AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

8-6-87
Vol. 52 No. 151
Pages 29173-29362

federal register

Thursday
August 6, 1987

Briefings on How To Use the Federal Register—
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FEDERAL REGISTER Published daily, Monday through Friday, (not published on Saturdays, Sundays, or on official holidays), by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (49 Stat. 500, as amended; 44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). Distribution is made only by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

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THE FEDERAL REGISTER
WHAT IT IS AND HOW TO USE IT

FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: The Office of the Federal Register.

WHAT: Free public briefings (approximately 2 1/2 hours) to present:

1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
2. The relationship between the Federal Register and Code of Federal Regulations.
3. The important elements of typical Federal Register documents.
4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WASHINGTON, DC

WHEN: September 29, at 9 a.m.
WHERE: Office of the Federal Register, First Floor Conference Room, 1100 L Street NW., Washington, DC.
RESERVATIONS: Janice Booker, 202-523-5239

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Rules and Regulations

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.
The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. 87-104]

Oriental Fruit Fly; Addition to the Quarantined Areas

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the Oriental fruit fly regulations by adding a portion of San Diego County in California to the list of areas designated as quarantined areas. This action is necessary as an emergency measure in order to prevent the artificial spread of the Oriental fruit fly into noninfested areas of the United States. The effect of this action is to impose certain restrictions on the interstate movement of regulated articles moving interstate from the quarantined area.

DATES: Interim rule effective July 31, 1987. Consideration will be given only to comments postmarked or received on or before October 5, 1987.

ADDRESSES: Send written comments to Steven B. Farbman, Assistant Director, Regulatory Coordination, APHIS, USDA, Room 728, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket Number 87-104. Comments received may be inspected at Room 728 of the Federal Building between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Milton C. Holmes, Acting Assistant Director, Survey and Emergency Response Staff, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Room 611, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301-436-6365.

SUPPLEMENTARY INFORMATION: The Oriental fruit fly, *Dacus dorsalis* Hendel, is a very destructive pest of numerous fruits (especially citrus fruits), nuts, vegetables, and berries. Heavy infestations of this pest can result in complete loss of these crops. The short life cycle of the Oriental fruit fly permits the rapid development of serious outbreaks.

A document published in the **Federal Register** on July 22, 1987, (52 FR 27529-27536, Docket Number 87-095) established the Oriental fruit fly regulations (7 CFR 301.93 *et seq.*; referred to below as the regulations). The regulations impose restrictions on the interstate movement of regulated articles from quarantined areas in order to prevent the artificial spread of the Oriental fruit fly to noninfested areas of the United States.

The regulations, among other things, designated portions of Los Angeles and Orange Counties as quarantined areas. These areas remain infested with Oriental fruit fly.

However, the Oriental fruit fly has now been found in an area of San Diego County in California, as a result of trapping surveys conducted by inspectors of the United States Department of Agriculture and state agencies of California. The regulations in § 301.93 provide that the Deputy Administrator for Plant Protection and Quarantine shall list as a quarantined area each state, or each portion of a state, in which the Oriental fruit fly has been found by an inspector. Therefore, we are amending the regulations by adding the following area in San Diego County in California as a quarantined area:

That portion of San Diego County bounded by a line beginning at the intersection of State Highway 163 and Interstate Highway 8, then east along Interstate Highway 8 to its intersection with Spring Street, then south along Spring Street to its intersection with Broadway, then southwest along Broadway to its intersection with Sweetwater Road, then south along Sweetwater Road to its intersection with South Bay Freeway, then southwest along South Bay Freeway to its intersection with Sweetwater Road, then west along Sweetwater Road to its intersection with 30th Street, then west along 30th Street to its intersection with National City Boulevard, then north along National City Boulevard to its intersection with 24th Street, then west along 24th Street to its intersection with Interstate Highway 5, then northwest along Interstate Highway 5 to its intersection with Harbor Drive, then northwest along Harbor Drive to its intersection with State Highway 75, then northeast along State Highway 75 to its intersection with Interstate Highway 5, then northwest along Interstate Highway 5 to its intersection with 6th Avenue, then north along 6th Avenue to its intersection with State Highway 163, then north along State Highway 163 to the point of beginning.

Emergency Action

The Deputy Administrator of the Animal and Plant Health Inspection Service for Plant Protection and Quarantine has determined that an emergency situation exists, which warrants publication of this interim rule without prior opportunity for a public comment period. Due to the possibility that the Oriental fruit fly could be spread artificially to noninfested areas of the United States, a situation exists requiring immediate action to help control the spread of this pest. Therefore, in accordance with the administrative procedure provisions of 5 U.S.C. 553, we find that it would be impracticable and contrary to the public interest to give advance notice and opportunity to comment on this rule.

Further, pursuant to the administrative procedure provisions of 5 U.S.C. 553, we find that there is good cause to make this interim rule effective upon signature. We are accepting comments on this interim rule for 60 days after it is published. As soon as possible after the comment period closes, we will publish another document in the **Federal Register** discussing the comments we received and any changes we are making in the rule.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this rule will have an effect on the economy of less than 100 million dollars; will not cause a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions; and will

not cause a significant adverse effect 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.

For this action, the Office of Management and Budget has waived the review process required by Executive Order 12291.

Within the part of San Diego County that is being added to the quarantined area, there are fewer than 40 small entities that may be affected, including 25 nurseries, 5 mobile fruit and vegetable vendors, and one farmers' market. Most of the sales by these entities are local intrastate and will not be affected by this rule. Also, the treatments and conditions in the Oriental Fruit Fly regulations and the Plant Protection and Quarantine Treatment Manual allow interstate movement of most products without significant added costs.

Based on these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

The regulations in this subpart contain no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with state and local officials. (See 7 CFR Part 3015, Subpart V).

List of Subjects in 7 CFR Part 301

Agricultural commodities, Plant diseases, Plant pests, Plants (Agriculture), Quarantine, Transportation, Oriental fruit fly.

PART 301—DOMESTIC QUARANTINE NOTICES

Accordingly, 7 CFR Part 301 is amended as follows:

1. The authority citation for Part 301 continues to read as follows:

Authority: 7 U.S.C. 150dd, 150ee, 150ff; 161, 162, and 167; 7 CFR 2.17, 2.51, and 371.2(c).

2. In § 301.93-3(c), the description of the quarantined areas are amended by adding a portion of San Diego County in California, to read as follows:

§ 301.93-3 Quarantined areas.

* * * * *

(c) * * *

California

* * * * *

That portion of San Diego County bounded by a line beginning at the intersection of State Highway 163 and Interstate Highway 8, then east along Interstate Highway 8 to its intersection with Spring Street, then south along Spring Street to its intersection with Broadway, then southwest along Broadway to its intersection with Sweetwater Road, then south along Sweetwater Road to its intersection with South Bay Freeway, then southwest along South Bay Freeway to its intersection with Sweetwater Road, then west along Sweetwater Road to its intersection with 30th Street, then west along 30th Street to its intersection with National City Boulevard, then north along National City Boulevard to its intersection with 24th Street, then west along 24th Street to its intersection with Interstate Highway 5, then northwest along Interstate Highway 5 to its intersection with Harbor Drive, then northwest along Harbor Drive to its intersection with State Highway 75, then northeast along State Highway 75 to its intersection wtih Interstate Highway 5, then northwest along Interstate Highway 5 to its intersection with 6th Avenue, then north along 6th Avenue to its intersection with State Highway 163, then north along State Highway 163 to the point of beginning.

Done at Washington, DC, this 31st day of July, 1987.

W.F. Helms,

Deputy Administrator, Plant Protection and Quarantine, Animal and Plant Health Inspection Service.

[FR Doc. 87-17904 Filed 8-5-87; 8:45 am]

BILLING CODE 3410-34-M

Farmers Home Administration

7 CFR Parts 1944 and 1951

Section 502 Rural Housing Loans

AGENCY: Farmers Home Administration, USDA.

ACTION: Final rule.

SUMMARY: The Farmers Home Administration (FmHA) amends its regulations concerning Section 502 rural housing loans to show that direct payments will be sent to the address on the payment coupons, rather than to the FmHA Finance Office. Form FmHA 451-34 is being renumbered for consistency within our directives system. References to the direct payment system and to the processing method for payment plan changes are being updated. The circumstance requiring this action is a change in the method that FmHA will use to process these section 502 direct payments after they are mailed by the borrowers to the Agency. The intended effect is to implement a new lockbox system for receipt and processing of these payments.

