trust Company of Florida) N.A., in activities that may be carried on by a trust company including activities of a

fiduciary, agency or custodian nature. These activities would be conducted from an office in West Palm Beach, Florida, serving the state of Florida.

C. **Federal Reserve Bank of Kansas City** (Thomas M. Hoenig, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64109:

Bankshares of Nebraska, Inc., Grand Island, Nebraska (financing, servicing, leasing activities; Midwest, United States): to engage, in making leases of personal property in accordance with the Board's Regulation Y. These activities would be conducted from an office at 202 West Third Street, Grand Island, Nebraska serving Nebraska, and contiguous states.

D. **Federal Reserve Bank of Dallas** (Anthony J. Montelaro, Assistant Vice President) 400 South Akard Street, Dallas, Texas 75222:

United Mercantile Bancshares, Shreveport, Louisiana (leasing and financing; Louisiana): to engage through its subsidiary, United Mercantile Leasing Company, in leasing activities, including brokering leases, and making and servicing wholly-owned and leveraged true leases. These activities would be conducted from an office in Shreveport, Louisiana, serving the city of Shreveport, Louisiana and surrounding cities and towns.

E. **Federal Reserve Bank of San Francisco** (Harry W. Green, Vice President) 400 Sansome Street, San Francisco, California 94120:

1. *BankAmerica Corp.*, San Francisco, California (financing, servicing, and insurance activities; office relocation; New Jersey and southeast Pennsylvania): to continue to engage, through its indirect subsidiary, FinanceAmerica Corporation, a New Jersey corporation, in making or acquiring for its own account loans and other extensions of credit such as would be made or acquired by a finance company; servicing loans and other extensions of credit; and offering credit-related life insurance and credit-related accident and health insurance. Credit-related property insurance will not be offered in either the state of New Jersey or the southeast region of Pennsylvania. Such activities will include, but not be limited to, making consumer installment loans, purchasing installment sales finance contracts, making loans and other extensions of credit to small businesses, making loans secured by real and personal property, and offering credit-related life and credit-related accident and health insurance directly related to extensions of credit made or acquired by FinanceAmerica Corporation.

These activities will be conducted from an office located in 3001 Greentree, Executive Campus, Burlington County, Marlton, New Jersey, serving the entire state of New Jersey and the southeast region of Pennsylvania. This application is for approval to relocate an office presently located in Camden, New Jersey.

2. *BankAmerica Corp.*, San Francisco, California (financing, servicing, and insurance activities; Wisconsin): to engage, through its indirect subsidiary, FinanceAmerica Corporation, a Wisconsin corporation, in the activities of making or acquiring for its own account loans and other extensions of credit such as would be made or acquired by a finance company; servicing loans and other extensions of credit; and offering credit-related life insurance, credit-related accident and health insurance and credit-related property insurance. Such activities will include, but not be limited to, making consumer installment loans; purchasing installment sales finance contracts; making loans and other extensions of credit to small businesses; making loans secured by real and personal property; and offering credit-related life, credit-related accident and health and credit-related property insurance directly related to extensions of credit made or acquired by FinanceAmerica Corporation. These activities will be conducted from a *de novo* office located in Wauwatosa, Wisconsin, serving the entire state of Wisconsin.

3. *Security Pacific Corp.*, Los Angeles, California (finance and insurance activities; New Jersey): to engage through its subsidiary, Security Pacific Finance Corp., in making or acquiring for its own account or for the account of others loans and extensions of credit, including making consumer installment personal loans, purchasing consumer installment sales finance contracts, making loans to small businesses and making other extensions of credit such as would be made by a factoring company of a consumer finance company; and acting as broker or agent for the sale of credit life and credit accident and health insurance. These activities would be conducted from an office of Security Pacific Finance Corp. located in West Orange, New Jersey, serving the state of New Jersey and would constitute a relocation of an existing office of Security Pacific Finance Corp. which is currently located in Maplewood, New Jersey.

F. **Other Federal Reserve Banks.** None.

Board of Governors of the Federal Reserve System, January 20, 1982.

Theodore E. Downing, Jr.,

Assistant Secretary of the Board.

[FR Doc. 82-1852 Filed 1-25-82; 8:45 am]

BILLING CODE 6210-01-M

GENERAL SERVICES ADMINISTRATION

Federal Procurement; GSA Bulletin FPR 55

January 6, 1982.

To: Heads of Federal agencies

Subject: Government entities and their addresses for bidders mailing list purposes.

1. *Purpose.* This bulletin provides a list of Government entities and their addresses for use by sources of products (domestic and foreign) that wish to be placed on bidders mailing lists.

2. *Expiration date.* The information contained in this bulletin is of a continuing nature and will remain in effect until canceled.

3. *Background.*

a. FPR Temporary Regulation 57, January 12, 1981, implemented the Agreement on Government Procurement, pursuant to the Trade Agreements Act of 1979. This bulletin has been prepared to assist foreign and domestic firms in competing for contracts subject to the Trade Agreements Act.

b. Section 1-6.1605-1(b)(1) of FPR Temporary Regulation 57 provides as follows:

Sources offering eligible products from designated countries shall be included, upon request by these sources, on bidders mailing lists and comparable source lists, in accordance with procedures in FPR § 1-2.205.

c. The entities with significant procurement programs are the Departments of Agriculture, Commerce, Health and Human Services, Interior, Labor, State, Treasury, the Environmental Protection Agency, General Services Administration, National Aeronautics and Space Administration, and Veterans Administration. The other entities have relatively small programs.

4. *Action by sources.* Sources of products (domestic and foreign) that wish to be placed on the bidders mailing lists of Government entities should contact the addressees in attachment A.

The list does not include the Department of Defense.

Gerald McBride,

Assistant Administrator for Acquisition Policy.

Addresses of Government Entities for Bidders Mailing List

Entities and Telephone Numbers

Action, Office of Contracts and Grants Management, 1735 I Street NW., Room 314, Washington, DC 20525, (202) 254–3513

Administrative Conference of the United States, 2120 L Street NW., Washington, DC 20037, (202) 254–7020

American Battle Monuments Commission, 20 Massachusetts Avenue NW., Washington, DC 20314, (202) 272–0533

Board of International Broadcasting, 1030 Fifteenth Street NW., Washington, DC 20005, (202) 254–8040

Civil Aeronautics Board, 1825 Connecticut Avenue NW., Room B–23, Washington, DC 20428, (202) 673–5262

Commission on Civil Rights, 1121 Vermont Avenue NW., Washington, DC 20425, (202) 254–6630

Commodity Futures Trading Company, 2033 K Street NW., Washington, DC 20425, (202) 254–9735

Consumer Product Safety Commission, Contracts Branch, 5401 Westbard Avenue, Bethesda, MD 20014, (301) 492–6444

*Department of Agriculture, Office of Operations and Finance, Procurement Division, Room 1575, South Building, Washington, DC 20250, (202) 447–7527

*Excludes the procurement of agricultural products made in furtherance of agricultural support programs or human feeding programs.

Department of Commerce, Office of Procurement, 14th & Constitution Avenue NW., Room 6600, Washington, DC 20230, (202) 377–2773

Department of Education, Management Support Division, Operations Support Branch, Room 5673, 400 Maryland Avenue SW., Washington, DC 20202, (202) 245–1773

Department of Health and Human Services, Office of Small and Disadvantaged Business Utilization, Room 531–H, 200 Independence Avenue SW., Washington, DC 20201, (202) 755–6694

Department of Housing and Urban Development, Office of Small and Disadvantaged Business Utilization, 451 7th Street SW., Room B–133 (711 Bldg.), Washington, DC 20410, (202) 724–0040

*Department of the Interior, Office of Administrative Services, 18th & C Street NW., Room 5412, Washington, DC 20240, (202) 343–6341

*Excludes the Bureau of Reclamation.

Department of Justice, Assistant Director Procurement Management Section, Property Management and Procurement Staff, Justice Management Division, 10th & Constitution Avenue NW., Room 6320, Washington, DC 20530, (202) 633–2075

Department of Labor, Office of Procurement, Room of Procurement, Room 1521, Washington, DC 20210, (202) 523–9174

Department of State, Office of Supply and Transportation and Procurement, Procurement Division, Room 530, State Annex 6, Washington, DC 20520, (202) 235–9529

Department of Treasury, Office of the Secretary, Office of Procurement, 1331 G Street NW., Room 900, Washington, DC 20220, (202) 376–0650

Environmental Protection Agency, Office of Contracts, 499 S. Capitol St., Washington, DC 20460, (202) 382–2368

Equal Employment Opportunity Commission, Contracts, Grants and Procurement Division, 2401 E Street NW., Room 3200, Washington, DC 20506, (202) 634–7674

Executive Office of the President, Procurement and Contracting Branch, 726 Jackson Place NW., Room 4203, Washington, DC 20503, (202) 395–3570

Export-Import Bank of the United States, 811 Vermont Avenue NW., Washington, DC 20571, (202) 566–8951

Farm Credit Administration, Procurement Office, 490 L'Enfant Plaza East SW., Washington, DC 20578, (202) 755–2128

Federal Communications Commission, Procurement Branch, 1919 M Street NW., Room A–104, Washington, DC 20554, (202) 632–6407

Federal Deposit Insurance Corporation, Office of Contracts and Small Purchases, 550 Seventeenth Street NW., Washington, DC 20409, (202) 389–4355

Federal Home Loan Bank Board, Office of Contracts, 1700 G Street NW., Washington, DC 20552, (202) 377–6000

Federal Maritime Commission, Office of Administrative Services, 1100 L Street NW., Room 9135, Washington, DC 20573, (202) 523–5900

Federal Mediation and Conciliation Service, Division of Administrative Services, 2100 K Street NW., Washington, DC 20427, (202) 653–5310

Federal Trade Commission, Office of Procurement and Contracts, 600 E Street NW., Room 850, Washington, DC 20580, (202) 376–7916

*General Services Administration, Office of Administration, Centralized Mail List Servies (8BRC), Denver Federal Center, Building No. 4, Denver, Colorado 80225, (303) 234–4195

*Excludes purchases by the National Tool Center and the Region 9 Office, San Francisco, California.

Inter-State Commerce Commission, Twelfth Street and Constitution Avenue NW., Room 1315, Washington, DC 20423, (202) 275–0893

Maritime Administration, Department of Transportation, Procurement Division (MAR–315), 400 7th Street SW. (Plaza level), Room 1200, Washington, DC 20590, (202) 382–0433

Merit Systems Protection Board, Procurement and Contracts Branch, 1120 Vermont Avenue NW., Suite 903, Washington, DC 20419, (202) 653–7196

National Aeronautics and Space Administration, Office of Small and Disadvantaged Business Utilization, 600 Independence Avenue SW. (Code K), Washington, DC 20546, (202) 755–2288

National Credit Union Administration, Division of Procurement, Room 7081, 1776 G Street NW., Washington, DC 20456, (202) 357–0157

National Labor Relations Board, Procurement Section, 1717 Pennsylvania Avenue NW., Room 834, Washington, DC 20570, (202) 633–0623

National Mediation Board, Administrative Office, 1425 K Street NW., Washington, DC 20572, (202) 523–5950

National Science Foundation, Division of Grants and Contracts, Procurement Office, 1800 G Street NW., Room 237, Washington, DC 20550, (202) 357–7922

National Transportation Safety Board, Procurement and Contracts Office, 800 Independence Avenue SW., Room 838–C, Washington, DC 20594, (202) 382–6731

Nuclear Regulatory Commission, Division of Contracts, 4550 Montgomery Avenue, Room 2223, Bethesda, MD 20014, (202) 492–4800

Office of Personnel Management, Office of Management and Budget, Acquisition Section, 1900 E Street NW., Room 1452, Washington, DC 20415, (202) 632–4575

Overseas Private Investment Corporation, Procurement Office, 1129 20th Street NW., 7th Floor, Washington, DC 20527, (202) 653–2812

Panama Canal Commission, 425 Thirteenth Street NW., Room 312, Washington, DC 20004, (202) 724–0104

Railroad Retirement Board, Purchasing Division, 844 N. Rush Street, Room 1230, Chicago, Illinois 60611, (312) 751–4535

Securities Exchange Commission, Procurement and Contracts Branch, 500 North Capitol Street, Room 2125, Washington, DC 20549, (202) 523–1678

Selective Service System, Purchasing and Contracting Division, 1023 31st Street NW., Washington, DC 20435, (202) 724–0733

Smithsonian Institution, Office of Supply Services, 955 L'Enfant Plaza SW., North Building, Room 3120, Washington, DC 20024, (202) 287–3335

U.S. Arms Control and Disarmament Agency, Administrative and Contracts Division, 320 21st Street NW., Washington, DC 20451, (202) 235–8248

U.S. International Communication Agency, Contract and Procurement Division, 1717 H Street NW., Room 613, Washington, DC 20547, (202) 653–5573

U.S. International Development Cooperation Agency, Agency for International Development, Office of Business Relations, Room 633, SA–14, 320 Twentieth Street NW., Washington, DC 20523, (202) 235–9156

U.S. International Trade Commission, Finance and Budget Division, 701 E Street NW., Room 159, Washington, DC 20436, (202) 523–4516

Veterans Administration, Office of Procurement Operations, 810 Vermont Avenue NW., Room 762, Washington, DC 20420, (202) 389–3521

[FR Doc. 82–1854 Filed 1–25–82; 8:45 am]

BILLING CODE 6820–61–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration; Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HF (Food and Drug Administration) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services as amended in pertinent part (39 FR 34318, September 24, 1974), is amended to reflect a retitling of the Division of Drug Advertising in the Bureau of Drugs as the Division of Drug Advertising and Labeling and a revising of the Division's functional statements to more clearly define its role in drug labeling activities.

Section HF-B, Organization and Functions, is amended as follows:

1. Delete paragraph (1-6-vii) *Division of Drug Advertising* (HFGQ) in its entirety and substitute the following:

(1-6-vii) *Division of Drug Advertising and Labeling* (HFGQ). Monitors and evaluates prescription drug promotion. Coordinates with other Bureau components to determine the compliance activity of the industry for prescription drug labeling.

Formulates and establishes policy for prescription drug labeling including professional labeling and patient package inserts and regulation of prescription drug promotion including advertisements, promotional labeling, and promotional practices.

Prepares, coordinates the review of, and implements special types of drug labeling such as generic, class, and patient package insert labeling.

Reviews for consistency with general labeling requirements and guidelines, labeling for new therapeutic entities and for previously marketed drugs about to be approved for major new indications.

Initiates or recommends administrative action to remedy violative prescription drug promotion, recommends field investigations, assists in the preparation of prospective cases.

Plans and supervises studies to evaluate the impact of patient package inserts, prescriptions drug promotion, and remedies for violative prescription drug promotion.

Plans and develops various informational and educational resources for health professionals, consumers, and FDA staff including a drug labeling manual, miscellaneous publications, symposia, and seminars.

Provides guidance and support in formulation of guidelines and regulations for prescription drug labeling and promotion.

Provides guidance to New Drug Evaluation Divisions, and to the Division of Generic Drug Monographs to assure quality, consistency, and timeliness in labeling of drugs during the premarketing and postmarketing periods.

Dated: January 18, 1982.

Richard S. Schweiker,

Secretary.

[FR Doc. 82-1834 Filed 1-25-82; 8:45 am]

BILLING CODE 4120-03-M

Food and Drug Administration; Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HF (Food and Drug Administration) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685-92, February 25, 1970, as amended in pertinent parts at 39 FR 18698-701, May 29, 1974, 43 FR 1136-37, January 6, 1978, and 43 FR 16420-21, April 18, 1978) is amended to reflect the establishment of a new division of Food Animal Additives, a revision in all fifteen current divisional functional statements, the movement of the Shellfish and Milk Sanitation Program from one division to another, the movement of the analysis functions for pesticides from one division to another, and a retitling of the Division of Retail Food Protection to the Division of Cooperative Programs. These changes will provide more efficient coordination of food animal additive issues between the Bureau of Foods and the Bureau of Veterinary Medicine and will more accurately reflect the functions of the respective organizational entities.

Section HF-B, Organization and Functions, is amended as follows:

1. Delete subparagraphs (k-3-i) through (k-3-iv) of paragraph (k) *Bureau of Foods (HFF)* in their entirety and substitute the following:

(k-3-i) *Division of Regulatory Guidance (HFFG).* Develops or participates in the development of regulations which implement, interpret, and grant exemptions to those provisions of the laws pertinent to bureau responsibilities.

Develops and recommends adoption of Agency compliance policy on food, cosmetic, pesticide, and food chemical matters.

Recommends legislation or reviews proposed legislation to solve compliance problems.

Manages the development of controversial or precedent-setting cases; develops and maintains legal guidelines for field use in specific areas and recommends delegations of authority to the Field-District Offices for direct handling of regulatory actions as necessary.

Reviews and approves or disapproves proposed regulatory actions in areas where authority for direct case handling has not been delegated to the Field-District Offices; provides guidance to the Field-District Offices in these areas and provides technical support for case development and contested court cases.

Manages and coordinates Headquarters activities associated with injunctions, seizures, and prosecutions. Provides bureau position on recalls with technical guidance to the field, as requested, and coordinates recall actions with other regulatory actions.

Issues letters providing informal comments in response to specific requests from industry trade associations, other Government agencies, and Congress.

Drafts and recommends issuance by the Commissioner of formal advisory opinions.

Reviews and evaluates present and prospective compliance problems involving foods, cosmetics, pesticides, and food chemicals and recommends solutions.

Plans and develops approaches to implement responsibilities in interstate travel sanitation under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act, including enforcement of applicable provisions of the Interstate Quarantine Regulations.

Develops and issues sanitation handbooks and standards relating to the sanitary design, construction, and operation of aircraft, buses, trains, and vessels.

Reviews and approves or disapproves plans for design and construction details of food service, water, and waste disposal facilities and equipment aboard conveyances.

(k-3-ii) *Division of Compliance and Industry Programs (HFFJ).* Develops and issues, with the concurrence of the Executive Director of Regional Operations (EDRO) and the Office of Regulatory Affairs (ORA), surveillance and compliance programs relating to the food, cosmetics, and related industries; coordinates the establishment of priorities for program activities.

Plans and assists in the development of information retrieval and appraisal systems for each compliance program. Manages the development of Compliance Program Evaluations,

develops Compliance Program Reports of Findings, and coordinates the development of Compliance Program Studies.

Coordinates the development of annual field workplans in conjunction with other bureau organization units and EDRO.

Develops and distributes, with assistance from the Office of Public Affairs (OPA), informational, instructional, and motivational materials designed to encourage voluntary compliance by food, cosmetics, and related industries.

Promotes a better understanding of the requirements and objectives of the laws and regulations enforced by FDA and serves as the bureau focal point for information concerning the compliance status of these industries.

Coordinates the promotion of technical, regulatory, and scientific assistance, including source country certification Memoranda of Understanding with foreign governments to obtain compliance with the Federal Food, Drug, and Cosmetic Act's requirements for imported food or cosmetic products. Maintains liaison with the ORA and the International Affairs Staff on matters relating to such activities.

Directs the registration of domestic and foreign low-acid canned food and acidified food manufacturers and their process filing under the requirements of 21 CFR Part 108.

Assists field offices, upon request, in the planning and implementation of workshops and seminars for food, cosmetics, and related industries on Current Good Manufacturing Practices and various problem areas.

Assists in the conduct of conferences, seminars, and meetings on specific industry compliance problems and on consumer educational activities in cooperation with the OPA, the Office of Consumer Affairs (OCA), and other FDA components, trade associations, and professional and academic groups.

Promotes the implementation of industry quality assurance assistance activities designed to prevent compliance failures; develops plans to help industry improve quality control capabilities.

Develops and issues, with the concurrence of EDRO, OCA, and OPA, consumer education programs for field implementation; coordinates the development and distribution to the field of programs support material.

(k–3–iii) *Division of Food Animal Additives (HFFK).* Develops policy statements and portions of **Federal Register** documents concerning the human safety aspects of food additive petitions and new animal drug applications for food-producing animals; transmits these documents, with supporting documentation, to the Bureau of Veterinary Medicine (BVM) for incorporation in the **Federal Register** documents in question.

Ensures that industry-submitted food additive petitions and new animal drug applications for food-producing animals are reviewed and evaluated by the appropriate divisions of the bureau, with respect to possible effects on the health of humans consuming food from the affected food-producing animals.

Plans and implements a cyclic review of approved food animal additives and new animal drugs for food-producing animals with regard to human safety.

In cooperation with other Agency components and appropriate divisions in the bureau, develops and applies scientific criteria for the approval or continued approval of substances used in food-producing animals; manages the development of testing protocols by the appropriate divisions in the bureau.

Analyzes and evaluates, in consultation with the appropriate divisions of the bureau industry and consumer comments on **Federal Register** documents concerning human safety aspects of food additives and new animal drugs for food-producing animals.

Compiles data for inclusion in administrative records to support proposed actions including Administrative Hearings, based on human safety concerns regarding food additives and new animal drugs for food-producing animals; prepares and transmits to the Office of General Counsel, through BVM, these data and other necessary documentation to support bureau scientific and regulatory positions.

Coordinates the preparation of human health hazard evaluations by the appropriate divisions of the bureau, as requested by BVM compliance units, and reviews evaluations prior to transmission to BVM.

Consults with BVM regarding preparation of compliance programs directed at monitoring residues of food additives and new animal drugs in animal products; reviews data from U.S. Department of Agriculture's residue monitoring programs.

Prepares portions of letters, for issuance by BVM, to sponsors of food additive petitions and new animal drug applications for food-producing animals to advise them of inadequacies in submitted required data to show safety; corresponds and schedules meetings with sponsors, in coordination with BVM.

(k–3–iv) *Division of Food and Color Additives (HFFH).* Develops bureau policy statements and procedural regulations concerning the review of the safety of food additives, color additives, Generally Recognized As Safe (GRAS) substances, and prior sanction substances.

Manages the bureau's petition review process, prepares proposed and final regulations for food and color additives and GRAS substances, and responds to any comments or objections received on the respective regulations.

Compiles and maintains for the bureau administrative records to support proposed actions on food and color additives, GRAS substances, and prior sanction substances.

Manages the agency's GRAS review program for cyclic reevaluation of GRAS substances; develops plans for and operates the cyclic review programs for direct food additives.

Provides bureau managers with accurate and consistent opinions and interpretations of regulations and of the status of substances under the regulations on food and color additives.

Operates a bureau control system for all petitions and letters pertaining to food and color additives, GRAS substances, and prior sanction substances.

(k–3–v) *Division of Cooperative Programs (HFFS).* Develops, publishes, revises, and promotes sanitation standards in the form of model ordinances for regulating food service, food store, and food vending operations, the shellfish industry, and the milk industry.

Cooperates with health-industry standards writing groups that produce milk and food equipment design and construction standards.

Provides information, training, and technical assistance to headquarters and field FDA components; other Federal agencies; State and local governments; international organizations; professional organizations; foreign governments; and the regulated industries relative to code interpretation, compliance procedures, and problem solving to maintain uniform FDA developed standards of sanitation for the retail food, shellfish (including the National Shellfish Sanitation Program), and milk industries (including the Federal-State Cooperative Interstate Milk Shippers Certification Program).

Plans and coordinates with EDRO field activities relating to the accomplishment of compliance program requirements, decisions in requests for special investigations, and the planning

and surveillance of food operations in federally managed locations.

Cooperates with the National Marine Fisheries Services, Department of State, and foreign governments in the development and conduct of bilateral international shellfish agreements.

2. Delete subparagraphs (k–4–i) of paragraph (k) *Bureau of Foods (HFF)* and substitute the following:

(k–4–i) *Division of Toxicology (HFFB).* Originates, plans, and conducts research on the toxic effects of substances for which the bureau has regulatory responsibility; i.e., direct and indirect food additives, food additives and new animal drugs for food-producing animals, color additives and other colors, GRAS substances, prior sanction substances, natural and human-made contaminants of food, natural toxicants in food, and cosmetics ingredients, and of metabolites of these substances.

Investigates mechanisms of the underlying toxicological reactions which may directly or indirectly cause adverse effects in man or laboratory animals.

Investigation, develops, and improves bases for establishing and evaluating toxicological injury to man or laboratory animals for substances for which the bureau has regulatory responsibility.

Conducts toxicological studies on various classes of substances for which the bureau has regulatory responsibility to provide data for evaluation of new petitions and proposals and for the review of current tolerances and applications.

Plans and conducts research pertinent to basic toxicity mechanisms affecting cell growth, reproduction, and function.

Performs toxicological analyses of regulatory samples, as requested, to support FDA compliance programs.

Provides toxicological evaluation of all chemical substances for which the bureau has regulatory responsibility.

Develops and makes recommendations regarding the establishment and updating of toxicologic evaluation criteria, guidelines, and protocols for application in the approval process of new substances and for the reaffirmation of presently used substances for which the bureau has regulatory responsibility.

Plans and implements discrete phases of the cyclic review of approved food additives and new animal drugs for food-producing animals as it applies to the toxicology component of the program.

Maintains liaison with other Federal agencies for harmonizing toxicologic procedures and information exchange.

Serves as the agency's chief source of advice on the toxicology of substances which are added to or become a component of food or cosmetics.

Interacts with and provides support to the National Toxicology Program (NTP) by identifying substances for which the bureau has regulatory responsibility that should be tested by the NTP, designing appropriate experiments for testing these substances, and assisting in the preparation of reports and other documents as required by NTP.

(k–4–ii) *Division of Pathology (HFFC).* Investigates the nature and significance of the gross and microscopic changes which occur in animal tissues and organs resulting from short- and long-term exposure to substances for which the bureau has regulatory responsibility.

Evaluates pathological data submitted in food and color additive petitions.

Provides support for the complete pathological evaluation of toxicological experiments and, upon request, provides pathology services to other bureaus.

Maintains a complete registry of pathological data on the effects of toxic stress on animals.

Develops new methods of anatomical and histochemical examination of organs and tissues from animals subjected to treatment with substances for which the bureau has regulatory responsibility.

Performs pathological analyses of regulatory samples, as requested, to support FDA compliance programs.

(k–4–iii) *Division of Mathematics (HFFE).* Develops mathematical methods and models and provides statistical analysis of bureau and field research, extramural, and regulatory programs.

Originates, plans, and conducts research with regard to the mathematical design, analysis, and interpretation of health, sanitation, and economic studies.

Reviews and evaluates experimental design and statistical data submitted in petitions for food and color additives, new animal drug applications for food-producting animals, and food standard regulations.

Provides statistical support to all components of the Bureau.

Investigates mathematical and statistical techniques for data analysis systems and for translation and interpretation of technical information for bureau use.

3. Delete subparagraphs (k–5–i) through (k–5–iv) paragraph (k) *Bureau of Foods (HFF)* and substitute the following:

(k–5–i) *Division of Chemistry and Physics (HFFA).* Devises new methods of analysis for food additives, natural contaminants and their alteration products in foods; conducts validation studies, recommends analytical procedures, and provides technical support when requested by the field laboratories. Conducts research to elucidate the chemical structure and properties of food components and potentially hazardous substances in foods.

Provides primary scientific evaluation of the chemical and tissue residue data in food additive petitions and of chemical methodology and chemical validation tests in new animal drug applications for food producing animals.

Provides expertise in specialized fields of advanced instrumentation and evaluates, designs, and adapts instrumentation to meet analytical needs in food research.

Provides other chemistry services, as requested, in support of bureau and field programs.

(k–5–ii) *Division of Chemical Technology (HFFM).* Investigates industrial practices and chemical uses and obtains information on the disposition, behavior, physical/chemical properties and fate of industrial chemicals, by-products, and process wastes and pollutants in the environment.

Maintains a registry of chemical products, manufacturing and processing information, and a repository of industrial chemicals.

Assesses and investigates the nature and magnitude of chemicals and chemical wastes in the environment and the factors which influence the uptake and persistence of these contaminants in food and in other parts of the ecosystem which interact with the human organism.

Devises new methods of analysis for pesticides, metals, industrial chemicals, and/or their alteration products in food; conducts validation studies, recommends analytical procedures, and provides technical support to FDA field and headquarters units and other Government agencies.

Obtains and evaluates technical information and data regarding production, use, properties, and incidence of residues of pesticides, industrial chemicals, and toxic metals in food and the environment. Assists in the development and direction of field regulatory and monitoring programs for these contaminants in food and "market basket" samples, prepares evaluations of the completed compliance programs.

(k–5–iii) *Division of Color Technology (HFFN).* Provides expert technical advice within FDA and to other Government agencies on problems relating to the chemistry and technology of colors.

Conducts laboratory research and development studies concerning the chemical properties, analysis, reactions, synthesis, impurities, and side reaction products of permitted colors.

Evaluates color additive petitions for the adequacy and reliability of chemical data (identity, composition, purity, stability), manufacturing controls, and methodology in proposals for listing color additives and color additive diluents.

Maintains liaison with technical personnel of manufacturers of certifiable color additives to maintain early awareness of new techniques, process changes, and other technical innovations.

Examines all batches of colors submitted for certification, and examines or administers examination of permitted colors exempt from certification, to assure conformance to the regulations on identity, composition, and purity.

Examines or administers examination of foods, drugs, and cosmetics for nonpermitted color additives and for permitted color additives used in an unsafe manner; develops examination methods for field use in determining if nonpermitted colors are used in foods, drugs, and cosmetics.

Performs inspections of color manufacturers in conjunction with the Office of the Executive Director of Regional Operations.

(k–5–iv) *Division of Cosmetics Technology (HFFP).* Provides expert technical advice within FDA and to other Government agencies on problems relating to the chemistry and technology of cosmetics.

Develops and maintains internationally recognized competence in the composition, function, and analysis of cosmetics. Maintains liaison with technical personnel of manufacturers to keep informed of new developments in cosmetic technology and products in order to prevent the use of potentially harmful ingredients such as primary irritants, sensitizers, and carcinogens.

Maintains and evaluates all cosmetic injury complaints received by the agency, including all pertinent corespondence, reports, replies, analyses of samples, and recommendations for regulatory actions.

Processes and evaluates all data received under the cosmetic registration program (location of cosmetic product establishments, ingredients in cosmetic product formulations, and cosmetic experience reports submitted by the cosmetic industry).

Performs chemical analysis of cosmetics for potential poisonous or deleterious substances and nonpermitted ingredients and develops analytical methods for field use.

Initiates requests for field inspection of cosmetic manufacturers and, in coordination with the Executive Director of Regional Operations, occasionally assists in these inspections.

4. Delete subparagraphs (k–6–i) through (k–6–iii) of paragraph (k) *Bureau of Foods (HFF)* and substitute the following:

(k–6–i) *Division of Consumer Studies (HFFQ).* Provides executive leadership and gives direction to all consumer matters that have an impact on the bureau's regulatory responsibilities; provides advice and guidance to bureau and agency management on consumer implications of agency philosophy, direction or policies; stimulates the development of consumer expertise and consumer orientation within the bureau and agency.

Identifies the consumer research needs of the Bureau; develops and conducts studies of consumers knowledge, beliefs, attitudes, perceptions, preferences, needs, and behavior as they relate to foods and cosmetics, including the nature and extent of consumer benefits that may accrue from regulations or other agency actions; uses existing psychological and sociological techniques and develops new methodologies; aids agency management in using consumer and market research findings to develop and evaluate agency policies.

Develops and maintains an ongoing data capacity on the organoleptic properties of foods, food and cosmetic packaging, and on advertising, promotion, distribution, pricing and composition, and of consumers' consumption and usage of food and cosmetic products.

Designs and conducts studies to measure the relationship between present and proposed agency regulations, actions, and policies, and consumer behavior; investigates the relationship between such factors as demographic or life style characteristics and/or independent experimental variables and purchase behavior of consumer or aggregate sales or consumption data, employing mathematical and statistical models and methods.

Analyzes the reliability, validity, and utility of consumption and sales data bases. Gives advice in regard to appropriate usage of the data.

Identifies consumer education needs. Plans, implements, monitors, and evaluates experimental and established consumer education programs in cooperation with the OPA, OCA, Executive Director for Regional Operations, and other bureau staff involved in consumer affairs activities. Provides bureau management with advice on appropriate material, media, methods and resources to ensure effective consumer education programs.

(k–6–ii) *Division of Microbiology (HFFD).* Originates, plans, and conducts research on the nature, extent, and significance of microbial and physical contaminants of foods and cosmetics.

Develops and evaluates microbiological methods for detecting harmful toxins, decomposition, extraneous matter, and other naturally occurring and biological hazards in raw and processed foods and in cosmetics.

Develops the technical and microbiological basis for recommended limits, guidelines, and practices applied to food in Current Good Manufacturing Practices and used by Federal, State, and local health agencies.

Evaluates, through laboratory investigations, the microbiological and other biological hazards associated with food processing and food service practices.

Performs microbiological and microanalytical analyses of regulatory samples, as requested, to support FDA compliance programs.

Develops standard analytical methodology and furnishes, in coordination with the Executive Director of Regional Operations, consultative and training services required for the microbiological and microanalytical control of the food industry by Federal, State, and local health agencies; approves State central milk testing laboratories and certifies State milk laboratory survey officers.

(k–6–iii) *Division of Nutrition (HFFT).* Develops and recommends plans, policies, and regulatory approaches to maintain and improve the nutritional quality of the national food supply.

Serves as the agency focal point for nutritional expertise and provides advice and support in nutritional matters, upon request, to other organizations or individuals, public or private.

Maintains FDA's nutrient research and nutrient analysis laboratory capabilities.

Originates, plans, and conducts research to elucidate the identity, priority, and amount of nutritionally significant substances in foods and of factors affecting the action of these substances; determines the effects of these substances on reproduction, growth, and development in biological and microbiological systems; and studies the metabolic fate of these

substances and their interaction with other food components such as food additives.

Devises new methods for the analysis of nutrients in different types of foods and investigates the mechanisms of the chemical reactions involved in such methods.

Organizes, plans, and conducts clinical nutrition studies to define the special dietary needs of individuals suffering from disease, injury, inborn errors of metabolism, or other conditions; the nutritional status of population groups; and the impact of dietary practices on human behavior, physical performance, mental acuity, and other quality of life parameters.

Maintains liaison with the national and international nutrition scientific community, both public and private.

(k–6–iv) *Division of Food Technology (HFFL).* Develops, collects, coordinates, and interprets technical information regarding the composition, quality, manufacture, packaging, and marketing of foods.

Develops, evaluates, and drafts the substantive content, including technological and engineering specifications, of Current Good Manufacturing Practices, Model Ordinances and Codes, Model Regulations, and amendments thereto.

Develops, evaluates, and drafts the substantive content of food standard proposals establishing standards of identity, quality, and fill of container.

Investigates currently developing food preservation processes, particularly their impact on established indices of decomposition, and develops new chemical indices.

Makes exploratory investigations into the technology of agricultural and industrial practices that may result in contamination of food with biotoxins.

Determines the minimum amount of a food additive necessary to achieve its intended functional effect.

Dated: January 18, 1982.

Richard S. Schweiker,

Secretary.

[FR Doc. 82–1835 Filed 1–25–82; 8:45 am]

BILLING CODE 4160–01–M

Food and Drug Administration; Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HF (Food and Drug Administration) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685–92, February 25, 1970, as amended most recently at 45 FR 67776 dated October 14, 1980) is amended to reflect a reorganization within the Office of the Commissioner.

Functions regarding environmental impact are being transferred from the Office of Health Affairs and added to the Bureau of Foods and the Bureau of Veterinary Medicine. Functions for the Office of the Director, Bureau of Veterinary Medicine are being revised to more accurately reflect its activities. Functions concerned with nonregulatory international affairs are being transferred from the Office of Regulatory Affairs to the Office of Health Affairs.

Section HF–B, Organization and Functions are amended as follows:

1. Delete paragraph (f) *Office of Regulatory Affairs (HFA4)* in its entirety and substitute the following:

(f) *Office of Regulatory Affairs (HFA4).* Advises and assists the Commissioner and other key officials on regulations and compliance-oriented matters which have an impact on policy development and execution and long-range goals.

Coordinates, interprets, and evaluates the Agency's overall compliance efforts; as necessary, establishes compliance policy or recommends policy to the Commissioner.

Stimulates an awareness within FDA of the need for prompt and positive action to assure compliance by regulated industries; works to assure an effective and uniform balance between voluntary and regulatory compliance and FDA responsiveness to consumer needs.

Acts as liaison with other Federal agencies on FDA compliance matters and coordinates Agencywide voluntary compliance and industry information activities.

Directs and coordinates the regulation-making activities of the Agency, including preparation of **Federal Register** material, in coordination with the Regulations Management Unit of the PHS and Departmental Executive Secretariat, and with the Deputy General Counsel for Regulatory Review.

Evaluates and coordinates all proposed legal actions to ascertain compliance with regulatory policy and enforcement objectives.

Directs and coordinates with the Executive Director of Regional Operations (EDRO), bureaus, and HHS General Counsel, new or novel cases which may be precedent setting.

Resolves appeals when compliance actions are refused by EDRO, the bureaus, or General Counsel.

Coordinates development of new or novel Agencywide compliance programs such as bioresearch monitoring activities; monitors compliance activities to assure uniform application of compliance policy; serves as liaison with other Federal agencies and outside organizations relating to such Agencywide activities.

2. Delete paragraph (g) *Office of Health Affairs (HFA5)* in its entirety and substitute the following:

(g) *Office of Health Affairs (HFA5).* Advises and assists the Commissioner and other key officials on health affairs which have an impact on policy, direction, and long-range program goals.

Develops Agency policy and guidelines concerning medical and scientific extramural research, training, and fellowship activities; provides for the continuing appraisal of these activities.

Evaluates the adequacy of medical and scientific resources available to the Agency.

Evaluates medical and scientific research results originating from other Government agencies and private institutions for potential Agency use.

Develops and implements professional education policy and programs designed to promote understanding of, and support for, Agency efforts in the protection of public health.

Coordinates the nonregulatory international affairs activities of FDA programs and acts as liaison with the Department of State, other nations, international groups, and foreign firms. Coordinates and evaluates international travel plans, including the Annual International Travel Plan for the Commissioner's approval. Promotes international scientific collaboration through Pub. L. 480 and other related statutes.

Conducts hearings and provides medical and scientific review of hearing requests and proposed findings of fact and conclusions of law recommended by the Administrative Law Judge after evidentiary hearings.

3. Delete paragraph (k) *Bureau of Foods (HFF)* in its entirety and substitute the following:

(k) *Bureau of Foods (HFF).* Develops FDA policy with respect to the safety, composition, quality (including nutrition), and labeling of foods, food additives, colors, and cosmetics.

Conducts research and develops standards on the composition, quality, and safety of foods, food additives, colors, and cosmetics.

Conducts research designed to improve the detection, prevention, and control of contamination that may be responsible for illness or injury

conveyed by foods, food additives, colors, and cosmetics.

Develops and promulgates current good manufacturing practices for the food processing industry and model ordinances and codes and model regulations for State and local government use in assuring food safety and quality.

Plans FDA surveillance and compliance programs and evaluates progress toward objectives of planned program and regulatory activities relating to foods, food additives, colors, and cosmetics.

Reviews industry petitions and recommends promulgation of regulations for food standards and for the safe use of color and food additives.

Collects and interprets data on nutrition, food additives, and environmental factors affecting the total chemical insult posed by direct and indirect food additives.

Analyzes regulatory samples as necessary to support Bureau compliance programs.

Participates in training of FDA field personnel and provides guidance to the regulated industries in the application of the most effective procedures to assure food safety and quality.

Studies consumer experience with, expectation of, and exposure to Bureau-regulated products and maintains a nutritional data bank.

Recommends to the Office of the Commissioner new or revised legislation pertinent to the Bureau's responsibilities.

In cooperation with other Agency components, provides FDA policy development and direction on environmental impact matters.

4. Delete paragraph (k-1) *Office of the Director (HFF1)* in its entirety and substitute the following:

(k-1) *Office of the Director (HFF1).* Develops FDA food, food additive, color, and cosmetic policy for approval of the Commissioner.

Provides overall executive direction to the Bureau programs and activities and coordinates programs with other FDA organizational components, HHS, and other Government agencies.

Directs the development of Bureau regulatory policy.

Recommends to the Office of the Commissioner new and revised legislation pertinent to Bureau responsibilities and participates in the preparation of legislative proposals and testimony for presentation at congressional hearings.

Directs and coordinates the overall application of Bureau scientific and technical capabilities, coordinating Bureau scientific research within FDA and with other governmental and private agencies, both nationally and internationally, to facilitate collaboration in attacking common problems.

Recommends, initiates, and terminates all Bureau extramural research contracts.

Directs the Bureau's administrative and management programs.

Develops and interprets compliance and surveillance programs, current good manufacturing practices, model ordinances and codes, and model regulations.

Reviews and approves food standard proposals and evaluates food and color additive petitions.

Establishes, promotes, and maintains a climate of mutual cooperation with scientists and scientific bodies, nationally and internationally, in order to maintain contact with scientific events which may impact on Bureau activities.

In conjunction with the Bureau of Veterinary Medicine, provides FDA policy development and direction on environmental impact matters.

5. Delete paragraph (m) *Bureau of Veterinary Medicine (HFV)* in its entirety and substitute the following:

(m) *Bureau of Veterinary Medicine (HFV).* Develops and recommends the veterinary medical policy of the Food and Drug Administration with respect to the safety and efficacy of animal drugs, feed additives, and devices.

Evaluates, for animal safety and efficacy, proposed and marketed animal drugs and feed additives and marketed devices for animal use.

Coordinates the veterinary medical aspects of the FDA inspection and investigational programs and provides veterinary medical opinions in drug hearings and court cases.

Plans, directs, and evaluates FDA's surveillance and compliance programs relating to animal drugs, animal feeds, and other veterinary medical matters.

In cooperation with other Agency components, provides FDA policy development and direction on environmental impact matters.

6. Delete paragraph (m-1) *Office of the Director (HFV1)* in its entirety and substitute the following:

(m-1) *Office of the Director (HFV1).* Directs overall Bureau activities and coordinates and establishes Bureau policy in the areas of research, management, scientific evaluation, compliance, and surveillance.

Directs systems for planning, programming, and budgeting and provides administrative, statistical, and informational support for the Bureau.

Approves new animal drug application and issues notices of withdrawal of new animal drug approvals when the opportunity for a hearing has been waived.

Authorizes, for use as edible products, animals treated with investigational drugs and terminates exemption for investigational trials.

In conjunction with the Bureau of Foods, provides FDA policy development and direction on enviromental impact matters.

Dated: January 18, 1982.

Richard S. Schweiker,

Secretary.

[FR Doc. 82-1836 Filed 1-25-82; 8:45 am]

BILLING CODE 4160-01-M

Food and Drug Administration; Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HF (Food and Drug Administration) of the Statement of Organization Functions and Delegations of Authority for the Department of Health and Human Services (35 FR 3685-92, dated February 25, 1970, as amended in the pertinent part at 45 FR 62905, September 22, 1980) is amended by revising Exhibit HF-1, Food and Drug Administration—Permanent Offices. Because of a reorganization in Region II two additional offices will be reflected in the Regional organizational structure.

Section HF-B Organization and Functions is amended by revising Exhibit HF-1 Food and Drug Administration—Permanent Offices by deleting the entry for New York State and entering the following:

State and city	Type of office	Address and ZIP Code
New York:		
Brooklyn	Field/District Office Import District Office.	850 Third Ave. 11232.
Buffalo	New York Laboratory Div. District Office.	599 Delaware Ave. 14202.

Dated: January 18, 1982.

Richard S. Schweiker,

Secretary.

[FR Doc. 82-1837 Filed 1-25-82; 8:45 am]

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Office of the Secretary

Statement of Organization, Functions, and Delegations of Authority

Part A, Chapter AD(1-X) (Office of the Principal Regional Official) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human

Services (last amended 46 FR 41215 of August 14, 1981) is amended. The amended statement reflects the change in title of the Principal Regional Official to the Regional Director, and makes other minor corrections to the Statement of Organization.

Part A, Chapter AD(1–X) Office of the Principal Regional Official is hereby replaced with the following:

Chapter AD(I–X)

Office of the Regional Director

AD.00 Mission
AD.10 Organization
AD.20 Functions
AD.30 Relationships to OPDIV Staffs
AD.40 Order of Succession
AD.50 Delegations of Authority

Section AD.00—Mission.—The Regional Director serves as the direct personal representative of the Secretary with the responsibility of carrying out the Secretary's policies in the Region. The Regional Director provides leadership, coordination, evaluation, and general administrative support to the complex activities of the Region.

Section AD.10—Organization. The Office of the Regional Director is under the direction and control of the Regional Director, who reports directly to the Secretary and Under Secretary through the Deputy Under Secretary for Intergovernmental Affairs, and consists of the following:

Regional Director AD(I-X)
Office of Intergovernmental and Congressional Affairs AD(I-X)H
Office of Public Affairs AD(I-X)K
Office of Service Delivery Assessment AD(I-X)R
Regional Administrative Support Center AD(I-X)L

Section AD.20—Functions.

A. The Regional Director:

1. Serves as the Secretary's representative in direct official dealings with State and local government organizations.

2. Establishes and maintains effective relationships with Governors, Mayors, county officials, and other key State and local officials; furnishes advice and assistance and strives to develop a mutually benefical Federal-State-local partnership; provides guidance and coordination to the efforts of all regional staff members on the priorities, emphasis, and merits of various programs based on the expression of needs and analyses by Governors, Mayors, and other key officials.

3. Provides a central focus in the Region for Department relations with Congressional delegations and individual Members of Congress.

4. Promotes general public understanding of the programs, policies, and objectives of the Department; participates in developing and carrying out of a region-wide public information program; and provides regional clearance on official public communiques.

5. Assesses the effectiveness of Department activities and makes reports and recommendations to the Secretary, Under Secretary, Deputy Under Secretary for Intergovernmental Affairs, and other Departmental officials concerning the application or improvement of policies and service delivery systems.

6. Serves as coordinator, facilitator, and expeditor in solving cross-cutting issues to assure effective, efficient, and responsible actions in the interest of total service to the public.

7. Advises the Secretary on the potential effect of proposed Department action, whether on legislation, regulation, or administrative decisions.

8. Provides input into policy decisions and strategy regarding the concerns and interests of State and local governments as derived from their key officials.

9. Provides highly professional and responsive centralized administrative services (such as personnel, financial management, administrative services, engineering and construction services) to regional program heads.

10. Develops plans for emergency preparedness and directs all Department activities necessary to ensure continuity of essential functions within the Region in case of an emergency due to enemy action or natural disaster.

B. Office of Intergovernmental and Congressional Affairs (AD(I–X)H).

1. The director serves as the Deputy to the Regional Director. Shares responsibility, as directed by the Regional Director, for carrying out the Department's regional missions and policies. Receives functional supervision from the Deputy Under Secretary for Intergovernmental Affairs and the Assistant Secretary for Legislation. Serves as Acting Regional Director in the absence or disability of the Regional Director. Supervises the staff of the Office of Intergovernmental and Congressional Affairs (ICA).

2. Serves as chief advisor to the Regional Director for carrying out the full range of Regional Director responsibilities for external relations with chief elected and appointed officials at the State and local levels, including legislative bodies and tribal leaders of reservation Indians, with a primary emphasis on obtaining from these officials indications of attitudes, trends, and issues affecting HHS programs to provide early warning and advice to top HHS management and to get specific issues and problems of State and local officials resolved.

3. Serves as the focal point in the regional office for developing close working relations with Congressional district offices in order to ensure that: (a) Congressional inquiries on constituent problems are promptly resolved, either through the Regional Director or directly by the Operating Division, as appropriate, and (b) Congressional field offices are provided with ongoing information about HHS initiatives, policies, and organization, particularly on those programs administered through the regional offices of the Operating Divisions (OPDIVs).

4. Establishes methods for ensuring adequate internal coordination among the ICA office, other OS units, and the Regional OPDIVs necessary to carry out assigned functions, avoid duplication of effort, and ensure most effective targeting of regional resources to serve HHS grantees and clients.

5. Serves to articulate and support the Administration's position on key pending legislative proposals in dealings with State and local officials and with interest groups, whether of a local or regional nature or with national affiliation. Also disseminates information on the overall HHS budget, new HHS initiatives and trends, and ongoing HHS services.

6. In accordance with national and/or regional plans and working closely with the Regional Office of Public Affairs, develops and carries out regional procedures and stategies for ensuring that a full range of views is presented by or obtained from public officials, interest and client groups, and the general public on legislative and other policy issues which are in the developmental stage; e.g., through public hearings, conferences, and other means.

7. Consults State and locally elected officials, including legislative bodies, regional clients, and interest groups, as to the need for new HHS initiatives, regulations, or statutes, including the identification of HHS-imposed barriers or other procedures which may unnecessarily impede the most effective delivery of services in a given State or local jurisdiction. Brings such issues to the attention of the Assistant Secretary for Legislation, the Assistant Secretary for Planning and Evaluation, and through the Regional Director, to the attention of the Deputy Under Secretary for Intergovernmental Affairs.

8. Is generally responsible for ensuring that adequate liaison and relationships are established between the regional office and minority groups; serves as the

Regional Director's representative on various committees and task forces for special concerns of minority groups

9. As directed by the Regional Director, serves as a coordinator with other Federal departments and agencies when interagency efforts are required to implement new policies and legislation and resolve problems and issues which affect HHS and other Federal agencies. Provides staff support to efforts and activities of the Federal Regional Councils and/or other Federal interagency groups. Director serves as the Regional Director's alternate on the Federal Regional Council.

10. Establishes and maintains, for each State in the Region, a close working relationship with the Governor's staff and with the staffs of human resource agencies, budget and finance agencies, planning offices, and other key State Government agencies. Develops similar relations with major sub-State Governments, including cities, counties, Regional Councils of governments, and with State associations of Cities and Counties.

11. Develops close working relationships with State legislative bodies in the Region by providing legislators and their staffs with information on HHS programs, services, and trends; responding promptly to program inquiries from State legislators; and arranging, on a selective basis with the guidance of the Assistant Secretary for Legislation, for the appropriate HHS official to respond to requests to testify on proposed State legislation before various State legislative committees.

12. In cooperation with the OPDIVs and other regional units, develops and maintains processes for identifying and resolving major HHS/States issues of a regional nature which State and local officials identify as problems which are not being resolved in a timely fashion by the appropriate HHS program staff, or when directed through the Regional Director by the Deputy Under Secretary, Under Secretary, or Secretary.

13. Brings to the attention of the Director, Office of Service Delivery Assessment, those issues which State and local officials view as most important in settling priorities for assessments.

14. In coordination with the Director, Regional Administrative Support Center, and the Regional OPDIV Heads, facilitates multi-program requests for Federal assistance under the Joint Funding and Simplification Act.

15. Establishes and maintains through the appropriate Regional OPDIVs, procedures for compliance with the Intergovernmental Cooperation Act (including the processing of waivers) and with OMB Circular No. A–95.

16. In coordination with the Director, Regional Administrative Support Center, and the Regional OPDIVs, assists in the exchanges of State and local personnel with Departmental staff under the Intergovernmental Personnel Act of 1970.

17. Manages the solicitation, review, funding, and project management of grants awarded under the Department's Partnership Grant Program within the Region.

18. Ensures that consumer protection agencies at State and local levels are provided with timely information related to HHS policies, programs, and procedures.

C. Office of Public Affairs (AD(1–X)K).

1. Serves as the principal public affairs advisor to the Regional Director. Also serves as a major policy coordinating official whose principal concern is fostering general public understanding of the programs and policies of the Department.

2. Receives functional supervision from the Assistant Secretary for Public Affairs (ASPA) and represents the ASPA in the Region. Provides feedback to the ASPA on sensitive public affairs policy matters requiring the attention of headquarters.

3. Plans public information activities designed to support the policies and program objectives of the Department and the Administration as identified by the Secretary.

4. Counsels and acts for the Regional Director and his/her staff on public affairs matters in carrying out Presidential directives and Secretarial orders.

5. Advises all units in the Region, including Regional OPDIVs, on the public affairs aspects of their duties and program responsibilities. Coordinates efforts related to this advisory responsibility with all regional units.

6. Serves as the principal news media contact for HHS units in the Region.

7. Maintains public affairs liaison with those nongovernment agencies and organizations affected by Department programs, goals, and policies.

8. Administers the Freedom of Information Act (FOIA) and serves as the initial denial authority for access to all regional documents requested under the FOIA.

9. Administers the Privacy Act of 1974 for offices under the direct supervision of the Regional Director. Counsels other regional agency staffs through their designated Privacy Act coordinators.

D. Office of Service Delivery Assessment (AD(I–X)R).

Is responsible for regional participation in the National Service Delivery Assessment (SDA) Program. (The program's objective is to provide the Secretary, the Heads of Operating Divisions, and the Regional Directors with information on the effectiveness, timeliness, and economy with which HHS programs are serving clients. SDAs are intended to concentrate on how and how well services are delivered to clients of HHS programs as well as on relevant program management and organizational issues.) Under the Regional Director's general direction, implements and executes SDA projects that are included in the Inspector General's annual SDA workplan or are initiated by the Secretary.

1. Identifies potential or actual service delivery issues for consideration as part of the national SDA workplan.

2. Organizes, directs, and coordinates regional participation in SDA projects specified in the annual SDA workplan or assigned higher priority by the Secretary. Responsibilities include the following:

a. Providing staff members to serve as: (1) national project leader responsible for all national activities associated with an SDA project, (2) regional project leader responsible for all regional activities associated with an SDA project, or (3) participant in an SDA project;

b. Developing assessment design, in cooperation with the Office of the Inspector General, to include defining assessment issue(s), specifying assessment scope and methodology, developing appropriate measures of performance, formulating sampling plans, and specifying data analysis and reporting techniques and format;

c. Identifying HHS and State organizational units with greatest interest in the SDA issue(s) and arranging appropriate participation;

d. Training all staff involved in an SDA project to assure detailed understanding of project objectives, methodology, and techniques;

e. Implementing SDA project design and managing all data-gathering activities specified in the project design; and

f. Synthesizing, analyzing, and reporting on all data-gathering and findings.

3. Provides feedback on assessment findings and Secretarial decisions to the OPDIVs, State and local agencies, and non-government officials involved in SDA projects.

4. Participates in assessing the utility and accuracy of individual SDAs as well as regional implementation of

Secretarial decisions resulting from SDAs.

5. Develops working knowledge of the location and the strengths and weaknesses of regional, State, and local data sources that can be used to examine how and how well HHS programs are serving clients.

6. Maintains liaison with regional staffs of the Office of Intergovernmental and Congressional Affairs, HHS Audit Agency, and OPDIVs, and with State and local governments regarding assessment objectives and activities.

7. Analyzes SDAs to identify problems common to many programs.

8. Identifies and participates in testing techniques that can improve the rapidity, validity, and reliability of SDAs.

9. Assists the Regional Director, as required, when he/she is directed by the Deputy Under Secretary to obtain State and local government views on specific issues or proposals.

E. Regional Administrative Support Center (AD(I–X)L).

Under the functional supervision of and in accordance with authorities delegated by the Assistant Secretary for Management and Budget and Assistant Secretary for Personnel Administration, provides centralized administrative, engineering, accounting, budget fiscal, cost allocation and indirect cost negotiation, data processing, environmental program, and personnel services to the Office of the Regional Director and to the regional offices of the Operating Divisions, the Office for Civil Rights, the Office of the General Counsel, and the Office of the Inspector General, as follows:

1. Provides regional accounting, fiscal services, and financial reporting for all HHS activities for which the Regional Director is delegated the authority to provide such services. Is responsible for the recording and reporting of all financial transactions of the Regional Director and OPDIVs' operations through the maintenance of a standardized Regional Accounting System. Provides regional coordination and liaison with the HHS Audit Agency, the Treasury Department, the General Services Administration, and the General Accounting Office on financial management matters.

2. Prepares regional budget justification and execution plans for the Regional Director, Office of Intergovernmental and Congressional Affairs, Office of Public Affairs, Office of Service Delivery Assessment, the Regional Administrative Support Center, and on request, for other HHS regional units.

3. In accordance with policies and procedures established by the Office of Grants and Logistics, conducts cost allocation activities. Negotiates and approves indirect cost rates; State and local government cost allocation plans; research patient care rates and amounts; fringe benefits, computer, and other special rates applicable to HHS awards. Provides financial management technical assistance on cost allocation to grantees and contractors, HHS grant and contract officials, and grant and contract officials of other Federal agencies.

4. Provides common administrative services (such as telecommunications support-telephone, teletype, and facsimile transmission; mail pickup and delivery; contract services, distribution of common supplies; maintenance of official regional files; moving and storage services; and printing and reproduction services) for all HHS activities colocated at the regional office location. Maintains a personal property management system (including property records). Operates and maintains the centralized regional data processing equipment.

5. Provides supervision of the Regional Office of Equal Employment Opportunity. Is responsible for the establishment and maintenance of a positive program on non-discrimination in Departmental employment in the Region. Has regional responsibility for the HHS Federal Women's Program and the Spanish Speaking Program. Monitors the OS/EEO complaint system and issues proposed dispositions on all formal complaints. With information provided by Regional Director and OPDIVs, prepares the Regional Annual Affirmative Action Plan. Coordinates the selection, training, and availability of EEO counselors and investigators. On request, provides assistance to OPDIVs and central and regional office staffs in the assignment of EEO investigators.

6. Provides personnel services. Exercises overall management direction for the provision of personnel services for all regional components. These services are provided by a regional personnel office which receives functional and technical direction from, and operates under policies established by, the Assistant Secretary for Personnel Administration. Included in the functions of a regional personnel office are: (a) the provision of the full range of sevices relating to the processes of staffing, position management and classification, training and career development, employee relations, labor-management relations, manpower planning, and employee appraisal; and (b) the provision of direct assistance to program managers in carrying out their personnel management responsibilities for employees within their organization; and (c) the exercise of the legal and regulatory personnel authorities which are delegated by the Assistant Secretary for Personnel Administration.

7. Administers regional facilities engineering, construction, and Federal surplus real property programs. Serves as principal advisor in the Region on all matters relating to Federal surplus real property program. Assures the delivery of total architectural and engineering services in support of HHS assisted and directed Federal construction programs. Carries out property management activities for HHS owned and utilized facilities. Conducts office space utilization surveys and allocation and periodic inspections of regional space and facilities. Ensures regional compliance with the Occupational Safety and Health Act. Develops and maintains the regional emergency operating center for use in natural disasters and war caused emergencies.

8. Is responsible for ensuring that the provisions of the National Environmental Policy Act and related laws and Executive Orders are carried out. Receives and monitors programs, provides technical assistance in effecting environmental determination and the preparation of supporting documents, and maintains timely consultation with environmental agencies at Federal, State and local levels.

Section AD. 30—Relationships to Regional OPDIV Staffs, Regional Office of Investigations, Regional Office of Audit, Office of Regional Attorney, and Regional Office for Civil Rights.

The above-named staffs and offices are under the line direction and control of their parent organizations. The functions for these staffs and offices are described in the functional statements of their parent organizations. These regional units receive administrative, financial, and other support services from the Regional Director and his staff.

Section AD.4—Order of Succession.— In the absence or disability of the Regional Director, the Director of Intergovernmental and Congressional Affairs serves as Acting Regional Director. In the absence or disability of the Regional Director and the Director of Intergovernmental and Congressional Affairs, the Director of Public Affairs acts as Acting Regional Director. In the event of the absence of all three, the Regional Director will designate and Acting Regional Director. In the event of a vacancy in all three positions, the

Secretary or Under Secretary will designate the Acting Regional Director.

Section AD.50—Delegations of Authority.— The delegations to the Regional Director are: [Reserved].

Dated: January 18, 1982.

Richard Schweiker,

Secretary.

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4310-84

Department of the Interior
Assistant Secretary, Land and Water Resources

Request for Comment on Outer Continental Shelf
Bidding Systems for Oil and Gas Lease Sales

SUMMARY

Specific comments are requested on the concept of a proposed planning guideline for Outer Continental Shelf (OCS) bidding systems. The Department of the Interior (DOI) is pursuing a policy which encourages expeditious exploration of frontier (wildcat) areas and which provides adequate incentives for efficient and diligent production in developed regions. Other objectives include the provision of incentives to improve technology, the assurance of receipt of fair market value by the government, the maintenance of competition, and the protection of the environment. An example of a proposed bidding systems guideline, in matrix form, distinguishes each geographic and geologic cost area in recognition of the variance of relative bidding system performance. This inquiry is directed towards bidding systems for sales starting in mid 1982 and thereafter which follow past and planned experiments with the alternative systems established in regulations promulgated by the Department of Energy (DOE). If a final guideline is issued, experimentation with certain systems may be discontinued while others would be tested further. The guideline concept would be consistent with the Department's new "streamlining" approach of offering larger areas for lease. More time would be available for planning purposes and a bidding system design would be provided for large groups of tracts within an entire region as opposed to individual tract designations.

PURPOSE AND SCOPE

The choice of bidding systems potentially affects (1) the receipt of fair market value, (2) the economic efficiency and physical recovery of resources, (3) the level of competition, (4) the distribution of risks between lessee and lessor, and (5) administrative costs to the lessees and the lessor. The bidding systems differ in the manner in which perceived risks are shared between lessees and lessors. There are two basic risks: geologic (the probability that hydrocarbons exist) and economic (the probability that hydrocarbons can be developed at a profit to lessees). The bidding systems have one or more fixed components and one variable component. The bidding variable may be a cash bonus, a work commitment or a contingency percentage (royalty, net profit share). The relationship between the initial payment and the contingency percentage influences the distribution of risks between the lessee and lessor, and the distribution of revenues obtained from production.

Experiments for alternative bidding systems have been conducted in 22 OCS lease sales. Four of the six systems established by DOE regulation have been tested. Future tests are planned for the remaining OCS sales in calendar year 1981 and early 1982. A summary of past and future experiments is presented in a following section. The Department recognizes the need to analyze the initial phases of experimentation and direct future tests toward those systems which offer the greatest promise to meet the goals prescribed in the OCS Lands Act (OCSLA). Moreover, a consistent, reliable policy is necessary for prudent investment planning by industry.

The next phase of testing seeks to avoid a random diffusion of numerous, unproven systems which may be incompatible for the purposes of unitization of adjacent tracts. Certain systems may be eliminated from future testing because either, (1) past experiments indicate the expected costs do not justify possible

gains, or (2) untested systems may be determined to present undue risks to the objectives of the OCS Lands Act.

It should be noted that a final analysis of the impacts of the tested alternative systems must ultimately await an observation of the effects on exploration, development, and production decisions. However, this does not mean that tests should continue until a final analysis is complete. It may be desirable to discontinue testing after an initial sample is deemed sufficient. If, in the future, the analysis concludes that a particular system enhances our achievement of the goals cited above, it may be determined that further leasing under that system is beneficial. The Department of the Interior currently plans to have substantially completed some testing of the most promising alternative systems by the end of calendar year 1981. At that time a sufficient sample size for those systems may have been offered for lease so that statistically significant results could be obtained. The analysis of the untested systems is continuing and the Department will inform interested members of the public of the results as they become available.

The purpose of this inquiry is to focus on the next phase of bidding system development for sales starting in mid 1982 and thereafter. A matrix of systems which offer the greatest contribution to our goals will be developed as a guideline for planning purposes. An example of a matrix is included in this notice. After receipt of comments, we plan to publish a final matrix which will serve as a policy base for specific sale designs. We recognize that specific conditions or new information and analysis may warrant the selection of different systems than those outlined. However, every effort will be made to inform interested parties of our bidding system plans. The goals of this approach are to provide adequate information to the public and to share the necessary expertise in order that consistent and efficient systems are selected.

BACKGROUND INFORMATION

The OCS Lands Act provides the Secretary of the Interior with the authority to issue oil and gas leases by competitive bidding on the submerged lands of the OCS. Bidders submit bids in response to a lease sale offering for particular tracts under the terms and conditions specified in a Notice of Sale and published in the Federal Register. The bidding system used determines the method by which successful high bidders pay the United States for the lease.

The bidding system or systems used by DOI in each OCS lease sale are chosen from those authorized by the OCSLA and prescribed by Department of Energy (DOE) regulation (10 CFR Part 376). The Secretary of Energy also has the authority to disapprove the proposed bidding systems selected by DOI prior to issuance of the final Notice of Sale.

Section 8(a) of the OCSLA provides that bidding shall be by sealed bid and, at the discretion of the Secretary of the Interior, on the basis of the following types of systems:

> "(A) cash bonus bid with a royalty at not less than 12-1/2 per centum fixed by the Secretary in amount or value of the production saved, removed, or sold;
>
> (B) variable royalty bid based on a per centum in amount or value of the production saved, removed, or sold, with either a fixed work commitment based on a dollar amount for exploration or a fixed cash bonus as determined by the Secretary, or both;

(C) cash bonus bid, or work commitment bid based on a dollar amount for exploration with a fixed cash bonus, and a diminishing or sliding royalty based on such formulae as the Secretary shall determine as equitable to encourage continued production from the lease area as resources diminish, but not less than 12-1/2 per centum at the beginning of the lease period in amount or value of the production saved, removed, or sold;

(D) cash bonus bid with a fixed share of the net profits of no less than 30 per centum to be derived from the production of oil and gas from the lease area;

(E) fixed cash bonus with the net profit share reserved as the bid variable;

(F) cash bonus bid with a royalty at no less than 12-1/2 per centum fixed by the Secretary in amount or value of the production saved, removed, or sold and a fixed per centum share of net profits of no less than 30 per centum to be derived from the production of oil and gas from the lease area;

(G) work commitment bid based on a dollar amount for exploration with a fixed cash bonus and a fixed royalty in amount or value of the production saved, removed, or sold; or

(H) subject to the requirements of paragraph (4) of this subsection, any modification of bidding systems authorized in subparagraphs (A) through (G), or any other systems of bid variables, terms and conditions which the Secretary determines to be useful to accomplish the purpose and policies of this Act, except that no such bidding system or modification shall have more than one bid variable."

The Department of Energy has issued regulations for the following systems:

(1) Cash bonus bid, fixed royalty;

(2) Royalty bid, fixed cash bonus;

(3) Cash bonus bid, sliding scale royalty;

(4) Cash bonus bid, fixed net profit share;

(5) Net profit share bid, fixed cash bonus; and

(6) Work commitment bid, fixed cash bonus, fixed royalty.

The statute requires that at least 20 percent, but not more than 60 percent of the total area offered each year be alternatives to a cash bonus bid, fixed royalty system (system A in the OCS Lands Act).

RECORD OF EXPERIMENTATION

A. Statistics for past sales The use of bidding systems other than the conventional cash bonus bid, fixed 16-2/3 percent royalty system began with OCS Sale 36 in the central Gulf of Mexico (GOM) in 1974, and testing has been conducted in a total of 22 OCS lease sales as of December 4, 1981. The following table displays this record of experimentation by bidding system.

Alternative Bidding System	Sale Name, Area, and Date
Royalty Bid, Fixed Cash Bonus	Sale 36, Central GOM, 10/16/74
	Sale CI, Lower Cook Inlet, 10/27/77
Cash Bonus Bid, Fixed 33-1/3% Royalty	Sale 35, Southern California, 12/11/75
	Sale 40, Mid-Atlantic, 8/17/76
	Sale A62, Central GOM, 9/30/80
	Sale 62, Western GOM, 11/18/80
	Sale 53, California, 5/28/81
Cash Bonus Bid, Sliding Scale Royalty 1/	
Sliding Scale Formula 1	Sale 43, South Atlantic, 3/28/78
	Sale 45, Central & Western GOM, 4/25/78
Sliding Scale Formula 2	Sale 65, Eastern GOM, 10/31/78
	Sale 51, Central & Western GOM, 12/19/78
	Sale 48, California, 6/29/79
	Sale 58, Central & Western GOM, 7/31/79
	Sale 58A, Central & Western GOM, 11/27/79
	Sale BF, Beaufort Sea, 12/11/79
Sliding Scale Formula 3	Sale 49, Mid-Atlantic, 2/28/79
	Sale 42, North Atlantic, 12/18/79
Sliding Scale Formula 4	Sale A62, Central GOM, 9/30/80
	Sale 62, Western GOM, 11/18/80
Sliding Scale Formula 5	Sale 55, Gulf of Alaska, 10/21/80
Sliding Scale Formula 6	Sale 53, California, 5/28/81
Cash Bonus Bid, Fixed Net Profit Share 2/	Sale A62, Central GOM, 9/30/80
	Sale 55, Gulf of Alaska, 10/21/80
	Sale 62, Western GOM, 11/18/80
	Sale A66, Central & Western GOM, 7/21/81
	Sale 56, South Atlantic, 8/4/81
	Sale 60, Lower Cook Inlet, 9/29/81
	Sale 66, Central GOM, 10/20/81

1/ The specific formulae cited herein include,
Formula 1 : R = 15.16667 ÷ V,
Formula 2 : R = 10(ln V/2.5),
Formula 3 : R = 9(ln V/2.5),
Formula 4 : R = 13(ln V/3.0),
Formula 5 : R = 9(ln V/3.5),
Formula 6 : R = 11(ln V/3.25),

where V equals the quarterly value of production, adjusted for inflation, in millions of dollars, and R equals the percent royalty that is due and payable on the unadjusted value of production saved, removed, or sold. Also, there are limits for R which are used in each formula. In formula 1, 16-2/3 ≤ R ≤ 50, while in all other formulae, 16-2/3 ≤ R ≤ 65. The symbol "ln" denotes a conversion to natural logarithms.

2/ Sales A62 and 62 provided a capital recovery factor of 1.00, while the design for Sale 55 permitted a 1.50 capital recovery factor. Sales A62 and 62 involved a 50 percent net profit share rate, while Sale 55 fixed a 40 percent rate. Sale A66 provided capital revocery factors (CRF's) ranging from 0.25-1.00, Sale 56 had CRF's of 0.50 and 1.50, Sale 60 had a CRF of 0.75, and Sale 66 had CRF's of 0.25 and 0.50. Sale A66 and 66 had a 50 percent net profit share rate, Sale 56 had profit share rates of 30 and 45 percent, and Sale 60 had a profit share rate of 40 percent.

Some comparative statistics of tract offerings for these 22 sales are as follows:

Bidding System	Tracts Offered	Tracts Bid On		Tracts Leased	
	No.	No.	% Offered	No.	% Offered
Cash Bonus Bid, Fixed 16-2/3% Royalty	2,246	1,096	48.8	995	44.3
Cash Bonus Bid, Fixed 12-1/2 % Royalty	85	38	44.7	33	38.8
Royalty Bid, Fixed Cash Bonus	56	38	67.9	38	67.9
Cash Bonus Bid, Fixed 33-1/3% Royalty	54	47	87.0	41	75.9
Cash Bonus Bid, Sliding Scale Royalty					
Sliding Scale Formula 1	96	50	52.1	41	42.7
Sliding Scale Formula 2	304	172	56.6	163	53.6
Sliding Scale Formula 3	113	64	56.6	58	51.3
Sliding Scale Formula 4	69	50	72.5	38	55.1
Sliding Scale Formula 5	32	3	9.4	3	9.4
Sliding Scale Formula 6	36	22	61.1	19	52.8
Cash Bonus Bid, Fixed Net Profit Share	384	157	40.9	139	36.2
TOTAL	3,475	1,737	50.0	1,568	45.1

B. Preliminary Analyses

The results from these tests are currently being analyzed with much attention being devoted to more detailed data disaggregations (e.g., comparisons between bidding system results for individual sales as well as tracts with similar resource, cost, or net worth expectations). Preliminary indications

from these detailed analyses, which might not be readily apparent from the aggregate data shown above, suggest that most of the alternative bidding systems have produced no statistically meaningful differences in industry competition in comparison to the conventional cash bonus, fixed 16-2/3 percent royalty system. Also, there have been no indications that these alternative bidding systems have resulted in an increased government share of the expected economic returns on tracts leased. The preliminary findings for each bidding system regarding industry competition and effects on exploration, development, and production are further discussed in the following paragraphs. The intention of each of these systems is to increase competition by requiring higher contingency payments and reducing front-end bonuses. No effect on the government share of the expected economic profit has been observed and is not addressed.

1. Royalty Bidding. Of the alternative systems tested by DOI thus far, the royalty bidding system results appear to depict the sharpest contrast to the conventional OCS leasing system. On the surface, significant increases in competition for tracts offered under this system were evident, particularly in Sale 36 which required only nominal bonus payments. However, there are concerns regarding this system, which have resulted in our proposal to discontinue its use. First, the royalty rates submitted by winning bidders in Sales 36 and CI were sufficiently high to make substantial production losses very likely. A high royalty means the minimum economically developable field size must be higher in order for exploration and development to proceed and for marginal fields to be developed. Second, the winner of a royalty bid tract, particularly in the case of only a nominal fixed cash bonus, has little investment at risk compared to other successful bidders under alternative systems for similar tracts. Such risk may be so low that tract owners will have greatly reduced incentives to explore and develop these tracts. The lessee is likely to delay exploration for many reasons, including speculation, or hopes that another developer on a nearby tract will prove or disprove resources of the royalty bid tract. Because the expected losses in production from these effects are likely to be substantial, it is not anticipated that this system will be used in future OCS sales.

2. Fixed 33-1/3% Royalty. Preliminary findings from actual tests indicate that this system may have only modest beneficial effects on competition for OCS leases. Furthermore, simulation analysis has shown that the use of this system for lower valued tracts or for tracts in frontier areas may result in tracts not receiving bids and may yield significant production losses due to the higher royalties. Because of the geologic uncertainty associated with most of the areas to be offered in future OCS lease sales, it is anticipated that the use of this system will be limited to the tracts with lower costs and better resource prospects where higher risk sharing is desirable. At present, we do not wish to test this system in 1982 sales because of the urgent need to avoid production and exploration disincentives.

3. Sliding Scale Royalty. In general, this system has had no significant statistical effect on competition in comparison to the conventional fixed 16-2/3 percent royalty system. This has probably resulted from the conservative specifications of the sliding scale formulae used thus far, in order to reduce potential production effects. Thus, prospective bidders may have assessed a low probability that the majority of tracts offered under this system would produce quantities of oil and gas sufficient to incur a royalty rate higher than the 16-2/3 percent minimum rate. In this case, they would have conceived this system to be identical to the

conventional one-sixth royalty system. Recent OCS sales have incorporated a sliding scale formula which is more aggressive. However, when such a formula is used there is a risk that production may be delayed in order to avoid higher royalty payments. In addition, an aggressive formula reduces the lessee's payoff from exploration if large discoveries are made and thus may dampen investment in exploration. Finally, it is difficult to design a proper schedule given the uncertainty of real price changes which greatly influence effective royalty rates. Thus, it may be advisable to defer further use of this system.

4. Fixed Net Profit Share. Data on tests of this system show no statistically significant effects of this bidding system on industry competition in comparison to the conventional bidding system. It is probable, however, that this result may have been highly influenced by the uncertainty surrounding this new leasing system, which is significantly different from the more common cash bonus, royalty payment combination. Perhaps the most important test result on this system is that the geometric means of bids and high bids submitted for profit share leases were significantly lower than the same variables examined for similar fixed 16-2/3 percent royalty leases. Thus, front-end requirements for firms appear lower. An appropriately defined profit share system may be capable of generating modestly improved production incentives if the lessee is allowed to earn a normal profit before sharing returns with the government. A greater number of tracts may be explored and developed as compared to use of a royalty system since that system extracts payments on production regardless of the costs incurred by lessees. The fixed net profit share system may be preferable especially in frontier areas where large-scale production is necessary to cover the unusually high costs of exploration and development. Fixed net profit share bidding reduces the bidders' risks in areas of high geologic uncertainty and moderate to high tract values. However, such benefits are offset by administrative and accounting burdens on both lessees and the government.

In addition, the determination of the parameters of a fixed profit share bidding system are critical in determining subsequent exploration, development and production strategies. The fixed capital recovery factors which have been used in the past in conjunction with the fixed profit share bidding system present some problem areas because of the ex ante assumptions regarding both a necessary rate of return and the appropriate timing of capital expenditures. Incorrect estimates could result in large revenue losses to the government or companies and could cause large inequities creating misallocations of resources. Therefore, the Department is taking into consideration using an Investment Accounts System in addition to the Fixed Capital Recovery System in its consideration of fixed profit share bidding. It is anticipated that this system will continue to be tested in future OCS offerings, but with important attempts to eliminate the uncertainties previously experienced. In this manner, it is hoped that significant increases in competition and exploration incentives may be realized.

C. Alternative System Plans for Upcoming Sales

There are two additional tests of alternative bidding systems either completed or scheduled. Proposed bidding system designs have been published in the Federal Register as part of each offering's Proposed or Final Notice of Sale. These offerings are as follows:

Sale Name, Area, Expected Date	Number of Tracts by Bidding System
59, Mid-Atlantic, 12/81	Cash Bonus Bid, Fixed 16-2/3% Royalty - 4 Tracts Cash Bonus Bid, Fixed 12-1/2% Royalty - 166 Tracts Cash Bonus Bid, Fixed Profit Share - 83 Tracts
67, GOM, 2/82	Cash Bonus Bid, Fixed 16-2/3% Royalty - 223 Tracts Cash Bonus Bid, Fixed Profit Share - 13 Tracts

Of these bidding systems, the Cash Bonus Bid, Fixed 12-1/2 percent royalty system has only been used in one previous OCS sale, Sale 56.