EFFECTIVE DATE: August 6, 1987.

FOR FURTHER INFORMATION CONTACT: Duane L. Ischer, Director, Financial and Management Analysis Staff, Farmers Home Administration, USDA, Room 5047 South Agriculture Building, 14th and Independence Avenue, SW, Washington, DC 20250. Telephone (202) 475-4618.

SUPPLEMENTARY INFORMATION: This action has been reviewed under USDA procedures established in Department Regulation 1512-1, which implements Executive Order 12291, and has been determined to be exempt from those requirements because it involves only Agency procedure. It is the policy of this Department to publish for comment rules relating to public property, loans, grants, benefits, or contracts notwithstanding the exemption in 5 U.S.C. 553 with respect to such rules. This action, however, is not published for proposed rulemaking, since it involves only Agency procedure and publication for comment is unnecessary.

FmHA Section 502 rural housing regulations previously required that direct payments be sent to the FmHA Finance Office for processing. However, as a result of a cost/benefit study performed jointly by FmHA and by the United States Department of Treasury, FmHA has determined that the cost to the Agency for receiving and processing these direct loan payments would be lower if the work were contracted to the private sector. This new method of processing direct payments, a lockbox, will be transparent to the borrowers, and the only change will be in the address which is preprinted on the payment coupons provided to the borrowers.

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.410. For the reasons set forth in the Final Rule related Notice to 7 CFR Part 3015, Subpart V, 48 FR 29115, June 24, 1983, this program/activity is excluded from the scope of Executive Order 12372 which requires intergovernmental consultation with State and local officials.

This document has been reviewed in accordance with 7 CFR Part 1940, Subpart G, "Environmental Program." It is the determination of FmHA that this action does not constitute a major Federal action significantly affecting the quality of the human environment and in accordance with the National Environmental Policy Act of 1969, Pub.

L. 91-190, an Environmental Impact Statement is not required.

List of Subjects

7 CFR Part 1944

Home improvement, Loan programs—Housing and community development, Low and moderate income housing—Rental, Mobile homes, Mortgages, Rural housing, Subsidies.

7 CFR Part 1951

Account servicing, Credit, Loan programs—Agriculture, Loan programs-Housing and Community Development, Low and moderate income housing loans—Servicing.

Therefore, Chapter XVII, Title 7 of the Code of Federal Regulations is amended as follows:

PART 1944—HOUSING

1. The authority citation for Part 1944 continues to read as follows:

Authority: 42 U.S.C. 1480; 7 CFR 2.23; 7 CFR 2.70.

Subpart A—Section 502 Rural Housing Loan Policies, Procedures, and Authorizations

2. Section 1944.33 is amended by revising paragraph (f) to read as follows:

§ 1944.33 Loan closing.

* * * * *

(f) *Direct payments.* Direct payment coupons for all new borrowers, including transferees, will be retained in the County Office until the borrower has made at least six monthly payments on time. The coupons may then be delivered to the borrower and payments made directly to the address shown on the payment coupon. The County Supervisor may retain the payment coupons for a longer period if such action is considered to be necessary to determine that the borrower is able to make timely payments as agreed. If the County Office is not on the Concentration Banking System (CBS), payments made to the County Office will be forwarded to the Finance Office with the appropriate direct payment coupon in the Finance Office mail. If the County Office is on CBS, direct payments made in the County Office will be deposited into the Treasury Limited Depositary Account and the direct payment coupon forwarded to the Finance Office in accordance with the applicable CBS procedures. Cash payments, refunds, and extra payments made by borrowers will be handled in accordance with Subpart B of Part 1951 of this chapter.

* * * * *

3. Section 1944.34 is amended by revising paragraph (b)(1) to read as follows:

§ 1944.34 Interest credit.

* * * * *

(b) * * *

(1) *Annual payment borrowers.* Borrowers who signed promissory notes providing for annual payments, including borrowers converted to monthly payments through the use of Form FmHA 1951-34, "Direct Payment Plan Change."

* * * * *

PART 1951—SERVICING AND COLLECTIONS

4. The authority citation for Part 1951 continues to read as follows:

Authority: 7 U.S.C. 1989; 42 U.S.C. 1480; 5 U.S.C. 301; 7 CFR 2.23; 7 CFR 2.70.

Subpart A—Account Servicing Policies

5. Section 1951.6 is amended by revising paragraphs (c)(1), (c)(2), (c)(3)(ii), (c)(3)(iv), (c)(3)(v), (c)(3)(vi), (c)(3)(vii), (d), (e)(1), and (e)(4) to read as follows:

§ 1951.6 Handling payments.

* * * * *

(c) * * *

(1) Payments made through the County Office without direct payment coupons for FO and SW loans will be handled in accordance with Part 1951, Subpart B.

(2) Payments for FO and SW individual loans made through the County Office with Form FmHA 370-46A, Expanded Direct Payment Coupon, will be handled as follows:

(i) County Supervisors may put FO and SW individual borrowers on the Expanded Direct Payment Coupon system if the borrower only needs limited credit counseling or only makes one annual installment payment per year on the loan.

(ii) For new loans, the County Supervisor will indicate by checking the appropriate block on Form FmHA 1940-1, "Request For Obligation of Funds," that for selected borrowers Expanded Direct Payment Coupons are to be mailed to the County Office.

(iii) An existing loan borrower may be put on or taken off this Expanded Direct Payment Coupon system by filling out Form FmHA 1951-34, "Direct Payment Plan Change," in accordance with the Forms Manual Insert (FMI) and entering it via the field office terminal system.

(iv) Payments must be made by check or money order payable to the Farmer Home Administration. If a field office is on concentration banking, the checks and/or money orders are deposited in the concentrator bank. The coupons are forwarded directly to the Finance Office in accordance with concentration banking procedures. If a field office is not on concentration banking, the coupons and checks and/or money orders are placed in one envelope and mailed to the Finance Office with any other items being mailed that day.

(v) The Finance Office, upon receipt of the payment coupon and check or money order, will credit the borrower's account with payment as of the date the payment is received in the field office.

(vi) When the Finance Office received payment coupon number 10, a new supply of coupons will be mailed to the County Office. All 12 payment coupons should be used before using the new supply.

(3) * * *

(ii) For new loans the County Supervisor will indicate on Form FmHA 1940-1 the selected borrowers by checking the appropriate box. The payment coupon packet will be forwarded to the County Office at the time the loan is obligated. It will be delivered to the borrower at loan closing, at which time the use of the payment coupons will be explained to the borrower.

* * * * *

(iv) The payment coupons and pre-addressed envelopes, together with instructions on how to use the coupons and a record keeping card, will be asembled into an envelope in which the borrower may retain the records. The Form FmHA 370-46, "Direct Payment Coupon," will be numbered 1-12, even though the borrower may have less or more than 12 payments scheduled during the year.

(v) The Finance Office, upon receipt of Form FmHA 370-46 and a check or money order, will credit the borrower's account with payment as of the date the payment is received by the Finance Office.

(vi) When the Finance Office receives Form FmHA 370-46 for payment number 10, a new supply of Forms FmHA 370-46 will be prepared and mailed to the borrower. All 12 copies of Form FmHA 370-46 should be used before using the new supply.

(vii) If a borrower is on direct payment and receives a subsequent FO or SW loan, the Finance Office will send a set of Form FmHA 370-46 with "FO" or "SW" in the loan number block. This indicates the borrower has more than one loan of the particular type. The borrower will be instructed by the County Office to send a Form FmHA

370–46 showing the amount and a check or money order for the total payment.

(d) *County Office handling of direct payment accounts.* Form FmHA 1905–1, "Management System Card—Individual," and Form FmHA 1905–1, "Management System Card—Individual (Rural Housing only)," will be used in the County Office Management System Box. These forms and the transaction records will be maintained as prescribed in FmHA Instruction 1905–A (available in any FmHA office). In addition, an orange signal will be placed to the left of Position A on Form FmHA 1905–1 to denote that the borrower is on the direct payment system. If a borrower fails to make payments as agreed, or becomes delinquent in taxes or insurance so that it is necessary for FmHA to pay taxes or insurance by voucher, the County Supervisor may request the Finance Office to remove the borrower from the direct payment method. If this decision is made, the County Supervisor will contact the borrower and collect the remaining supply of Forms FmHA 370–46 which will be destroyed. The borrower will be informed that payments after that date should be made to the County Office. If at a later date the borrower is making payments on schedule, the County Supervisor may request the Finance Office to put the borrower back on the direct payment method and provided a new set of Forms FmHA 370–46. These changes are made by filling out Form FmHA 1951–34 in accordance with the FMI and entering it via the field office terminal system.