The use of this system has been recommended for certain deep water tracts for Sale 56 and Sale 59. These tracts are expected to require substantially higher exploration, development, and production costs, as well as longer times before initial production, in comparison to shallow water tracts. DOI analyses indicate that the minimum developable discovery on a tract in such deep water areas under a fixed 12-1/2 percent royalty system would be about 14 percent less than for the same tracts under a fixed 16-2/3 percent royalty system. As a result, more tracts may be explored and developed. In addition, the lower royalty rate system is expected to yield more rapid production rates and higher economic profits. It is not anticipated, however, that the slightly larger cash bonus bids associated with a lower royalty rate will significantly reduce competition, since the higher costs for exploration and development are the primary restraints to competition.

Of the remaining tests planned for 1981 and early 1982, the Cash Bonus Bid, Fixed Profit Share tests include specific variations in design. These are:

Sale	Formula
59	NPSR = 30%: CRF = 1.50
67	NPSR = 50%; CRF = .50, and NPSR = 40%; CRF = 1.00

These tests will permit a broader analysis on the performance of this system.

C. Untested Systems

The DOE has promulgated regulations on the following alternative systems which have not been tested and are, at present, not planned for future testing.

1. Net Profit Share Bid, Fixed Cash Bonus A possible benefit of this system is the encouragement of competition because of its lower cash bonus, but it may also produce profit share bids that are excessively high. This problem may result from an improperly defined cost recovery feature, and because a bidder can increase his chance of obtaining a tract by submitting higher bids with little financial commitment. At high profit share rates, the incentive to explore is relatively low and should production ensue, it will generally occur at too slow a pace. All of the strengths and weaknesses already discussed on the fixed net profit share system are also applicable to a variable net profit share approach in addition to the problems just mentioned. Finally, if the recovery factor is too high relative to the profit share rate, there may be an incentive for firms to make uneconomical expenditures to take advantage of the recovery feature.

2. Work Commitment Bidding, Fixed Bonus, Fixed Royalty The major goal of experimentation with alternative systems is to encourage increased competition through reduced front-end bonuses. The purpose of this system is to achieve such an improvement in competition by mitigating risk-averse behavior. However, firms must commit an expenditure equal to the estimated cash bonus plus expected exploration costs. Payments would be deferred until costs are expended or until the account is voluntarily closed before the commitment is satisfied.

Another objective of this system is to expedite exploration by permitting credits for actual expenditures and thereby forcing intensive exploration. However, this creates an incentive for firms to waste expenditures to avoid payments to the government. The result would be a serious misallocation of valuable resources. In order to prevent such an outcome Section 8(a) (7)(B) of the OCSLA provides that only 50 percent of qualifying exploration expenditures be included to satisfy the commitment. Despite this provision, our analysis indicates a potential for the drilling of exploratory wells which would not otherwise be economic.

MATRIX OF BASE SYSTEMS

The following example matrix is to serve as a guideline for the selection of bidding systems in each geographic area. A key variable in the determination of the appropriate system is the relevant cost function for the area involved. Exploration, development, and production decisions, as well as bid submission, are based on the relationship of the cost function with respect to an expected revenue profile. The contingency component of the bidding system can be viewed as a direct addition to the cost curve and thus influences the optimal private levels of investment in exploration and development and resulting rates of production. In frontier and deep water areas, costs may be at such extreme levels that substantial resources may go undeveloped if contingency payments are added at the margin. In the more developed and low cost areas, most resources will be developed irrespective of the contingencies since revenues usually allow higher contingencies to be added before production is affected or before the minimal economic field size is increased. In addition, there is some theoretically optimal percentage of profits which may be extracted before production losses are generated. If it is a goal of our bidding system to avoid negative impacts to production, it becomes necessary to design systems which yield the government this optimal fraction of profits. Thus, the analysis must concentrate on cost and revenue functions.

For these reasons we propose a matrix which differentiates bidding systems by generalized cost areas and water depth. After analysis of the comments received, a final guideline may be published if the matrix is deemed to be a useful planning tool.

Example Bidding System Matrix *

Water Depth

Geographic Area+	0-50 meter	50-200 meter	200-400 meter	400+ meter
Central, Western, and Eastern Gulf of Mexico	Cash Bonus Bid Fixed 1/6 Royalty	Cash Bonus Bid Fixed 1/6 Royalty	Cash Bonus Bid Fixed 1/6 or 1/8 Royalty	Cash Bonus Bid Fixed 1/8 Royalty Fixed Profit Share
Northern and Southern Calif.	Cash Bonus Bid Fixed 1/6 Royalty	Cash Bonus Bid Fixed 1/6 Royalty	Cash Bonus Bid Fixed 1/6 Royalty	Cash Bonus Bid Fixed 1/6 or 1/8 Roy Fixed Profit Share
Portion of North Atlantic - Northern Georges Bank	Cash Bonus Bid Fixed 1/6 Royalty	Cash Bonus Bid Fixed 1/8 Royalty	Cash Bonus Bid Fixed 1/8 Royalty Fixed Profit Sh.	Cash Bonus Bid Fixed 1/8 Royalty Fixed Profit Share
Mid, South and North Atlantic (except Northern Georges Bank)	Cash Bonus Bid Fixed 1/6 Royalty	Cash Bonus Bid Fixed 1/6 Royalty	Cash Bonus Bid Fixed 1/6 or 1/8 Royalty Fixed Profit Sh.	Cash Bonus Bid Fixed 1/8 Royalty Fixed Profit Share
South Alaska (Includes Cook Inlet, Shumagin, Kodiak, Gulf of Alaska)	Cash Bonus Bid Fixed 1/6 Royalty	Cash Bonus Bid Fixed 1/6 Royalty	Cash Bonus Bid Fixed 1/6 or 1/8 Royalty	N/A
N. Aleutian, Navarian, and Norton Basins	Cash Bonus Bid Fixed 1/6 Royalty	Cash Bonus Bid Fixed 1/8 Royalty	Cash Bonus Bid Fixed 1/8 Royalty	Cash Bonus Bid Fixed 1/8 Royalty Fixed Profit Share
Diapir Field	Cash Bonus Bid Fixed 1/6 Royalty	Cash Bonus Bid Fixed 1/8 Royalty Fixed Profit Share	Cash Bonus Bid Fixed 1/8 Royalty Fixed Profit Share	N/A
Barrow Arch & Hope Basin	Cash Bonus Bid Fixed 1/8 Royalty	Cash Bonus Bid Fixed 1/8 Royalty Fixed Profit Share	Cash Bonus Bid Fixed 1/8 Royalty Fixed Profit Share	N/A

* Note: Where the profit share system is listed it may also be used in combination with a fixed royalty (System F in the OCS Lands Act, as amended).

+ These areas correspond to those designated on the July, 1981 Proposed 5-Year OCS Oil and Gas Leasing Schedule.

In addition to water depth, there are several factors which may affect the level of oil and gas exploration, development, and production costs for each OCS area. These include distance to shore, physical field dimensions, production characteristics, quality of oil and gas, geologic surface conditions, and climatic elements. These influences have been considered in the bidding system recommendations shown in the above matrix and included in the analysis wherever possible.

SPECIFIC QUESTIONS

To assist in this determination of policy direction regarding bidding systems, the following questions are presented to all interested persons. Respondents are invited to offer comments on these specific issues, or any other topics germane to bidding systems which may be appropriate to use in future OCS lease sales.

1. Is the publication of a base case matrix useful as a means of informing the public on policy direction?
2. Are there any additional systems not discussed above which should be considered for future sales?
3. As indicated in the bidding system matrix, the bidding systems recommended for use are a function of water depth and location. Is this approach acceptable? What specific alternative form should a matrix follow? Are the specific area and water depth delineations we propose considered adequate to distinguish cost features?
4. What changes should be made to the specific bidding systems proposed in this matrix?
5. Should bidding systems recommended be a function of wildcat, development, or drainage type on a tract-by-tract basis?
6. Our proposal relies upon the continued testing of a fixed net profit share system in high cost areas as a means of promoting exploration and development, without the risk of contingency payments being obligated before costs are recovered. Is this a viable system? What are the administrative costs associated with this system?
7. What profit share parameters are suited to each region?

DATE AND ADDRESS

Information must be submitted by March 5, 1982 to the Assistant Secretary, Land and Water Resources, Attention David Russell, Department of the Interior, Washington, D.C. 20240.

FOR FURTHER INFORMATION

Questions concerning this request should be referred to either Thomas Readinger on (202) 343-5121 or H. Theodore Heintz on (202) 343-7258.

Garrey E. Carruthers

Assistant Secretary for Land and Water Resources

JAN 1. 19[illegible]

Certified to be a true copy of the original

Certifying Officer

[FR Doc. 82-1868 Filed 1-25-82; 8:45 am]
BILLING CODE 4310-84-C

Geological Survey

Oil and Gas and Sulphur Operations in the Outer Continental Shelf; Shell Oil Co.

AGENCY: Geological Survey, Interior.

ACTION: Notice of the receipt of a proposed supplemental development and production plan.

SUMMARY: Notice is hereby given that Shell Oil Company has submitted a Development and Production Plan describing the activities it proposes to conduct on Lease OCS–G 3594, Block 301, South Timbalier Area, offshore Louisiana.

The purpose of this Notice is to inform the public, pursuant to Section 25 of the OCS Lands Act Amendments of 1978, that the Geological Survey is considering approval of the Plan and that it is available for public review at the Office of the Conservation Manager, Gulf of Mexico OCS Region, U.S. Geological Survey, 3301 North Causeway Blvd., Room 147, Metairie, Louisiana 70002.

FOR FURTHER INFORMATION CONTACT: U.S. Geological Survey, Public Records, Room 147, open weekdays 9 a.m. to 3:30 p.m., 3301 North Causeway Blvd., Metairie, Louisiana 70002, Phone (504) 837–4720, Ext. 226.

SUPPLEMENTARY INFORMATION: Revised rules governing practices and procedures under which the U.S. Geological Survey makes information contained in Development and Production Plans available to affected States, executives of affected local governments, and other interested parties became effective December 13, 1979, (44 FR 53685). Those practices and procedures are set out in a revised § 250.34 of Title 30 of the Code of Federal Regulations.

Dated: January 18, 1982.

Lowell G. Hammons,

Conservation Manager, Gulf of Mexico OCS Region.

[FR Doc. 82–1859 Filed 1–25–82; 8:45 am]

BILLING CODE 4310–31–M

Oil and Gas and Sulphur Operations in the Outer Continental Shelf; Aminoil USA, Inc.

AGENCY: Geological Survey, Interior.

ACTION: Notice of the receipt of a proposed development and production plan.

SUMMARY: Notice is hereby given that Aminoil USA, Inc. has submitted a Development and Production Plan describing the activities it proposes to conduct on Lease OCS–G 3378, Block A–310, High Island Area, offshore Texas. The purpose of this Notice is to inform the public, pursuant to Section 25 of the OCS Lands Act Amendments of 1978, that the Geological Survey is considering approval of the Plan and that it is available for public review at the Office of the Conservation Manager, Gulf of Mexico OCS Region, U.S. Geological Survey, 3301 North Causeway Blvd., Room 147, Metairie, Louisiana 70002.

FOR FURTHER INFORMATION CONTACT: U.S. Geological Survey, Public Records, Room 147, open weekdays 9 a.m. to 3:30 p.m., 3301 North Causeway Blvd., Metairie, Louisiana 70002, Phone (504) 837–4720, Ext. 226.

SUPPLEMENTARY INFORMATION: Revised rules governing practices and procedures under which the U.S. Geological Survey makes information contained in Development and Production Plans available to affected States, executives of affected local governments, and other interested parties became effective December 13, 1979, (44 FR 53685). Those practices and procedures are set out in a revised § 250.34 of Title 30 of the Code of Federal Regulations.

Dated: January 18, 1982.

Lowell G. Hammons,

Conservation Manager, Gulf of Mexico OCS Region.

[FR Doc. 82–1857 Filed 1–25–82; 8:45 am]

BILLING CODE 4310–31–M

Oil and Gas and Sulphur Operations in the Outer Continental Shelf; Exxon Co., U.S.A.

AGENCY: Geological Survey, Interior.

ACTION: Notice of the receipt of a proposed development and production plan.

SUMMARY: Notice is hereby given that Exxon Company, U.S.A. has submitted a Development and Production Plan describing the activities it proposes to conduct on Lease OCS 026, Block 30, West Delta Area, offshore Louisiana. The purpose of this Notice is to inform the public, pursuant to Section 25 of the OCS Lands Act Amendments of 1978, that the Geological Survey is considering approval of the Plan and that it is available for public review at the Office of the Conservation Manager, Gulf of Mexico OCS Region, U.S. Geological Survey, 3301 North Causeway Blvd., Room 147, Metairie, Louisiana 70002.

FOR FURTHER INFORMATION CONTACT: U.S. Geological Survey, Public Records, Room 147, open weekdays 9 a.m. to 3:30 p.m., 3301 North Causeway Blvd., Metairie, Louisiana 70002, Phone (504) 837–4720, Ext. 226.

SUPPLEMENTARY INFORMATION: Revised rules governing practices and procedures under which the U.S. Geological Survey makes information contained in Development and Production Plans available to affected States, executives of affected local governments, and other interested parties became effective December 13, 1979, (44 FR 53685). Those pratices and procedures are set out in a revised § 250.34 of Title 30 of the Code of Federal Regulations.

Dated: January 18, 1982.

Lowell G. Hammons,

Consevation Manager, Gulf of Mexico OCS Region.

[FR Doc. 82–1858 Filed 1–25–82; 8:45 am]

BILLING CODE 4310–31–M

Bureau of Land Management

[PHX 075476, etc.]

Arizona; Order Providing for Opening of Public Lands

January 18, 1982.

1. In exchanges of lands made under the provisions of Section 8 of the Act of June 28, 1934 (49 Stat. 1272, amended, 43 U.S.C. 315g) the following lands have been reconveyed to the United States under the serial numbers listed below:

Gila and Salt River Meridian, Arizona

PHX 075476
T. 14 N., R. 12 W.,
Sec. 32.
T. 19 N., R. 20 W.,
Sec. 36, N½, SW¼, NW¼SE¼.
T. 19 N., R. 21 W.,
Sec. 36.

PHX 078045
T. 11 N., R. 15 W.,
Sec. 2.
T. 12 N., R. 17 W.,
Sec. 32.
T. 12 N., R. 15 W.,
Secs. 16, 32 and 36.
T. 12 N., R. 14 W.,
Sec. 2, S½.
T. 12 N., R. 16 W.,
Sec. 16, N½, SW¼, W½SE¼, NE¼SE¼;
Sec. 32.
T. 10 N., R. 17 W.,
Sec. 16, excepting land withdrawn for the Colorado River Survey;
Sec. 36.

PHX 079403
T. 16½ N., R. 10 W.,
Sec. 31, Lot 1.

T. 27 N., R. 20 W.,
Sec. 30, Lots 1, 2 and 3.
PHX 079911
T. 19 N., R. 16 W.,
Sec. 36, SW¼, NE¼SE¼.
T. 19 N., R. 18 W.,
Sec. 32, SW¼, W½SE¼.
T. 19 N., R. 21 W.,
Sec. 2.
PHX 080648
T. 16 N., R. 15 W.,
Sec. 3, W½SW¼;
Sec. 15, W½, W½E½;
Sec. 25, W½NW¼;
Secs. 27 and 35.
T. 27 N., R. 20 W.,
Sec. 20, SE¼NW¼, NW¼NE¼.
PHX 080766
T. 22 N., R. 18 W.,
Sec. 31.
T. 23 N., R. 19 W.,
Sec. 5, Lots 2, 3 and 4.
T. 27 N., R. 20 W.,
Sec. 28, E½, SE¼SW¼.
PHX 080849
T. 27 N., R. 20 W.,
Sec. 20, NE¼NE¼, S½NE¼, SE¼;
Sec. 28, NW¼, N½SW¼.
A 4558
T. 5 S., R. 14 E.,
Sec. 18, NE¼SW¼, NW¼SE¼;
N½SE¼SW¼, N½SW¼SE¼.
A 7840
T. 11 S., R. 29 E.,
Sec. 10, NE¼, E½NW¼, E½SE¼;
SW¼NW¼.

The areas described aggregate approximately 12,240 acres in Graham, Mohave, Pinal and Yuma counties.

2. The United States did not acquire the mineral rights on any of the lands described in paragraph 1 with the exception of the lands described under Serial Nos. A 4558 and A 7840.

3. Subject to valid existing rights, the provisions of existing withdrawals and the requirements of applicable law, the lands described in paragraph 1 are hereby open to operation of the public land laws. The lands described under Serial No. A 4558 are also opened to mining under the mining laws (Ch. 2, Title 30 U.S.C.) and mineral leasing under the mineral leasing laws. Lands described under Serial No. A 7840 are opened to mineral leasing only. All valid applications received at or prior to March 21, 1982, shall be considered as simultaneously filed at that time. Those received thereafter shall be considered in the order of filing.

4. Inquiries concerning the lands should be addressed to the Bureau of Land Management, Department of the Interior, 2400 Valley Bank Center, Phoenix, Arizona 85073 (602–261–3706).

Mario L. Lopez,

Chief, Branch of Lands and Minerals Operations.

[FR Doc. 82–1861 Filed 1–25–82; 8:45 am]

BILLING CODE 4310–84–M

[AR 030451]

Arizona; Partial Termination of Segregative Effect of Withdrawal Application

1. Notice of Application, AR 030451, filed by the Corps of Engineers, for the withdrawal and reservation of lands was published as FR Doc. 62–8983 on page 9827 of the issue of September 7, 1962. The application segregated the lands from all forms of appropriation under the public land laws, including the mining and mineral leasing laws, subject to existing valid claims. The proposed withdrawal was for the construction of the Camelsback Dam and Reservoir. The applicant agency has amended its application to permit mineral leasing under the mineral leasing laws on the following described lands;

Gila and Salt River Meridian, Arizona

T. 5 S., R. 28 E.,
Sec. 36, SE¼.
T. 6 S., R. 28 E.,
Sec. 1, Lots 1 and 2, S½NE¼, W½, SE¼;
Sec. 12, N½NE¼, NW¼, and N½SW¼.
T. 5 S., R. 29 E.,
Sec. 7, W½E½, E½W½, and SW¼NW¼;
Sec. 11, E½NE¼, S½SW¼, SE¼;
Sec. 12, Lot 1, Lots 5 to 16 inclusive, NW¼NW¼, S½NW¼, SW¼, and patented mineral surveys 1029B to 1033B, inclusive;
Sec. 13, NW¼NW¼;
Sec. 14, SW¼NE¼, N½NE¼, W½;
Sec. 15, E½NE¼, S½SW¼, SE¼;
Sec. 16, SE¼SE¼,
Sec. 18, N½, E½SW¼, SE¼;
Sec. 19, W½E½, and E½W½;
Sec. 21, NE¼, E½SW¼, SE¼;
Sec. 22, N½, NW¼SW¼, S½S½;
Sec. 25, Lots 2 and 3, Lots 5 to 16, inclusive, S½NW¼, SW¼;
Sec. 26;
Sec. 27, N½, N½N½SW¼, SE¼;
Sec. 28, N½N½,
Sec. 29, NE¼, S½NW¼, W½SW¼, N½SE¼,
Sec. 30;
Sec. 31, N½NE¼, W½;
Sec. 32, NW¼NW¼;
Sec. 35, N½N½;
Sec. 36, Lots 1 and 2.
T. 6 S., R. 29 E.,
Sec. 6, NW¼, W½SW¼;
Sec. 7, NW¼NW¼.
T. 5 S., R. 30 E.,
Sec. 6, Lots 3 to 6 inclusive, Lots 8, 9, 12, 13, 14, 15, 16, 17, 19, 20, 23 and 24, and Mineral Survey 1654B;
Sec. 7, Lots 1 to 4, inclusive, and NE¼NW¼;
Sec. 30, Lots 2, 3, 4, SE¼NW¼, and E½SW¼;
Sec. 31, Lot 1, NW¼NE¼, S½NE¼, E½W½, SE¼;
Sec. 32, S½NW¼, SW¼;
Sec. 33, SE¼NE¼, S½;
Sec. 34, SW¼NW¼, W½SW¼.
T. 6 S., R. 30 E.,
Sec. 1, Lots 5 to 12 inclusive;
Sec. 2, Lots 1 to 12 inclusive;
Sec. 3, Lots 1 to 7, inclusive;
Sec. 4, Lots 1 to 6, inclusive, the North 9.44 acres of Lot 7, SE¼NW¼, and the Gila River between the meander lines of said lots of secs. 1, 2, 3, and 4.

The areas described contain approximately 12,422 acres in Graham and Greenlee Counties.

Therefore, pursuant to the regulations contained in 43 CFR 2310.2–1(c) the above described lands will be at 10 a.m. on February 28, 1982, relieved of the segregative effect as to mineral leasing. The lands will remain segregated as to mining under the mining laws (Ch. 2, Title 30 U.S.C.).

Mario L. Lopez,

Chief, Branch of Lands and Minerals Operations.

[FR Doc. 82–1862 Filed 1–25–82; 8:45 am]

BILLING CODE 4310–84–M

[AR 032143]

Arizona; Termination of Proposed Withdrawal and Reservation of Lands

January 18, 1982.

Notice of application, AR 032143, filed by the Bureau of Land Management, U.S. Department of the Interior, for withdrawal and reservation of lands was published as FR Doc. 62–12317 on Page 12379 of the issue of December 13, 1962. The withdrawal was proposed to establish a townsite to facilitate expansion of the existing community of Parker, Arizona. The applicant agency has cancelled its application in its entirety. The lands involved are described as follows:

Gila and Salt River Meridian, Arizona

T. 9 N., R. 18 W.,
Secs. 6, 7, 18, 19, 30 and 31.
T. 9 N., R. 19 W.,
Secs. 1, 2,
Sec. 3, Lot 7,
Sec. 11, Lots 3, 4, 5, 6, E½, NE¼NW¼,
Secs. 12 and 13,
Sec. 14, Lots 5, 6, 7, 8, E½,
Sec. 22, Lot 5,
Sec. 23, Lots 2, 3, 4, E½, E½W½, SW¼SW¼,
Secs. 24, 25, 26,
Sec. 27, Lots 5, 6, 7, 8, E½SE¼,
Sec. 34, Lots 5, 6, 7, 8, E½NE¼, SW¼NE¼, SE¼,
Secs. 35 and 36.
T. 10 N., R. 18 W.,
Sec. 31, Lots 1, 2, 3, 4, E½.

T. 10 N., R. 9 W.,
Sec. 34, Lots 5, 6, 7, E½E½,
Secs. 35 and 36.

The areas described contain 13,736.37 acres in Yuma County, Arizona.

Therefore, pursuant to the regulations contained in 43 CFR 2310.2–1(c), the lands will be at 10 a.m. on February 26, 1982, relieved of the segregative effect of the above-mentioned application.

Mario L. Lopez,

Chief, Branch of Lands and Minerals Operations.

[FR Doc. 82–1863 Filed 1–25–82; 8:45 am]

BILLING CODE 4310–84–M

Land Resource Management; Stillwater Lake

January 18, 1982.

AGENCY: Bureau of Land Management, Montana State Office, Interior.

ACTION: Notice of filing of plat of survey.

SUMMARY: The Plat of survey of three islands in Stillwater Lake will be officially filed in the Montana State Office, Bureau of Land Management, Billings, Montana, at 8 a.m. on March 29, 1982. The islands are described as follows:

Principal Meridian

T. 32 N., R. 23 W.,
Sec. 20, Lot 8 (1.02 acres), Lot 9 (0.57 acre), and Lot 10 (0.20 acre)

The area described aggregates 1.79 acres.

The subject islands are located in Lower Stillwater Lake northwest of Whitefish, Montana. Lots 8 and 9 have a heavy cover of fir and larch, some lodge pole pine, with alder and willow brush along the shore line. Lot 10 was completely logged by an early day logging operation, leaving numerous stumps and a light cover of alder and willow brush. All three islands are currently under the jurisdiction of the Bureau of Land Management.

At 8 a.m. on March 29, 1982 the survey plat will be officially filed, but the islands will not be opened to the operation of the public land laws or the mining laws pending proposed transfer of jurisdiction to the U.S. Forest Service.

EFFECTIVE DATE: March 29, 1982.

ADDRESS: Bureau of Land Management, 222 North 32nd Street, P.O. Box 30157, Billings, Montana 59107.

FOR FURTHER INFORMATION CONTACT:
Bureau of Land Management, P.O. Box 30157, Billings, Montana 59107.

DATED: January 14, 1982.

Delores M. James,

Chief, Branch of Records and Data Management.

[FR Doc. 82–1855 Filed 1–26–82; 8:45 am]

BILLING CODE 4310–84–M

[M 45993–B (944)]

Land Resource Management; Horsehose Lake

AGENCY: Bureau of Land Management, Montana State Office, Interior.

ACTION: Notice of filing of plat of survey.

SUMMARY: The plat of survey of two islands in Horseshoe Lake will be officially filed in the Montana State Office, Bureau of Land Management, Billings, Montana, at 8 a.m. on March 29, 1982. The islands are described as follows:

Principal Meridian

T. 27 N., R. 28 W.,
Sec. 23, Lot 10 (0.09 acre) and Lot 11 (0.11 acre)

The area described aggregates 0.2 acre.

The subject islands are located southeast of Libby, Montana. Lot 10 has several ponderosa pine and larch trees, with alder and willow brush along the shoreline. The soil is similar to that of the uplands. Lot 11 has several ponderosa pines with a medium cover of smaller pine and douglas fir scattered over the island. There is alder and willow brush along the shoreline, and the soil is also similar to that of the upland. Both islands are currently under the jurisdiction of the Bureau of Land Management.

At 8 a.m. on March 29, 1982 the survey plat will be officially filed, but the islands will not be opened to the operation of the public land laws or the mining laws pending proposed transfer of jurisdiction to the U.S. Forest Service.

EFFECTIVE DATE: March 29, 1982.

ADDRESS: Bureau of Land Management, 222 North 32nd Street, P.O. Box 30157, Billings, Montana 59107.

FOR FURTHER INFORMATION CONTACT:
Bureau of Land Mangement, P.O. Box 30157, Billings, Montana 59107.

Dated: January 14, 1982

Delores M. James,

Chief, Branch of Records and Data Management.

[FR Doc. 82–1856 Filed 1–25–82; 8:45 am]

BILLING CODE 4310–84–M

Scientific Committee of the Outer Continental Shelf (OCS) Advisory Board; Agenda of Meeting

This notice is issued in accordance with the provisions of the Federal Advisory Committee Act, Pub. L. 92–463, 5 U.S.C. App. I and the Office of Management and Budget's Circular A–63 Revised.

The Scientific Committee of the Outer Continental Shelf Advisory Board will meet on February 22–24, 1982. Meetings will begin at 8:00 a.m. each day, and adjourn at 5:00 p.m., except for the 24th when the meeting will adjourn at 11:00 a.m. The meeting will be held in the Congressional Room of the Quality Inn-Capitol Hill Hotel, 415 New Jersey Ave., NW, Washington D.C.

The agenda for the meeting will include the following subjects:

- Peer Review and Publication of Environmental Studies Data.
- Disciplinary Subgourp Activities.
- Discussions with Assistant Secretary, Land and Water Resources.
- Measuring the long-term effects of OCS operations.
- FY 1983 National Study Plan.

The meeting of this committee is open to the public. Approximatley 50 visitors can be accommodated on a first-come/first-served basis. All inquiries concerning this meeting should be addressed to: Piet deWitt, Chief, Branch of Offshore Studies (623) Bureau of Land Management, Washington, D.C. 20240. Telephone: (202) 343–7744.

January 20, 1982.

David C. Russell,

Acting Assistant Secretary of the Interior.

James M. Parker,

Associate Director, Bureau of Land Management.

[FR Doc. 82–1803 Filed 1–25–82; 8:45 am]

BILLING CODE 4310–84–M

[INT DEIS 82–2]

Twin Falls Livestock Grazing Draft Environmental Impact Statement; DEIS Availability and Public Hearing

AGENCY: Bureau of Land Management, Interior.

ACTION: Public hearing on Twin Falls Livestock Grazing DEIS.

SUMMARY: Pursuant to section 102(2)(c) of the National Environmental Policy Act of 1969, the Department of the Interior has prepared a draft environmental impact statement for a proposed grazing management program for the Twin Falls Planning Unit of the Burley District in southcentral Idaho. The proposal involves changes in initial

stocking rates, implementing improved grazing systems and installation of certain range improvements. Approximately 231,000 acres of public lands are involved. Copies of the draft environmental impact statement are available for inspection at the following locations:

Burley District Office, Bureau of Land Management, Route 3, Box 1, Burley, ID 83318, Telephone: (208) 678–5514

Idaho State Office, Bureau of Land Management, Federal Building, 550 West Fort Street, Boise, ID 83724, Telephone: (208) 384–1770

Public Affairs, Bureau of Land Management, Interior Building, 18th and C Streets NW., Washington, D.C. 20240.

A limited number of single copies may be obtained from the Idaho State Director or the Burley District Manager, Bureau of Land Management, at the above addresses.

Notice is hereby given that the draft environmental impact statement is available for public review and comment. The Department of the Interior invites written comments on the adequacy of the draft statement. Notice is also given that a public hearing will be held at City Council Chambers, Twin Falls City Hall, 321 2nd Avenue East, Twin Falls, Idaho, on Thursday, February 25, 1982, at 7:00 p.m. m.s.t.

DATES: February 25, 1982—Public hearing in Twin Falls; March 26, 1982—Deadline for receiving written testimony.

ADDRESS: Written comments on the Draft EIS should be sent to: Burley District Office, Bureau of Land Management, Attention: Scott Anderson, Magic Resource Area Manager, Route 3, Box 1, Burley, ID 83318.

FOR FURTHER INFORMATION CONTACT: Scott Anderson, Magic Resource Area Manager, or Nick Cozakos, District Manager, Burley district Office, Telephone: (208) 678–5514.

SUPPLEMENTARY INFORMATION: The public hearing will be conducted by the Chief, Division of Resources, Idaho State Office, Bureau of Land Management. Individuals wishing to testify may do so by appearing at the hearing place as previously specified. Persons wishing to give testimony will be limited to ten minutes, with written submissions invited. Prior to giving testimony at the public hearing, individuals or spokesmen are requested to complete a hearing registration form. Registration forms may be obtained by contacting the Burley District Manager at the above address.

Dated: January 15, 1982.

Clair Whitlock,

Idaho State Director.

[FR Doc. 82–1807 Filed 1–25–82; 8:45 am]

BILLING CODE 4310–84–M

National Park Service

Cape Cod National Seashore, South Wellfleet, Mass.; Availability of Analysis of Water Resource Management Alternatives

SUMMARY: The National Park Service has prepared an Analysis of Water Resource Management Alternatives (with Environmental Assessment) for Cape Cod National Seashore, Massachusetts. This analysis includes a description of National Park Service policies for water resource management alternatives, including an assessment of the environmental impacts of each alternative. With this Notice of Availability, the National Park Service is seeking comments on the Analysis of Water Resource Management Alternatives. These comments will assist the National Park Service in the selection of alternatives and the preparation of a Water Resource Management Plan for Cape Code National Seashore.

Written comments on the Analysis of Water Resource Management Alternatives will be accepted until April 1, 1982. Comments should be directed to: Superintendent, Cape Cod National Seashore, South Wellfleet, Massachusetts 02663. Copies of the Analysis of Water Resource Management Alternatives may be obtained from the Regional Director, North Atlantic Regional Office, 15 State Street, Boston, Massachusetts 02109, or the Superintendent, Cape Cod National Seashore, South Wellfleet, Masschusetts 02663.

Dated: January 15, 1982.

Steven H. Lewis,

Acting Regional Director, North Atlantic Region.

[FR Doc. 82–1882 Filed 1–25–82; 8:45 am]

BILLING CODE 4310–70–M

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before January 18, 1982. Pursuant to § 60.13 of 36 CFR Part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, U.S. Department of the Interior, Washington, D.C. 20243. Written comments should be submitted by February 10, 1982.

Bruce MacDougal,

Acting Keeper of the National Register.

ALABAMA

Jefferson County

Birmingham, *Downtown Birmingham Historic District,* Roughly bounded by 1st and 3rd Aves., 20th and 25th Sts.

Birmingham, *Fourth Avenue Historic District,* 4th Ave., 17th and 18th Sts.

CALIFORNIA

Alameda County

Oakland, *McCrea House,* 3500 Mountain Blvd.

Humboldt County

Eureka, *Eureka Inn,* 7th and F Sts.

Los Angeles County

Los Angeles, *Golden Gate Theater,* 5170–5188 E. Whittier Blvd.

Malibu vicinity, *Saddle Rock Ranch Pictograph Site (4–LAN–717)*

Napa County

Napa vicinity, *Kreuzer Ranch,* 167 Kreuzer Lane

Riverside County

Palm Springs, *El Mirador Hotel and Tower,* 1150 N. Indian Ave.

San Francisco County

San Francisco, *Saint Paulus Lutheran Church,* 999 Eddy St.

Siskiyou County

Macdoel, *Hotel Macdoel,* Montezuma Ave. and Mt. Shasta St.

CONNECTICUT

Fairfield County

Newtown, *Glover House,* 50 Main St.

Hartford County

Hartford, *Dillon Building,* 69—71 Pratt St.

Hartford, *Houses at 140 and 144 Retreat Avenue*

Hartford, *Isham-Terry House,* 211 High St.

Windham County

Canterbury, *Wheeler, Jonathan, House,* Society Rd.

ILLINOIS

Cook County

Berwyn, *Dunham, Arthur J., House,* 3131 S. Wisconsin Ave.

Chicago, *Old Main Building,* 3235 W. Foster Ave. on North Park College campus

Oak Park, *Masonic Temple Building,* 119—137 N. Oak Park Ave.

Henry County

Galva, *Galva Opera House (Blue Ribbon Temperance Hall)* 334—348 Front St.

Galva, *Johnson, Olof, House,* 408 NW. 4th St.

Kane County

Batavia vicinity, *Stearns-Wadsworth House*, 1 S. 570 Bliss Rd.

Lake County

Lake Forest, *Armour, J. Ogden, House*, 1500 W. Kennedy Rd.

Lee County

Dixon, *Van Epps, William H., House*, 212 S. Ottawa Ave.

Peoria County

Bartonville, *Peoria State Hospital*, 600 Ricketts Ave.

Williamson County

Marion, *Allen, Willis, House*, 514 S. Market St.

INDIANA

Fayette County

Bentonville vicinity, *Lowry, William, House*, Kniese Rd.

Huntington County

Huntington, *Taylor-Zent House*, 715 N. Jefferson St.

Huntington vicinity, *Chief Richardville House and Miami Treaty Grounds*, W of Huntington on U.S. 24 and IN 9/32

Union County

Liberty, *Grove, Dr. John, House and Office*, 23, 25, and 27 S. Market St.

Vanderburgh County

Evansville, *Hose House No. 10*, 119 E. Columbia St.

Evansville, *Schaeffer, Michael, House*, 118 E. Chandler Ave.

KENTUCKY

Jefferson County

Louisville, *Vogt, Henry, Machine Company Shop*, 10th St. and Ormsby Ave.

MAINE

MAINE COMMERCIAL SCHOONERS THEMATIC RESOURCES. Reference—see individual listings under Knox County.

Cumberland County

Portland, *Lancaster Block*, 474 Congress St.

Portland, *Masonic Temple*, 415 Congress St.

Kennebec County

Augusta, *Tappan-Viles House*, 154 State St.

Benton vicinity, Reed, G. W., Travellers Home

Knox County

Camden, *Adventure (schooner) (Maine Commercial Schooners Thematic Resources)*

Camden, *Mattie (schooner) (Maine Commercial Schooners Thematic Resources)*

Camden, *Mercantile (schooner) (Maine Commercial Schooners Thematic Resources)*

Camden, *Roseway (schooner) (Maine Commercial Schooners Thematic Resources)*

Camden, *Taber, Stephen (schooner) (Maine Commercial Schooners Thematic Resources)*

Rockland, *French, Lewis R. (schooner) (Maine Commercial Schooners Thematic Resources)*

Sagadahoc County

Woolwich, *Reed, Robert, House*, ME 128 and Chop Point Rd.

Waldo County

Belfast, *Black Horse Tavern*, Searsport Ave.

Washington County

Calais, *Washburn, George, House*, 318 Main St.

York County

North Berwick, *Hobbs, Thomas, Jr., House*, Wells St.

MINNESOTA

Benton County

St. Cloud, *Ice Service Company Building*, Burlington Northern RR and 3rd Ave.

Sauk Rapids, *Wippich's Rock Garden*, 3rd Ave. North and 6th St., North

Pope County

Glenwood vicinity, *Sunset Beach Hotel*, SR 17

Sedan vicinity, *Iverson, Urjans, Cabin*, Off MN 104

Stearns County

St. Cloud, *Bensen, John N., House*, 402 6th Ave., South

St. Cloud, *Pan Motor Company Office and Sheet Metal Works*, 435—437 33rd Ave. North

Sauk Centre, *Palmer House Hotel*, 500 Sinclair Lewis Ave.

MONTANA

Custer County

Miles City, *Miles, George M., House*, 28 S. Lake St.

NEBRASKA

Dodge County

Millard vicinity, *Ehlers, Hans, Farmstead*, W of Millard

OHIO

Summit County

Peninsula vicinity, *Stanford, George, Farm*, 6093 Stanford Rd.

OKLAHOMA

Rogers County

Claremore, *Eastern University Preparatory School*, College Hill

Claremore, *Meyer, Maurice, Barracks*, College Hill

UTAH

Davis County

West Layton, *Layton, John Henry, House*, 683 W. Gentile St.

Iron County

Cedar City, *Hunter, Joseph S., House*, 86 E. Center St.

San Juan County

Bluff, *Nielson, Jens, House*, Off UT 47

[FR Doc. 82-1881 Filed 1-25-82; 8:45 am]

BILLING CODE 4310-70-M

Bureau of Reclamation

[INT-DES 81-43]

Chikaskia Project—Kansas-Oklahoma; Extension of Review and Comment Period

Pursuant to a request from the Governor of the State of Kansas, the Commissioner of Reclamation has extended the review and comment period for the draft environmental statement on the Chikaskia Project, Kansas-Oklahoma. The Governor requested a 90-day extension in order that the newly appointed Kansas Water Office Director may be afforded time to review the draft statement and review the comments of the other State agencies. This extension of time is granted to anyone who wishes to comment during this time period. The draft statement presents alternatives for meeting municipal and industrial water needs of the city of Wichita and the surrounding area. Corbin dam and reservoir is recommended as the most viable alternative. The dam would be located on the Chikaskia River in Sumner County, about 5 miles northeast of Caldwell, Kansas. The closing date for receiving comments is extended from December 31, 1981, to March 31, 1982.

Comments should be sent to: Regional Director, Bureau of Reclamation, Department of the Interior, 714 South Tyler Street, Suite 201, Amarillo, Texas 79101, Telephone: (806)-378-5477.

Dated: January 20, 1982.

Eugene Hinds,

Assistant Commissioner.

[FR Doc. 82-1885 Filed 1-25-82; 8:45 am]

BILLING CODE 4310-09-M

INTERSTATE COMMERCE COMMISSION

[Ex Parte No. 311]

Motor Carriers; Expedited Procedures for Recovery of Fuel Costs

Decided: January 20, 1982.

In our recent decisions, an 18.0-percent surcharge was authorized on all owner-operator traffic, and on all truckload traffic whether or not owner-operators were employed. We ordered that all owner-operators were to receive compensation at this level.

The weekly figure set forth in the appendix for transportation performed by owner-operators and for truckload traffic is 18.0-percent. Accordingly, we are authorizing that the surcharge for this traffic remain at 18.0 percent. All owner-operators are to receive compensation at this level.

No change is authorized in the 2.1-percent surcharge for United Parcel Service, the 3.1-percent surcharge on less-than-truckload (LTL) traffic performed by carriers not using owner-operators, or the 6.7-percent surcharge for the bus carriers.

Notice shall be given to the general public by mailing a copy of this decision to the Governor of each State having jurisdiction over transportation, by depositing a copy in the Office of the Secretary, Interstate Commerce Commission, Washington, D.C. for public inspection and by depositing a copy to the Director, Office of the Federal Register, for publication therein.

It is ordered:

This decision shall become effective Friday, 12:01 a.m. January 22, 1982.

By the Commission, Chairman Taylor, Vice-Chairman Gilliam, Commissioners Gresham and Clapp.

Agatha L. Mergenovich,

Secretary.

APPENDIX—FUEL SURCHARGE

Base date and price per gallon (including tax)

Jan. 18, 1979 ..... 63.5¢

Date of current price measurement and price per gallon (including tax)

Jan. 18, 1982 ..... 131.2¢

	Transportation performed by—			
	Owner-Operator [1]	Other [2]	Bus carrier	UPS
	(1)	(2)	(3)	(4)
Average percent fuel expenses (including taxes) of total revenue	16.9	2.9	6.3	3.3
Percent surcharge developed	18.0	3.1	6.7	[3] 2.9
Percent surcharge allowed	18.0	3.1	6.7	[4] 2.1

[1] Apply to all truckload rated traffic.
[2] Including less-than-truckload traffic.
[3] The percentage surcharge developed for UPS is calculated by applying 8-percent of the percentage increase in the current price per gallon over the base price per gallon to UPS average percent of fuel expense to revenue figure as of January 18, 1979 (3.3 percent).
[4] The developed surcharge is reduced 0.8 percent to reflect fuel-related increases already included in UPS rates.

[FR Doc. 82-1724 Filed 1-25-82; 8:45 am]

BILLING CODE 7035-01-M

[Volume No. OP1-332]

Motor Carriers; Permanent Authority Decisions; Decision-Notice; Correction

Decided: December 29, 1981.

The following volume was incorrectly published on January 8, 1982 (47 FR 1044) under the fitness guidelines, and is being republished this issue to reflect that the following applications fall under the non-fitness standards.

The following applications, filed on or after February 9, 1981, are governed by special rule of the Commission's rules of practice, see 49 CFR 1100.251. Special Rule 251 was published in the **Federal Register** of December 31, 1980, at 45 FR 86771. For compliance procedures, refer to the **Federal Register** issue of December 3, 1980, at 45 FR 80109.

Persons wishing to oppose an application must follow the rules under 49 CFR 1100.252. A copy of any application, including all supporting evidence, can be obtained from applicant's representative upon request and payment to applicant's representative of $10.00.

Amendments to the request for authority are not allowed. Some of the applications may have been modified prior to publication to conform to the Commission's policy of simplifying grants of operating authority.

Findings

With the exception of those applications involving duly noted problems (e.g., unresolved common control, fitness, water carrier dual operations, or jurisdictional questions) we find, preliminarily, that each applicant has demonstrated a public need for the proposed operations and that it is fit, willing, and able to perform the service proposed, and to conform to the requirements of Title 49, Subtitle IV, United States Code, and the Commission's regulations. This presumption shall not be deemed to exist where the application is opposed. Except where noted, this decision is neither a major Federal action significantly affecting the quality of the human environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

In the absence of legally sufficient opposition in the form of verified statements filed on or before 45 days from date of publication (or, if the application later becomes unopposed), appropriate authorizing documents will be issued to applicants with regulated operations (except those with duly noted problems) and will remain in full effect only as long as the applicant maintains appropriate compliance. The unopposed applications involving new entrants will be subject to the issuance of an effective notice setting forth the compliance requirements which must be satisfied before the authority will be issued. Once this compliance is met, the authority will be issued.

Within 60 days after publication an applicant may file a verified statement in rebuttal to any statement in opposition.

To the extent that any of the authority granted may duplicate an applicant's other authority, the duplication shall be construed as conferring only a single operating right.

By the Commission, Review Board No. 1, Members Parker, Chandler and Fortier.

Agatha L. Mergenovich,

Secretary.

Note.—All applications are for authority to operate as a motor common carrier in interstate or foreign commerce over irregular routes, unless noted otherwise. Applications for motor contract carrier authority are those where service is for a named shipper "under contract".

Please direct status inquiries to the Ombudsman's Office, (202) 275-7326.

MC 38591 (Sub-3), filed December 17, 1981. Applicant: NATIONWIDE MOVING & STORAGE CO., INC., 100 Peters Road, Bloomfield, CT 06002. Representative: Sidney L. Goldstein, 109 Church St., New Haven, CT 06510 (203) 787-1288.

MC 39491 (Sub-18), filed December 2, 1981. Applicant: COLONIAL COACH CORP., 17 Franklin Turnpike, Mahwah, NJ 07430. Representative: Samuel B. Zinder, 98 Cutter Mill Rd., Great Neck, NY 11021, (516) 482-0881.

MC 113271 (Sub-84), filed December 18, 1981. Applicant: TRANSYSTEMS INC., P.O. Box 399, Black Eagle, MT 59414. Representative: Patrick W. Rice, P.O. Box 2644, Great Falls, MT 59403, (406) 727-7500.

MC 116101 (Sub-15), filed December 21, 1981. Applicant: QUICK AIR FREIGHT, INC., Cargo Bldg., Columbus International Airport, Columbus, OH 43219. Representative: Russell S. Bernhard, 1625 K St. NW., Washington, DC 20006, (202) 393-3390.

MC 120080 (Sub-7), filed December 18, 1981. Applicant: MORGAN EXPRESS, INC., 10130 Monroe Dr., Dallas, TX 75229. Representative: Max G. Morgan, P.O. Box 1540, Edmond, OK 73034, (405) 348-7700.

MC 121171 (Sub-2), filed December 18, 1981. Applicant: WILLIAMS TRANSPORTATION, INC., 1925 East Vernon Avenue, Los Angeles, CA 90058. Representative: Robert L. Cope, 1730 M St. NW., Suite 501, Washington, DC 20036.

MC 123490 (Sub-18), filed December 15, 1981. Applicant: CHIP CARRIERS INCORPORATED, 11218 Elm St.,

Omaha, NE 68144. Representative: James F. Crosby, 7363 Pacific St., Suite 210B, Omaha, NE 68114, (402) 397–9900.

MC 124170 (Sub-193), filed December 21, 1981. Applicant: FROSTWAYS, INC., 3000 Chrysler Service Drive, Detroit, MI 48207. Representative: William J. Boyd, 2021 Midwest Rd., Suite 205, Oak Brook, IL 60521, (312) 629–2900.

MC 124170 (Sub-194), filed December 21, 1981. Applicant: FROSTWAYS, INC., 3000 Chrysler Service Drive, Detroit, MI 48207. Representative: William J. Boyd, 2021 Midwest Rd., Suite 205, Oak Brook, IL 60521, (312) 629–2900.

MC 140950 (Sub-5), filed December 22, 1981. Applicant: BROOKVILLE TRANSPORT, LTD., 1170 Old Rothesay, Rd., St. John, New Brunswick, Canada. Representative: John C. Lightbody, 30 Exchange St., Portland, ME 04101, (207) 773–5651.

MC 143741 (Sub-1), filed December 15, 1981. Applicant: WILLIAMS BROTHERS TRUCKING, INC., P.O. Box 188, Hazelhurst, GA 31539. Representative: Clyde W. Carver, P.O. Box 720434, Atlanta, GA 30328, (404) 256–4320.

MC 147020 (Sub-4), filed December 21, 1981. Applicant: NORTHWESTERN TRADING COMPANY, INC., Route 4, Box 116B, Milton-Freewater, OR 97863. Representative: M. C. Risser, Suite 501, 1410 S.W. Morrison St., Portland, OR 97205, (503) 222–9261.

MC 147821 (Sub-2), filed December 14, 1981. Applicant: JOEL OLSON TRUCKING, INC., P.O. Box 837, Clatskanie, OR 97016. Representative: Lawrence V. Smart, Jr., 419 NW. 23rd Ave., Portland, OR 97210, (503) 226–3755.

MC 148021, filed December 21, 1981. Applicant: TRUXILLO DELIVERY SERVICE, INC., 364 Hord St., Harahan, LA 70123. Representative: Michael Truxillo, 2221 Pasadena St., Metairie, LA 70001, (504) 454–3332.

MC 151450 (Sub-2), filed December 14, 1981. Applicant: JOE GILBERT GONZALES, P.O. Box 93, Dixon, NM 82527. Representative: Charles M. Williams, 1600 Sherman St., #665, Denver, CO 80203, (303) 839–5856.

MC 151471 (Sub-13), filed December 21, 1981. Applicant: STEINBECKER BROS., INC., P.O. Box 852, Greeley, CO 80632. Representative: Jack B. Wolfe, 1600 Sherman St., #665, Denver, CO 80203, (303) 839–5856.

MC 152730 (Sub-14), filed December 21, 1981. Applicant: DEPENDABLE TRANSIT, INC., P.O. Box 349, County Road 300 South, Hartford City, IN 47348. Representative: Larry Garrett, P.O. Box 349, County Road 300 South, Hartford City, IN 47348, (317) 348–0051.

MC 153560 (Sub-1), filed December 14, 1981. Applicant: AGRICULTURAL CARRIERS, INC., P.O. Box 13081, Wichita, KS 67213. Representative: Jack B. Wolfe, 1600 Sherman St., #665, Denver, CO 80203, (303) 839–5856.

MC 154170 (Sub-1), filed December 22, 1981. Applicant: BUNYON TRUCKING COMPANY, INC., 6500 Mt. Zion Blvd., Morrow, GA 30260. Representative: Alan E. Serby, 3390 Peachtree Rd., N.E., 5th Floor—Lenox Towers South, Atlanta, GA 30260, (404) 262–7855.

MC 156611 (Sub-1), filed December 18, 1981. Applicant: FOOD TRANSPORT, INC., 614 W. Sycamore St., P.O. Box 446, Fayetteville, AR 72701. Representative: Grant M. Davis, 2217 Juneway Terrace, Fayetteville, AR 72701, (501) 443–3257.

MC 157400 (Sub-2), filed December 7, 1981. Applicant: W. N. PHELPS DRAYAGE, INC., 2109 Angelica Street, St. Louis, MO 63133. Representative: Austin C. Knetzger, 214 No. Clay, Kirkwood, MO 63122, (314) 821–4616.

MC 159720, filed December 14, 1981. Applicant: JORASON TRANSPORT CORP., Municipal Pier, Providence, RI 02905. Representative: Wesley S. Chused, 15 Court Square, Boston, MA 02108, (617) 742–3530.

MC 159791, filed December 21, 1981. Applicant: ENGLER AUTOMOTIVES, INC., P.O. Box 223, Wind Gap, PA 18091. Representative: Stanley S. Engler, 592 Getz Rd., Pen Argyl, PA 18072, (215) 759–5943.

MC 159801, filed December 21, 1981. Applicant: LARRY D. SMITH, P.O. Box 285, Marshville, NC 28103. Representative: Judy E. Smith, P.O. Box 285, Marshville, NC 28103, (704) 847–8804.

MC 159821, filed December 21, 1981. Applicant: ALLAN L. BLACKBURN, d.b.a. A & B TRUCKING, 343 Schneiders Lane, Elkton, MD 21921. Representative: Allan L. Blackburn, 343 Schneiders Lane, Elkton, MD 21921, (301) 398–8687.

[FR Doc. 82–1720 Filed 1–25–82; 8:45 am]
BILLING CODE 7035–01–M

Motor Carriers; Finance Applications; Decision Notice

As indicated by the findings below, the Commission has approved the following applications filed under 49 U.S.C. 10924, 10926, 10931 and 10932.

We find:

Each transaction is exempt from section 11343 (formerly section 5) of the Interstate Commerce Act, and complies with the appropriate transfer rules.

This decision is neither a major Federal action significantly affecting the quality of the human environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

Petitions seeking reconsideration must be filed within 20 days from the date of this publication. Replies must be filed within 20 days after the final date for filing petitions for reconsiderations; any interested person may file and serve a reply upon the parties to the proceeding. Petitions which do not comply with the relevant transfer rules at 49 CFR 1132.4 may be rejected.

If petitions for reconsideration are not timely filed, and applicants satisfy the conditions, if any, which have been imposed, the application is granted and they will receive an effective notice. The notice will indicate that consummation of the transfer will be presumed to occur on the 20th day following service of the notice, unless either applicant has advised the Commission that the transfer will not be consummated or that an extension of time for consummation is needed. The notice will also recite the compliance requirements which must be met before the transferee may commence operations.

Applicants must comply with any conditions set forth in the following decision-notices within 30 days after publication, or within any approved extension period. Otherwise, the decision-notice shall have no further effect.

It is Ordered:

The following applications are approved, subject to the conditions stated in the publication, and further subject to the administrative requirements stated in the effective notice to be issued hereafter.

By the Commission, Review Board No. 3, Members Krock, Joyce, and Dowell.

MC FC–79494. By Decision of December 3, 1981 issued under 49 U.S.C. 10926 and the transfer rules at 49 C.F.R. 1132, Review Board Number approved the transfer to Perry Motor Freight, Inc. of Certificate No. MC-147677 (Sub-No. 2F and 3) issued April 22 and September 22, to J&L Truck Lines, Inc. 1981, respectively authorizing the transportation over regular routes of general commodities (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), (1) between Odessa, TX and Artesia, NM, serving all intermediate points in New Mexico, including the off-route points of Monument and Oil Center, NM: from Odessa over U.S. Hwy 385 to Andrews, TX, then over Texas Hwy 176 to junction New Mexico Hwy

18, then over New Mexico Hwy 18 to junction Hwy 82, then over U.S. Hwy 82 to Artesia, and return over the same route, and (2) between Odessa, TX and Artesia, NM, serving all intermediate points in New Mexico; from Odessa over Texas Hwy 302 to junction Texas Hwy 18; then over Texas Hwy 18 to junction U.S. Hwys 62 and 180 then over U.S. Hwys 62 and 180 to junction U.S. Hwy 285, then over U.S. Hwy 285 to Artesia, and return over the same route; (3) betweem Dallas and Odessa, TX, over Interstate Hwy 20, serving no intermediate points, (4) between Lovington and Roswell, NM: from Lovington over New Mexico Hwy 18 to junction U.S. Hwy 380, then over U.S. Hwy 380 to Roswell, and return over the same route, serving all intermediate points, (5) between Roswell and Artesia, NM, over U.S. Hwys 285 and Alternate 285, serving all intermediate points, (6) between Carlsbad and Whites City, NM, over combined U.S. Hwy 62 and 180, serving all intermediate points, and (7) between Whites City and Malaga, NM.: from Whites City over combined U.S. Hwys 62 and 180 to junction New Mexico Hwy 396, then over New Mexico 396 to Malaga, and return over the same route, serving all intermediate points. Applicants' representative: G. William Fowler, 115 West Fifth Street, Odessa, TX 79761.

MC FC–79027. By decision of January 1, 1982 issued under 49 U.S.C. 10926 and the transfer rules at 49 C.F.R. 1132, Review Board Number 3 approved the transfer to Fast Food Transport, Inc. of Certificate No. MC-142048 (Sub No. 4 and 10) and Permit No. MC-13499 and MC-13499 (Sub-Nos. 3 and 5) to issued to Pacific Transportation Lines, Inc. authorizing the transportation of such *merchandise as is dealt in by wholeside retail and chain grocery and food business houses, and equipment, materials and supplies as used in the conduct of such business* bounded by a line beginning at Buffalo, NY and extending to Erie, PA, then to certain areas in Western New York and Eastern Pennsylvania; and (2) from the facilities of Great Atlantic and Pacific Tea Company at Horseheads, NY to various counties in Eastern Pennsylvania, and (3) between the plantsite of Welch Foods, Inc. at North East and Erie, PA on the one hand, and on the other, points in New York (except New York, NY) *Frozen Foods* from Solon, OH to Cleveland, OH to Syracuse, NY, *Frozen foods* from Syracuse, NY to points in Connecticut, Delaware, Maine, Maryland, Massachusetts, Michigan, New Hampshire, New York, Ohio, Pennsylvania, Rhode Island, Vermont, Virginia, West Virginia, and the District of Columbia. Subject to the following conditions: Applicants' representative: William J. Hirsch, 1125 Conventions Tower, 43 Court Street, Buffalo, NY 14202.

Note.—These authorites are subject to certain restrictions.

MC FC–79536. By decision of January 5, 1982, issued under 49 U.S.C. 10931 or 10932 and the transfer rules at 49 CFR 1132, Review Board Number 3 approved the transfer to Safe Express of San Jose, CA of Certificate of Registration No. MC-121710 issued 9/7/73, to Dynamic Freight Corporation of Oakland, CA evidencing a right to engage in transportation in interstate commerce corresponding in scope to state certificate No. 81494 dated 6/19/73 issued by the Public Utilities Commission of the State of California. The Certificate authorizes the movement of general commodities (with exceptions) between points in CA which are located in the San Francisco Territory as described in the Certificate's Appendix. Subject to the following condition: Transferee shall, prior to or concurrently with consummation of this transaction, furnish to the Commission a certified copy of the California certificate as reissued to it, or if the Public Utilities Commission of the State of California does not reissue the certificate, a certified copy of the order which approves the transfer of the California intrastate certificate, together with a statement in writing confirming the date of consummation of the intrastate transaction. Applicant's representative is: Victoria A. Oldberg, 2510 Channing Ave., San Jose, CA 95131.

MC–FC–79541. By decision of January 4, 1982, issued under 49 U.S.C. 10926 and the transfer rules at 49 CFR 1132, Review Board Number 3 approved the transfer to Allied International Trucking Co., Inc. of Everett, MA of Certificate No. MC–150618 and Sub 2 issued to Avion Transport, Inc. of Nashua, NH authorizing the transportation of (A)(1) paper, paper products, copying machines, inks, tapes and computer machine parts (except in bulk), and (2) materials equipment and supplies used in the manufacture and distribution of the commodities in (1) (except in bulk), between points in the United States (except Alaska and Hawaii), restricted to traffic originating at or destined to the facilities of Nashua Corporation and (B)(1) general commodities (except classes A and B explosives), between points in MA, NH, and RI on the one hand, and, on the other points in the United States, (2) pet products and pet supplies between points in Winnebago County, IL, on the one hand, and, on the other, points in the United States. Applicant's representative: Raymond Keigher, 400 E. Jefferson St., Ste. 102, Rockville, MD 20850. TA lease is not sought. Transferee is a carrier.

MC–FC–79542. By decision of January 4, 1982, issued under 49 U.S.C. 10926 and the transfer rules at 49 C.F.R. 1132, Review Board Number 3 approved the transfer to Mohawk Moving & Storage Corp. of Schenectady, NY of Certificate No. MC–76462 issued to Cook Moving & Storage, Inc. of Schenectady, NY authorizing household goods as defined by the Commission, between Schenectady, NY and points within 35 miles of Schenectady, on the one hand, and, on the other, points in VT, MA, CT, RI, NH, NY, NJ, PA, MD, OH, and the DC. Representative: James Dunbar, 450 Duane Ave., Schenectady, NY 12303. TA lease is not sought. Transferee is not a carrier.

MC–FC–79545. By decision of December 28, 1981 issued under 49 U.S.C. 10926 and the transfer rules at 49 CFR 1133, Review Board Number 3 approved the transfer to CALIFORNIA–NEVADA GOLDEN TOURS, d/b/a/ SUNWEST COUNTRY—BETTY'S TOURS, INC., of Reno, NV of License No. MC–130133, issued March 20, 1981, to BETTY'S TOURS, INC., of San Francisco, CA, authorizing the transportation, as a *broker*, at San Francisco, Oakland, Fresno, Payward, San Jose, Los Angeles, Palo Alto, Redwood City, Sacramento, San Diego, San Mateo, Walnut Creek, Lafayette, Concord, San Rosa, Stockton, Vallejo, Santa Ana, Corona, San Bernardino, and Long Beach, CA, in arranging for the transportation of *passengers and their baggage*, in round-trip, special and charter operations, beginning and ending at points in CA and extending to points in AZ, CA, CO, ID, MT, NV, NM, OR, UT, WA, and WY. Representative: Irwin J. Borof, 2133 San Pablo Avenue, Oakland, CA 94612.

Notes.—TA has not been filed. Transferee is a non-carrier which is affiliated with motor carriers: Peerless Stages, Inc. (MC–66505) and Gray Line Scenic Tours (MC–106170).

MC–FC–79550. By decision of 1/7/82 issued under 49 U.S.C. 10926 and the transfer rules at 49 CFR 1132, Review Board Number 3 approved the transfer to Golden West Express, Inc., a non-carrier of Certificate No. MC–145608(5X) and 145608(7) issued August 13, and October 14, 1981 respectively, to Henry Johnson, Inc., in MC–145608 5(X) authorizing operation as a common

carrier transporting food and related products between Chicago and Carol Stream, IL and Moultree County, IL and Davenport, IA, on the one hand, and, on the other, Washoe County, NV between Washoe County, NV, on the one hand, and, on the other, points in AZ, CA, ID, MT, OR, UT, and WA. In MC–145608(7) authorizing operation as a common carrier transporting Confectionery and related advertising and display items from the facilities of E.J. Branch & Sons, Inc., at Chicago, Sullivan and Carol Stream, IL and Davenport, IA to the holders of E.J. Branch & Sons, Inc. at Reno, NV. TA application has been filed. Applicant's representative: James F. Crosby & Associates, 7363 Pacific Street, Suite 210B, Anotta, NE 68114.

MC–FC–79527. By decision of December 29, 1981, Review Board No. 3 approved the transfer to Russell Transport, Inc., of Ft. Collins, CO of a portion of Certificate No. MC–51489 Sub 1 issued to Boyd L. Collins, dba Boyd's Hotshot Service, of Commerce City, CO authorizing: Machinery and transportation equipment, Between Denver, CO, on the one hand, and, on the other, points in SD, NE, and in Albany, Laramie, Platte, Goshen, Natrona, Converse, Niobrara, Johnson, Campbell, Weston and Crook Counties, WY. Representative: Charles M. Williams, Capitol Life Center, Suite 665, 1600 Sherman St., Denver, CO 80203.

MC–FC–79528. By decision of December 28, 1981, issued under 49 U.S.C. 10926 and the transfer rules at 49 CFR 1132, Review Board Number 3 approved the transfer to VENTURA TRANSPORTATION, INC., of Quebec, Canada, of Certificate Nos. MC–66512 and MC–66512 (Sub-Nos. 7, 8, 9, 10, and 12), issued to P & G MOTOR FREIGHT, INCORPORATED, of South Windsor, CT, authorizing the transportation of *general commodities* (with exceptions), over various regular and irregular routes, between points in ME, NH, VT, MA, CT, RI, NY, NJ, and PA; and *specified commodities* such as paper and paper products, wool and silk waste, nursery stock, silk and silk products, machinery, dyes and chemicals, and paint and paint material, between points in CT, NY, NJ, and MA. Representative: Frank J. Weiner, 15 Court Square, Boston, MA 02108.

MC–FC–79532. By decision of December 28, 1981, issued under 49 CFR 1132, Review Board Number 3 approved the transfer to JOHN J. BRANDT MOVING & STORAGE, of Lebanon, PA, of Certificate Nos. MC–1 7868 and MC–17868 (Sub-Nos. 5 and 7G), issued to H. E. BRINKERHOFF AND SONS TRANSPORTATION CO. (Charles J. DeHart, III, Trustee in Bankruptcy), authorizing the transportation of *household goods*, as defined by the Commission, between specified points in AL, CT, DE, FL, GA, IL, IN, IA, KY, LA, ME, MA, MD, MI, MO, NH, NJ, NY, NC, OH, PA, RI, SC, TN, TX, VT, VA, WV,and DC, and *wardrobes, cabinets, and tables*, uncrated, from Littlestown, Adams County, PA, to points in ME, NH, VT, MA, CT, RI, DE, NY, NJ, MD, VA, WV, NC, SC, KY, TN, GA, FL, OH, IL, IA, MI, AL, LA, MO, TX, and DC. Representative: John E. Fullerton, 407 N. Front St., Harrisburg, PA 17101.

Notes.—TA has not been filed. Transferee is not a carrier. Transfer of GT–887–80 is not approved. Certificates issued in accordance with Ex Parte No. MC–107, *Transportation of Government Traffic*, 131 M.C.C. 845, 870 (1979) are not transferable by sale or otherwise.

MC–79538. By decision of January 4, 1982, issued under 49 U.S.C. 10926 and the transfer rules at 49 CFR 1132, Review Board Number 3 approved the transfer to Betty A. Thompson d.b.a. Thompson Motor Freight of Certificate No. MC–40994 issued to Harlan H. Thompson d.b.a Thompson Motor Freight authorizing *general commodities*, except those of unusual value, and Class A and B explosives, livestock, household goods as defined by the Commission, and commodities requiring special equipment. Between Mason City, IA, and the jct. of unnumbered IA Hwy and MN Hwy 22, at the IA–MN State Line; from Mason City over U.S. Hwy 18 to jct. unnumbered hwy, then over unnumbered hwy via Hanlantown, IA to Fertile, IA, then over IA Hwy 9 to jct. unnumbered hwy, then over unnumbered hwy via Joice, IA, to jct. IA Hwy 105 to Lake Mills, IA, then over unnumbered hwy, via Scarville, IA, to jct. MN Hwy 22, at the IA-MN State line, and return over the same route, serving the intermediate and off-route points of Hanlontown, Fertile, Joice, Lake Mills, Scarville, and Vinge, IA.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82–1887 Filed 1–25–82; 8:45 am]

BILLING CODE 7035–01–M

Motor Carriers; Long- and Short-Haul Application for Relief (Formerly Fourth Section Application)

January 20, 1982.

This application for long- and short-haul relief has been filed with the I.C.C.

Protests are due at the I.C.C. within 15 days from the date of publication of the notice.

No. 43955, H. H. Kirchoff, Agent (No. 7), reduced rates on beet or cane sugar, from Bingham, East Grand Forks, and Wilds, MN; and Wahpeton, Drayton, and Redco, ND to Wheeling, IL, for account Burlington Northern Railroad Company, in Supplement 96 to its Tariff ICC KHH 3605–R, effective January 19, 1982. Grounds for Relief—market competition and rate relationships. This application was received by the Commission's Suspension Board on January 15, 1982. This precluded the Board from publishing the requested relief in the **Federal Register** in order to give interested parties an opportunity to protest.

By action of January 18, 1982, the Commission, Suspension Board, Members Fitzgerald, Halvarson, and O'Malley, concluded to grant the requested relief in 111th Supplemental Long-And-Short-Haul Order No. 17508, subject to the proviso that the authority will expire 45 days' from January 18, 1982. This notice is to advise that the Commission's Suspension Board will reopen this proceeding on its own motion (if not protested), to consider the expiration date of this authority. Interested parties wishing to object may file objections with the Suspension Board not later than the 10th day before the expiration date.

By the Commission.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82–1886 Filed 1–25–82; 8:45 am]

BILLING CODE 7035–01–M

[Permanent Authority Vol. No. 7]

Motor Carriers; Republications of Grants of Operating Rights Authority Prior to Certification

The following grants of operating rights authorities are republished by order of the Commission to indicate a broadened grant of authority over that previously noticed in the **Federal Register.**

An original and one copy of petitions for leave to intervene must be filed with the Commission within 30 days after the date of this **Federal Register** notice. Such pleadings shall address specifically the issue(s) indicated as the purpose for republication.

By the Commission.

Agatha L. Mergenovich,

Secretary.

MC 157200 (republication), filed July 17, 1981, published in the **Federal Register** of September 10, 1981, and republished this issue. Applicant: ALL-SEASON ENTERPRISES, INC., 769 Fifth Avenue, Brooklyn, NY 11232. Representative: Brian S. Stern, North

Springfield Professional Center II, 5411–D Backlick Rd., Springfield, VA 22151. A decision by the Commission, Review Board #3, decided December 7, 1981, served January 13, 1982, finds that applicant is authorized to operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *such commodities* as are dealt in or used by grocery stores and food business houses, hardware, discount, and department stores, between Boston, MA, Cleveland, OH, Fairless Hills, PA, and points in Frederick County, MD, Chester County, PA, Pulaski County, KY, Tucker County, WV, Orange County, IN, and Hudson, Union, Ocean, Bergen, Passaic, and Middlesex Counties, NJ, on the one hand, and, on the other, those points in the United States in, east, and north of Michigan, Indiana, Kentucky, and Virginia, and (2) *pulp, paper, and related products, plastic products, and containers and closures*, between Chicago, IL, Baltimore, MD, Boston, MA, Brunswick, NJ, Fairport, NJ, Geneva, NJ, Cleveland, OH, Philadelphia, PA, Shelbyville, SC, Milwaukee, WI, and points in Fairfield County, CT, Lake, Kane, Cook, and Vermilion Counties, IL, Fayette County, KY, Cumberland County, ME, Worcester County, MA, Middlesex, Bergen, Hudson, and Warren Counties, NJ, Lucas County, OH, Franklin, Northampton, Dauphin, and Cumberland Counties, PA, Darlington County, SC, and Ashland, Brown, Marathon and Winnebago Counties, WI, on the one hand, and, on the other, those points in the United States in, east, and north of Wisconsin, Illinois, Kentucky, Tennessee, North Carolina, and South Carolina. Applicant is fit, willing, and able properly to perform such service and to conform to statutory and administrative requirements. The purpose of this republication is to indicate that applicant has been granted broader authority.

[FR Doc. 82-1886 Filed 1-25-82; 8:45 am]
BILLING CODE 7035-01-M

Motor Carriers; Long- and Short-Haul Application for Relief (Formerly Fourth Section Application)

January 21, 1982.

This application for long- and short-haul relief has been filed with the I.C.C.

Protests are due at the I.C.C. within 15 days from the date of publication of the notice.

FSA 43954: Southwestern Freight Bureau, carload rates on cottonseed hulls, and kindred and related articles, between Stations in Southwestern Territory, including Mississippi River Crossings Memphis, TN., and South, also between points in Southwestern Territory, on the one hand, and stations in Illinois and Western Trunk Line Territory, on the other hand, and only for the accounts of ATSF and/or TPW., in Tariff ICC SWFB 4450, to become effective February 10, 1982.

Grounds for relief: Origin rate relationship.

By the Commission

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-1721 Filed 1-25-82; 8:45 am]
BILLING CODE 7035-01-M

Motor Carriers; Finance Applications; Decision-Notice

As indicated by the findings below, the Commission has approved the following applications filed under 49 U.S.C. 10924, 10926, 10931 and 10932.

We find:

Each transaction is exempt from section 11343 (formerly section 5) of the Interstate Commerce Act, and complies with the appropriate transfer rules.

This decision is neither a major Federal action significantly affecting the quality of the human environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

Petitions seeking reconsideration must be filed within 20 days from the date of this publication. Replies must be filed within 20 days after the final date for filing petitions for reconsiderations; any interested person may file and serve a reply upon the parties to the proceeding. Petitions which do not comply with the relevant transfer rules at 49 CFR 1132.4 may be rejected.

If petitions for reconsideration are not timely filed, and applicants satisfy the conditions, if any, which have been imposed, the application is granted and they will receive an effective notice. The notice will indicate that consummation of the transfer will be presumed to occur on the 20th day following service of the notice, unless either applicant has advised the Commission that the transfer will not be consummated or that an extension of time for consummation is needed. The notice will also recite the compliance requirements which must be met before the transferee may commence operations.

Applicants must comply with any conditions set forth in the following decision-notices within 30 days after publication, or within any approved extension period. Otherwise, the decision-notice shall have no further effect.

It is Ordered:

The following applications are approved, subject to the conditions stated in the publication, and further subject to the administrative requirements stated in the effective notice to be issued hereafter.

By the Commission, Review Board No. 3, Members Krock, Joyce, and Dowell.

MC–FC–79460. By decision of December 28, 1981, issued under 49 U.S.C. 10926 and the transfer rules at 49 CFR 1132, Review Board Number 3 approved the transfer to ARK CITY EXPRESS, INC., of Arkansas City, KS, of Certificate No. MC–57393 (Sub-No. 2) and a portion of Certificate No. MC–57393 (Sub-No. 7), issued to WINTERS TRUCK LINE, INC., of Wichita, KS, which authorize the transportation, as a motor common carrier, over regular routes, of *general commodities*, (with the usual exceptions), as follows: (Sub-2) (a) between Wichita and Ashland, KS, serving all intermediate points and the off-route point of Buttermilk, KS: from Wichita over U.S. Hwy 81 to Wellington, KS, then over U.S. Hwy 160 to Harper, KS, then over KS Hwy 14 to Anthony, KS, then return over KS Hwy 14 to junction U.S. Hwy 160, and then over U.S. Hwy 160 to Ashland, and return over the same route; and between Anthony and Hardtner, KS, over KS Hwy 14, serving the intermediate points of Hazelton and Kiowa, KS, restricted against service to points in the Kiowa and Hardtner commercial zones which are outside the State of KS; and (Sub-7) (a) between Wichita and Wellington, KS, over U.S. Hwy 81, and (b) between Wellington and Ashland, KS, over U.S. Hwy 160, and (c) between Harper and Anthony, KS, over KS Hwy 14, serving all intermediate points in (a), (b), and (c) above. Representative: Charles J. Kimball, 655 Capitol Life Center, 1600 Sherman Street, Denver, CO 80203.

Notes.—TA has been filed. Transferee is authorized to operate as a motor common carrier under MC–121625.

MC–FC–79490. By decision of December 28, 1981, issued under the Transfer Rules at 49 U.S.C. 10926 and 49 CFR 1132, Review Board Number 3 approved the transfer to SAN RAFAEL TRUCK LINE, of Phoenix, AZ, of a portion of Certificate No. MC–127602 (Sub-No. 30)X, issued to DENVER-MIDWEST MOTOR FREIGHT, INC., of Litchfield Park, AZ, which authorizes the transportation, as a motor common carrier, over regular routes, of *general commodities* (except classes A and B explosives), as follows: Paragraph No. 49, between Grand Junction, CO, and Denver, CO, over Interstate Hwy 70; and

Paragraph No. 72, between Phoenix, AZ, and Grand Junction, CO, serving all intermediate points: from Phoenix over AZ Hwy 79 (Interstate Hwy 17) to Flagstaff, AZ, then over US Hwy 89 to junction US Hwy 160, then over US Hwy 160 to Durango, CO, then over US Hwy 550 to Montrose, CO, and then over US Hwy 50 to Grand Junction, and return over the same route. Representatives: William S. Richards, 48 Post Office Place, P.O. Box 2465, Salt Lake City, UT 84110; and Brian K. Ridenour, 1200 N Street, 500 The Atrium, P.O. Box 82028, Lincoln NE 68501.

Notes.—TA has been filed. Transferee is not a motor carrier.

MC–FC–79509. By decision of January 4, 1982 issued under 49 U.S.C. 10926 and the transfer rules at 49 CFR 1132, Review Board Number 3 approved the transfer to NEIL'S BAKERY PRODUCTS TRANSPORTATION CO., INC. (formerly MTS, Inc.) of Permit No. MC–116282 and sub numbers 11, 12, 16, 19, 20, 22, 24, and 29 thereunder issued to NEIL'S BAKERY PRODUCTS TRANSPORTATION CO., INC. (now known as N.I.F. Corp.) authorizing: Bakery products and containers within various specified points in CT, MA, ME, NH, NJ, NY, RI and VT under continuing contract(s) with: MC 116282 Drake's Bakeries, Inc., Roxbury, MA, Continental Baking Company, Rye, NY, Berwick Cake Company, Boston, MA, Drake Bakeries Divisions of the Borden Company, Boston, MA, Drake Bakeries Division of the Borden Company, New York, NY, Lonsdale Bakery Co., Lincoln, RI, Drake's Bakeries, Inc., Boston, MA. Sub No. 11—Leo's Bakery, Inc., Woonsocket, RI. Sub No. 12—Jenny Lee Bakery Division of Elm Farm Foods Co., Lynn, MA. Sub No. 16—Pepperidge Farm, Inc., Norwalk, CT. Sub No. 19—Pepperidge Farm, Inc., Norwalk, CT. Sub No. 20—Borden, Inc., New York, NY. Sub No. 22—Drakes Bakeries, Food Division, Borden, Inc., Wayne, NJ, Pepperidge Farm, Inc., Norwalk, CT, Arnold Bakers, Inc., Greenwich, CT. Sub No. 24—Karnes Kitchens, Ltd., Woodstock, New Brunswick, Canada. Sub No. 29—F. R. Legape Bakery, Inc., Auburn, ME, Karnes Kitchen, Ltd., Woodstock, New Brunswick, Canada, S. B. Thomas, Inc., Totowa, NJ. Representative: John E. Hess, Eaton, Peabody, Bradford & Veague, P.O. Box 1210, Bangor, ME 04401. TA lease is sought. Transferee is not a carrier.

MC–FC–79514. (Republication) (previously published in the **Federal Register** on December 17, 1981) By decision of December 10, 1981, issued under 49 U.S.C. 10926 and the transfer rules at 49 CFR 1132, Review Board number 3 approved the transfer to GLOBAL FORWARDING, INC., A DELAWARE CORPORATION, of Permit No. FF–350 (Sub–No. 1), issued September 15, 1977, to GLOBAL FORWARDING, INC., A CALIFORNIA CORPORATION, authorizing the transportation of (a) *used household goods and unaccompanied baggage and (b) automobiles,* between points in the United States (including HI and AK), restricted in (b) above to the transportation of export-import traffic. Representative: Alan F. Wohlstetter, 1700 K Street, NW, Washington, DC 20006.

Notes.—TA has not been filed. Transferee is not a carrier, but is a wholly-owned subsidiary of transferor. Transferor is a subsidiary of Global Van Lines, Inc., a motor carrier under MC–41098. The purpose of this republication is to correctly identify Transferee as a Delaware Corporation—not a Texas Corporation.

MC–FC–79537. By decision of December 28, 1981 issued under 49 U.S.C. 10926 and the transfer rules at 49 CFR 1132, Review Board Number 3 approved the transfer to SOUTHERN KENTUCKY BUS LINES, INC., of Rockfield, KY, of Certificate No. MC–153247, issued to BOWLING GREEN ALL SPORTS, INCORPORATED, of Bowling Green, KY, authorizing the transportation of *passengers and their baggage,* in charter operations, between points in Allen, Barren, Butler, Simpson, and Warren Counties, KY, on the one hand, and, on the other, points in the United States (except HI). Representative: Louis J. Amato, P.O. Box E, Bowling Green, KY.

Notes.—TA has not been filed. Transferee is not a carrier.

MC–FC–79539. By decision of December 29, 1981 Review Board No. 3 approved the transfer to Maria Freight Ltd., of Lake Orion, MI, of Certificate No. MC–149146 Sub 2 issued to Stoney's Express, Inc., of Pontiac, MI authorizing: Automobile parts and accessories, between Detroit, MI, on the one hand, and, on the other, the facilities of Ford Motor Company at Louisville, KY. Representative: Alex J. Miller, 555 S Woodward, Suite 512, Birmingham, MI 48011.

Note.—TA lease is not sought. Transferee is not a carrier.

MC–FC–79549. By decision of January 5, 1982 issued under 49 U.S.C. 10926 and the transfer rules at 49 CFR 1133, Review Board Number 3 approved the transfer to R. G. HOBELMAN & COMPANY, INC., of Baltimore, MD, of License No. MC–130767 issued to FREIGHT TRANSPORTATION SERVICES, INC., of Baltimore, MD, to engage in operations, as a *broker,* arranging for the transportation of *general commodities,* (except household goods), between all points in the United States. Representative: Frank J. Weiner, 15 Court Square, Boston, MA 02108.

Notes.—TA has not been filed. Transferee is not a carrier.

MC–FC–79551. By decision of January 4, 1982, issued under 49 U.S.C. 10926 and the transfer rules at 49 CFR 1132, Review Board Number 3 approved the transfer to Robin Transport, Inc. which seeks to purchase a portion of Robinson Cartage Company's Certificate No. MC–107103 (Sub No. 28X) authorizing (1) *Clay, concrete, glass or stone products, lumber and wood products, metal products, and pulp, paper and related products,* between points in Chippewa County, MI, on the one hand, and, on the other, points in the United States, and (2) *Forest products* and lumber and wood products, between the ports of entry on the International Boundary line between the United States and Canada in Michigan, on the one hand, and, on the other, points in Michigan, Indiana, Illinois, Ohio, Wisconsin, and Minnesota. Representative: Ronald J. Mastej, 900 Guardian Bldg., Detroit, MI 48226.

Notes.—TA application has not been filed. Transferee is not a carrier.

MC–FC–79552. By decision January 4, 1982 Review Board 3 approved the transfer to Eact Coast Trucks Lines, Inc., of Columbia, SC, of Permit No. MC–143161 Subs 2, 3, and 4 issued to Beverage Transport, Inc., of Columbia, SC, authorizing: a beverage and bottle service under contract with Carolina Carriers South, Inc., Carolina Carriers, Inc., and Carolina Packaging, Inc. from or between facilities in Lexington County and Cheraw, SC, and (radially) various named states. Representative: Raymond P. Rivers, 1130 Bluff Rd, Columbia, SC 29201. TA lease is sought. Transferee is not a carrier.

Agatha L. Mergenovich,
Secretary.

[FR Doc. 82–1722 Filed 1–25–82; 8:45 am]
BILLING CODE 7035–01–M

Motor Carriers; Permanent Authority Decisions; Decision-Notice

The following applications, filed on or after February 9, 1981, are governed by Special Rule of the Commission's Rules of Practice, see 49 CFR 1100.251. Special Rule 251 was published in the **Federal Register** on December 31, 1980, at 45 FR 86771. For compliance procedures, refer to the **Federal Register** issue of December 3, 1980, at 45 FR 80109.

Persons wishing to oppose an application must follow the rules under 49 CFR 1100.252. Applications may be protested *only* on the grounds that applicant is not fit, willing, and able to provide the transportation service or to comply with the appropriate statutes and commission regulations. A copy of any application, including all supporting evidence, can be obtained from applicant's representative upon request and payment to applicant's representative of $10.00.

Amendments to the request for authority are not allowed. Some of the applications may have been modified prior to publication to conform to the Commission's policy of simplifying grants of operating authority.

Findings

With the exception of those applications involving duly noted problems (e.g., unresolved common control, fitness, water carrier dual operations, or jurisdictional questions) we find, preliminarily, that each applicant has demonstrated a public need for the proposed operations and that it is fit, willing, and able to perform the service proposed, and to conform to the requirements of Title 49, Subtitle IV, United States Code, and the Commission's regulations. This presumption shall not be deemed to exist where the application is opposed. Except where noted, this decision is neither a major Federal action significantly affecting the quality of the human environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

In the absence of legally sufficient opposition in the form of verified statements filed on or before 45 days from date of publication (or, if the application later become unopposed), appropriate authorizing documents will be issued to applicants with regulated operations (except those with duly noted problems) and will remain in full effect only as long as the applicant maintains appropriate compliance. The unopposed applications involving new entrants will be subject to the issuance of an effective notice setting forth the compliance requirements which must be satisfied before the authority will be issued. Once this compliance is met, the authority will be issued.

Within 60 days after publication an applicant may file a verified statement in rebuttal to any statement in opposition.

To the extent that any of the authority granted may duplicate an applicant's other authority, the duplication shall be construed as conferring only a single operating right.

Note.—All applications are for authority to operate as a motor common carrier in interstate or foreign commerce over irregular routes, unless noted otherwise. Applications for motor contract carrier authority are those where service is for a named shipper "under contract".

Please direct status inquiries to the Ombudsman's Office, (202) 275–7326.

Volume OP 4–Vol. 1

Decided: January 18, 1982.

By the Commission Review Board No. 2 Members Carleton, Fisher & Williams.

MC 159947, filed January 4, 1982. Applicant: SUNSHINE BROKERAGE, INC., 4415 W. Harrison St., Suite 322, Hillside, IL 60162. Representative: Anthony E. Young, 29 So. LaSalle St., Suite 350, Chicago, IL 60603, (312) 782–8880. As a *broker of general commodities* (except household goods), between points in the U.S.

MC 159996, filed January 7, 1982. Applicant: M. McNAMA, INC., P.O. Box 5243, Salinas, CA 93915. Representative: Edward P. Bocko, P.O. Box 496, Mineral Ridge, OH 44440, (216) 652–2789. As a *broker of general commodities* (except household goods) between points in the U.S.

Volume OP 4–12

Decided: January 11, 1982.

By the Commission, Review Board No. 2, Members Carleton Fisher, and Williams.

MC 1936 (Sub-53), filed January 4, 1982. Applicant: B & P MOTOR EXPRESS COMPANY, 825 W. Federal St., Youngstown, OH 44501. Representative: David A. Turano, 100 E. Broad St., Columbus, OH 43215, (614) 228–1541. Transporting, for or on behalf of the United States Government, *general commodities* (except used household goods, hazardous or secret materials, and sensitive weapons and munitions), between points in the U.S.

MC 159936, filed January 4, 1982. Applicant: MIKE LAURENT, d.b.a. M & D TRUCKING, 6903 Chinook Dr., Yakima, WA 98908. Representative: Mike Laurent (same address as applicant), (509) 966–4180. Transporting *food and other edible products and byproducts intended for human consumption* (except alcoholic beverages and drugs), *agricultural limestone and fertilizers, and other soil conditioners* by the owner of the motor vehicle in such vehicle, between points in the U.S.

MC 159956, filed January 4, 1982. Applicant: JAMES J. BOYLE & CO., 529 Commercial St., San Francisco, CA 94111. Representative: Tsutomu Kozuka, 1500 S.W. First Ave., #320, Portland, OR 97201, (503) 221–0909. As a *broker of general commodities* (except household goods), between points in the U.S.

Volume OP5–09

Decided: January 12, 1982.

By the Commission, Review Board No. 3, Members Krock, Joyce and Dowell.

MC 152229 (Sub-9), filed December 29, 1981. Applicant: SALINAS MOTOR EXPRESS, INC., P.O. Box 177, Salinas, CA 93902. Representative: Ben Ryburn (same address as applicant), 408–757–2991. Transporting, for or on behalf of the United States Government, *general commodities* (except used household goods, hazardous or secret materials, and sensitive weapons and munitions), between points in the U.S.

MC 152838 (Sub-1), filed December 21, 1981. Applicant: MALISSA COMPANY INCORPORATED, 1112 Haynes Drive, P.O. Box 2502, Leesville, LA 71446. Representative: Marvin E. Haynes (same address as applicant), (318) 239–9561. Transporting, (1) for or on behalf of the United States Government, *general commodities* (except used household goods, hazardous or secret materials, and sensitive weapons and munitions), between points in the U.S., (2) *food and other edible products and byproducts intended for human consumption* (except alcoholic beverages and drugs), *agricultural limestone and fertilizers, and other soil conditioners* by the owner of the motor vehicle in such vehicle, between points in the U.S., (3) *used household goods* for the account of the United States Government incident to the performance of a pack-and-crate service on behalf of the Department of Defense between points in the U.S., and (4) as a *broker of general commodities* (except household goods), between points in the U.S.

MC 159908, filed December 29, 1981. Applicant: FREDERICK J. VERCHOT, d.b.a. A-TRUCK SERVICE, P.O. Box 1706, Oneco, FL 33558. Representative: Susan Nichols, P.O. Drawer 17308, Pensacola, FL 32522, 800–874–1558. Transporting *food and other edible products and byproducts intended for human consumption* (except alcoholic beverages and drugs), *agricultural limestone and fertilizers, and other soil conditioners*, by the owner of the motor vehicle in such vehicle, between points in the U.S.

Volume OP–5–11

Decided: January 18, 1982.

By the Commission, Review Board No. 3, Members Krock, Joyce and Dowell.

MC 149608 (Sub-4), filed January 5, 1982. Applicant: REBEL EXPRESS COMPANY, 6241 North Dixie Highway,

Fort Lauderdale, FL 33334. Representative: David A. Turano, 100 E. Broad St., Columbus, OH 43215, (614) 228–1541. Transporting for or on behalf of the United States Government, *general commodities* (except used household goods, hazardous or secret materials, and sensitive weapons and munitions), between points in the U.S.

MC 159939, filed January 5, 1982. Applicant: GLENN L. & ROBERT G. MORLAN, d.b.a. MORLAN TRUCKING, Rt. 2, Box 76, Moses Lake, WA 98837. Representative: Glenn L. Morlan (same address as applicant), (509) 765–7288. Transporting *food and other edible products and byproducts intended for human consumption* (except alcoholic beverages and drugs), *agricultural limestone and fertilizers, and other soil conditioners,* by the owner of the motor vehicle in such vehicle, between points in the U.S.

MC 159949, filed January 5, 1982. Applicant: RUSSELL R. WILSON, d.b.a. COLSTRIP COMMUTER SERVICE, 136 Moore Lane #6, Billings, MT 59104–1241. Representative: Russell R. Wilson (same address as applicant), 406–245–5002.Transporting *general commodities* (except classes A and B explosives, household goods as defined by the Commission, and commodities in bulk), between Billings and Colstrip, MT on the one hand, and, on the other, points in the U.S.

Volume No. OP–5–14

Decided: January 19, 1981.

By the Commission, Review Board No. 3, Members Krock, Joyce and Dowell.

MC 71718 (Sub-5), filed January 5, 1982. Applicant: SPOKANE TRANSFER & STORAGE CO., North 117 Napa, Spokane, WA 99202. Representative: Dale D. Ross (same address as applicant), (509) 535–7636. Transporting *Used household goods* for the account of the United States Government incident to a pack-and-crate service on behalf of the Department of Defense, between points in the U.S.

MC 159999, filed January 7, 1982. Applicant: DONALD G. OSTRANDER, 2629 SE 166th Ave., Portland, OR 97236. Representative: Donald G. Ostrander (same address as above), (503) 760–1116. Transporting *food and other edible products and byproducts intended for human consumption* (except alcoholic beverages and drugs), *agricultural limestone and fertilizer, and other soil conditioners,* between points in the U.S.

Volume OP2–12

Decided: January 12, 1982.

By the Commission, Review Board No. 1 Members, Parker, Chandler and Fortier.

MC 155993 (Sub-2), filed January 4, 1982. Applicant: ISIS LEASING CORPORATION, 5800 Stilwell, Kansas City, MO 64120. Representative: E. Wayne Farmer, City Center Square—27th Floor, P.O. Box 26010, Kansas City, MO 64196, (816) 474–6420. Transporting, for or on behalf of the United States Government *general commodities* (except used household goods, hazardous or secret materials, and sensitive weapons and munitions), between points in the U.S.

MC 159953, filed January 4, 1982. Applicant: JENSEN & ASSOCIATES, INC., 355 South Santa Fe, Los Angeles, CA 90013. Representative: Frederick J. Coffman, P.O. Box 1455, Upland, CA 91786, (714) 981–9981. As a *broker* of *general commodities* (except household goods), between points in the U.S.

Volume No. OP–3–009

Decided: January 12, 1982.

By the Commission, Review Board No. 2 Members Carleton, Fisher and Williams.

MC 159804, filed January 5, 1982. Applicant: CITY DELIVERY SERVICE, 601 South 22nd St., Fort Smith, AR 72901. Representative: Don Jordan (same address as applicant), (501) 783–2088. Transporting *shipments weighing 100 pounds or less* if transported in a motor vehicle in which no one package exceeds 100 pounds, between points in the U.S.

MC 159925, filed January 4, 1982. Applicant: CUSTOM FREIGHT SALES, INC., 5230 Olentangy Dr., Dayton, OH 45431. Representative: Stephen J. Habash, 100 E. Broad St., Columbus, OH 43215, (614) 228–1541. As a *broker of general commodities* (except household goods), between points in the U.S.

MC 159985, filed January 4, 1982. Applicant: N. WAYNE VAWDREY, d.b.a. V. X. R. SUPPLY, 535 W 5987 S, Murray, UT 84017. Representative: Irene Warr, 311 S. State St., Suite 280, Salt Lake City, UT 84111, (801) 531–1300. Transporting *food and other edible products and byproducts intended for human consumption* (except alcoholic beverages and drugs), *agricultural limestone and fertilizers,* and *other soil conditioners* by the owner of the motor vehicle in such vehicle, between points in the U.S.

Volume OP 3–012

Decided: January 20, 1982.

By the Commission, Members Carleton, Fisher and Williams.

MC 126635 (Sub-6), filed January 6, 1982. Applicant: CHRISTIE-LAMBERT VAN & STORAGE CO., INC.,1010 6th Ave N., Kent, WA 98031. Representative: Michael D. Duppenthaler, 211 S. Washington St., Seattle, WA 98104, (206) 622–3220. As a broker of *general commodities* (except household goods), between points in the U.S.

MC 160014, filed January 5, 1982. Applicant: ROBERT R. EBBERT, d.b.a. ROBERT EBBERT TRUCKING, 1200 S.E. 6th St., Prineville, OR 97754. Representative: Robert R. Ebbert (same address as applicant) (503) 447–4335. Transporting *food and other edible products and byproducts intended for human consumption* (except alcoholic beverages and drugs), *agricultural limestone and fertilizers, and other soil conditioners,* by the owner of the motor vehicle in such vehicle, between points in the U.S.

MC 160015, filed January 8, 1982. Applicant: GLENN R. WRIGHT, P.O. Box 33, Tolleson, AZ 85353. Representative: Harry F. Horak, 5001 Brentwood Stair Rd., Suite 115, Fort Worth, TX 76112, (817) 457–0804. Transporting *food and other edible products and byproducts intended for human consumption* (except alcoholic beverages and drugs), *agricultural limestone and fertilizers, and other soil conditioners* by the owner of the motor vehicles in such vehicle, between points in the U.S.

MC 160025, filed January 11, 1982. Applicant: SCAC TRANSPORT (USA), INC., 405 Lexington Ave., New York, NY 10007. Representative: Richard K. Bernstein, 485 Madison Ave., New York, NY 10022, (212) 371–8700. As a *broker of general commodities,* (except household goods), between points in the U.S

MC 160074, filed January 11, 1982. Applicant: TRI–Border Transportation, INC., P.O. Box 258, Port Orford, OR 97465. Representative: John A. Anderson, Suite 801–The 1515 Bldg., 1515 SW 5th Ave., Portland, OR 97201, (503) 227–4586. As a broker of *general commodities* (except household goods), between points in the U.S.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82–1891 Filed 1–25–82; 8:45 am]

BILLING CODE 7035–01–M

[Volume No. 222]

Motor Carriers; Permanent Authority Decisions; Restriction Removals; Decision-Notice

Decided: January 20, 1982.

The following restriction removal applications, filed after December 28, 1980, are governed by 49 CFR 1137. Part

1137 was published in the **Federal Register** of December 31, 1980, at 45 FR 86747.

Persons wishing to file a comment to an application must follow the rules under 49 CFR 1137.12. A copy of any application can be obtained from any applicant upon request and payment to applicant of $10.00.

Amendments to the restriction removal applications are not allowed.

Some of the applications may have been modified prior to publication to conform to the special provisions applicable to restriction removal.

Findings

We find, preliminarily, that each applicant has demonstrated that its requested removal of restrictions or broadening of unduly narrow authority is consistent with 49 U.S.C. 10922(h).

In the absence of comments filed within 25 days of publication of this decision-notice, appropriate reformed authority will be issued to each applicant. Prior to beginning operations under the newly issued authority, compliance must be made with the normal statutory and regulatory requirements for common and contract carriers.

By the Commission, Restriction Removal Board, Members Sporn, Ewing, and Shaffer.

Agatha L. Mergenovich,

Secretary.

MC 682 (Sub-29)X, previously filed 9–3–81, and noticed in the **Federal Register** of February 22, 1981, republished as follows: Applicant: BURNHAM VAN SERVICE, INC., P.O. Box 7966, Columbus, GA 31908. Representative: Paul F. Sullivan, 711 Washington Building, Washington, DC 20005. Applicant seeks to remove restrictions in its Sub-No. 26X certificate to broaden the commodity description in part (1) from "household goods, as defined by the Commission" to "household goods and furniture and fixtures" in its authority to operate between points in the U.S. Sub-No. 26X superseded applicant's Sub-Nos. 11 and 12F. This application previously was denied. The Commission's decision in No. MC–8575 (Sub-No. 8)X, *Ferguson Van Lines, Inc.* (not printed) served 1–12–82 requires this Board to refile and republish the application.

MC 7585 (Sub-7)X, filed August 25, 1981, previously noticed in the **Federal Register** of September 8, 1981, republished as follows: Applicant: ANTHONY P. SPARACINO AND RALPH SPARACINO, a partnership, d.b.a. SPARACINO BROTHERS, P.O. Box 1382, 1031 Capouse Avenue, Scranton, PA 185011. Representative: David E. Tinker, 1000 Conn. Ave., NW Suite 1112, Washington, DC 20036. Applicant seeks to remove restrictions in its Sub-Nos. 2 and 6 certificates to (1) broaden the community description to "household goods and furniture and fixtures" from household goods in both subs. This portion of the application previously was denied. The Commission's decision in No. MC–8575 (Sub-No. 8)X, *Ferguson Van Lines, Inc.* (not printed) served 1–12–82 requires this Board to republish the application.

MC 6992 (Sub-20)X, previously filed July 31, 1981 and noticed in the **Federal Register** of August 24, 1981, republished as follows: Applicant: AMERICAN RED BALL TRANSIT COMPANY, INC., P.O. Box 1127, Indianapolis, IN 46206. Representative: Alan F. Wohlstetter, 1700 K Street NW., Washington, DC 20006. Applicant seeks to remove restrictions in its Sub-Nos. 10 and 16 certificates to (1) broaden the commodity description from household goods, as defined by the Commission, to "household goods, and furniture and fixtures." This application previously was denied. The Commission's decision in No. MC–8575 (Sub-No. 8)X, Ferguson Van Lines, Inc. (not printed) served 1–12–82 requires this Board to refile and republish the application.

MC 93620 (Sub-14)X, filed September 21, 1981, previously noticed in **Federal Register** on October 16, 1981, republished to notice the following omissions: Applicant: STERLING TRUCKING, INC., 721 Waverly St., Framingham, MA 01701. Representative: Frank J. Weiner, 15 Court Square, Boston, MA 02108. Sub-No. 13 (identified in previous notice as Lead; reissued as Sub-No. 13 pursuant to MC–FC–78602): (1) Authorize radial operations in lieu of one-way authority; (2) eliminate the service restriction "except those located on, south, and east of U.S. Highway 202" in the irregular route portion of the certificate.

MC 111676 (Sub-6)X, previously filed September 9, 1981, and noticed in the **Federal Register** of October 5, 1981, republished as follows: Applicant: CROWDER'S TRANSFER & STORAGE COMPANY, INC., 1219 First Street, Alexandria, VA 22314. Representative: Thomas R. Kingsley, 10614 Amherst Avenue, Silver Spring, MD 20902. Applicant seeks to remove restrictions in its Sub-No. 4 certificate to broaden the commodity description from household goods, as defined by the Commission, to "household goods and furniture and fixtures and materials, equipment, and supplies used in the manufacture, sale and distribution of furniture and fixtures." This application previously was denied. The Commission's decision in No. MC–8575 (Sub-No. 8)X, Ferguson Van Lines, Inc. (not printed) served 1–12–82, requires this Board to refile and republish the application.

MC 113651 (Sub-350)X, filed December 8, 1981, previously noticed in the **Federal Register** of December 18, 1981, republished as follows: Applicant: INDIANA REFRIGERATOR LINES, INC., 10838 Old Mill Road, Suite 1, Omaha, NE 68154. Representative: James F. Crosby, 7363 Pacific St., Suite 210B, Omaha, NE 68114. Subs 142, 203, 244, and 336F, broaden the commodity description from meat, meat products, meat by-products and articles distributed by meat packinghouses to "food and related products and chemicals and related products." The purpose of republication is to include chemicals and related products in the proposed commodity description.

MC 125353 (Sub-3)X, filed December 7, 1981, previously noticed in the **Federal Register** of December 30, 1981, republished as corrected this issue. Applicant: ROCHESTER AIR FREIGHT SERVICE CORPORATION, 73 Deep Rock Road, Rochester, NY 14624. Representative: Robert D. Gunderman, 101 Niagara Street, Buffalo, NY 14202. Sub-No. 1: to Livingston, Monroe, Ontario, and Wayne Counties, NY for the Rochester-Monroe County Airport, NY; Bergen, Essex, Hudson, Middlesex, Morris, Passaic, and Somerset Counties, NJ, and Kings, New York, Queens and Richmond Counties, NY, for Newark Airport, NJ; Albany, Rensselaer, Saratoga, and Schenectady Counties, NY, for Albany County Airport, NY; Broome County, NY, and Susquehanna County, PA, for Broome County Airport, NY; Chemung County, NY, and Bradford County, PA, for Chemung County Airport, NY; Erie and Niagara Counties, NY, for the Greater Buffalo International Airport, NY; Jefferson County, NY, for Watertown Airport, NY; Oneida and Herkimer Counties, NY, for Oneida County Airport, NY; Madison, Onondaga and Oswego Counties, NY, for Clarence E. Hancock Airport, NY; New York, for LaGuardia Airport and John F. Kennedy International Airport, NY; St. Lawrence County, NY, for Massena Airport, NY; Tompkins County, NY, for Tompkins County Airport, NY; and Cuyahoga, Geauga, Lake, Lorain, Medina, Portage, and Summit Counties, OH, for Cleveland-Hopkins Airport, OH. The purpose of this republication is to correct the territorial broadening noted above.

MC 134440 (Sub-4)X, previously filed August 14, 1981, and noticed in the **Federal Register** of September 8, 1981, republished as follows: Applicant: LA VENTURE BROS. VAN LINES, d.b.a. La Venture Bros. Transfer and La Venture Bros. Van Lines, 3808 E. Slauson Avenue, Maywood, CA 90270. Representative: Robert J. Gallagher, 1000 Connecticut Avenue NW., Suite 1200, Washington, D.C. 20036. Applicant seeks to remove restriction from its Sub-No. 3 certificate to broaden the commodity description from household goods to "household goods and furniture and fixtures." This application previously was denied. The Commission's decision in MC-8575 (Sub-8)X, Ferguson Van Lines, Inc. (not printed) served 1-12-82 requires us to refile and republish this application.

MC 135895 (Sub-132)X, filed January 7, 1982. Applicant: B & R DRAYAGE, INC., P.O. Box 8534, Battlefield Station, Jackson, MS 39204. Representative: Douglas C. Wynn, P.O. Box 1295, Greenville, MS 38701. Sub 127X: applicant seeks to broaden cities to counties. This board previously broadened some of these cities to counties but omitted certain counties which are included within their respective commercial zones. Part 7—Rankin County (Flowood), MS to Hinds and Rankin Counties, MS; parts 12, 19(h) & (i), 27(b), & 32—Houston, TX to Brazoria, Chambers, Ft. Bend, Galveston, Harris, Liberty, Montgomery and Waller Counties, TX; parts 12, 19(h), & 40(b)—Jacksonville, FL to Baker, Bradford, Clay, Duvall, Nassau, and St. Johns Counties, FL and Camden and Charlton Counties, GA; parts 12, 19(a) & (g) & 26—Baton Rouge, LA to Ascension, East Baton Rouge, East Feliciana, Iberville, Pointe Coupee, West Baton Rouge and West Feliciana Parishes, LA; part 16—Mobile, AL to Mobile and Baldwin Counties, AL and Jackson County, MS; parts 19(a) & 27(b)—Fort Worth, TX to Dallas, Denton, Hood, Johnson, Parker, Wise and Tarrant Counties, TX; part 19(a) & (b)—Monroe, LA to Ouachita Parish, LA; part 19(a)—Bolivar County (Cleveland), MS to Bolivar and Sunflower Counties, MS; part 19(a)—Adams County (Natchez), MS to Adams County, MS and Concordia Parish, LA; parts 19(b), 29, 50(c), & 71(b)—Memphis, TN to points in Fayette, Shelby and Tipton Counties, TN; DeSoto, Marshall and Tunica Counties, MS, and Crittenden and St. Francis Counties, AR; part 19(b)—La Fourche Parish (Thibodaux), LA to La Fourche and Terrebonne Parishes, LA; part 19(b)—Forest County (Hattiesburg), MS to Forest and Lamar Counties, MS; part 19(c)—San Antonio, TX, to Atascosa, Bandera, Bexar, Comal, Guadalupe, Kendall, Medina, and Wilson Counties, TX; parts 19(d) & 83(a)—Washington County (Greenville), MS to Bolivar and Washington Counties, MS and Chicot County, AR; part 19(d)—Leflore County (Greenwood), MS to Carroll and Leflore Counties, MS; parts 19(e), 29 & 50(a)—Longview, TX to Gregg, Harrison, Rusk and Upshur Counties, TX part 19(f)—New Orleans, LA to Jefferson, Orleans, Placquemine, St. Bernard, St. Charles, St. John The Baptist, and St. Tammany Parishes, LA, and Hancock County, MS; part 19(f)—Galveston, TX to Chambers, Galveston, and Harris Counties, TX; parts 19(g) & 50(b)—Albany, GA to Dougherty, Lee, Terrell and Worth Counties, GA; part 19(h)—Tampa, FL to Hillsborough, Pasco, and Pinellas Counties, FL; part 19(i)—Terrebonne Parish (Houma), LA to LaFourche and Terrebonne Parishes, LA; parts 27(b), 34(a), 56 & 57(a)—Dallas, TX to Collin, Dallas, Denton, Ellis, Hunt, Johnson, Kaufman, and Tarrant Counties, TX; part 28—Clarke County (Pachuta), MS to Clarke and Jasper Counties, MS and Bronson, MO to Stone and Taney Counties, MO; part 32(a)—Birmingham, AL to Jefferson, Shelby and St. Clair Counties, AL; parts 34(c)—St. Petersburg, FL to Hillsborough, Manatee and Pinellas Counties, FL; part 34(d)—Charlotte, NC to Cabarrus, Gaston, Lincoln, Mecklenburg and Union Counties, NC and York County, SC; parts 34(e) & 40(a)—Atlanta, GA to Clayton, Cobb, DeKalb, Douglas, Fayette, Fulton, Gwinette, Henry and Rockdale Counties, GA part 37—Oklahoma City, OK to Canadian, Grady, Kingfisher, Lincoln, Logan, McClain, Oklahoma, and Pottawatomie Counties, OK; part 40(a)—Lowndes County (Valdosta), GA to Brooks and Lowndes Counties, GA; part 40(c)—Pearl River County (Picayune), MS to Hancock and Pearl River Counties, MS and St. Tammany Parish, LA; parts 41 & 67—Warren County (Vicksburg), MS to Warren County, MS and Madison Parish, LA; part 50(b)—Rockingham County (Eden), NC to Rockingham County, NC and Henry and Pittsylvania Counties, VA; parts 52(c)—Monroe County (Clarendon), AR to Monroe and Prairie Counties, AR; part 52(d)—Salt Lake City, UT to Davis, Morgan and Salt Lake Counties, UT; part 66—Alcorn County (Corinth), MS to Alcorn County, MS and McNairy County, TN; parts 67, 68(b) and 73—Jackson, MS to Hinds, Madison and Rankin Counties, MS; part 68(a)—Mississippi County (Blytheville), AR to Mississippi County, AR and Dunklin County, MO; part 68(c)—Fairfield County (Bridgeport), CT to Fairfield and New Haven Counties, CT part 68(d)—Paterson, NJ to Bergen, Essex, Morris, and Passiac Counties, NJ; part 76(b)—Buncombe County (Arden), NC to Buncombe and Henderson Counties, NC; part 80—St. John The Baptist Parish (Reserve), LA to St. John The Baptist and St. Charles Parishes, LA; part 83(b)—St. Clair County (Memphis), MI to Macomb and St. Clair Counties, MI.

MC 143553 (Sub-8)X, filed December 31, 1981. Applicant: CONTINENTAL TRANSPORT SYSTEMS, INC., 35 Main Street, P.O. Box 236, Versailles, CT 06383. Representative: Bradford I. Greene (same as applicant). Subs 2, 4F, and 5 permits: (1) broaden paper, paper products, and supplies and materials to "pulp, paper and related products, and supplies and materials", Sub 2; (2) remove except commodities in bulk restriction and the facilities limitation, Sub 2; and (3) broaden the territorial authority to between points in the U.S. (except AK and HI), under continuing contract(s) with named shippers.

MC 146840 (Sub-9)X, filed December 18, 1981. Applicant: BOYCHUKS' TRANSPORT LTD., P.O. Box 399, Black Eagle, MT 59414. Representative: Kenneth G. Thomas (same address as applicant). Subs 1F, 3F, 5F, 6F and 7F (1) broaden to: (a) "general commodities (except classes A & B explosives, and Household Goods as defined by the Commission)" from general commodities (with usual exceptions), Sub 1F; (b) "chemicals and related products" from lime and limestone products, Sub 3F; (c) "furniture and fixtures" from new furniture and materials, equipment and supplies used in the manufacture and distribution of new furniture, Sub 5F; (d) "textile mill products" from (1) rugs, carpets, and floor coverings and (2) materials and supplies used in the installation and maintenance of the commodities in (1) above, Sub 6F; (e) "pulp, paper and related products" from fiberboard, Sub 7F; (2) to radial service in Subs 3F, 5F, 6F and 7F, (3) remove "in containers" and "in bulk" restriction in Subs 3F, 5F and 6F, (4) delete foreign commerce only restriction in Sub 3.

[FR Doc. 82-1890 Filed 1-25-82; 8:45 am]
BILLING CODE 7035-01-M

Motor Carriers; Permanent Authority Decisions; Decision-Notice

The following applications, filed on or after February 9, 1981, are governed by Special Rule of the Commission's Rules of Practice, see 49 CFR 1100.251. Special Rule 251 was published in the **Federal**

Register of December 31, 1980, at 45 FR 86771. For compliance procedures, refer to the Federal Register issue of December 3, 1980, at 45 FR 80109.

Persons wishing to oppose an application must follow the rules under 49 CFR 1100.252. A copy of any application, including all supporting evidence, can be obtained from applicant's representative upon request and payment to applicant's representative of $10.00.

Amendments to the request for authority are not allowed. Some of the applications may have been modified prior to publication to conform to the Commission's policy of simplifying grants of operating authority.

Findings

With the exception of those applications involving duly noted problems (e.g., unresolved common control, fitness, water carrier dual operations, or jurisdictional questions) we find, preliminarily, that each applicant has demonstrated a public need for the proposed operations and that it is fit, willing, and able to perform the service proposed, and to conform to the requirements of Title 49, Subtitle IV, United States Code, and the Commission's regulations. This presumption shall not be deemed to exist where the application is opposed. Except where noted, this decision is neither a major Federal action significantly affecting the quality of the human environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

In the absence of legally sufficient opposition in the form of verified statements filed on or before 45 days from date of publication, (or if the application later becomes unopposed) appropriate authorizing documents will be issued to applicants with regulated operations (except those with duly noted problems) and will remain in full effect only as long as the applicant maintains appropriate compliance. The unopposed applications involving new entrants will be subject to the issuance of an effective notice setting forth the compliance requirements which must be satisfied before the authority will be issued. Once this compliance is met, the authority will be issued.

Within 60 days after publication an applicant may file a verified statement in rebuttal to any statement in opposition.

To the extent that any of the authority granted may duplicate an applicant's other authority, the duplication shall be construed as conferring only a single operating right.

Note.—All applications are for authority to operate as a motor common carrier in interstate or foreign commerce over irregular routes, unless noted otherwise. Applications for motor contract carrier authority are those where service is for a named shipper "under contract".

Please direct status inquiries to the Ombudsman's Office, (202) 275-7326.

OP5-13

Decided: January 19, 1982.

By the Commission, Review Board No. 3, Members Krock, Joyce and Dowell.

MC 60848 (Sub-1), filed January 5, 1982. Applicant: ACE MOVING & STORAGE, INC., d.b.a. EASTERN MOVING SYSTEMS, 1898 Leland Drive, Marietta, GA 30067. Representative: Alan E. Serby, 3390 Peachtree Rd., NE., 5th Floor, Lenox Towers, South, Atlanta, GA 30326, (404) 262-7855. Transporting *household goods* as defined by the Commission, between points in the United States in and east of WI, IL, MO, OK, and TX.

MC 108359 (Sub-8), filed January 6, 1982. Applicant: WESTERN NEW YORK MOTOR LINES, INC., d.b.a. EMPIRE TRAILWAYS, 67 Chestnut St., Rochester, NY 14604. Representative: Lawrence E. Lindeman, 4660 Kenmore Ave., Suite 1203, Alexandria, VA 22304. (703) 751-2441. Transporting *passengers and their baggage*, and express and newspapers in the same vehicle with passengers, between Rochester and Corning, NY from Rochester over Interstate Hwy 590 to junction Interstate Highways 590 and 390, then over Interstate Hwy 390 to Corning, and return over the same route, serving all intermediate points.

MC 118978 (Sub-13), filed January 7, 1982. Applicant: MERCURY EXPRESS, LTD., 2100 United Blvd., Coquitlam, BC, Canada V3K 3V4. Representative: Jack R. Davis, 1100 IBM Bldg., Seattle, WA 98101 (206) 624-7373. Transporting *pulp, paper and related products* between points in WA, OR, CA, NM, CO, TX, ID, MT, UT, NV, and AZ, on the one hand, and, on the other, points on the International boundary line between the U.S. and Canada.

MC 136818 (Sub-140), filed January 8, 1982. Applicant: SWIFT TRANSPORTATION COMPANY, INC., 5601 W. Mohave, Phoenix, AZ 85031. Representative: Donald E. Fernaays, 4040 E. McDowell Rd., Suite 320, Phoenix, AZ 85008, (602) 275-3124. Transporting *food and related products* (except in bulk), between points in Brown and Wood Counties, WI, Barry, Jasper, Lawrence, Newton, and Greene County, MO, and Cache County, UT, on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 149389 (Sub-5), filed December 28, 1981. Applicant: DELIVERY SERVICE CORPORATION, P.O. Box 448, Dearborn, MI 48126. Representative: William B. Elmer, 615 E. Eighth St., Traverse City, MI 49684, (616) 941-5313. Transporting *medicine and toilet preparations*, between points in St. Louis County, MO, Union County, NJ, and Wake County, NC, on the one hand, and, on the other, points in the U.S.

MC 150398 (Sub-10), filed January 6, 1982. Applicant: BLUE EXPRESS, INC., P.O. Box 292, Canton, SD 57013. Representative: Rick A. Rude, 1730 Rhode Island Ave., NW., Suite 611, Washington, DC 20036, 202-223-5900. Transporting *general commodities* (except household goods as defined by the Commission and classes A and B explosives), between facilities used by Road Mark, Inc., at points in the U.S., on the one hand, and, on the other, points in the U.S.

MC 152649 (Sub-9), filed January 11, 1982. Applicant: RIVERLAND TRUCKING CO., INC., P.O. Drawer BC, Reserve, LA 70084. Representative: Norman A. Cooper, 145 W. Wisconsin Ave., Neenah, WI 54956, 414-722-2848. Transporting *general commodities* (except classes A and B explosives and household goods as defined by the Commission), between points in the U.S. under continuing contract(s) with Scott Paper Company of Philadelphia, PA.

MC 153138 (Sub-2), filed January 8, 1982. Applicant: LARRY DON EASLEY d.b.a. EASLEY TRUCKING, P.O. Box 103, Ben Wheeler, TX 75754. Representative: Edwin M. Snyder, P.O. Box 45538, Dallas, TX 75245, 214-358-3341. Transporting *machinery, and metal products*, between points in Smith County, TX on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 153719 (Sub-1), filed December 21, 1981. Applicant: COMMERCIAL CARTAGE CORPORATION, 23845 Ecorse Road, P.O. Box 157, Taylor, MI 48180. Representative: Paul E. Dufault, 1222 Catalpa Drive, Royal Oak, MI 48060, (313) 399-7272. Transporting *general commodities*, between points in St. Joseph, Branch, Hillsdale, Lenawee, Monroe, Wayne, Washtenaw, Jackson, Calhoun, Kalamazoo, Barry, Eaton, Ingham, Livingston, Oakland, Macomb, St. Clair, Lapeer, Genesee, Shiawassee, Clinton, Ionia, Kent, Montcalm, Gratiot, Saginaw, Tuscola, Sanilac, Huron, Bay, Midland, Isabella, and Mecosta Counties, MI and Lucas and Wood Counties, OH.

MC 157049 (Sub-2), filed January 8, 1982. Applicant: AMATO MOTORS,

INC., 977 West Cermak Rd., Chicago, IL 60608. Representative: Anthony E. Young, 29 South LaSalle St., Suite 350, Chicago, IL 60603, (312) 782–8880. Transporting *such commodities* as are dealt in or used by manufacturers and distributors of telecommunication equipment, between points in the U.S., under continuing contract(s) with Reliance Comm Tech, a division of Reliance Electric, of Franklin Park, IL.

MC 157948, filed December 30, 1981. Applicant: ROBERT J. WHITE d.b.a. YUBA SUTTER AIRPORTER, 954 Cooper Ave., Yuba City, CA 95901. Representative: Robert J. White, 1534 La Palma Court, Yuba City, CA 95991, (916) 671–1199. Transporting *passengers and their baggage* in same vehicle with passengers, in vehicles of 16 passengers or less (excluding the driver), in charter operations between Sacramento, Yuba City, and Marysville, CA, on the one hand, and, on the other, Lake Tahoe and Reno, NV.

MC 158878, filed December 21, 1981. Applicant: ZIMMERMAN TRUCKING, INC., P.O. BOX 306, Morgantown, IN 46160. Representative: Robert W. Loser II, 1101 Chamber of Commerce Bldg., Indianapolis, IN 46204, (317) 635–2339. Transporting *malt beverages*, between points in IN on and south of IN Hwy 28, on the one hand, and, on the other, Milwaukee, WI, Detroit, MI, Peoria, IL, St. Paul, MN, Memphis, TN, Columbus, OH, Newport, KY, and St. Louis, MO.

MC 159579, filed January 11, 1982. Applicant: SIMPSON'S CARRIER, INC., Rural Route, Box 72, Plainview, NE 68769. Representative: Bradford E. Kistler, P.O. Box 82028, Lincoln, NE 68501, 402–475–6761. Transporting *such commodities* as are dealt in or used by manufacturers and distributors of metal buildings, between Milwaukee, WI; Oklahoma City, OK; and points in Cullman County, AL, on the one hand, and, on the other, points in CO, IA, KS, MN, MO, MT, NE, ND, SD, and WY.

MC 159809, filed January 6, 1982. Applicant: ATLANTIC HORIZON TRANS TOURS, INC., 2100 E. Verona Blvd., W. Atlantic City, NJ 08232. Representative: Dean N. Wolfe, Suite 145, 4 Professional Dr., Gaithersburg, MD 20879, 301–840–8565. Transporting *passengers and their baggage* in the same vehicle with passengers, in charter operations, between points in the U.S. under continuing contract(s) with Playboy Hotel & Casino, Tropicana Hotel & Casino, and Sands Hotel & Casino, all of Atlantic City, NJ.

MC 159889, filed December 28, 1981. Applicant: NEW CASTLE COLD STORAGE TRANSPORTATION, INC., 100 East Oakwood Way, New Castle, PA 16105. Representative: Harold G. Hernly, Jr., P.O. Box 1281, Old Town Station, Alexandria, VA 22313, (703) 836–6115. Transporting *general commodities* (except classes A and B explosives), between points in the U.S., under continuing contract(s) with Robert D. Johnston, d/b/a New Castle Cold Storage, Shenango Phenolics Corporation, Crisci Food Equipment Company, and Waldman's Meats, Inc., all of New Castle, PA.

MC 159919, filed January 5, 1982. Applicant: A TOUCH OF CLASS LIMOUSINES, INC., 5517 Roberts Ave., Sea Isle City, NJ 08243. Representative: Frank J. Pacifico (same address as applicant), (609) 263–8749. Transporting *passengers and their baggage*, in the same vehicle with passengers, in special operations, limited to the transportation of not more than eight passengers in the same vehicle (including the driver), between points in NJ, on the one hand, and, on the other, points in VA, MD, DE, PA, NJ, CT, MA, NY, and DC.

MC 159988, filed January 6, 1982. Applicant: KILLINGTON SKI TOURS, INC., 11 South American Street, Woodbury, NJ 08096. Representative: Peter D. Campana (Same address as applicant), (609) 845–5729. To operate as a *broker* at Woodbury, NJ, arranging for the transportation of *passengers and their baggage*, in the same vehicle with passengers, between Killington, VT, on the one hand, and, on the other, points in NJ and PA.

OP–5–10

Decided: January 18, 1982.

By the Commission Review Board No. 3, members Krock, Joyce, and Dowell.

MC 116118 (Sub-7), filed January 7, 1982. Applicant: GARDINER'S EXPRESS, INC, MR 1 Moss Hill Road, Hammonton, NJ 08037. Representative: Fritz R. Kahn, Suite 1100, 1660 L St., NW, Washington, DC 20036, (202) 452–7484. Transporting *general commodities*, (except classes A and B explosives) between points in CT, DE, MA, MD, NJ, NY, PA, RI, VA, and DC.

MC 138018 (Sub-71), filed January 4, 1982. Applicant: RFI TRANSPORT, INC., P.O. Box 17560, Denver, CO 80217. Representative: Jo Ann M. Harvey (same address as applicant), 303–292–1960. Transporting *food and related products*, between points in the U.S.

MC 143209 (Sub-22), filed January 4, 1982. Applicant: HOUSTON FREIGHTWAYS, INC., P.O. Box 607, Galena Park, TX 77545. Representative: C. W. Ferebee, 3910 F.M. 1960 W, Suite 106, Houston, TX 77068, 713–537–8156. Transporting (1) *commodities which because of their size or weight require the use of special equipment*, and (2) *metal articles*, between points in the U.S.

MC 143578 (Sub-3), filed January 6, 1982. Applicant: WILSON BUS CO., INC., 314 Alexander St., Fayetteville, NC 28301. Representative: Wilmer B. Hill, 805 McLachlen Bank Bldg., 666 Eleventh Street N.W., Washington, DC 20001, 202–625–9243. Transporting *passengers and their baggage* in the same vehicle with passengers, in special and charter operations, beginning and ending at points in Beaufort, Bertie, Brunswick, Carteret, Columbus, Craven, Duplin, Halifax, Jones, Lenoir, Martin, New Hanover, Onslow, Pender and Washington Counties, NC, and Horry and Marion Counties, SC, and extending to points in the U.S.

MC 144369 (Sub-2), filed January 5, 1982. Applicant: GERARDO & SON MOTOR SERVICE, INC., 9850 Balmoral Avenue, Rosemont, IL 60018. Representative: Donald S. Mullins, 1033 Graceland Ave., Des Plaines, IL 60016, (312) 298–1094. Transporting *such commodities* as are dealt in by retail department stores, between points in the U.S. (except AK and HI), under continuing contract(s) with Zayre Corp. of Framingham, MA.

MC 145559 (Sub-18), filed January 4, 1982. Applicant: NORTH ALABAMA TRANSPORTATION, INC., P.O. Box 38, Ider, AL 35981. Representative: William P. Jackson, Jr., 3426 N. Washington Blvd., P.O. Box 1240, Arlington, VA 22210, 703–525–4050. Transporting *such commodities* as are dealt in or used by manufacturers or distributors of medical and health care products, between points in the U.S. (except AK and HI), under continuing contract(s) with C. R. Bard, Incorporated, of Murray Hill, NJ.

MC 147549 (Sub-4), filed January 5, 1982. Applicant: ROADAIR LEASING, INC., 3999 Erie Avenue, Cincinnati, OH 45208. Representative: David Earl Tinker, 1000 Connecticut Ave. NW, Suite 1112, Washington, DC 20036–5391, (202) 887–5368. Transporting *general commodities* (except classes A and B explosives), between points in the U.S., under continuing contract(s) with Pri-Pak, Inc., of Sunman, IN. Condition: The person or persons who appear to be engaged in common control of another regulated carrier must either file an application under 49 U.S.C. 11343(A) or submit an affidavit indicating why such approval is unnecessary. In order to expedite issuance of any authority please submit a copy of the affidavit or proof of filing the application(s) for common control to Team 5 Room 6370.

MC 147609 (Sub-3), filed January 4, 1982. Applicant: ARCH'S TRANSFER LTD., 2491 McKenzie St., Penticton, B.C. Canada V2A6H9. Representative: J. K. Thompson, 319 Robinson St., Penticton, B.C. Canada V2A 6M9, 604–493–4240. Transporting *lumber and wood products,* in foreign commerce only, between points in the U.S. under continuing contract(s) with Kee Pee Laminating Ltd., and Structurlam Products Ltd. both Penticton, B.C. Canada.

MC 148538 (Sub-3), filed January 8, 1982. Applicant: JOMAR TRUCK LINE, INC., 7547 W. Ponderosa Court, Orland Park, IL 60462. Representative: James C. Hardman, 33 N. LaSalle St., Chicago, IL 60602, 312–236–5944. Transporting *metal products,* between Hammond, IN, on the one hand, and, on the other, points in Muscatine County, IA.

MC 150818 (Sub-3), filed January 5, 1982. Applicant: SUSQUEHANNA TRANSPORTATION, INC., 7400 So. Alton Court, Englewood, CO 80112. Representative: William J. Monheim, P.O. Box 1756, Whittier, CA 90609, (213) 945–2745. Transporting *general commodities* (except classes A and B explosives, commodities in bulk, and household goods as defined by the Commission) between points in Los Angeles County, CA, and Cuyahoga and Lake Counties, OH, on the one hand, and, on the other, points in the U.S.

MC 151118 (Sub-14), filed December 7, 1981. Originally published in the **Federal Register** on December 21, 1981. Applicant: MDR CARTAGE, INC., 516 West Jackson, Jonesboro, AR 72401. Representative: Douglas C. Wynn, P.O. Box 1295, Greenville, MS 38701, 601–335–3576. Transporting *general commodities* (except classes A and B explosives, and household goods as defined by the Commission), between the facilities of Uncle Ben's Inc., at points in the U.S., on the one hand, and, on the other, points in the U.S.

Note.—The purpose of this republication is to reflect the appropriate territorial description.

MC 151118 (Sub-16), filed January 7, 1982. Applicant: MDR CARTAGE, INC., 516 West Johnson St., Jonesboro, AR 72401. Representative: Ralph D. Golden, Suite 2348–100 N. Main Bldg., Memphis, TN 38103, 901–526–1122. Transporting *general commodities* (except classes A and B explosives, household goods as defined by the Commission and commodities in bulk), between points in the U.S. (except HI), under continuing contract(s) with U.S. Freight Forwarder Co., Inc. of Memphis, TN.

MC 151118 (Sub-17), filed January 7, 1982. Applicant: M.D.R. CARTAGE, INC., 516 West Johnson, Jonesboro, AR 72401. Representative: Douglas C. Wynn, P.O. Box 1295, Greenville, MS 38701 (601) 335–3576. Transporting *such commodities* as are dealt in or used by manufacturers, distributors or retailers of footwear, between points in Bristol and Plymouth Counties, MA, Gibson, Williamson and Wilson Counties, TN, Christian and Todd Counties, KY, and points in AR, on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 151528 filed January 7, 1982. Applicant: L. E. TUCKER & SON, INC., 2660 Greenway Dr., Jackson, MS 39204. Representative: Fred W. Johnson, Jr., P.O. Box 1291, Jackson, MS 39205, 601–355–3543. Transporting *furniture and fixtures,* between points in Madison County, MS, on the one hand, and, on the other, points in CA, OR and UT.

MC 152609 (Sub-4), filed January 4, 1982. Applicant: SHIPPERS FREIGHT SERVICES, INC., P.O. Box 1248, Lake Oswego, OR 97034. Representative: Lawrence V. Smart, Jr., 419 N.W. 23rd Ave., Portland, OR 97210, 503–226–3755. Transporting *paper and paper articles,* between points in the U.S. under continuing contract(s) with Paper Pak Products, Inc. of LaVerne, CA.

MC 154969 (Sub-1), filed January 6, 1982. Applicant: WILLIAM S. LEE, d.b.a., WILLIAM S. LEE TRUCKING, Hidden Valley, Rt. 10, Box 249, McMinnville, TN 37110. Representative: Robert K. Goren, Suite 1025, 1875 Eye St., NW., Washington, DC 20006, (202) 463–6400. Transporting (1) *such commodities* as are dealt in by grocery stores between points in Davidson County, TN, on the one hand, and, on the other, points in Dade and Orange Counties, FL, and (2) *meats and meat products* between points in Lincoln County, TN, on the one hand, and, on the other, Los Angeles, CA and points in Dade County, FL.

MC 155258 (Sub-2), filed January 8, 1982. Applicant: ALTON DELIVERY SERVICE CO., INC., 100 West 43rd St., New York, NY 10036. Representative: John D. Heffner, 1776 K St., N.W., Suite 700, Washington, D.C. 20006, (202) 296–0600. Transporting (1) *food and related products,* under continuing contract(s) with Revere Sugar Corporation, of New York, NY, and (2) *printed matter,* under continuing contract(s) with Commerce Clearing House, Inc., of Clark, NJ, between points in the U.S.

MC 158949 (Sub-1), filed December 28, 1981. Applicant: SANTONE CONSTRUCTION & TRUCKING CO., INC., 32 Clark St., Greensburg, PA 15601. Representative: Arthur J. Diskin, 806 Frick Bldg., Pittsburgh, PA 15219, 412–281–9494. Transporting *general commodities* (except classes A and B explosives), between points in Westmoreland County, PA on the one hand, and, on the other, points in VA, MI, MD, IL, NY, WV, OH, IN, NJ and KY.

MC 159888 filed January 5, 1982. Applicant: TAZEWELL AUTO SALVAGE, INC., Route 2, Box 590, N. Tazewell, VA 24603. Representative: Terrell C. Clark, P.O. Box 25, Stanleytown, VA 24168, 703–629–2818. Transporting *machinery,* between points in Tazewell County, VA, on the one hand, and, on the other, points in AL, KY, IL, IN, OH, PA, TN, VA and WV.

MC 159928, filed January 4, 1982. Applicant: MICHAEL ALLEN SMITH, d.b.a. L–B TRUCK LINES, P.O. Box M, Harbor City, CA 90710. Representative: William J. Monheim, P.O. Box 1756, Whittier, CA 90609, 213–945–2745. Transporting *metal products,* between Oakland and San Francisco, CA, New Orleans, LA, and Portland, OR and points in Los Angeles County, CA; Duval and Hillsborough Counties, FL; Chatham County, GA; and Harris, Chambers, and Galveston Counties, TX on the one hand, and, on the other, points in AZ, CA, CO, FL, GA, ID, MT, NV, NM, ND, OR, SD, TX, UT, WA, and WY.

P–5–08

Decided: January 12, 1982.

By the Commission, Review Board No. 3. Members Kroch, Joyce and Dowell.

MC 29328 (Sub-12), filed December 31, 1981. Applicant: SCHIEK MOTOR EXPRESS, INC., 90 Casseday Ave., Joliet, IL 60432. Representative: Anthony E. Young, 29 South LaSalle St., Suite 350, Chicago, IL 60603, 312–242–3194. Transporting *general commodities* (except classes A and B explosives), between points in Will, Cook, DuPage, Grundy and Kane Counties, IL, on the one hand, and, on the other, points in IL, WI, IN, IA, MO, MI, KY, and OH.

MC 40978 (Sub-88), filed January 4, 1982. Applicant: CHAIR CITY MOTOR EXPRESS COMPANY, 3321 South Business Dr., Sheboygan, WI 53081. Representative: Daniel R. Dineen, 710 North Plankinton Ave., Milwaukee, WI 53203, 414–273–7410. Transporting *furniture and fixtures,* between points in NC on the one hand, and, on the other, points in IL, MN, WI, and the Upper Peninsula of MI.

MC 74609 (Sub-4), filed January 4, 1982. Applicant: JOHN E. MURRAY MOVING & STORAGE CO., INC., 88 Middle St., Geneva, NY 14456. Representative: Roy D. Pinsky, Suite 1020 State Tower Bldg., Syracuse, NY

13202, 315–422–2384. Transporting *general commodities* (except classes A and B explosives), between points in Monroe, Ontario, Seneca, Wayne and Yates Counties, NY.

MC 114868 (Sub-7), filed December 29, 1981. Applicant: HARRY EARL NEWLON, d.b.a. NEWLON'S TRANSFER, 1511 North Nelson St., Arlington, VA 22201. Representative: Betty Jo Christian, 1250 Connecticut Ave., N.W., Washington, DC 20036, 202–862–2158. Transporting *household goods* as defined by the Commission, between points in the U.S.

MC 120818 (Sub-4), filed January 4, 1982. Applicant: ALLFREIGHT LINES, INC., 309 New Boston Rd., Woburn, MA 01888. Representative: Robert G. Parks, 20 Walnut St., Suite 101, Wellesley Hills, MA 02181, 617–235–5571. Transporting (1) *machinery*, and (2) *metal products*, between points in the U.S. under continuing contract(s) with General Electric Company, Medium Turbine Department (E&M) of Lynn, MA.

MC 123329 (Sub-61), filed January 4, 1982. Applicant: H. M. TRIMBLE & SONS LTD., P.O. Box 3500, Calgary, Alberta Canada T2P2P9. Representative: D. S. Vincent, (same address as applicant), 403–265–9900. Transporting *lumber and wood products*, between ports of entry on the international boundary line between the United States and Canada on the one hand, and, on the other, points in AZ, CA, CO, ID, IL, IN, IA, KS, LA, MI, MN, MO, MT, NE, NV, NM, ND, OH, OK, OR, SD, TN, TX, VT, WA and WY.

MC 134518 (Sub-8), filed January 4, 1982. Applicant: CHEESE HAULING, INC., 305 Bis-Man Ave., Mandan, ND. 58554. Representative: Carl E. Munson, 469 Fischer Bldg., P.O. Box 796, Dubuque, IA 52001, 319–557–1320. Transporting (1) *cheese and cheese products*, between points in Sioux County, ND and Dewey County, SD on the one hand, and, on the other, points in Los Angeles and Orange Counties, CA; and Maricopa and Pima Counties, AZ. (2) *cheese supplies*, between points in Washington and Waukesha Counties, WI on the one hand, and, on the other, points in ND and SD; and (3) *glass bottles*, between points in La Salle and Livingston counties IL on the one hand, and, on the other, points in Morton County, ND.

MC 152128 (Sub-6), filed December 28, 1981. Applicant: STATE TRANSPORT SERVICE, INC., 13029 Market St., Houston, TX 77015. Representative: C. W. Ferebee, 14614 Falling Creek, #124, Houston, TX 77068, 713–537–8156. Transporting *Mercer commodities* and *earth drilling equipment*, between points in TX on the one hand, and, on the other, points in AL, AZ, CA, FL, GA, ID, KS, MT, NE, NV, ND, OR, SD, UT and WA.

MC 152629 (Sub-4), filed December 29, 1981. Applicant: ATLAS WAREHOUSE COMPANY, 923 Osborn Street, P.O. Box 456, Burlington, IA 52601. Representative: Michael D. Bromley, 366 Executive Bldg., 1030 15th St., NW., Washington, DC 20005, (202) 296–3555. Transporting *building materials, pulp, paper and related products, and chemicals and related products*, between the facilities of Georgia-Pacific Corporation at points in the U.S., on the one hand, and, on the other, points in the U.S.

MC 153429 (Sub-2), filed December 17, 1981. Applicant: ANSELM JOLLEY, C. F. FOWLER, AND BOBBY NOE, d.b.a. LAKEWAY TRUCKING COMPANY, P.O. Box 763, Morristown, TN 37814. Representative: Kim D. Mann, 7101 Wisconsin Ave., Suite 1010, Washington, DC 20014, (301) 986–1410. Transporting (1) (*a*) *wood products and (b) furniture and fixtures* (except those in (a)), between points in Hancock, Grainger, Hawkins, and Cocke Counties, TN, on the one hand, and, on the other, those points in the U.S. in and east of TX, OK, KS, NE, SD, and ND, and (2) *textile mill products and rubber and plastic products*, between points in Hamblen County, TN, on the one hand, and, on the other, those points in the U.S. in and east of TX, OK, KS, NE, SD, and ND.

MC 155658 (Sub-6), filed December 18, 1981. Applicant: D. F. SYSTEM, INC., 875 Providence Hwy., P.O. Box 242, Dedham, MA 02026. Representative: Robert G. Parks, 20 Walnut St., Suite 101, Wellesley Hills, MA 02181, (617) 235–5571. Transporting *such commodities* as are dealt in or used by retail drug and grocery business houses and department stores, between points in the U.S., under continuing contract(s) with The Gillette Company of Boston, MA.

MC 158279 (Sub-1), filed December 29, 1981. Applicant: LEONEL A. BROUILLARD, d.b.a. LEO'S TRUCKING, 315 Turnpike Rd., Windsor Locks, CT 06096. Representative: Vincent W. Oswecki, Jr., 20 Maple Ave., P.O. Box 504, Windsor, CT 06095, (203) 688–8505. Transporting *general commodities* (except classes A and B explosives), between points in Queens, Broome, Monroe, and Albany Counties, NY, Bennington, Chittenden, Windham, and Windsor Counties, VT, Providence County, RI, and MA, NH, and CT.

MC 159658, filed January 5, 1982. Applicant: L & R TRUCKING, INC., 802 West South Omaha Bridge Road, Council Bluffs, IA 51501. Representative: Donald L. Stern, Suite 610, 7171 Mercy Road, Omaha, NE 68106, (402) 392–1220. Transporting *meats and packinghouse products*, between points in the U.S., under continuing contract(s) with Dominic Pesavento Co., of West Covina, CA.

MC 159849, filed December 28, 1981. Applicant: DAYMARK FOODS, INC., d.b.a. ODISCO TRANSPORTATION, 500 West Main St., Suite 208, Russellville, AR 72801. Representative: Jeff McEowen (same address as applicant), (501) 968–4038. Transporting *frozen food* between points in Riverside County, CA, on the one hand, and, on the other, points in IL, MN, and TX.

MC 159898, filed December 29, 1981. Applicant: NORTHRAIL CORPORATION, Box A–15, Hanover, NH 03755. Representative: Yusuk Chang (same address as applicant). To operate as a *broker* at Hanover, NH, arranging for the transportation of *passengers and their baggage*, in the same vehicle with passengers, beginning and ending at Hanover, NH, and extending to points in the U.S.

MC 159899, filed December 30, 1981. Applicant: ROGER F. BARTNIK, d.b.a. QUICK TOURS AND CHARTER CO., P.O. Box 8, Mountain, WI 54149. Representative: Roger F. Bartnik (same address as applicant), (715) 276–7550. Transporting *passengers and their baggage*, in the same vehicle with passengers, in charter operations, beginning and ending at Mountain, WI, and extending to points in the U.S. (except AK and HI).

MC 159909, filed December 29, 1981. Applicant: ADVANCED TRANSPORTATION SERVICES, INC., 1212 O'Neill Highway, Dunmore, PA 18512. Representative: Robert L. Cope, Suite 501, 1730 M Street N.W., Washington, DC 20036, 202–296–2900. Transporting *general commodities* (except classes A and B explosives, household goods as defined by the Commission and commodities in bulk), between points in the U.S. under continuing contract(s) with Northeastern Pennsylvania Shippers Cooperative Association, Inc., of Dunmore, PA.

MC 159918, filed December 31, 1981. Applicant: SOUTHWESTERN EXPRESS, INC., P.O. Box 52112, Oklahoma City, OK 73152. Representative: Greg E. Summy, P.O. Box 2650, Edmond, OK 73083, 405–348–7700. Transporting *general commodities* (except classes A and B explosives), (1) between Tulsa, OK and Ft. Worth, TX: from Tulsa over Interstate Hwy 44 to Oklahoma City,

then over Interstate Hwy 35 to junction Interstate Hwy 35W; then over Interstate Hwy 35W to Fort Worth, serving all intermediate points; (2) between Tulsa, OK and Dallas, TX, over U.S. Hwy 75, serving all intermediate points; and (3) between Dallas, TX, and junction Interstate Hwy 35E and 35W, over Interstate Hwy 35E, serving all intermediate points.

OP2-14

Decided: January 18, 1982.

By the Commission, Review Board No. 1. Members: Parker, Chandler, and Fortier. Member Fortier not participating.

W-303 (Sub-3), filed January 5, 1982. Applicant: WESTERN TRANSPORTATION CO., P.O. Box 3869, Portland, OR 97208. Representative: C. P. Blaskowsky (same address as applicant), (503) 221-0933. To operate as a *common carrier* by water, in interstate and foreign commerce, transporting *general commodities,* by nonself propelled vessels with the use of separate towing vessels and by towing vessels in the performance of *general* towage, between all ports and points in WA on Puget Sound, The Strait of Juan de Fuca, Georgia Strait, Washington Sound, Admiralty Inlet, Saratoga Passage, Possession Sound, Hood Canal, Lake Union, Lake Washington and tributary waters.

MC 35153 (Sub-3), filed December 30, 1981. Applicant: RUPP-SOUTHERN TIER FREIGHT LINES, INC., P.O. Box 489, Rt. 211, Middletown, NY 10940. Representativ: Michael R. Werner, 241 Cedar Lane, Teaneck, NJ, 201-836-1144. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in CT, PA, NY, and NJ.

MC 52473 (Sub-17), filed December 29, 1981. Applicant: BEHNKE, INC., 77 South Monroe St., Battle Creek, MI 49017. Representative: Karl L. Gotting, 1200 Bank of Lansing Bldg., Lansing, MI 48933, 517-482-2400. Transporting *scrap paper,* between points in MI, IN, IL, OH, MN, WI, and IA.

MC 105902 (Sub-30), filed January 4, 1982. Applicant: PENN YAN EXPRESS, INC., 100 West Lake Rd., Penn Yan, NY 14527. Representative: Jeffrey A. Vogelman, P.O. Box 11278, Overlook Bldg., 6121 Lincolnia Rd., Alexandria, VA 22312, (703) 750-1112. Transporting *jet engine housings, jet engine assemblies, and parts* for jet engine housings and assemblies, between Baltimore, MD, on the one hand, and, on the other, points in Adams County, OH.

MC 113983 (Sub-7), filed January 5, 1982. Applicant: CLEVELAND'S TRUCK LINES, INC., RD 2, Hormell, NY 14843. Representative: Lawrence Le Clair, 1 West Church St., Elmira, NY 14901, (607) 734-2271. Transporting *general commodities* (except classes A and B explosives), between points in Allegany, Broome, Cattaraugus, Chemung, Erie, Genesee, Livingston, Monroe, Niagara, Schuyler, Steuben, Tioga, Wyoming, and Yates Counties, NY, and Bradford, Tioga, and McKean Counties, PA. Condition: Coincidental cancellation of applicant's Certificate of Registration under MC-113983 Sub 6, issued May 11, 1981.

MC 146213 (Sub-16), filed January 6, 1982. Applicant: WISCONSIN FARM LINES, LTD., P.O. Box 76, Wisconsin Dells, Wi 53965. Representative: Stanley C. Olsen, Jr., 5200 Willson Rd., Suite 307, Minneapolis, MN 55424, (612) 927-8855. Transporting *chemicals and related products,* between Chicago, IL, points in Washoe County, NV, King County, WA, WI, and NJ, on the one hand, and, on the other, points in the U.S.

MC 146602 (Sub-8), filed January 5, 1982. Applicant: ODEAN DUANE BAKKEN, d.b.a. BAKKEN TRUCK LINE, 1301 Third Ave South, Northwood, IA 50459. Representative: Samuel Rubenstein, P.O. Box 5, Minneapolis, MN 55440, 612-542-1121. Transporting *food and related products,* between Kansas City, MO, Omaha, NE, points in Warren County, IL, Saline County, MO, Freeborn County, MN and IA, on the one hand, and, on the other, points in AR, CT, DE, IA, IL, IN, KS, KY, LA, ME, MD, MA, MI, MN, MO, NE, NJ, NY, NC, ND, OH, OK, PA, RI, SC, SD, TN, TX, VT, VA, WV, WI and DC.

MC 148832 (Sub-7), filed January 4, 1982. Applicant: DELTA MOTOR FREIGHT, INC., 1616 Rowe Blvd., P.O. Box 1083, Poplar Bluff, MO 63901 Representative: Ronald D. Dodds (same address as applicant), 314-785-2340. Over *regular routes,* transporting *general commodities* (except classes A and B explosives and household goods), between Kansas City and Poplar Bluff, MO: (A) From Kansas City over U.S. Hwy 71 to junction MO Hwy 7, then over MO Hwy 7 to junction MO Hwy 13, then over MO Hwy 13 to junction U.S. Hwy 60, then over U.S. Hwy 60 to Poplar Bluff, and return over the same route, and (B) From Kansas City over U.S. Hwy 50 to junction U.S. Hwy 63, then over U.S. Hwy 63 to junction MO Hwy 72, then over MO Hwy 72 to junction MO Hwy 21, then over MO Hwy 21 to junction U.S. Hwy 60, then over U.S. Hwy 60 to Poplar Bluff, and return over the same route, serving all intermediate points and serving all points in Jackson, Platte, Clay, Greene, Webster, Wright, Douglas, Texas, Howell, Dent, Shannon, Oregon, Carter, Reynolds, Iron, Phelps, Butler, Laclede, Ripley and Pulaski Counties, MO, and Wyandotte and Johnson Counties, KS as off-route points in connection with routes (A) and (B) above.

MC 149133 (Sub-10), filed January 4, 1982. Applicant: DIST/TRANS MULTI-SERVICES, INC., d.b.a. TAHWHEELALEN EXPRESS, INC., 1333 Nevada Blvd., P.O. Box 7191, Charlotte, NC 28217. Representative: Wyatt E. Smith (same address as applicant), 704-588-2109. Transporting *general commodities* (except classes A and B explosives, household goods and commodities in bulk), between points in the U.S., under continuing contract(s) with Minnesota Fabrics, Inc., of Charlotte, NC.

MC 153093 (Sub-1), filed January 5, 1982. Applicant: ASSOCIATED MOVING & STORAGE CO., INC., P.O. Box 23053, New Orleans, LA 70183. Representative: Robert J. Gallagher, 1000 Connecticut Ave., NW, Suite 1200, Washington, DC 20036, (202) 785-0024. Transporting *household goods,* between points in AL, AR, FL, GA, LA, MS, TN, TX, OK, CA, AZ, NM, CO, MO, NE, KS, KY, NC, SC, VA, and DC.

MC 153973 (Sub-4), filed January 5, 1982. Applicant SPARTAN SERVICE TRANSPORTATION, INC., 1501 W. Pershing Rd., Chicago, IL 60608. Representative: Donald E. Weishaar, Suite 202 1301 W 22nd St., Oak Brook, IL 60521, (312) 986-5855. Transporting *beverages,* between points in the U.S., under continuing contract(s) with Vierk Corporation, of Harvey, IL.

MC 154103 (Sub-5), filed January 5, 1982. Applicant: MID SOUTH FREIGHT, INC., P.O. Box 446, Hendersonville, TN 37075. Representative: John M. Nader, 1600 Citizens Plaza, Louisville, KY 40202, (502) 589-5400. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between St. Louis, MO, Detroit, MI, and Chicago, IL, on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 158733 (Sub-1), filed January 4, 1982. Applicant: LEONARD FEED & GRAIN, INC., 5511 16th Ave., SW, Cedar Rapids, IA 52404. Representative: Richard D. Howe, 600 Hubbell Bldg., Des Moines, IA 50309, (515) 244-2329. Transporting *popcorn,* between points in Marshall County, IA, on the one hand, and on the other, points in AL, AR, CO, GA, IL, IN, KS, KY, LA, MI, MN, MS, MO, NE, NM, ND, OH, OK, PA, SC, SD, TN, TX, WI, and WY.

MC 159942, filed January 4, 1982. Applicant: CHEMICAL INDUSTRIES, INC., P.O. Box 890 Borger, TX 79007. Representative: Paul D. Angenend, 1806 Rio Grande, P.O. Box 2207, Austin, TX 78768, 512–476–6391. Transporting *lumber and wood products,* between points in the U.S., under continuing contract(s) with Maywood, Incorporated, of Amarillo, TX.

MC 159952, January 4, 1982. Applicant: GOLDEN DISTRIBUTING, INC., 200 Hastings Ave., Newport, MN 55055. Representative: Stephen F. Grinnell, 1600 TCF Tower, Minneapolis, MN 55402, 612–333–1341. Transporting *food and related products,* between points in ID, IL, IN, MN, NE, ND, OH, SD, and WI, on the one hand, and, on the other, points in the U.S.

MC 159962, filed January 5, 1982. Applicant: JACK DALE TRIPP AND CLARENCE H. TRIPP, d.b.a. TRIPP BROTHERS TRUCKING, 803 Park View Way, P.O. Box 8436, Missoula, MT 59807. Representative: William E. Seliski, 2 Commerce St. P.O. Box 8255, Missoula, MT 59807, 406–543–8369. Transporting *such commodities* as are dealt in or used by lumber yards (a) between points in ID, MT, OR and WA, on the one hand, and, on the other, those points in the U.S. in and west of WI, IL, MO, OK and TX, (b) between points in Scott County, MN, on the one hand, and, on the other, points in ND and SD.

MC 159993, filed January 7, 1982. Applicant: ROCKET EXPRESS, INC., P.O. Box 45065, Atlanta, GA 30320. Representative: Virgil H. Smith, 74 Hwy. N., Box 245, Tyrone, GA 30290, (404) 969–1980. Transporting *general commodities* (expect classes A and B explosives), between points in NC, SC, and those in GA on and north of U.S. Hwy 80.

Op–4 Vol. 14

Decided: January 18, 1982.

By the Commission, Review Board No. 2 Members Carleton, Fisher and Williams.

MC 123876 (Sub-10), filed January 7, 1982. Applicant: PRATT TRANSPORTATION CO., INC., P.O. Box 1501, Omaha, NE 68101. Representative: Jack L. Shultz, P.O. Box 82028, Lincoln, NE 68501, (402) 475–6761. Transporting *cement,* between points in Butler County, PA, on the one hand, and, on the other, points in MD, NY, OH, and WV.

MC 129576 (Sub-8), filed January 4, 1982. Applicant: HORNER TRUCK SERVICE, INCORPORATED, 207 Ninth St., Coralville, IA 52241. Representative: Melvin M. Porter (same address as applicant), (319) 354–3666. Transporting *anhydrous ammonia and liquid and dry fertilizer,* between points in IA, IL, MN, MO, and WI.

MC 143776 (Sub-40), filed January 6, 1982. Applicant: C.D.B., INCORPORATED, 155 Spaulding Ave, S.E., Grand Rapids, MI 49506 Representative: C. Michael Tubbs (same address as applicant), (800) 253–9527. Transporting *food and related products* between points in U.S., under continuing contract(s) with Swift Independent Packing Company, of Chicago, IL.

MC 147196 (Sub-23), filed January 6, 1982. Applicant: ECONOMY TRANSPORT, INC., P.O. Box 50262, New Orleans, LA 70150. Representative: Fletcher W. Cochran, P.O. Box 741, Slidell, LA 70459 (504) 643–1700. Transporting *printed matter* between points in the U.S. (except AK and HI) under continuing contract(s) with Storm Printing Company, of Memphis, Tennessee.

MC 147216 (Sub-6), filed January 4, 1982. Applicant: CAR: KLEMM, INC., d.b.a. KLEMM TANK LINES, 1126 Terry LA, De Pere, WI 54115. Representative: James A. Spiegel, 6333 Odana Rd., Madison, WI 53719, (608) 273–1003. Transporting *petroleum, natural gas and their products,* between Butler and Hamilton Counties, OH, on the one hand, and, on the other, points in IA, IL, IN, MI, MN, MO, ND, NE, SD, and WI.

MC 150746 (Sub-12), filed January 4, 1982. Applicant: DFS TRANSPORTATION COMPANY, 12007 Smith Dr., P.O. Box 929, Huntley, IL 60142. Representative: Joel H. Steiner, 29 South La Salle St., Chicago, IL 60603, (312) 236–9375. Transporting *alcoholic beverages* between points in the U.S., under continuing contracts(s) with Federated Industries, Inc. of Chicago, IL and its subsidiaries, Federated Distributors, Inc., of Chicago, IL, Lake Shore Distributing Co., of Rockford, IL, Illinois Wine and Spirits, of Plainfield, IL, Capitol Husting, of Milwaukee, WI, Tampa Crown Distributors, Inc., of Tampa, FL and Bohemian Distributing Company, of N. Hollywood, CA.

MC 150806 (Sub-5), filed January 8, 1982. Applicant: WECO, INC., 500 Scott St., P.O. Box 5128, Kansas City, KS 66119. Representative: Erle W. Francis, 719 Capitol Federal Bldg., Topeka, KS 66603, (913) 232–0601.Transporting *foodstuffs,* between points in Shawnee County, KS, on the one hand, and, on the other, points in AR, GA, MS, TN, and TX.

MC 156046 (Sub-2), filed January 7, 1982. Applicant: HABIT MOTOR LINES, INC., 9959 Nathan Lane, Maple Grove, MN 55369. Representative: John B. Van de North, Jr., 2200 First National Bank Bldg., St. Paul, MN 55101, (612) 291–1215.Transporting *plastic, wire and wood products, sporting goods and accessories, and dispenser containers,* between points in the U.S., under continuing contract(s) with Forster Mfg. Company, Inc., of Wilton, ME.