(e) * * *

(1) Any regular payments a borrower is to make prior to receiving the packet of payment coupons will be made through the County Office in the usual manner.

* * * * *

(4) If an uncollectible item is received, the Finance Office will reverse the amount from the borrower's account and a new Form FmHA 451–26, "Transaction Record," reflecting the uncollectible amount will be prepared. The Form FmHA 451–26 will be mailed to the County Office. The uncollectible item with a transmittal memorandum will be sent to the County Office. The County Office will return the uncollectible check to the borrower after it is fully redeemed. The borrower will make payment by sending a new check and a new payment coupon to the Finance Office.

* * * * *

Subpart G—Borrower Supervision, Servicing and Collection of Single Family Housing Loan Accounts

6. Section 1951.308 is amended by revising the introductory text of paragraph (a) and paragraph (b) to read as follows:

§ 1951.308 Payment coupons and changes in payment plan.

(a) *Issuing payment coupons.* A booklet of 12 payment coupons and envelopes is provided initially for each borrower. The Finance Office will mail the payment coupons to the County Supervisor who will forward them to the borrower or keep them in the County Office depending on the status of the borrower's account. The County Supervisor will use Form FmHA 1951–34, "Direct Payment Plan Change," to request new coupons when not automatically provided by the Finance Office. The Finance Office will automatically provide a new booklet of 12 coupons and envelopes when:

* * * * *

(b) *Changes in payment plan*—(1) *From annual payment to monthly payment.* With their concurrence, borrowers may be converted at anytime from annual payments to the monthly payment plan by using Form FmHA 1951–34, completed in accordance with the Forms Manual Insert (FMI). The County Office must be careful not to create a delinquency when making this conversion. When the form is processed in the Finance Office, the required monthly payments will be established as 1/12th of the annual installment. Cents will be rounded to the next higher dollar.

(2) *From monthly payments to annual payment.* Borrowers with annual payment notes who voluntarily converted to the monthly payment plan may be removed from the monthly payment plan upon request provided their account is current. The change will be accomplished by completing Form FmHA 1951–34.

* * * * *

7. Section 1951.309 is amended by revising paragraph (a)(1) to read as follows:

§ 1951.309 Receiving and applying payments.

(a) * * *

(1) *Direct payments.* Normally, borrowers should mail their payments directly to the address shown on the payment coupon in one of the window envelopes provided with the coupon packet. However, for all new borrowers, the payment coupons will be held in the County Office for at least the first six payments or for a longer period of time if needed to determine that borrowers understand their responsibility to make payments in a timely manner.

* * * * *

Dated: June 4, 1987.

Eric Thor,

Acting Administrator, Farmers Home Administration.

[FR Doc. 87–17905 Filed 8–5–87; 8:45 am]

BILLING CODE 3410–07–M

DEPARTMENT OF COMMERCE

International Trade Administration

15 CFR Parts 379, 389 and 399

[Docket No. 70631–7131]

Editorial Changes to the Export Administration Regulations

AGENCY: Export Administration, International Trade Administration, Commerce.

ACTION: Final rule.

SUMMARY: This rule, which neither expands nor limits the provisions of the Export Administration Regulations (15 CFR Parts 368–399), makes editorial corrections and clarifications and, in some cases, inserts material inadvertently omitted from earlier regulatory amendments.

Among these corrections and clarifications, are the following:

(a) Several cross-references are revised and others are added for the sake of clarity. Another cross-reference to a regulatory section that no longer exists is removed.

(b) A paragraph that was inadvertently omitted from an earlier revision of § 399.1 is reinserted.

(c) An "Advisory Note" in the Commodity Control List is amended by removing incorrect references to certain commodities.

(d) The processing code, used to facilitate the internal routing and processing of export license applications, is revised for two entries of the Commodity Control List.

(e) Entry 1558A of the Commodity Control List, covering electronic vacuum tubes, is amended by reinserting material inadvertently omitted from an earlier revision.

(f) Entry 5998B of the Commodity Control List is amended by revising the wording of the validated license requirements for shipment of shotguns. This revision is for the sake of clarity only and does not represent any change in export licensing policy.

EFFECTIVE DATE: This rule is effective August 6, 1987.

FOR FURTHER INFORMATION CONTACT: John Black or Patricia Muldonian, Office of Technology and Policy Analysis, Export Administration, Telephone: (202) 377-2440.

SUPPLEMENTARY INFORMATION:

Rulemaking Requirements

1. Because this rule concerns a foreign and military affairs function of the United States, it is not a rule or regulation within the meaning of section 1(a) of Executive Order 12291, and it is not subject to the requirements of that Order. Accordingly, no preliminary or final Regulatory Impact Analysis has to be or will be prepared.

2. Section 13(a) of the Export Administration Act of 1979, as amended (50 U.S.C. App. 2412(a)), exempts this rule from all requirements of section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553), including those requiring publication of a notice of proposed rulemaking, an opportunity for public comment, and a delay in effective date. This rule also is exempt from these APA requirements because it involves a foreign and military affairs function of the United States. Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule.

3. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by section 553 of the Administrative Procedure Act (5 U.S.C. 553), or by any other law, under sections 603(a) and 604(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a) and 604(a)) no initial or final Regulatory Flexibility Analysis has to be or will be prepared.

4. This rule mentions a collection of information subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). This collection has been approved by the Office of Management and Budget under control number 0625-0001.

List of Subjects in 15 CFR Parts 373, 379 and 399

Computer technology, Exports, Reporting and recordkeeping requirements, Science and technology.

Accordingly, the Export Administration Regulations (15 CFR Parts 368-399) are amended as follows:

1. The authority citation for Parts 379, 389 and 399 continues to read as follows:

Authority: Pub. L. 96-72, 93 Stat. 503, 50 U.S.C. App. 2401 *et seq.*, as amended by Pub. L. 97-145 of December 29, 1981 and by Pub. L. 99-64 of July 12, 1985; E.O. 12525 of July 12, 1985 (50 FR 28757, July 16, 1985); Pub. L. 95-223, 50 U.S.C. 1701 *et seq.*; E.O. 12532 of September 9, 1985 (50 FR 36861, September 10, 1985) as affected by notice of September 4, 1986 (51 FR 31925, September 8, 1986); Pub. L. 99-440 (October 2, 1986); E.O. 12571 of October 27, 1986 (51 FR 39505, October 29, 1986).

PART 379—[AMENDED]

Supplement No. 3 [Amended]

2. Supplement No. 3 to Part 379, "Technical Data," is amended by revising paragraph (d)(1) to read: "Technical data described in Supplement No. 4 to Part 379 for metal-working manufacturing processes;".

Supplement No. 4 [Amended]

3. Supplement No. 4 to Part 379, "Additional Specifications for Certain Technical Data Requiring a Validated License to All Destinations Except Canada," is amended by revising paragraph (1)(i) introductory text to read "The following are definitions of terms used in section (1) of this Supplement:".

PART 389—[AMENDED]

§ 389.2 [Amended]

4. Section 389.2(b)(1) is amended by revising the phrase "Room 6716" to read "Room 3898B".

PART 399—[AMENDED]

5. Section 399.1 is amended by redesignating paragraphs (f)(1) (iii) and (iv) as (iv) and (v) and by adding a new (iii), reading as follows:

§ 399.1 The commodity control list and how to use it.

* * * * *

(f) * * *

(1) * * *

(iii) No more than five commodities will be considered in a single request. Exceptions may be made on a case-by-case basis for several related products if the relationship between these products is substantiated and documented;

* * * * *

Supplement No. 1 [Amended]

6. In Supplement No. 1 to § 399.1 (the Commodity Control List), ECCNs 1501A, 1502A, 1516A, 1519A, 1520A, 1572A and 1588A (in Commodity Group 5, Electronics and Precision Instruments) and ECCN 1763A (in Commodity Group 7, Chemicals, Metalloids, Petroleum Products and Related Materials) are amended by adding a Note immediately preceding the heading "Controls for ECCN * * *" reading as follows: "NOTE: For 'specially designed software', see Supp. No. 3 to Part 379."