MC 151746 (Sub-7), filed January 4, 1982. Applicant: ORANGE DISTRIBUTION SERVICE, INC., P.O. Box 2277, Short Beach, CT 06405. Representative: Gerald A. Joseloff, 410 Asylum St., Hartford, Ct 06103, (203) 728–0700. Transporting *such merchandise as is dealt in or used by distributors and manufacturers of automobile parts and accessories* between points in the U.S., under a continuing contract(s) with EIS, Division of Parker Corporation of Berlin, CT.

MC 154176, filed January 31, 1982. Applicant: EDDIE LAVERNE ELDRIDGE, d.b.a. ELDRIDGE TRUCKING, Route 22, Box 86, Lake Odessa, MI 48849. Representative: William R. Ralls, 118 West Ottawa, Suite B, Lansing, MI 48933, (517) 372–6622. Transporting *agricultural chemicals* between points in the U.S., under continuing contract(s) with Agrico Chemical Company, of Saginaw, MI, and Lake Odessa Co-op, of Lake Odessa, MI.

MC 159916, filed January 29, 1982. Applicant: ROMAR, INC., P.O. Box 1843, Idaho Falls, ID 83401. Representative: Timothy R. Stivers, P.O. Box 1576, Boise, ID 83701, (208) 343–3071. Transporting *general commodities* (except classes A and B explosives), between points in the U.S., under continuing contract(s) with King B. Jerky, Inc., of Idaho Falls, ID, Leaf Confectionary, Inc., of Chicago, IL, and Ball Packing Co., of Idaho Falls, ID.

MC 159986, filed January 5, 1982. Applicant: AMAZON INDEPENDENT TRANSPORTATION, INC., 12480 24th Ave., Marne, MI 49435. Representative: Edward Malinzak, 900 Old Kent Bldg., Grand Rapids, MI 49503, (616) 459–6121. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in MI, on the one hand, and, on the other, points in the U.S., under continuing contract(s) with S. D. Warren Paper Company, of Muskegon, MI.

OP4—Volume 13

Decided: January 15, 1982.

By the Commission, Carleton, Fisher and Williams.

MC 99877 (Sub-3), filed January 4, 1982. Applicant: RAPID FREIGHT SYSTEMS, 824 So. Vail Ave., Montebello, CA 90640. Representative:

William J. Monheim, P.O. Box 1756, Whittier, CA 90609, (213) 945–2745. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in CA, on the one hand, and, on the other, points in AZ, NV, OR, and WA.

MC 119917 (Sub-69), filed January 6, 1982. Applicant: DUDLEY TRUCKING COMPANY, INC., 724 Memorial Drive, SE, Atlanta, GA 30316. Representative: Archie B. Culbreth, Suite 202, 2200 Century Parkway, Atlanta, GA 30345, (404) 321–1765. Transporting *containers, container closures, container components and related items*, between Atlanta, GA, on the one hand, and, on the other, those points in the U.S. in and east of IL, KY, TN, MS, and LA.

MC 134547 (Sub-14), filed January 4, 1982. Applicant: BILBO TRANSPORTS, INC., 2722 Singleton Blvd., Dallas, TX 75212. Representative: Austin L. Hatchell, P.O. Box 2023, Austin, TX 78768, (512) 472–8355. Transporting *building materials, and iron and steel articles*, between points in AR, LA, NM, OK, and TX.

MC 140857 (Sub-2), filed January 5, 1982. Applicant: EMMETT BARRICK d.b.a. B & B HOT SHOT SERVICE, 6509 S. Lindsay, Oklahoma City, OK 73149. Representative: G. Timothy Armstrong, 200 N. Choctaw, P.O. Box 1124, El Reno, OK 73036, (405) 262–1322. Transporting *Mercer commodities*, between points in OK, on the one hand, and, on the other, points in LA, NM, TX, and WY.

MC 149137 (Sub-13), filed January 4, 1981. Applicant: MASTER TRANSPORT SERVICES, INC., 500 Wyoming Ave., Suite 203, Dearborn, MI 48126. Representative: William B. Elmer, 615 E. Eighth St., Traverse, MI 49684, (616) 941–5313. Transporting *food and related products*, between Detroit, MI and points in Dade County, FL, Buncombe Country, NC, Muskingum County, OH, Brazoria, Fort Bend, Galveston and Harris Counties, TX, and points in IN, MD, PA, on the one hand, and, on the other, points in U.S.

MC 152257 (Sub-2), filed January 6, 1982. Applicant: LORDCO TRUCKING, INC., 555 N. Tripp St., Chicago, IL 60624. Representative: Paul J. Maton, 10 S. La Salle St., Suite 1620, Chicago, IL 60603, (312) 332–0905. Transporting *non-alcoholic beverages*, between points in the U.S., under continuing contract(s) with Joyce Beverages of Wisconsin, of Madison, WI.

MC 159867 filed December 29, 1981. Applicant: T. J. DELIVERY, INC., Bldg. 504, Raritan Center, Edison, NJ 08837. Representative: Guy H. Postell, Suite 713, 3384 Peachtree Rd., N.E., Atlanta, GA 30326, (404) 237–6472. Transporting *general commodities* (except classes A and B explosives, and commodities in bulk), between points in the U.S. (except AK and HI), under continuing contract(s) with Avon Products, Inc., of New York N.Y.

MC 159907, filed January 4, 1981. Applicant: M.A.K. FREIGHT, LTD., 5 Arapaho Drive, Brookfield, CT 06805. Representative: Gerald A. Joseloff, 410 Asylum St., Hartford, CT 06103, (203) 728–0700. Transporting *petroleum, natural gas and related products*, between points in the U.S., under continuing contract(s) with Intercontinental Lubricants Corp., of Brookfield, CT.

MC 159917, filed December 31, 1981. Applicant: BURCO CHEMICAL SERVICES, INC., 1689 Columbus Rd., Cleveland, OH 44113. Representative: Lynn R. Delnoce, 10219 Brecksville Rd., Brecksville, OH 44141, (216) 526–2718. Transporting *chemicals, lumber, and building materials*, between points in DE, IL, IN, KY, MD, ME, MI, MO, NH, NY, OH, PA, VA, and WV.

MC 159337, filed January 5, 1982. Applicant: KING TRANSPORTATION CO., 6727 Cottonwood, Shawnee, KS 66216. Representative: Daniel R. Hedrick (same address as applicant), (913) 631–0846. Transporting *automobile parts and accessories*, between points in the U.S., under continuing contract(s) with Ford Motor Company, of Dearborn, MI.

MC 159967, filed January 6, 1981. Applicant: INDY–O INC., 105 S.W. Third, Richmond, IN 47374. Representative: Donald W. Smith, P.O. Box 40248, Indianapolis, IN 46240, (317) 846–6655. Transporting *general commodities* (except household goods, commodities in bulk, and classes A and B explosives), between points in IN, IL, MI, and KY, on the one hand, and, on the other, points in KY, IL, OH, IN, MI, WI, NY, PA, MO, TN, and IA.

Op–3–013

Decided: January 20, 1982.

By the Commission, Review Board No., Members Carleton, Fisher and Williams.

MC 43165 (Sub-17), filed January 11, 1982. Applicant: LOUDOUN TRANSFER, INC., P.O. Box 703, Leesburg, VA 22075. Representative: Dean N. Wolfe, Suite 145, 4 Professional Dr., Gaithersburg, MD 20879, (301) 840–8565. Transporting *machinery*, between points in Fairfax County, VA, on the one hand, and, on the other, points in Orange, Durham, Wake and Chatham Counties, NC.

MC 99535 (Sub-6), filed January 11, 1982. Applicant: STEVEN FREIGHT SERVICE CO., INC., 16 Sturtevant St., Somerville, MA 02145. Representative: Robert L. Cope, Suite 501, 1730 M St., NW, Washington, DC 20036, (202) 296–2900. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in the U.S., under continuing contract(s) with The Nestle Company, Inc., of White Plains, NY.

MC 99975 (Sub-4), filed January 11, 1982. Applicant: CATAWBA TRUCKING CO., INC., P.O. Box 10352, Rock Hill, SC 29730. Representative: Edward L. Nehez, P.O. Box Y, 7 Becker Farm Rd., Roseland, NJ 07068, (201) 992–2200. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in the U.S., under continuing contract(s) with Synally Corporation, Blackman Uhler Chemical Division, of Spartansburg, SC, Kenco Chemical & Manufacturing Corporation, of Jacksonville, FL, Distribution Services of America, Inc., of Boston, MA, M. Lowenstein Corporation, of New York, NY, Mobay Chemical Corporation, of Union, NJ, Pfister Chemical, Inc., of Ridgefield, NJ, Martin Marietta Corporation, Sodyeco Division, of Charlotte, NC, Sonoco Products Company, of Hartsville, SC, and United Freight, Inc., of Morrow, GA.

MC 107825 (Sub-4), filed January 11, 1982. Applicant: MIDDLE CREEK GARAGE, INC., 95 National Rd., Triadelphia, WV 26059. Representative: Woodrow Knollinger Jr., Box 85, Triadelphia, WV 26059, (304) 547–1195. Transporting *mobile homes*, between points, in WV, PA, OH, KY, IN, NY, VA, TN, NC, SC, AL, GA, FL, and DC.

MC 111274 (Sub-81), filed January 12, 1982. Applicant: SCHMIDGALL TRANSFER INC., P.O. Box 351, Morton, IL 61550. Representative: Frederick C. Schmidgall (same address as applicant), (309) 266–9773. Transporting *lumber and lumber mill products*, between points in the U.S. under continuing contract(s) with Allee Lumber Co., of Mattoon, IL.

MC 125535 (Sub-35), filed January 8, 1982. Applicant: NATIONAL SERVICE LINES INC. OF NEW JERSEY, 2275 Schuetz Rd., St. Louis, MO 63141. Representative: Donald S. Helm (same address as applicant), (314) 569–1161. Transporting *steel articles*, between points in the U.S., under continuing contract(s) with Doolan Steel Corporation, of Moorestown, NJ.

MC 127264 (Sub-7), filed January 11, 1982. Applicant: AMERICAN PARCEL SERVICE, INC., 1800 Bessemer Ave.,

Greensboro, NC 27405. Representative: Guy H. Postell, Suite 713, 3384 Peachtree Rd., NE., Atlanta, GA 30326, (404) 237–6472. Transporting *such commodities* as are dealt in or used by manufacturers or distributors of home care products, between points in the U.S. (except AK and HI), under continuing contract(s) with Amway Corporation of Norcross, GA.

MC 128075 (Sub-42), filed January 11, 1982. Applicant: JOHNSRUD TRANSPORT, INC., P.O. Box 447, Cresco, IA 52136. Representative: William L. Fairbank, 2400 Financial Center, Des Moines, IA 50309, (515) 282–3525. Transporting *vegetable oils*, between points in the U.S., under continuing contract(s) with Agri Industries of Des Moines, IA.

MC 136774 (Sub-25), filed January 11, 1982. Applicant: MC-MOR-HAN TRUCKING CO., INC., P.O. Box 368, Shullsburg, WI 53586. Representative: Donald B. Levine, 29 South LaSalle St., Chicago, IL 60603, (312) 236–9375. Transporting *food and related products*, between points in the U.S., under continuing contract(s) with Dean Foods Co. and its subsidiaries, of Franklin Park, IL.

MC 143915 (Sub-3), filed January 11, 1982. Applicant: KAPTUR ENTERPRISES, INC., 2250 E. 198th St., Lynwood, IL 60411. Representative: James C. Hardman, 33 N. LaSalle St., Chicago, IL 60602, (312) 236–5944. Transporting *lumber and wood products*, between points in Cass County, IL, on the one hand, and, on the other, points in IA, IL, IN, WI, MI, and MN.

MC 143924 (Sub-7), filed January 12, 1982. Applicant: FUGATE TRUCKING, INC., P.O. Box 14, Danville, VA 24541. Representative: Theodore Polydoroff, 1307 Dolley Madison Blvd., Suite 301, McLean, VA 22101, (703) 893–4924. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between those points in the U.S. in and east of MN, IA, MO, AR, and LA.

MC 145124 (Sub-1), filed January 11, 1982. Applicant: GOLD CITY TOURS & TRAVEL LTD., No. 102, 8610 Jasper Ave., Edmonton, Alberta, Canada T5H 3S5. Representative: George LaBissoniere, 15 S. Grady Way, Suite 233, Renton, WA 98055, (206) 228–3807. Transporting *passengers and their baggage*, in the same vehicle with passengers, in special and charter operations, beginning and ending at ports of entry on the International Boundary line between the U.S. and Canada, and extending to points in the U.S.

MC 145384 (Sub-59), filed January 8, 1982. Applicant: ROSE-WAY, INC., P.O. Box 4644, Des Moines, IA 50306. Representative: James M. Hodge, 3730 Ingersoll Avenue, Des Moines, IA 50312, (515) 274–4985. Transporting *general commodities* (except classes A and B explosives), between points in IA, on the one hand, and, on the other, points in AZ, CA, CO, ID, NM, NV, OR, UT, and WA.

MC 150124 (Sub-2), filed January 11, 1982. Applicant: MARBERN TRUCKING, INC., RD 1, Box 75, Albany St., West Winfield, NY 13491. Representative: Murray J. S. Kirshtein, 118 Bleecker St., Utica, NY 13501, (315) 797–1970. Transporting *electrical appliances* and *metal products*, between points in the U.S., under continuing contract(s) with Broan Manufacturing Co., Inc., of Hartford, WI.

MC 152104 (Sub-3), filed January 11, 1982. Applicant: HOME RUN, INC., 1299 Lavelle Dr., Xenia, OH 45385. Representative: Boyd B. Ferris, 50 W. Broad St., Columbus, OH 43215, (614) 464–4103. Transporting *such commodities* as are dealt in or used by manufacturers and distributors of building materials, between points in Monroe County, IN, on the one hand, and, on the other, points in the U.S.

MC 152544 (Sub-11), filed January 12, 1982. Applicant: CYPRESS TRUCK LINES, INC., 1746 E. Adams St., Jacksonville, FL 32202. Representative: Sol H. Proctor, 1101 Blackstone Bldg., Jacksonville, FL 32202, (904) 632–2300. Transporting *metal products*, between points in Georgetown County, SC, on the one hand, and, on the other, points in and east of MN, IA, MO, AR, and LA.

MC 154185 (Sub-2), filed January 11, 1982. Applicant: RENN TRANSPORTATION CO., INC., 949 Advance St., Green Bay, WI 54304. Representative: L. F. Abel, P.O. Box 949, Green Bay, WI 54305, (414) 497–7400. Transporting *general commodities* (except classes A and B explosives and household goods), between points in the U.S., under continuing contract(s) with Peter Paul Cadbury, Inc., of Naugatuck, CT, Swiss Colony, Inc., of Monroe, WI, and Stouffer Foods Corporation, of Solon, OH.

MC 154475, filed January 11, 1982. Applicant: MARGARET WEIR, d.b.a. WEIR EXPRESS, 11256 Cornell Park Drive, Suite 508, Blue Ash, OH 45242. Representative: Edward R. Kirk, 85 East Gay St., Columbus, OH 43215, (614) 221–8126. Transporting *confectionery and food and related products*, between points in the U.S., under continuing contract(s) with Hershey Chocolate Company, Division of Hershey Foods Corporation of Hershey, PA.

MC 155435 (Sub-2), filed January 11, 1982. Applicant: STILES TRUCK LINE, INC., 1901 Jasmine, Pasadena, TX 77503. Representative: Claude W. Ferebee, 3910 F.M. 1960 West, Suite 106, Houston, TX 77068, (713) 537–8156. Transporting *metal articles*, between points in the U.S.

MC 156274 (Sub-2), filed January 5, 1982. Applicant: IOWA MEAT DISTRIBUTING CO., INC., P.O. Box 36, Hope Hull, AL 36043. Representative: Terry P. Wilson, 428 S. Lawrence St., Montgomery, AL 36104, (205) 262–2756. Transporting *general commodities* (except classes A and B explosives), between the facilities of Chelsea Industries, Inc., its subsidiaries and affiliates, at points in the U.S., on the one hand, and, on the other, points in the U.S.

MC 158504, filed January 11, 1982. Applicant: GULFPORT AUTO AUCTION, INC., Route 3, Box 163, Gulfport, MS 39501. Representative: Harold D. Miller, Jr., 17th Floor, Deposit Guaranty Plaza, P.O. Box 22567, Jackson, MS 39205, (601) 948–5711. Transporting *automobiles* and *pickup trucks*, between Gulfport, MS, on the one hand, and, on the other, points in AL, FL, LA, and TX.

MC 159474 (Sub-1), filed January 8, 1982. Applicant: U.S. EXPRESS, INC., P.O. Box 9652, Little Rock, AR 72219. Representative: Stephen F. Grinnell, 1600 TCF Tower, Minneapolis, MN 55402, (612) 333–1341. Transporting *food and related products*, between those points in the U.S. in and east of ND, SD, NE, CO, OK, and TX.

MC 159794, filed January 11, 1982. Applicant: WILSON'S TRUCKAWAY, INCORPORATED, 120 W. Madison St., Suite 14 N, Chicago, IL 60602. Representative: Brady J. Langford, One N. LaSalle St., Suite 2265, Chicago, IL 60602, (312) 641–2260. Transporting *transportation equipment*, between points in the U.S.

MC 159975, filed January 11, 1982. Applicant: GEORGE KYER & SON, INC., 341 Maple Ave., Oradell, NJ 07649. Representative: Robert G. Parks, 20 Walnut St., Suite 101, Wellesley Hills, MA 02181, (617) 235–5571. Transporting *malt beverages*, between points in Oswego and Onondaga Counties, NY, on the one hand, and, on the other, points in MA.

MC 160035, filed January 11, 1982. Applicant: SAFE-WAY BUS TRANSPORTATION, INC., 4230 80th St. South, Wisconsin Rapids, WI 54494.

Representative: Patrick H. Smyth, 105 West Madison St., Suite 1008, Chicago, IL 60603, (312) 263–2397. Transporting *passengers and their baggage*, in the same vehicle with passengers, in charter operations, beginning and ending at points in Adams, Clark, Jackson, Juneau, Marathon, Portage, Sauk, Waushara, and Wood Counties, WI, and extending to points in the U.S. (including AK and HI).

MC 160044, filed January 11, 1982. Applicant: SOUTHERN NEVADA FREIGHT LINES, INC., 123 West Colorado, Las Vegas, NV 89102. Representative: Miles L. Kavaller, 315 So. Beverly Dr., Suite 315, Beverly Hills, CA 90212, (213) 277–2323. Transporting *Food and related products, alcoholic beverages*, and *restaurant supplies*, between points in CA and NV.

MC 160045, filed January 11, 1982. Applicant: RICHARD A. HODGES, d.b.a. HODGES TRUCKING, Box 314, Monticello, IL 61852. Representative: Michael W. O'Hara, 300 Reisch Bldg., Springfield, IL 62701, (217) 544–5468. Transporting *Drugs, corn starch, containers, and cartons*, between points in the U.S., under continuing contract(s) with Sterling Drugs, Inc., of Monticello, IL.

MC 160054, filed January 11, 1982. Applicant: SHANNON TRUCKING, INC., 2002 Preston St., Rockford, IL 61102. Representative: Carl L. Steiner, 29 So. LaSalle St., Chicago, IL 60603, (312) 236–9375. Transporting (1) *iron and steel articles*, (2) *machinery* and (3) *fabricated structures*, between points in the U.S., under continuing contract(s) with Liebovich Bros., Inc. of Rockford, IL.

MC 160055, filed January 11, 1982. Applicant: AWC TRANSPORTATION CORPORATION, 355 Boyce-Greeley Bldg., Sioux Falls, SD 57102. Representative: Foster L. Kent, P.O. Box 285, Council Bluffs, IA 51502–285, (712) 323–9124. Transporting (1) *such merchandise* as is dealt in or used by food business houses and (2) *such merchandise* as is dealt in or used by distributors of paper and related products, between points in the U.S., under continuing contract(s) with Hy Vee Food Stores, Inc. of Cherokee, IA and Paper Service Company of Mankato, MN.

MC 160065, filed January 12, 1982. Applicant: COSMO COACH LINE, LTD., 2006 Memorial Ave., Lynchburg, VA 24501. Representative: Mark Pestronk, 805 King St., Box 1417 A-40, Alexandria, VA 22313, (703) 549-8666. Transporting *passengers and their baggage*, in charter and special operations, between points in VA, on the one hand, and, on the other, points in the U.S.

Volume OP–1–8

Decided: January 18, 1982.

By the Commission, Review Board No. 1, Members Parker, Chandler and Fortier.

MC 127100 (Sub-21), filed January 6, 1982. Applicant: B & B MOTOR LINES, INC., 911 Summit Street, Toledo, OH 43604. Representative: Charles K. Boxell, First Federal PLaza, 711 Adams Street, Toledo, OH 43624, (419) 243–6281. Transporting *malt beverages*, between points in the U.S., under continuing contract(s) with Metropolitan Distributing Company, The Defiance Beverage Company, Shawnee Distributors, Inc., and The Thornburgh Sales Company, all of Toledo, OH.

MC 142461 (Sub-10), filed January 5, 1982. Applicant: H & W TRUCKING CO., INC., P.O. Box 1545, Mt. Airy, NC 27030. Representative: Eric Meierhoefer, Suite 1000, 1029 Vermont Avenue, N.W., Washington, DC 20005, (202) 347–9332. Transporting *Furniture and fixtures*, between points in VA, NC, and TN, on the one hand, and, on the other, points in CA, AZ, NV, NM, TX, WA, CO, OR, ID, and UT.

MC 151941 (Sub-5), filed January 5, 1982. Applicant: DELMONT E. HARTT, INC., U.S. Route 2, Etna, ME 04435. Representative: John C. Lightbody, 30 Exchange Street, Portland, ME 04101, (207) 773–5651. Transporting *general commodities* (except household goods as defined by the Commission, and Classes A and B explosives), between points in the U.S., under continuing contract(s) with Armour Food Company, of Phoenix, AZ.

MC 160000, filed January 6, 1982. Applicant: MARTIN TRUCKING INC., 27330 Ecorse Road, Taylor, MI 48180. Representative: Alex J. Miller, 555 S. Woodward Ave., Suite 512, Birmingham, MI 48011, (313) 647–3350. Transporting *general commodities* (except classes A and B explosives), between points in MI, OH, IN, IL, and MO.

Volume OP–5–23

Decided: January 19, 1982

By the Commission, Review Board No. 3, Members, Krock, Joyce and Dowell.

MC 153068, filed January 11, 1982. Applicant: CONWAY TRANSPORTATION, INC., 5723 Este Ave., Cincinnati, OH 45232. Representative: Robert Neville, 3906 Lori Drive, Erlanger, KY 41018, (606) 342–8647. Transporting *general commodities* (except classes A and B explosives and commodities in bulk), between Cincinnati, OH, on the one hand, and, on the other, points in the U.S.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82–1889 Filed 1–25–82; 8:45 am]

BILLING CODE 7035–01–M

[Finance Docket No. 29475]

Rail Carriers; TeCe Corp. Purchase (Portion)-Chicago, Rock Island and Pacific Railroad Co., Debtor (William M. Gibbons, Trustee) in Texas, Oklahoma, and Kansas

AGENCY: Interstate Commerce Commission.

ACTION: Proceedings scheduled.

SUMMARY: The Commission is setting a procedural schedule for the filing of comments and evidence.

DATES: 1. Within 10 days of this publication, verified statements supporting or opposing this proposal must be filed.

2. Within 15 days of this publication, verified statements in reply must be filed.

ADDRESSES: The original and 10 copies of each submission should be sent to: Interstste Commerce Commission, Section of Finance, Room 5414, 12th & Constitution Ave., NW., Washington, DC 20423.

FOR FURTHER INFORMATION CONTACT: Richard A. Kelly, (202) 275–7245.

SUPPLEMENTARY INFORMATION: By application filed September 15, 1980, TeCe Corporation (TeCe), a non-carrier, seeks authority to purchase a segment of Rock Island property between Pringle, TX and Hardesty, OK (51 miles) and between Etter Junction and Morse Junction, TX, (9 miles) or, alternatively, between Liberal, KS and Pringle, and between Morse Junction and Wilco, TX, totalling 132.127 miles. Under its amended application filed January 4, 1982, TeCe proposes to purchase only 97.4 miles of track between Stinnet, Tx and Hardesty and between Etter Junction and Morse Junction, for total consideration of $2,450,000.

TeCe has submitted applications for financial assistance for the porposed transaction to the Texas Railroad Commission and to the Federal government under § 505 of the Railroad Revitalization and Regulatory Reform Act of 1976 (4R Act). Consummation is not contingent on federal or state financial assistance.

TeCe contemplates weekday operations on the line between Etter Junction (where applicant will connect with Atchison, Topeka and Santa Fe

Railway Company) and Morse Junction, and 2 to 3 days of operations a week on the line between Pringle and Hardesty. The only portion of the track proposed for joint operations is that part between Etter Junction and Sheerin, TX. TeCe anticipates it will handle 2, 000 cars annually. All of the involved track except the 9.8 miles between Pringle and Stinnet, TX is to be rehabilitated during the first 3 years of operation.

By decision served December 18, 1980, the Commission determined that TeCe's application was incomplete and would be treated as a purchase offer and handled expeditiously as an application when the pertinent information was filed.

Preliminary authorization of the proposed transaction by the Court overseeing the reorganization of Rock Island in *In the Matter of Chicago, Rock Island and Pacific Railroad Company, Debtor,* No. 75 B 2697 (U.S. Dist. Court, N.D. Ill.), was obtained December 3, 1981. The court has also directed that the Commission approve or disapprove TeCe's purchase application on or before February 16, 1982. Parties wishing to comment on the application may do so within the time outlined above.

Decided: January 19, 1982.

By the Commission, Herber P. Hardy, Director, Office of Proceedings.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-1723 Filed 1-25-82; 8:45 am]

BILLING CODE 7035-01-M

[Finance Docket No. 29808]

Rail Carriers; Transfer of Control of Rail Carrier Subsidiaries of the Continental Group, Inc., to a Wholly-Owned Subsidiary, Continental Forest Industries, Inc.; Exemption

January 20, 1982.

On December 24, 1981, the Continental Group, Inc. (Continental) which controls two rail carrier subsidiaries,[1] through stock ownership, notified the Commission that it intends to transfer its control of the two rail carriers to Continental Forest Industries, Inc. (CFI), Continental's wholly-owned non-carrier subsidiary. Continental will continue to control the two carriers through its control of CFI.

This is a transaction within a corporate family which is exempt because it does not result in adverse changes in service levels, significant operational changes, or a change in the competitive balance with carriers outside the corporate family (49 CFR 1111.5(c)(3)). Continental is undertaking this transaction for the purpose of improving its operating and managerial flexibility and efficiency.

As a condition to the use of this exemption, any NL&G and CL&G employees affected by this transaction shall be protected pursuant to *New York Dock Ry.-Control-Brooklyn Eastern Dist.,* 360 I.C.C. 60 (1979). This will satisfy the statutory requirements of 49 U.S.C. 10505(g)(2).

By the Commission, Heber P. Hardy, Director, Office of Proceedings.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-1725 Filed 1-25-82; 8:45 am]

BILLING CODE 7035-01-M

[1] North Louisiana & Gulf Railroad Company (NL&G), and Central Louisiana & Gulf Railroad Company (CL&G). Control of these two carriers was authorized pursuant to notice of exemption decided March 26, 1981 and published at 46 FR 19873-19875 (April 1, 1981). Petition for reconsideration denied May 22, 1981.

DEPARTMENT OF LABOR

Employment and Training Administration

Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for adjustment assistance issued during the period January 11, 1982 to January 15, 1982.

In order for an affirmative determination to be made and a certification of eligibility to apply for adjustment assistance to be issued, each of the group eligibility requirements of Section 222 of the Act must be met.

(1) That a significant number or proportion of the workers in the worker's firm, or an appropriate subdivision thereof, have become totally or partially separated,

(2) That sales or production, or both, of the firm or subdivision have decreased absolutely, and

(3) That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Negative Determinations

In each of following cases the investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-12,001; Washington Stove Works, Everett, WA.
TA-W-12,074; Klingman Brothers, Inc., Sedro Woolley, WA.
TA-W-12,485; Peterson Shake Co., Amanda Park, WA.
TA-W-12,371; Musgrove Milling, Olympia, WA.
TA-W-11,664; Diane Handbags, Inc., Newburgh, NY.
TA-W-11,517; Thorntown Textile Co., Thornton, IN.
TA-W-11,329; Industrial Strainer Co., Plymouth, MI.
TA-W-11,915; Smallwood Packing Co., Inc., Middlefield, OH.
TA-W-12,343; North Shore Shake, Inc., Hoquia, WA.
TA-W-12,830; J & W Cedar Products, Ridgefield, WA.
TA-W-12,264; Red Cedar Products, Amanda Park, WA.
TA-W-12,092; B & W Shake Co., Inc., Forks, WA.

In each of the following cases the investigation revealed that criterion (3) has not been met. Aggregate U.S. imports of *emblems* are negligible.

TA-W-12,283; D. L. Auld Co., Columbus, OH.
TA-W-12,009; Sebewaing Industries, Inc., Sebewaing, MI.
TA-W-12,062; J & V Products, Arcanum, OH.

In each of the following cases the investigation revealed that criterion (3) has not been met. Increased imports did not contribute importantly to workers separations at the firm.

TA-W-12,368; Automatic Feed Co., Napoleon, OH.
TA-W-12,427; Elizabeth Fashions, Inc., Hoboken, NJ.
TA-W-12,784; Broderick & Bascom Rope Co., Houston, TX.
TA-W-12,448; Fortune Fashions, Inc., Jersey City, NJ.

In each of the following cases the investigation revealed that criterion (2) has not been met.

TA-W-12,149; Exide Corp., Cheektowaga, NY.
TA-W-11,221; The Gaines, Co., Gaines, PA.

In each of the following cases the investigation revealed that sales by manufacturers for which the subject firm produced under contract did not decline.

TA-W-12,112; B & B Coat Corp., Paterson, NJ.
TA-W-11,974; Nickoletta Fashions, Inc., Jersey City NJ.

Affirmative Determinations

TA–W–11,020; Adesol Dress Corp., Selden, Long Island, NY.

A certification was issued in response to a petition received on September 8, 1980 covering all workers engaged in employment related to the production of sportswear, separated on or after April 6, 1980 and before February 8, 1981.

TA–W–11,438; General Electric Corp., Wiring Device Dept., Providence, RI.

A certification was issued in response to a petition received on October 20, 1980 covering all workers separated on or after September 1, 1980 and before June 30, 1981.

TA–W–11,490; General Electric Corp., Wiring Device Dept., Middletown, RI.

A certification was issued in response to a petition received on October 20, 1980 covering all workers separated on or after September 1, 1980 and before June 30, 1981.

I hereby certify that the aforementioned determinations were issued during the period January 11–15, 1982. Copies of these determinations are available for inspection in Room 10,332, U.S. Department of Labor, 601 D Street, NW, Washington, D.C. 20213 during normal business hours or will be mailed to persons who write to the above address.

Dated: January 18, 1982.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 82–1880 Filed 1–25–82; 8:45 am]

BILLING CODE 4510–30–M

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221 (a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 211 (a) of the Act and 29 CFR 90.12.

The purpose of each of the investigations is to determine whether absolute or relative increases of imports of articles like or directly competitive with articles produced by the workers' firm or an appropriate subdivision thereof have contributed importantly to an absolute decline in sales or production, or both, of such firm or subdivision and to the actual or threatened total or partial separation of a significant number or proportion of the workers of such firm or subdivision.

Petitioners meeting these eligibility requirements will be certified as eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act in accordance with the provisions of Subpart B of 29 CFR Part 90. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

Pursuant to 29 CFR 90.13, the petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than February 5, 1982.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than February 5, 1982.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 601 D Street, NW., Washington, D.C. 20213.

Signed at Washington, D.C., this 18th day of January, 1982.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

APPENDIX

Petitioner (Union/workers or former workers of:)	Location	Date received	Date of petition	Petition number	Articles produced
Allegheny Ludlum (USWA)	Breckenridge, PA	1–12–82	1–7–82	TA–W–13,179	Silicon electrical steel.
Allegheny Ludlum (USWA)	West Leechburg, PA	1–12–82	1–7–82	TA–W–13,180	Silicon electrical steel stainless steel alloys.
Bethlehem Steel Corp. (USWA)	Chesterton, IN	1–12–82	1–8–82	TA–W–13,181	Steel plate.
Charleston Garment Co. (workers)	Nitro, W. VA	1–12–82	12–18–81	TA–W–13,182	Sportswear.
Harbison-Walker Refractories (USWA)	Cape May Point, N.J	1–12–82	12–30–81	TA–W–13,183	Magnesite.
SKW Alloys (UAW)	Calvert City, KY	1–13–82	1–8–82	TA–W–13,184	Ferromanganese, silocomanganese.
True Temper Corp. (USWA)	Charleston, W. VA	1–12–82	1–5–82	TA–W–13,185	Striking tools and dies.
Union Carbide (workers)	Columbus, GA	1–12–82	10–28–81	TA–W–13,186	Electronic components.

[FR Doc. 82–1877 Filed 1–22–82; 8:45 am]

BILLING CODE 4510–30–M

[TA–W–10,523]

Merck and Company, Inc., and Calgon Corp., Neville Island Carbon Plant, Pittsburgh, Pennsylvania; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on December 22, 1981, published in the **Federal Register** on January 8, 1982, (47 FR 1060), applicable to all workers of the Calgon Corporation's Neville Island Carbon plant in Pittsburgh, Pennsylvania producing coconut based activated carbon.

On the basis of additional information, the Office of Trade Adjustment Assistance, on its own motion, reviewed the certification. The additional information revealed that several layoffs occurred two months prior to the impact date set in the certification.

The intent of the certification is to cover all workers of Calgon's Neville Island Carbon plant who were affected by the decline in the sales or production of coconut based activated carbon related to increased import competition.

The Certification, therefore, is amended to include a new impact date of August 1, 1980 for workers at the Neville Island Carbon plant of the Calgon Corporation, Pittsburgh, Pennsylvania.

The Certification applicable to TA–W–10,523 is hereby amended and issued as follows:

All workers of Merck and Company, Incorporated, Calgon Corporation, Neville Island Carbon Plant, Pittsburgh, Pennsylvania engaged in the production of coconut-based

activated carbon who became totally or partially separated from employment on or after August 1, 1980 and before February 1, 1981 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington, D.C., this 12th day of January 1982.

Robert O. Deslongchamps,

Acting Deputy Administrator, Unemployment Insurance Service.

[FR Doc. 82-1678 Filed 1-25-82; 8:45 am]

BILLING CODE 4510-30-M

TA-W-12,925]

Reid Stevens, Commack, New York; Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on January 12, 1981 in response to a worker petition received on January 2, 1981 which was filed on behalf of workers and former workers producing ladies' coats at Reid Stevens, Commack, New York.

On August 24, 1981, an investigation (TA-W-12,925) was initiated on behalf of the same group of workers as TA-W-12,045.

Since the identical group of workers is the subject of the ongoing investigation TA-W-12,045, a new investigation would serve no purpose. Consequently, the investigation has been terminated.

Signed at Washington, D.C., this 12th day of January 1982.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 82-1679 Filed 1-25-82; 8:45 am]

BILLING CODE 4510-30-M

Office of Pension and Welfare Benefit Programs

[Application No. D-2772]

Proposed Exemption for Certain Transactions Involving Kennedy Associates, Inc., Seattle, Washington

AGENCY: Pension and Welfare Benefit Programs, Labor.

ACTION: Notice of proposed exemption.

SUMMARY: This document contains a notice of pendency before the Department of Labor (the Department) of a proposed exemption from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and the Internal Revenue Code of 1954 (the Code). The proposed exemption would exempt the investment of plan assets on behalf of employee benefit plans (the Plan/Plans), with respect to which Kennedy Associates, Inc. (Kennedy) is a fiduciary, by Kennedy in the Multi-Employer Property Trust (MPT) or the EBT Real Estate Fund (EBT) both of which receive investment advisory services from Kennedy Associates Real Estate Counsel, Inc. (KAREC), an affiliate of Kennedy. The proposed exemption, if granted would affect participants and beneficiaries of the Plans, fiduciaries of the Plans, and Kennedy.

DATES: Written comments and requests for a public hearing must be received by the Department on or before February 26, 1982.

ADDRESS: All written comments and requests for a hearing (at least three copies) should be sent to the Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-4526, U.S. Department of Labor, 200 Constitution Avenue, NW, Washington, D.C. 20216, Attention: Application No. D-2772. The application for exemption and the comments received will be available for public inspection in the Public Documents Room of Pension and Welfare Benefit Programs, U.S. Department of Labor, Room N-4677, 200 Constitution Avenue, NW, Washington, D.C. 20216.

FOR FURTHER INFORMATION CONTACT: Richard Small of the Department, telephone (202) 523-8881. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Notice is hereby given of the pendency before the Department of an application for exemption from the restrictions of section 406 of the Act and from the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) of the Code. The proposed exemption was requested in an application filed by Kennedy and KAREC pursuant to section 408(a) of the Act and section 4975(c)(2) of the Code, and in accordance with procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, this notice of pendency is issued solely by the Department.

Summary of Facts and Representations

The application contains representations with regard to the proposed exemption which are summarized below. Interested persons are referred to the application on file with the Department for the complete representations of the applicant.

1. Kennedy is an investment adviser registered under the Investment Advisers Act of 1940. Kennedy specializes in providing services to jointly trusteed multiemployer pension funds. Such services involve providing continuous advice as to the investment of funds on the basis of the individual needs of the clients. When Kennedy exercises discretionary authority or control of assets of the Plans, Kennedy is a fiduciary with respect to such Plans.

2. KAREC is an affiliated company of Kennedy. KAREC provides investment advice to MPT. MPT is a pooled real estate equity fund which was established by the National Bank of Washington (NBW) and which offers pension plans a vehicle for participating in the ownership of commercial real estate. Fiduciary responsibility for MPT's performance rests with NBW. NBW also acts as custodian for MPT's assets. MPT has received a ruling from the Internal Revenue Service that it is a tax-exempt common trust fund within the meaning of section 548(a) of the Code. NBW, the trustee of the fund, is also subject to examination by the Comptroller of the Currency.

3. KAREC is also an investment adviser to EBT established by The First National Bank of Fairbanks (FNBF) in Fairbanks, Alaska, another pooled real estate equity fund. Like NBW, FNBF acts as trustee and as custodian of EBT's assets and in all relevant respects, EBT's organizational structure and method of operation are substantially the same as MPT.

4. It is often preferable, for reasons such as investment diversification, for pension plans to invest in an open-end investment entity rather than investing directly in portfolio securities of the type held by an investment company. It is also often preferable for a pension plan that seeks to engage in real estate investment to do so indirectly through its ownership of an interest in a pooled real estate fund. Real estate investment, while potentially profitable for pension plans, could not be undertaken directly by most plan trustees or other fiduciaries, as it involves experience and expertise not normally required of such persons. The investment philosophy of MPT and EBT is designed to maximize the primary benefits inherent in ownership of real property, including a competitive level of current income, stability of investment return and protection from inflation. Kennedy represents that because participation in MPT or EBT will be based on units of ownership, and because the value of the ownership units is based on a proportional formula, an investment in

MPT of EBT would be an attractive and appropriate investment for pension funds of all sizes.

5. Kennedy and KAREC are requesting an exemption that will permit the investment of assets of the Plans in MPT or EBT. Because KAREC will be retained to render certain advisory services to MPT or EBT, the investment of Plan assets may be prohibited by the Act.

6. Kennedy represents that it will impose the following conditions to assure that the contemplated transactions be consistent with the Act and the standards set forth in section 408(a). The conditions are as follows:

1. Neither Kennedy, KAREC nor its shareholders or employees will be an officer, director or trustee of NBW or FNBF.

2. Services with regard to both MPT and EBT will be limited to investment advisory services, including but not necessarily limited to:

(a) Providing the trustee of EBT or MPT with direct access to Kennedy's research, personal and other professional resources;

(b) Referring appropriate investment opportunities for consideration by EBT or MPT;

(c) Advising on management of cash and money market instruments; and

(d) Advising on general economic conditions.

3. No sales commission will be paid to Kennedy or KAREC by a Plan in connection with the purchase of any interest in MPT or EBT and there will be no charge for the redemption of any interest in MPT or EBT.

4. The Plan will not pay to Kennedy an investment management, investment advisory or similar fee with respect to the Plan assets invested in MPT or EBT. A Plan which has its assets managed by Kennedy pays a fee of one percent and, for such fee, Kennedy provides investment advice, assists in establishing policy, and handles all relevant transactions, including lease negotiations and sales. Such fee does not include custodial services. Plans which invest in MPT or EBT will pay to MPT or EBT a fee of one and one-half percent. For this fee MPT or EBT will perform the above stated services that Kennedy would have performed and in addition will provide custodial service. The applicants represent that as a result of the many services provided by a bank-managed commingled fund, the cost are higher than those associated with managing individual accounts. KAREC, as a fee for its investment advisory services to MPT or EBT, receives there quarters of one percent from MPT or EBT on the assets of the Plans that are managed by MPT or EPT. In addition, each Plan's investment in MPT or EBT will be limited to 10 percent of the assets of such Plan at the time the investment is entered into.

5. Prior to any Plan entering into the proposed transaction, a second fiduciary with the respect to the Plan, who is independent of and unrelated to Kennedy, KAREC, MPT, EBT, NBW or FNBF must:

(a) Authorize investment of Plan assets in pooled real estate funds;

(b) Receive an offering memorandum describing material information about MPT or EBT in which Plan assets may be invested, including a description of the services to be rendered by KAREC to pooled real estate funds it advises and the compensation to be received by KAREC therefor;

(c) Approve in writing any prospective "fee differential" to be earned by KAREC by reason of the investments. The term "*fee differential*" means the fee to be received by KAREC for services to be rendered to MPT or EBT attributable to a Plan's investment, less the investment management fee otherwise payable to Kennedy in connection with the management of those assets;

(d) Be notified of any proposed change in fees to be paid to KAREC on account of services provided to MPT or EBT and approve in writing any fee differential resulting therefrom; and

(e) Receive periodic statements concerning the performance of the real estate fund(s), including an audited annual report by an independent public accounting firm as well as quarterly unaudited reports showing the cost and fair market value of each holding as determined by the relevant real estate fund's valuation committee.

6. In summary, the Applicant represents that the requested exemption would satisfy the statutory criteria contained in section 408(a) of the Act because: (1) All terms and conditions with respect to the investment by the Plans in MPT and EBT are specific and require review and approval by an independent fiduciary; (2) the independent fiduciary will be provided with adequate disclosure concerning the investments in MPT and EBT; and (3) the investments in real estate funds will be appropriate for the Plans as part of a program of diversification of their portfolios.

Notice to Interested Persons

In addition to the publication of the notice of pendency in the **Federal Register**, Kennedy will provide a copy of the notice of pendency to the trustee of any Plan that is currently considering an investment in the proposed transaction.

General Information

The attention of interested persons is directed to the following: (1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions of the Act and the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) Before an exemption may be granted under section 408(a) of the Act and section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries and protective of the rights of participants and beneficiaries of the plan; and

(3) The proposed exemption, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

Written Comments and Hearing Requests

All interested persons are invited to submit written comments or requests for a hearing on the pending exemption to the address above, within the time period set forth above. All comments will be made a part of the record. Comments and request for a hearing should state the reasons for the writer's interest in the pending exemption. Comments received will be available for

public inspection with the application for exemption at the address set forth above.

Proposed Exemption

Based on the facts and representations set forth in the application, the Department is considering granting the requested exemption under the authority of section 408(a) of the Act and section 4975(c) (2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75–1 (40 FR 18471, April 28, 1975). If the exemption is granted, the restrictions of section 406 of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) of the Code shall not apply to the investment of Plan assets, with respect to which Kennedy is a fiduciary, by Kennedy in MPT or EBT, both of which receive investment advisory services by KAREC provided that the terms and conditions of such investments are at least as favorable as those obtainable with an unrelated party in an arms length transaction.

The proposed exemption, if granted, will be subject to the express condition that the material facts and representations contained in the application are true and complete, and that the application accurately describes all material terms of the transaction to be consummated pursuant to the exemption.

Signed at Washington, D.C., this 15th day of January, 1982.

Alan D. Lebowitz,

Assistant Administrator for Fiduciary Standards, Pension and Welfare Benefit Programs, Labor-Management Services Administration, Department of Labor.

[FR Doc. 82–1759 Filed 1–25–82; 8:45 am]

BILLING CODE 4510–29–M

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards, Subcommittee on Qualification Program for Safety Related Equipment; Meeting

The ACRS Subcommittee on Qualification Program for Safety Related Equipment will hold a meeting on February 10, 1982, at the Federal Home Loan Bank Board Building, 1700 G Street, NW, 5th Floor Conference Room, Washington, D.C. The Subcommittee will begin review of the NRC Equipment Qualification Program as outlined in SECY 81–504.

In accordance with the procedures outlined in the **Federal Register** on September 30, 1981, (46 FR 47903), oral or written statements may be presented by members of the public, recordings will be permitted only during those portions of the meeting when a transcript is being kept, and questions may be asked only by members of the Subcommittee, its consultants, and Staff. Persons desiring to make oral statements should notify the Designated Federal Employee as far in advance as practicable so that appropriate arrangements can be made to allow the necessary time during the meeting for such statements.

The entire meeting will be open to public attendance except for those sessions which will be closed to protect proprietary information (Sunshine Act Exemption 4). One or more closed sessions may be necessary to discuss such information. To the extent practicable, these closed sessions will be held so as to minimize inconvenience to members of the public in attendance.

The agenda for subject meeting shall be as follows:

Wednesday, February 10, 1982—8:30 a.m. until the conclusion of business.

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, may exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittee will then hear presentations by and hold discussions with representatives of the NRC Staff, their consultants, and other interested persons regarding this review.

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 to the cognizant Designated Federal Employee, Mr. Paul Boehnert (telephone 202/634–3267) between 8:15 a.m. and 5:00 p.m., EST.

I have determined, in accordance with subsection 10(d) of the Federal Advisory Committee Act, that it may be necessary to close portions of this meeting to public attendance to protect proprietary information. The authority for such closure is Exemption (4) to the Sunshine Act, 5 U.S.C. 552b(c)(4).

Dated: January 19, 1982.

John C. Hoyle,

Advisory Committee Management Officer.

[FR Doc. 82–1921 Filed 1–25–82; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–293]

Boston Edison Co., Pilgrim Nuclear Power Station; Modification of January 13, 1981, Order

I

The Boston Edison Company (the licensee) is the holder of Facility Operating License No. DPR–35 which authorizes the licensee to operate the Pilgrim Nuclear Power Station (the facility) at steady state reactor power levels not in excess of 1998 megawatts thermal (rated power). The facility is a boiling water reactor located at the licensee's site in Plymouth County, Massachusetts.

II

On January 13, 1981 the Commission issued an Order modifying the license requiring: (1) The licensee to promptly assess the suppression pool hydrodynamic loads in accordance with NEDO–21888 and NEDO–24583–1 and the Acceptance Criteria contained in Appendix A to NUREG–0661 and (2) design and install any plant modifications needed to assure that the facility conforms to the Acceptance Criteria contained in Appendix A to NUREG–0661. The Order, published in the **Federal Register** on January 28, 1981 (46 FR–9305), required installation of any plant modifications needed to provide compliance with the Acceptance Criteria in Appendix A to NUREG–0661 be completed not later than October 31, 1981 or, if the plant is shutdown on that date, before the resumption of power operation thereafter.

III

On October 31, 1979 the staff issued an initial version of its acceptance criteria to the affected licensees. These criteria were subsequently revised in February 1980 to reflect acceptable alternative assessment techniques which would enhance the implementation of this program. Throughout the development of these acceptance criteria, the staff has worked closely with the Mark I Owners Group in order to encourage partial plant-unique assessments and modifications to be undertaken.

Since the development of these acceptance criteria, significant progress has been made by the licensee in meeting the Order requirements. However, in the June 29, 1981 Mark I Owners Group Status Summary Report, the licensee identified unforeseen difficulties and delays encountered primarily related to one or more of the

following: (1) Torus and torus attached piping analyses; (2) equipment delivery; (3) the use of interpretations and/or alternate approaches to the NUREG–0661 Acceptance Criteria; (4) plant-unique design and modification problems; and (5) slippages in refueling outages that have necessitated revision of the Order date.

The major modifications, which are those associated with the torus, vent system, internal structures and safety relief valve piping, which comprise approximately 75% of the total program effort, will be completed within six months of the existing Order date. The remaining items to be completed are primarily associated with the torus attached piping modifications.

The Commission believes that substantial improvements have already been made in the margins of safety of the containment systems and expects improvements will continue to be made during the period until all the modifications required for compliance with this Order are completed. The Commission further believes an acceptable balance has been achieved between completion of most of the major modifications, which provide significant improvement in the safety margin, and the granting of additional time for completion of the remaining modifications which fully restore the originally intended safety margin. In consideration of the range of completion dates submitted by all of the affected licensees and an assessment of the nature of the remaining effort involved in the analysis, design and installation of the needed plant modifications, the Commission has concluded that the licensee's proposed completion schedule is both responsive and practicable.

The Commission has, therefore, determined to modify the January 13, 1981 Order to extend the previously imposed completion date for needed plant modifications. This Order continues in effect the exemption to General Design Criterion 50 of Appendix A to 10 CFR Part 50 granted on January 13, 1981.

IV

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, including sections 103 and 161i, and the Commission's rules and regulations in 10 CFR Parts 2 and 50, it is ordered that the completion date specified in Section V of the January 13, 1981, "Order for Modification of License," is hereby changed to read as follows: "May 1, 1982 for completion of the major modifications and prior to the start of Cycle 7 for completion of the remaining modifications." The Order of January 13, 1981, except as modified herein, remains in effect in accordance with its terms.

V

The licensee may request a hearing on this Order on or before February 25, 1982. A request for hearing shall be submitted to the Director, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Copies of the request shall also be sent to the Secretary of the Commission and the Executive Legal Director at the same address.

If a hearing is requested by the licensee, the Commission will issue an order designating the time and place of any such hearing. If a hearing is held, the issue to be considered at such a hearing shall be whether the completion date specified in section V of the January 13, 1981, "Order for Modification of License," should be changed to "May 1, 1982 for completion of the major modifications and prior to the start of Cycle 7 for completion of the remaining modifications."

This Order shall become effective upon expiration of the period within which a hearing may be requested or, if a hearing is requested, on the date specified in an order issued following further proceedings on this Order.

Dated at Bethesda, Md., this 19th day of January 1982.

For the Nuclear Regulatory Commission.

Darrell G. Eisenhut,

Director, Division of Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 82–1903 Filed 1–25–82; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–325]

Carolina Power & Light Co., Brunswick Steam Electric Plant, Unit No. 1; Modification of January 13, 1981 Order

I

The Carolina Power and Light Company (the licensee) is the holder of Facility Operating License No. DPR–71 which authorizes the licensee to operate the Brunswick Steam Electric Plant, Unit No. 1 (the facility) at power levels not in excess of 2436 megawatts thermal (rated power). The facility is a boiling water reactor located at the licensee's site in Brunswick County, North Carolina.

II

On January 13, 1981 the Commission issued an Order modifying the license requiring: (1) The licensee to promptly assess the suppression pool hydrodynamic loads in accordance with NEDO–21888 and NEDO–24583–1 and the Acceptance Criteria contained in Appendix A to NUREG–0661 and (2) design and install any plant modifications needed to assure that the facility conforms to the Acceptance Criteria contained in Appendix A to NUREG–0661. The order, published in the **Federal Register** on January 28, 1981 (46 FR 9306) required installation of any plant modifications needed to provide compliance with the Acceptance Criteria in Appendix A to NUREG–0661 be completed not later than February 28, 1982, or, if the plant is shutdown on that date, before the resumption of power operation thereafter. On February 27, 1981, the licensee requested a hearing to contest the completion date specified in the Order.

III

The licensee's request for a hearing has been held in abeyance pending efforts to resolve the contested completion date by administrative means. By letter dated March 9, 1981, the licensee set forth various unforeseen difficulties and delays that have been encountered primarily related to: (1) Delay in completion of plant-unique analyses; and (2) slippages in refueling outages that have necessitated revision of the Order date.

Most of the major modifications, which are those associated with the torus, vent system, internal structures and safety relief valve piping have been or will be completed by the existing order date. These modifications comprise a significant portion of the total program effort. The remaining items to be completed are primarily associated with the torus attached piping modifications.

The Commission believes that substantial improvements have already been made in the margins of safety of the containment systems and expects improvements will continue to be made during the period until all the modifications required for compliance with this Order are completed. The Commission further believes an acceptable balance has been achieved between completion of most of the major modifications, which provide significant improvement in the safety margin, and the granting of additional time for completion of the remaining modifications which fully restore the originally intended safety margin. In consideration of the range of completion dates submitted by all of the affected licensees and an assessment of the nature of the remaining effort involved in the analysis, design and installation of the needed plant modifications, the Commission has concluded that the

licensee's proposed completion schedule is both responsive and practicable.

The Commission has, therefore, determined to withdraw the completion date proposed in the January 13, 1981 Order and substitute the completion date set forth below. The exemption to General Design Criterion 50 of Appendix A to 10 CFR Part 50 granted on January 13, 1981, continues in effect.

IV

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, including sections 103 and 161i, and the Commission's rules and regulations in 10 CFR Parts 2 and 50, it is ordered that the completion date proposed in Section V of the January 13, 1981, "Order for Modification of License," is hereby withdrawn and the following completion date is substituted: "Prior to the start of Cycle 5."

V

The licensee may request a hearing on this Order on or before February 25, 1982. A request for hearing shall be submitted to the Director, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Copies of the request shall also be sent to the Secretary of the Commission and the Executive Legal Director at the same address.

If a hearing is requested by the licensee, the Commission will issue an order designating the time and place of any such hearing. If a hearing is held, the issue to be considered at such a hearing shall be whether the licensee should be required to complete the design and installation of plant modifications needed to assure that the facility conforms to the Acceptance Criteria contained in Appendix A to NUREG–0661 prior to the start of Cycle 5.

This Order shall become effective upon expiration of the period within which a hearing may be requested or, if a hearing is requested, on the date specified in an order issued following further proceedings on this Order.

Dated at Bethesda, Md., this 19th day of January 1982.

For the Nuclear Regulatory Commission.

Darrell G. Eisenhut,

Director, Division of Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 82-1904 Filed 1-25-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-237]

Commonwealth Edison Co., Dresden Nuclear Power Station Unit No. 2; Modification of January 13, 1981 Order

I

The Commonwealth Edison Company (the licensee) is the holder of Provisional Operarting License No. DPR–19 which authorizes the licensee to operate the Dresden Nuclear Power Station, Unit 2 (the facility) at power levels not in excess of 2527 megawatts thermal (rated power). The facility is a boiling water reactor located at the licensee's site in Grundy County, Illinois.

II

On January 13, 1981 the Commission issued an Order modifying the license requiring: (1) The licensee to promptly assess the suppression pool hydrodynamic loads in accordance with NEDO–21888 and NEDO–24583–1 and the Acceptance Criteria contained in Appendix A to NUREG–0661 and (2) design and install any plant modifications needed to assure that the facility conforms to the Acceptance Criteria contained in Appendix A to NUREG–0661. The Order, published in the **Federal Register** on January 28, 1981 (46 FR 9309) required installation of any plant modifications needed to provide compliance with the Acceptance Criteria in Appendix A to NUREG–0661 be completed not later than January 31, 1983, or if the plant is shutdown on that date, before the resumption of power operation thereafter.

III

On October 31, 1979 the staff issued an initial version of its acceptance criteria to the affected licensees. These criteria were subsequently revised in February 1980 to reflect acceptable alternative assessment techniques which would enhance the implementation of this program. Throughout the development of these acceptance criteria, the staff has worked closely with the Mark I Owners Group in order to encourage partial plant-unique assessments and modifications to be undertaken.

Since the development of these acceptance criteria, significant progress has been made by the licensee in meeting the Order requirements. However, in the June 29, 1981 Mark I Owners Group Status Summary Report, the licensee identified unforeseen difficulties and delays encountered primarily related to one or more of the following: (1) Torus and torus attached piping analyses; (2) equipment delivery; (3) the use of interpretations and/or alternate approaches to the NUREG–0661 Acceptance Criteria; (4) plant-unique design and modification problems; and (5) slippages in refueling outages that have necessitated revision of the Order date.

The major modifications, which are those associated with the torus, vent system, internal structures and safety relief valve piping, which comprise approximately 75% of the total program effort, will be completed during the outage that is prior to or expected to coincide with the existing Order date. The remaining items to be completed are primarily associated with the torus attached piping modifications.

The Commission believes that substantial improvements have already been made in the margins of safety of the containment systems and expects improvements will continue to be made during the period until all the modifications required for compliance with this Order are completed. The Commission further believes an acceptable balance has been achieved between completion of the major modifications, which provide significant improvement in the safety margin, and the granting of additional time for completion of the remaining modifications which fully restore the originally intended safety margin. In consideration of the range of completion dates submitted by all of the affected licensees and an assessment of the nature of the remaining effort involved in the analysis, design and installation of the needed plant modifications, the Commission has concluded that the licensee's proposed completion schedule is both responsive and practicable.

The Commission has, therefore, determined to modify the January 13, 1981 Order to extend the previously imposed completion date for needed plant modifications. This Order continues in effect the exemption to General Design Criterion 50 of Appendix A to 10 CFR Part 50 granted on January 13, 1981.

IV

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, including Sections 103 and 161i, and the Commission's rules and regulations in 10 CFR Parts 2 and 50, it is ordered that the completion date specified in Section V of the January 13, 1981, "Order for Modification of License," is hereby changed to read as follows: "Prior to start of Cycle 9 for completion of the major modifications and prior to July 1, 1983 for completion of the remaining modifications." The Order of January 13,

1981, except as modified herein, remains in effect in accordance with its terms.

V

The licensee may request a hearing on this order on or before February 25, 1982. A request for hearing shall be submitted to the Director, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Copies of the request shall also be sent to the Secretary of the Commission and the Executive Legal Director at the same address.

If a hearing is requested by the licensee, the Commission will issue an order designating the time and place of any such hearing. If a hearing is held, the issue to be considered at such a hearing shall be whether the completion date specified in section V of the January 13, 1981, "Order for Modification of License," should be changed to read as follows: "Prior to start of Cycle 9 for completion of the major modifications and prior to July 1, 1983 for completion of the remaining modifications."

This Order shall become effective upon expiration of the period within which a hearing may be requested or, if a hearing is requested, on the date specified in an order issued following futher proceedings on this Order.

Dated at Bethesda, Maryland, this 19th day of January 1982.

For the Nuclear Regulatory Commission.

Darrell G. Eisenhut,

Director, Division of Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 82-1906 Filed 1-25-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-249]

Commonwealth Edison Co., Dresden Nuclear Power Station Unit No. 3; Modification of January 13, 1981 Order

I

The Commonwealth Edison Company (the licensee) is the holder of Facility Operating License No. DPR-25 which authorizes the licensee to operate the Dresden Nuclear Power Station, Unit 3 (the facility) at power levels not in excess of 2527 megawatts thermal (rated power). The facility is a boiling water reactor located at the licensee's site in Grundy County, Illinois.

II

On January 13, 1981 the Commission issued an Order modifying the license requiring: (1) The licensee to promptly assess the suppression pool hydrodynamic loads in accordance with NEDO-21888 and NEDO-24583-1 and the Acceptance Criteria contained in Appendix A to NUREG-0661 and (2) design and install any plant modifications needed to assure that the facility conforms to the Acceptance Criteria contained in Appendix A to NUREG-0661. The Order, published in the Federal Register on January 28, 1981 (46 FR 9311) required installation of any plant modifications needed to provide compliance with the Acceptance Criteria in Appendix A to NUREG-0661 be completed not later than July 31, 1982, or if the plant is shutdown on that date, before the resumption of power operation thereafter.

III

On October 31, 1979 the staff issued an initial version of its acceptance criteria to the affected licensees. These criteria were subsequently revised in February 1980 to reflect acceptable alternative assessment techniques which would enhance the implementation of this program. Throughout the development of these acceptance criteria, the staff has worked closely with the Mark I Owners Group in order to encourage partial plant-unique assessments and modifications to be undertaken.

Since the development of these acceptance criteria, significant progress has been made by the licensee in meeting the Order requirements. However, in the June 29, 1981 Mark I Owners Group Status Summary Report, the licensee identified unforeseen difficulties and delays encountered primarily related to one or more of the following: (1) Torus and torus attached piping analyses; (2) equipment delivery; (3) the use of interpretations and/or alternate approaches to the NUREG-0661 Acceptance Criteria; (4) plant-unique design and modification problems; and (5) slippages in refueling outages that have necessitated revision of the Order date.

The major modifications, which are those associated with the torus, vent system, internal structures and safety relief valve piping, which comprise approximately 75% of the total program effort, will be completed within five months of the existing Order date. The remaining items to be completed are primarily associated with the torus attached piping modifications.

The Commission believes that substantial improvements have already been made in the margins of safety of the containment systems and expects improvements will continue to be made during the period until all the modifications required for compliance with this Order are completed. The Commission further believes an acceptable balance has been achieved between completion of most of the major modifications, which provide significant improvement in the safety margin, and the granting of additional time for completion of the remaining modifications which fully restore the originally intended safety margin. In consideration of the range of completion dates submitted by all of the affected licensees and an assessment of the nature of the remaining effort involved in the analysis, design and installation of the needed plant modifications, the Commission has concluded that the licensee's proposed completion schedule is both responsive and practicable.

The Commission has, therefore, determined to modify the January 13, 1981 Order to extend the previously imposed completion dates for needed plant modifications. This Order continues in effect the exemption to General Design Criterion 50 of Appendix A to 10 CFR Part 50 granted on January 13, 1981.

IV

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, including sections 103 and 161i, and the Commission's rules and regulations in 10 CFR Parts 2 and 50, it is ordered that the completion date specified in section V of the January 13, 1981, "Order for Modification of License," is hereby changed to read as follows: "December 30, 1982 for completion of the major modifications and prior to the start of Cycle 9 for completion of the remaining modifications." The Order of January 13, 1981, except as modified herein, remains in effect in accordance with its terms.

V

The licensee may request a hearing on this Order on or before February 25, 1982. A request for hearing shall be submitted to the Director, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Copies of the request shall also be sent to the Secretary of the Commission and the Executive Legal Director at the same address.

If a hearing is requested by the licensee, the Commission will issue an order designating the time and place of any such hearing. If a hearing is held, the issue to be considered at such a hearing shall be whether the completion date specified in section V of the January 13, 1981, "Order for Modification of License," should be changed to read as follows: "December 30, 1982 for completion of the major

modifications and prior to the start of Cycle 9 for completion of the remaining modifications."

This Order shall become effective upon expiration of the period within which a hearing may be requested or, if a hearing is requested, on the date specified in an order issued following further proceedings on this Order.

Dated at Bethesda, Maryland, this 19th day of January 1982.

For the Nuclear Regulatory Commission.

Darrell B. Eisenhut,

Director, Division of Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 82-1907 Filed 1-25-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-254]

Commonwealth Edison Co. and Iowa-Illinois Gas & Electric Co., Quad Cities Nuclear Power Station, Unit No. 1; Modification of January 13, 1981 Order

I

The Commonwealth Edison Company, et. al. (the licensee) is the holder of Facility Operating License No. DPR-29 which authorizes the licensee to operate the Quad Cities Nuclear Power Station, Unit No. 1 (the facility) at power levels not in excess of 2511 megawatts thermal (rated power). The facility is a boiling water reactor located at the licensee's site near Cordova, Illinois.

II

On January 13, 1981 the Commission issued an Order modifying the license requiring: (1) The licensee to promptly assess the suppression pool hydrodynamic loads in accordance with NEDO-21888 and NEDO-24583-1 and the Acceptance Criteria contained in Appendix A to NUREG-0661 and (2) design and install any plant modifications needed to assure that the facility conforms to the Acceptance Criteria contained in Appendix A to NUREG-0661. The Order, published in the **Federal Register** on January 28, 1981 (46 FR 9312) required installation of any plant modifications needed to provide compliance with the Acceptance Criteria in Appendix A to NUREG-0661 be completed not later than December 31, 1982, or if the plant is shutdown on that date, before the resumption of power operation thereafter.

III

On October 31, 1979 the staff issued an initial version of its acceptance criteria to the affected licensees. These criteria were subsequently revised in February 1980 to reflect acceptable alternative assessment techniques which would enhance the implementation of this program. Throughout the development of these acceptance criteria, the staff has worked closely with the Mark I Owners Group in order to encourage partial plant-unique assessments and modifications to be undertaken.

Since the development of these acceptance criteria, significant progress has been made by the licensee in meeting the Order requirements. However, in the June 29, 1981 Mark I Owners Group Status Summary Report, the licensee identified unforeseen difficulties and delays encountered primarily related to one or more of the following: (1) Torus and torus attached piping analyses; (2) equipment delivery; (3) the use of interpretations and/or alternate approaches to the NUREG-0661 Acceptance Criteria; (4) plant-unique design and modification problems; and (5) slippages in refueling outages that have necessitated revision of the Order date.

The major modifications, which are those associated with the torus, vent system, internal structures and safety relief valve piping, which comprise approximately 75% of the total program effort, will be completed during the outage that is prior to or expected to coincide with the existing Order date. The remaining items to be completed are primarily associated with the torus attached piping modifications.

The Commission believes that substantial improvements have already been made in the margins of safety of the comtainment systems and expects improvements will continue to be made during the priod until all the modifications required for compliance with this Order are completed. The Commission further believes an acceptable balance has been achieved between completion of the major modifications, which provide significant improvement in the safety margin, and the granting of additional time for completion of the remaining modifications which fully restore the originally intended safety margin. In consideration of the range of completion dates submitted by all of the affected licensees and an assessment of the nature of the remaining effort involved in the analysis, design and installation of the needed plant modifications, the Commission has concluded that the licensee's proposed completion schedule is both responsive and practicable.

The Commission has, therefore, determined to modify the January 13, 1981 Order to extent the previously imposed completion dates for needed plant modifications. This Order continues in effect the exemption of General Design Criterion 50 of Appendix A to 10 CFR Part 50 granted on January 13, 1981.

IV

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, including sections 103 and 161i, and the Commission's rules and regulations in 10 CFR Parts 2 and 50, it is ordered that the completion date specified in Section V of the January 13, 1981, "Order for Modification of License," is hereby changed to read as follows: "Prior to start of Cycle 7 for completion of the major modifications and prior to July 1, 1983 for completion of the remaining modifications." The Order of January 13, 1981, except as modified herein, remains in effect in accordance with its terms.

V

The licensee may request a hearing on this Order on or before February 25, 1982. A request for hearing shall be submitted to the Director, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Copies of the request shall also be sent to the Secretary of the Commission and the Executive Legal Director at the same address.

If a hearing is requested by the licensee, the Commission will issue an order designating the time and place of any such hearing. If a hearing is held, the issue to be considered at such a hearing shall be whether the completion date specified in Section V of the January 13, 1981, "Order for Modification of License," should be changed to read as follows: "Prior to start of Cycle 7 for completion of the major modifications and prior to July 1, 1983 for completion of the remaining modifications."

This Order shall become effective upon expiration of the period within which a hearing may be requested or, if a hearing is requested, on the date specified in an order issued following further proceedings on this Order.

Dated at Bethesda, Maryland, this 19th day of January 1982.

For the Nuclear Regulatory Commission.

Darrell G. Eisenhut,

Director, Division of Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 82-1908 Filed 1-25-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-265]

Commonwealth Edison Co. and Iowa-Illinois Gas & Electric Co., Quad Cities Nuclear Power Station, Unit No. 2; Modification of January 13, 1981 Order

I

The Commonwealth Edison Company, et al. (the licensee) is the holder of Facility Operating License No. DPR-30 which authorizes the licensee to operate the Quad Cities Nuclear Power Station, Unit No. 2 (the facility) at power levels not in excess of 2511 megawatts thermal (rated power). The facility is a boiling water reactor located at the licensee's site near Cordova, Illinois.

II

On January 13, 1981 the Commission issued an Order modifying the license requiring: (1) The licensee to promptly assess the suppression pool hydrodynamic loads in accordance with NEDO-21888 and NEDO-24583-1 and the Acceptance Criteria contained in Appendix A to NUREG-0661 and (2) design and install any plant modifications needed to assure that the facility conforms to the Acceptance Criteria contained in Appendix A to NUREG-0661. The Order, published in the Federal Register on January 28, 1981 (46 FR 9314) required installation of any plant modifications needed to provide compliance with the Acceptance Criteria in Appendix A to NUREG-0661 be completed not later than July 31, 1982, or if the plant is shut down on that date, before the resumption of power operation thereafter.

III

On October 31, 1979 the staff issued an initial version of its acceptance criteria to the affected licensees. These criteria were subsequently revised in February 1980 to reflect acceptable alternative assessment techniques which would enhance the implementation of this program. Throughout the development of these acceptance criteria, the staff has worked closely with the Mark I Owners Group in order to encourage partial plant-unique assessments and modifications to be undertaken.

Since the development of these acceptance criteria, significant progress has been made by the licensee in meeting the Order requirements. However, in the June 29, 1981 Mark I Owners Group Status Summary Report, the licensee identified unforeseen difficulties and delays encountered primarily related to one or more of the following: (1) Torus and torus attached piping analyses; (2) equipment delivery; (3) the use of interpretations and/or alternate approaches to the NUREG-0661 Acceptance Criteria; (4) plant-unique design and modification problems; and (5) slippages in refueling outages that have necessitated revision of the Order date.

The major modifications, which are those associated with the torus, vent system, internal structures and safety relief valve piping have been or will be completed by the existing Order date. These modifications comprise a significant portion of the total program effort. The remaining items to be completed are primarily associated with the torus attached piping modifications.

The Commission believes that substantial improvements have already been made in the margins of safety of the containment systems and expects improvements will continue to be made during the period until all the modifications required for compliance with this Order are completed. The Commission further believes an acceptable balance has been achieved between completion of most of the major modifications, which provide significant improvement in the safety margin, and the granting of additional time for completion of the remaining modifications which fully restore the originally intended safety margin. In consideration of the range of completion dates submitted by all of the affected licensees and an assessment of the nature of the remaining effort involved in the analysis, design and installation of the needed plant modifications, the Commission has concluded that the licensee's proposed completion schedule is both responsive and practicable.

The Commission has, therefore, determined to modify the January 13, 1981 Order to extend the previously imposed completion dates for needed plant modifications. This Order continues in effect the exemption to General Design Criterion 50 of Appendix A to 10 CFR Part 50 granted on January 13, 1981.

IV

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, including sections 103 and 161i, and the Commission's rules and regulations in 10 CFR Parts 2 and 50, it is ordered that the completion date specified in Section V of the January 13, 1981, "Order for Modification of License," is hereby changed to read as follows: "Prior to the start of Cycle 7." The Order of January 13, 1981, except as modified herein, remains in effect in accordance with its terms.

V

The licensee may request a hearing on this Order on or before February 25, 1982. A request for hearing shall be submitted to the Director, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Copies of the request shall also be sent to the Secretary of the Commission and the Executive Legal Director at the same address.

If a hearing is requested by the licensee, the Commission will issue an order designating the time and place of any such hearing. If a hearing is held, the issue to be considered at such a hearing shall be whether the completion date specified in Section V of the January 13, 1981, "Order for Modification of License," should be changed to read as follows: "Prior to the start of Cycle 7."

This Order shall become effective upon expiration of the period within which a hearing may be requested or, if a hearing is requested, on the date specified in an order issued following further proceedings on this Order.

Dated at Bethesda, Maryland, this 19th day of January 1982.

For the Nuclear Regulatory Commission.

Darrell G. Eisenhut,

Director, Division of Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 82-1909 Filed 1-25-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-324]

Carolina Power & Light Co., Brunswick Steam Electric Plant, Unit No. 2; Modification of January 13,1981 Order

I

The Carolina Power and Light Company (the licensee) is the holder of Facility Operating License No. DPR-62 which authorizes the licensee to operate the Brunswick Steam Electric Plant, Unit No. 2 (the facility) at power levels not in excess of 2436 megawatts thermal (rated power). The facility is a boiling water reactor located at the licensee's site in Brunswick County, North Carolina.

II

On January 13, 1981 the Commission issued an Order modifying the license requiring: (1) The licensee to promptly assess the suppression pool hydrodynamic loads in accordance with NEDO-21888 and NEDO-24583-1 and the Acceptance Criteria contained in Appendix A to NUREG-0661 and (2) design and install any plant modifications needed to assure that the

facility conforms to the Acceptance Criteria contained in Appendix A to NUREG–0661. The Order, published in the Federal Register on January 28, 1981 (46 FR 9308) required installation of any plant modifications needed to provide compliance with the Acceptance Criteria in Appendix A to NUREG–0661 be completed not later than November 30, 1981, or, if the plant is shutdown on that date, before the resumption of power operation thereafter. On February 27, 1981, the licensee requested a hearing to contest the completion date specified in the Order.

III

The licensee's request for a hearing has been held in abeyance pending efforts to resolve the contested completion date by adminstrative means. By letter dated March 9, 1981, the licensee set forth various unforeseen difficulties and delays that have been encountered primarily related to: (1) Delay in completion of plant-unique analyses; and (2) slippages in refueling outages that have necessitated revision of the Order date.

The major modifications, which are those associated with the torus, vent system, internal structures and safety relief valve piping, which comprise approximately 75% of the total program effort have already been completed. The remaining items to be completed are primarily associated with the torus attached piping modifications.

The Commission believes that substantial improvements have already been made in the margins of safety of the containment systems and expects improvements will continue to be made during the period until all the modifications required for compliance with this Order are completed. The Commission further believes an acceptable balance has been achieved between completion of the major modifications, which provide significant improvement in the safety margin, and the granting of additional time for completion of the remaining modifications which fully restore the originally intended safety margin. In consideration of the range of completion dates submitted by all of the affected licensees and an assessment of the nature of the remaining effort involved in the analysis, design and installation of the needed plant modifications, the Commission has concluded that the licensee's proposed completion schedule is both responsive and practicable.

The Commission has, therefore, determined to withdraw the completion date proposed in the January 13, 1981 Order and substitute the completion date set forth below. The exemption to General Design Criterion 50 of Appendix A to 10 CFR Part 50 granted on January 13, 1981, continues in effect.

IV

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, including Sections 103 and 161i, and the Commission's rules and regulations in 10 CFR Parts 2 and 50, it is ordered that the completion date proposed in Section V of the January 13, 1981, "Order for Modification of License," is hereby withdrawn and the following completion date is substituted: "Prior to the start of Cycle 6."

V

The licensee may request a hearing on this Order on or before February 25, 1982. A request for hearing shall be submitted to the Director, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Copies of the request shall also be sent to the Secretary of the Commission and the Executive Legal Director at the same address.

If a hearing is requested by the licensee, the Commission will issue an order designating the time and place of any such hearing. If a hearing is held, the issue to be considered at such a hearing shall be whether the licensee should be required to complete the design and installation of plant modifications needed to assure that the facility conforms to the Acceptance Criteria contained in Appendix A to NUREG–0661 prior to the start of Cycle 6.

This Order shall become effective upon expiration of the period within which a hearing may be requested or, if a hearing is requested, on the date specified in an order issued following further proceedings on this Order.

Dated at Bethesda, Maryland, this 19th day of January 1982.

For the Nuclear Regulatory Commission.

Darrell G. Eisenhut,

Director, Division of Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 82-1905 Filed 1-25-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-219]

GPU Nuclear Corp. and Jersey Central Power and Light Co., Oyster Creek Nuclear Generating Station; Modification of January 13, 1981 Order and December 29, 1981 Order

I

The GPU Nuclear Corporation and Jersey Central Power and Light Company (the licensees) are the holders of provisional Operating License No. DPR–16 which authorized GPU Nuclear Corporation, (the licensee) to operate the Oyster Creek Nuclear Generating Station (the facility) at power levels not in excess of 1930 megawatts thermal (rated power). The facility is a boiling water reactor located in Ocean County, New Jersey.

II

On January 13, 1981 the Commission issued an Order modifying the license requiring: (1) The licensee to promptly assess the suppression pool hydrodynamic loads in accordance with NEDO–21888 and NEDO–24583–1 and the Acceptance Criteria contained in Appendix A to NUREG–0661 and (2) design and install any plant modifications needed to assure that the facility conforms to the Acceptance Criteria contained in Appendix A to NUREG–0661. The Order, published in the Federal Register on January 26, 1981 (46 FR 8139) required installation of any plant modifications needed to provide compliance with the Acceptance Criteria in Appendix A to NUREG–0661 be completed not later than December 31, 1981 or, if the plant is shutdown on that date, before the resumption of power operation thereafter.