7. In Supplement No. 1 to § 399.1 (the Commodity Control List), Commodity Group 5 (Electronics and Precision Instruments), ECCN 1501A is amended by adding in Advisory Note 1 the phrase "listed in paragraph (a) of this ECCN" immediately after the phrase "commercial airborne equipment".

8. In Supplement No. 1 to § 399.1 (the Commodity Control List), ECCN 1519A is amended by adding a Note immediately following Technical Note 2 reading: "Note: see § 379.4(f)(1)(i)(Q) for written assurance requirement for exports of technical data related to equipment described in paragraph (b) or (d) of the List of this ECCN, but having a data signalling rate of 2.1 megabits per second or less."

9. In Supplement No. 1 to § 399.1 (the Commodity Control List), Commodity Group 5 (Electronics and Precision Instruments), ECCN 1529A is amended by revising the Processing Code paragraph to read: *"Processing Code:* EE."

10. In Supplement No. 1 to § 399.1 (the Commodity Control List), Commodity Group 5 (Electronics and Precision Instruments), ECCN 1531A is amended by revising the Processing Code paragraph to read: *Processing Code:* EE for items in paragraphs (a), (b) and (c); MT for all other items."

11. In Supplement No. 1 to § 399.1 (the Commodity Control List), Commodity Group 5 (Electronics and Precision Instruments), ECCN 1558A is amended by revising paragraphs (a)(1)(ii), (a)(2)(i), and (a)(3) to read as follows:

1558A Electronic vacuum tubes (valves), and specially designed components therefor.

Controls for ECCN 1558A

* * * * *

List of Electronic Vacuum Tubes (Valves) and Specialized Parts Controlled by ECCN 1558A

(a) * * *

(1) * * *

(ii) Within the frequency range 0.3 to 4 GHz and for which, under any condition of cooling, the product of the maximum rated anode dissipation (expressed in watts) and the square of the maximum frequency (expressed in GHz) at the maximum rated anode dissipation is greater than 10^4, *except for tubes specially designed for television transmitters operating in the frequency range of 0.47 to 0.96 GHz and rated for operation without a grid current, for which the product of the rated anode dissipation (expressed in watts) and the square of the maximum frequency (expressed in GHz) may reach* 2×10^4;

(2) * * *

(i) Above 1 GHz at the peak pulse output power; *or*

(ii) * * *

(3) Tubes specially designed for use as pulse modulators for radar or similar applications, having a peak anode voltage rating of 100kV or more, or rated for a peak pulse power of 6 MW or more (See also ECCN 1514A.);

* * * * *

12. In Supplement No. 1 to § 399.1 (the Commodity Control List), Commodity Group 5 (Electronics and Precision Instruments), ECCN 1565A is amended by removing the second Note following *Nuclear Non-Proliferation Controls*, which begins "Certain digital computers and/or devices. . . ."

13. In Supplement No. 1 to § 399.1 (the Commodity Control List), Commodity Group 5 (Electronics and Precision Instruments), ECCN 1567A is amended by redesignating "Advisory Note 8" (which begins "The following are definitions of terms . . .") as "Note 8".

14. In Supplement No. 1 to § 399.1 (the Commodity Control List), Commodity Group 5 (Electronics and Precision Instruments), ECCN 1572A is amended by revising in paragraph (b) of (Advisory) Note 8 the phrase "Department of Commerce" to read "Office of Export Licensing".

15. In Supplement No. 1 to § 399.1 (the Commodity Control List), Commodity Group 9 (Miscellaneous), ECCN 5998B is amended by revising the Validated License Required paragraph to read as follows: *"Validated License Required:* Country Groups QSTVWYZ, except for Australia, Japan, New Zealand, and members of NATO.

(a) Shotguns with a barrel length 24 inches or over require a validated license for shipment to:

(1) Country Groups QSWYZ, regardless of end-user;

(2) South Africa, Namibia, Botswana, Lesotho and Swaziland, regardless of end-user; and

(3) Other destinations in Country Groups T and V, except for Australia, Japan, New Zealand, and members of NATO, *only* if for sale or resale to police or law enforcement agencies.

(b) Shotguns with a barrel length of at least 18 inches but less than 24 inches require a validated license for shipment to all destinations, except Australia, Japan, New Zealand, and members of NATO, regardless of end-user.

(c) Shotguns with a barrel length of less than 18 inches are controlled by the Office of Munitions Control, Department of State.

Date: July 30, 1987.

Vincent F. DeCain,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 87-17705 Filed 8-5-87; 8:45 am]

BILLING CODE 3510-DT-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

[Docket No. 80F-0499]

Indirect Food Additives: Adhesives and Components of Coatings

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of 1,2-bis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamoyl) hydrazine as a component of adhesives in articles intended for food-contact use. This action responds to a petition filed by Ciba-Geigy Corp.

DATES: Effective August 6, 1987; objections by September 8, 1987.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of January 16, 1981 (46 FR 3982), FDA announced that a petition (FAP OB3487) had been filed by Ciba-Geigy Corp., Ardsley, NY 10502 (the firm is now located at Three Skyline Dr., Hawthorne, NY 10532), proposing that § 175.105 *Adhesives* (21 CFR 175.105) be amended to provide for the safe use of 1,2-bis (3,5-di-*tert*-butyl-4-hydroxyhydrocinnamoyl) hydrazine as a component of adhesives in articles intended for food-contact use.

FDA, in its evaluation of the safety of this additive, reviewed the safety of both the additive and the starting materials used to manufacture the additive. Although, 1,2-bis (3,5-di-*tert*-butyl-4-hydroxyhydrocinnamoyl) hydrazine has not been found to cause cancer, it may contain minute amounts of an impurity, hydrazine, as a byproduct of its production. Hydrazine has been shown to cause cancer in test animals. Residual amounts of reactants and manufacturing aids, such as this chemical, are commonly found as contaminants in chemical products, including food additives.

FDA proposed to prohibit the use of hydrazine as a food additive in boiler water used to produce steam for food processing (21 CFR 173.310) in the **Federal Register** of June 12, 1979 (44 FR 33693). The agency's proposal was based upon information, using new analytical methods, that hydrazine was present at low levels (parts per billion) in steam condensate from boilers using hydrazine as a boiler water additive. The agency intends to take further action on the June 12, 1979, proposal at a future date.

FDA's evaluation of any risks created by the presence of hydrazine as an impurity in 1,2-bis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamoyl) hydrazine is based on different considerations than its evaluation of the safety of hydrazine as a food additive, however. Therefore, FDA concludes that it can proceed with this rulemaking independently of the latter evaluation.

I. Determination of Safety

Under section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), the so-called "general safety clause" of the statute, a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. The concept of safety enbodied in the Food Additives Amendment of 1958 is explained in the legislative history of the provision: "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstances." H. Rept. 2284, 85th Cong., 2d Sess. 4 (1958). This definition of safety has been incorporated into FDA's food additive regulations (21 CFR 170.3(i)). The anticancer or Delaney clause of the Food Additives Amendment (section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A))) provides further that no food additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal.

In the past, FDA has often refused to approve the use of an additive that contained or was suspected of containing even minor amounts of a carcinogenic chemical, even though the additive as a whole had not been shown to cause cancer. The agency now believes, however, that developments in

scientific technology and experience with risk assessment procedures make it possible for FDA to establish the safety of additives that contain carcinogenic chemicals but that have not themselves been shown to cause cancer.

In the preamble to the final rule permanently listing D&C Green No. 6, published in the **Federal Register** of April 2, 1982 (47 FR 14138), FDA explained the basis for approving the use of a color additive that had not been shown to cause cancer, even though it contains a carcinogenic impurity. Since that decision, FDA has approved the use of other color additives and food additives on the same basis.

An additive that has not been shown to cause cancer, but that contains a carcinogenic impurity, may properly be evaluated under the general safety clause of the statute using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive.

The agency's position is supported by *Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984). That case involved a challenge to FDA's decision to approve the use of D&C Green No. 5, which contains a carcinogenic chemical but has itself not been shown to cause cancer. Relying heavily on the reasoning in the agency's decision to list this color additive, the United States Court of Appeals for the Sixth Circuit rejected the challenge to FDA's action and affirmed the listing regulation.

II. Safety of Petitioned Use

FDA estimates that the petitioned use of 1,2-bis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamoyl)hydrazine will result in extremely low levels of exposure to this additive. FDA does not ordinarily consider chronic testing to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Refs. 1 and 2), and the agency has not required such testing here. Because 1,2-bis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamoyl)hydrazine has not been shown to cause cancer, the anticancer clause does not apply to it.

FDA has evaluated the safety of this additive under the general safety clause, considering all available data and using risk assessment procedures to estimate the upper bound limit of risk presented by the carcinogenic chemical that may be present as an impurity in the additive. Based on this evaluation, the agency has concluded that the additive is safe under the proposed conditions of use.

The risk assessment procedures that FDA used in this evaluation are similar to the methods that it has used to examine the risk associated with the presence of minor carcinogenic impurities in various other food and color additives that contain carcinogenic impurities (see, e.g., 49 FR 13018, 13019; April 2, 1984). This risk evaluation of the carcinogenic impurity hydrazine has two aspects: (1) Assessment of the worst case exposure to the impurity from the proposed use of the additive and (2) extrapolation of the risk observed in the animal bioassay to the conditions of probable exposure to humans.

A. Hydrazine

Based on the fraction of the daily diet that may be in contact with surfaces containing 1,2-bis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamoyl)hydrazine and on the level of hydrazine that may be present in the additive (Ref. 3), FDA estimated the hypothetical worst case exposure to hydrazine from the use of this additive to be 20 nanograms per person per day. The agency used data in a carcinogenesis bioassay on hydrazine conducted by Toth et al. at the University of Nebraska College of Medicine (Ref. 4) to estimate the upper bound limit of lifetime human risk from exposure to this chemical stemming from the proposed use of 1,2-bis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamoyl)hydrazine. The results of the Toth bioassay on hydrazine demonstrated that the material was carcinogenic for male and female mice under the conditions of the study. The test material caused significantly increased incidences of lung tumors in male and female mice.

The Center for Food Safety and Applied Nutrition's Cancer Assessment Committee reviewed this bioassay and other relevant data available in the literature and concluded that the findings of carcinogenicity were supported by this information on hydrazine. The committee further concluded that the Toth bioassay provided the appropriate basis on which to calculate an estimate of the upper bound level of lifetime human risk from potential exposure to hydrazine stemming from the proposed use of 1,2-bis(3,5-di-*tert*-butyl-4-hydroxy-hydrocinnamoyl)hydrazine.

The agency used a quantitative risk assessment procedure (linear proportional model) to extrapolate from the dose used in the animal experiment to the very low doses encountered under the proposed conditions of use. This procedure is not likely to underestimate the actual risk from very low doses and may, in fact, exaggerate it because the extrapolation models used are designed to estimate the maximum risk consistent with the data. For this reason, the estimate can be used with confidence to determine to a reasonable certainty whether any harm will result from the proposed conditions and levels of use of the food additive.

Based on a worst case exposure of 20 nanograms per person per day, FDA estimates that the upper bound limit of individual lifetime risk from potential exposure to hydrazine from the use of 1,2-bis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamoyl)hydrazine is 7×10^{-8} or less than 1 in 10 million. Because of numerous conservatisms in the exposure estimate, lifetime averaged individual exposure to hydrazine is expected to be substantially less than the estimated daily intake, and, therefore, the calculated upper bound limit of risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from the exposure to the hydrazine that might result from the proposed use of 1,2-bis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamoyl)hydrazine.

B. Need for Specifications

The agency has also considered whether a specification is necessary to control the amount of the hydrazine impurity in the food additive. The agency finds that a specification is not necessary for the following reasons: (1) Because excess hydrazine is removed during the additive's manufacturing process, the agency would not expect this impurity to become a component of food at other than extremely small levels; and (2) the upper bound limit of lifetime risk from exposure to this impurity, even under worst case assumptions, is very low, less than 1 in 10 million.

III. Conclusion on Safety

FDA has evaluated the available toxicity data and the exposure calculation for the additive and has determined that the additive is safe for its proposed use.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition (address above) by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action and has concluded that the

action will not have significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. Under FDA's regulations implementing the National Environmental Policy Act (21 CFR Part 25), an action of this type would require an abbreviated environmental assessment under 21 CFR 25.31a(b)(1).

References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Carr, G.M., "Carcinogenicity Testing Programs" *in* "Food Safety: Where Are We?," Committee on Agriculture, Nutrition, and Forestry, United States Senate, July 1979, p. 59.

2. Kokoski, C.J., "Regulatory Food Additive Toxicology" presented at the "Second International Conference on Safety Evaluation and Regulation of Chemicals," October 24, 1983, Cambridge, MA.

3. Memorandum dated October 2, 1985, from Food Additive Chemistry Evaluation Branch to Indirect Additive Branch. "FAP 0B3487—Exposure to Hydrazine."

4. Toth, et al., "Hydrazine Methylhydrazine and Methylhydrazine Sulfate Carcinogenesis in Swiss Mice," *International Journal of Cancer*, 9:109, 1972.

Any person who will be adversely affected by this regulation may at any time on or before September 8, 1987, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 175

Adhesives, Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR Part 175 continues to read as follows:

Authority: Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. Section 175.105 is amended in paragraph (c)(5) by alphabetically inserting a new item in the table to read as follows:

§ 175.105 Adhesives.

* * * * *

(c) * * *

(5) * * *

Substances	Limitations
* * * * *	
1,2-Bis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamoyl)hydrazine (CAS Reg. No. 32687-78-8).	For use at a level not to exceed 2 percent by weight of the adhesive.
* * * * *	

Dated: July 30, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87-17889 Filed 8-5-87; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 816

Permanent Program Performance Standards-Surface Mining Activities; Use of Explosives

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

ACTION: Final rule; technical amendment.

SUMMARY: This rule makes a technical correction to the Office of Surface Mining Reclamation and Enforcement's (OSMRE) final rule governing the use of explosives which was published March 8, 1983 (48 FR 9788), under provisions of the Surface Mining Control and Reclamation Act of 1977 (SMCRA).

EFFECTIVE DATE: August 6, 1987.

FOR FURTHER INFORMATION CONTACT: Gertrude Dark, Regulatory Development and Issues Management, Office of the Director, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Avenue NW., Washington, DC 20240; (202) 343-5261.

SUPPLEMENTARY INFORMATION:

I. Background and Discussion of the Amendment

II. Procedural Matters

I. Background and Discussion of the Amendment

OSMRE published a final rule on March 8, 1983 (48 FR 9788) revising the requirements in 30 CFR Part 816 relating to the use of explosives. Section 816.68 requires operators to maintain blasting records for at least 3 years and to make them available for inspection by the regulatory authority and the public upon request. This is required in section 515(b)(15)(B) of SMCRA.

One of the items to be reported in the record of blasting operations is the condition of the weather as explained in the preamble to the March 8, 1983 rule at 48 FR 9803. However, in 30 CFR 816.68(e), the word "weather" meaning climatic condition appeared in error as the word "whether". This rule corrects that spelling error. The correction is considered a technical amendment and no change in the meaning or application of the rule as explained in the preamble at 48 FR 9803 is intended.

II. Procedural Matters

Executive Order 12291 and the Regulatory Flexibility Act

OSMRE has determined that this document is not a major rule and does not require a regulatory impact analysis under Executive Order 12291 because the rule is an administrative correction and has no economic effect on the public. The Department has also determined that this document will not have a significant economic effect on a substantial number of small entities and does not require a regulatory flexibility analysis under the Regulatory Flexibility Act.

National Environmental Policy Act

This rulemaking is not a major Federal action, but an administrative

rule covered under previous rulemakings. Therefore, an environmental assessment is not required for this rulemaking which is covered under the environmental assessment and environmental impact statements prepared for the previous rulemakings.

Federal Paperwork Reduction Act

It has been determined that the information collection requirements do not change due to the corrections of this rulemaking and therefore, it is exempt from the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and does not require clearance by the Office of Management and Budget.

List of Subjects in 30 CFR Part 816

Environmental protection, Reporting and recording keeping requirements, Surface mining.

Accordingly, the Office of Surface Mining Reclamation and Enforcement is amending 30 CFR Part 816 as set forth herein.

Date July 29, 1987.