On December 29, 1981 a 45-day extension of this January 13, 1981 Order, published in the Federal Register on January 6, 1982 (47 FR 702) was granted by the Director of the Division of Licensing pending Commission approval of a staff generic proposal to extend the completion dates for the Mark I long-term program containment modifications for all affected licensees.

III

On October 31, 1979 the staff issued an initial version of its acceptance criteria to the affected licensees. These criteria were subsequently revised in February 1980 to reflect acceptable alternative assessment techniques which would enhance the implementation of this program. Throughout the development of these acceptance criteria, the staff has worked closely with the Mark I Owners Group in order to encourage partial plant-unique assessments and modifications to be undertaken.

Since the development of these acceptance criteria, significant progress has been made by the licensee in meeting the Order requirements. However, by letter dated August 27, 1981 the licensee stated that unforeseen difficulties and delays have been encountered primarily related to one or

more of the following: (1) Torus and torus attached piping analyses; (2) equipment delivery; (3) the use of interpretations and/or alternate approaches to the NUREG–0661 Acceptance Criteria; (4) plant-unique design and modification problems; and (5) slippages in refueling outages that have necessitated revision of the Order date.

The major modifications, which are those associated with the torus, vent system, internal structures and safety relief valve piping, which comprise approximately 75% of the total program effort, will be completed within 8 months of the existing Order date. The remaining items to be completed are primarily associated with the torus attached piping modifications.

The Commission believes that substantial improvements have already been made in the margins of safety of the containment systems and expects improvements will continue to be made during the period until all the modifications required for compliance with this Order are completed. The Commission further believes an acceptable balance has been achieved between completion of most of the major modifications, which provide significant improvement in the safety margin, and the granting of additional time for completion of the remaining modifications which fully restore the originally intended safety margin. In consideration of the range of completion dates submitted by all of the affected licensees and an assessment of the nature of the remaining effort involved in the analysis, design and installation of the needed plant modifications, the Commission has concluded that the licensee's proposed completion schedule is both responsive and practicable.

The Commission has, therefore, determined to modify the January 13, 1981 Order, as modified by the Order of December 29, 1981, to extend the previously imposed completion dates for needed plant modifications. This Order continues in effect the exemption to General Design Criterion 50 of Appendix A to 10 CFR Part 50 granted on January 13, 1981.

IV

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, including sections 103 and 161i, and the Commission's rules and regulations in 10 CFR Parts 2 and 50, it is ordered that the completion date specified in Section V of the January 13, 1981, "Order for Modification of License," is hereby changed to read as follows: "Prior to start of Cycle 10 for completion of the major modifications and prior to the start of Cycle 11 for completion of the remaining modifications." The Order of January 13, 1981 as modified December 29, 1981, except as modified herein, remains in effect in accordance with its terms.

V

The licensee may request a hearing on this Order on or before February 25, 1982. A request for hearing shall be submitted to the Director, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington D.C. 20555. Copies of the request shall also be sent to the Secretary of the Commission and the Executive Legal Director at the same address.

If a hearing is requested by the licensee, the Commission will issue an order designating the time and place of any such hearing. If a hearing is held, the issue to be considered at such a hearing shall be whether the completion date specified in Section V of the January 13, 1981, "Order for Modification of License," should be changed to "Prior to start of Cycle 10 for completion of the major modifications and prior to the start of Cycle 11 for completion of the remaining modifications."

This Order shall become effective upon expiration of the period within which a hearing may be requested or, if a hearing is requested on the date specified in an order issued following further proceedings on this Order.

Dated at Bethesda, Maryland, this 19th day of January, 1982.

For the Nuclear Regulatory Commission.

Darrell G. Eisenhut,

Director, Division of Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 82–1910 Filed 1–25–82; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–331]

Iowa Electric Light & Power Co. et al., Duane Arnold Energy Center; Modification of January 13, 1981 Order

I

The Iowa Electric Light and Power Company, et al. (the licensee) is the holder of Facility Operating License No. DPR–49 which authorizes the licensee to operate the Duane Arnold Energy Center (the facility) at steady state reactor core power levels not in excess of 1658 megawatts thermal (rated power). The facility is a boiling water reactor located at the licensee's site near Palo in Linn County, Iowa.

II

On January 13, 1981 the Commission issued an Oder modifying the license requiring: (1) The licensee to promptly assess the suppression pool hydrodynamic loads in accordance with NEDO–21888 and NEDO–24583–1 and the Acceptance Criteria contained in Appendix A to NUREG–0661 and (2) design and install any plant modifications needed to assure that the facility conforms to the Acceptance Criteria contained in Appendix A to NUREG–0661. The Order, published in the **Federal Register** on January 28, 1981 (46 FR 9282), required installation of any plant modifications needed to provide compliance with the Acceptance Criteria in Appendix A to NUREG–0661 be completed not later than June 30, 1982 or, if the plant is shutdown on that date, before the resumption of power operation thereafter.

III

On October 31, 1979 the staff issued an intitial version of its acceptance criteria to the affected licensees. These criteria were subsequently revised in February 1980 to reflect acceptable alternative assessment techniques which would enhance the implementation of this program. Throughout the development of these acceptance criteria, the staff has worked closely with the Mark I Owners Group in order to encourage partial plant-unique assessments and modifications to be undertaken.

Since the development of these acceptance criteria, significant progress has been made by the licensee in meeting the Order requirements. However, in the June 29, 1981 Mark I Owners Group Status Summary Report, the licensee identified unforeseen difficulties and delays encountered primarily related to one or more of the following: (1) Torus and torus attached piping analyses; (2) equipment delivery; (3) the use of interpretations and/or alternate approaches to the NUREG–0661 Acceptance Criteria; (4) plant-unique design and modification problems; and (5) slippages in refueling outages that have necessitated revision of the Order date.

The major modifications, which are those associated with the torus, vent system, internal structures and safety relief valve piping, which comprise approximately 75% of the total program effort, will be completed within four months of the existing Order date. The remaining items to be completed are primarily associated with the torus attached piping modifications.

The Commission believes that substantial improvements have already been made in the margins of safety of the containment systems and expects improvements will continue to be made during the period until all the modifications required for compliance with this Order are completed. The Commission further believes an acceptable balance has been achieved between completion of most of the major modifications, which provide significant improvement in the safety margin, and the granting of additional time for completion of the remaining modifications which fully restore the originally intended safety margin. In consideration of the range of completion dates submitted by all of the affected licensees and an assessment of the nature of the remaining effort involved in the analysis, design and installation of the needed plant modifications, the Commission has concluded that the licensee's proposed completion schedule is both responsive and practicable.

The Commission has, therefore, determined to modify the Janaury 13, 1981 Order to extend the previously imposed completion date for needed plant modifications. This Order continues in effect the exemption to General Design Criterion 50 of Appendix A to 10 CFR Part 50 granted on January 13, 1981.

IV

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, including sections 103 and 161i, and the Commission's rules and regulations in 10 CFR Parts 2 and 50, it is ordered that the completion date specified in Section V of the January 13, 1981, "Order for Modification of License," is hereby changed to read as follows: "Prior to the start of Cycle 7 for completion of major modifications and prior to July 1, 1983 for completion of the remaining modifications." The Order of January 13, 1981, except as modified herein, remains in effect in accordance with its terms.

V

The licensee may request a hearing on this Order on or before February 25, 1982. A request for hearing shall be submitted to the Director, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Copies of the requests shall also be sent to the Secretary of the Commission and the Executive Legal Director at the same address.

If a hearing is requested by the licensee, the commission will issue an order designating the time and place of any such hearing. If a hearing is held, the issue to be considered at such a hearing shall be whether the completion date specified in Section V of the January 13, 1981, "Order for Modification of License," should be changed to "prior to the start of Cycle 7 for completion of major modifications and prior to July 1, 1983 for completion of the remaining modifications."

This Order shall become effective upon expiration of the period within which a hearing may be requested or, if a hearing is requested, on the date specified in an order issued following further proceedings on this Order.

Dated at Bethesda, Maryland, this 19th day of January 1982.

For the Nuclear Regulatory Commission.

Darrell G. Eisenhut,

Director, Division of Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 82-1911 Filed 1-25-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-220]

Niagara Mohawk Power Corp., Nine Mile Point Nuclear Station, Unit No. 1; Modification of January 13, 1981 Order.

I

The Niagara Mohawk Power Corporation (the licensee) is the holder of Facility Operating License No. DPR-63 which authorizes the licensee to operate the Nine Mile Point Nuclear Station, Unit No. 1 (the facility) at power levels not in excess of 1850 megawatts thermal (rated power). The facility is a boiling water reactor (BWR) located at the licensee's site in Oswego County, New York.

II

On January 13, 1981 the Commission issued an Order modifying the license requiring: (1) The licensee to promptly assess the suppression pool hydrodynamic loads in accordance with NEDO-21888 and NEDO-24583-1 and the Acceptance Criteria contained in Appendix A to NUREG-0661 and (2) design and install any plant modifications needed to assure that the facility conforms to the Acceptance Criteria contained in Appendix A to NUREG-0661. The Order, published in the **Federal Register** on January 28, 1981 (46 FR-9288), required installation of any plant modifications needed to provide compliance with the Acceptance Criteria in Appendix A to NUREG-0661 be completed not later than January 31, 1983 or, if the plant is shutdown on that date, before the resumption of power operation thereafter.

III

On October 31, 1979 the staff issued an initial version of its acceptance criteria to the affected licensees. These criteria were subsequently revised in February 1980 to reflect acceptable alternative assessment techniques which would enhance the implementation of this program. Throughout the development of these acceptance criteria, the staff has worked closely with the Mark I Owners Group in order to encourage partial plant-unique assessments and modifications to be undertaken.

Since the development of these acceptance criteria, significant progress has been made by the licensee in meeting the Order requirements. However, in the June 29, 1981 Mark I Owners Group Status Summary Report, the licensee stated that unforeseen difficulties and delays have been encountered primarily related to one or more of the following: (1) Torus and torus attached piping analyses; (2) equipment delivery; (3) the use of interpretations and/or alternate approaches to the NUREG-0661 Acceptance Criteria; (4) plant-unique design and modification problems; and (5) slippages in refueling outages that have necessitated revision of the Order date.

The major modifications, which are those associated with the torus, vent system, internal structures and safety relief valve piping, which comprise approximately 75% of the total program effort completed have already been. The remaining items are primarily associated with the torus attached piping modifications.

The Commission believes that substantial improvements have already been made in the margins of safety of the containment systems and expects improvements will continue to be made during the period until all the modifications required for compliance with this Order are completed. The Commission further believes an acceptable balance has been achieved between completion of the major modifications, which provide significant improvement in the safety margin, and the granting of additional time for completion of the remaining modifications which fully restore the originally intended safety margin. In consideration of the range of completion dates submitted by all of the affected licensees and an assessment of the nature of the remaining effort involved in the analysis, design and installation of the needed plant modifications, the Commission has concluded that the

licensee's proposed completion schedule is both responsive and practicable.

The Commission has, therefore, determined to modify the January 13, 1981 Order to extend the previously imposed completion date for needed plant modifications. This Order continues in effect the exemption to General Design Criterion 50 of Appendix A to 10 CFR Part 50 granted on January 13, 1981.

IV

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, including sections 103 and 161i, and the Commission's rules and regulations in 10 CFR Parts 2 and 50, it is ordered that the completion date specified in Section V of the January 13, 1981, "Order for Modification of License," is hereby changed to read as follows: "Prior to the start of Cycle 8 at the completion of your Spring 1983 refueling outage." The Order of January 13, 1981, except as modified herein, remains in effect in accordance with its terms.

V

The licensee may request a hearing on this Order on or before February 25, 1982. A request for hearing shall be submitted to the Director, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Copies of the request shall also be sent to the Secretary of the Commission and the Executive Legal Director at the same address.

If a hearing is requested by the licensee, the Commission will issue an order designating the time and place of any such hearing. If a hearing is held, the issue to be considered at such a hearing shall be whether the completion date specified in Section V of the January 13, 1981, "Order for Modification of License," should be changed to "Prior to the start of Cycle 8 at the completion of your Spring 1983 refueling outage."

This Order shall become effective upon expiration of the period within which a hearing may be requested or, if a hearing is requested, on the date specified in an order issued following further proceedings on this Order.

Dated at Bethesda, Maryland, this 19th day of January 1982.

For the Nuclear Regulatory Commission.

Darrell G. Eisenhut,

Director, Division of Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 82-1912 Filed 1-25-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-245]

Northeast Nuclear Energy Co. et al., Millstone Nuclear Power Station, Unit 1; Modification of January 13, 1981 Order

I

The Northeast Nuclear Energy Company, The Connecticut Power Company, the Hartford Electric Light Company, and Western Massachusetts Electric Company (the licensees) are the holders of Operating License No. DPR-21 which authorizes the Northeast Nuclear Energy Company (the licensee) to operate the Millstone Nuclear Power Station, Unit 1 (the facility) at power levels not in excess of 2011 megawatts thermal (rated power). The facility is a boiling water reactor located in the Town of Waterford, Connecticut.

II

On January 13, 1981 the Commission issued an Order modifying the license requiring: (1) The licensee to promptly assess the suppression pool hydrodynamic loads in accordance with NEDO-21888 and NEDO-24583-1 and the Acceptance Criteria contained in Appendix A to NUREG-0661 and (2) design and install any plant modifications needed to assure that the facility conforms to the Acceptance Criteria contained in Appendix A to NUREG-0661. The Order, published in the **Federal Register** on February 4, 1981 (46 FR 10877) required installation of any plant modifications needed to provide compliance with the Acceptance Criteria in Appendix A to NUREG-0661 be completed not later than April 30, 1982, or, if the plant is shutdown on that date, before the resumption of power operation thereafter.

III

On October 31, 1979 the staff issued an initial version of its acceptance criteria to the affected licensees. These criteria were subsequently revised in February 1980 to reflect acceptable alternative assessment techniques which would enhance the implementation of this program. Throughout the development of these acceptance criteria, the staff has worked closely with the Mark I Owners Group in order to encourage partial plant-unique assessments and modifications to be undertaken.

Since the development of these acceptance criteria, significant progress has been made by the licensee in meeting the Order requirements. However, in the June 29, 1981 Mark I Owner' Group Status Summary Report, the licensee identified unforeseen difficulties and delays encountered primarily related to one or more of the following: (1) Torus and torus attached piping analyses; (2) equipment delivery; (3) the use of interpretations and/or alternate approaches to the NUREG-0661 Acceptance Criteria; (4) plant-unique design and modification problems; and (5) slippages in refueling outages that have necessitated revision of the Order date.

The major modifications, which are those associated with the torus, vent system, internal structures and safety relief valve piping, which comprise approximately 75% of the total program effort have already been completed. The remaining items to be completed are primarily associated with the torus attached piping modifications.

The Commission believes that substantial improvements have already been made in the margins of safety of the containment systems and expects improvements will continue to be made during the period until all the modifications required for compliance with this Order are completed. The Commission further believes an acceptable balance has been achieved between completion of the major modifications, which provide significant improvement in the safety margin, and the granting of additional time for completion of the remaining modifications which fully restore the originally intended safety margin. In consideration of the range of completion dates submitted by all of the affected licensees and an assessment of the nature of the remaining effort involved in the analysis, design and installation of the needed plant modifications, the Commission has concluded that the licensee's proposed completion schedule is both responsive and practicable.

The Commission has, therefore, determined to modify the January 13, 1981 Order to extend the previously imposed completion dates for needed plant modifications. This Order continues in effect the exemption to General Design Criterion 50 of Appendix A to 10 CFR Part 50 granted on January 13, 1981.

IV

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, including sections 103 and 161i, and the Commission's rules and regulations in 10 CFR Parts 2 and 50, it is ordered that the completion date specified in Section V of the January 13, 1981, "Order for Modification of License," is hereby changed to read as follows: "Prior to the start of Cycle 9 for all modifications

inside containment and no later than July 1, 1983 for all remaining modifications." The Order of January 13, 1981, except as modified herein, remains in effect in accordance with its terms.

V

The licensee may request a hearing on this Order on or before February 25, 1982. A request for hearing shall be submitted to the Director, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Copies of the request shall also be sent to the Secretary of the Commission and the Executive Legal Director at the same address.

If a hearing is requested by the licensee, the Commission will issue an order designating the time and place of any such hearing. If a hearing is held, the issue to be considered at such a hearing shall be whether the completion date specified in Section V of the January 13, 1981, "Order for Modification of License," should be changed to "Prior to the start of Cycle 9 for all modifications inside containment and no later than July 1, 1983 for all remaining modifications."

This Order shall become effective upon expiration of the period within which a hearing may be requested or, if a hearing is requested, on the date specified in an order issued following further proceedings on this Order.

Dated at Bethesda, Maryland, this 19th day of January 1982.

For the Nuclear Regulatory Commission.

Darrell G. Eisenhut,

Director, Division of Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 82-1913 Filed 1-25-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-263]

Northern States Power Co., Monticello Nuclear Generating Plant; Modification of January 13, 1981 Order

I

The Northern States Power Company (the licensee) is the holder of Facility Operating License No. DPR-22 which authorizes the licensee to operate the Monticello Nuclear Generating Plant (the facility) at power levels not in excess of 1670 megawatts thermal (rated power). The facility is a boiling water reactor located at the licensee's site in Wright County, Minnesota.

II

On January 13, 1981 the Commission issued an Order modifying the license requiring: (1) The licensee to promptly assess the suppression pool hydrodynamic loads in accordance with NEDO-21888 and NEDO-24583-1 and the Acceptance Criteria contained in Appendix A to NUREG-0661 and (2) design and install any plant modifications needed to assure that the facility conforms to the Acceptance Criteria contained in Appendix A to NUREG-0661. The Order, published in the **Federal Register** on January 28, 1981 (46 FR 9291), required installation of any plant modifications needed to provide compliance with the Acceptance Criteria in Appendix A to NUREG-0661 be completed not later than April 30, 1982 or, if the plant is shutdown on that date, before the resumption of power operation thereafter.

III

On October 31, 1979 the staff issued an initial version of its acceptance criteria to the affected licensees. These criteria were subsequently revised in February 1980 to reflect acceptable alternative assessment techniques which would enhance the implementation of this program. Throughout the development of these acceptance criteria, the staff has worked closely with the Mark I Owners Group in order to encourage partial plant-unique assessments and modifications to be undertaken.

Since the development of these acceptance criteria, significant progress has been made by the licensee in meeting the Order requirements. However, by letter dated February 27, 1981 the licensee stated that unforeseen difficulties and delays have been encountered primarily related to one or more of the following: (1) Torus and torus attached piping analyses; (2) equipment delivery; (3) the use of interpretations and/or alternate approaches to the NUREG-0661 Acceptance Critieria; (4) plant-unique design and modification problems; and (5) slippages in refueling outages that have necessitated revision of the Order date.

The major modifications, which are those associated with the torus, vent system, internal structures and safety relief valve piping, which comprise approximately 75% of the total program effort, will be completed within three months of the existing Order date. The remaining items to be completed are primarily associated with the torus attached piping modifications.

The Commission believes that substantial improvements have already been made in the margins of safety of the containment systems and expects improvements will continue to be made during the period until all the modifications required for compliance with this Order are completed. The Commission further believes an acceptable balance has been achieved between completion of most of the major modifications, which provide significant improvement in the safety margin, and the granting of additional time for completion of the remaining modifications which fully restore the originally intended safety margin. In consideration of the range of completion dates submitted by all of the affected licensees and an assessment of the nature of the remaining effort involved in the analysis, design and installation of the needed plant modifications, the Commission has concluded that the licensee's proposed completion schedule is both responsive and practicable.

The Commission has, therefore, determined to modify the January 13, 1981 Order to extend the previously imposed completion date for needed plant modifications. This Order continues in effect the exemption to General Design Criterion 50 of Appendix A to 10 CFR Part 50 granted on January 13, 1981.

IV

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, including sections 103 and 161i, and the Commission's rules and regulations in 10 CFR Parts 2 and 50, it is ordered that the completion date specified in Section V of the January 13, 1981, "Order for Modification of License," is hereby changed to read as follows: "Prior to the start of Cycle 10 for completion of major modifications and prior to the start of Cycle 11 for completion of the remaining modifications." The Order of January 13, 1981, except as modified herein, remains in effect in accordance with its terms.

V

The licensee may request a hearing on this Order on or before February 25, 1982. A request for hearing shall be submitted to the Director, Office of Nuclear Reactor Regulations, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Copies of the requests shall also be sent to the Secretary of the Commission and the Executive Legal Director at the same address.

If a hearing is requested by the licensee, the Commission will issue an order designating the time and place of any such hearing. If a hearing is held, the issue to be considered at such a hearing shall be whether the completion date specified in Section V of the January 13, 1981, "Order for Modification of License," should be

changed to "prior to the start of Cycle 10 for completion of the major modifications and prior to the start of Cycle 11 for completion of the remaining modifications."

This Order shall become effective upon expiration of the period within which a hearing may be requested or, if a hearing is requested, on the date specified in an order issued following further proceedings on this Order.

Dated at Bethesda, Maryland, this 19th day of January 1982.

For the Nuclear Regulatory Commission.

Darrell G. Eisenhut,

Director, Division of Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 82-1914 Filed 1-25-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket Nos. 50-277 and 50-278]

Philadelphia Electric Co., et al., Peach Bottom Atomic Power Station, Units 2 and 3; Exemption

I

The Philadelphia Electric Company (the licensee) and three other co-owners are the holder of Facility Operating License Nos. DPR-44 and DPR-56 which authorize operation of the Peach Bottom Atomic Power Station, Units 2 and 3 (Peach Bottom or the facilities). These licenses provide, among other things, that they are subject to all rules, regulations and Orders of the Nuclear Regulatory Commission (the Commission) now or hereafter in effect.

The facilities are boiling water reactors located at the licensee's site in York County, Pennsylvania.

II

Sections 50.48(c)(2) and 50.48(d)(2) of 10 CFR Part 50 require that certain fire protection systems in the Peach Bottom Station be operatble by November 17, 1981.

By letters dated October 14, 27, November 13, 19, and December 24, 1981, the licensee requested exemptions from the 10 CFR 50.48 schedular requirements. Specifically, the following four systems are involved:

1. Sprinkler systems in three plant areas,
2. Smoke detector systems,
3. Breathing air bottle charging system, and
4. Remote supervision of the fire door system. In every instance, operability by November 17, 1981, is suffering a delay due to equipment delivery difficulties. The licensee's exemption request consists of a delay in the operability date of the three systems from November 17, 1981 to January 29, 1982 and to March 31, 1982 of the fourth system.

The licensee stated that in spite of delivery delays the work on the modifications remains in progress. For each of the four systems, the licensee has proposed compensatory measures to become effective on November 17, 1981, the effective date of the rule for these components; and to retain the compensatory measures until the systems are placed in an operable status. The compensatory measures consist of a patrol of the affected plant areas pending installation of required smoke detectors and suppression system (sprinklers) as described in the licensee's October 14 and November 19, 1981 letters, at a once per shift interval. These patrols will ensure that adequate housekeeping and fire control practices are in effect in these areas. In addition, an inspection of selected fire doors, that is, those lacking remote supervision, will be conducted, once per shift, to verify that the subject doors are closed. These doors are identified in the licensee's November 13, 1981 letter.

To compensate for installation of a qualified breathing air bottle charging system the licensee has provided for double the amount of self-contained breathing apparatus (SCBA) required by 10 CFR 50.48. In addition, the licensee has brought an unspecified number of additional SCBA and charged air bottles on site, which are stated to bring the total air supply to triple that required by the rule.

We conclude that the licensee's request to be exempt from the schedular requirements of 10 CFR 50.48(c)(2) and (d)(2), i.e., delaying the operability date of three of the systems from November 17, 1981, to January 29, 1982, and the fourth system to March 31, 1982, should be granted based on the following evaluation. The licensee is continuing work on the modifications despite equipment delivery delays and is instituting adequate compensatory measures until the systems are operable. The licnesee's letter of December 24, 1981, which contained the request for the January 29 and March 31, 1982, dates, did not make the dates contingent on equipment deliveries.

III

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12, an exemption is authorized by law and will not endanger life or property or the common defense and security, is otherwise in the public interest, and is hereby granted.

The Commission has determined that the granting of this exemption will not result in any significant evironmental impact and that pursuant to 10 CFR 51.5(d)(4) an environmental impact statement or negative declaration and environmental impact appraisal need not be prepared in connection with this action.

This exemption is effective upon issuance.

Dated at Bethesda, Maryland, this 13th day of January 1982.

For the Nuclear Regulatory Commission.

Darrell G. Eisenhut,

Acting Director, Office of Nuclear Reactor Regulation.

[FR Doc. 82-1915 Filed 1-25-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-333]

Power Authority of State of New York, James A. FitzPatrick Nuclear Station; Modification of January 13, 1981 Order

I

The Power Authority of the State of New York (the licensee) is the holder of Facility Operating License No. DPR-59 which authorizes the licensee to operate the James A. FitzPatrick Nuclear Station (the facility) at power levels not in excess of 2436 megawatts thermal (rated power). The facility is a boiling water reactor (BWR) located at the licensee's site in Oswego County, New York.

II

On January 13, 1981 the Commission issued an Order modifying the license requiring: (1) The licensee to promptly assess the suppression pool hydrodynamic loads in accordance with NEDO-21888 and NEDO-24583-1 and the Acceptance Criteria contained in Appendix A to NUREG-0661 and (2) design and install any plant modifications needed to assure that the facility conforms to the Acceptance Criteria contained in Appendix A to NUREG-0661. The Order, published in the **Federal Register** on January 28, 1981 (46 FR 9317) required installation of any plant modifications needed to provide compliance with the Acceptance Criteria in Appendix A to NUREG-0661 be completed not later than October 31, 1981, or if the plant is shutdown on that date, before the resumption of power operation thereafter.

III

On October 31, 1979 the staff issued an initial version of its acceptance criteria to the affected licensees. These criteria were subsequently revised in February 1980 to reflect acceptable alternative assessment techniques which would enhance the

implementation of this program. Throughout the development of these acceptance criteria, the staff has worked closely with the Mark I Owners Group in order to encourage partial plant-unique assessments and modifications to be undertaken.

Since the development of these acceptance criteria, significant progress has been made by the licensee in meeting the Order requirements. However, by letter dated February 27, 1981 the licensee stated that unforeseen difficulties and delays have been encountered primarily related to one or more of the following: (1) Torus and torus attached piping analyses; (2) equipment delivery; (3) the use of interpretations and/or alternate approaches to the NUREG–0661 Acceptance Criteria; (4) plant-unique design and modification problems; and (5) slippages in refueling outages that have necessitated revision of the Order date.

The major modifications, which are those associated with the torus, vent system, internal structures and safety relief valve piping, which comprise approximately 75% of the total program effort, have already been completed or are in the process of being completed during the current outage. The remaining items are primarily associated with the torus attached piping modifications.

The Commission believes that substantial improvements have already been made in the margins of safety of the containment systems and expects improvements will continue to be made during the period until all the modifications required for compliance with this Order are completed. The Commission further believes an acceptable balance has been achieved between completion of the major modifications, which provide significant improvement in the safety margin, and the granting of additional time for completion of the remaining modifications which fully restore the originally intended safety margin. In consideration of the range of completion dates submitted by all of the affected licensees and an assessment of the nature of the remaining effort involved in the analysis, design and installation of the needed plant modifications, the Commission has concluded that the licensee's proposed completion schedule is both responsive and practicable.

The Commission has, therefore, determined to modify the January 13, 1981 Order to extend the previously imposed completion date for needed plant modifications. This Order continues in effect the exemption to General Design Criterion 50 of Appendix A to 10 CFR Part 50 granted on January 13, 1981.

IV

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, including sections 103 and 161i, and the Commission's rules and regulations in 10 CFR Parts 2 and 50, it is ordered that the completion date specified in section V of the January 13, 1981, "Order for Modification of License," is hereby changed to read as follows: "Prior to the start of Cycle 5 for the completion of major modifications and prior to the start of Cycle 6 for completion of the remaining modifications." The Order of January 13, 1981, except as modified herein, remains in effect in accordance with its terms.

V

The licensee may request a hearing on this Order by February 25, 1982. A request for hearing shall be submitted to the Director, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Copies of the request shall also be sent to the Secretary of the Commission and the Executive Legal Director at the same address.

If a hearing is requested by the licensee, the Commission will issue an order designating the time and place of any such hearing. If a hearing is held, the issue to be considered at such a hearing shall be whether the completion date specified in Section V of the January 13, 1981, "Order for Modification of License," should be changed to "Prior to the start of Cycle 5 for completion of the major modifications and prior to the start of Cycle 6 for completion of the remaining modifications."

This Order shall become effective upon expiration of the period within which a hearing may be requested or, if a hearing is requested, on the date specified in an order issued following further proceedings on this Order.

Dated at Bethesda, Maryland, this 19th day of January 1982.

For the Nuclear Regulatory Commission.

Darrell G. Eisenhut,

Director, Division of Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 82–1916 Filed 1–25–82; 8:45 am]

BILLING CODE 7590–01–M

Regulatory Guide; Issuance and Availability

The Nuclear Regulatory Commission has issued a new guide in its Regulatory Guide Series. This series has been developed to describe and make available to the public methods acceptable to the NRC staff of implementing specific parts of the Commission's regulations and, in some cases, to delineate techniques used by the staff in evaluating specific problems or postulated accidents and to provide guidance to applicants concerning certain of the information needed by the staff in its review of applications for permits and licenses.

Regulatory Guide 3.50, "Guidance on Preparing a License Application To Store Spent Fuel in an Independent Spent Fuel Storage Installation," suggests a format acceptable to the NRC staff for submitting the information required by 10 CFR Part 72 in an application for a license to store spent fuel in an independent spent fuel storage installation.

Comments and suggestions in connection with (1) items for inclusion in guides currently being developed or (2) improvements in all published guides are encouraged at any time. Comments should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch.

Regulatory guides are available for inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, D.C. Copies of active guides may be purchased at the current Government Printing Office price. A subscription service for future guides in specific divisions is available through the Government Printing Office. Information on the subscription service and current prices may be obtained by writing to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Publications Sales Manager.

(5 U.S.C. 552(a))

Dated at Silver Spring, Maryland this 19th day of January 1982.

For the Nuclear Regulatory Commission.

Robert B. Minogue,

Director, Office of Nuclear Regulatory Research.

[FR Doc. 82–1920 Filed 1–25–82; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–259]

Tennessee Valley Authority, Browns Ferry Nuclear Plant, Unit 1; Modification of January 13, 1981, and November 25, 1981 Order

I

The Tennessee Valley Authority (the licensee) is the holder of Facility Operating License No. DPR–33 which authorizes the licensee to operate the

Browns Ferry Nuclear Plant, Unit 1 (the facility) at power levels not in excess of 3293 megawatts thermal (rated power). The facility is a boiling water reactor located at the licensee's site in Limestone County, Alabama.

II

On January 13, 1981 the Commission issued an Order modifying the license requiring: (1) The licensee to promptly assess the suppression pool hydrodynamic loads in accordance with NEDO–21888 and NEDO–24583–1 and the Acceptance Criteria contained in Appendix A to NUREG–0661 and (2) design and install any plant modifications needed to assure that the facility conforms to the Acceptance Criteria contained in Appendix A to NUREG–0661. The Order, published in the **Federal Register** on January 28, 1981 (46 FR–9318), required installation of any plant modifications needed to provide compliance with the Acceptance Criteria in Appendix A to NUREG–0661 be completed not later than October 31, 1981, or, if the plant is shutdown on that date, before the resumption of power operation thereafter.

On November 25, 1981 a 45-day extension of this January 13, 1981 Order, published in the **Federal Register** on December 3, 1981 (46 FR–58759), was granted by the Director of the Division of Licensing pending Commission approval of a staff generic proposal to extend the completion dates for the Mark I long-term program containment modifications for all affected licensees.

III

On October 31, 1979 the staff issued an initial version of its acceptance criteria to the affected licensees. These criteria were subsequently revised in February 1980 to reflect acceptable alternative assessment techniques which would enhance the implementation of this program. Throughout the development of these acceptance criteria, the staff has worked closely with the Mark I Owners Group in order to encourage partial plant-unique assessments and modifications to be undertaken.

Since the development of these acceptance criteria, significant progress has been made by the licensee in meeting the Order requirements. However, by letter dated May 22, 1981 the licensee stated that unforeseen difficulties and delays have been encountered primarily related to torus and torus attached piping analyses, equipment delivery, outage scheduling at a three unit site, and personnel safety concerns associated with prolonged overtime during extended outages that have necessitated revision of the Order date.

Browns Ferry Unit 1 was shutdown for six months (April 11 to October 1, 1981) primarily for torus modifications. During that outage most of the major modifications, which are those associated with the torus, vent system, internal structures and safety relief valve piping were completed. These modifications comprise a significant portion of the total program effort. The remaining items to be completed are primarily associated with the torus attached piping modifications.

The Commission believes that substantial improvements have already been made in the margins of safety of the containment systems and expects improvements will continue to be made during the period until all the modifications required for compliance with this Order are completed. The Commission further believes an acceptable balance has been achieved between completion of most of the major modifications, which provide significant improvement in the safety margin, and the granting of additional time for completion of the remaining modifications which fully restore the originally intended safety margin. In consideration of the range of completion dates submitted by all of the affected licensees and an assessment of the nature of the remaining effort involved in the analysis, design and installation of the needed plant modifications, the Commission has concluded that the licensee's proposed completion schedule is both responsive and practicable.

The Commission has, therefore, determined to modify the January 13, 1981 Order, as modified by the Order of November 25, 1981, to extend the previously imposed completion date for needed plant modifications. This Order continues in effect the exemption to General Design Criterion 50 of Appendix A to 10 CFR Part 50 granted on January 13, 1981.

IV

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, including Sections 103 and 161i, and the Commission's rules and regulations in 10 CFR Parts 2 and 50, it is ordered that the completion date specified in Section V of the January 13, 1981 "Order for Modification of License," as modified by the Order of November 25, 1981, is hereby changed to read as follows: "prior to the start of Cycle 6." The Order of January 13, 1981 except as modified herein, remains in effect in accordance with its terms.

V

The licensee may request a hearing on this Order by February 25, 1982. A request for hearing shall be submitted to the Director, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Copies of the request shall also be sent to the Secretary of the Commission and the Executive Legal Director at the same address.

If a hearing is requested by the licensee, the Commission will issue an order designating the time and place of any such hearing. If a hearing is held, the issue to be considered at such a hearing shall be whether the completion date specified in Section V of the Janaury 13, 1981, "Order for Modification of License," should be changed to "prior to start of Cycle 6."

This Order shall become effective upon expiration of the period within which a hearing may be requested or, if a hearing is requested, on the date specified in an order issued following further proceedings on this Order.

Dated at Bethesda, Maryland, this 19th day of January 1982.

For the Nuclear Regulatory Commission.

Darrell G. Eisenhut,

Director, Division of Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 82–1917 Filed 1–25–82; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–260]

Tennessee Valley Authority, Browns Ferry Nuclear Plant, Unit 2; Modification of January 13, 1981, Order

I

The Tennessee Valley Authority (the licensee) is the holder of Facility Operating License No. DPR–52 which authorizes the licensee to operate the Browns Ferry Nuclear Plant, Unit 2 (the facility) at power levels not in excess of 3293 megawatts thermal (rated power). The facility is a boiling water reactor located at the licensee's site in Limestone County, Alabama.

II

On January 13, 1981 the Commission issued an Order modifying the license requiring: (1) The licensee to promptly assess the suppression pool hydrodynamic loads in accordance with NEDO–21888 and NEDO–24583–1 and the Acceptance Criteria contained in Appendix A to NUREG–0661 and (2) design and install any plant modifications needed to assure that the facility conforms to the Acceptance

Criteria contained in Appendix A to NUREG–0661. The Order, published in the **Federal Register** on January 28, 1981 (46 FR 9320), required installation of any plant modifications needed to provide compliance with the Acceptance Criteria in Appendix A to NUREG–0661 be completed not later than September 30, 1982, or, if the plant is shutdown on that date, before the resumption of power operation thereafter.

III

On October 31, 1979 the staff issued an initial version of its acceptance criteria to the affected licensees. Thses criteria were subsequently revised in February 1980 to reflect acceptable alternative assessment techniques which would enhance the implementation of this program. Throughout the development of these acceptance criteria, the staff has worked closely with the Mark I Owners Group in order to encourage partial plant-unique assessments and modifications to be undertaken.

Since the development of these acceptance criteria, significant progress has been made by the licensee in meeting the Order requirements. However, by letter dated May 22, 1981 the licensee stated that unforeseen difficulties and delays have been encountered primarily related to torus and torus attached piping analyses, equipment delivery, outage scheduling at a three unit site, and personnel safety concerns associated with prolonged overtime during extended outages that have necessitated revision of the Order date.

The major modifications, which are those associated with the torus, vent system, internal structures and safety relief valve piping, which comprise approximately 75% of the total program effort, will be completed during the outage that is expected to coincide with the existing Order date. The remaining items to be completed are primarily associated with the torus attached piping modifications.

The Commission believes that substantial improvements have already been made in the margins of safety of the containment systems and expects improvements will continue to be made during the period until all the modifications required for compliance with this Order are completed. The Commission further believes an acceptable balance has been achieved between completion of the major modifications, which provide significant improvement in the safety margin, and the granting of additional time for completion of the remaining modifications which fully restore the originally intended safety margin. In consideration of the range of completion dates submitted by all of the affected licensees and an assessment of the nature of the remaining effort involved in the analysis, design and installation of the needed plant modifications, the Commission has concluded that the licensee's proposed completion schedule is both responsive and practicable.

The Commission has, therefore, determined to modify the January 13, 1981 Order, to extend the previously imposed completion date for needed plant modifications. This Order continues in effect the exemption to General Design Criterion 50 of Appendix A to 10 CFR Part 50 granted on January 13, 1981.

IV

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, including Sections 103 and 161i, and the Commission's rules and regulations in 10 CFR Parts 2 and 50, it is ordered that the completion date specified in Section V of the January 13, 1981, "Order for Modification of License," is hereby changed to read as follows: "prior to the start of Cycle 5 for completion of all the major modifications and prior to the start of Cycle 6 for completion of all the remaining modifications." The Order of January 13, 1981, except as modified herein, remains in effect in accordance with its terms.

V

The licensee may request a hearing on this Order by February 25, 1982. A request for hearing shall be submitted to the Director, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Copies of the request shall also be sent to the Secretary of the Commission and the Executive Legal Director at the same address.

If a hearing is requested by the licensee, the Commission will issue an order designating the time and place of any such hearing. If a hearing is held, the issue to be considered at such a hearing shall be whether the completion date specified in Section V of the January 13, 1981, "Order for Modification of License," should be changed to "prior to start of Cycle 5 for completion of major modifications and prior to the start of Cycle 6 for completion of all the remaining modifications."

This Order shall become effective upon expiration of the period within which a hearing may be requested or, if a hearing is requested, on the date specified in an order issued following further proceedings on this Order.

Dated at Bethesda, Md. this 19th day of January 1982.

For the Nuclear Regulatory Commission.

Darrell G. Eisenhut,

Director, Division of Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 82-1918 Filed 1-25-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-296]

Tennessee Valley Authority, Browns Ferry Nuclear Plant, Unit 3; Modification of January 13, 1981, Order

I

The Tennessee Valley Authority (the licensee) is the holder of Facility Operating License No. DPR–68 which authorizes the licensee to operate the Browns Ferry Nuclear Plant, Unit 3 (the facility) at power levels not in excess of 3293 megawatts thermal (rated power). The facility is a boiling water reactor located at the licensee's site in Limestone County, Alabama.

II

On January 13, 1981 the Commission issued an Order modifying the license requiring: (1) The licensee to promptly assess the suppression pool hydrodynamic loads in accordance with NEDO–21888 and NEDO–24583–1 and the Acceptance Criteria contained in Appendix A to NUREG–0661 and (2) design and install any plant modifications needed to assure that the facility conforms to the Acceptance Criteria contained in Appendix A to NUREG–0661. The Order, published in the **Federal Register** on January 28, 1981 (46 FR–9321), required installation of any plant modifications needed to provide compliance with the Acceptance Criteria in Appendix A to NUREG–0661 be completed not later than March 31, 1982, or, if the plant is shutdown on that date, before the resumption of power operation thereafter.

III

On October 31, 1979 the staff issued an initial version of its acceptance criteria to the affected licensees. These criteria were subsequently revised in February 1980 to reflect acceptable alternative assessment techniques which would enhance the implementation of this program. Throughout the development of these acceptance criteria, the staff has worked closely with the Mark I Owners Group in order to encourage partial plant-unique assessments and modifications to be undertaken.

Since the development of these acceptance criteria, significant progress has been made by the licensee in meeting the Order requirements. However, by letter dated May 22, 1981 the licensee stated that unforeseen difficulties and delays have been encountered primarily related to torus and torus attached piping analyses, equipment delivery, outage scheduling at a three unit site, and personnel safety concerns associated with prolonged overtime during extended outages that have necessitated revision of the Order date.

Browns Ferry Unit 3 will be shutdown for over 4 months (October 30, 1981 to approximately March 6, 1982) primarily for torus modifications. During this outage most of the major modifications, which are those associated with the torus, vent system, internal structures and safety relief valve piping will be completed. These modifications comprise a significant portion of the total program effort. The remaining items to be completed are primarily associated with the torus attached piping modifications.

The Commission believes that substantial improvements have already been made in the margins of safety of the containment systems and expects improvements will continue to be made during the period until all the modifications required for compliance with this Order are completed. The Commission further believes an acceptable balance has been achieved between completion of most of the major modifications, which provide significant improvement in the safety margin, and the granting of additional time for completion of the remaining modifications which fully restore the originally intended safety margin. In consideration of the range of completion dates submitted by all of the affected licensees and an assessment of the nature of the remaining effort involved in the analysis, design and installation of the needed plant modifications, the Commission has concluded that the licensee's proposed completion schedule is both responsive and practicable.

The Commission has, therefore, determined to modify the January 13, 1981 Order to extend the previously imposed completion date for needed plant modifications. This Order continues in effect the exemption to General Design Criterion 50 of Appendix A to 10 CFR Part 50 granted on January 13, 1981.

IV

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, including Sections 103 and 161i, and the Commission's rules and regulations in 10 CFR Parts 2 and 50, it is ordered that the completion date specified in Section V of the January 13, 1981, "Order for Modification of License," is hereby changed to read as follows: "prior to the start of Cycle 6." The Order of January 13, 1981, except as modified herein, remains in effect in accordance with its terms.

V

The licensee may request a hearing on this Order by February 25, 1982. A request for hearing shall be submitted to the Director, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Copies of the request shall also be sent to the Secretary of the Commission and the Executive Legal Director at the same address.

If a hearing is requested by the licensee, the Commission will issue an order designating the time and place of any such hearing. If a hearing is held, the issue to be considered at such a hearing shall be whether the completion date specified in Section V of the January 13, 1981, "Order for Modification of License," should be changed to "prior to start of Cycle 6."

This Order shall become effective upon expiration of the period within which a hearing may be requested or, if a hearing is requested, on the date specified in an order issued following further proceedings on this Order.

Dated at Bethesda, Md., this 19th day of January 1982.

For the Nuclear Regulatory Commission.

Darrell G. Eisenhut,

Director, Division of Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 82-1919 Filed 1-25-82; 8:45 am]

BILLING CODE 7590-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 18432; SR-BSE-82-1]

Boston Stock Exchange, Inc.; Filing and Order Granting Accelerated Approval of Proposed Rule Change

January 20, 1982.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on January 12, 1982, the Boston Stock Exchange, Inc. ("BSE"), One Boston Place, Boston, Mass. 02108, filed with the Securities and Exchange Commission the proposed rule change as described herein. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

The proposed rule change increases the BSE's original listing fee from $3,500 to $5,000 for each class of stock or bonds. The exchange stated that the purpose of the proposed change in listing fees is to partially offset the increasing costs to the exchange of supplying services to the issuers. The BSE cited Section 6(b)(4) of the Act, relating to the exchange's provision for equitable allocation of reasonable dues, fees and other charges among its members, issuers and other persons using its services, as the statutory basis for the proposed rule change.

Interested persons are invited to submit written data, views and arguments concerning the proposed rule change on or before February 16, 1982. Persons desiring to make written comments 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 make to File No. SR-BSE-82-1.

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change which are filed with the Commission and all written communications relating to the proposed rule change between the Commission and any person, other than those which may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room, 1100 L Street, NW., Washington, D.C. Copies of the filing and of any subsequent amendments also will be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization.

The Commission finds that the proposed rule change 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 and the rules and regulations thereunder.

The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of notice of filing thereof, in that several listing applications are presently pending at the BSE,[1] and, in

[1] The BSE has informed the Commission that all issuers with pending listing applications were notified befors submitting their listing applications that the proposed fee increase had been approved by the BSE Board of Directors and would probably become effective in early January, 1982, following

Continued

light of the exchange's unique current financial situation, the Commission believes the rule appears to be an appropriate measure for the exchange to employ in an effort to meet its near term financial needs.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change referenced above be, and hereby is, approved.

For the Commission, by the Division of Market Regulation pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82-1840 Filed 1-25-82; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 18431; SR-CBOE-81-26]

Chicago Board Options Exchange, Inc.; Order Approving Proposed Rule Change

January 19, 1982.

The Chicago Board Options Exchange, Inc., LaSalle at Jackson, Chicago, Illinois 60604, submitted on November 12, 1981, copies of a proposed rule change pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act") and Rule 19b–4 thereunder, to make explicit the authority of floor officials relating to the enforcement of certain exchange rules. Among other things, the amendment allows floor officials, in addition to any disciplinary action taken by the exchange's business conduct committees, to impose fines for violations of its rules other than those related to decorum and to break or adjust trades that were effected in violation of specified rules.

Notice of the proposed rule change together with the terms of substance of the proposed rule change was given by the issuance of a Commission Release (Securities Exchange Act Release No. 18295, November 30, 1981) and by publication in the **Federal Register** (46 FR 59683, December 7, 1981). No comments were received with respect to the proposed rule filing.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange and, in particular, the requirements of Section 6 of the Act, and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the above-mentioned proposed rule change be, and hereby is, approved.

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approval by the Securities and Exchange Commission.

For the Commission, by the Division of Market Regulation pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82-1841 Filed 1-25-82; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 17976; SR-CSE-81-3]

Cincinnati Stock Exchange; Order Approving Proposed Rule Change

July 27, 1981.

On June 4, 1981, the Cincinnati Stock Exchange ("CSE"), 209 Dixie Terminal Building, Cincinnati, Ohio 45202, 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) ("Act") and Rule 19b–4 thereunder, copies of a proposed rule change which amends the exchange's listing fee schedule. The proposed rule change imposes a $1,000 maximum charge for the initial listing of a single class or issue of a security, and a $500 maximum charge for the initial listing of each additional class of a security.

Notice of the proposed rule change together with the terms of substance of the proposed rule change was given by issuance of a Commission Release (Securities Exchange Act Release No. 17874, July 17, 1981) and by publication in the **Federal Register** (46 FR 32981, June 25, 1981). No comments were received with respect to the proposed rule filing.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange and, in particular, the requirements of Section 6 and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the above-mentioned proposed rule change be, and it hereby is, approved.

For the Commission, by the Division of Market Regulation pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82-1842 Filed 1-25-82; 8:45 am]

BILLING CODE 8010-01-M

Cincinnati Stock Exchange; Applications for Unlisted Trading Privileges and of Opportunity for Hearing

January 20, 1982.

The above named national securities exchange has filed applications with the Securities and Exchange Commission pursuant to Section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f–1 thereunder, for unlisted trading privileges in the following stocks:

MidCon Corporation, Common Stock, No Par Value (File No. 7–6116)

Omnicare Inc., Common Stock, $1 Par Value (File No. 7–6117)

These securities are listed and registered on one or more other national securities exchanges and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before February 10, 1982 written data, views and arguments concerning the above-referenced applications. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, Washington, D.C. 20549. Following this opportunity for hearing, the Commission will approve the applications if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such applications are consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82-1844 Filed 1-25-82; 8:45 am]

BILLING CODE 8010-01-M

Midwest Stock Exchange, Inc.; Applications for Unlisted Trading Privileges and of Opportunity for Hearing

January 20, 1982.

The above named national securities exchange has filed applications with the Securities and Exchange Commission pursuant to Section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f–1 thereunder, for unlisted trading privileges in the following stocks:

Koger Properties Incorporated, Common Stock, $.10 Par Value (File No. 7–6118)

USF & G Corporation, Common Stock, $2.50 Par Value (File No. 7–6119)

These securities are listed and registered on one or more other national securities exchanges and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before February 10, 1982 written data, views and arguments concerning the above-referenced applications. Persons desiring to make

written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, Washington, D.C. 20549. Following this opportunity for hearing, the Commission will approve the applications if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such applications are consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82-1845 Filed 1-25-82; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-18430; File No. SR PHLX 81-23]

Philadelphia Stock Exchange, Inc.; Self-Regulatory Organizations; Proposed Rule Change

Proposed Rule Change by Philadelphia Stock Exchange, Inc., relating to Automated Communication and Execution System. Comments requested on or before February 16, 1982.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on January 5, 1982, the Philadelphia Stock Exchange, Inc. filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change would increase from 399 to 599 the number of shares eligible for the Philadelphia Stock Exchange Communication and Execution System ("PACE") and amend Phlx Rule 229 to revise certain standards for execution of orders under the PACE system. The revised standards would provide for (1) execution on the best bid/ask quote among the American, Boston, Cincinnati, Midwest, New York, Pacific or Philadelphia Stock Exchanges ("PACE Quote"); (2) elimination of the requirement that executions of market orders must be at or within the New York Stock Exchange daily high/low range; and (3) execution of round-lot limit orders when 1000 shares of the particular security print at the limit price on any exchange(s) eligible to compose the PACE Quote.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statements of the Purpose of, and Statutory Basis for the Proposed Rule Change

PACE currently provides to Phlx member organizations on voluntary basis, a cost efficient, competitive order delivery and execution system through which specialists can expand their market making activities. The present submission would expand the size of orders eligible for PACE and revise certain standards for execution of those orders through PACE, in an effort to remain competitive with similar systems of other exchanges. The proposed rule change is based on Section 6(b)(5) of the Act which provides, in part, that the rules of the exchange be designed to promote just and equitable principles of trade, to facilitate transactions in securities, and, in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The PHLX does not believe that the proposed rule change will impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments on the proposed rule change have been received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

On or before March 2, 1982, 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 self-regulatory organization consents, the Commission will:

A. By order approve such proposed rule change, or

B. Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 500 North Capitol Street, Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 1100 L Street, NW., 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 in the caption above and should be submitted on or before February 16, 1982.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

Dated: January 19, 1982.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82-1843 Filed 1-25-82; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 12166; 812-5005]

Narragansett Capital Corp. and Bevis Industries, Inc.; Filing of an Application for an Exemption Order

January 19, 1982.

Notice is hereby given that Narragansett Capital Corporation ("Narragansett"), registered under the Investment Company Act of 1940 ("Act") as a closed-end, non-diversified, management investment company and licensed as a small business investment company ("SBIC") under the Small Business Investment Act of 1958, and Bevis Industries, Inc. ("Bevis"), 40 Westminster Street, Providence, Rhode Island 02903, a corporation presumed to be controlled by Narragansett (hereinafter Narragansett and Bevis are collectively referred to as "Applicants")

filed an application on October 29, 1981, for an order pursuant to Sections 17(b) and 17(d) of the Act and Rule 17d–1 thereunder, exempting from the provisions of Section 17(a) of the Act and permitting under Section 17(d) of the Act, two groups of interrelated refinancing transactions. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein, which are summarized below.

According to the application, the first set of transactions consists of the refinancing of indebtedness involving (1) the agreement by the holders of certain subordinated installment notes ("6% Notes") of Greenville Tube Corporation ("Greenville") a wholly-owned subsidiary of Bevis, to the deferral of installments of principal totaling $5,500,000 due January 15, 1982, under the 6% Notes; (2) the agreement by Narragansett as the holder of certain other subordinated installment notes of Greenville ("Subordinated Notes") to the deferral of principal payments totaling $1,700,000 due February 15, 1982, thereunder and (3) concessions made by Bevis and Greenville to obtain those agreements. The second group of transactions consists of (1) the purchase of Bevis and possibly Narragansett of 639,225 shares of the common stock of Bevis from three substantial stockholders of Bevis, including Bernhardt Denmark ("Denmark"), who is a director of Bevis; (2) the related resignations from the board of directors of Denmark and his two nominees on that board, Michael J. Lichtenstein ("Lichtenstein") and Wilson H. Kierstead ("Kierstead"); and (3) certain commitments by the principal officers of Greenville in the event the order applied for is not obtained.

Bevis conducts its business through two wholly-owned subsidiaries, Greenville and MD Pneumatics, Inc. ("MD"). Bevis has issued 2,924,963 shares of common stock, of which 425,000 shares are held as treasury shares and 2,499,963 are outstanding. The stock is traded in the over-the-counter market. The only persons known by Bevis to own more than 5% of such common stock, as of September 30, 1981, are Narragansett, which owns 836,952 shares (33.48%) and Denmark, who owns 500,000 shares (20%).

Arthur D. Little ("Little") is president of Bevis; Arthur H. McGonigal, Sr. ("McGonigal") and George K. Painter ("Painter") are president and executive vice president, respectively, of Greenville and Earl L. Fester ("Fester") is president of MD. All four serve as directors of Bevis (of which there are 10) with Frederick G. Frost, III ("Frost"), who is a nominee on the Bevis board and a director of Narragansett, Robert G. Huckins ("Huckins"), James E. Macdonald, Jr., Denmark, Lichtenstein and Kierstead.

According to Applicants, the refinancing transactions are the result of negotiations starting in March, 1980, between Bevis and the holders of the 6% Notes ("Noteholders") to obtain the agreement of the Noteholders to the deferral of the final installments thereunder totaling $5,500,000 which would otherwise be payable January 15, 1982. The 6% Notes were issued on December 28, 1976, pursuant to a Stock Purchase Agreement dated September 28, 1976 ("Stock Purchase Agreement"), under which Narragansett, McGonigal, Joseph H. Filner, R. J. Goss, Raymond Landfried, Donald Weaver, M. W. Weaver and Painter, (the former stockholders, other than Narragansett, are collectively referred to as the "Individual Noteholders") sold all of the stock of the former Greenville Tube Corporation to a subsidiary of Bevis for $125,000 in cash and $13,000,000 of 6% Notes, of which $6,500,000 were issued to Narragansett and $6,500,000 to the Individual Noteholders.

The 6% Notes are payable in interim installments totaling $1,500,000 due on January 15 of 1977 through 1981, and final installments totaling $5,500,000 due January 15, 1982, of which $2,000,000 is payable to the Individual Noteholders and $3,500,000 to Narragansett. By a Guaranty and Pledge Agreement dated December 28, 1976, Bevis guaranteed the payment of the 6% Notes and pledged the stock of Greenville as collateral for that guaranty. At the closing held December 28, 1976, (1) McGonigal and Painter entered into employment agreements with Greenville for terms ending on the later of January 15, 1982, or the date of payment of the 6% Notes; (2) Narragansett granted McGonigal and Painter options to purchase shares of the common stock of Bevis owned by Narragansett at a price of $1.51 per share exercisable at any time during the month of January, 1982, or if the 6% Notes had not been paid by January 31, 1982, during the 30 days following the date of such payment (in no event after December 31, 1982), provided the 6% Notes shall have been paid and Greenville shall have a tangible net worth of at least $5,000,000 and shall not have indebtedness in excess of $3,000,000 ("McGonigal and Painter Options from Narragansett"); and (3) Narragansett agreed to defer payment of $1,700,000 principal amount of Subordinated Notes until the first to occur of February 15, 1982, or payment of the 6% Notes.

On September 27, 1976, Bevis, Narragansett, Denmark, Royal Little, Sol Kittay ("Kittay") and Stanley Goldstein ("Goldstein") had entered into an agreement ("Bevis Stockholders Agreement") pursuant to which certain restrictions were placed on the sale of the shares of common stock of Bevis owned by the parties (other than Bevis) and Denmark was entitled, until the 6% Notes were paid, to have vacancies on the board of directors of Bevis caused by the resignations or inability to serve of Denmark, Kittay or Jack Brier filled by persons agreeable to him. Narragansett was entitled to fill two other vacancies.

On May 1, 1979, at the time of the purchase by Bevis of the stock of MD, the Bevis Stockholders Agreement was amended to add Fester as a party, to make the commitments with respect to the right of Denmark and others to fill vacancies on the Bevis board of directors effective until the payment of not only the 6% Notes but also the $4,900,000 of 6% Subordinated Installment Notes issued as part of the purchase price for the stock of MD, and to make certain other changes.

The above described prior transactions were the subject of applications and Commission orders permitting the transactions (Investment Company Act Release Nos. 9584 and 10752). Pursuant to a First Amendment to the Stock Purchase Agreement executed in October, 1978, and a Second Amendment thereto executed in January, 1980, certain installments of principal due under the 6% Notes on January 15, 1979, and January 15, 1980, were partially deferred. All such deferred payments had been fully paid by March 13, 1980. However, according to the Applicants, it became clear at that time that the final installments totaling $5,500,000 which would otherwise come due January 15, 1982, could not be paid when due without substantial borrowing by Bevis or Greenville and that efforts should be made to negotiate a deferral of the final installments agreeable to the Noteholders as well as a deferral agreeable to Narragansett of the $1,700,000 payable on February 15, 1982, under the Subordinated Notes.

At the April 17, 1980, meeting of the board of directors of Bevis, a memorandum was discussed recommending a deferral of the final installments of the 6% Notes due January 15, 1982, and the proposed form of the Third Amendment to the Stock Purchase Agreement ("Third

Amendment") to effect that deferral and to establish the terms of the related transactions required to obtain the approval of the Noteholders were dicussed at meetings of the Bevis board held August 5, and October 9, 1980.

Applicants state that following negotiations discussed at meetings held April 17, August 5 and October 8, 1980, the Bevis board on January 8, 1981, approved the execution of the Third Amendment pursuant to which the final installments of the 6% Notes totaling $5,500,000 would be payable $750,000 on January 15, 1982, $500,000 on January 15, 1983, and January 15, 1984, and $3,750,000 on September 30, 1984 (of which $2,625,000 would be paid to Narragansett and $1,125,000 would be paid to the Individual Noteholders), and the annual payments by Greenville to Bevis to cover general corporate overhead would be increased as of January 1, 1981, and again as of January 15, 1983. The Third Amendment included the agreement of Narragansett to defer payment of the $1,700,000 owed to it by Greenville under the Subordinated Notes until one month after the 6% Notes are paid or October 31, 1984, whichever shall first occur. To obtain those agreements, Bevis and Greenville agreed to increase the annual rate of interest on both the 6% Notes and the Subordinated Notes to 15% commencing January 15, 1982. Bevis obtained the agreement of Narragansett in the Third Amendment to extend the option periods under the McGonigal and Painter Options from Narragansett from January 31, 1982, until December 31, 1984, provided the other conditions precendent to their exercise are satisfied. Bevis and Greenville obtained the agreement of McGonigal and Painter in the Third Amendment to amend the McGonigal and Painter employment agreements, in consideration of (1) and increase in their minimum salaries; (2) to extend the terms thereof until December 31, 1984; and (3) to increase the duration of their agreements not to compete. The Third Agreement also included the agreement of Bevis to grant additional options to McGonigal and Painter to purchase shares of Bevis common stock at $2 per share, exercisable during the period from January 1, 1985, to December 31, 1985, provided that 6% Notes and the Subordinated Notes shall have been paid in full and to grant additional options covering in the aggregate 100,000 shares of common stock (12,500 shares to each) to eight other key employees at Greenville ("Employee Option Holders") on the same terms, except that the options will be exercisable until December 31, 1986.

According to the application, before the Third Amendment and related documents could be executed, the serious differences over management policy which had existed for several years between Denmark (and his two nominees on the Bevis board of directors) on the one hand and the remaining members of the Bevis board and the subsidiaries' management on the other, came to a head. The Bevis directors, other than Denmark and his nominees, agreed with the positions taken by the managements at Greenville and MD and felt that the continuing services of these management groups were vital to the success of Bevis. As a result of the disagreement, Narragansett, McGonigal and Painter indicated on July 22, 1981, that they were unwilling to proceed with the refinancing contemplated by the Refinancing Transactions authorized on January 8, 1981, so long as Denmark and his nominees were directors of Bevis and Denmark, Kittay and Goldstein were stockholders of Bevis. Under the terms of an agreement among Bevis and certain of its stockholders, until the 6% Notes and the notes involved in the purchase of MD are paid, Denmark is entitled to nominate three directors of Bevis.

On July 22, 1981, Narragansett and McGonigal owned $6,500,000 and $4,615,000, respectively, of the principal amounts of the 6% Notes, and were entitled to $3,500,000 and $1,420,000, respectively, of the final installments due January 15, 1982, thereunder. Any waiver of a default on the 6% Notes requires the consent of both Narragansett and McGonigal. On July 22, 1981, McGonigal and Painter were, and had been since the acquisition of Greenville by Bevis, the President and Vice-President, respectively of Greenville. In the opinion of a majority of the Bevis directors, the success of Greenville has been due to the managerial talents of McGonigal and Painter.

Applicants state that any refinancing that involved the payment of the 6% Notes when due would terminate the McGonigal and Painter Employment Agreements, and without their agreement to the extension of their employment arrangements thereafter, Greenville would lack experienced management, a condition which Applicants assert made it impractical to obtain loans from banks or other institutional lenders with which to pay the final installments.

Applicants state that when Bevis' negotiations with the Noteholders broke down, the Bevis board of directors appointed a committee of disinterested directors to investigate the various possibilities of refinancing the obligations due in January and February of 1982 under the 6% Notes and the Subordinated Notes. Efforts of the disinterested directors committee led to an offer on August 31, 1981, by Denmark, Kittay and Goldstein to Bevis to sell the 639,225 shares of Bevis common stock owned by them ("Shares to be Sold") at $3.25 a share, which was the asked price in the over-the-counter market on that date.

Applicants represent that the members of the board of directors of Bevis, other than Denmark and his nominees, met informally on September 2, 1981, to consider the offer. The disinterested directors committee recomended that the offer be accepted as the best way to obtain agreement to the refinancing contemplated by the Third Amendment and eliminate the friction among the directors in view of the refusal of banks to make loans (absent assurances of continued experienced management at Greenville) and the disadvantages of the possible alternative of bankruptcy proceedings. The committee felt that the proposed price was fair and that the purchase would be advantageous to the Bevis stockholders. The proposed price of $3.25 a share was the asked price according to the National Daily Quotation Service on August 31, 1981 (the date when the offer was made). Applicants assert that based on the pro forma cash flow projections as of December 31, 1981, prepared by management, the proposed price was less than the book value ($3.31), approximately 2 times tangible book value ($1.57) and 4.9 times fully taxed projected earnings for 1981 ($.67). The directors present agreed that the price was fair and that the redemption of the 639,225 shares offered at this price would be in the best interests of the stockholders, provided Denmark and his nominees agreed to resign from the Bevis Board.

According to the application, at a meeting held September 11, 1981, the board of directors of Bevis voted to accept the offer and approved an agreement among Bevis and certain of its stockholders and directors ("Purchase Agreement for Bevis Stock") setting forth the commitments of the various parties with respect to the purchase of the 639,225 shares owned by Denmark, Kittay and Goldstein. The Purchase Agreement for Bevis Stock provides that in the event that Bevis does not have sufficient earned surplus on the closing date to purchase the

Shares to be Sold without violating the Rhode Island Business Corporate Act, Narragansett will purchase those shares that Bevis cannot purchase. Bevis and Narragansett agree that any shares purchased by Narragansett will be sold to Bevis at the same price when and as Bevis has sufficient earned surplus with which to make the purchase. The Purchase Agreement for Bevis Stock is subject to the entry of the order by the Commission sought by Applicants. Bevis and Narrangansett may assign their rights to purchase the Shares to be Sold to persons not affiliated with Bevis or Narragansett. If no purchase is made by Bevis, Narragansett or their assignees on or before June 30, 1982, the agreement will terminate on that date. Should the Purchase Agreement terminate on June 30, 1982, the Purchase Agreement provides that McGonigal and Painter will serve in their present capacities at Greenville in accordance with the terms of their present employment contracts for a period of 120 days after such termination, provided the duration of their agreement not to compete shall not be adversely affected by such further service and the annual rate of their salaries shall be increased by 20% during such 120-day period.

At the same September 11, 1981, meeting, the Bevis board of directors approved the Third Amendment and related transactions in the form previously authorized on January 8, 1981, except that the Noteholders agreed that the $750,000 of installments under the 6% Notes previously scheduled for January 15, 1982 would be further deferred until July 15, 1982, and Narragansett agreed that the McGonigal and Painter Options from Narragansett would be further amended to make them immediately exercisable upon the effective date of the Third Amendment by eliminating the various conditions that must now be met before the options may be exercised, including the condition that the 6% Notes and Subordinated Notes shall have been paid. Narragansett and the Individual Noteholders agreed to these amendments.

According to Applicants, Bevis is an affiliate of Narragansett, which owns 33.4% of the outstanding common stock of Bevis and is presumed to control Bevis. Greenville, a wholly-owned subsidiary of Bevis, is an affiliate of Bevis and therefore an affiliate of Narragansett. Each of the Individual Noteholders is an affiliate of Greenville by virtue of his past or present employment, and hence is an affiliate of an affiliate of Narragansett.

Section 17(a) of the Act prohibits any affiliated person, as defined by Section 2(a)(3) of the Act, of a registered investment company or any affiliated person of such a person, acting as principal, from (1) selling any secruity to such registered investment company, unless such sale involves securities of which the buyer is the issuer, and (2) from purchasing from such registered company or a company controlled by such registered company any security, except securities of which the seller is the issuer. Under Section 17(b) of the Act, however, the Commission may, upon the filing of an application, exempt a transaction from the provisions of Section 17(a) upon finding that the terms of the proposed transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned, that the proposed transaction is consistent with the policy of each registered investment company concerned, and that the proposed transaction is consistent with the general purposes of the Act.

Applicants request an order exempting from the provisions of Section 17(a) of the Act (1) the sale by Denmark to Narragansett of some or all of the shares of Bevis common stock pursuant to the Purchase Agreement for Bevis stock in the event that Bevis does not have sufficient earned surplus to purchase such shares; (2) the amendment of the McGonigal and Painter Options from Narragansett previously granted pursuant to which McGonigal and Painter may purchase from Narragansett shares of Bevis common stock; and (3) the agreement of Bevis to purchase from Narragansett any shares of Bevis common stock purchased by Narragansett from Denmark, Kittay, or Goldstein.

Section 17(d) of the Act and Rule 17d–1 thereunder, taken together, provide, among other things, that it shall be unlawful for any affiliated person of a registered investment company or any affiliated person of such a person, acting as principal, to effect any transaction in which such registered company or a company controlled by such registered company is a participant, unless an application regarding that transaction has been granted by an order of the Commission. In passing upon such an application, the Commission will consider whether the participation of such registered or controlled company in the transaction is consistent with the provisions, policies and purposs of the Act and the extent to which that participation is on a basis different from or less advantageous than that of other participants.

Applicants also request, an order permitting, under Section 17(d) of the Act and Rule 17d–1 thereunder, all of the transactions described in the application since they are interrelated and involve parties who are affiliates of Narragansett or affiliates of affiliates of Narragansett who may be deemed to be engaging in transactions in connection with a joint enterprise or other joint arrangement or profit sharing plan in which Narragansett or Bevis is a participant.

Applicants assert that the terms of the Third Amendment and related transactions and those of the Purchase Agreement for Bevis stock and related transactions were negotiated over many months of arms-length negotiations between the various parties who are sophisticated and were represented by independent counsel. Those terms were also approved by the disinterested directors committee which also had the benefit of independent counsel. The price paid for the common stock of Bevis to be sold pursuant to the Purchase Agreement for Bevis stock is asserted to be fair under the accepted standards of valuation described above, and the price was deemed to be fair by the Noteholders, the disinterested directors committee and the principal stockholders of Bevis who will remain after the proposed purchase is consummated—namely, Narragansett, Fester, Huckins, Little, McGonigal, Frost and Painter. Applicants also assert that the proposed transactions do not involve overreaching on the part of any person involved and that the transactions benefit each party to them.

With respect to the Purchase Transactions, the Applicants assert that the transactions are reasonable and fair and do not involve overreaching on the part of any person involved. The stockholders of Bevis, including Narragansett, assertedly will benefit by the elimination of the dissention on the board of directors that had jeopardized the continued services of McGonigal and Painter at Greenville and Fester at MD and hence, the future profitability of Bevis. Applicants argue that the Bevis stockholders also will benefit by the reduction in the number of outstanding Bevis shares by 25.6% and an increase in the earnings and book value per share by over 34%. Applicants assert that without the purchase of these shares and the related resignations from the Bevis board, the Refinancing Transactions contemplated by the Third Amendment could not have been consummated and Bevis might have

been required to seek protection under Chapter 11 of the Bankruptcy Act to the detriment of the Noteholders. Narragansett and the Bevis stockholders in order to prevent the reversion of the stock of Greenville to the Noteholders. Narragansett and its stockholders are asserted to benefit in that Narragansett is by far the largest stockholder of Bevis and is owed $3,500,000 on 6% Notes and $1,700,000 on Subordinated Notes, all of which indebtedness is to be on a basis providing for a higher yield and greater assurance of payment.

Applicants also assert that the proposed transactions are consistent with the policies of Narragansett and with the general purposes of the Act.

Applicants assert that the participation of Narragansett and Bevis in the proposed transaction is consistent with the provisions, policies and purposes of the Act, and to the extent that their participation is on a basis different from or less advantageous than that of other participants, the transactions are fair and reasonable and do not involve any overreaching.

Notice is further given that any interested party may, not later than February 16, 1982, at 5:00 p.m., submit to the Commissionm a request in writing for a hearing on the matter accompanied by a statement as to the nature of such party's interest, the reason for such request, and the issues of fact or law proposed to be controverted, or such party may request to be notified if the Commission shall order a hearing thereon. Any such communication should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request shall be served personnally or by mail (priority mail if the person being served is located more than 500 miles from the point of mailing) upon the Applicants at the addresses stated above. Proof of such service (by affidavit, or in the case of an attorney-at-law, by certificate) shall be filed contemporaneously with the request. At any time after said date, as provided by Rule 0–5 of the rules and regulations promulgated under the 1940 Act, an order disposing of the application herein may be issued by the commission upon the basis of the showing contained in the application, unless an order for a hearing upon the application shall be issued upon request or upon the Commission's own motion.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82–1839 Filed 1–25–82; 8:45 am]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

[License No. 02/02–0434]

Faulkner Investment Co.; Issuance of a License To Opperate as a Small Business Investment Company

On June 19, 1981, a notice was published in the **Federal Register** (46 FR 32122) stating that Faulkner Investment Company, 870 Seventh Avenue, New York, New York 10019, had filed an application with the Small Business Administration pursuant to Section 107.102 of the SBA Rules and Regulations governing small business investment companies (13 CFR 107.102(1981)), for a license to operate as a small business investment company.

Interested parties were given until the close of business July 6, 1981, to submit their comments. No comments were received.

Notice is hereby given that, having considered the application and all other pertinent information, SBA on November 5, 1981 issued License No. 02/02–0434 to Faulkner Investment Company, pursuant to Section 301(c) of the Small Business Investment Act of 1958, as amended.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies.)

Dated: January 19, 1982.

Robert G. Lineberry,

Acting Deputy Associate Administrator for Investment.

[FR Doc. 82–1869 Filed 1–25–82; 8:45 am]

BILLING CODE 8025–01–M

[License No. 02/02–5432]

International Paper Capital Formation, Inc.; Issuance of a Small Business Investment Company License

On April 6, 1981, a notice was published in the **Federal Register** (46 FR 20647) stating that an application has been filed by International Paper Capital Formation, Inc., 77 West 45th Street, New York, New York 10036, with the Small Business Administration (SBA), pursuant to § 107.102 of the Regulations governing small business investment companies (13 CFR 107.102 (1981)), for a license as a small business investment company.

Interested parties were given until close of business April 21, 1981, to submit their comments to SBA. No comments were received.

Notice is hereby given that, pursuant to Section 301(d) of the Small Business Investment Act of 1958, as amended, after having considered the application and all other pertinent information, SBA issued License No. 02/02–5432 on November 5, 1981 to International Paper Capital Formation, Inc., to operate as a small business investment company.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies.)

Dated: January 19, 1982.

Robert G. Lineberry,

Acting Deputy Associate Administrator for Investment.

[FR Doc. 82–1870 Filed 1–25–82; 8:45 am]

BILLING CODE 8025–01–M

[License No. 01/01–0314]

Vadus Capital Corp.; Issuance of License To Operate as a Small Business Investment Company

On July 16, 1981, a notice was published in the **Federal Register** (46 FR 36981) stating that Vadus Capital Corporation, Three Center Plaza, Boston, Massachusetts 02108 had filed an Application with the Small Business Administration, pursuant to § 107.102 of the Regulations governing small business investment companies (13 CFR 107.102 (1981)), for a license to operate as a small business investment company.

Interested parties were given until the close of business on July 31, 1981, to submit written comments on the Application to the SBA.

Notice is hereby given that no written comments were received, and having considered the Application and all other pertinent information, the SBA approved the issuance of License No. 01/01–0314 on November 3, 1981, to Vadus Capital Corporation, pursuant to Section 301(c) of the Small Business Investment Act of 1958, as amended.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies).

Dated: January 19, 1982.

Robert G. Lineberry,

Acting Deputy Associate Administrator for Investment.

[FR Doc. 82–1871 Filed 1–25–82; 8:45 am]

BILLING CODE 8025–01–M

Sunshine Act Meetings

Federal Register
Vol. 47, No. 17
Tuesday, January 26, 1982

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

CONTENTS

	Items
Consumer Product Safety Commission	1
Federal Communications Commission	2, 3
Federal Mine Safety and Health Review Commission	4

1

CONSUMER PRODUCT SAFETY COMMISSION

TIME AND DATE: 9:30 a.m., Wednesday, January 27, 1982.

LOCATION: Third floor hearing room, 1111 18th Street, NW. Washington, D.C.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. *Prednisone Exemption Petition PP 81-1*
   The Commission will consider a request for an exemption to the child resistant packaging requirements of the Poison Prevention Packaging Act for Prednisone.
2. *School Laboratory Chemicals Status Report*
   The staff will brief the Commission on the School Laboratory Chemicals Status Report. The purpose of the project was to identify potential chemical hazards in the school laboratory and to access the need for development of information/education materials to increase school laboratory safety awareness.
3. *Voluntary Standards—Policy on Acknowledgement*
   The staff will brief the Commission on a policy on acknowledge for voluntary standards.

STATUS: Closed to the public.

MATTERS TO BE CONSIDERED:

4. *Section 15 Matters: Status*
   The staff will brief the Commission on recent activities under Section 15 of the Consumer Product Safety Act.
5. *Enforcement Matter: OS 1085*
   The staff will brief the Commission on issues concerning enforcement matter OS 1085.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Sheldon D. Butts, Office of the Secretary, Room 342, 5401 Westbard Ave., Bethesda, Md. 20207.

[S-107-82 Filed 1-21-82; 4:35 pm]

BILLING CODE 6355-01-M

2

FEDERAL COMMUNICATIONS COMMISSION

Closed Commission Meeting, Thursday, January 28, 1982

The Federal Communications Commission will hold a Closed Meeting on the subjects listed below on Thursday, January 28, 1982, following the Open Meeting which is scheduled to commence at 9:30 a.m., in room 856, at 1919 M Street, NW., Washington, D.C.

Agenda, Item No., and Subject

Complaints and Compliance—1—Results of a field investigation into the operation of Radio Station KRDD, Roswell, New Mexico

Complaints and Compliance—2—Request by Curran Communications, Inc. for reconsideration of Commission's letter of admonition issued to Radio Station WPAM, Pottsville, Pennsylvania.

Hearing—1—Application for Review of a Review Board Memorandum Opinion and Order denying a request to reopen the record and enlarge issues in the Laredo, Texas, comparative FM proceeding (Docket Nos. 79-316, 79-317).

Hearing—2—Applications for Review in the Gulf Coast Communications, Inc., Tampa, Florida Public Coast III-B Maritime Mobile Radio proceeding. (PR Docket No. 78-259-60).

Hearing—3—Petition for Reconsideration in the Stereo Broadcasters, Inc., Garden City, New York, FM license renewal proceeding (Docket No. 20590).

Hearing—4—Petition for Leave to Amend; Motion to Enlarge Issues against Radio Station WABZ, Inc.; and Contingent Petitions to Enlarge Issues Against Victor Broadcasting, Inc., in the Albermarle, North Carolina FM radio proceeding (Docket Nos. 78-63 and 78-64).

Hearing—5—Petition for Reconsideration of the Commission's Decision in the Albuquerque, New Mexico TV renewal proceeding (Docket No. 20540).

Hearing—6—Certified Exemptions and related pleadings requesting review of the Initial Decision in the New York Metropolitan area Domestic Public Land Mobile Radio Service comparative proceeding (CC Docket Nos. 78-200, 78-201, and 78-202).

This meeting may be continued the following work day to allow the Commission to complete appropriate action.

Additional information concerning this meeting may be obtained from Maureen P. Peratino, FCC Public Affairs Office, Telephone number (202) 254-7674.

Issued: January 21, 1982.

William J. Tricarico,
Secretary, Federal Communications Commission.

[S-109-82 Filed 1-22-82; 3:31 pm]

BILLING CODE 6712-01-M

3

FEDERAL COMMUNICATIONS COMMISSION

Open Commission Meeting, Thursday, January 28, 1982

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Thursday, January 28, 1982, which is scheduled to commence at 9:30 a.m., in Room 856, at 1919 M Street, N.W., Washington, D.C.

Agenda, Item No., and Subject

General—1—*Title:* Radio Technical Commission for Aeronautics (RTCA). *Summary:* The Commission Participates in the RTCA with other government agencies. However, the current austere budget requires program reductions. The Private Radio Bureau has proposed cancelling the FCC membership in the RTCA.

General—2—*Title:* Responsibility of the Federal Communications Commission to consider biological effects of radiofrequency radiation when authorizing the use of radiofrequency devices. Potential effects of a reduction in the allowable level of radiofrequency radiation on FCC authorized communications services and equipment (Docket 79-144). *Summary:* It is proposed to amend § 1.1305 of the Commission's Rules implementing the National Environmental Policy Act. Would expand the list of "major actions" subject to environmental processing standards to include equipment or operations not in compliance with federal health and safety standards for radiofrequency or microwave radiation.

General—3—*Title:* Report of the United States Delegation to the Regional Administrative MF Broadcasting Conference (Region 2), Second Session, Rio de Janeiro, 1981. *Summary:* The United States participated in a conference in Rio de Janeiro which developed an agreement and master assignment plan governing AM broadcasting in the Western Hemisphere. The Chairman of the U.S. Delegation will report on the outcome of the Conference and its potential effect on the AM broadcasting service in the U.S.

Private Radio—1—*Title:* Reinstatement of expired Club and Military Recreation station licenses. *Summary:* The Commission will consider whether the staff should reinstate certain expired amateur radio licenses.

Private Radio—2—*Title:* Petition for Reconsideration of Commission's action of October 1, 1981, relating to Amateur station identification requirements. *Summary:* The Commission will consider whether to grant or to deny the Petition for Reconsideration.

Private Radio—3—*Title:* Amendment of Section 90.61 of the Commission's Rules concerning general eligibility in the Industrial Radio Services. *Summary:* The FCC will consider whether to adopt a rule amendment to permit the licensing of non-profit corporations and associations of eligible users in the Business and Special Industrial Radio Services in the bands below 512 MHz.

Common Carrier—1—American Telephone & Telegraph Company *et al.* For Authority Under Section 214 of the Communications Act to Construct and Operate a Submarine Cable System (Third Florida-St. Thomas Cable) Between the Continental United States and St. Thomas, U.S. Virgin Islands. (I–P–C–81–050) We are considering the aforementioned joint application for authority pursuant to Section 214 of the Communications Act of 1934 as amended to participate in the construction and operation of an approximately 3,000 circuit submarine cable (SG type—3,150 4 kHz circuits) between Florida and St. Thomas, U.S. Virgin Islands. Of the 3,000 circuits, the joint applicants intend to place 1,901 in service initially to be used solely for international service.

Common Carrier—2—*Title:* Application by AT&T, ITTCIVI, ITT Worldcom, RCA Globcom, TRT, and WUI (joint applicants) for a cable landing license to land and operate a submarine cable between Florida and St. Thomas, U.S. Virgin Islands. *Summary:* The joint applicants request a license pursuant to the provisions of 47 U.S.C. 34–39 to land and operate a submarine cable between Florida and St. Thomas, U.S. Virgin Islands.

Common Carrier—3—*Title:* American Telephone and Telegraph Company Restrictions on Resale and Sharing of Private Line Services to Form Equivalents of Message Telecommunications Service and Wide Area Tele-Communications Service. *Summary:* The Commission will decide whether to investigate the lawfulness of certain provisions in the American Telephone and Telegraph Company's private line tariffs which forbid the use of private line services in such a manner as to form services which are the equivalents of Message Telecommunications Service and Wide Area Telecommunications Service.

Common Carrier—4—*Title:* CC Docket No. 81–351, investigation of proposed revisions to AT&T's Series 7000 terrestrial television service offering. *Summary:* In Feb. 1981 AT&T proposed revisions to its Series 7000 terrestrial television transmission service offering. By order adopted in May 1981, the Commission suspended the revisions and set various issues for investigation (86 FCC 2d 861). These issues include the reasonableness of the proposed rate structure. During the investigation AT&T submitted an alternative rate structure and various parties filed comments. The Commission will consider the reasonableness of the proposed revisions based on the issues and comments in the investigation.

Common Carrier—5—*Title:* In the Matter of The Prescription of Revised Percentages of Depreciation pursuant to Section 220(b) of the Communications Act of 1934, as amended, for: General Telephone Company of Florida, General Telephone Company of Indiana, Incorporated, General Telephone Company of Michigan, General Telephone Company of Ohio. *Summary:* The Commission is considering prescription of depreciation rates for new additions to the outside plant accounts of the GTE companies of Florida, Indiana, Michigan and Ohio using the equal life group method of calculating such rates.

Common Carrier—6—*Title:* RCA American Communications Revisions to Tariff F.C.C. Nos. 1 and 2, Transmittal Nos. 323 and 328. *Summary:* The Commission considers petitions to reject or alternatively suspend and investigate tariff revisions filed by RCA Americom, Inc. proposing to establish a competitive bidding procedure for assigning transponders.

Common Carrier—7—*Title:* In the matter of Domestic Satellite Transponder Sales. *Summary:* The Commission considers proposals of domestic satellite space station licensees to sell transponders to users rather than leasing them pursuant to tariff.

Common Carrier—8—*Title:* In the matter of Satellite Common Carriers' Transponder Assignment Procedures. *Summary:* The Commission considers the petition of RCA American Communications Inc. requesting the Commission to direct all satellite common carriers to tariff their procedures for assigning transponders to customers or to remove such requiremets from RCA Americom

Cable Television—1—Amendment of Part O of the Commission's Rules and Regulations Concerning Delegations of Authority to the Chief, Cable Television Bureau. The Commission will consider modifying its delegation of authority to the Chief of the Cable Television Bureau, pursuant to Section 0.288 of the Commission's Rules in regard to the imposition of forfeitures on cable television system operators and Cable Television Relay Service (CARS) station licensees.

Cable Television—2—*Title:* Petitions for special relief filed by Stations WBRE–TV and WDAU–TV to be found significantly viewed in certain communities located in Pennylvania. *Summary:* Requests for declaratory rulings filed by Stations WBRE–TV and WDAU–TV, CSR–1764 an 1819, respectively, to be found significantly viewed in certain communities in Pennsylvania.

Cable Television—3—"Petition for Reconsideration" (CAR–14997–01) and Petitions for Orders to Show Cause (CSC–242, 243) filed March 4, 6, and 13, 1981, by American Cable Television, Inc. American Cable Television, Inc., operator and franchisee of several Arizona cable systems, seeks reconsideration of the grant of a construction permit for a new CARS Station WGZ–233 to Mesa Community Cable TV, Inc. American also seeks issuance of orders to show cause against Mesa for alleged violations of the Commission's Rules.

Cable Television—4—Petitions for Issuance of Tax Certificates (CSR–1843, CSR–1945) filed November 26, 1980, and May 15, 1981, by Kansas State Network, Inc. Kansas State Network, Inc., licensee of several television broadcast stations, seeks tax certificates, pursuant to Section 1071 of the 1954 Internal Revenue Code, for divestitures of its cable television interests.

Complaints and Compliance—1—*Title:* Application for Review of the Broadcast Bureau's ruling of March 31, 1981, filed by Minnesota Farmers Union on June 29, 1981. *Summary:* The Commission will consider whether to affirm the Bureau ruling which denied the complaint of the Minnesota Farmers Union ("Union") against Hubbard Broadcasting, Inc., licensee of KSTP–TV, St. Paul, Minnesota. The Bureau ruled that the licensee was not unreasonable in determining that the Union's use of a tax-exempt educational fund did not constitute a controversial issue of public importance within its service area. The Bureau declined to rule upon the Union's allegations of news distortion, in the absence of extrinsic evidence.

This meeting may be continued the following work day to allow the Commission to complete appropriate action.

Additional information concerning this meeting may be obtained from Maureen P. Peratino, FCC Public Affairs Office, telephone number (202) 254–7674.

Issued: January 21, 1982.

William J. Tricarico,

Secretary, Federal Communications Commission.

[S–110–82 Filed 1–22–82; 3:31 pm]

BILLING CODE 6712–01–M

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FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

January 18, 1982.

TIME AND DATE: 10 a.m., January 27, 1982.

PLACE: Room 600, 1730 K Street, N.W., Washington, D.C.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will hear oral argument on the following cases:

1. Secretary of Labor, MSHA v. Alexander Brothers, Inc., Docket No. HOPE 79–221–P.

2. Secretary of Labor, MSHA v. San Kennedy, d.b.a. Energy Salvage Company, Docket Nos. VINC 78–11 through VINC 78–15.

CONTACT PERSON FOR MORE INFORMATION: Jean Ellen (202) 653–5632.

[S–108–82 Filed 1–22–82; 10:19 am]

BILLING CODE 6820–12–M

Federal Register

Tuesday
January 26, 1982

Part II

Department of Health and Human Services

Food and Drug Administration

Ophthalmic Devices; General Provisions and Classification of 119 Devices; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. 78N-3128]

Ophthalmic Devices; General Provisions and Classification of 119 Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing general rules applicable to the classification of all ophthalmic devices. The Medical Device Amendments of 1976 require the agency to classify all medical devices intended for human use into three categories: class I, general controls; class II, performance standards; and class III, premarket approval. In the preamble to this proposal, FDA describes the development of the proposed regulation classifying 119 ophthalmic devices. The preamble also describes the activities of the Ophthalmic Device Section of the Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel (formerly the Ophthalmic Device Classification Panel), an FDA advisory committee that makes recommendations to FDA concerning the classification of ophthalmic devices.

DATES: Comments by March 29, 1982. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Dockets Management Branch (formerly the Hearing Clerk's Office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Max M. Talbott, Bureau of Medical Devices (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

Device Classification System

The Medical Device Amendments of 1976 (the amendments) (Pub. L. 94-295) establish a comprehensive system for the regulation of medical devices intended for human use. One provision of the amendments, section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories are as follows: class I, general controls; class II, performance standards; and class III, premarket approval.

Most devices are not classified under section 513 of the act unit after FDA has (1) received a recommendation from a device panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. These steps must precede the classification of any device that was in commercial distribution before May 28, 1976 (the date of enactment of the amendments) and that was not previously regarded by FDA as a new drug under section 505 of the act (21 U.S.C. 355). A device that is first offered for commercial distribution after May 28, 1976, and that is substantially equivalent to a device classified under this scheme, is classified in the same as the device to which it is substantially equivalent.

A device that FDA previously regarded as a new drug, or a newly offered device that is not substantially equivalent to a device that was in commercial distribution before the amendments, is classified by statute into class III. These two types of devices are classified into class III without any FDA rulemaking proceedings. The agency determines whether new devices are substantially equivalent to proviously offered devices by means of the premarket notification procedure in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the regulations (21 CFR Part 807).

Related Regulations

In the **Federal Register** of July 28, 1978 (43 FR 32988), the agency issued final regulations describing the procedures for classifying devices intended for human use. These regulations, which were propsed in the **Federal Register** of September 13, 1977 (42 FR 46028), supplement the agency's regulations in Part 14 (21 CFR Part 14) governing the use of advisory committees. The agency also issued interim device classification procedures in a notice published in the **Federal Register** of May 19, 1975 (40 FR 21848). Related regulations on several ophthalmic devices that FDA considered new drugs before enactment of the amendments or that are subject to the Radiation Control for Health and Safety Act are discussed elsewhere in this preamble.

Activities of Panel

Anticipating enactment of the amendments, FDA established several advisory committees to make preliminary recommendations on device classification. The Ophthalmic Device classification Panel (the Panel) was originally chartered on August 9, 1976, as the Panel on Review of Ophthalmic Devices. FDA placed a report of the Panel's tentative classification recommendations on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, and announced the availability of the report to the public by notice published in the **Federal Register** of June 25, 1976 (41 FR 26245). On August 9, 1976, the Panel and other preamendments device classification panels were rechartered to reflect their new responsibilities under the amendments. The agency directed each panel to reconsider its preamendments classification recommendations in light of the new requirements. In 1976 and 1977, the Panel reviewed all devices that FDA has referred to it to make certain that its recommendations were in accord with the amendments. Throughout the Panel's deliberations, interested persons were given an opportunity to present their views, data, and other information concerning the classification of ophthalmic devices. The Panel also invited experts to testify and sought information on many devices from the published literature.

In October 1977, the Panel submitted to FDA a preliminary report of its recommendations. The report included a roster of current and former Panel members and consultants and listed all meeting dates. The agency placed a copy of the report in the Dockets Management Branch (HFA-305), Food and Drug Administration, and announced its availability to the public by notice published in the **Federal Register** of November 29, 1977 (42 FR 60792). At meetings held on February 16, 1978, June 13, 1978, and May 14, 1979, the Panel changed its previous recommendations concerning the classification of several devices. An addendum to the Panel report showing these changes has been placed in the Docket Management Branch, Food and Drug Administration. Also available in the Docket Management Branch are summary minutes from all Panel meetings, verbatim transcripts of meetings held after May 28, 1976 (the date of enactment of the amendments), and all references cited in this proposal.

On April 28, 1978, the agency terminated all of the device classification panels and then reestablished them with the same functions, but with new names and new structure. FDA published notices of

these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). The Ophthalmic Device classification Panel was terminated, and its functions are now conducted by the Ophthalmic Device Section of the Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel.

Relationship Between the Device Names in the Device Registration and Listing Codes and the Device Names in Classification Regulations

Some manufacturers have become accustomed to identifying a device by its registration and listing name and three-letter code used for purposes of device listing under section 510 of the act (21 U.S.C. 360). However, FDA is still making changes in the names and identifications of generic types of devices in the classification regulations for all devices for which final regulations have not been published. Because FDA has not used the present device registration and listing names in the proposed and final classification regulations, FDA has prepared an index of names of generic types of medical devices used in classification regulations to aid a manufacturer in matching its device with the proper classification regulation. The index shows the device registration and listing product code for each device reviewed by a classification panel and the corresponding name of the generic type of device and classification panel in which the device classification will be published in the **Federal Register**. The agency announced the availability of this index in the **Federal Register** of March 6, 1979 (44 FR 12269). If necessary, this index will be updated and the availability of the revised index will be reannounced in the **Federal Register**. FDA believes that, because this index is available, it is unnecessary to include or cross-reference the present device registration and listing name and product code in the classification regulations. In the future, following publication of most of the device classification regulations, the agency will revise and reissue the device registration and listing product code, so the device names to be used for registratrion and listing correspond to the device names in the final device classification regulations.

List of Ophthalmic Devices

In 1972, FDA surveyed device manufacturers to identify the devices for which classifiction regulations would be needed. Following this survey, FDA developed a list of ophthalmic devices. The Panel supplemented the list using its members' knowledge of ophthalmic devices in use. Devices that were solely for experimental or investigational use, that were not generally available, or that had been regarded as new drugs were not included. Additional ophthalmic devices, which were not included in this list and which were commercially available before May 28, 1976, will be added to the list as necessary.

FDA is proposing to establish a new Part 886 in Title 21 of the Code of Federal Regulations. Part 886 will consist of sections identifying each ophthalmic device with a brief narrative description and stating the classification of that device. The list of ophthalmic devices appears elsewhere in the preamble.

Ophthalmic Device Classification Regulations

FDA is proposing to classify 119 ophthalmic devices. The agency is proposing to classify 45 ophthalmic devices into class I (general controls), 51 ophthalmic devices into class II (performance standards), 4 ophthalmic devices into class III (premarket approval), and with respect to 19 other devices, FDA is proposing to classify them into class I when the device is battery-powered and into class II when the device is AC-powered. The agency also is publishing the recommendations of the Panel regarding these devices, as required by section 513(c)(2) and (d)(1) of the act (21 U.S.C. 360c(c)(2) and (d)(1)).

Panel Recommendations

The Panel recommendation concerning an ophthalmic device includes the information described below.

1. *Identification.* Both the Panel recommendation and the proposed FDA classification regulation include a brief narrative identification of the generic type of the device. The identification statement is necessarily broad because it applies to a category or type of device rather than to a specific device. As explained in proposed § 886.1, any manufacturer of a newly offered device who files a premarket notification submission under section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 (21 CFR Part 807) of the regulations cannot show merely that the device is accurately described by the section title and identification provisions of a classification regulation. Although a newly offered device may be described accurately by the title and identification in a classification regulation, it is nevertheless in class III under section 513(f) of the act if it is not substantially equivalent to a preamendments device (or to a postamendments device that has already been reclassified from class III into class I or class II). It is not practical for FDA to publish an identification of each type of device that is so detailed as to anticipate every product feature that may be relevant in determining whether a new device is substantially equivalent to previous devices classified by the regulation. The agency believes that this problem was recognized in, and addressed by, the premarket notification procedures in section 510(k) of the act. Accordingly, any manufacturer who submits a premarket notification submission should state why the manufacturer believes the device is substantially equivalent to other devices in commercial distribution, as required by § 807.87 (21 CFR 807.87), and whether the device is described in a classification regulation.

Some products have both medical and nonmedical uses. FDA will regulate a multipurpose product as a medical device if it is intended for a medical purpose, i.e., for "use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease," or "to affect the structure or any function of the body." (Section 201(h) of the act (21 U.S.C. 321(h)).) FDA will determine the intended use of a product based upon the expressions of the person legally responsible for its labeling and by the circumstances surrounding its distribution. The most important factors the agency will consider in determining the intended use of a particular product are the labeling, advertising, and other representations accompanying the product. Products that have medical uses only are clearly intended for medical purposes and, therefore, will be regulated as medical devices whether or not medical claims are made for them.

2. *Recommended classification.* Each Panel's recommendation describes whether the device is recommended for classification into class I (general controls), class II (performance standards), or class III (premarket approval).

For each device recommended for classification into class I, the Panel considered whether the device should be exempt from any requirements under certain sections of the act: section 510 (21 U.S.C. 360, registrtion), section 519 (21 U.S.C. 360i, records and reports), and section 520(f) (21 U.S.C. 360j(f), good manufacturing practice requirements). Although the Panel did not recommend that any device be exempted at this time from section 510 of the act, the Panel did recommend that the manufacturers of

several class I devices be exempted from the records and reports requirements under section 519 of the act and from the good manufacturing practice regulation in section 520(f) of the act in the manufacture of these devices. The agency's policy concerning these exemption recommendations is discussed below in the section of this proposal concerning "Exemptions for Class I Devices."

A Panel recommendation that a device be classified into class II includes the Panel's recommended priority ("high," "medium," or "low") for establishing a performance standard for the device. Similarly, each Panel recommendation that a device be classified into class III includes the Panel's recommended priority ("high," "medium," or "low") for application of premarket approval requirements to that device. As explained below in the section of this notice concerning "Priorities for Class II and Class III Devices," FDA is not, however, proposing the establishment of FDA priorities at this time.

3. *Summary of reasons for recommendation.* The summary of reasons for the Panel's recommendation explains why the Panel believes a particular device meets the statutory criteria for classification into class I, II, or III.

Except in those instances in which FDA's classification proposal differs from the Panel's recommendation, FDA is adopting the Panel's summary of reasons as the agency's statement of the reasons for issuing the regulations, as required by section 517(f) of the act (21 U.S.C. 360g(f)).

In the "Panel Recommendations and FDA's Proposed Classifications" section the summary of the Panel's reasons for a recommendation identifies any device that is an implant or a life-supporting or life-sustaining device. The summary of reasons for any implant or life-supporting or life-sustaining device that is not recommended for classification into class III also explains why the Panel determined that classification of the device into class III is not necessary to provide reasonable assurance of its safety and effectiveness. Also, FDA's proposed classifications provide a similar explanation for an implant or a life-supporting or life-sustaining device that is proposed to be classified into a class other than class III.

For many of the devices that the Panel recommends be classified into class II (performance standards), the only aspect of the devices that needs to be addressed by a performance standard is electrical safety; the Panel referred to two voluntary electrical safety standards that address safety problems presented by these devices (Refs. 1 and 2).

4. *Summary of data on which the recommendation is based.* In many cases, the Panel based its recommendations on Panel members' personal knowledge of, and clinical experience with, the devices under review. The Panel particularly relied upon clinical experience and judgment when considering a simple device that had been used extensively and was accepted widely before the amendments were enacted. The legislative history of the amendments provides that the term "data" has a special meaning in section 513(c)(2)(A) of the act, which requires that a Panel recommendation summarize the data upon which a recommendation is based. As used in that section, "data" refers not only to the results of scientific experiments but also to less formal evidence, other scientific information, or judgments of experts (House Committee on Interstate and Foreign Commerce, Medical Device Amendments of 1976, H.R. Rept. 94–853, 94th Congress, 2d Session 40 (1976)). FDA has determined that clinical experience and judgment is valid scientific evidence for classifying certain devices.

In several cases, FDA sought more data and information concerning the classification of a device than were cited by the Panel. References to these data and information are found in the section for each ophthalmic device under the heading "Panel Recommendations and FDA's Proposed Classifications." The agency is adopting as its statement of the basis for issuing the regulation under section 517(f) of the act the Panel's summary of the data on which a recommendation to classify a device is based, together with any additional data and information cited in the preamble to the proposed classification regulation.

5. *Risks to health.* In identifying the risks to health presented by ophthalmic devices, the Panel recognized that few devices are completely free of risk. The Panel listed the risks it considered most significant, especially those that are unique to the individual device. In some cases, FDA has identified risks to health presented by a device in addition to those listed by the Panel. These additional risks are set out for each device in the preamble under the heading "Panel Recommendations and FDA's Proposed Classifications." The term "electrical shock" in this section includes other adverse effects of electricity, such as burns and the consequences of electrically induced muscular contractions.

Because the classification recommendations and FDA regulations may not identify all risks to health presented by ophthalmic devices, future regulations establishing performance standards under section 514 of the act (21 U.S.C. 360d) or requiring premarket approval under section 515(b) of the act (21 U.S.C. 360e(b)) may identify additional risks to health to be addressed by FDA requirements.

Proposed Classification

Each section for an ophthalmic device under the heading "Panel Recommendations and FDA's Proposed Classifications," states whether FDA agrees with the Panel's recommendation and describes the agency's proposed classification of the device.

FDA cautions that the final classification of a device may differ from the proposal. Factors that may cause such a change include comments, the agency's reconsideration of existing data and information, and the agency's consideration of new data and information.

Priorities for Class II and Class III Devices

For a device that the Panel recommends to be classified into class II or class III, section 513(c)(2)(A) of the act requires that the Panel's recommendation include, to the extent practicable, a recommendation for the assignment of a priority for application to the device of a performance standard or premarket approval requirements. In developing its advice concerning priorities ("high," "medium," or "low") of devices recommended for classification into class II, the Panel compared the devices with other ophthalmic devices, based on information available to the Panel members concerning the relative importance of use of the device and the relative risks presented by the device. The Panel recommended assignment of a "high priority" only to those class II devices that the Panel believed should receive the agency's immediate attention.

FDA is not proposing at this time to establish priorities for development of performance standards for all class II devices. Section 513(d)(3) of the act authorizes, but does not require, establishment of these priorities. In the **Federal Register** of February 1, 1980 (45 FR 7489), FDA published a notice identifying which class II devices the agency found to warrant a high priority for the development of performance standards. However, no ophthalmic devices are listed in this notice. At a

later date, the agency will establish priorities for the development of standards for the remaining class II devices. All priorities established by the agency are based on the panels's recommendations, available resources, and other relevant factors. The agency's priorities will be reflected in the agency's annual budget request and other publicly available documents and may be published in the **Federal Register.**

The agency intends to proceed as quickly as the agency and panel resources permit to require premarket approval of devices classified into class III. There are two factors affecting the length of time necessary before FDA requires subsmission of premarket approval applications for any particular device that is classified by an FDA regulation into class III: the number of devices reviewed by a panel and the priority of a particular device in relation to other class III devices considered by a panel. For example, where FDA classifies into class III only a few devices within a panel's specialty area, FDA may at the same time also publish regulations under section 515(b) of the act requiring premarket approval for many of the class III devices considered by the panel, regardless of whether of a high or a low priority. Where practical, FDA will publish these section 515(b) regulations during the grace period (30 months) following classification during which a device classified into class III by FDA regulation may lawfully remain on the market without a permarket approval application. The grace period is provided for in section 501(f) of the act (21 U.S.C. 351(f)).

Exemptions for Class I Devices

Section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) provides that FDA may exempt a device recommended for classification into class I from a requirement under the following sections of the act: Section 510 (21 U.S.C.360), registration; section 519 (21 U.S.C. 360i), records and reports; and section 520(f) (21 U.S.C.360j(f)), good manufacturing practice.

Under section 510 of the act, a person "engaged in the manufacture, preparation, propagation, compounding, or processing of * * * a device or devices" must register with FDA (section 510(b) through (i)), file a list of devices (section 510(j)), and notify FDA at least 90 days before beginning commercial distribution of a device (section 510(k)). (See Part 807 (21 CFR Part 807).) Section 510(g)(4) authorizes the agency to exempt a device from section 510 if it finds that compliance with that section is not necessary for the protection of the public health. In § 807.65 (21 CFR 807.65), FDA has exempted certain classes of persons from section 510 of the act. Several device classification panels have recommended that manufacturers of certain class I devices also be exempted from all or some of the requirements of section 510. The agency has determined that protection of the public health requires that manufacturers of medical devices, other than those already exempt under § 807.65, register and list their products with FDA to ensure that the agency can identify these manufacturers and their products and conduct necessary inspections.

The agency has determined, however, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions for certain devices. Thus, the agency has proposed to exempt manufacturers of certain devices from Subpart E of Part 807 of the regulations which implements section 510(k) of the act. The agency does not, at this time, anticipate that premarket approval will be required for these devices. The agency believes that the semiannual updating of device listing under section 510(j)(2) of the act will provide FDA with adequate notice of new products within these generic types of devices.

Section 519 of the act authorizes FDA to issue regulations requiring device manufacturers, importers, and distributors to establish and maintain such records, make such reports, and provide such information as the agency may reasonably require to assure that devices are not adulterated or misbranded and to otherwise assure their safety and effectiveness. The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation under Part 820 (21 CFR Part 820), published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA may publish other regulations in accordance with section 519 of the act, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. Whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempted from the requirements, and FDA will issue exemptions that are appropriate.

The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from most requirements of the device GMP regulation. As explained below, the exemption will not extend to two device GMP records requirements.

The device GMP regulation was published in final form in the **Federal Register** of July 21, 1978 (43 FR 31508). At the time of the Panel's recommendations, the GMP regulation had not yet been promulgated, and the agency had not yet developed criteria for exempting manufacturers of a class I device from GMP requirements. The agency has now decided that, if any one of the following criteria is met, FDA will consider exempting from the GMP regulation manufacturers of a class I device that is not labeled or otherwise represented as sterile. The agency will not, however, exempt manufacturers of a device from general requirements concerning records or complaint files. The criteria are:

1. FDA has determined, based on adequate information about current practices in the manufacture of the device and about user experience with the device, that application of the GMP regulation is unlikely to improve the safety and effectiveness of the device.

2. FDA has determined that all possible defects relating to the safety and effectiveness of the device are readily detectable before use, either through visual examination by the user or routine testing before use, e.g., testing a clinical laboratory reagent with positive and negative controls.

3. FDA has determined that any defect in the device that is not readily detectable will not result in a device failure that could have an adverse effect on the patient or other user.

FDA has determined that no device that is labeled or otherwise represented as sterile will be exempted from the device GMP regulation. A sterile device must be subject to the entire GMP regulation to ensure that manufacturers adequately reduce the bioburden (number of microorganisms) on the device and its components during the manufacturing process. This reduction is accomplished through adherence to a comprehensive quality assurance program as is required by the GMP regulation, with adequate environmental controls, trained personnel, appropriate maintenance and calibration of sterilization equipment, recordkeeping concerning lot sterility, strict packaging

and labeling controls, and other quality assurance measures.

The agency also has determined that no exemption from the device GMP regulation will extend to § 820.180, with respect to general requirements concerning records, or § 820.198, with respect to complaint files. The agency believes that granting exemptions from these sections would not be in the public interest, and that compliance with these sections is not unduly burdensome for device manufacturers. To ensure that device manufacturers have adequate systems for complaint investigation and followup, all manufacturers are required to comply with the complaint file requirements. All device manufacturers also are required to comply with the general requirements concerning records to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

In general, FDA has not initiated proposals to exempt manufacturers of devices from requirements under section 510 or 520(f) of the act, but has acted on the basis of exemption recommendations of the device classification panels. However, FDA has proposed occasionally to exempt manufacturers of certain devices classified into class I or class II from the requirements of certain sections of the GMP regulation, according to the above exemption criteria. Manufacturers and other interested persons may submit comments on the appropriateness of the proposed exemptions of manufacturers of devices, whether the exemptions are proposed in response to recommendations of the panels or on the agency's initiative. Comments requesting additional exemptions should be supported by information showing that the exemption of manufacturers of a device from the premarket notification requirement or the GMP regulation is consistent with the criteria discussed above.

Guidelines for Preparing Petitions Requesting Exemption or Variance From the Device GMP Regulation for Devices Classified Into Class I or Class II

FDA has prepared guidelines on the procedures that should be followed by persons who wish to submit petitions for exemption or variance from the device GMP regulation. These petitions may be submitted in accordance with provisions of section 520(f)(2) of the act (21 U.S.C. 360j(f)(2)). The agency announced the availability of the guidelines in a notice published in the **Federal Register** of January 18, 1980 (45 FR 3671).

List of Ophthalmic Devices

The following is a list of ophthalmic devices that FDA is proposing to classify, the section and the Subpart of Part 886 in Title 21 of the Code of Federal Regulations under which the regulation classifying the device will be codified, the docket number of the proposed classification regulation, and the proposed classification of each device:

Section	Device	Docket No.	Class
	SUBPART B—OPHTHALMIC DIAGNOSTIC DEVICES		
886.1040	Ocular esthesiometer.	78N-3129	I.
886.1050	Adaptometer (biophotometer).	78N-3130	II.
886.1070	Anomaloscope.	78N-3132	II.
886.1090	Haidinger brush.	78N-3133	II.
886.1120	AC-powered ophthalmic camera.	78N-3135	II.
886.1140	Ophthalmic chair.	78N-3137	I, II.
886.1150	Visual acuity chart.	78N-3139	II.
886.1160	Color vision plate illuminator.	78N-3140	II.
886.1170	Color vision tester.	78N-3141	I.
886.1190	Distometer.	78N-3142	I.
886.1200	Optokinetic drum.	78N-3143	I.
886.1220	Corneal electrode.	78N-3144	II.
886.1250	Euthyscope.	78N-3145	I, II.
886.1270	Exophthalmometer.	78N-3147	I.
886.1290	AC-powered fixation device.	78N-3148	II.
886.1300	After-image flasher.	78N-3149	II.
886.1310	Fluorescein strip.	78N-3150	I.
886.1320	Fornixscope.	78N-3151	I.
886.1330	Amsler grid.	78N-3152	I.
886.1340	Haploscope.	78N-3295	II.
886.1350	Keratoscope.	78N-3153	I, II.
886.1360	Visual field laser instrument.	78N-3155	II.
886.1375	Bagolini lens.	78N-3156	I.
886.1380	Diagnostic condensing lens.	78N-3157	I.
886.1385	Polymethylmethacrylate diagnostic contact lens.	78N-3158	II.
886.1390	Flexible diagnostic Fresnel lens.	78N-3159	I.
886.1395	Diagnostic Hruby fundus lens.	78N-3160	I.
886.1440	Maddox lens.	78N-3161	I.
886.1405	Ophthalmic trial lens set.	78N-3162	II.
886.1410	Ophthalmic trial lens clip.	78N-3163	I.
886.1415	Ophthalmic trial lens frame.	78N-3164	I.
886.1420	Ophthalmic lens gauge.	78N-3165	I.
886.1425	AC-powered lens measuring instrument.	78N-3166	II.
886.1430	Ophthalmic contact lens radius measuring device.	78N-3167	II.

Section	Device	Docket No.	Class
886.1435 AC-powered Maxwell spot.	78N-3168		II.
886.1450 Corneal radius measuring device.	78N-3169		II.
886.1460 Stereopsis measuring instrument.	78N-3170		I.
886.1500 Headband mirror.	78N-3171		I.
886.1510 Eye movement monitor.	78N-3172		II.
886.1570 Ophthalmoscope.	78N-3175		I, II.
886.1605 Perimeter.	78N-3178		I, II.
886.1630 AC-powered photostimulator.	78N-3181		II.
886.1640 Ophthalmic preamplifier.	78N-3182		II.
886.1650 Ophthalmic bar prism.	78N-3184		I.
886.1655 Ophthalmic Fresnel prism.	78N-3185		I.
886.1660 Gonioscopic prism.	78N-3186		I.
886.1665 Ophthalmic rotary prism.	78N-3187		I.
886.1670 Ophthalmic isotope uptake probe.	78N-3188		II.
886.1680 Ophthalmic projector.	78N-3189		II.
886.1690 Pupillograph.	78N-3190		II.
886.1700 Pupillometer.	78N-3191		I, II.
886.1750 Skiascopic rack.	78N-3193		II.
886.1760 Ophthalmic refractometer.	78N-3194		II.
886.1770 Manual refractor.	78N-3195		I.
886.1780 Retinoscope.	78N-3196		I, II.
886.1790 Near-point ruler.	78N-3198		I.
886.1800 Schirmer strip.	78N-3199		I.
886.1810 Tangent screen (campimeter).	78N-3200		I, II.
886.1840 Simulatan (including crossed cylinder).	78N-3206		I.
886.1850 AC-powered slitlamp biomicroscope.	78N-3207		II.
886.1860 Ophthalmic instrument stand.	78N-3208		I, II.
886.1870 Stereoscope.	78N-3210		I, II.
886.1880 Fusion and stereoscopic target.	78N-3212		I.
886.1905 Nystagmus tape.	78N-3213		I.
886.1910 Spectacle dissociation test system.	78N-3214		I, II.
886.1930 Tonometers and accessories.	78N-3218		II.
886.1940 Tonometer sterilizer.	78N-3220		II.
886.1945 Transilluminator.	78N-3221		I, II.

SUBPART D—OPHTHALMIC PROSTHETIC DEVICES

Section	Device	Docket No.	Class
886.3100 Ophthalmic tantalum clip.	78N-3224		II.
886.3130 Ophthalmic conformer.	78N-3225		II.
886.3200 Artificial eye.	78N-3226		II.
886.3300 Absorbable implant (scleral buckling method).	78N-3227		II.
886.3320 Eye sphere implant.	78N-3228		II.
886.3340 Extraocular orbital implant.	78N-3229		II.
886.3400 Keratoprosthesis.	78N-3230		III.
886.3800 Scleral shell.	78N-3231		II.
886.3920 Eye valve implant.	78N-3232		III.

SUBPART E—OPHTHALMIC SURGICAL DEVICES

Section	Device	Docket No.	Class
886.4070 Powered corneal burr.	78N-3233		I, II.
886.4100 Radiofrequency cautery apparatus.	78N-3235		II.
886.4115 Thermal cautery unit.	78N-3237		II.
886.4150 Vitreous aspiration and cutting instrument.	78N-3239		III.
886.4170 Cryophthalmic unit.	78N-3241		II.
886.4230 Ophthalmic knife test drum.	78N-3243		I.
886.4250 Ophthalmic electrolysis unit.	78N-3244		I, II.
886.4300 Intraocular lens guide.	78N-3250		I.
886.4335 Operating headlamp.	78N-3252		I, II.
886.4350 Manual ophthalmic surgical instrument.	78N-3253		I.
886.4360 Ocular surgery irrigation device.	78N-3254		I.
886.4370 Keratome.	78N-3255		I, II.
886.4390 Ophthalmic laser.	78N-3257		II.
886.4400 Electronic metal locator.	78N-3258		II

Section	Device	Docket No.	Class
886.4440 AC-powered magnet.	78N-3259		II.
886.4445 Permanent magnet.	78N-3260		I.
886.4570 Ophthalmic surgical marker.	78N-3261		I.
886.4610 Ocular pressure applicator.	78N-3264		II.
886.4650 Eye pad.	78N-3265		I.
886.4670 Phacofragmentation system.	78N-3266		III.
886.4690 Ophthalmic photocoagulator.	78N-3267		II.
886.4750 Ophthalmic eye shield.	78N-3268		I.
886.4770 Ophthalmic operating spectacles (loupes).	78N-3269		I.
886.4790 Ophthalmic sponge.	78N-3270		II.
886.4855 Ophthalmic instrument table.	78N-3272		I, II.

SUBPART F—OPHTHALMIC THERAPEUTIC DEVICES

886.5100 Ophthalmic beta radiation source.	78N-3273		II.
886.5120 Low-power binocular loupe.	78N-3274		I.
886.5270 Spectacle frame.	78N-3276		II.
886.5400 Polymethylmethacrylate contact lens.	78N-3277		II.
886.5420 Contact lens inserter/remover.	78N-3278		I.
886.5450 Prescription spectacle lens.	78N-3279		II.
886.5540 Low-vision magnifer.	78N-3281		I.
886.5600 Ptosis crutch.	78N-3282		I.
886.5800 Ophthalmic bar reader.	78N-3283		I.
886.5810 Ophthalmic prism reader.	78N-3284		I.
886.5820 Closed-circuit television reading system.	78N-3285		II.
886.5840 Magnifying spectacles.	78N-3286		II.
886.5850 Sunglasses (nonprescription).	78N-3287		II.
886.5870 Low-vision telescope.	78N-3288		I.
886.5900 Electronic vision aid.	78N-3290		I, II.
886.5910 Battery-powered image intensification vision aid.	78N-3292		I.
886.5915 Optical vision aid.	78N-3293		I, II.

Ophthalmic Devices Formerly Considered New Drugs

Before the passage of the Medical Device Amendments of 1976, certain ophthalmic devices were considered by FDA to be new drugs subject to 21 U.S.C. 355. Section 520(1) of the 1976 amendments (21 U.S.C. 360j(1)), contains transitional provisions to ensure that articles previously considered as new drugs continue to be subject to regulatory control until the amendments are implemented. The transitional provisions are applicable to any product that is a device (under a revised definition in 21 U.S.C. 321(h)) and that satisfies one or more of six criteria. These criteria are that the device is a product (1) for which an approved New Drug Application (NDA) was in effect on May 28, 1976 (the enactment date of the amendments); (2) for which an NDA was filed and no order of approval or refusal to approve had been issued by May 28, 1976; (3) for which a notice of claimed investigational exemption for a new drug (IND) was in effect on May 28, 1976; (4) which is substantially equivalent to a product described in item (1), (2), or (3), above, (5) which has been declared to be a new drug by a **Federal Register** notice before May 28, 1976; or (6) which was the subject of a legal action pending on May 28, 1976, for alleged violation of new drug requirements. Under section 520(1), these devices are classified into class III.

Several generic types of ophthalmic devices were regarded by FDA as new drugs before enactment of the amendments and are subject to the transitional provisions under one or more of the criteria listed above. These devices are:

1. Soft contact lenses and ophthalmic lens cleaning (sterilizing) solutions and wetting agents for use with soft contact lenses.

2. Intraocular lenses.

3. Gases used within the eye to place pressure on a detached retina if the device was subject to an IND or NDA or is substantially equivalent to a device that was subject to an IND or NDA.

4. Ophthalmic devices for measuring intraocular pressure that were subject to an IND or NDA or that are substantially equivalent to a device that was subject to an IND or NDA.

The statute has classified these devices into class III without need for regulations or other action on the part of the agency. See 21 U.S.C. 360j(1); 42 FR 63472 (December 16, 1977). The transitional devices above are thus not included in the list of ophthalmic devices that are the subject of this proposed rulemaking, but will be the subject of final regulations describing their statutory classification, to be published on the same date as the final regulations on ophthalmic devices based on this proposal. By notice published in the **Federal Register** of November 24, 1981 (46 FR 57648), FDA already has announced its intent to initiate proceedings to reclassify certain soft contact lenses from class III to class II.

FDA has published other **Federal Register** documents on contact lenses and intraocular lenses. See 40 FR 44844 (September 30, 1975) (proposed notice of FDA policy that soft contact lenses are regarded as new drugs and that hard contact lenses are regarded as medical devices); 43 FR 1966 (January 13, 1978) (withdrawal of proposed notice); 41 FR 14750 (April 6, 1976) (notice that intraocular lenses are regarded as new drugs); 41 FR 38802 (September 13, 1976) (notice that intraocular lenses were

classified by statute into class III); 42 FR 58874 (November 11, 1977) (requirements for distribution, investigation, and use of intraocular lenses).

Devices Subject to the Radiation Control for Health and Safety Act

In addition to FDA's authority over devices under the Federal Food, Drug, and Cosmetic Act, the agency also administers the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90–602) which authorizes FDA to establish and carry out an electronic product radiation control program, including development of performance standards for electronic products and related accessories. Under this program, radiation emission performance standards have been, and will continue to be, set and enforced for certain medical devices that emit electronic product radiation. Performance standards have been promulgated for diagnostic X-ray systems and their major components (21 CFR 1020.30); radiographic equipment (21 CFR 1020.31); fluoroscopic equipment (21 CFR 1020.32); laser products, whether or not used medically (21 CFR 1040.10 and 1040.11); and ultrasonic therapy products (21 CFR 1050.10). The agency will use its authority over radiation-emitting electronic medical products under the Medical Device Amendments of 1976 or the Radiation Control for Health and Safety Act of 1968, as appropriate. In the **Federal Register** of April 24, 1979 (44 FR 24236), FDA published a notice of the availability of a document determining the division of responsibility between FDA's Bureau of Medical Devices and its Bureau of Radiological Health with respect to products regulated under both statutes.

Devices Considered by Two or More Panels

Many devices were reviewed by two or more device classification panels. For these devices, FDA will publish each panel's recommendations and a single proposed classification regulation.

The Ophthalmic Device Section of the Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel and the other panels listed below made classification recommendations concerning the following devices:

Device	Other panel(s)
Radiofrequency diathermy	Physical Medicine Device Section of the Surgical and Rehabilitation Devices Panel.
Surgical marking pen	General and Plastic Surgery Device Section of the Surgical and Rehabilitation Devices Panel.
Trephine engine	Do.
Ophthalmic operating microscope and accessories.	Do.
Microscope drape	Do.
Patient drape	Do.
AC-powered flucrescein lamp	Do.
Absorbable suture	Do.
Nonabsorbable suture	Do.
Analog and digital recorder	Circulatory Systems Devices Panel.
Needle electrode	Neurological Device Section of the Respiratory and Nervous Systems Devices Panel.
Skin surface electrode	Do.
Ophthalmodynamometer	Do.
Ophthalmodynamograph	Do.
Syringe	General Hospital and Personal Use Device Section of the General Medical Devices Panel.
Ophthalmic ultrasonic imaging systems.	Radiology Device Section of the Obstetrics-Gynecology and Radiologic Devices Panel.

FDA is not at this time publishing the Panels' recommendations to classify the devices listed above. FDA will publish these recommendations, and proposed classification regulations, when the agency publishes the recommendations of the other panels that reviewed the devices.

Classification Regulations Published to Date

The following table shows the current structure of the advisory committees involved with the classification of medical devices and a list of all proposed and final classification regulations published to date:

Panel/Section Name	Publication date in FEDERAL REGISTER
Circulatory Systems Devices Panel	March 9, 1979, 44 FR 13284–13434 (propsals); February 5, 1980, 45 FR 7904–7971 (final regulations).
Clinical Chemistry and Hematology Devices Panel:	
Clinical Chemistry Device Section.	
Clinical Toxicology Device Section.	
Hematology and Pathology Device Section.	September 11, 1979, 44 FR 52950–53063 (proposals); September 12, 1980, 45 FR 60576–60651 (final regulations).
General Medical Devices Panel:	
General Hospital and Personal Use Device Section	August 24, 1979, 44 FR 49844–49954 (proposals); October 21, 1980, 45 FR 69678–69737 (final regulations).
Gastroenterology-Urology Device Section.	January 23, 1981, 46 FR 7562–7641 (proposals).
Immunology and Microbiology Devices Panel:	
Immunology Device Section.	April 22, 1980, 45 FR 27204–27359 (proposals).
Microbiology Device Section.	April 22, 1980, 45 FR 27204–27359 (proposals).
Obstetrics-Gynecology and Radiologic Devices Panel:	
Obstetrics-Gynecology Device Section.	April 3, 1979, 44 FR 19894–19971 (proposals); February 26, 1980, 45 FR 12682–12720 (final regulations).
Radiology Device Section	
Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel:	
Ophthalmic Device Section	January 26, 1982 (proposals).
Ear, Nose, and Throat Device Section.	
Dental Device Section	December 30, 1980, 45 FR 85962–86168 (proposals).
Respiratory and Nervous System Devices Panel:	
Anesthesiology Device Section.	November 2, 1979, 44 FR 63292–63426 (proposals).
Neurological Device Section.	November 28, 1978, 43 FR 54640–55732 (proposals); September 4, 1979, 44 FR 51726–51778 (final regulations).
Surgical and Rehabilitation Devices Panel:	
Physical Medicine Device Section:.	August 28, 1979, 44 FR 50458–50537 (proposals).
Orthopedic Device Section	
General and Plastic Surgery Device Section.	

Panel Recommendations and FDA's Proposed Classifications

Section 886.1040; Docket No. 78N–3129; Ocular esthesiometer.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ocular esthesiometers:

1. Identification: An ocular esthesiometer is a device such as a single-hair brush used to touch the cornea to assess corneal sensitivity.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that ocular esthesiometers be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that the materials used in the device and the recommended method of sterilization should be specified in the labeling of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that ocular esthesiometers be classified into class I (general controls) with no exemptions. The agency believes that general controls alone are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 886.1050; Docket No. 78N–3130; Adaptometer (biophotometer).

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of adaptometers (biophotometers):

1. Identification: An adaptometer (biophotometer) is an AC-powered device that provides a stimulating light source which has various controlled intensities used to measure the time required for retinal adaptation (regeneration of the visual purple) and the minimum light threshold.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that adaptometers (biophotometers) be classified into class II because the electrical properties of the device should be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel believes that this device requires special labeling to indicate to the user the accuracy, reproducibility, or limitations in its measurements.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of this device may cause electrical shock to the patient or user.

FDA agrees with the Panel recommendation and is proposing that adaptometers (biophotometers) be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1070; Docket No. 78N-3132; Anomaloscope.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of anomaloscopes:

1. Identification: An anomaloscope is an AC-powered device used to test for anomalies of color vision by displaying mixed spectral lines to be matched by the patient.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that anomaloscopes be classified into class II because the Panel believes that the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel believes that this device requires special labeling to indicate to the user the accuracy, reproductibility, or limitations in its measurements.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or malfunction of this device may cause electrical shock to the patient or user.

FDA agrees with the Panel recommendation and is proposing that anomaloscopes be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1090; Docket No. 78N-3133; Haidinger brush.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of Haidinger brushes:

1. Identification: A Haidinger brush is an AC-powered device that provides two conical brushlike images with apexes touching which are viewed by the patient through a Nicol prism and used to evaluate visual function. It may include a component for measuring macular integrity.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that Haidinger brushes be classified into class II because the Panel believes that the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or malfunction of this device may cause electrical shock to the patient or user.

FDA agrees with the Panel recommendation and is proposing that Haidinger brushes be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1120; Docket No. 78N-3135; AC-powered ophthalmic camera.

The Ophthalmic Device classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of AC-powered ophthalmic cameras;

1. Identification: An AC-powered ophthalmic camera is a device used to take photographs of the eye and the surrounding area.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that AC-powered ophthalmic cameras be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of this device may cause electrical shock to the patient or user.

FDA agrees with the Panel recommendation and is proposing that AC-powered ophthalmic cameras be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency

also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1140; Docket No. 78N-3137; Ophthalmic chair.

The Ophthalmic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of ophthalmic chairs:

1. Identification: An ophthalmic chair is an AC-powered or manual device with adjustable positioning in which a patient sits or reclines during ophthalmological examination or treatment.

2. Recommended classification: Class II (performance standards). The Panel recommends that AC-powered ophthalmic chairs be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority. The Panel recommends that manual ophthalmic chairs be classified into class I (general controls) and that there be no exemptions.

3. Summary of reasons for recommndation: The Panel recommends that AC-powered ophthalmic chairs be classified into class II because the design of the device must be controlled to prevent patient injury due to mechanical failure and to prevent electrical shock to the patient or user. The Panel believes that general controls alone would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the AC-powered device and that there is sufficient information to establish a performance standard. The Panel recommends that manual ophthalmic chairs be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Traumatic injury: Failure of mechancial features of the device could result in unjury to the patient. (b) Electrical shock: Improper design or a malfunction of AC-powered ophthalmic chairs may cause electrical shock to the patient or user.

FDA agrees with the Panel recommendation and is proposing that AC-powered ophthalmic chairs be classified into class II (performance standards) and that manual ophthalmic chairs be classified into class I (general controls) with no exemptions. The agency believes that a performance standard is necessary for the AC-powered device because general controls alone are insufficient to control the risks to health presented by the AC-powered device. A performance standard will provide reasonable assurance of the safety and effectiveness of the AC-powered device. The agency also believes that there is sufficient information to establish a performance standard for this device. The agency is proposing that manual ophthalmic chairs be classified into class I (general controls) with no exemptions because the agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the manual device. The agency believes that the mechanical features of the device can be sufficiently controlled by general controls to ensure the safety of the manual device.

Section 886.1150; Docket No. 78N-3139; Visual acuity chart.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of visual acuity charts:

1. Identification: A visual acuity chart is a device that is a chart such as a Snellen chart with block letters or other symbols in graduated sizes used to test visual acuity.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that visual acuity charts be classified into class II because the contrast of colors and the separation of letters or symbols on the chart must be standardized to prevent misdiagnosis. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel recognizes the existence of current work being done in the area of visual acuity chart standardization by the Committee on Optics and Visual Physiology of the American Academy of Ophthalmology. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Misdiagnois and inappropriate therapy: Improper design of the device could result in an incorrect measurement of the patient's visual acuity resulting in inappropriate therapy.

FDA agrees with the Panel recommendation and is proposing that visual acuity charts be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1160; Docket No. 78N-3140; Color vision plate illuminator.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of color vision plate illuminators:

1. Identification: A color vision plate illuminator is an AC-powered device that is a lamp used to properly illuminate color vision testing plates. It may include a filter.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that color vision plate illuminators be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling of the device include a statement of the illumination characteristics of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's knowledge of, and clinical experience with, this device.

5. Risk to health: None identified.

FDA disagrees with the Panel recommendation and is proposing that color vision plate illuminators be classified into class II (preformance standards). The agency believes that a performance standard is necessary for this device because the electrical properties of the device must be controlled to prevent electrical shock ot the patient or user. The agency believes that general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1170; Docket No. 78N-3141; Color vision tester.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of color vision testers:

1. Identification: A color vision tester is a device that consists of various colored materials such as colored yarns or color vision plates (multicolored plates which patients with color vision deficiency would perceive as being of one color) used to evaluate color vision.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that

color vision testers be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that this device requires special labeling to indicate to the user the accuracy, reproducibility, or limitations in their measurements.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that color vision testers be classified into class I (general control) with no exemptions. The agency believe that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 886.1190; Docket No. 78N–3142; Distometer.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of distometers:

1. Identification: A distometer is a device used to measure the distance between the cornea and a corrective lens during refraction (measuring the change of the visual image when a lens is in place).

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that distometers be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that this device be exempt from the good manufacturing practice regulation because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements because the Panel believes that these requirements are not necessary to assure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that distometers be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulations. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of distometers be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of distometers be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.1200; Docket No. 78N–3143; Optokinetic drum.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of optokinetic drums:

1. Identification: An optokinetic drum is a drumlike device that is covered with alternating white and dark stripes or pictures that can be rotated on its handle. The device is used to elicit and evaluate nystagmus (involuntary rapid movement of the eyeball) in patients.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that optokinetic drums be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that this device be exempt from the good manufacturing practice regulation because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements because the Panel believes that these requirements are not necessary to assure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that optokinetic drums be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagress with the Panel's recommendation that manufacturers of optokinetic drums be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

FDA disagrees with the Panel's recommendation that manufacturers of optokinetic drums be exempt from the GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)). The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent production of optokinetic drums having defects that could harm users. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.1220; Docket No. 78N–3144; Corneal electrode.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of corneal electrodes:

1. Identification: An corneal electrode is an AC-powered device usually part of a special contact lens, that is applied directly to the cornea and used to provide data showing the changes in electrical potential in the retina after electroretinography (stimulation by light).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that corneal electrodes be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock or burns to the patient or user, and the materials used in the construction of the device must be controlled to ensure biocompatibility. The Panel believes that general controls alone would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Electrical shock: Inadequate design or a malfunction of the device may cause electrical shock. (b) Corneal abrasion: If improper construction

procedures are used, corneal abrasion may result.

FDA agrees with the Panel recommendation and is proposing that corneal electrodes be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1250; Docket No. 78N-3145; Euthyscope.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of euthyscopes:

1. Identification: A euthyscope is a device that is a modified AC/powered or battery-powered ophthalmoscope (a perforated mirror device used in inspecting the interior of the eye) that projects a bright light encompassing an arc of about thirty degrees onto the fundus of the eye. The center of the light bundle is blocked by a black disk covering the fovea (the central depression of the macular retinae where only cones are present and blood vessels are lacking). The device is used in the treatment of amblyopia (dimness of vision without apparent disease of the eye).

2. Recommended classification: The Panel recommends that AC-powered euthyscopes be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority. The Panel recommends that battery-powered euthyscopes be classified into class I (general controls) and that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that AC-powered euthyscopes be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel recommends that battery-powered euthyscopes be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that the risk of electrical shock is minimal with battery-powered euthyscopes.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of AC-powered euthyscopes may cause electrical shock to the patient or user. The Panel identified no risks to health associated with the use of battery-powered euthyscopes.

FDA agrees with the Panel recommendation and is proposing that AC-powered euthyscopes be classified into class II (performance standards) and that battery-powered euthyscopes be classified into class I (general controls) with no exemptions. The agency believes that a performance standard is necessary for AC-powered euthyscopes because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the AC-powered device. The agency also believes that there is sufficient information to establish a performance standard for the AC-powered device. The agency is proposing that battery-powered euthyscopes be classified into class I with no exemptions because the agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the battery-powered device.

Section 886.1270; Docket No. 78N-3147; Exophthalmometer.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of exophthalmometers:

1. Identification: An exophthalmometer is a device, such as a ruler, gauge, or caliper, used to measure the degree of exophthalmos (abnormal protrusion of the eyeball).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

Summary of reasons for recommendation: The Panel recommends that exophthalmometers be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that instructions for calibration be included in the labeling of the device and that the device be capable of recalibration.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that exophthalmometers be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 886.1290; Docket No. 78N-3148; AC-powered fixation device.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of AC-powered fixation devices:

1. Identification: An AC-powered fixation device is an AC-powered device used as a fixation target for the patient during ophthalmological examination. The patient directs his or her gaze so that the visual image of the object falls on the fovea centralis (the center of the macula retina of the eye).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that AC-powered fixation devices be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of this device may cause electrical shock to the patient or user.

FDA agrees with the Panel recommendation and is proposing that AC-powered fixation devices be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1300; Docket No. 78N-3149; Afterimage flasher.

The ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of afterimage flashers:

1. Identification: An afterimage flasher is an AC-powered light that automatically switches on and off to allow performance of an afterimage test in which the patient indicates the positions of afterimages after

the light is off. The device is used to determine harmonious/anomalous retinal correspondence (the condition in which corresponding points on the retina have the same directional value).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that afterimage flashers be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of this device may cause electrical shock to the patient or user.

FDA agrees with the Panel recommendation and is proposing that afterimage flashers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1310; Docket No. 78N–3150; Fluorescein strip.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of fluorescein strips:

1. Identification: A fluorescein strip is a device that is a small strip of filter paper impregnated with fluorescein (a dye used for the diagnosis of certain ocular diseases) used to apply the fluorescein to the surface of the eye.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that fluorescein strips be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that this device be packaged sterile.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that fluorescein strips be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 886.1320; Docket No. 78N–3151; Fornixscope.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of fornixscopes:

1. Identification: An fornixscope is a device used to pull back and hold open the eyelid to aid examination of the conjunctiva.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that fornixscopes be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that fornixscopes be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 886.1330; Docket No. 78N–3152; Amsler grid.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of Amsler grid:

1. Identification: An Amsler grid is a device that is a series of charts with grids of different sizes that are held at 30 centimeters distance from the patient and used for the rapid detection of central and paracentral irregularities in the visual field.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that Amsler grids be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)) because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act (21 U.S.C. 360i) because the Panel believes that these requirements are not necessary to assure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's knowledge of, and clinical experience with, this device.

5. Risk to health: None identified.

FDA agrees with the Panel recommendation and is proposing that Amsler grids be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulation. The agency believes that general controls alone are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of Amsler grids be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of Amsler grids be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacturer of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to comlaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.1340; Docket No. 78N–3295; Haploscope.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of haploscopes:

1. Identification: A haploscopes is an AC-powered device that consists of two movable viewing tubes, each contained a slide carrier, a low-intensity light source for the illuminiation of the slides, and a high-intensity light source for creating after-images. The device is used to measure strabismus (eye muscle imbalance), to assess binocular vision (use of both eyes to see), and to treat suppression and amblyopia (dimness of vision without any apparent disease of the eye).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that haploscopes be classified into class II because the electrical properties of the device must be contolled to prevent electrical shock to the patient or user. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel beleives that this device requires special labeling to indicate to the user the accuracy, reproducibility, or limitations in its measurements.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of this device may cause electrical shock to the patient or user.

FDA agrees with the Panel recommendation and is proposing that haploscopes be classified into class II (performance standards). The agency believe that a performance standard is necessary for this device because general controls alone are insufficient to control the risk to health presented by the device. A preformance standard will provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1350; Docket No. 78N–3153; Keratoscope.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of keratoscopes:

1. Identification: A keratoscope is an AC-powered or battery-powered device used to measure and evaluate the corneal curvature of the eye. Lines and circles within the Keratoscope are used to observe the corneal reflex. This generic type of device includes the photokeratoscope which records corneal curvature by taking photographs of the cornea.

2. Recommended classification: The Panel recommends that AC-powered keratoscopes be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority. The Panel recommends that battery-powered keratoscopes be classified into class I (general controls) and that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that AC-powered keratoscopes be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the AC-powered device and that there is sufficient information to establish a performance standard. The Panel also recommends that photokeratoscopes be calibrated to provide data in millimeters and diopters and that calibration instructions should be included in the labeling of the device. The Panel recommends that battery-powered keratoscopes be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that the risk of electrical shock is minimal with battery-powered keratoscopes. The Panel recommends that battery-powered keratoscopes be exempt from the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)) because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act (21 U.S.C. 360i) because the Panel believes that these requirements are not necessary to ensure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of AC-powered keratoscopes may cause electrical shock to the patient or user. The Panel identified no risks to health associated with battery-powered keratoscopes.

FDA agrees with the Panel recommendation and is proposing that AC-powered keratoscopes be classified into class II (performance standards) and that battery-powered keratoscopes be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulation. FDA believes that a performance standard is necessary for AC-powered keratoscopes because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the AC-powered device. FDA also believes that there is sufficient information to establish a performance standard for the AC-powered device. FDA is proposing that battery-powered keratoscopes be classified into class I (general controls) because the agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the battery-powered device.

FDA disagrees with the Panel's recommendation that manufacturers of keratoscopes be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of keratoscopes be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.1360; Docket No. 78N–3155; Visual field laser instrument.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of visual field laser instruments:

1. Identification: A visual field laser instrument is an AC-powered device that provides visible laser radiation that produces an interference pattern on the retina used to evaluate retinal function.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that visual field laser instruments be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user; the accuracy of the device must be controlled to ensure detection of visual field defects; and the design and performance of the device must be controlled to prevent unnecessary exposure of the patient or operator to laser radiation. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel believes that this device requires special labeling to indicate to the user the accuracy, reproducibility, or limitations in its measurements.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Electrical shock: Improper design or a malfunction of this device may cause electrical shock to the patient or user. (b) Tissue damage: Exposure of the patient or operator to laser light radiation not appropriate for the device's function could cause tissue damage. (c) Misdiagnosis and inappropriate therapy: The failure of the device to properly detect visual field defects could result in misdiagnosis and inappropriate therapy.

FDA agrees with the Panel recommendation and is proposing that visual field laser instruments be classified into class II (performance standards). The agency believes that an additional performance standard is necessary for this device because general controls and the present performance standard for laser products (21 CFR 1040.10 and 1040.11, issued under the Radiation Control for Health and Safety Act of 1968) alone are insufficient to control the risks to health that are characteristic of medical laser devices. Exposure to laser radiation must be limited to that necessary to conduct effective examination and testing procedures. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1375; Docket No. 78N–3156; Bagolini lens.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of Bagolini lenses:

1. Identification: A Bagolini lens is a device consisting of a plane lens containing almost imperceptible striations that do not obscure visualization of objects. The device is placed in a trial frame and used to determine harmonious/anomalous retinal correspondence (the condition in which corresponding points on the retina have the same directional value).

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that Bagolini lenses be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to assure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that Bagolini lenses be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulation. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of Bagolini lenses be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of Bagolini lenses be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.1380; Docket No. 78N–3157; Diagnostic condensing lens.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of diagnostic condensing lenses:

1. Identification: A diagnostic condensing lens is a device that is a lens used to focus reflected light from the fundus of the eye in binocular indirect ophthalmoscopy (a procedure that produces an inverted or reversed direct magnified image of the eye).

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that diagnostic condensing lenses be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to assure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that diagnostic condensing lenses be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulations. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of diagnostic condensing lenses be exempt from records and reports regulations under secton 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of diagnostic condensing lenses be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.1385; Docket No. 78N–3158; Polymethylmethacrylate diagnostic contact lens.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of polymethylmethacrylate diagnostic contact lenses:

1. Identification: A polymethylmethacrylate diagnostic contact lens is a device that is a curved shell of polymethylmethacrylate applied for a short period of time directly onto the globe or cornea of the eye for diagnosis or therapy of intraocular abnormalities.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that polymethylmethacrylate diagnostic contact lenses be classified into class II because the Panel believes that a contaminated lens could result in eye infection and that vacuum contact lenses must be controlled to prevent suction of the aqueous which could result in angle closure glaucoma. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that materials used in this device in contact with the eye are generally acceptable or have known and acceptable properties. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device. The Panel also recognizes the existence of the American National Standards Institute Z–80 Committee Standards for contact lenses.

5. Risks to health: (a) Infection: If the device cannot be sterilized properly, an infection in the patient may result. (b) Glaucoma: Suction of the aqueous by vacuum contact lenses could enhance angle closure resulting in glaucoma.

FDA agrees with the Panel recommendation and is proposing that polymethylmethacrylate diagnostic contact lenses be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1390; Docket No. 78N–3159; Flexible diagnostic Fresnel lens.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of flexible diagnostic Fresnel lenses.

1. Identification: A flexible diagnostic Fresnel lens is a device that is a very thin lens which has on its surface a concentric series of increasingly refractive zones. The device may be applied to the back of the spectable lenses of patients with aphakia (absence of the lens of the eye).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that flexible diagnostic Fresnel lenses be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based it recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that flexible diagnostic Fresnel lenses be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 886.1395; Docket No. 78N–3160; Diagnostic Hruby fundus lens.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of diagnostic Hruby fundus lenses:

1. Identification: A diagnostic Hruby fundus lens is a device that is a 55 diopter lens used in examination of the vitreous body and the fundus of the eye under slit-lamp illumination and magnification.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that diagnostic Hruby fundus lenses be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to assure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that diagnostic Hruby fundus lenses be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulation. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of diagnostic Hruby fundus lenses be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of diagnostic Hruby fundus lenses be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.1400; Docket No. 78N–3161; Maddox lens.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of Maddox lenses:

1. Identification: A Maddox lense is a device with that is a series of red cylinders that change the size, shape, and color of an image. The device is handheld or placed in a trial frame and used to evaluate eye muscle dysfunction.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that Maddox lenses be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to assure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that Maddox lenses be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulation. The agency believes that

general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of Maddox lenses be exempt from records and reports regulations under setion 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of Maddox lenses be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.1405; Docket No. 78N-3162; Ophthalmic trial lens set.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ophthalmic trial lens sets:

1. Identification: An ophthalmic trial lens set is a device that is a set of lenses of various dioptric powers that are handheld or inserted in a trail frame and used in vision testing to determine refraction.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that ophthalmic trial lens sets be classified into class II because the performance characteristics of the device, including lens power, centration, front curve, thickness, additive sphee, and cylindrical powers at a constant vertex distance, and axis alignment for cylindrical lenses, must be controlled to prevent misdetermination of refraction. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Misdiagnosis and inadequate therapy: Improper design of the device could result in misdetermination of refraction, resulting in misdiagnosis and inadequate therapy.

FDA agrees with the Panel recommendation and is proposing that ophthalmic trial lens sets be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1410; Docket No. 78N-3163; Ophthalmic trial lens clip.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ophthalmic trial lens clips:

1. Identification: An ophthalmic trial lens clip is a device used to place prisms, spheres, cylinders, or occluders on a trial frame or spectacles for vision testing.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that ophthalmic trial lens clips be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to ensure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that ophthalmic trial lens clips be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulation. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of ophthalmic trial lens clips be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of ophthalmic trial lens clips be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198 with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.1415; Docket No. 78N-3164; Ophthalmic trial lens frame.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ophthalmic trial lens frames:

1. Identification: An ophthalmic trial lens frame is a mechanical device used to hold trial lenses during vision testing.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that ophthalmic trial lens frames be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that ophthalmic trial lens frames be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 886.1420; Docket No. 78N-3165; Ophthalmic lens gauge.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ophthalmic lens gauges:

1. Identification: An ophthalmic lens gauge is a calibrated device used manually to measure the curvature of a spectacle lens.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that ophthalmic lens gauges be classified into class I because the Panel believes general controls are sufficient to provide reasonable

assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that ophthalmic lens gauges be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 886.1425; Docket No. 78N-3166; AC-powered lens measuring instrument.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of AC-powered lens measuring instruments:

1. Identification: An AC-powered lens measuring instrument is an AC-powered device used to measuer the power of lenses, prisms, and their centers (e.g., lensometer).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for these devices be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that AC-powered lens measuring instruments be classified into class II because the electrical properties of the devices must be controlled to prevent electrical shock to the user. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that these devices require special labeling to indicate to the user the accuracy, reproducibility, or limitations in their measurements. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, these devices.

5. Risks to health: Electrical shock: Improper design or malfunction of these devices may cause electrical shock to the user.

FDA agrees with the Panel recommendation and is proposing that AC-powered lens measuring instruments be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1430; Docket No. 78N-3167; Ophthalmic contact lens radius measuring device.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ophthalmic contact lens radius measuring devices:

1. Identification: An ophthalmic contact lens radius measuring device is an AC-powered device that is a microscope and dial gauge used to measure the radius of a contact lens.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that ophthalmic contact lens radius measuring devices be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the user. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel believes that this device requires special labeling to indicate to the user the accuracy, reproducibility, or limitations in its measurements.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of this device may cause electrical shock to the patient or user.

FDA agrees with the Panel recommendation and is proposing that ophthalmic contact lens radius measuring devices be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1435; Docket No. 78N-3168; AC-powered Maxwell spot.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of AC-powered Maxwell spots:

1. Identification: An AC-powered Maxwell spot is an AC-powered device that is a light source with a red and blue filter used to test macular function.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that AC-powered Maxwell spots be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of this device may cause electrical shock to the patient or user.

FDA agrees with the Panel recommendation and is proposing that AC-powered Maxwell spots be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard alone will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1450; Docket No. 78N-3169; Corneal radius measuring device.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of corneal radius measuring devices:

1. Identification: A corneal radius measuring device is an AC-powered device used to measure corneal size by superimposing the image of the cornea on a scale at the focal length of the lens of a small handheld single tube penscope or eye gauge magnifier.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that corneal radius measuring devices be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel recommends that calibration instructions be included in the

labeling of the device and that the device should enable measurement in millimeters and diopters. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of this device may cause electrical shock to the patient or user.

FDA agrees with the Panel recommendation and is proposing that corneal radius measuring devices be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1460; Docket No. 78N-3170; Stereopsis measuring instrument.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of Stereopsis measuring instruments:

1. Identification: A stereopsis measuring instrument is a device used to measure depth perception by battery-powered illumination or natural daylight illumination of objects placed on different planes.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that stereopsis measuring instruments be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that stereopsis measuring instruments be classified into class I (general controls) with no exemptions. The agency believes that general controls alone are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 886.1500; Docket No. 78N-3171; Headband mirror.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of headband mirrors:

1. Identification: A headband mirror is a device that is strapped to the head of the user to reflect light for examination of the eye.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that headband mirrors be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to assure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that headband mirrors be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulation. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of headband mirrors be exempt from records and reports regulations under setion 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of headband mirrors be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.1510; Docket No. 78N-3172; Eye movement monitor.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of eye movement monitors:

1. Identification: An eye movement monitor is an AC-powered device with an electrode used to measure and record ocular movements.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that eye movement monitors be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of this device may cause electrical shock to the patient or user.

FDA agrees with the Panel recommendation and is proposing that eye movement monitors be classified into class II (performance standards). The agency believes that general controls alone are sufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1570; Docket No. 78N-3175; Ophthalmoscope.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ophthalmoscopes:

1. Identification: An ophthalmoscope is an AC-powered or battery-powered device containing illumination and viewing optics used to examine the media (cornea, aqueous, lens, and vitreous) and the retina of the eye.

2. Recommended classification: The Panel recommends that AC-powered ophthalmoscopes be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority. The Panel recommends that battery-powered ophthalmoscopes be classified into class I

(general controls) and that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360j).

3. Summary of reasons for recommendation: The Panel recommends that AC-powered ophthalmoscopes be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel recommends that battery-powered ophthalmoscopes be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that the risk of electrical shock is minimal with battery-powered ophthalmoscopes. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to assure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of AC-powered ophthalmoscopes may cause electrical shock to the patient or user.

FDA agrees with the Panel recommendation and is proposing that AC-powered ophthalmoscopes be classified into class II (performance standards) and that battery powered ophthalmoscopes be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulation. The agency believes that a performance standard is necessary for AC-powered ophthalmoscopes because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the AC-powered device. FDA also believes that there is sufficient information to establish a performance standard for the AC-powered device. FDA is proposing that battery-powered ophthalmoscopes be classified into class I (general controls) because the agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of ophthalmoscopes be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of ophthalmoscopes be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.1605; Docket No. 78N-3178; Perimeter.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of perimeters.

1. Identification: A perimeter is an AC-powered or manual device used to determine the extent of the peripheral visual field of a patient. The device project's light on various points of a curved surface, and the patient indicates whether he or she sees the light.

2. Recommended classification: The Panel recommends that AC-powered perimeters be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority. The Panel recommends that manual perimeters be classified into class I (general controls) and that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that AC-powered perimeters be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that any automatic features of the device must be controlled to prevent inaccuracy of measurements. The Panel believes that general controls alone would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel recommends that manual perimeters be classifed into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to ensure the safety or effectiveness of the device. The Panel recommends that the labeling of all perimeters include instructions for calibration.

4. Summary of data on which the recommendation is based: The Panel basic its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Electrical shock: Improper design or a malfunction of AC-powered perimeters may cause electrical shock to the patient or user. (b) Misdiagnosis and inappropriate therapy: Improper design or a malfunction of automatic features of AC-powered perimeters may result in misdiagnosis and subsequent inappropriate therapy. The Panel identified no risks to health associated with manual perimeters.

FDA agrees with the Panel recommendation and is proposing that AC-powered perimeters be classified into class II (performance standards) and that manual perimeters be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulation. The agency believes that a performance standard is necessary for AC-powered perimeters because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the AC-powered device. FDA also believes that there is sufficient information to establish a performance standard for the AC-powered device. FDA is proposing that manual perimeters be classified into class I because FDA believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of manual perimeters be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of manual perimeters be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements

concerning records, and § 820.198, with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.1630; Docket No. 78N-3181; AC-powered photostimulator.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of AC-powered photostimulators:

1. Identification: An AC-powered photostimulator is an AC-powered device that provides light stimulus which allows measurement of retinal or visual function by perceptual or electrical methods (e.g., stroboscope).

2. Recommended classification: Class II (performance standards). The panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that AC-powered photostimulators be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user and the intensity of the light produced by the device must be controlled to prevent damage to the retina. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Electrical shock: Improper design or a malfunction of this device may cause electrical shock to the patient or user. (b) Retinal damage: If the light produced by the device is too intense, it could cause damage to the retina.

FDA agrees with the Panel recommendation and is proposing that AC-powered photostimulators be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1640; Docket No. 78N-3182; Ophthalmic preamplifier.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ophthalmic preamplifiers:

1. Identification: An ophthalmic preamplifier is an AC-powered or battery-powered device used to amplify electrical signals from the eye in electroretinography (recording retinal action currents from the surface of the eyeball after stimulation by light), electro-oculography (testing for retinal dysfunction by comparing the standing potential in the front and the back of the eyeball), and electromyography (recording electrical currents generated in active muscle).

2. Recommended classification: Class II (performance standards). The Panel recommends that AC-powered ophthalmic preamplifiers be classified into class II (performance standards) and that establishing a performance standard for this device be a high priority. The Panel recommends that battery-powered ophthalmic preamplifiers be classified into class I (general controls) and that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that AC-powered ophthalmic preamplifiers be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel also believes that the design and measurement function of the device must be controlled to prevent misdiagnosis and subsequent inappropriate therapy. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel recommends that battery-powered ophthalmic preamplifiers be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that the risk of electrical shock is minimal with battery-powered ophthalmic preamplifiers. The Panel believes that this device requires special labeling to indicate to the user the accuracy, reproducibility, or limitations in its measurements.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Electrical shock: Improper design or a malfunction of AC-powered ophthalmic preamplifiers may cause electrical shock to the patient or user. (b) Misdiagnosis and inappropriate therapy: Improper design or a malfunction of ophthalmic preamplifiers may result in misdiagnosis and subsequent inappropriate therapy.

FDA agrees in part with the Panel recommendation and is proposing that AC-powered ophthalmic preamplifiers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the AC-powered device. A performance standard will provide reasonable assurance of the safety and effectiveness of the AC-powered device. The agency believes that there is sufficient information to establish a performance standard for this device. However, FDA disagrees with the Panel recommendation that battery-powered ophthalmic preamplifiers be classified into class I (general controls) and is proposing that this device be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because the design and measurement function of all ophthalmic preamplifiers must be controlled to prevent misdiagnosis and inappropriate therapy. FDA believes that although the risk of electrical shock is minimal with battery-powered ophthalmic preamplifiers, general controls alone are insufficient to control the risk of misdiagnosis and inappropriate therapy presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the battery-powered device. FDA also believes that there is sufficient information to establish a performance standard for the battery-powered device.