J. Steven Griles,

Assistant Secretary for Land and Minerals Management.

PART 816—PERMANENT PROGRAM PERFORMANCE STANDARDS-SURFACE MINING ACTIVITIES

1. The authority citation for Part 816 is revised to read as follows:

Authority: Pub. L. 95-87, 91 Stat. 445 (30 U.S.C. 1201 *et seq.*), as amended; and Pub. L. 100-34.

§ 816.68 [Amended]

2. Paragraph (e) of § 816.68 is amended by removing the word "Whether" and adding in its place the word "Weather".

[FR Doc. 87-17825 Filed 8-5-87; 8:45 am]

BILLING CODE 4310-05-M

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 174

Ocean Transportation Service; Amendment

AGENCY: Department of the Navy, DOD.

ACTION: Final rule.

SUMMARY: The Military Sealift Command amends this part by outlining its authority and responsibilities, relationships with military services, and updating its organization and contact numbers. It reflects changes in awarding contracts for ship repair under the Federal Acquisition Regulation. Also, it gives the availability for DOD Instruction 7410.4 of April 16, 1982. This revision is intended to reflect current agency procedures for better understanding by the public.

EFFECTIVE DATE: September 8, 1987.

FOR FURTHER INFORMATION CONTACT: Nancy H. Barr, Bldg. 210, Washington Navy Yard, Washington, DC 20398-5100, telephone (202) 433-0642.

SUPPLEMENTARY INFORMATION: Part 174 of Chapter I, Title 32 of the Code of the Federal Regulations, is being amended to update and clarify Department of the Navy procedures for the Military Sealift Command. This regulation involves an established body of technical regulations. Routine amendments are necessary to keep them operationally current. Since this regulation contains only minor technical amendments to DON procedures, notice and public comment under 5 U.S.C. 553(b) are unnecessary.

The Department of the Navy determined this regulation is not a major rule as defined by Executive Order 12291, is not subject to relevant provisions of the Regulatory Flexibility Act of 1980 (Pub. L. No. 96-354), is not subject to relevant provisions of the National Environmental Policy Act of 1969 (42 U.S.C. 4321-4347), and does not contain reporting or record-keeping requirements under the Paperwork Reduction Act of 1980 (Pub. L. No. 96-511).

List of Subjects in 32 CFR Part 174

Transportation.

For the reasons set out in the preamble, Title 32, Chapter I, Subchapter F of the Code of Federal Regulations, is amended as set forth below.

PART 174—OCEAN TRANSPORTATION SERVICE

1. The authority citation for Part 174 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. 125, 133.

2. Section 174.1 is amended by revising the second sentence of paragraph (d) and the last sentence of paragraph (e) to read as follows:

§ 174.1 Authority and responsibility.

* * * * *

(d) * * * MSC is a part of the Operating Forces of the Navy, and the Commander, Military Sealift Command, is under the military command of the Chief of Naval Operations, except that the Assistant Secretary of the Navy (Shipbuilding and Logistics) exercises policy supervision in procurement, administrative, management principles affecting the Military Sealift Command including, inter alia; (1) Justification and approval documentation authorizing other than full and open competition and (2) business clearances as required by Navy Acquisition Regulations Supplement section 1.690. * * *

(e) * * * MSC operates Government-owned ships and augments this capability by shipping cargo and passengers in commercially operated ships, chartering ships, and exercising operational control over ships activated from the National Defense Reserve Fleet and Ready Reserve Force to meet emergency needs.

3. Section 174.3 is amended by revising the first sentence of paragraph (b), the second and third sentences of paragraph (c), paragraph (d), paragraph (e), and the second paragraph of paragraph (f) to read as follows:

§ 174.3 Organization.

* * * * *

(b) Under the Commander, Military Sealift Command, with the headquarters at Washington, DC, are area commands, with headquarters as follows:

Commander, Military Sealift Command, Far East, Yokohama, Japan
Commander, Military Sealift Command, Pacific, Oakland, California
Commander, Military Sealift Command, Atlantic, Bayonne, New Jersey
Commander, Military Sealift Command, Europe, London, United Kingdom * * *

(c) * * * This fleet is comprised of dry cargo ships, tankers, special mission ships, and naval fleet auxiliary force ships, all civilian-manned. Operational and administrative control of this fleet, is generally accomplished by MSC area commands and MSC headquarters.* * *

(d) Augmentation of MSC USNS fleet capability is accomplished by shipping less-than-shipload lots of cargo in commercially-operated berth line merchant ships under the terms of MSC Shipping Agreements or MSC Shipping Contracts, and by the chartering of commercial dry-cargo ships and tankers. Chartered ships are under the operational control of MSC and become part of the MSC controlled fleet during the tenure of the charters. Merchant ships activated from the National Defense Reserve Fleet and Ready Reserve Force to meet emergency needs are placed under MSC operational control by means of U.S. Maritime Administration General Agency Agreements (GAA).

(e) The negotiation, execution, and administration of ship charters are

accomplished at MSC headquarters, Washington, DC and area commands. Negotiation and execution of MSC shipping agreements and shipping contracts are accomplished at MSC headquarters. Policy concerning MSC operation and maintenance of National Defense Reserve Fleet and Ready Reserve Force ships is also determined at MSC headquarters; scheduling and other operational matters for these ships are accomplished at MSC area commands.

(f) * * * Mail address:
Commander, Military Sealift Command, Department of the Navy, Washington, DC 20398-5100
Street address:
Washington Navy Yard, Bldg. 210, Washington, DC 20398-5100
Telephone numbers:
Commander (202 area code)—433-0001
Vice Commander—433-0007
Deputy Commander—433-0005
Legislative and Public Affairs Officer—433-0333
Deputy EEO Officer—(301 area code)—427-5559
Flag Secretary Headquarters Secretariat—433-0004
Personnel, Manpower, and Management Officer—433-0445
Readiness and Program Introduction Officer—433-0497
Operations Officer—433-0075
Engineering Officer—433-0170
Force Medical Officer—(301 area code)—427-5612
Supply Officer—433-0116
Comptroller—(301 area code)—427-5615
Strategic Mobility Officer—433-0296
Counsel—433-0140
Command Information Systems Officer—433-0320
Contracts and Business Management Officer—433-0315
Commander, Military Sealift Command, Atlantic, Military Ocean Terminal, Bldg. 42, Bayonne, New Jersey 07002-5399.
Commander (201 area code)—823-7504
Chief Staff Officer—823-7506
Civilian Personnel Officer—823-6683
Fleet Operations Officer—823-7516
Transportation and Sealift Readiness Officer—823-7154
Engineering Officer—823-7431
Medical Officer—823-7220
Supply Officer—823-7424
Comptroller—823-7572
Strategic Mobility Officer—823-7528
Counsel—823-7510
Management Information Systems Officer—823-7583
Contracting Officer—823-5383
Public Affairs—823-7622
Commander, Military Sealift Command, Pacific, Naval Supply Center, Oakland, California 94625-5010.
Commander (415 area code)—466-4111
Chief Staff Officer—466-4247
Administration and Manpower Officer—466-4717
Public Affairs Officer—466-4802
Civilian Personnel Officer—466-4949
Fleet Operations Officer—466-4918
Transportation Officer—466-4848
Engineering Officer—466-4866
Supply Officer—466-4271
Comptroller—466-4796
Strategic Mobility Officer—466-4828
Counsel—466-4923
Contracting Officer—466-4840
Commander, Military Sealift Command, Europe (mailing address) Box 3, FPO New York 09510-3700 (location not to be included in mailing address) Eastcote Ruislip Middlesex, HA 48135 England.
Commander—place call with overseas operator and ask for 441-868-5588.
Public inquiries may be addressed to the Commander, Military Sealift Command, Far East, who will direct the inquiries to cognizant members of his staff.
Commander, Military Sealift Command, Far East (mailing address), FPO Seattle 98760-2600 (location not to be included in mailing address) Bldg. S-200, North Pier, Yokohama, Japan.
Commander—place call with overseas operator and ask for Yokohama, North Pier, 235-6318/6418.
Public inquiries may be addressed to the Commander, Military Sealift Command, Far East, who will direct the inquiries to cognizant members of his staff.

4. Section 174.4 is amended by revising paragraph (c) to read as follows:

§ 174.4 Relationships.