Section 886.1650; Docket No. 78N-3184; Ophthalmic bar prism.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ophthalmic bar prisms:

1. Identification: An ophthalmic bar prism is a device that is a bar composed of fused prisms of gradually increasing strengths used to measure latent and manifest strabismus (eye muscle deviation) or the power of fusion of the patients' eyes.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that ophthalmic bar prisms be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and

reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to assure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that ophthalmic bar prisms be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulation. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of ophthalmic bar prisms be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of ophthalmic bar prisms be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.1655; Docket No. 78N–3185; Ophthalmic Fresnel prism.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ophthalmic Fresnel prisms:

1. Identification: An ophthalmic Fresnel prism is a device that is a thin plastic sheet with embossed rulings which provides the optical effect of a prism. The device is applied to spectacle lenses to give a prismatic effect.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that ophthalmic Fresnel prisms be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that ophthalmic Fresnel prisms be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 886.1660; Docket No. 78N–3186; Gonioscopic prisms.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gonioscopic prisms:

1. Identification: A gonioscopic prisms is a device that is a prism which may be placed on the eye for the study of anterior chamber angles. The device may have angled mirrors to facilitate visualization of antomical features.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that gonioscopic prisms be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel noted that corneal abrasion could result if the surface of the device is rough, and that the device should be capable of being sterilized.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Infection: (a) If the device cannot be sterilized properly, an infection in the patient may result. (b) Corneal abrasion: If the device has a rough surface, placing the device on the eye could cause a corneal abrasion.

FDA agrees with the Panel recommendation and is proposing that gonioscopic prisms be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The agency believes that infection and corneal abrasion would only result from improper use of the device and that general controls would be sufficient to control any risks to health presented by the device.

Section 886.1665; Docket No. 78N–3187; Ophthalmic rotory prism.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ophthalmic rotory prisms:

1. Identification: An ophthalmic rotory prism is a handheld device with various prismatic powers used to measure ocular deviation in latent and manifest strabismus (eye muscle deviation).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that ophthalmic rotory prisms be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that ophthalmic rotory prisms be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 886.1670; Docket No. 78N–3188; Ophthalmic isotope uptake probe.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ophthalmic isotope uptake probes:

1. Identification: An ophthalmic isotope uptake probe is an AC-powered device used to measure, by a probe which is placed in close proximity to the eye, the uptake of a radioisotope (phosphorus 32) by tumors to detect tumor masses on, around, or within the eye.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that ophthalmic isotope uptake probes be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. In addition, the design and performance characteristics of the device must be controlled to prevent: misdiagnosis or to prevent the need for a repeat examination which may result in higher than normal amounts of phosphorus 32 being delivered to the patient. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel also recommends that the device be capable of being sterilized and that its use be restricted to qualified personnel.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Electrical shock: Improper design or a malfunction of the device may cause electrical shock to the

patient or user. (b) Infection: If the device cannot be properly sterilized, an infection in the patient may result. (c) Misdiagnosis and inappropriate therapy: Improper design or a malfunction of this device may result in misdiagnosis and subsequent inappropriate therapy.

FDA agrees with the Panel recommendation and is proposing that ophthalmic isotope uptake probes be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1680; Docket No. 78N-3189; Ophthalmic projector.

The Opthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ophthalmic projectors:

1. Identification: An ophthalmic projector is an AC-powered device used to project an image on a screen for vision testing.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that ophthalmic projectors be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the user. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of this device may cause electrical shock to the user.

FDA agrees with the Panel recommendation and is proposing that ophthalmic projectors be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1690; Docket No. 78N-3190; Pupillograph.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarging the classification of pupillographs:

1. Identification: A pupillographs is an AC-powered device that measures the pupil of the eye by reflected light and records the responses of the pupil.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that pupillographs be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel believes that this device requires special labeling to indicate to the user the accuracy, reproducibility, or limitations in its measurements.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of this device may cause electrical shock to the patient or user.

FDA agrees with the Panel recommendation and is proposing that pupillographs be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1700; Docket No. 78N-3191; Pupillometer.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of pupillometers:

1. Identification: A pupillometer is an AC-powered or manual device used to measure by reflected light the width or diameter of the pupil of the eye.

2. Recommended classification: Class II (performance standards). The Panel recommends that AC-powered pupillometers be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority. The Panel recommends that manual pupillometers be classified into class I (general controls) and that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that AC-powered pupillometers be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel recommends that manual pupillometers be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that manual pupillometers be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to ensure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of AC-powered pupillometers may cause electrical shock to the patient or user. The Panel identified no risks to health associated with the use of manual pupillometers.

FDA agrees with the Panel recommendation and is proposing that AC-powered pupillometers be classified into class II (performance standards) and that manual pupillometers be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulation. FDA believes that a performance standard is necessary for AC-powered pupillometers because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the AC-powered device. FDA also believes that there is sufficient information to establish a performance standard for the AC-powered device. FDA is proposing that manual

pupillometers be classified into class I (general controls) because it believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the manual device.

FDA disagrees with the Panel's recommendation that manufacturers of pupillometers be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of pupillometers be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.1750; Docket No. 78N-3193; Skiascopic rack.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of skiascopic racks:

1. Identification: An skiascopic rack is a device that is a rack and a set of attached ophthalmic lenses of various dioptric strengths used as an aid in refraction.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that skiascopic racks be classified into class II because the performance characteristics of the device including lens power, centration, front curves, thickness, additive sphere, cylindrical powers at a constant vertex distance, and the axis alignment for cylindrical lenses must be controlled to prevent misdetermination of refraction. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Misdiagnosis and inappropriate therapy: Improper design of this device may result in misdetermination of refraction, resulting in misdiagnosis and inappropriate therapy.

FDA agrees with the Panel recommendation and is proposing that skiascopic racks be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1760; Docket No. 78N-3194; Ophthalmic refractometer.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ophthalmic refractometers:

1. Identification: An ophthalmic refractometer is an automatic AC-powered device that consists of a fixation system, a measurement and recording system, and an alignment system used to measure the refractive power of the eye by measuring light reflexes from the retina.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that ophthalmic refractometers be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user, and the accuracy of the measurement function of the device must be controlled to prevent misdetermination of refraction. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel believes that this device requires special labeling to indicate to the user the accuracy, reproducibility, or limitations in its measurements.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Electrical shock: Improper design or a malfunction of this device may cause electrical shock to the patient or user. (b) Misdiagnosis and inappropriate therapy: Inaccuracy of the measurement function of the device could result in misdetermination of refraction, resulting in misdiagnosis and inappropriate therapy.

FDA agrees with the Panel recommendation and is proposing that ophthalmic refractometers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1770; Docket No. 78N-3195; Manual refractor.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of manual refractors:

1. Identification: A manual refractor is a device that is a set of lenses of various dioptric powers that are used to measure the refractive error of the eye.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that manual refractors be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling of the device include a calibration procedure.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that manual refractors be classified into class I (general controls) with no exemptions. The agency believes that general controls alone are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 886.1780; Docket No. 78N-3196; Retinoscope.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of retinoscopes:

1. Identification: A retinoscope is an AC-powered or battery-powered device used clinically to measure the refraction of the eye by illuminating the retina and noting the direction of movement of the light on the retinal surface and of the refraction by the eye of the emergent rays.

2. Recommended classification: The Panel recommends that AC-powered retinoscopes be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority. The Panel recommends that battery-powered retinoscopes be classified into class I (general controls) and that this device be exempt from the good

manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that AC-powered retinoscopes be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard to provide such assurance. The Panel recommends that battery-powered retinoscopes be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that the risk of electrical shock is minimal with battery-powered retinoscopes. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to ensure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of AC-powered retinoscopes may cause electrical shock to the patient or user. The Panel identified no risks to health associated with battery-powered retinoscopes.

FDA agrees with the Panel recommendation and is proposing that AC-powered retinoscopes be classified into class II (performance standards) and that battery-powered retinoscopes be classified into class I (general controls) with exemptions from some requirements of the GMP regulation. FDA believes that a performance standard is necessary for AC-powered retinoscopes because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the AC-powered device. FDA also believes that there is sufficient information to establish a performance standard for AC-powered device. FDA is proposing that battery-powered retinoscopes be classified into class I (general controls) because FDA believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of battery-powered retinoscopes be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of battery-powered retinoscopes be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.1790; Docket No. 78N-3198; Nearpoint ruler.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nearpoint rulers:

1. Identification: A nearpoint ruler is a device calibrated in centimeters that is used to measure the nearpoint of convergence (the point to which the visual lines are directed when convergence is at its maximum).

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that nearpoint rulers be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to assure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that nearpoint rulers be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulation. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of nearpoint rulers be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of nearpoint rulers be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.1800; Docket No. 78N-3199; Schirmer strip.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of Schirmer strips:

1. Identification: A Schirmer strip is a device made of filter paper or similar material used to test for tear formation ability. It is inserted under the lower eyelid.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that Schirmer strips be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that this device be packaged sterile.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that Schirmer strips be classified into class I (general controls) with no exemptions. The agency believes that general controls alone are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 886.1810; Docket No. 78N-3200; Tangent screens (campimeter).

The ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation

regarding the classification of tangent screen (campimeters):

1. Identification: A tangent screen (campimeter) is an AC-powered or battery-powered device that is a large square cloth chart with a central mark of fixation used to map the central thirty degrees of the patient's visual field on a flat surface. This generic type of device includes projection tangent screens, target tangent screens and targets, felt tangent screens, and battery-powered stereo campimeters.

2. Recommended classification: The Panel recommends that AC-powered tangent screens be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority. The Panel recommends that battery-powered tangent screens be classified into Class I (general controls) and that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that AC-powered tangent screens be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel recommends that battery-powered tangent screens be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that the risk of electrical shock is minimal with battery-powered tangent screens. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to assure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of AC-powered tangent screens may cause electrical shock to the patient or user. The Panel identified no risks to health associated with the use of battery-powered tangent screens.

FDA agrees with the Panel recommendation and is proposing that AC-powered tangent screens (campimeters) be classified into Class II (performance standards) and that battery-powered tangent screens (campimeters) be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulation. The agency believes that a performance standard is necessary for AC-powered tangent screens because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the AC-powered device. FDA believes that there is sufficient information to establish a performance standard for the AC-powered device. FDA is proposing that battery-powered tangent screens be classified into class I (general controls) because the agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of battery-powered tangent screens be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of battery-powered tangent screens be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, with respect to genaral requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for complete explanation of the agency's policies concerning exemptions.

Section 886.1840; Docket No. 78N-3206; Simulatan (including crossed cylinder).

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of simulatans (including crossed cylinders):

1. Identification: A simulatan (including crossed cylinder) is a device that is a set of pairs of cylinder lenses that provides equal plus and minus various refractive strengths. The lenses are arranged so that the user can exchange the positions of plus and minus cylinder lenses of equal strengths. The device is used for subjective refraction (refraction in which the patient judges whether a given object is clearly in focus, as the examiner uses different lenses).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that simulatans (including crossed cylinders) be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that simulatans (including crossed cylinders) be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 886.1850; Docket No. 78N-3207; AC-powered slitlamp biomicroscope.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of AC-powered slitlamp biomicroscopes:

1. Identification: An AC-powered slitlamp biomicroscope is an AC-powered device that is a microscope for eye examination that projects into the patient's eye through a control diaphragm a thin, intense beam of light.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that AC-powered slitlamp biomicroscopes be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of this device may cause electrical shock to the patient or user.

FDA agrees with the Panel recommendataion and is proposing that AC-powered slitlamp biomicroscopes be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide

reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1860; Docket No. 78N–3208; Ophthalmic instrument stand.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ophthalmic instrument stands:

1. Identification: An ophthalmic instrument stand is an AC-powered or nonpowered device used to store ophthalmic instruments and make them readily accessible.

2. Recommended classification: The Panel recommends that AC-powered ophthalmic instrument stands be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority. The Panel recommends that nonpowered ophthalmic instrument stands be classified into class I (general controls) and that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that AC-powered instrument stands be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the user. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that general controls would not provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel recommends that nonpowered ophthalmic instrument stands be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to assure the safety or effectiveness of the device. The Panel recommends that labeling include a warning regarding the sudden release of any springs that may be present.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of AC-powered ophthalmic instrument stands may cause electrical shock to the user. The Panel identified no risks to health associated with nonpowered ophthalmic instrument stands.

FDA agrees with the Panel recommendation and is proposing that AC-powered ophthalmic instrument stands be classified into class II (performance standards) and that nonpowered ophthalmic instrument stands be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulations. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the AC-powered device. A performance standard would provide reasonable assurance of the safety and effectiveness of the AC-powered device. The agency believes that there is sufficient information to establish a performance standard for the AC-powered device. FDA is proposing that nonpowered ophthalmic instrument stands be classified into class I (general controls) because the agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of ophthalmic instrument stands be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of ophthalmic instrument stands be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.1870; Docket No. 78N–3210; Stereoscope.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of stereoscopes:

1. Identification: A stereoscope is an AC-powered or battery-powered device that combines the images of two similar objects to produce a three-dimensional apppearance of solidity and relief. It is used to measure the angle of strabismus (eye muscle deviation) and to evaluate binocular vision (usage of both eyes to see). The device is also used for corrective exercises for eye muscles.

2. Recommended classification: The panel recommends that AC-powered stereoscopes be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority. The Panel recommends that battery-powered stereoscopes be classified into class I (general controls) and that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that AC-powered stereoscopes be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel recommends that battery-powered stereoscopes be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The panel believes that the risk of electrical shock is minimal with battery-powered stereoscopes. The panel recommends that battery-powered stereoscopes be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that battery-powered stereoscopes be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to ensure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of AC-powered stereoscopes may cause electrical shock to the patient or user.

FDA agrees with the Panel recommendation and is proposing that AC-powered stereoscopes be classified into class II (performance standards) and that battery-powered stereoscopes be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulation. FDA believes that a performance standard is necessary for AC-powered stereoscopes because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the AC-powered device. FDA also believes that there is sufficient

information to establish a performance standard for the AC-powered device. FDA is proposing that battery-powered stereoscopes be classified into class I (general controls) because the agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagress with the Panel's recommendation that manufacturers of battery-powered stereoscopes be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of battery-powered stereoscopes be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.1880; Docket No. 78N-3212; Fusion and stereoscopic target.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of fusion and stereoscopic targets:

1. Identification: A fusion and stereoscopic target is a device that is a viewing object used with a stereoscope (a device that combines the images of two similar objects to produce a three-dimensional appearance of solidity and relief). It is used in various ophthalmological examinations for eye muscle disorders, such as amblyopia (weak eye muscles), and for corrective exercises for eye muscles.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that fusion and stereoscopic targets be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to assure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that fusion and stereoscopic targets be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulation. The agency believes that general controls alone are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of fusion and stereoscopic targets be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of fusion and stereoscopic targets be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.1905; Docket No. 78N-3213; Nystagmus tape.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nystagmus tapes:

1. Identification: Nystagmus tape is a device that is a long, narrow strip of fabric or other flexibile material on which a series of printed objects are moved across the patient's field of vision to elicit optokinetic nystagmus (abnormal and irregular eye movements) and to test for blindness.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exemp from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that nystagmus tape be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to assure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that nystagmus tape be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulation. The agency believes that general controls alone are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of nystagmus tape be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of nystagmus tape be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section. 886.1910; Docket No. 78N-3214; Sepctacle dissociation test system.

The Ophthalmic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of spectacle dissociation test systems:

1. Identification: A spectacle dissociation test system is an AC-powered or battery-powered device, such as a Lancaster test system, that consists of a light source and various filters, especially red/green filters, that is used subjectively to measure ocular muscle imbalance.

2. Recommended classification: The Panel recommends that AC-powered spectacle dissociation test systems be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority. The Panel recommends that battery-powered spectacle

dissociation test systems be classified into class I (general controls) and that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that AC-powered spectacle dissociation test systems classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel recommends that battery-powered spectacle dissociation test systems be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that the risk of electrical shock is minimal with battery-powered spectacle dissociation test systems. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to ensure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of AC-powered spectacle dissociation test systems may cause electrical shock to the patient or user. The Panel identified no risks to health associated with the use of battery-powered spectacle dissociation test systems.

FDA agrees with the Panel recommendation and is proposing that AC-powered spectacle dissociation test systems be classified into class II (performance standards) and battery-powered spectacle dissociation test systems be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulation. FDA believes that a performance standard is necessary for AC-powered spectacle dissociation test systems because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the AC-powered device. FDA also believes that there is sufficient information to establish a performance standard for the AC-powered device. FDA is proposing that battery-powered spectacle dissociation test systems be classified into class I (general controls) because the agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of battery-powered spectacle dissociation test systems be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of battery-powered spectacle dissociation test systems be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.1930; Docket No. 78N-3218; Tonometer and accessories.

The Ophthalmic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of tonometers and accessories:

1. Identification: A tonometer and accessories is an AC-powered or manual device used to measure intraocular pressure by the degree of indentation produced by the application of a known force on the globe of the eye (Schiotz type) or to measure intraocular tension by applanation (the application of a small flat disk to the cornea). Accessories for the device may include a tonometer calibrator or a tonograph recording system. The device is used in the diagnosis of glaucoma.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that tonometers and accessories be classified into class II because the performance characteristics of the device, including the accuracy of the measurement function, must be controlled to prevent misdiagnosis. The electrical properties of AC-powered tonometers must also be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel acknowledges the existence of the American Academy of Ophthalmology and Otolaryngology Committee on Standards for Tonometers. The Panel recommends that the labeling of the device indicate to the user the accuracy, reproducibility, or limitations in the device's measurements.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Improper design or a malfunction of the device may result in misdiagnosis and subsequent inappropriate therapy. (b) Infection: If the device cannot be sterilized properly, an infection in the patient may result. (c) Electrical shock: Improper design or a malfunction of AC-powered tonometers may cause electrical shock to the patient or user.

FDA agrees with the Panel recommendation and is proposing that tonometers and accessories be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1940; Docket No. 78N-3220; Tonometer sterilizer.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of tonometer sterilizers:

1. Identification: A tonometer sterilizer is an AC-powered device that is used to sterilize by heat a tonometer (a device used to measure intraocular pressure).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that tonometer sterilizers be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the user. The Panel also believes that a performance standard is necessary to ensure that the device provides adequate sterilization and to ensure that the design of the heating element allows sufficient cooling of the tonometer to prevent injury to the cornea. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Corneal burns: Improper design or a malfunction of the device could result in burns to the cornea from use of an insufficiently cool tonometer. (b) Infection: If the device fails to sterilize the tonometer adequately, infection in the patient may result. (c) Electrical shock: Improper design or a malfunction of this device may cause electrical shock to the user.

FDA agrees with the Panel recommendation and is proposing that tonometer sterilizers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.1945; Docket No. 78N-3221; Transilluminator.

The Ophthalmic Device Classification Panel and the Ear, Nose, and Throat Device Classification Panel, FDA advisory committees, made the following recommendation regarding the classification of transilluminators:

1. Identification: A transilluminator is an AC-powered or battery-powered device that is a light source used to transmit light through tissues to aid patient examination.

2. Recommended classification: The Panels recommend that AC-powered transilluminators be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority. The Panels recommend that battery-powered transilluminators be classified into class I (general controls) and that there be no exemptions.

3. Summary of reasons for recommendation: The Panels recommend that AC-powered transilluminators be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panels believe that general controls would not provide sufficient control over this characteristic. The Panels believe that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panels recommend that battery-powered transilluminators be classified into class I because the Panels believe that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panels believe that the risk of electrical shock is minimal with battery-powered transilluminators.

4. Summary of data on which the recommendation is based: The Panel based its recommendations on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of AC-powered transilluminators may cause electrical shock to the patient or user. The Panel identified no risks to health associated with the use of battery-powered transilluminators.

FDA agrees with the recommendations of both Panels and is proposing that AC-powered transilluminators be classified into class II (performance standards) and that battery-powered transilluminators be classified into class I (general controls) with no exemptions. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the AC-powered device.

A performance standard would provide reasonable assurance of the safety and effectiveness of the AC-powered device. FDA believes that there is sufficient information to establish a performance standard for the AC-powered device. FDA is proposing that battery-powered transilluminators be classified into class I with no exemptions because the agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 886.3100; Docket No. 78N-3224; Ophthalmic tantalum clip.

The Ophthalmic Device Classification Panel, an FDA advisory Committee, made the following recommendation regarding the classification of ophthalmic tantalum clips:

1. Identification: An ophthalmic tantalum clip is a malleable metallic device used to bring together the edges of a wound to facilitate healing or to prevent bleeding from small blood vessels in the eye. The device may be implanted permanently, or removed after a short period of time.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that ophthalmic tantalum clips be classified into class II because the design of the device must be controlled to prevent breakage of the device, or erosion of the device through the sclera into the vitreous, and the materials used in the construction of the device must be controlled to ensure biocompatibility. The Panel believes that general controls would not provide sufficent control over these characteristics. Although this device is implanted in the human body, the Panel believes that premaket approval is not necessary because sufficient information exists to establish a performance standard that would provide reasonable assurance of the safety and effectiveness of the device. The Panel also recommends that the device be capable of being sterilized to prevent infection.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Infection: If the device cannot be properly sterilized, an infection in the patient may result. (b) Eye damage: Breakage of the device or erosion of the device into the vitreous could cause damage to the eye.

FDA agrees with the Panel recommendation and is proposing that ophthalmic tantalum clips be classified into class II (performance standards). The agency has reviewed certain literature regarding ophthalmic tantalum clips. Henry M. Carney (Ref. *3*) conducted a study on the effects of tantalum implants in dogs and found that there were no instances of discoloration or edema and no inflammatory changes in surrounding tissue. Robert H. Pudenz, M.D. (Ref. *4*) found that tissue reaction to tantalum consists of a "minimal investment by connective tissue and/or neuroglia fibrils" and that a characteristic foreign body reaction does not occur. Although this is an implanted device, the agency believes that premarket approval is not necessary because a performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device. The agency believes that a performance standard is necessary because general controls alone are insufficient to control the risks to health presented by the device.

Section 886.3130; Docket No. 78N-3225; Ophthalmic conformer.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of opthalmic conformers:

1. Identification: An ophthalmic conformer is a device, usually made of molded plastic, that is inserted temporarily between the eyeball and eyelid to maintain space in the orbital cavity and used to prevent closure or adhesions during the healing process following plastic surgery.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that ophthalmic conformers be classified into class I because the Panel believes that

general controls alone are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA disagrees with the Panel recommendation and is proposing that ophthalmic conformers be classified into class II (performance standards). The agency believes that this device may present a risk of tissue damage from leaching of materials used in the device into tissues or by the bioincompatibility of the materials. FDA believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is sufficient information to establish a performance standard for this device.

Section 886.3200; Docket No. 78N–3226; Artificial eye.

The Ophthalmic Device Classification Panel and the General and Plastic Surgery Device Classification Panel, FDA advisory committees, made the following recommendation regarding the classification of artificial eyes:

1. Identification: An artificial eye is a removable, prosthetic device resembling the eyeball, usually made of glass or plastic, that is placed in the eye socket for cosmetic purposes following removal of the eye.

2. Recommended classification: The Ophthalmic Device Classification Panel recommends that the device be classified into class I (general controls) and that there be no exemptions. The General and Plastic Surgery Device Classification Panel recommends that the device be classified into class II (performance standards) and that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: the Ophthalmic Device Classification Panel recommends that artificial eyes be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The General and Plastic Surgery Device Classification Panel recommends that artificial eyes be classified into class II because a performance standard is necessary to ensure the biocompatibility of the materials used in the construction of the device. The Panel believes that the device should be nonallergenic, noncarcinogenic, and nonantigenic and that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel also recommends that the device be sterilized before use.

4. Summary of data on which the recommendation is based: the Panels based their recommendations on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Infection: If the device cannot be sterilized properly, an infection in the patient may result. (b) Adverse tissue reaction: If the materials used in the construction of the device are not biocompatable, the patient may have an adverse tissue reaction.

FDA agrees with the recommendation of the General and Plastic Surgery Device Classification Panel and is proposing that artificial eyes be classified into class II (performance standards). The agency disagrees with the recommendations of the Ophthalmic Classification Panel that this device be classified into class I. The agency believes that general controls alone are insufficient to control the risks to health presented by the device. The agency believes that a performance standard is necessary for artificial eyes because the materials used in the construction of the device must meet a satisfactory level of tissue compatibility to prevent adverse tissue reactions. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.3300; Docket No. 78N–3227; Absorbable implant (scleral buckling method).

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of absorbable implants (scleral buckling method):

1. Identification: An absorbable implant (scleral buckling method) is an implanted device placed on the sclera to aid retinal reattachment.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that absorbable implants (scleral buckling method) be classified into class II because the materials used in the construction of the device must be controlled to ensure biocompatibility. The Panel believes that general controls would not provide sufficient control over this characteristic. Although an absorbable implant (scleral buckling method) is an implanted device, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because sufficient information exists to establish a performance standard. The Panel also recommends that the device be sterilized before use to prevent infection.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Adverse tissue reaction: If the materials used in the construction of the device are not biocompatible, the patient may have an adverse tissue reaction. (b) Infection: If the device cannot be sterilized properly, an infection in the patient may result.

FDA agrees with the Panel recommendation and is proposing that absorbable implants (scleral buckling method) be classified into class II (performance standards). L'Esperance (Ref. *5*) states that the use of absorbable collagen implants in retinal repair may obviate many of the delayed complications associated with nonabsorbable silicone implants, such as extrusion, intrusion, orbital migration, and permanent anatomic and physiologic impairment of the eye. King, et al. (Ref. *6*) states, for example, that an absorbable gelatin implant is an "excellent absorbable implant when used in repairing retinal detachments that do not need a permanent buckle or an encircling element." King also states that the thickness of the gelatin implant is important in reducing the rate of complications, i.e., a higher complication rate was recorded for 0.75 millimeter gelatin implants than for 0.5 millimeter gelatin implants. Although this is an implanted device, the agency believes that premarket approval is not necessary because a performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device because absorbable implants have been used successfully for over 15 years. The agency believes that a performance standard is necessary because general controls alone are insufficient to control the risks to health presented by the device.

Section 886.3320; Docket No. 78N–3228; Eye sphere implant.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of eye sphere implants:

1. Identification: An eye sphere implant is an implanted device used to occupy the space in the eyeball following the removal of the contents of the eyeball with the sclera left intact.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that eye sphere implants be classified into class II because, although the device is implanted in the human body, the Panel believes that premarket approval is not necessary to assure its safety and effectiveness because the risks to health presented by the device can be adequately controlled by a performance standard. The Panel believes that a performance standard is necessary because the design and materials of the device must be controlled to prevent its coming out (extrusion), to ensure that the device is biocompatible to prevent adverse tissue reaction, and to ensure that the device can be adequately sterilized to prevent infection. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Infection: If the device cannot be sterilized properly, an infection in the patient may result. (b) Extrusion of the implant: Improper design or materials of the device may result in extrusion. (c) Adverse tissue reaction: If the materials used in the construction of the device are not biocompatible, the patient may have an adverse tissue reaction.

FDA agrees with the Panel recommendation and is proposing that eye sphere implants be classified into class II (performance standards). Vistnes and Paris (Ref. *7*) state that when the normal globe is removed and replaced with an implant and a prosthesis, there remains a volume deficit which is corrected by adding various space-occupying materials to the orbit. In addition to autogenous and homologous materials, foreign material such as polytef (Teflon®), silicone, and glass beads have been used to occupy the potential space. These authors describe the use of room temperature vulcanizing silicone in the reconstruction of the socket.

Lyall (Ref. *8*) states that many implants of various materials, such as acrylate, nylon mesh, and tantalum mesh, have been used after enucleation to improve movement of the prosthesis and the patient's appearance. He describes the use of an inert alloplastic material prepared from a combination of Telflon® fluorocarbon polymer and vitreous carbon fibers that when wholly implanted is invaded by fibrous tissue and is not rejected.

Although this is an implanted device, the agency believes that premarket approval is not necessary because a performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device because eye sphere implants have been in use for over 15 years (Refs. *9* and *10*). The agency believes that a performance standard is necessary because general controls alone are insufficient to control the risks to health presented by the device.

Section 886.3340; Docket No. 78N-3229; Extraocular orbital implant.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of extraocular orbital implants:

1. Identification: An extraocular orbital implant is a device used in scleral surgery for buckling or building up the floor of the eye, usually in conjunction with retinal reattachment. This nonabsorbable device includes implants and floor support for scleral buckling methods, but excludes injected substances.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that extraocular orbital implants be classified into class II because, although the device is implanted in the human body, the Panel believes that a large percentage of the problems associated with this device are the result of poor surgical techniques and not of the device, and that premarket approval is not necessary to assure its safety and effectiveness because the risk to health presented by the device can be adequately controlled by a performance standard. The Panel believes that a performance standard is necessary because the design and materials of the device must be controlled to prevent its coming out (extrusion), to ensure that the device is biocompatible to prevent adverse tissue reaction, and to ensure that the device can be adequately sterilized to prevent infection. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clincial experience with, this device.

5. Risks to health: (a) Infection: If the device cannot be sterilized properly, an infection in the patient may result. (b) Extrusion of the implant: Improper design or materials of the device may result in extrusion. (c) Adverse tissue reaction: If the materials used in the contruction of the device are not biocompatible, the patient may have an adverse tissue reaction.

FDA agrees with the Panel recommendation and is proposing that extraocular orbital implants be classified into class II (performance standards). Otto and Bourghouts (Ref. *11*) state that after a severe trauma of the face, patients complain of diplopia because of eyeball dislocation and incarceration or fibrosis of the external eye muscles.

The treatment consists of closing and raising the orbital floor. To cover the floor fracture, implants are placed under the periost of the orbital floor. Kumpf (Ref. *12*), states that auto-, homo-, and hetero-plastic materials have been used by various investigators; silicone (silastic dimethylpolysiloxane) being preferred by most surgeons. Chrome cobalt, gold, and methylmethacrylate prosthesis also have been used successfully. Although this is an implanted device, the agency believes that premarket approval is not necessary because a performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that sufficient information exists, relative to design, sterilization characteristics, and biocompatibility, to establish a performance standard for the device. Extraocular orbital implants have been used successfully for over 20 years (Ref. *13*). The agency believes that a performance standard is necessary because general controls alone are insufficient to control the risks to health presented by the device.

Section 886.3400; Docket No. 78N-3230; Keratoprosthesis.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of keratoprostheses:

1. Identification: A keratoprosthesis is an implanted device, made of plastic, used to replace the central area of the opacified natural cornea of the eye and used to maintain or restore sight.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that keratoprostheses be classified into class III because the device is purported or represented to be for a use (replacing the natural cornea of the eye) in maintaining or restoring human sight, the device is intended to be implanted in the human body, and the device presents a potential unreasonable risk of illness or injury since extrusion (coming

out) of this implant can lead to loss of the patient's eye. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and that there is not sufficient information to establish a performance standard. Therefore the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and, thus, assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clincial experience with, this device and on the lack of medical data available to assure the safety and effectiveness of the device.

5. Risks to health: (a) Loss of eye: Extrusion of the implant, resulting from faulty materials or design of the device, may cause loss of the patient's eye. (b) Infection: If the device cannot be sterilized properly, an infection in the patient may result. (c) Adverse tissue reaction: If the materials used in the construction of the device are not biocompatible, the patient may have an adverse tissue reaction.

FDA agrees with the Panel recommendation and is proposing that keratoprostheses be classified into class III (premarket approval). The agency believes the device is purported or represented to be for a use (replacing the natural cornea of the eye to maintain or restore human sight) that is of substantial importance in preventing impairment of human health. The device is intended to be implanted in the human body, and the device presents a potential unreasonable risk of illness or injury because extrusion of the device can lead to loss of the patient's eye. The Federal Food, Drug, and Cosmetic Act requires FDA to classify an implant into class III unless the agency determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the agency has determined that premarket approval is necessary. The agency believes that insufficient information exists to determine that general controls or performance standards would provide reasonable assurance of the safety and effectiveness of the device.

Section 886.3800; Docket No. 78N-3231; Scleral shell.

The Ophthalmic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of scleral shells:

1. Identification: A scleral shell is a removable device made of plastic or glass that fits over the cornea and proximal-cornea sclera for cosmetic or reconstructive purposes. The device usually has an artificial eye painted on it.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that scleral shells be classified into class II because the materials used in the construction of the device must be controlled to ensure biocompatibility, and the design and finish of the device must be controlled to prevent corneal abrasion. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Adverse tissue reaction: If the materials used in the construction of the device are not biocompatible, the patient may have an adverse tissue reaction. (b) Corneal abrasion: Improper design or finish of the device may cause corneal abrasion.

FDA agrees with the Panel recommendation and is proposing that scleral shells be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.3920; Docket No. 78N-3232; Eye valve implant.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of eye valve implants:

1. Identification: An eye valve implant is a one-way pressure-sensitive, valve-like device used to normalize intraocular pressure. The device may be used in the treatment of glaucoma.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that eye valve implants be classified into class III because the device is intended to be implanted in the human body and is purported or represented to be used in normalizing intraocular pressure and in supporting or sustaining human sight. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and that there is not sufficient information to establish a performance standard. Therefore the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness. The Panel also believes that the materials used in the construction of the device must be biocompatible to prevent adverse tissue reaction, that the device must be sterile to prevent infection, and that the design and performance characteristics of the device must be adequate to prevent extrusion.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device and on the lack of medical data available to assure the safety and effectiveness of the device.

5. Risks to health: (a) Adverse tissue reaction: If the materials used in the construction of the device are not biocompatible, the patient may have an adverse tissue reaction. (b) Extrusion of the implant: Improper design or a malfunction of the device may result in extrusion. (c) Infection: If the device cannot be sterilized properly, an infection in the patient may result.

FDA agrees with the Panel recommendation and is proposing that eye valve implants be classified into class III (premarket approval). The agency believes the device is purported or represented to be for a use (normalizing intraocular pressure to support or sustain human sight) that is of substantial importance in preventing impairment of human health. The device is intended to be implanted in the human body. The Federal Food, Drug, and Cosmetic Act requires the agency to classify an implant into class III unless the agency determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. In this case, the agency has determined that premarket approval is necessary. The agency believes that insufficient information exists to determine that general controls or performance standards would provide reasonable assurance of the safety and effectiveness of the device.

Section 886.4070; Docket No. 78N-3233; Powered corneal burr.

The Ophthalmic Device Classification Panel, FDA advisory committee, made the following recommendation regarding the classification of powered corneal burrs:

1. Identification: A powered corneal burr is an AC-powered or battery-powered device that is a motor and drilling tool used to remove rust rings from the cornea of the eye.

2. Recommended classification: The Panel recommends that AC-powered corneal burrs be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority. The Panel recommends that battery-powered corneal burrs be classified into class I (general controls) and that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that AC-powered corneal burrs be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel recommends that battery-powered corneal burrs be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that for all powered corneal burrs the material composition and the recommended method of sterilization of the device should be specified in the labeling.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of AC-powered corneal burrs may cause electrical shock to the patient or user. The Panel identified no risks to health associated with the use of battery-powered corneal burrs.

FDA agrees with the Panel recommendation and is proposing that AC-powered corneal burrs be classified into class II (performance standards) and that battery-powered corneal burrs be classified into class I (general controls). The agency believes that a performance standard is necessary for AC-powered corneal burrs because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device. The agency is proposing that battery-powered corneal burrs be classified into class I (general controls) with no exemptions because the agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 886.4100; Docket No. 78N-3235; Radiofrequency cautery apparatus.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of radiofrequency cautery apparatus:

1. Identification: Radiofrequency cautery apparatus is an AC-powered or battery-powered device used during ocular surgery to coagulate tissue or arrest bleeding by a high-frequency electric current.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel reommends that AC-powered or battery-powered radiofrequency cautery apparatus be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that a performance standard is necessary for all radiofrequency cautery apparatus to ensure that the amount of electric current delivered by the device can be adequately controlled to ensure sufficient tissue coagulation or arrest of bleeding without unwanted effects. The Panel recommends that the device's electrodes be capable of being sterilized in order to prevent infection. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel believes that radiofrequency cautery apparatus should not be used in the presence of inflammable objects or explosive gases. The Panel also notes that the device may cause interference with other devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Electrical shock: Improper design or a malfunction of AC-powered or battery-powered radiofrequency cautery apparatus may cause electrical shock to the patient or user. (b) Infection: If the device cannot be sterilized properly, an infection in the patient may result. (c) Inadequate tissue coagulation or failure to arrest bleeding: If the device fails to deliver sufficient amounts of electrical current, inadequate coagulation of tissue or failure to arrest bleeding may result.

FDA agrees with the Panel recommendation and is proposing that radiofrequency cautery apparatus be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is sufficient information to establish a perfomrnace standard for this device.

Section 886.4115; Docket No. 78N-3237; Thermal cautery unit.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of thermal cautery units:

1. Identification: A thermal cautery unit is an AC-powered or battery-powered device used during ocular surgery to coagulate tissue or arrest bleeding by heat conducted through a wire tip.

2. Recommended classificaton: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of the reasons for recommendation: The Panel recommends that thermal cautery units be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that a performance standard is necessary for all thermal cautery units to ensure that the amount of heat delivered by the device can be adequately controlled to ensure sufficient tissue coagulation or to ensure arrest of bleeding without burns to tissue. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel believes that thermal cautery units should not be used in the presence of inflammable objects or explosive gases. The Panel recommends that the device tip be capable of being sterilized in order to prevent infection.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Electrical shock: Improper design or a malfunction of thermal cautery units may cause electrical shock to the patient or user. (b) Traumatic injury: The use of this device near highly inflammable objects or in the presence of explosive gases could result in fire or an explosion. (c) Infection: If the device cannot be sterilized properly, an infection in the patient may result. (d) Tissue burns: Burns to tissue may result if excessive amounts of heat are delivered by the device. (e) Inadequate tissue coagulation or failure to arrest bleeding: If the device fails to deliver sufficient amounts of heat, inadequate coagulation of tissue or failure to arrest bleeding may result.

FDA agrees with the Panel recommendation and is proposing that thermal cautery units be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and

effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.4150; Docket No. 78N-3239; Vitreous aspiration and cutting instrument.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of vitreous aspiration and cutting instruments:

1. Identification: A vitreous aspiration and cutting instrument is an electrically powered device, which may use ultrasound, that is used for the removal of vitreous matter from the vitreous cavity or for removal of the crystalline lens.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that vitreous aspiration and cutting instruments be classified into class III because this device presents a potential unreasonable risk of injury. A malfunction of this device may result in destruction of the retina, choroid, or iris. Exposure of tissue to ultrasonic vibrations or tip shavings from this device may result in tissue damage. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and that there is not sufficient information to establish a performance standard. The device, therefore, should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and, thus, assure its safety and effectiveness. The Panel believes that the electrical properties of AC-powered vitreous aspiration and cutting instruments must be controlled to prevent electrical shock to the patient or user. The Panel believes that the device tip should be capable of being sterilized and that the composition of materials used in the device should be specified in the labeling.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Traumatic injury: Destruction of the retina, choroid, or iris may result from malfunction of the device. (b) Adverse tissue reaction: Tip shavings from the device may become imbedded in the eye and cause an adverse tissue reaction. (c) Energy damage to tissue: Tissue damage may result from exposure to ultrasonic energy from the device. (d) Infection: If the device cannot be sterilized properly, an infection in the patient may result. (e) Electrical shock: Improper design or a malfunction of AC-powered vitreous aspiration and cutting instruments may cause electrical shock to the patient or user.

FDA agrees with the Panel recommendation and is proposing that vitreous aspiration and cutting instruments be classified into class III (premarket approval). The agency believes that this device presents a potential unreasonable risk of injury because serious eye damage could result from a mechanical malfunction of the device and damage to tissue could result from either tip shavings or ultrasonic energy from the device. In addition, the agency believes that the device is purported or represented to be for a use (removal of vitreous matter from the vitreous cavity or removal of the crystalline lens) that is of substantial importance in preventing the impairment of human health. The agency believes that insufficient information exists to determine that general controls or performance standards would provide reasonable assurance of the safety and effectiveness of the device.

Section 886.4170; Docket No. 78N-3241; Cryophthalmic unit.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of cryophthalmic units:

1. Identification: A cryophthalmic unit is a device that is a probe with a small tip that becomes extremely cold through the controlled use of a refrigerant or gas. The device may be AC-powered. The device is used to remove cataracts by the formation of an adherent ice ball in the lens, to freeze the eye and adjunct parts for surgical removal of scars, and to freeze tumors.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that cryophthalmic units be classified into class II because the Panel believes that the mechanical strength of the tip of the unit should be able to withstand appropriate safe levels of pressure without bursting of the tip. The Panel believes that the temperature of the tip should be predictable and reproducible. If the tip is excessively cold, it may injure the eye. The Panel believes that an unpredictable freeze/thaw time could result in eye damage. If the device is AC-powered, the Panel believes that the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls alone would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Traumatic eye injury: Eye damage could result from bursting of the tip. (b) Ocular freezing damage: Eye damage could result from an excessively cold tip or an unpredictable freeze/thaw time. (c) Infection: If the device cannot be sterilized properly, an infection to the patient may result.

FDA agrees with the Panel recommendation and is proposing that cryophthalmic units be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is sufficient information to establish a performance standard for this device.

Section 886.4230; Docket No. 78N-3243; Ophthalmic knife test drum.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ophthalmic knife test drums:

1. Identification: An ophthalmic knife test drum is a device used to test the keenness of ophthalmic surgical knives to determine whether resharpening is needed.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that ophthalmic knife test drums be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to ensure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that ophthalmic knife test drums be classified into class I (general controls) with exemptions from some of the

requirements of the GMP regulation. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of ophthalmic knife test drums be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of ophthalmic knife test drums be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacturer of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.4250; Docket No. 78N-3244; Ophthalmic electrolysis unit.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ophthalmic electrolysis units:

1. Identification: An ophthalmic electrolysis unit is an AC-powered or battery-powered device used to destroy ocular hair follicles by the passage of a galvanic electric current.

2. Recommended classification: Class II (performance standards). The Panel recommends that AC-powered ophthalmic electrolysis units be classified ino class II (performance standards) and that establishing a performance standard for this device be a low priority. The Panel recommends that battery-powered ophthalmic electrolysis units be classified into class I (general controls) and that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that AC-powered ophthalmic electrolysis units be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel recommends that battery-powered ophthalmic electrolysis units be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that the risk of electrical shock is minimal with battery-powered ophthalmic electrolysis units.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of AC-powered ophthalmic electrolysis units may cause electrical shock to the patient or user. The Panel identified no risks to health associated with battery-powered ophthalmic electrolysis units.

FDA agrees with the Panel recommendation and is proposing that AC-powered ophthalmic electrolysis units be classified into class II (performance standards) and that battery-powered ophthalmic electrolysis units be classified into class I (general controls) with no exemptions. The agency believes that a performance standard is necessary for the AC-powered device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the AC-powered device. The agency believes that there is sufficient information to establish a performance standard for the AC-powered device. The agency is proposing that battery-powered ophthalmic electrolysis units be classified into class I (general controls) with no exemptions because the agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 886.4300; Docket No. 78N-3250; Intraocular lens guide.

The Ophthalmic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of intraocular lens guides:

1. Identification: An intraocular lens guide is a device that is inserted into the eye during surgery to direct the insertion of an intraocular lens.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that intraocular lens guides be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that the device should be packaged sterile and that the composition of materials used in the device should be specified in the labeling.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that intraocular lens guides be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 886.4335; Docket No. 78N-3252; Operating headlamp.

The Ophthalmic Device Classification Panel, the Ear, Nose, and Throat Device Classification Panel, the General and Plastic Surgery Device Classification Panel, the Neurology Device Classification Panel, and the Gastroenterology and Urology Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of operating headlamps:

1. Identification: An operating headlamp is an AC-powered or battery-powered device worn around the head of the user to provide a light source to aid visualization during surgical, diagnostic, or therapeutic procedures.

2. Recommended classification: The Ophthalmic Device Classification Panel and the Ear, Nose, and Throat Device Classification Panel recommend that AC-powered operating headlamps be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority. The Ophthalmic Device Classification Panel, the General and Plastic Surgery Device Classification Panel, the Neurology Device Classification Panel, and the Gastroenterology and Urology Device Classification Panel recommend that battery-powered operating headlamps be classified into class I (general controls) and that there be no exemptions.

3. Summary of reasons for recommendation: The Ophthalmic Device Classification Panel and the Ear, Nose, and Throat Device Classification Panel recommend that AC-powered operating headlamps be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panels believe that general controls would not provide sufficient control over this characteristic. The Panels believe that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Ophthalmic Device Classification Panel, the General and Plastic Surgery Device Classification Panel, the Neurology Device Classification Panel, and the Gastroenterology and Urology Device Classification Panel recommend that battery-powered operating headlamps be classified into class I because the Panels believe that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panels believe that the risk of electrical shock is

minimal with battery-powered operating headlamps.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of AC-powered operating headlamps may cause electrical shock to the patient or user. The Panels identified no risk to health associated with the use of battery-powered operating headlamps.

FDA is proposing that AC-powered operating headlamps be classified into class II (performance standards) and that battery-powered operating headlamps be classified into class I (general controls) with no exemptions. The agency thus agrees with the recommendations of the Ophthalmic Device Classification Panel and the Ear, Nose, and Throat Device Classification Panel for AC-powered operating headlamps, and with the recommendations of the Ophthalmic Device Classification Panel, the General and Plastic Surgery Device Classification Panel, the Neurology Device Classification Panel, and the Gastoenterology and Urology Device Classification Panel for battery-powered operating headlamps. The agency believes that a performance standard is necessary for AC-powered operating headlamps because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the AC-powered device. FDA also believes that there is sufficient information to establish a performance standard for the AC-powered device. FDA is proposing that battery-powered operating headlamps be classified into class I with no exemptions because it believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 886.4350; Docket No. 78N-3253; Manual ophthalmic surgical instrument.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of manual ophthalmic surgical instruments:

1. Identification: A manual ophthalmic surgical instrument is a nonpowered, handheld device used to aid or perform ophthalmic surgical procedures. This general type of device includes the manual corneal burr, ophthalmic caliper, ophthalmic cannula, eyelid clamp, ophthalmic muscle clamp, iris retractor clip, orbital compressor, ophthalmic curette, cystotome, orbital depressor, lachrymal dilator, erisophake, expressor, ophthalmic forcep, ophthalmic hook, sphere introducer, ophthalmic knife, ophthalmic suturing needle, lachrymal probe, trabeculotomy probe, corneo-scleral punch, ophthalmic retractor, ophthalmic ring (Flieringa), lachrymal sac rongeur, ophthalmic scissors, enucleating snare, ophthalmic spatula, ophthalmic specula, ophthalmic spoon, ophthalmic spud, trabeculotome, or ophthalmic manual trephine.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that manual ophthalmic surgical instruments be classified into class I because the panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices. The Panel believes that the material composition of the devices and the recommended method of sterilization should be specified in the labeling of the devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, these devices.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that manual ophthalmic surgical instruments be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices.

Section 886.4360; Docket No. 78N-3254; Ocular surgery irrigation device.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ocular surgery irrigation devices:

1. Identification: An ocular surgery irrigation device is a device that is suspended over the ocular area during ophthalmic surgery and delivers continuous, controlled irrigation to the surgical field.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that ocular surgery irrigation devices be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices. The Panel believes that the material composition of the devices and the recommended method of sterilization should be specified in the labeling of this device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that ocular surgery irrigation devices be classified into class I (general controls) with no exemptions. The agency believes that general controls alone are sufficient to provide reasonable assurance of the safety and effectiveness of the devices.

Section 886.4370; Docket No. 78N-3255; Keratome.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of keratomes:

1. Identification: A keratome is an AC-powered or battery-powered device used to shave tissue from sections of the cornea for a lamellar (partial thickness) transplant.

2. Recommended classification: The Panel recommends that AC-powered keratomes be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority. The Panel recommends that battery-powered keratomes be classified into class I (general controls) and that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that AC-powered keratomes be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel recommends that battery-powered keratomes be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that the labeling of keratomes should include instructions for depth calibration of the device. The Panel believes that the recommended method of sterilization be specified in the labeling of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of AC-powered keratomes may cause electrical shock to the patient or user.

FDA agrees with the Panel recommendation and is proposing that AC-powered keratomes be classified into class II (performance standards) and that battery-powered keratomes be classified into class I (general controls) with no exemptions. The agency believes that a performance standard is necessary for the AC-powered device because general controls alone are

insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the AC-powered device. FDA believes that there is sufficient information to establish a performance standard for the AC-powered device. FDA is proposing that battery-powered keratomes be classified into class I (general controls) with no exemptions because the agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the battery-powered device.

Section 886.4390; Docket No. 78N-3257; Ophthalmic laser.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ophthalmic lasers:

1. Identification: An ophthalmic laser is an AC-powered device used to coagulate tissue of the eye, orbit, and surrounding skin by a laser beam.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that lasers be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user, and the design and performance of the device must be controlled to prevent exposure to excessive intensity of the laser beam. The Panel believes that general controls would not provide sufficient control over these characteristcs. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Electrical shock: Improper design or a malfunction of this device may cause electrical shock to the patient or user. (b) Tissue damage: Insufficiently controlled energy levels emitted by this device may cause unnecessary tissue damage.

FDA agrees with the Panel recommendation and is proposing that ophthalmic lasers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls and the performance standard for laser products (21 CFR 1040.10 and 1040.11) promulgated under the Radiation Control for Health and Safety Act (42 U.S.C. 263f) alone are insufficient to control the risks to health that are characteristic of medical laser devices. Control must be exerted to limit the exposure to laser radiation of the patient and personnel to that necessary to conduct effective surgical examination and testing procedures. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.4400; Docket No. 78N-3258; Electronic metal locator.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of electronic metal locators:

1. Identification: An electronic metal locator is an AC-powered device with probes used to locate metallic foreign bodies in the eye or eye socket.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that electronic metal locators be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel believes that the device should be capable of being sterilized to prevent infection and that this device requires special labeling to indicate to the user the accuracy, reproducibility, or limitations in its measurements.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Electrical shock: Improper design or a malfunction of this device may cause electrical shock to the patient or user. (b) Infection: If the device cannot be sterilized properly, an infection in the patient may result.

FDA agrees with the Panel recommendation and is proposing that electronic metal locators be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is sufficient information to establish a performance standard for this device.

Section 886.4440; Docket No. 78N-3259; AC-powered magnet.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of AC-powered magnets:

1. Identification: An AC-powered magnet is an AC-powered device that generates a magnetic field and that is used to find and remove metallic foreign bodies from eye tissue.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that AC-powered magnets be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel also believes that the temperature of the tip should be controlled to prevent burns. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Electrical shock: Improper design or a malfunction of this device may cause electrical shock to the patient or user. (b) Burns: If the tip of the device overheats, burns to the eye may result.

FDA agrees with the Panel recommendation and is proposing that AC-powered magnets be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is sufficient information to establish a performance standard for this device.

Section 886.4445; Docket No. 78N-3260; Permanent magnet.

The Ophthalmic Device Classification Panel and the General and Plastic Surgery Device Classification Panel, FDA advisory committees, made the following recommendation regarding the classification of permanent magnets:

1. Identification: A permanent magnet is a nonelectronic device that generates a magnetic field and that is used to find and

remove metallic foreign bodies from eye tissue.

2. Recommended classification: Class I (general controls). The Panels recommend that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panels recommend that permanent magnets be classified into class I because the Panels believe that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panels recommend that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panels believe that the quality of the device is easily discernible and defects are readily apparent to the user. The Panels recommend that this device be exempt from records and reports requirements under section 519 of the act because the Panels believe that these requirements are not necessary to ensure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the recommendations of both Panels and is proposing that permanent magnets be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of permanent magnets be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i)

FDA disagrees with the Panel's recommendation that manufacturers of permanent magnets be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)). See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.4570; Docket No. 78N–3261; Ophthalmic surgical marker.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ophthalmic surgical markers:

1. Identification: An ophthalmic surgical marker is a device used to mark the location of ocular or scleral surgical manipulation by ink, dye, or indentation.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that ophthalmic surgical markers be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to ensure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that ophthalmic surgical markers be classified into class I. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of ophthalmic surgical markers be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

FDA disagrees with the Panels' recommendation that manufacturers of ophthalmic surgical markers be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360(f)). See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.4610; Docket No. 78N–3264; Ocular pressure applicator.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ocular pressure applicators:

1. Identification: An ocular pressure applicator is a manual device that consists of a sphygmomanometer-type squeeze bulb, a dial indicator, a band, and bellows, and that is used to apply pressure on the eye in preparation for ophthalmic surgery.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that ocular pressure applicators be classified into class II because the design and performance characteristics of the pressure regulator of the device must be controlled to prevent ocular damage as a result of excessive pressure exerted on the eye. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Traumatic injury: Improper design or a malfunction of the device, resulting in excessive pressure exerted on the eye, may cause ocular damage.

FDA agrees with the Panel recommendation and is proposing that ocular pressure applicators be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is sufficient information to establish a performance standard for this device.

Section 886.4650; Docket No. 78N–3265; Eye pad.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of eye pads:

1. Identification: An eye pad is a device that consists of a pad of gauze and cotton used as a bandage over the eye for protection and absorption of secretions.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that eye pads be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that the device must be packaged sterile.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Infection: If the device cannot be sterilized properly, an infection in the patient may result.

FDA agress with the Panel recommendation and is proposing that eye pads be classified into class I (general controls) with no exemptions.

The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. FDA believes that general controls are sufficient to ensure the sterility of the device.

Section 886.4670; Docket No. 78N-3266; Phacofragmentation system.

The Ophthalmic Device Classfication Panel, an FDA advisory committee, made the following recommendation regarding the classification of phacofragmentation systems:

1. Identification: A phacofragmentation system is an AC-powered device with a fragmenting needle used in cataract surgery to disrupt a cataract with ultrasound and extract the cataract.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that phacofragmentation systems be classified into class III because the device presents unreasonable risks of illness or injury. Use of the device may expose the eye to unacceptably high ultrasonic energy levels or cause burns to eye tissue if the flow rate of the irrigating solution in the device is inadequate to prevent overheating of the device. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and that there is not sufficient information to establish a performance standard. The device, therefore, should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and, thus, assure its safety and effectiveness. The Panel believes that the materials used in the construction of the device are not considered generally acceptable for contact with the body and may necessitate additional control requirements. The Panel also believes that the electrical properties of the device must be controlled to prevent electrical shock to the patient or user.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device and on the lack of medical data to assure the safety and effectiveness of the device.

5. Risks to health: (a) Electrical shock: Improper design or a malfunction of this device may cause electrical shock to the patient or user. (b) Infection: If the device cannot be sterilized properly, an infection in the patient may result. (c) Energy damage to tissue: Excessive ultrasonic energy emitted by the device may cause tissue damage. (d) Burns: A reduced flow rate of the irrigation solution could result in overheating of the device and burns to eye tissue.

FDA agrees with the Panel recommendation and is proposing that the phacofragmentation systems be classified into class III (premarket approval). The agency believes the device presents a potential unreasonable risk of illness or injury because burns or damage to eye tissue could result from excessive ultrasonic energy levels delivered by the device or from an inappropriate flow rate of the irrigating solution in the device. In addition, the agency believes the device is purported or represented to be for a use (disrupting and extracting a cataract) that is of substantial importance in preventing impairment of human health. The agency believes that insufficient information exists to determine that general controls or performance standards would provide reasonable assurance of the safety and effectiveness of the device.

Section 886.4690; Docket No. 78N-3267; Ophthalmic photocoagulator.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ophthalmic photocoagulators:

1. Identification: An ophthalmic photocoagulator is an AC-powered device that uses the energy from an extended, noncoherent light source to occlude blood vessels of the retina, choroid, or iris.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that ophthalmic photocoagulators be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user and to prevent power surges that could cause tissue destruction in the patient's eye. The Panel also believes that malfunction of the device's filter could cause burns to the operator's eye and injury could result from explosion of the device's xenon tube. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Damage to tissue: Power surges could result in tissue destruction of the patient's eye. (b) Electrical shock: Improper design or a malfunction of the device may cause electrical shock to the patient or user. (c) Burns: A malfunction of the filter could result in burns to the operator's eyes. (d) Traumatic injury: Explosion of the xenon tube in the device could result in injury to the patient or operator.

FDA agrees with the Panel recommendation and is proposing that ophthalmic photocoagulators be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.4750; Docket No. 78N-3268; Ophthalmic eye shield.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ophthalmic eye shields:

1. Identification: An ophthalmic eye shield is a device that consists of a plastic or aluminum eye covering that is used to protect the eye or retain dressing materials in place.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that ophthalmic eye shields be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to ensure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that ophthalmic eye shields be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulation. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of ophthalmic eye shields be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of ophthalmic eye shields be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device who does not label or otherwise represent it as sterile be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.4770; Docket No. 78N-3269; Ophthalmic operating spectacles (loupes).

The Ophthalmic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of ophthalmic operating spectacles (loupes):

1. Identification: Ophthalmic operating spectacles (loupes) are devices that consist of convex lenses or lens systems worn by a surgeon to magnify the surgical site during ophthalmic surgery.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that ophthalmic operating spectacles (loupes) be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based. The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that ophthalmic operating spectacles (loupes) be classified into class I (general controls) with no exemptions. The agency believes that general controls alone are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 886.4790; Docket No. 78N-3270; Ophthalmic sponge.

The Ophthalmic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of ophthalmic sponges:

1. Identification: An ophthalmic sponge is a device that is a sponge or an absorbent pad of folded gauze or cotton used to absorb fluids from the operative field in ophthalmic surgery.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that ophthalmic sponges be classified into class II because the Panel believes that a performance standard is necessary to prevent shedding of particles of the device material which may subsequently become intraocular foreign bodies. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel also believes that the device should be capable of being sterilized and that the composition of materials used in the device should be specified in the labeling.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Surgical reintervention and adverse tissue reaction: If particles of the device material shed, they may become intraocular foreign bodies, resulting in an adverse tissue reaction and possible requiring corrective followup surgery. (b) Infection: If the device cannot be sterilized properly, and infection in the patient may result.

FDA agrees with the Panel recommendation and is proposing that ophthalmic sponges be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is sufficient information to establish a performance standard for this device.

Section 886.4855; Docket No. 78N-3272; Ophthalmic instrument table.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ophthalmic instrument tables:

1. Identification: An ophthalmic instrument table is an AC-powered or manual device on which ophthalmic instruments are placed.

2. Recommended classification: The Panel recommends that AC-powered ophthalmic instrument tables be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority. The Panel recommends that manual ophthalmic instrument tables be classified into class I (general controls) and that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that AC-powered ophthalmic instrument tables be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel recommends that manual ophthalmic instrument tables be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to assure the safety and effectiveness of the device. The Panel recommends that labeling include a warning regarding the sudden release of any springs that may be present.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of AC-powered ophthalmic instrument tables may cause electrical shock to the patient or user. The Panel identified no risks to health associated with manual ophthalmic instrument tables.

FDA agrees with the Panel recommendation and is proposing that AC-powered ophthalmic instrument tables be classified into class II (performance standards) and that manual ophthalmic instrument tables be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulation. The agency believes that a performance standard is necessary for AC-powered ophthalmic instrument tables because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the AC-powered device. FDA believes that there is sufficient information to establish a performance standard for the AC-powered device. FDA is proposing that manual ophthalmic instrument tables be

classified into class I (general controls) because it believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of manual ophthalmic instrument tables be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). In response to the Panel's recommendation that manufacturers of manual ophthalmic instrument tables be exempt from the device GMP regulation under section 520 (f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.5100; Docket No. 78N–3273; Ophthalmic beta radiation source.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ophthalmic beta radiation sources:

1. Identification: An ophthalmic beta radiation source is a therapeutic medical device used to apply radiation superficially to benign and malignant ocular growths.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that beta radiation sources be classified into class II because the radiation properties of the device must be controlled to prevent exposure of the patient or user to excessive radiation and that the materials used in the construction of the device must be controlled to ensure biocompatibility. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel believes that this device should be restricted to use by operators with adequate training and that the device comply with applicable regulations of the Nuclear Regulatory Commission.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Energy damage to tissue: Inadequate shielding or poor calibration of the device could result in exposure of the patient or operator to excessive radiation resulting in tissue damage. (b) Adverse tissue reaction: If the materials used in the construction of this device are not biocompatible, the patient may have an adverse tissue reaction.

FDA agrees with the Panel recommendation and is proposing that ophthalmic beta radiation sources be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.5120; Docket No. 78N–3274; Low-power binocular loupe.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of low-power binocular loupes:

1. Identification: A low-power binocular loupe is a device that consists of two eyepieces, each with a lens or lens system, intended for medical purposes to magnify the appearance of objects.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that low-power binocular loupes be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to ensure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that low-power binocular loupes be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulation. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of low-power binocular loupes be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of low-power binocular loupes be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See the discussion under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.5270; Docket No. 78N–3276; Spectacle frame.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of spectacle frames:

1. Identification: A spectacle frame is a device made of metal or plastic used to hold lenses worn by a patient to correct refractive errors.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that spectacle frames be classified into class II because the Panel believes that a performance standard is necessary to ensure that the materials used in the construction of the device are nonflammable and do not cause dermatitis. The Panel also believes that the design of the device must be controlled to prevent interference with the patient's vision. The design and construction of the device must also be controlled to prevent breakage of the frame or lens. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device. The Panel also recognizes the existence of the American National Standards Institute Z–80 standards for spectacle frames.

5. Risks to health: (a) Dermatitis: Certain frame materials could cause dermatitis. (b)

Burns: If the materials used in the Construction of the device are flammable, burns to the patient could result. (c) Traumatic injury: Faulty construction of the device could result in breakage of the frame or lens and subsequent injury to the patient. (d) Vision blockage: Improper design of the device could result in blockage of the patient's vision.

FDA agrees with the Panel recommendation and is proposing that spectacle frames be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is sufficient information to establish a performance standard for this device.

Section 886.5400; Docket No. 78N-3277; Polymethylmethacrylate contact lens.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classifiction of polymethylmethacrylate contact lenses:

1. Identification: A polymethylmethacrylate (hard) contact lens is a device that is a curved shell of polymethylmethacrylate that is worn by a patient for extended periods of time directly on the globe or cornea of the eye to correct refractive errors.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that polymethylmethacrylate contact lenses be classified into class II because the Panel believes that a performance standard is necessary to prevent poor lens configuration, rough lens edges, or insufficient polishing, which may cause corneal epithelial abrasion. The Panel believes that a contaminated lens may cause corneal infection. The Panel also believes that a performance standard is necessary to ensure that the materials used in the contruction of the device are biocompatible. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device. The Panel recognizes the existence of the American National Standards Institute Z-80.2 standards for polymethylmethacrylate contact lenses.

5. Risks to health: (a) Corneal damage. Corneal epithelial abrasions may result from poor lens configuration, rough lens edges, or an insufficiently polished lens. (b) Infection: If the device cannot be sterilized properly, an infection in the patient may result. (c) Adverse tissue reaction: If the materials used in the construction of the device are not biocompatible, the patient may have an adverse tissue reaction.

FDA agrees with the Panel recommendation and is proposing that polymethylmethacrylate contact lenses be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is sufficient information to establish a performance standard for this device.

The lenses subject to this proposal are commonly known as hard contact lenses. FDA is not publishing a proposal on soft contact lenses, for the reasons given in the discussion in this preamble under the heading "Ophthalmic Devices Formerly Considered New Drugs." FDA will publish a final regulation on soft contact lenses on the same date as the final regulation based on this proposal.

Section 886.5420; Docket No. 78N-3278; Contact lens inserter/remover.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of contact lens inserters/removers:

1. Identification: A contact lens inserter/remover is a handheld device used to insert or remove contact lenses by surface adhesion or suction.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that contact lens inserters/removers be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that contact lens inserters/removers be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 886.5450; Docket No. 78N-3279; Prescription spectacle lens.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of prescription spectacle lenses:

1. Identification: A prescription spectacle lens is a glass or plastic device that is a lens worn in a frame by a patient to correct refractive errors.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that prescription spectacle lenses be classified into class II because the Panel believes that a performance standard is necessary to ensure that the device is impact resistant to prevent eye trauma as a result of lens breakage. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel recognizes the existence of the American National Standards Institute Z-80 Committee standards for spectacle lenses. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Traumatic injury: Trauma to the eye could result from lens breakage.

FDA agrees with the Panel recommendation and is proposing that prescription spectacle lenses be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. FDA believes that there is sufficient information to establish a performance standard for this device and that the performance standard promulgated at 21 CFR 801.410 provides reasonable assurance of the safety and effectiveness of the device.

Section 886.5540; Docket No. 78N-3281; Low-vision magnifier.

The Ophthalmic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of low-vision magnifiers:

1. Identification: A low-vision magnifier is a device that consists of a magnifying lens, which may be handheld or attached to spectacles, and that is intended for use by a patient who has impaired vision.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from the good manufacturing practice regulation under

section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that low-vision magnifiers be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is readily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to ensure the safety or effectiveness of the device. The Panel recommends that the degree of magnification provided by the device should be specified in the labeling.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that low-vision magnifiers be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulation. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of low-vision magnifiers be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of low-vision magnifiers be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.5600; Docket No. 78N-3282; Ptosis crutch.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ptosis crutches:

1. Identification: A ptosis crutch is a device that is mounted on the spectacles of a patient who has ptosis (drooping of the upper eyelid as a result of faulty development or paralysis) to hold the upper eyelid open.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that ptosis crutches be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that this device may cause abrasion of the eyeball if the device is improperly aligned.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Eyeball abrasion: If the device is improperly aligned, it may press against the upper eyelid and cause abrasion of the eyeball.

FDA agrees with the Panel recommendation and is proposing that ptosis crutches be classified into class I (general controls) with no exemptions. The agency believes that general controls alone are sufficient to provide reasonable assurance of the safety and effectiveness of the device. FDA believes that the risk to health noted by the Panel (eyeball abrasion) would occur only if the device was misused.

Section 886.5800; Docket No. 78N-3283; Ophthalmic bar reader.

The Ophthalmic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of ophthalmic bar readers:

1. Identification: An ophthalmic bar reader is a device that consists of a magnifying lens that is intended for use by a patient who has impaired vision and that is placed directly onto reading material to magnify print.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that ophthalmic bar readers be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 530(f) of the act because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to ensure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that ophthalmic bar readers be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulation. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of ophthalmic bar readers be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of ophthalmic bar readers be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacturer of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.5810; Docket No. 78N-3284; Ophthalmic prism reader.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ophthalmic prism readers:

1. Identification: An ophthalmic prism reader is a device intended for use by a patient who is in a supine position, to change the angle of print to aid reading.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that ophthalmic prism readers be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is

easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to assure the safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that ophthalmic prism readers be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulation. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of ophthalmic prism readers be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of ophthalmic prism readers be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.5820; Docket No. 78N–3285; Closed-circuit television reading system.

The Ophthalmic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of closed-circuit television reading systems:

1. Identification: A closed-circuit television reading system is a device that consists of a lens, video camera, and video monitor and that is intended for use by a patient who has subnormal vision, to magnify reading material.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that closed-circuit television reading systems be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper electrical design or a malfunction of this device may cause electrical shock to the patient or user.

FDA agrees with the Panel recommendation and is proposing that closed-circuit television reading systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 886.5840; Docket No. 78N–3286; Magnifying spectacles.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of magnifying spectacles:

1. Identification: Magnifying spectacles are devices with convex lenses intended to be worn by a patient who has impaired vision, to enlarge the image of objects.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: the Panel recommends that magnifying spectacles be classified into class II because a performance standard is necessary to ensure that the device is impact resistant to prevent eye trauma as a result of lens breakage. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel noted the American National Standards Institute Z–80 Committee standards for lenses for spectacles.

4. Summary of data on which the recommendation is based: the Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Traumatic injury: Trauma to the eye could result from breakage of the device.

FDA agrees with the Panel recommendation and is proposing that magnifying spectacles be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. FDA believes that there is sufficient information to establish a performance standard for this device and that the performance standard promulgated at 21 CFR 801.410 provides reasonable assurance of the safety and effectiveness of the device.

Section 886.5850; Docket No. 78N–3287; Sunglasses (nonprescription).

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of sunglasses (nonprescription):

1. Identification: Sunglasses (nonprescription) are a device that consists of absorbing, reflective, tinted, or polarizing lenses in a frame that an individual wears to protect the eyes from bright sunlight. This generic type of device also includes sunglasses with photosensitized lenses.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for these devices be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that sunglasses (nonprescription) be classified into class II because the Panel believes that the materials used in the construction of devices must be controlled to prevent shattering of the lenses and flammability of the frame and lenses. The Panel recognizes the existence of the American National Standards Institute Z–80 Committee standards for sunglasses. The Panel recommends that flammability standards should be developed for the frame and lenses. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, these devices.

5. Risks to health: (a) Traumatic injury: Trauma to the eye or orbit could result from lens breakage. (b) Burns: Serious burns could result from the use of flammable material in the frame or lenses.

FDA agrees with the Panel recommendation and is proposing that sunglasses (nonprescription) be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by the device. FDA

believes that there is sufficient information to establish a performance standard for this device and that the performance standard promulgated at 21 CFR 801.410 provides assurance of the safety and effectiveness of the device regarding impact resistance. However, this standard has no requirements concerning reducing the possible hazard of flammability of the device.

Section 886.5870; Docket No. 78N-3288; Low-vision telescope.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of low-vision telescopes:

1. Identification: A low-vision telescope is a device that consists of an arrangement of lenses or mirrors and that is intended for use by a patient who has impaired vision, to increase the apparent size of objects. This generic type of device includes handheld or spectacle telescopes.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) or the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)), and exempt from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that low-vision telescopes be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to ensure the safety or effectiveness of the device. The Panel recommends that the degree of magnification provided by the device be specified in the labeling of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommmendation and is proposing that low-vision telescopes be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of low-vision telescopes be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

FDA disagrees with the Panel's recommendation that manufacturers of low-vision telescopes be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)). The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent production of low-vision telescopes having defects that could harm users. See the discussion under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 886.5900; Docket No. 78N-3290; Electronic vision aid.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of electronic vision aids:

1. Identification: An electronic vision aid is an AC-powered or battery-powered device that consists of an electronic sensor/transducer and that is intended for use by a patient who has impaired vision or blindness, to translate visual images of objects into tactile or auditory signals.

2. Recommended classification: The Panel recommends that AC-powered electronic vision aids be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority. The Panel recommends that battery-powered electronic vision aids be classified into class I (general controls) and that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that AC-powered electronic vision aids be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient or user. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel recommends that battery-powered electronic vision aids be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that the risk of electrical shock is minimal with battery-powered electronic vision aids. The Panel also recommends that the labeling of all electronic vision aids include instructions written in braille.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of AC-powered electronic vision aids may cause electrical shock to the patient or user. The Panel identified no risks to health associated with the use of battery-powered electronic vision aids.

FDA agrees with the Panel recommendation and is proposing that AC-powered electronic vision aids be classified into class II (performance standards) and that battery-powered electronic vision aids be classified into class I (general controls) with no exemptions. The agency believes that a performance standard is necessary for AC-powered electronic vision aids because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the AC-powered device. The agency also believes that there is sufficient information to establish a performance standard for the AC-powered device. FDA is proposing that battery-powered electronic vision aids be classified into class I (general controls) because the agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 886.5910; Docket No. 78N-3292; Battery-powered image intensification vision aid.

The Ophthalmic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of battery-powered image intensification vision aids:

1. Identification: A battery-powered image intensification vision aid is a battery-powered device that is intended for use by a patient who has limited dark adaptation or impaired vision, to amplify ambient light.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that battery-powered image intensification vision aids be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that battery-powered image intensification vision aids be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide

reasonable assurance of the safety and effectiveness of the device.

Section 886.5915; Docket No. 78N-3293; Optical vision aid.

The Ophthalmic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of optical vision aids:

1. Identification: An optical vision aid is a device that consists of a magnifying lens with accompanying AC-powered or battery-powered light source and that is intended for use by a patient who has impaired vision, to increase the apparent size of object detail.

2. Recommended classification: The Panel recommends that AC-powered optical vision aids be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority. The Panel recommends that battery-powered optical vision aids be classified into class I (general controls) and that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that AC-powered optical vision aids be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock to the patient. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel recommends that battery-powered optical vision aids be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that the risk of electrical shock is minimal with battery-powered optical vision aids. The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the act because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user. The Panel recommends that this device be exempt from records and reports requirements under section 519 of the act because the Panel believes that these requirements are not necessary to assure the safety or effectiveness of the device. The Panel recommends that the labeling of all optical vision aids include instructions written in braille.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: Electrical shock: Improper design or a malfunction of the AC-powered device may cause electrical shock to the patient. The Panel identified no risks to health associated with the use of battery-powered optical vision aids.

FDA agrees with the Panel recommendation and is proposing that AC-powered optical vision aids be classified into class II (performance standards) and that battery-powered optical vision aids be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulation. The agency believes that a performance standard is necessary for AC-powered optical vision aids because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the AC-powered device. The agency also believes that there is sufficient information to establish a performance standard for the AC-powered device. The ageny is proposing that battery-powered optical vision aids be classified into class I (general controls) because the agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of battery-powered optical vision aids be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i).

In response to the Panel's recommendation that manufacturers of battery-powered optical vision aids be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

References

The following information has been placed in the Dockets Management Branch (HFA-305) (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

(1) Association for the Advancement of Medical Instrumentation, "American National Standard: Safe Current Limits for Electromedical Apparatus," ANSI/AAMI SCL 12/78, Association for the Advancement of Medical Instrumentation, Arlington, VA, 1978.

(2) Underwriters Laboratory, "UL 544: Standard for Medical and Dental Equipment," Underwirters Laboratory, Northbrook, IL, 1972.

(3) Carney, H. M., "An Experimental Study With Tantalum," *Proceedings of the Society for Experimental Biology and Medicine*, 51:147-148, 1942.

(4) Pudenz, R. H., "The Use of Tantalum Clips for Hemostasis in Neurosurgery," *Surgery*, 12:791, 1942.

(5) L'Esperance, F. A., Jr., "Absorbable Collagen and Encircling Elements in Retinal Detachment Surgery," *Transactions of the American Academy of Ophthalmology and Otolaryngology*, March-April 1966.

(6) King, L. M., Jr., et al., "Gelatin Implants in Scleral Buckling Procedures," *Archives Ophthalmology*, Vol. 93, September 1975.

(7) Vistnes, L. M. and G. L. Paris, "Uses of RTV Silicone in Orbital Reconstruction," *American Journal of Ophthalmology*, Vol. 83, April 1977.

(8) Lyall, M. G., Proplast® Implant in Tenon's Capsule After Excision of the Eye," Transactions of the Ophthalmological Society of the United Kingdom, Vol. 96, 1976.

(9) Hill, J. C. and C. J. Radford, "Treatment of Advancing Enophthalmos," *American Journal of Ophthalmology*, Vol. 60, 1965.

(10) Freeman, R. S., T. M. Biggs, and A. E. Beall, "Injectable Silastic in Deformities of the Facial Skeleton," *Archives of Surgery*, Vol. 90, 1965.

(11) Otto, A. J. and J. M. H. M. Bourghouts, "Orbital Corrections with the Use of Alloplastic Material," Proceedings of the 2d International Symposium on Orbital Disorders, Amsterdam, 1973, *Modern Problems in Ophthalmology*, Vol. 14, pp. 641-644 (Karger, Basel 1975).

(12) Kumpf, W., "Orbital Floor Support Using Silicone Tubes," Proceedings of the 2d International Symposium on Orbital Disorders, Amsterdam, 1973, *Modern Problems in Ophthalmology*, Vol. 14, pp. 489-492, (Karger, Basel 1975).

(13) Converse, J. M., B. Smith, M. F. Obear, and D. Wood-Smith, "Orbital Blow-Out Fractures. A Ten-Year Survey," *Plastic Reconstructive Surgery*, Vol. 39, P. 20, 1967.

Environmental Impact

The agency has determined pursuant to 21 CFR 25.24(b)(12) (proposed December 11, 1979; 44 FR 71742) that this proposed action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), it is proposed that Chapter I of Title 21 of the Code of Federal Regulations be amended by adding new Part 886, to read as follows:

PART 886—OPHTHALMIC DEVICES

Subpart A—General Provisions

Sec.
886.1 Scope.

Subpart B—Ophthalmic Diagnostic Devices

886.1040 Ocular esthesiometer.
886.1050 Adaptometer (biophotometer).
886.1070 Anomaloscope.
886.1090 Haidinger brush.
886.1120 AC-powered ophthalmic camera.
886.1140 Ophthalmic chair.
886.1150 Visual Acuity chart.
886.1160 Color vision plate illuminator.
886.1170 Color vision tester.
886.1190 Distometer.
886.1200 Optokinetic drum.
886.1220 Corneal electrode.
886.1250 Euthyscope.
886.1270 Exophthalmometer.
886.1290 AC-powered fixation device.
886.1300 Afterimage flasher.
886.1310 Fluorescein strip.
886.1320 Fornixscope.
886.1330 Amsler grid.
886.1340 Haploscope.
886.1350 Keratoscope.
886.1360 Visual field laser instrument.
886.1375 Bagolini lens.
886.1380 Diagnostic condensing lens.
886.1385 Polymethylmethacrylate diagnostic contact lens.
886.1390 Flexible diagnostic Fresnel lens.
886.1395 Diagnostic Hruby fundus lens.
886.1400 Maddox lens.
886.1405 Ophthalmic trial lens set.
886.1410 Ophthalmic trial lens clip.
886.1415 Ophthalmic trial lens frame.
886.1420 Ophthalmic lens gauge.
886.1425 AC-powered lens measuring instrument.
886.1430 Ophthalmic contact lens radius measuring device.
886.1435 AC-powered Maxwell spot.
886.1450 Corneal radius measuring device.
886.1460 Stereopsis measuring instrument.
886.1500 Headband mirror.
886.1510 Eye movement monitor.
886.1570 Ophthalmoscope.
886.1605 Perimeter.
886.1630 AC-powered photostimulator.
886.1640 Ophthalmic preamplifier.
886.1650 Ophthalmic bar prism.
886.1655 Ophthalmic Fresnel prism.
886.1660 Gonioscopic prism.
886.1665 Ophthalmic rotary prism.
886.1670 Ophthalmic isotope uptake probe.
886.1680 Ophthalmic projector.
886.1690 Pupillograph.
886.1700 Pupillometer.
886.1750 Skiascopic rack.
886.1760 Ophthalmic refractometer.
886.1770 Manual refractor.
886.1780 Retinoscope.
886.1790 Nearpoint ruler.
886.1800 Schirmer strip.
886.1810 Tangent screen (campimeter).
886.1840 Simulatant (including crossed cylinder).
886.1850 AC-powered slitlamp biomicroscope.
886.1860 Ophthalmic instrument stand.
886.1870 Stereoscope.
886.1880 Fusion and stereoscopic target.
886.1905 Nystagmus tape.
886.1910 Spectacle dissociation test system.
886.1930 Tonometer and accessories.
886.1940 Tonometer sterilizer.
886.1945 Transilluminator.

Subpart C—[Reserved]

Subpart D—Ophthalmic Prosthetic Devices

886.3100 Ophthalmic tantalum clip.
886.3130 Ophthalmic conformer.
886.3200 Artificial eye.
886.3300 Absorbable implant (scleral buckling method).
886.3320 Eye sphere implant.
886.3340 Extraocular orbital implant.
886.3400 Keratoprosthesis.
886.3800 Scleral shell.
886.3920 Eye valve implant.

Subpart E—Ophthalmic Surgical Devices

886.4070 Powered corneal burr.
886.4100 Radiofrequency cautery apparatus.
886.4115 Thermal cautery unit.
886.4150 Viterous aspiration and cutting instrument.
886.4170 Cryophthalmic unit.
886.4230 Ophthalmic knife test drum.
886.4250 Ophthalmic electrolysis unit.
886.4300 Intraocular lens guide.
886.4335 Operating headlamp.
886.4350 Manual ophthalmic surgical instrument.
886.4360 Ocular surgery irrigation device.
886.4370 Keratome.
886.4390 Ophthalmic laser.
886.4400 Electronic metal locator.
886.4440 AC-powered magnet.
886.4445 Permanent magnet.
886.4570 Ophthalmic surgical marker.
886.4610 Ocular pressure applicator.
886.4650 Eye pad.
886.4670 Phacofragmentation system.
886.4690 Ophthalmic photocoagulator.
886.4750 Ophthalmic eye shield.
886.4770 Ophthalmic operating spectacles (loupes).
886.4790 Ophthalmic sponge.
886.4855 Ophthalmic instrument table.

Subpart F—Ophthalmic Therapeutic Devices

886.5100 Ophthalmic beta radiation source.
886.5120 Low-power binocular loupe.
886.5270 Spectacle frame.
886.5400 Polymethylmethacrylate contact lens.
886.5420 Contact lens inserter/remover.
886.5450 Prescription spectacle lens.
886.5540 Low-vision magnifier.
886.5600 Ptosis crutch.
886.5800 Ophthalmic bar reader.
886.5810 Ophthalmic prism reader.
886.5820 Closed-circuit television reading system.
886.5840 Magnifying spectacles.
886.5850 Sunglasses (nonprescription).
886.5870 Low-vision telescope.
886.5900 Electronic vision aid.
886.5910 Battery-powered image intensification vision aid.
886.5915 Optical vision aid.

Authority: Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).

Subpart A—General Provisions

§ 886.1 Scope.

(a) This part sets forth the classification of ophthalmic devices intended for human use.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, an ophthalmic device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed in one subpart only.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

Subpart B—Ophthalmic Diagnostic Devices

§ 886.1040 Ocular esthesiometer.

(a) *Identification.* An ocular esthesiometer is a device such as a single-hair brush used to touch the cornea to assess corneal sensitivity.

(b) *Classification.* Class I (general controls).

§ 886.1050 Adaptometer (biophotometer).

(a) *Identification.* An adaptometer (biophotometer) is an AC-powered device that provides a stimulating light source which has various controlled intensities used to measure the time required for retinal adaptation (regeneration of the visual purple) and the minimum light threshold.

(b) *Classification.* Class II (performance standards).

§ 886.1070 Anomaloscope.

(a) *Identification.* An anomaloscope is an AC-powered device used to test for anomalies of color vision by displaying mixed spectral lines to be matched by the patient.

(b) *Classification.* Class II (performance standards).

§ 886.1090 Haidinger brush.

(a) *Identification.* A Haidinger brush is an AC-powered device that provides two conical brushlike images with apexes touching which are viewed by the patient through a Nicol prism and used to evaluate visual function. It may

include a component for measuring macular integrity.

(b) *Classification.* Class II (performance standards).

§ 886.1120 AC-powered ophthalmic camera.

(a) *Identification.* An AC-powered ophthalmic camera is a device used to take photographs of the eye and the surrounding area.

(b) *Classification.* Class II (performance standards).

§ 886.1140 Ophthalmic chair.

(a) *Identification.* An ophthalmic chair is an AC-powered or manual device with adjustable positioning in which a patient sits or reclines during ophthalmological examination or treatment.

(b) *Classification.* (1) Class II (performance standards) for AC-powered ophthalmic chairs.

(2) Class I (general controls) for manual ophthalmic chairs.

§ 886.1150 Visual acuity chart.

(a) *Identification.* A visual acuity chart is a device that is a chart such as a Snellen chart with block letters or other symbols in graduated sizes used to test visual acuity.

(b) *Classification.* Class II (performance standards).

§ 886.1160 Color vision plate illuminator.

(a) *Identification.* A color vision plate illuminatior is an AC-powered device that is a lamp used to properly illuminate color vision testing plates. It may include a filter.

(b) *Classification.* Class II (performance standards).

§ 886.1170 Color vision tester.

(a) *Identification.* A color vision tester is a device that consists of various colored materials such as colored yarns or color vision plates (multicolored plates which patients with color vision deficiency would perceive as being of one color) used to evaluate color vision.

(b) *Classification.* Class I (general controls).

§ 886.1190 Distometer.

(a) *Identification.* A distometer is a device used to measure the distance between the cornea and a corrective lens during refraction (measuring the change of the visual image when a lens is in place).

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1200 Optokinetic drum.

(a) *Identification.* An optokinetic drum is a drumlike device that is covered with alternating white and dark stripes or pictures that can be rotated on its handle. The device is used to elicit and evaluate nystagmus (involuntary rapid movement of the eyeball) in patients.

(b) *Classification.* Class I (general controls).

§ 886.1220 Corneal electrode.

(a) *Identification.* A corneal electrode is an AC-powered device, usually part of a special contact lens, that is applied directly to the cornea and used to provide data showing the changes in electrical potential in the retina after electroretinography (stimulation by light).

(b) *Classification.* Class II (performance standards).

§ 886.1250 Euthyscope.

(a) *Identification.* A euthyscope is a device that is a modified AC-powered or battery-powered ophthalmoscope (a perforated mirror device used in inspecting the interior of the eye) that projects a bright light encompassing an arc of about thirty degrees onto the fundus of the eye. The center of the light bundle is blocked by a black disk covering the fovea (the central depression of the macular retinae where only cones are present and blood vessels are lacking). The device is used in the treatment of amblyopia (dimness of vision without apparent disease of the eye).

(b) *Classification.* (1) Class II (performance standards) for AC-powered euthyscopes.

(2) Class I (general controls) for battery-powered euthyscopes.

§ 886.1270 Exophthalmometer.

(a) *Identification.* An exophthalmometer is a device, such as a ruler, gauge, or caliper, used to measure the degree of exophthalmos (abnormal protrusion of the eyeball).

(b) *Classification.* Class I (general controls).

§ 886.1290 AC-powered fixation device.

(a) *Identification.* An AC-powered fixation device is an AC-powered device used as a fixation target for the patient during ophthalmological examination. The patient directs his or her gaze so that the visual image of the object falls on the fovea centralis (the center of the macula retina of the eye).

(b) *Classification.* Class II (performance standards).

§ 886.1300 Afterimage flasher.

(a) *Identification.* An afterimage flasher is an AC-powered light that automatically switches on and off to allow performance of an afterimage test in which the patient indicates the positions of afterimages after the light is off. The device is used to determine harmonious/anomalous retinal correspondence (the condition in which corresponding points on the retina have the same directional value).

(b) *Classification.* Class II (performance standards).

§ 886.1310 Fluorescein strip.

(a) *Identification.* A fluorescein strip is a device that is a small strip of filter paper impregnated with fluorescein (a dye used for the diagnosis of certain ocular diseases) used to apply the fluorescein to the surface of the eye.

(b) *Classification.* Class I (general controls).

§ 886.1320 Fornixscope.

(a) *Identification.* A fornixscope is a device used to pull back and hold open the eyelid to aid examination of the conjunctiva.

(b) *Classification.* Class I (general controls).

§ 886.1330 Amsler grid.

(a) *Identification.* An Amsler grid is a device that is a series of charts with grids of different sizes that are held at 30 centimeters distance from the patient and used for the rapid detection of central and paracentral irregularities in the visual field.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1340 Haploscope.

(a) *Identification.* A haploscope is an AC-powered device that consists of two movable viewing tubes, each containing a slide carrier, a low-intensity light source for the illumination of the slides, and a high-intensity light source for creating afterimages. The device is used to measure strabismus (eye muscle imbalance), to assess binocular vision (use of both eyes to see), and to treat suppression and amblyopia (dimness of vision without any apparent disease of the eye).

(b) *Classification.* Class II (performance standards).

§ 886.1350 Keratoscope.

(a) *Identification.* A keratoscope is an AC-powered or battery-powered device used to measure and evaluate the corneal curvature of the eye. Lines and circles within the keratoscope are used to observe the corneal reflex. This generic type of device includes the photokeratoscope which records corneal curvature by taking photographs of the cornea.

(b) *Classification.* (1) Class II (performance standards) for AC-powered keratoscopes.

(2) Class I (general controls) for battery-powered keratoscopes. The battery-powered keratoscope is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1360 Visual field laser instrument.

(a) *Identification.* A visual field laser instrument is an AC-powered device that provides visible laser radiation that produces an interference pattern on the retina used to evaluate retinal function.

(b) *Classification.* Class II (performance standards).

§ 886.1375 Bagolini lens.

(a) *Identification* A Bagolini lens is a device consisting of a plane lens containing almost imperceptible striations that do not obscure visualization of objects. The device is placed in a trial frame and used to determine harmonious/anomalous retinal correspondence (the condition in which corresponding points on the retina have the same directional value).

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1380 Diagnostic condensing lens.

(a) *Identification.* A diagnostic condensing lens is a device that is a lens used to focus reflected light from the fundus of the eye in binocular indirect ophthalmoscopy (a procedure that produces an inverted or reversed direct magnified image of the eye).

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1385 Polymethylmethacrylate diagnostic contact lens.

(a) *Identification.* A polymethylmethacrylate diagnostic contact lens is a device that is a curved shell of polymethylmethacrylate applied for a short period of time directly onto the globe or cornea of the eye for diagnosis or therapy of intraocular abnormalities.

(b) *Classification.* Class II (performance standards).

§ 886.1390 Flexible diagnostic Fresnel lens.

(a) *Identification.* A flexible diagnostic Fresnel lens is a device that is a very thin lens which has on its surface a concentric series of increasingly refractive zones. The device may be applied to the back of the spectacle lenses of patients with aphakia (absence of the lens of the eye).

(b) *Classification.* Class I (general controls).

§ 886.1395 Diagnostic Hruby fundus lens.

(a) *Identification.* A diagnostic Hruby fundus lens is a device that is a 55 diopter lens used in examination of the vitreous body and the fundus of the eye under slit-lamp illumination and magnification.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1400 Maddox lens.

(a) *Identification.* A Maddox lens is a device that is a series of red cylinders that change the size, shape, and color of an image. The device is handheld or placed in a trial frame and used to evaluate eye muscle dysfunction.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1405 Ophthalmic trial lens set.

(a) *Identification.* An ophthalmic trial lens set is a device that is a set of lenses of various dioptric powers that are handheld or inserted in a trial frame and used in vision testing to determine refraction.

(b) *Classification.* Class II (performance standards).

§ 886.1410 Ophthalmic trial lens clip.

(a) *Identification.* An ophthalmic trial lens clip is a device used to place prisms, spheres, cylinders, or occluders on a trial frame or spectacles for vision testing.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1415 Ophthalmic trial lens frame.

(a) *Identification.* An ophthalmic trial lens frame is a mechanical device used to hold trial lenses during vision testing.

(b) *Classification.* Class I (general controls).

§ 886.1420 Ophthalmic lens gauge.

(a) *Identification.* An ophthalmic lens gauge is a calibrated device used manually to measure the curvature of a spectacle lens.

(b) *Classification.* Class I (general controls).

§ 886.1425 AC-powered lens measuring instrument.

(a) *Identification.* An AC-powered lens measuring instrument is an AC-powered device used to measure the power of lenses, prisms, and their centers (e.g., lensometer).

(b) *Classification.* Class II (performance standards).

§ 886.1430 Ophthalmic contact lens radius measuring device.

(a) *Identification.* An ophthalmic contact lens radius measuring device is an AC-powered device that is a microscope and dial gauge used to measure the radius of a contact lens.

(b) *Classification.* Class II (performance standards).

§ 886.1435 AC-powered Maxwell spot.

(a) *Identification.* An AC-powered Maxwell spot is an AC-powered device that is a light source with a red and blue filter used to test macular function.

(b) *Classification.* Class II (performance standards).

§ 886.1450 Corneal radius measuring device.

(a) *Identification.* A corneal radius measuring device is an AC-powered device used to measure corneal size by superimposing the image of the cornea on a scale at the focal length of the lens of a small handheld single tube penscope or eye gauge magnifier.

(b) *Classification.* Class II (performance standards).

§ 886.1460 Stereopsis measuring instrument.

(a) *Identification.* A stereopsis measuring instrument is a device used to measure depth perception by battery-powered illumination or natural daylight illumination of objects placed on different planes.

(b) *Classification.* Class I (general controls).

§ 886.1500 Headband mirror.

(a) *Identification.* A headband mirror is a device that is strapped to the head of the user to reflect light for examination of the eye.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1510 Eye movement monitor.

(a) *Identification.* An eye movement monitor is an AC-powered device with an electrode used to measure and record ocular movements.

(b) *Classification.* Class II (performance standards).

§ 886.1570 Ophthalmoscope.

(a) *Identification.* An ophthalmoscope is an AC-powered or battery-powered device containing illumination and viewing optics used to examine the media (cornea, aqueous, lens, and vitreous) and the retina of the eye.

(b) *Classification.* (1) Class II (performance standards) for AC-powered ophthalmoscopes.

(2) Class I (general controls) for battery-powered ophthalmoscopes. The battery-powered device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1605 Perimeter.

(a) *Identification.* A perimeter is an AC-powered or manual device used to determine the extent of the peripheral visual field of a patient. The device projects light on various points of a curved surface, and the patient indicates whether he or she sees the light.

(b) *Classification.* (1) Class II (performance standards) for AC-powered perimeters.

(2) Class I (general controls) for manual perimeters. The manual device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1630 AC-powered photostimulator.

(a) *Identification.* An AC-powered photostimulator is an AC-powered device that provides light stimulus which allows measurement of retinal or visual function by perceptual or electrical methods (e.g., stroboscope).

(b) *Classification.* Class II (performance standards).

§ 886.1640 Ophthalmic preamplifier.

(a) *Identification.* An ophthalmic preamplifier is an AC-powered or battery-powered device used to amplify electrical signals from the eye in electroretinography (recording retinal action currents from the surface of the eyeball after stimulation by light), electro-oculography (testing for retinal dysfunction by comparing the standing potential in the front and the back of the eyeball), and electromyography (recording electrical currents generated in active muscle).

(b) *Classification.* Class II (performance standards).

§ 886.1650 Ophthalmic bar prism.

(a) *Identification.* An ophthalmic bar prism is a device that is a bar composed of fused prisms of gradually increasing strengths used to measure latent and manifest strabismus (eye muscle deviation) or the power of fusion of the patient's eyes.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1655 Ophthalmic Fresnel prism.

(a) *Identification.* An ophthalmic Fresnel prism is a device that is a thin plastic sheet with embossed rulings which provides the optical effect of a prism. The device is applied to spectacle lenses to give a prismatic effect.

(b) *Classification.* Class I (general controls).

§ 886.1660 Gonioscopic prism.

(a) *Identification.* A gonioscopic prism is a device that is a prism which may be placed on the eye for the study of anterior chamber angles. The device may have angled mirrors to facilitate visualization of anatomical features.

(b) *Classification.* Class I (general controls).

§ 886.1665 Ophthalmic rotary prism.

(a) *Identification.* An ophthalmic rotary prism is a handheld device with various prismatic powers used to measure ocular deviation in latent and manifest strabismus (eye muscle deviation).

(b) *Classification.* Class I (general controls).

§ 886.1670 Ophthalmic isotope uptake probe.

(a) *Identification.* An ophthalmic isotope uptake probe is an AC-powered device used to measure, by a probe which is placed in close proximity to the eye, the uptake of a radioisotope (phosphorus 32) by tumors to detect tumor masses on, around, or within the eye.

(b) Classification. Class II (performance standards).

§ 886.1680 Ophthalmic projector.

(a) *Identification.* An ophthalmic projector is an AC-powered device used to project an image on a screen for vision testing.

(b) *Classification.* Class II (performance standards).

§ 886.1690 Pupillograph.

(a) *Identification.* A pupillograph is an AC-powered device that measures the pupil of the eye by reflected light and records the responses of the pupil.

(b) *Classification.* Class II (performance standards).

§ 886.1700 Pupillometer.

(a) *Identification.* A pupillometer is an AC-powered or manual device used to measure by reflected light the width or diameter of the pupil of the eye.

(b) *Classification.* (1) Class II (performance standards) for AC-powered pupillometers.

(2) Class I (general controls) for manual pupillometers. The manual pupillometer is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1750 Skiascopic rack.

(a) *Identification.* A skiascopic rack is a device that is a ract and a set of attached ophthalmic lenses of various dioptric strengths used as an aid in refraction.

(b) *Classification.* Class II (performance standards).

§ 886.1760 Ophthalmic refractometer.

(a) *Identification.* An ophthalmic refractometer is an automatic AC-powered device that consists of a

fixation system, a measurement and recording system, and an alignment system used to measure the refractive power of the eye by measuring light reflexes from the retina.

(b) *Classification.* Class II (performance standards).

§ 886.1770 Manual refractor.

(a) *Identification.* A manual refractor is a device that is a set of lenses of various dioptric powers that are used to measure the refractive error of the eye.

(b) *Classification.* Class I (general controls).

§ 886.1780 Retinoscope.

(a) *Identification.* A retinscope is an AC-powered or battery-powered device used clinically to measure the refraction of the eye by illuminating the retina and noting the direction of movement of the light on the retinal surface and of the refraction by the eye of the emergent rays.

(b) *Classification.* (1) Class II (performance standards) for AC-powered retinoscopes.

(2) Class I (general controls) for battery-powered retinoscopes. The battery-powered device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1790 Nearpoint ruler.

(a) *Identification.* A near point ruler is a device calibrated in centimeters that is used to measure the nearpoint of convergence (the point to which the visual lines are directed when convergence is at its maximum).

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1800 Schirmer strip.

(a) *Identification.* A Schirmer strip is a device made of filter paper or similar material used to test for tear formation ability. It is inserted under the lower eyelid.

(b) *Classification.* Class I (general controls).

§886.1810 Tangent screen (campimeter).

(a) *Identification.* A tangent screen (compimeter) is an AC-powered or battery-powered device that is a large square cloth chart with a central mark of fixation used to map the central thirty degrees of the patient's visual field on a flat surface. This generic type of device includes projection tangent screens, target tangent screens and targets, felt tangent screens, and battery-powered stereo campimeters.

(b) *Classification.* (1) Class II (performance standards) for AC-powered tangent screens (campimeters).

(2) Class I (general controls) for battery-powered tangent screens (campimeters). The battery-powered device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1840 Simulatan (including crossed cylinder).

(a) *Identification.* A simulatan (including crossed cylinder) is a device that is a set of pairs of cylinder lenses that provides equal plus and minus various refractive strengths. The lenses are arranged so that the user can exchange the positions of plus and minus cylinder lenses of equal strengths. The device is used for subjective refraction (refraction in which the patient judges whether a given object is clearly in focus, as the examiner uses different lenses).

(b) *Classification.* Class I (general controls).

§ 886.1850 AC-powered slitlamp biomicroscope.

(a) *Identification.* An AC-powered slitlamp biomicroscope is an AC-powered device that is a microscope for eye examination that projects into the patient's eye through a control diaphragm a thin, intense beam of light.

(b) *Classification.* Class II (performance standards).

§ 886.1860 Ophthalmic instrument stand.

(a) *Identification.* An ophthalmic instrument stand is an AC-powered or nonpowered device used to store ophthalmic instruments and make them readily accessible.

(b) *Classification.* (1) Class II (performance standards) for AC-powered ophthalmic instrument stands.

(2) Class I (general controls) for nonpowered ophthalmic instrument stands. The nonpowered device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1870 Stereoscope

(a) *Identification.* A stereoscope is an AC-powered or battery-powered device tht combines the images of two similar objects to produce a three dimensional appearance of solidity and relief. It is used to measure the angle of strabismus (eye muscle deviation) and to evaluate binocular vision (usage of both eyes to see). The device is also used for corrective exercises for eye muscles.

(b) *Classification.* (1) Class II (performance standards for AC-powered stereoscopes.

(2) Class I (general controls) for battery-powered stereoscopes. The battery-powered device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1880 Fusion and stereoscopic target.

(a) *Identification.* A fusion and stereoscopic target is a device that is a viewing object used with a stereoscope (a device that combines the images of two similar objects to produce a three-dimensional appearance of solidity and relief). It is used in various ophthalmological examinations for eye muscle disorders, such as amblyopia (weak eye muscles), and for corrective exercises for eye muscles.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1905 Nystagmus tape.

(a) *Identification.* Nystagmus tape is a device that is a long, narrow strip of fabric or other flexible material on which a series of printed objects are moved across the patient's field of vision to elicit optokinetic nystagmus (abnormal and irregular eye movements) and to test for blindness.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1910 Spectacle dissociation test system.

(a) *Identification.* A spectacle dissociation test system is an AC-powered or battery-powered device, such as a Lancaster test system, that consists of a light source and various filters, especially red/green filters, that

is used subjectively to measure ocular muscle imbalance.

(b) *Classification.* (1) Class II (performance standards) for the AC-powered spectacle dissociation test system.

(2) Class I (general controls) for the battery-powered spectacle dissociation test system. The battery-powered device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1930 Tonometer and accessories.

(a) *Identification.* A tonometer and accessories is an AC-powered or manual device used to measure intraocular pressure by the degree of indentation produced by the application of a known force on the globe of the eye (Schiotz type) or to measure intraocular tension by applanation (the application of a small flat disk to the cornea). Accessories for the device may include a tonometer calibrator or a tonograph recording system. The device is used in the diagnosis of glaucoma.

(b) *Classification.* Class II (performance standards).

§ 886.1940 Tonometer sterilizer.

(a) *Identification.* A tonometer sterilizer is an AC-powered device that is used to sterilize by heat a tonometer (a device used to measure intraocular pressure).

(b) *Classification.* Class II (performance standards).

§ 886.1945 Transilluminator.

(a) *Identification.* A transilluminator is an AC-powered or battery-powered device that is a light source used to transmit light through tissues to aid patient examination.

(b) *Classification.* (1) Class II (performance standards) for AC-powered transilluminators.

(2) Class I (general controls) for battery-powered transilluminators.

Subpart C—[Reserved]

Subpart D—Ophthalmic Prosthetic Devices

§ 886.3100 Ophthalmic tantalum clip.

(a) *Identification.* An ophthalmic tantalum clip is a malleable metallic device used to bring together the edges of a wound to facilitate healing or to prevent bleeding from small blood vessels in the eye. The device may be implanted permanently, or removed after a short period of time.

(b) *Classification.* Class II (performance standards).

§ 886.3130 Ophthalmic conformer.

(a) *Identification.* An ophthalmic conformer is a device, usually made of molded plastic, that is inserted temporarily between the eyeball and eyelid to maintain space in the orbital cavity and used to prevent closure or adhesions during the healing process following plastic survey.

(b) *Classification.* Class II (performance standards).

§ 886.3200 Artificial eye.

(a) *Identification.* An artificial eye is a removable, prosthetic device resembling the eyeball, usually made of glass or plastic, that is placed in the eye socket for cosmetic purposes following removal of the eye.

(b) *Classification.* Class II (performance standards).

§ 886.3300 Absorbable implant (scleral buckling method).

(a) *Identification.* An absorbable implant (scleral buckling method) is an implanted device placed on the sclera to aid retinal reattachment.

(b) *Classification.* Class II (performance standards).

§ 886.3320 Eye sphere implant.

(a) *Identification.* An eye sphere implant is an implanted device used to occupy the space in the eyeball following the removal of the contents of the eyeball with the sclera left intact.

(b) *Classification.* Class II (performance standards).

§ 886.3340 Extraocular orbital implant.

(a) *Identification.* An extraocular orbital implant is a device used in scleral surgery for buckling or building up the floor of the eye, usually in conjunction with retinal reattachment. This nonabsorbable device includes implants and floor support for scleral buckling methods, but excludes injected substances.

(b) *Classification.* Class II (performance standards).

§ 886.3400 Keratoprosthesis.

(a) *Identification.* A keratoprosthesis is an implanted device, made of plastic, used to replace the central area of the opacified natural cornea of the eye and used to maintain or restore sight.

(b) *Classification.* Class III (premarket approval).

§ 886.3800 Scleral shell.

(a) *Identification.* A scleral shell is a removable device made of plastic or glass that fits over the cornea and proximalcornea sclera for cosmetic or reconstructive purposes. The device usually has an artificial eye painted on it.

(b) *Classification.* Class II (performance standards).

§ 886.3920 Eye valve implant.

(a) *Identification.* An eye valve implant is a one-way, pressure-sensitive, valve-like device used to normalize intraocular pressure. The device may be used in the treatment of glaucoma.

(b) *Classification.* Class III (premarket approval).

Subpart E—Ophthalmic Surgical Devices

§ 886.4070 Powered corneal burr.

(a) *Identification.* A powered corneal burr is an AC-powered or battery-powered device that is a motor and drilling tool used to remove rust rings from the cornea of the eye.

(b) *Classification.* (1) Class II (performance standards) for AC-powered corneal burrs.

(2) Class I (general controls) for battery-powered corneal burrs.

§ 886.4100 Radiofrequency cautery apparatus.

(a) *Identification.* Radiofrequency cautery apparatus is an AC-powered or battery-powered device used during ocular surgery to coagulate tissue or arrest bleeding by a high-frequency electric current.

(b) *Classification.* Class II (performance standards).

§ 886.4115 Thermal cautery unit.

(a) *Identification.* A thermal cautery unit is an AC-powered or battery-powered device used during ocular surgery to coagulate tissue or arrest bleeding by heat conducted through a wire tip.

(b) *Classification.* Class II (performance standards).

§ 886.4150 Vitreous aspiration and cutting instrument.

(a) *Identification.* A vitreous aspiration and cutting instrument is an electrically powered device, which may use ultrasound, that is used for the removal of vitreous matter from the vitreous cavity or for removal of the crystalline lens.

(b) *Classification.* Class III (premarket approval).

§ 886.4170 Cryophthalmic unit.

(a) *Identification.* A cryophthalmic unit is a device that is a probe with a small tip that becomes extremely cold through the controlled use of a refrigerant or gas. The device may be AC-powered. The device is used to remove cataracts by the formation of an adherent ice ball in the lens, to freeze

the eye and adjunct parts for surgical removal of scars, and to freeze tumors.

(b) *Classification.* Class II (performance standards).

§ 886.4230 Ophthalmic knife test drum.

(a) *Identification.* An ophthalmic knife test drum is a device used to test the keenness of ophthalmic surgical knives to determine whether resharpening is needed.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.4250 Ophthalmic electrolysis unit.

(a) *Identification.* An ophthalmic electrolysis unit is an AC-powered or battery-powered device used to destroy ocular hair follicles by the passage of a galvanic electric current.

(b) *Classification.* (1) Class II (performance standards) for AC-powered ophthalmic electrolysis units.

(2) Class I (general controls) for battery-powered ophthalmic electrolysis units.

§ 886.4300 Intraocular lens guide.

(a) *Identification.* An intraocular lens guide is a device that is inserted into the eye during surgery to direct the insertion of an intraocular lens.

(b) *Classification.* Class I (general controls).

§ 886.4335 Operating headlamp.

(a) *Identification.* An operating headlamp is an AC-powered or battery-powered device worn around the head of the user to provide a light source to aid visualization during surgical, diagnostic, or therapeutic procedures.

(b) *Classification.* (1) Class II (performance standards) for AC-powered operating headlamps.

(2) Class I (general controls) for battery-powered operating headlamps.

§ 886.4350 Manual ophthalmic surgical instrument.

(a) *Identification.* A manual ophthalmic surgical instrument is a nonpowered, handheld device used to aid or perform ophthalmic surgical procedures. This generic type of device includes the manual corneal burr, ophthalmic caliper, ophthalmic cannula, eyelid clamp, ophthalmic muscle clamp, iris retractor clip, orbital compressor, ophthalmic curette, cystotome, orbital depressor, lachrymal dilataor, erisophake, expressor, ophthalmic forcep, ophthalmic hook, sphere introducer, ophthalmic knife, ophthalmic suturing needle, lachrymal probe, trabeculotomy probe, corneoscleral punch, ophthalmic retractor, ophthalmic ring (Flieringa), lachrymal sac rongeur, ophthalmic scissors, enucleating snare, ophthalmic spatula, ophthalmic specula, ophthalmic spoon, ophthalmic spud, trabeculotome, or ophthalmic manual trephine.

(b) *Classification.* Class I (general controls).

§ 886.4360 Ocular surgery irrigation device.

(a) *Identification.* An ocular surgery irrigation device is a device that is suspended over the ocular area during ophthalmic surgery and delivers continuous controlled irrigation to the surgical field.

(b) *Classification.* Class I (general controls).

§ 886.4370 Keratome.

(a) *Identification.* A keratome is an AC-powered or battery-powered device used to shave tissue from sections of the cornea for a lamellar (partial thickness) transplant.

(b) *Classification.* (1) Class II (performance standards) for AC-powered keratomes.

(2) Class I (general controls) for battery-powered keratomes.

§ 886.4390 Ophthalmic laser.

(a) *Identification.* An ophthalmic laser is an AC-powered device used to coagulate tissue of the eye, orbit, and surrounding skin by a laser beam.

(b) *Classification.* Class II (performance standards).

§ 886.4400 Electronic metal locator.

(a) *Identification.* An electronic metal locator is an AC-powered device with probes used to locate metallic foreign bodies in the eye or eye socket.

(b) *Classification.* Class II (performance standards).

§ 886.4440 AC-powered magnet.

(a) *Identification.* An AC-powered magnet is an AC-powered device that generates a magnetic field and that is used to find and remove metallic foreign bodies from eye tissue.

(b) *Classification.* Class II (performance standards).

§ 886.4445 Permanent magnet.

(a) *Identification.* A permanent magnet is a nonelectronic device that generates a magnetic field and that is used to find and remove metallic foreign bodies from eye tissue.

(b) *Classification.* Class I (general controls).

§ 886.4570 Ophthalmic surgical marker.

(a) *Identification.* An ophthalmic surgical marker is a device used to mark the location of ocular or scleral surgical manipulation by ink, dye, or indentation.

(b) *Classification.* Class I (general controls).

§ 886.4610 Ocular pressure applicator.

(a) *Identification.* An ocular pressure applicator is a manual device that consists of a sphygmomanometer-type squeeze bulb, a dial indicator, a band, and bellows, and that is used to apply pressure on the eye in preparation for ophthalmic surgery.

(b) *Classification.* Class II (performance standards).

§ 886.4650 Eye pad.

(a) *Identification.* An eye pad is a device that consists of a pad of gauze and cotton used as a bandage over the eye for protection and absorption of secretions.

(b) *Classification.* Class I (general controls).

§ 886.4670 Phacofragmentation system.

(a) *Identification.* A phacofragmentation system is an AC-powered device with a fragmenting needle used in cataract surgery to disrupt a cataract with ultrasound and extract the cataract.

(b) *Classification.* Class III (premarket approval).

§ 886.4690 Ophthalmic photocoagulator.

(a) *Identification.* An ophthalmic photocoagulator is an AC-powered device that uses the energy from an extended, noncoherent light source to occlude blood vessels of the retina, choroid, or iris.

(b) *Classification.* Class II (performance standards).

§ 886.4750 Ophthalmic eye shield.

(a) *Identification.* An ophthalmic eye shield is a device that consists of a plastic or aluminum eye covering that is used to protect the eye or retain dressing materials in place.

(b) *Classification.* Class I (general controls). If the device is not labeled or otherwise represented as sterile, it is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.4770 Ophthalmic operating spectacles (loupes).

(a) *Identification.* Ophthalmic operating spectacles (loupes) are devices that consist of convex lenses or

lens systems worn by a surgeon to magnify the surgical site during ophthalmic surgery.

(b) *Classification.* Class I (general controls).

§ 886.4790 Ophthalmic sponge.

(a) *Identification.* An ophthalmic sponge is a device that is a sponge or an absorbent pad of folded gauze or cotton used to absorb fluids from the operative field in ophthalmic surgery.

(b) *Classification.* Class II (performance standards).

§ 886.4855 Ophthalmic instrument table.

(a) *Identification.* An ophthalmic instrument table is an AC-powered or manual device on which ophthalmic instruments are placed.

(b) *Classification.* (1) Class II (performance standards) for AC-powered ophthalmic instrument tables.

(2) Class I (general controls) for manual ophthalmic instrument tables. The manual device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Subpart F—Ophthalmic Therapeutic Devices

§ 886.5100 Ophthalmic beta radiation source.

(a) *Identification.* An ophthalmic beta radiation source is a therapeutic medical device used to apply radiation superficially to benign and malignant ocular growths.

(b) *Classification.* Class II (performance standards).

§ 886.5120 Low-power binocular loupe.

(a) *Identification.* A low-power binocular loupe is a device that consists of two eyepieces, each with a lens or lens system, intended for medical purposes to magnify the appearance of objects.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.5270 Spectacle frame.

(a) *Identification.* A spectacle frame is a device made of metal or plastic used to hold lenses worn by a patient to correct refractive error.

(b) *Classification.* Class II (performance standards).

§ 886.5400 Polymethylmethacrylate contact lens.

(a) *Identification.* A ploymethylmethacrylate (hard) contact lens is a device that is a curved shell of polymethylmethacrylate that is worn by a patient for extended periods of time directly on the globe or cornea of the eye to correct refractive errors.

(b) *Classification.* Class II (performance standards).

§ 886.5420 Contact lens inserter/remover.

(a) *Identification.* A contact lens inserter/remover is a handheld device used to insert or remove contact lenses by surface adhesion or suction.

(b) *Classification.* Class I (general controls).

§ 886.5450 Prescription spectacle lens.

(a) *Identification.* A prescription spectale lens is a glass or plastic device that is a lens worn in a frame by a patient to correct refractive errors.

(b) *Classification.* Class II (performance standards).

§ 886.5540 Low-vision magnifier.

(a) *Identification.* A low-vision magnifier is a device that consists of a magnifying lens, which may be handheld or attached to spectacles, and that is intended for use by a patient who has impaired vision.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.5600 Ptosis crutch.

(a) *Identification.* A ptosis crutch is a device that is mounted on the spectacles of a patient who has ptosis (drooping of the upper eyelid as a result of faulty development or paralysis) to hold the upper eyelid open.

(b) *Classification.* Class I (general controls).

§ 886.5800 Ophthalmic bar reader.

(a) *Identification.* An ophthalmic bar reader is a device that consists of a magnifying lens that is intended for use by a patient who has impaired vision and that is placed directly onto reading material to magnify print.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.5810 Ophthalmic prism reader.

(a) *Identification.* An ophthalmic prism reader is a device intended for use by a patient who is in a supine position, to change the angle of print to aid reading.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.5820 Closed-circuit television reading system.

(a) *Identification.* A closed-circuit television reading system is a device that consists of a lens, video camera, and video monitor and that is intended for use by a patient who has subnormal vision, to magnify reading material.

(b) *Classification.* Class II (performance standards).

§ 886.5840 Magnifying spectacles.

(a) *Identification.* Magnifying spectacles are devices with convex lenses intended to be worn by a patient who has impaired vision, to enlarge the image of objects.

(b) *Classification.* Class II (performance standards).

§ 886.5850 Sunglasses (nonprescription).

(a) *Identification.* Sunglasses (nonprescription) are a device that consists of absorbing, reflective, tinted, or polarizing lenses in a frame that an individual wears to protect the eyes from bright sunlight. This generic type of device also includes sunglasses with photosensitized lenses.

(b) *Classification.* Class II (performance standards).

§ 886.5870 Low-vision telescope.

(a) *Identification.* A low-vision telescope is a device that consists of an arrangement of lenses or mirrors and that is intended for use by a patient who has impaired vision, to increase the apparent size of objects. This generic type of device includes handheld or spectacle telescopes.

(b) *Classification.* Class I (general controls).

§ 886.5900 Electronic vision aid.

(a) *Identification.* An electronic vision aid is an AC-powered or battery-powered device that consists of an electronic sensor/transducer and that is intended for use by a patient who has impaired vision or blindness, to translate visual images of objects into tactile or auditory signals.

(b) *Classification.* (1) Class II (performance standards) For AC-powered electronic vision aids.

(2) Class I (general controls) for battery-powered electronic vision aids.

§ 886.5910 Battery-powered image intensification vision aid.

(a) *Identification.* A battery-powered image intensification vision aid is a battery-powered device that is intended for use by a patient who has limited dark adaptation or impaired vision, to amplify ambient light.

(b) *Classification.* Class I (general controls).

§ 886.5915 Optical vision aid.

(a) *Identification.* An optical vision aid is a device that consists of a magnifying lens with accompanying AC-powered or battery-powered light source and that is intended for use by a patient who has impaired vision, to increase the apparent size of object detail.

(b) *Classification.* (1) Class II (performance standards) for AC-powered optical vision aids.

(2) Class I (general controls) for battery-powered optical vision aids. The battery-powered device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before March 29, 1982, submit to the Dockets Management Branch (address above), written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments regarding the general provisions are to be identified with the docket number found in brackets in the heading of this document. Comments regarding a particular device are to be identified with the docket number for that device found in the "Panel Recommendations and FDA's Proposed Classifications" sections. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

The Food and Drug Administration has carefully analyzed the economic effects of this proposed rule and has determined that, if promulgated, the rule will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. In accordance with section 3(g)(1) of Executive Order 12291, the impact of this proposed rule has been carefully analyzed, and it has been determined that this proposal does not constitute a major rule as defined in section 1(b) of the Executive Order. Rules proposing classification of devices into class I generally maintain the status quo: These devices are now subject to only the general controls provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j) and, under the proposed rules, would remain subject only to such controls either in their entirety or with certain exemptions. Devices classified into class II would also remain subject only to the general controls provisions of the act unless and until an applicable performance standard were established. Similarly, devices classified into class III remain subject only to the general controls provisions of the act until an additional regulation is promulgated pursuant to section 515(b) of the act (21 U.S.C. 360e(b)) requiring that such devices have in effect approved applications for premarket approval. In accordance with section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)), devices classified by regulation into class III may remain in commercial distribution without an approved premarket approval application for 30 months following the effective date of classification of the device into class III, or for 90 days following the promulgation of a regulation under section 515(b) of the act (21 U.S.C. 360e(b)), whichever occurs later. In sum, device classification rules do not have a significant impact on a substantial number of small entities and are not major rules.

Dated: December 16, 1981.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

[FR Doc. 82-1537 Filed 1-25-82; 8:45 am]

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federal register

Tuesday
January 26, 1982

Part III

Department of Justice

Bureau of Prisons

Control, Custody, Care, Treatment and Instruction of Inmates; Proposed Rulemaking and Request for Comments

DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Parts 524, 544 and 549

Control, Custody, Care, Treatment and Instruction of Inmates; Proposed Rulemaking and Request for Comments

AGENCY: Bureau of Prisons, Justice.

ACTION: Proposed rules.

SUMMARY: The Bureau of Prisons is proposing a set of rules for the management of inmates in Federal correctional institutions. This proposal is part of the Bureau's program to publish in the **Federal Register**, and subsequently in the Code of Federal Regulations, Bureau rules relating to the control, custody, care, treatment, and instruction of inmates. This installment encompasses the Bureau of Prisons' proposed rules on (1) Youth Corrections Act (YCA) Institutions; (2) Adult Basic Education (ABE) Program; and (3) Suicide Prevention Program. The first rule establishes procedures to ensure that offenders committed under provisions of the Youth Corrections Act are housed separate from other inmates. The rule also establishes procedures to ensure that the YCA inmate is afforded treatment, as required by 18 U.S.C. 5011. The Bureau of Prisons' rule on the ABE program is intended to replace the Bureau's existing rule on optional programming. The new rule requires Federal inmates who are unable to read, write, or do mathematics at the 6.0 academic grade level to attend an adult basic education program for a minimum of 90 calendar days. The rule on suicide prevention program provides guidelines for Bureau of Prisons' management of potentially suicidal inmates.

DATE: Comments must be received on or before March 4, 1982.

ADDRESS: Office of General Counsel, Bureau of Prisons, Room 760, 320 1st Street, NW., Washingotn, D.C. 20534. Comments received will be available for examination by interested persons at the above address.

FOR FURTHER INFORMATION CONTACT: Mike Pearlman, Office of General Counsel, Bureau of Prisons, phone 202/274/3062.

SUPPLEMENTARY INFORMATION: Pursuant to the rulemaking authority vested in the Attorney General in 5 U.S.C. 552(a) and delegated to the Director of the Bureau of Prisons in 28 CFR 0.96(q), notice is hereby given that the Bureau of Prisons intends to pubish in the **Federal Register** its proposed rules on Youth Corrections Act Institutions, Adult Basic Education Program, and Suicide Prevention Program.

Recent Federal court rulings have held that persons committed under the provisions of the Youth Corrections Act are to be housed separate from other inmates. These rulings did not consider the Bureau of Prisons previously established "YCA Units" to meet the statutory requirements of the Youth Corrections Act. Accordingly, the Bureau of Prisons developed a plan for separating YCA offenders from other inmates. This plan has been subject to the review of, and approval by, several Federal courts. The plan calls for the establishment of "all-YCA" institutions and the development of an individualized treatment program for each YCA inmate housed within the YCA institution. The proposed rule discusses aspects of this program.

The proposed rule on the Adult Basic Education Program recognizes the importance for each individual to function at a minimal grade level of 6.0. The sixth grade level is generally accepted as the basic standard for measuring functional literacy in our society. Persons functioning below that level often encounter serious difficulties in obtaining employment and in carrying out their day-to-day activities and responsibilities.

The Bureau's rule on its suicide prevention program provides guidelines for the management of potentially suicidal inmates. While suicides occur infrequently within the Bureau of Prisons, it is the Bureau's responsibility to monitor the health and welfare of individual inmates, and to ensure that procedures are pursued to preserve life.

The Bureau of Prisons has determined that these rules are not major rules for the purpose of EO 12291. The Bureau of Prisons has determined that EO 12291 does not apply to these rules since the rules involve agency management. After review of the law and the regulations, the Director, Bureau of Prisons has certified that these rules, for the purpose of the Regulatory Flexibility Act (Pub. L. 96–354), do not have a significant impact on a substantial number of small entities.

Interested persons may participate in this proposed rulemaking by submitting data, views, or arguments in writing to the Bureau of Prisons, Room 760, 320 1st Street, NW., Washington, D.C. 20534. Comments received on or before March 4, 1982 will be considered before final action is taken. The proposed rules may be changed in light of the comments received. No oral hearings are contemplated.

In consideration of the foregoing, it is proposed to amend 28 CFR, Chapter V as follows:

1. In Subchapter B, add Subpart C to Part 524;

2. In Subchapter C, remove existing Subpart H and add a new Subpart H to Part 544; and

3. In Subchapter C, add Subpart F to Part 549.

SUBCHAPTER B—INMATE ADMISSION, CLASSIFICATION, AND TRANSFER

In Part 524, by adding Subpart C to read as follows:

PART 524—CLASSIFICATION OF INMATES

* * * * *

Subpart C—Youth Corrections Act (YCA) Institutions

Sec.

524.20 Purpose and scope.
524.21 Definitions.
524.22 Designation to a YCA institution.
524.23 YCA program.
524.24 Classification.
524.25 Treatment.
524.26 Pre-release.
524.27 Educational and work-oriented programs.
524.28 Conditional release (parole).
524.29 Parole violators.
524.30 Exceptions.

Authority: 5 U.S.C. 301; 18 U.S.C. 4001, 4042, 4081, 4082, 5005–5026, 5039; 28 U.S.C. 509, 510; 28 CFR 0.95–0.99.

Subpart C—Youth Corrections Act (YCA) Institutions

§ 524.20 Purpose and scope.

The Director, Bureau of Prisons has designated selected federal institutions to house only those persons committed under the provisions of the "Federal Youth Corrections Act" (YCA). 18 U.S.C. 5011 of this Act states "Insofar as practical, such institutions * * * shall be used only for treatment of committed youth offenders, and such youth offenders shall be segregated from other offenders * * *." The Warden at each YCA institution shall ensure that a three-phase program, comprised of a classification, a treatment, and a pre-release phase, is developed for every YCA commitment. Designated Bureau of Prisons staff (ordinarily the Warden) may authorize an inmate committed under the Youth Corrections Act to be housed with non-YCA inmates only under conditions specified in this rule. Other exceptions to the requirements of this rule for commitment of YCA inmates shall be made only upon written approval of the Director, Bureau of Prisons.

§ 524.21 Definitions.

(a) For purposes of this rule, a "YCA inmate" is an inmate confined under the provisions of 18 U.S.C. 5010 (b), (c), or (e), who is not also sentenced to a concurrent adult term, whether state or federal.

(b) For purposes of this rule, an inmate confined under the provisions of 18 U.S.C. 5010 (b), (c), or (e) who has a subsequent consecutive adult sentence is not considered a "YCA inmate" when the court that imposed the consecutive adult sentence states that, in the court's opinion, YCA treatment will not be of further benefit to the inmate. Absent this determination by the court, the inmate is to be considered a "YCA inmate" and treated accordingly.

(c) Study Cases. YCA inmates committed for a period of study (under 18 U.S.C. 5010(e)).

(d) Committed Youth Offenders. YCA inmates sentenced under 18 U.S.C. 5010 (b) or (c). This category includes those individuals who have been sentenced after undergoing a 5010(e) study, and those sentenced to a period of confinement without the study procedure.

§ 524.22 Designation to a YCA institution.

A YCA inmate shall be designated to a YCA institution at the time of initial commitment by appropriate staff in the Regional Office.

§ 524.23 YCA Program.

Each Warden of a YCA institution is to ensure that each committed youth offender is involved in a three-phase program, to include a classification, a treatment, and a pre-release phase (See §§ 524.24–26). The program is to incorporate a graduated release concept to specifically address the return to the inmate of increasing levels of liberty and personal responsibility. In accordance with policy guidelines, the inmate is to be advised of the earliest possible date when consideration may be given to possible reductions in custody level. The graduated release concept is also to focus on the earliest date when the inmate's unit team will consider the inmate for town trips (for purpose of attending a nearby social or sports event), work and/or study release, and furloughs. The inmate is to be advised that for these steps toward release to occur, the inmate will be required to maintain a level of behavior which complies with Bureau of Prisions rules and institutions guidelines.

§ 524.24 Classification.

This phase shall include an inmate orientation period, a system for unit assignment, and the development of an individualized program plan incorporating the graduated release concept. Except for those inmates returned as committed youth offenders subsequent to a 5010(e) study, YCA inmates are to participate in a classification procedure prior to the development of their individualized program plans. YCA inmates who were returned by the court as committed youth offenders subsequent to a 5010(e) study may be placed immediately into their assigned units and begin the individualized program outlined in the report submitted to the court.

(a) *Orientation.* During the classification period, an inmate is expected to participate in general orientation activities to become familiar with the overall operations of the institution and the types of programs available. Staff shall schedule the inmate for a variety of other activities, including medical and dental examination, and psychological, eductional, and vocational screening. In addition, each unit shall develop its own orientation program to introduce the new arrival to the specific programs within the inmate's assigned unit.

(b) *Unit Assignment.* The Warden shall develop procedures to systematically assign newly admitted inmates to unit living quarters.

(c) *Initial Classification.* Within four weeks of the committed inmate's arrival at the designated YCA institution, the Unit Team shall meet with that inmate for purpose of initial classification and program assignment. Staff shall notify the inmate of this meeting at least 48 hours prior to the inmate's scheduled appearance before the Unit Team. An inmate may waive in writing the requirement of 48 hours notice. The inmate is expected to attend, and to participate in, the initial classification meeting. If the inmate refuses to appear, staff shall document in the record of the meeting the inmate's refusal to appear and, if known, the reasons for refusal.

(d) *Program Plan.* The Unit Team shall prepare a staff evaluation which summarizes the inmate's needs and outlines the program plan developed jointly with the inmate. The program plan shall specify the inmate's individualized correctional goals, the programs in which the inmate will participate to attain these goals, an estimate of the time needed to reach these goals, and a recommendation to the Parole Commission. The Unit Team in their evaluation shall explicitly address and document their decision as to whether the YCA inmate's needs can best be met in the presently assigned institution, in another YCA institution, in a community program, or in some other setting as specified in 18 U.S.C. 5011.

§ 524.25 Treatment.

Each YCA inmate is to be exposed to unit-based, institution-based, and community-based programs. Each YCA inmate shall be provided periodic reviews during this phase. The treatment phase begins when the inmate attends the programs and activities described in the program plan and ends approximately six months prior to the inmate's anticipated release date.

(a) *Program Structure.* Each inmate in a YCA institution shall be assigned program involvement in accordance with the inmate's needs. The "program day" shall consist of morning, afternoon, and evening time periods, during which the inmate shall be scheduled for self-improvement, work, and leisure-time activities. The inmate shall be expected to comply with the program plan. The inmate's refusal to participate may result in disciplinary action.

(b) *Programs.* Program activities consist of those conducted within the unit, those conducted at centralized locations within the institution, and those conducted within the community. Each YCA institution shall offer programs in each of these three areas.

(1) *Unit-Based Programs.* This includes those activities designed to enhance staff/inmate and inmate-to-inmate relationships, and to help ensure the orderly running of the unit. Examples of unit-based programs include unit business and information-sharing meetings, individual and group counseling sessions, leisure-time and recreation activities, daily sanitation details, periodic drug surveillance, and group and individual psychotherapy.

(2) *Institution-Based Programs.* This includes activities conducted at a centralized location within the institution and includes self-improvement, educational and work-oriented programs (see § 524.27), physical recreation and other leisure-time activities. Examples of institution-based programs include religious services and related study groups, community volunteer programs, music and drama clubs, and ethnic groups.

(3) *Community-Based Programs.* This includes those activities designed to help re-orient the inmate to a successful return to free society living. The activities may be similar to institutional activities, with the primary difference being the community location. Examples of specific activities which may be found only in the community include enrollment in a community vocational training program, an institutional choir

that sings at churches, lectures by selected inmates to school groups and community organizations concerning crime, drugs, etc.

(c) *Reclassification.* Staff shall conduct periodic reviews of the inmate's program plan and shall modify the plan in accord with the level of progress shown. Each YCA inmate shall be afforded a review at least once each 90 days and shall have a formal progress report prepared at least yearly summarizing the inmate's level of achievement. Staff shall notify the inmate of the 90-day review at least 48 hours prior to the inmate's scheduled appearance before the Unit Team. An inmate may waive in writing the requirement of 48 hours notice. The inmate is expected to attend and to participate in the review. If the inmate refuses to appear, staff shall document in the record of the meeting the inmate's refusal to appear and, if known, the reasons for refusal. Each review shall be documented and the results placed in the inmate central file.

(d) *Incentives.* Staff may establish incentives to motivate YCA inmates and to encourage program completion. Examples of such incentives may include special recognition, ceremonies, awards, and "vacation days."

§ 524.26 Pre-release.

The YCA inmate shall enter the pre-release phase approximately six months prior to release. The Pre-Release phase is ordinarily divided into two portions: A pre-release program in the institution, and a stay at a halfway house.

(a) Each YCA institution shall develop a formal pre-release program. All inmates who are within six months of a release date shall be assigned to this program. The pre-release program shall focus on the types of problems the inmate may face upon return to the community, such as reestablishing family relationships, managing a household, finding and keeping a job, and developing a successful life style. In addition, the pre-release program may include visits from prospective employers who describe what they look for in a job applicant and from former inmates who have demonstrated a successful post-release community adjustment for at least one year.

(b) Halfway House. A YCA inmate released from a YCA institution is ordinarily expected to serve a period of time in a halfway house, to ease community transition. Exceptions to halfway house placement must be approved by the Warden, with a written record of the reasons for exclusion placed in the inmate central file.

§ 524.27 Educational and work-oriented programs.

Each YCA institution shall offer the following types of educational and work-oriented programs:

(a) Academic Education—Programs in this area are to include the following.

(1) *Adult Basic Education (ABE).* Designed to assist the inmate whose academic skills are below the sixth grade level.

(2) *Adult Secondary Education (ASE).* Designed to assist the inmate in preparation for obtainment of a high school level diploma (General Equivalency Degree (GED)).

(3) *Adult Continuing Education (ACE).* Designed to assist the inmate who wishes to continue to expand or to "brush up" in a specific educational area, such as English as a second language.

(4) *Postsecondary Education (PSE).* Designed to assist the inmate who desires to take accredited courses above the high school level. These courses may be in either the educational or vocational area.

(5) *Social Education (SE).* Designed to assist the inmate in his adjustment. These programs concern personal growth, increased ability to cope with problems such as stress, self-image, alcoholism, and responsibilities as a parent.

(b) Occupational Education.—(1) Programs in this area are to focus on helping the inmate acquire or improve upon marketable skills. Each YCA institution shall offer at least three training areas, in such skills as automotive repair, computer programming, welding, heating, and air conditioning.

(2) Within the occupational education area, each YCA institution shall also offer at least two approved apprenticeship programs, such as baking, cooking, painting, and stationary engineering.

(c) Work-Oriented Programs. Programs in this area include Federal Prison Industries (UNICOR) and institutional maintenance and service details. UNICOR is to operate apprenticeship training programs. Eligibility for an industrial placement requires the recommendation of the Unit Team and an indication that the inmate is either functioning at least at a 6.0 grade level (as shown by the Stanford Achievement Test), or is presently participating in an ABE program with progress toward attaining a 6.0 grade level. The inmate who works full time in an industrial assignment must possess at least a 6.0 grade level.

§ 524.28 Conditional release (parole).

The U.S. Parole Commission is the releasing authority for all YCA inmates. Upon request of the U.S. Parole Commission, the Bureau of Prisons shall provide the U.S Parole Commission with a progress report on the YCA inmate. When institutional staff wish to notify the Parole Commission of a special post-release need of the inmate, the Unit Team shall either make notation of this need in the progress report or may submit a separate report bringing the post-release need to the attention of the U.S. Parole Commission.

§ 524.29 Parole violators.

A YCA inmate whose conditional release is revoked by the U.S. Parole Commission shall ordinarily enter the Bureau of Prisons' three-phase program for YCA inmates as described in this rule.

§ 524.30 Exceptions.

A YCA inmate may be considered for transfer to a non-YCA institution under the following conditions.

(a) A YCA inmate may be housed within the general population of a community treatment center, halfway house, or work release facility, and may work with non-YCA's at a factory, office, or other workplace in the community during the pre-release phase of treatment.

(b) A YCA inmate may be confined at the Medical Center for Federal Prisoners, Springfield, Missouri, or at the Federal Correctional Institution, Butner, North Carolina, or at the Federal Correctional Institution, Lexington, Kentucky, as necessary for the duration of special medical or mental health treatment not available within the inmate's present YCA institution.

(c) A YCA inmate may be confined temporarily in a non-YCA institution on "holdover" status (en route to another institution). The YCA inmate who is confined temporarily on "holdover" status must be physically separated from non-YCA inmates at all times.

(d) A YCA inmate, upon approval of the Director, Bureau of Prisons, may be confined in a non-YCA institution for other compelling reasons.

SUBCHAPTER C—INSTITUTIONAL MANAGEMENT

In Part 544, by removing existing Subpart H and adding a new Subpart H to read as follows:

PART 544—EDUCATION

* * * * *

Subpart H—Adult Basic Education (ABE) Program

Sec.
544.70 Purpose and scope.
544.71 Procedures.
544.72 Federal Prison Industries (UNICOR) and Inmate Performance Pay (IPP) Assignments.
544.73 Incentives.
544.74 Disciplinary action.
544.75 Exceptions.

Authority: 5 U.S.C. 301; 18 U.S.C. 4001, 4042, 4081, 4082, 4161–4166, 5006–5024, 5038; 28 U.S.C. 509; 510; 28 CFR 0.95–0.99.

Subpart H—Adult Basic Education (ABE) Program

§ 544.70 Purpose and scope.

The Bureau of Prisons requires that all federal inmates who cannot read, write, or do mathematics at the 6.0 grade level attend an Adult Basic Education Program (ABE) for a minimum of 90 calendar days. The Warden may establish incentives to encourage an inmate to complete an ABE program.

§ 544.71 Procedures.

(a) The Warden at each federal institution shall ensure that an inmate who is functioning below a 6.0 grade level in reading, writing, and mathematics, is enrolled in an ABE program.

(b) The Warden or designee shall assign to an education staff member the responsibility to coordinate the institution's ABE program. The ABE coordinator shall meet initially with the inmate for the purpose of enrolling the inmate in the ABE program. Subsequently, the ABE coordinator shall meet with each inmate involved in the ABE program at least once every 30 days to review and record the inmate's progress in this program. The ABE coordinator shall place documentation of this interview in the inmate's education file.

(c) At the end of 90 consecutive days in class, excluding sick time, furloughs, or other authorized absences from scheduled classes, the inmate shall meet with the inmate's team in respect to continued involvement in the ABE program towards attainment of the 6.0 academic grade level. At this time, the inmate may elect not to continue in the ABE program, without negative consequences.

§ 544.72 Federal Prison Industries (UNICOR) and Inmate Performance Pay (IPP) Assignments.

Inmates who wish to secure a UNICOR or IPP work assignment above the fourth grade of compensation must be able to demonstrate achievement of at least a 6.0 academic grade level.

§ 544.73 Incentives.

The Warden shall establish a system of incentives to encourage an inmate to obtain a minimum academic grade level of 6.0.

§ 544.74 Disciplinary action.

As with other mandatory programs, such as work assignments, staff may take disciplinary action against an inmate whose academic level is below the 6.0 grade level when that inmate refuses to enroll in, or to complete, the mandatory 90-day ABE program.

§ 544.75 Exceptions.

The provisions of this subpart on the adult basic education program do not apply to:

(a) Pre-trial inmates;

(b) Sentenced aliens with a deportation detainee;

(c) Those inmates already in UNICOR or IPP assignments in pay grades 1, 2, and 3 at the time of implementation of this rule who do not presently function at the 6.0 academic grade level;

(d) Those inmates for whom treatment is mandated by statute (for example, Youth Corrections Act); and

(e) Other inmates who for good cause, the Warden may determine are exempt from the provisions of this rule (for example, those inmates who are either physically or mentally handicapped).

When an inmate is exempted from the provisions of paragraphs (a)–(e) of this section, the Warden shall document the reasons for the exemption in the inmate's education file.

In Part 549, by adding Subpart F to read as follows:

PART 549—MEDICAL SERVICES

* * * * * * *

Subpart F—Suicide Prevention Program

Sec.
549.70 Purpose and scope.
549.71 Suicide prevention program.

Authority: 5 U.S.C. 301; 18 U.S.C. 4001, 4005, 4042, 4081, 4082, 4161–4166, 5006–5024, 5039; 28 U.S.C. 509, 510; 28 CFR 0.95–0.99.

Subpart F—Suicide Prevention Program

§ 549.70 Purpose and scope.

The Bureau of Prisons provides guidelines for the management of potentially suicidal inmates. While such occurrences as suicide attempts are infrequent, it is the responsibility of the Bureau of Prisons to monitor the health and welfare of individual inmates, and to ensure that procedures are pursued to preserve life. Towards fulfillment of this objective, each Warden shall designate a staff member (ordinarily the Chief Psychologist or, in the absence of the Chief Psychologist, the Hospital Administrative Officer) to serve as Program Coordinator for an institution suicide prevention program.

§ 549.71 Suicide prevention program.

The Program Coordinator shall ensure that the institution's suicide prevention program contains the following elements.

(a) *Identification.* Staff at each institution shall be trained (ordinarily by psychology services personnel) to recognize those signs exhibited by an inmate which may be indicative of a potential suicide.

(b) Referral staff shall immediately refer to the Program Coordinator an inmate who exhibits behavior indicative of a potential suicide. Documentation of the referral shall be placed in the inmate medical file.

(c) *Crisis Intervention.* Upon receipt of a referral, the Program Coordinator is to immediately initiate appropriate crisis intervention techniques. These techniques include, but are not limited to, the following:

(1) Meeting with the inmate;

(2) Demonstrating a caring concern; and

(3) Not leaving the inmate unattended.

(d) *Maintenance.* The Program Coordinator shall arrange for the inmate identified as a potential suicide to be under frequent surveillance. The Program Coordinator shall also utilize, as determined appropriate, other maintenance techniques. Examples of such techniques include, but are not limited to, temporary reassignment of housing, increased contact with those staff members with whom the inmate has developed a positive relationship, and the provision of treatment services.

(e) *Documentation.* Staff shall document in the inmate medical file all efforts made on behalf of the potentially suicidal inmate.

(f) *Training.* The Program Coordinator shall ensure that both staff and selected inmates are provided training in suicide prevention techniques. Staff shall receive this training as part of their annual refresher training. Selected inmates shall be trained as "suicide prevention aides", with their function to monitor suicide-prone inmates. "Suicide prevention aides" shall be compensated for time spent monitoring a potentially suicidal inmate.

Norman A. Carlson,

Director, Bureau of Prisons.

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Reader Aids

Federal Register

Vol. 47, No. 17

Tuesday, January 26, 1982

INFORMATION AND ASSISTANCE

PUBLICATIONS

Code of Federal Regulations

CFR Unit	202-523-3419 523-3517
General information, index, and finding aids	523-5227
Incorporation by reference	523-4534
Printing schedules and pricing information	523-3419

Federal Register

Corrections	523-5237
Daily Issue Unit	523-5237
General information, index, and finding aids	523-5227
Privacy Act	523-5237
Public Inspection Desk	523-5215
Scheduling of documents	523-3187

Laws

Indexes	523-5282
Law numbers and dates	523-5282 523-5266
Slip law orders (GPO)	275-3030

Presidential Documents

Executive orders and proclamations	523-5233
Public Papers of the President	523-5235
Weekly Compilation of Presidential Documents	523-5235

United States Government Manual 523-5230

SERVICES

Agency services	523-4534
Automation	523-3408
Dial-a-Reg	
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Washington, D.C.	202-523-5022
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Public Inspection Desk	523-5215
Special Projects	523-4534
Subscription orders (GPO)	783-3238
Subscription problems (GPO)	275-3054
TTY for the deaf	523-5229

FEDERAL REGISTER PAGES AND DATES, JANUARY

1-128....4
129-588....5
589-744....6
745-934....7
935-1108....8
1109-1256....11
1257-1366....12
1367-2072....13
2073-2282....14
2283-2474....15
2475-2766....18
2767-2854....19
2855-2976....20
2977-3070....21
3071-3338....22
3339-3538....25
3539-3756....26

CFR PARTS AFFECTED DURING JANUARY

At the end of each month, the Office of the Federal Register publishes separately a list of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
4707 (Amended by Proc. 4889)....1
4889....1
4890....2855
4891....2977
4892....3339

Executive Orders:
1643 (Revoked by PLO 6101)....769
11157 (Amended by EO 12337)....1367
11476 (See EO 12340)....3071
11835 (See EO 12340)....3071
12018 (See EO 12340)....3071
12171 (Amended by EO 12338)....1369
12198 (See EO 12340)....3071
12233 (See EO 12340)....3071
12251 (Revoked by EO 12341)....3341
12306 (See EO 12340)....3071
12310 (Amended by EO 12339)....2475
12315 (See EO 12340)....3071
12337....1367
12338....1369
12339....2475
12341....3341

5 CFR

Ch. XIV....3343
293....3077
359....2283
410....935
832....2284
1201....936

Proposed Rules:
Ch. I....154
352....956
550....958
610....958
890....961

6 CFR

Ch. VI....2285
Ch. VII....2285

7 CFR

Ch. XII....2981
Subtitle B....745
1a....2073
2....5, 6
68....129, 2074
160....3343
226....3539
282....532
301....1257
319....3082, 3086
425....6
631....130
701....937
800....131, 2254
801....2979
905....589
906....1265
907....746, 2074, 2980
910....939, 2767, 3082
944....747, 1265
1300....2981
1701....3088
1924....590
1942....590

Proposed Rules:
Ch. I....3126
102....631
360....2874
979....631
1004....2118
1006....814
1007....962, 2122
1011....2999
1012....814
1013....814
1033....814
1036....814
1040....814
1046....2999
1098....2999
1124....814
1125....814
1133....814
1134....778, 814
1135....814
1136....778, 814
1137....778, 814
1139....814, 3361
1250....1105
1701....3126, 3554, 3555
1865....33
1942....2774
1951....33

8 CFR

101....940
204....942
238....131
264....940
316a....132

Proposed Rules
3....1396

9 CFR

Ch. I.....745
Ch. II.....745
Ch. III.....745
82.....1109, 3089
92.....591
331.....3089
381.....3089

Proposed Rules

78.....3490

10 CFR

2.....2286
40.....8
50.....2286
70.....8
71.....596
73.....600
150.....8
504.....749
508.....749

Proposed Rules:

Ch. XVI.....1138
50.....2876, 2879
317.....1137
378.....817
440.....1299
455.....2880
457.....1301
486.....3127
500.....161
501.....161
503.....161
710.....2874
790.....1302

12 CFR

Ch. VII.....1371
5.....132
203.....750
207.....2981
213.....755
217.....9, 2857
220.....2981
221.....2981
226.....755
327.....943
541.....3541
545.....3541
561.....3541
563.....3091, 3543
563c.....2857, 3091
614.....2477

Proposed Rules:

2.....3555
309.....3127
311.....3127
332.....3127
335.....3127
338.....3127
345.....3127
349.....3127
701.....963
702.....633, 2122

13 CFR

101.....2074, 2305
107.....2859
120.....9
124.....1109

14 CFR

21.....756
39.....10-14, 759, 1110-1113, 2477, 2479, 3346, 3347, 3544
61.....3486
71.....15-18, 759, 760, 1113-1115, 2079, 2481, 2984, 2985, 3348-3350
73.....18, 2986
75.....18
93.....2079
97.....1115
159.....2079
201.....132
207.....134
208.....134
212.....135
231.....137
245.....761
246.....762
298.....604
302.....138
321.....139
380.....140
399.....140
1214.....3095

Proposed Rules:

Ch. I.....817, 3369
39.....1140-1142, 2485
71.....36-38, 1144, 1145, 2488, 2489, 3002-3005, 3370
73.....1146, 2488, 2490
91.....818
121.....3068
296.....633
297.....633

15 CFR

0.....3350
50.....18
371.....609
373.....609
376.....609
378.....609
379.....141
385.....141, 609
390.....144
399.....141, 609

Proposed Rules:

30.....2122
369.....2320

16 CFR

1.....3095
13.....1372, 3350
305.....18, 19

Proposed Rules:

13.....3371
14.....3128

17 CFR

201.....609
211.....1266
230.....3098
240.....1372, 1373, 2079, 3512

Proposed Rules:

1.....2325
210.....2776
230.....3130
239.....3130
240.....2124, 3521-3534
274.....3130

18 CFR

Ch. I.....613
141.....1267, 2083
270.....614
282.....20

Proposed Rules:

141.....39, 2329, 3374
271.....39, 638, 2883, 2884
273.....638
274.....638

19 CFR

4.....2084
6.....2085
10.....944
18.....2086
101.....1286, 2088

Proposed Rules:

4.....3374
10.....2124
18.....2125
111.....1396
177.....2126, 3375

20 CFR

Ch. I.....145
Ch. V.....145
Ch. VI.....145
416.....3099

Proposed Rules:

Ch. I.....402
Ch. V.....402
Ch. VI.....402
404.....642
416.....642, 2127

21 CFR

1.....946
2.....946
73.....946
105.....946
135.....1287
145.....2311
166.....3108
170.....946
172.....946
173.....145
175.....1288
176.....1288
178.....1288
193.....616, 1374, 2986
510.....146, 2312, 2767
522.....146
558.....1289, 2312
561.....1375, 1376, 2860

Proposed Rules:

7.....2331
20.....162
146.....963
168.....163
310.....424, 430
333.....436
357.....444-512
358.....522
874.....3280
878.....2810
886.....3694

22 CFR

42.....2089

23 CFR

Proposed Rules:

635.....1146

24 CFR

201.....616, 617
203.....916
234.....916
511.....1117
540.....1117
541.....1117
551.....1117
555.....1117
556.....1117
561.....1117

25 CFR

700.....2089

26 CFR

1.....147
5e.....2986
31.....3545, 3546
32.....3545
37.....3546

Proposed Rules:

1.....163, 164, 988, 3006, 3559, 3562
15A.....164
53.....3558
301.....3007

27 CFR

Proposed Rules:

5.....1148
9.....1149-1153, 3564

28 CFR

2.....2312
17.....2861

Proposed Rules:

524.....3752
544.....3752
549.....3752

29 CFR

Subtitle A.....145
Ch. V.....145
Ch. XVII.....145
1952.....1289
2619.....2313

Proposed Rules:

Subtitle A.....402
Ch. V.....402
Ch. XVII.....402
Ch. XXV.....402
5.....966
1910.....3566
1990.....187
2672.....1304

30 CFR

904.....3108
936.....2989

Proposed Rules:

Ch. I.....402
Ch. VII.....820, 2338, 3571
100.....2335
211.....819
700.....41, 3377
701.....41, 3377
716.....928, 2340
764.....41, 3377
770.....41, 3377
771.....41, 3377
779.....41, 3377
780.....41, 3377
783.....41, 3377
784.....41, 3377
785.....41, 3377

786.....41, 3377
788.....41, 3377
816.....41, 3377
817.....41, 3377
825.....41, 3377
826.....928, 2340
828.....41, 3377
870.....967
872.....967
874.....967
875.....967
877.....967
879.....967
882.....967
884.....967
886.....967
888.....967
913.....57
914.....3008
921.....560, 3377
922.....560
937.....560
939.....560, 3377
948.....2340

31 CFR

535.....145

32 CFR

230.....2112

Proposed Rules:

543.....822
585.....190

33 CFR

80.....3351
82.....3351
110.....1117
117.....1118
165.....1118

Proposed Rules:

88.....826
89.....826
117.....3010

34 CFR

219.....3328
220.....3328
624.....540
625.....540
626.....540
627.....540
644.....2258
674.....736
675.....736
676.....736
690.....736

Proposed Rules:

674.....908
675.....908
676.....908

35 CFR

103.....2991

36 CFR

Ch. II.....745
60.....3109

Proposed Rules:

Ch. II.....2886
60.....3138

39 CFR

111.....3351, 3352
601.....1377

Proposed Rules:

111.....3377

40 CFR

52.....762, 763, 947, 948, 1119, 1290–1292, 2112, 2113, 2768, 3110–3115, 3352, 3353, 3548–3550
60.....950, 2314
65.....1293
80.....764
81.....763, 952, 1120, 1377, 2113, 2115, 3354
123.....618, 1248, 2314, 3551
180.....619–623, 1378–1384, 2862, 2863
193.....1385
262.....1248
264.....953
265.....1254, 2316
702.....2771
762.....148, 149

Proposed Rules:

50.....2127, 2341
52.....191, 1304, 1398, 2129 3138
58.....2127
65.....969, 2889
81.....2131, 3011
86.....972, 1306, 1642
123.....1155, 2378, 3378
180.....651–654, 2889
244.....1307
245.....1307
246.....1307, 2379
761.....2379
775.....193
799.....973, 2379

41 CFR

Ch. 50.....145
Ch. 60.....145
5–12.....1385
5A–7.....2481
5A–16.....2481
5A–72.....2481

Proposed Rules:

Ch. 60.....402

42 CFR

122.....3551
405.....1386
441.....1386

43 CFR

7.....2995
20.....2316, 2995
428.....624
3100.....2864
3110.....2864

Public Land Orders:

6100.....21, 3351
6101.....769

Proposed Rules:

Subtitle A.....2381
426.....2890
4100.....1155

44 CFR

64.....3116, 3119, 3355
65...770, 3121, 3122, 3357, 3358
66.....770
67.....22, 3123
70.....771, 772, 3124, 3125

Proposed Rules:

13.....2491
67.....3012, 3140–3147, 3379
205.....827

45 CFR

Ch. XII.....3553
680.....193
681.....193
682.....193
683.....193
684.....193

46 CFR

547.....3359

Proposed Rules:

69.....2131
510.....215
536.....655

47 CFR

0.....1294, 2864
2.....953, 1386
21.....953
73.....150, 1386, 2116, 2865–2871
74.....150, 953, 1392, 2864
83.....2317
97.....2872, 3360

Proposed Rules:

2.....983, 1308
15.....216, 836
25.....3573
73.....58, 837, 983, 985, 1308, 2135, 2136, 2384, 2385, 2890–2893, 3388, 3389
74.....983
81.....2894
83.....2894
90.....1310

48 CFR

Proposed Rules:

13.....1400
17.....1400

49 CFR

Ch. X.....613
1.....1122
571.....2996
635.....3391
650.....3391
658.....3391
830.....773
1033.....151, 152, 624, 773, 776, 2482
1056.....777, 3553
1136.....2117
1139.....2317

Proposed Rules:

Ch. X.....3392
1031.....1155
1033.....3574
1039.....220
1254.....3774
1300.....220
1310.....59

50 CFR

17.....2317
23.....1294, 2117
32.....1122–1135
611.....625, 1294, 1295
662.....629
675.....1295

Proposed Rules:

23.....1242
611.....2386
672.....2386

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The following agencies have agreed to publish all documents on two assigned days of the week (Monday/Thursday or Tuesday/Friday).

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Monday	Tuesday	Wednesday	Thursday	Friday
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Documents normally scheduled for publication on a day that will be a Federal holiday will be published the next work day following the holiday. Comments on this program are still invited.

Comments should be submitted to the Day-of-the-Week Program Coordinator, Office of the Federal Register, National Archives and Records Service, General Services Administration, Washington, D.C. 20408.

REMINDERS

List of Public Laws

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws.**

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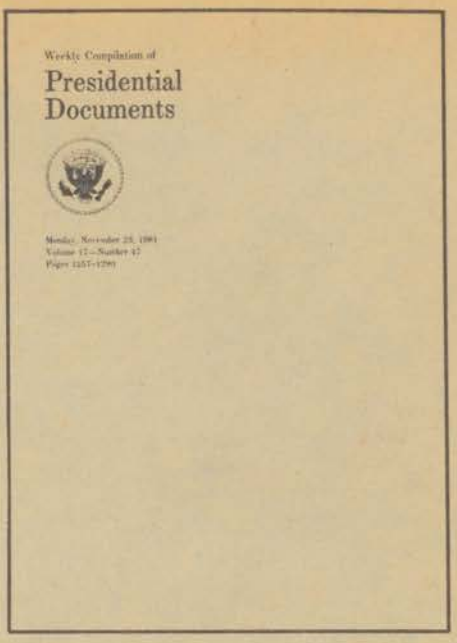

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