* * * * *

(c) *Joint policies.* The Assistant Secretary of Defense (Acquisition and Logistics) (ASD (A&L)) is responsible for issuing policy direction in connection with the single manager assignment except as otherwise specifically designated in Department of Defense Directive 5160.10. In developing such policies, ASD(A&L) will collaborate with the Assistant Secretary of Defense (Comptroller) to assure maximum utilization of the assignment for budgetary purposes. Similarly he will te with the Assistant Secretary of Defense (System Analysis) to assure maximum application of the assignment for manpower utilization effectiveness purposes. The ASD(A&L) will also collaborate with other elements of the Office of Secretary of Defense, as appropriate.

5. Section 174.5 is amended by revising paragraph (b) and paragraph (d) to read as follows:

§ 174.5 Engineering

* * * * *

(b) *Maintenance and repair.* MSC ships are maintained, repaired, overhauled, and where necessary, modified under Department of Defense Master Ship Repair Agreements. Awards under these contracts are made by both Commander, Military Sealift Command and the responsible area commanders. In the case of government-owned, contract-operated ships, repair contracts are awarded in accordance with the particular operating contract and the Federal Acquisition Regulation.

* * * * *

(d) *Ship classification.* MSC ships (public vessels) of a commercial type are constructed and classified according to the American Bureau of Shipping rules, then surveyed and retained in the assigned class after construction.

* * * * *

6. Section 174.6 is amended by revising paragraph (a) to read as follows:

§ 174.6 Fiscal.

(a) The operations of the Military Sealift Command are financed under the Navy Industrial Fund. For additional information, see DOD Instruction 7410.4 of April 16, 1982. Contact COMSC Directives Control on 202-433-0642, Bldg. 219, Washington Navy Yard, Washington, DC 20398-5100.

* * * * *

Dated: August 3, 1987.

Jane M. Virga,

LT, JAGC, USNR, Federal Register Liaison Officer.

[FR Doc. 87-17826 Filed 8-5-87; 8:45 am]

BILLING CODE 3810-AE-M

Defense Intelligence Agency

32 CFR Part 292a

[DIA Reg. 12-12]

Defense Intelligence Agency Privacy Program

AGENCY: Defense Intelligence Agency (DIA), DoD.

ACTION: Final rule.

SUMMARY: This final rule revises the Defense Intelligence Agency's earlier version of § 292a.13. Part 292a implements the Privacy Act (5 U.S.C.

552a) within the DIA. This revision supersedes § 292a.13 published on December 8, 1986 (51 FR 44064). This revision merely re-formats the existing § 292a.13 in a manner consistent with the format of the announcements of other components within the Department of Defense.

EFFECTIVE DATE: August 6, 1987.

FOR FURTHER INFORMATION CONTACT: Mr. Robert C. Hardzog, Chief, Freedom of Information and Privacy Act Staff, Defense Intelligence Agency, RTS-1, Washington, DC 20340-3299. Telephone: (202) 373-3910 or autovon 243-3910.

SUPPLEMENTARY INFORMATION: The DIA has determined that this final rule revision is not a major rule as defined by E.O. 12291, is not subject to the relevant provisions of the Regulatory Flexibility Act of 1980 (Pub. L. 90-354), and does not contain reporting or recordkeeping requirements under criteria of the Paperwork Reduction Act of 1980 (Pub. L. 96-511).

List of Subjects in 32 CFR Part 292a

Privacy.

PART 292a—[AMENDED]

Accordingly, 32 CFR Part 292a is amended as follows:

1. The authority citation for Part 292a continues to read as follows:

Authority: Privacy Act of 1974 (Pub. L. 93-579, section 3 (f) and (k) of 5 U.S.C. 552a).

2. Section 292a.13 is revised to read as follows:

§ 292a.13 Specific exemptions.

(a) All systems of records maintained by the Defense Intelligence Agency shall be exempt from the requirements of 5 U.S.C. 552a(d) pursuant to 5 U.S.C. 552a(k)(1) to the extent that the system contains any information properly classified under Executive Order 12356 "National Security Information" (47 FR 14874, April 2, 1982), or which is required by Executive Order to be kept secret in the interest of national defense or foreign policy. This exemption, which may be applicable to parts of all systems of records, is necessary because certain record systems not specifically designated for exemption may contain isolated information which has been properly classified.

(b) The Director, Defense Intelligence Agency, designates the systems of records listed below for exemptions under the specified provisions of the Privacy Act of 1974 (Pub. L. 93-579).

LDIA 0271

System Name:

Investigations and Complaints.

Exemption:

Parts of this record system may be exempt from the following portions of Title 5, U.S.C.; section 552a (c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), and (e)(4)(I).

Authority.

5 U.S.C. 552a: (k)(2), (k)(5), and (k)(7).

Reason:

The reasons for asserting these exemptions are to insure the integrity of the Inspector General process within the Agency. The execution of this function requires that information be provided in a free and open manner without fear of retribution or harassment in order to facilitate a just, thorough and timely resolution of the complaint or inquiry. Disclosures from this system can enable individuals to conceal their wrongdoings or mislead the course of the investigation by concealing, destroying or fabricating evidence or documents. Also, disclosures can subject sources and witnesses to harassment or intimidation which may cause individuals not to seek redress for wrongs through Inspector General channels for fear of retribution or harassment.

LDIA 0275

System Name:

DoD Hotline Referrals.

Exemption:

Parts of this record system may be exempt from the following portions of Title 5, U.S.C.; section 552a (c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), and (e)(4)(I).

Authority:

5 U.S.C. 552a: (k)(2), (k)(5), and (k)(7).

Reason:

The reasons for asserting these exemptions are to insure that informants can report instances of fraud and mismanagement without fear of reprisal or unauthorized disclosure of their identity. The execution of this function requires that information be provided in a free and open manner without fear of retribution of harassment in order to facilitate a just, thorough and timely resolution of the case. These records are priviledged Director, DIA, documents and information contained therein is not routinely released or disclosed to anyone.

LDIA 0800

System Name:

Security Files.

Exemption:

Parts of this record system may be exempt from the following portions of Title 5, U.S.C.; section 552a (c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), and (e)(4)(I).

Authority:

5 U.S.C. 552a: (k)(2), (k)(5), and (k)(7).

Reason:

The reason for asserting these exemptions are to insure the integrity of the adjudication process used by the Agency to determine the suitability, eligibility or qualification for Federal service with the Agency and to make determinations concerning the questions of access to classified materials and activities. The proper execution of this function requires that the Agency have the ability to obtain candid and necessary information in order to fully develop or resolve pertinent information developed in the process. Potential sources, out of fear of retaliation, exposure or other action, may be unwilling to provide needed information or may not be sufficiently frank to be a value in personnel screening, thereby seriously interfering with the proper conduct and adjudication of such matters.

LDIA 0800

System Name:

Operation Record System.

Exemption:

Parts of this record system may be exempt from the following portions of Title 5, U.S.C.; section 552a: (c)(3), (d), (e)(1), (e)(4)(G), (e)(45)(H), and (e)(4)(I).

Authority:

5 U.S.C. 552a (k)(2), (k)(5), and (k)(7).

Reason:

The reason for asserting these exemptions are to insure the integrity of ongoing foreign intelligence collection and/or training activities conducted by the Defense Intelligence Agency and the Department of Defense. The execution of these functions requires that information in response to national level intelligence requirements be provided in a free and open manner without fear of retribution or unauthorized disclosure. Disclosures from this system can jeopardize sensitive sources and methodology.

Linda M. Lawson,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 87-17802 Filed 8-5-87; 8:45 am]

BILLING CODE 3810-01-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 64

[Docket No. FEMA 6760]

Suspension of Community Eligibility; New Jersey et al.

AGENCY: Federal Emergency Management Agency, FEMA.

ACTION: Final rule.

SUMMARY: This rule lists communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are suspended on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If FEMA receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will be withdrawn by publication in the **Federal Register**.

EFFECTIVE DATES: The third date ("Susp.") listed in the third column.

FOR FURTHER INFORMATION CONTACT: Frank H . Thomas, Assistant Administrator, Office of Loss Reduction, Federal Insurance Administration, (202) 646–2717, Federal Center Plaza, 500 C Street, Southwest, Room 416, Washington, DC 20472.

SUPPLEMENTARY INFORMATION: The National Flood Insurance Program (NFIP), enables property owners to purchase flood insurance at rates made reasonable through a Federal subsidy. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended (42 U.S.C. 4022), prohibits flood insurance coverage as authorized under the National Flood Insurance Program (42 U.S.C. 4001–4128) unless an appropriate public body shall have adopted adequate floodplain management measures with effective enforcement measures. The communities listed in this notice no longer meet that statutory requirement for compliance with program regulations (44 CFR Part 59 et seq.). Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. However, some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue their eligibility for the sale of insurance. A notice withdrawing the suspension of the communities will be published in the **Federal Register**. In the interim, if you wish to determine if a particular community was suspended on the suspension date, contact the appropriate FEMA Regional Office or the NFIP servicing contractor.

In addition, the Federal Emergency Management Agency has identified the special flood hazard areas in these communities by publishing a Flood Hazard Boundary Map. The date of the flood map, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Disaster Relief Act of 1974 not in connection with a flood) may legally be provided for construction or acquisition of buildings in the identified special flood hazard area of communities not participating in the NFIP and identified for more than a year, on the Federal Emergency Management Agency's initial flood insurance map of the community as having flood-prone areas. (Section 202(a) of the Flood Disaster Protection Act of 1973 (Pub. L. 93–234), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column.

The Administrator finds that notice and public procedure under 5 U.S.C. 553(b) are impracticable and unnecessary because communities listed in this final rule have been adequately notified. Each community receives a 6–month, 90–day, and 30–day notification addressed to the Chief Executive Officer that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. For the same reasons, this final rule may take effect within less than 30 days.

Pursuant to the provision of 5 U.S.C. 605(b), the Admininstrator, Federal Insurance Administration, FEMA, hereby certifies that this rule if promulgated will not have a significant economic impact on a substantial number of small entities. As stated in Section 2 of the Flood Disaster Protection Act of 1973, the establishment of local floodplain management together with the availability of flood insurance decreases the economic impact of future flood losses to both the particular community and the nation as a whole. This rule in and of itself does not have a significant economic impact. Any economic impact results from the community's decision not to (adopt) (enforce) adequate floodplain management, thus placing itself in noncompliance of the Federal standards required for community participation. In each entry, a complete chronology of effectivce dates appears for each listed community.

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

PART 54—[AMENDED]

The authority citation for Part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 et. seq., Reorganization Plan No. 3 of 1978, E.O. 12127).

Section 64.6 is amended by adding in alphabetical sequence new entries to the table.

§ 64.6 List of eligible communities.

State and location	Community No.	Effective dates of authorizaiton/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in special flood hazard areas
Region II				
New Jersey: Bridgewater, township of, Somerset County.	340432	Nov. 26, 1971, Emerg.; Dec. 1, 1978, Reg.; Aug. 19, 1987, Susp.	Aug. 19, 1987	Aug. 19, 1987
Region III				
Pennsylvania:				
Conewango, township of, Warren County	422117	Aug. 20, 1975, Emerg.; Aug. 19, 1987, Reg.; Aug. 19, 1987, Susp.	do	Do.

State and location	Community No.	Effective dates of authorizaiton/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in special flood hazard areas
Muncy, township of, Lycoming County	421847	May 9, 1980, Emerg.; Aug. 19. 1987, Reg.; Aug. 19, 1987, Susp.	do	Do.
North Beaver, township of, Lawrence County	421795	Mar. 2, 1977, Emerg.; Aug. 19, 1987, Reg.; Aug. 19, 1987, Susp.	do	Do.
Pine Grove, township of, Warren County	422124	Aug. 19, 1975, Emerg.; Aug. 19, 1987, Reg.; Aug. 19, 1987, Susp.	do	Do.
Warren, borough of, Warren County	420843	July 3, 1974, Emerg.; Aug. 19, 1987, Reg.; Aug. 19, 1987, Susp.	do	Do.
Region IV				
Kentucky:				
Oldham County, unincoporated areas	210185	Mar. 10, 1987, Emerg.; Aug. 19, 1987, Reg.; Aug. 19, 1987, Susp.	do	Do.
Warsaw, city of, Gallatin County	210080	Jan. 19, 1976, Emerg.; Aug. 19, 1987, Reg.; Aug. 19, 1987, Susp.	do	Do.
North Carolina: Mars Hill, town of, Madison County.	370385	Oct. 4, 1979, Emerg.; Aug. 19, 1987, Reg.; Aug. 19, 1987, Susp.	do	Do.
Region VI				
Arkansas: Gould, city of, Lincoln County	050127	July 26, 1974, Emerg.; Aug. 19, 1987, Reg.; Aug. 19, 1987, Susp.	do	Do.
Oklahoma: Rogers County, unincorporated areas	405379	Nov. 6, 1970, Emerg.; Nov. 5, 1971, Reg.; Aug. 19, 1987, Susp.	do	Do.
Region VIII				
Utah: St. George, city of, Washington County	490177	Aug. 28, 1974, Emerg; Aug. 19, 1987, Reg.; Aug. 19, 1987, Susp..	do	Do.
Region X				
Washington: Pierce County, unincorporated areas	530138	Feb. 15, 1974, Emerg.; Aug. 19, 1987, Reg.; Aug. 19, 1987, Susp.	do	Do.
Minimal Conversions—Region II				
New York: Tupper Lake, village of, Franklin County.	360274	May 29, 1975, Emerg.; Mar. 1, 1987, Reg.; Aug. 19, 1987, Susp.	Mar. 1, 1987	Mar. 1, 1987.
Minimal Conversions—Region III				
Pennsylvania: Franklin, township of, Lycoming County.	420973	Jan. 28, 1974, Emerg.; June 1, 1987, Reg.; Aug. 19, 1987, Susp.	June 1, 1987	June 1, 1987.
Minimal Conversions—Region IV				
Kentucky: Fleming-Neon, city of, Letcher County	210139	July 21, 1976, Emerg.; Aug. 19, 1987, Reg.; Aug. 19, 1987, Susp.	Aug. 19, 1987	Aug. 19, 1987.
North Carolina: Williamston, town of, Martin County.	370157	Oct. 2, 1974, Emerg.; Aug. 19, 1987, Reg.; Aug. 19, 1987, Susp.	do	Do.
Minimal Conversions—Region V				
Illinois:				
Carterville, city of, Williamson County	170716	Sept. 30, 1975, Emerg.; Aug. 19, 1987, Reg.; Aug. 19, 1987, Susp.	do	Do.
Christopher, city of, Franklin County	170238	May 15, 1975, Emerg.; Aug. 19, 1987, Reg.; Aug. 19, 1987, Susp.	do	Do.
Forreston, village of, Ogle County	170527	July 21, 1975, Emerg.; Aug. 19, 1987, Reg.; Aug. 19, 1987, Susp.	do	Do.
Nokomis, city of, Montgomery County	170515	Apr. 15, 1976, Emerg.; Aug. 19, 1987, Reg.; Aug. 19, 1987, Susp.	do	Do.
Michigan: Fredonia, township of, Calhoun County	260562	Dec. 22, 1975, Emerg.; Aug. 19, 1987, Reg.; Aug. 19, 1987, Susp.	do	Do.
Minnesota: Pope County, unincorporated areas	270368	June 25, 1974, Emerg.; Aug. 19, 1987, Reg.; Aug. 19, 1987, Susp.	do	Do
Traverse County, unincorporated areas	270621	Apr. 11, 1974, Emerg.; Aug. 19, 1987, Reg.; Aug. 19, 1987, Susp.	do	Do.
Ohio: Dellroy, village of, Carroll County	390049	Mar. 11, 1977, Emerg.; Aug. 19, 1987, Reg.; Aug. 19, 1987, Susp.	do	Do.
Dexter City, village of, Noble County	390431	Aug. 19, 1975, Emerg.; Aug. 19, 1987, Reg.; Aug. 19, 1987, Susp.	do	Do.
Hemlock, village of, Perry County	390708	Feb. 27, 1976, Emerg.; Aug. 19, 1987, Reg.; Aug. 19, 1987, Susp.	do	Do.
Leetonia, village of, Columbiana County	390084	Sept. 8, 1975, Emerg.; Aug. 19, 1987, Reg.; Aug. 19, 1987, Susp.	do	Do.
Mount Gilead, village of, Morrow County	390424	Apr. 29, 1975, Emerg.; Aug. 19, 1987, Reg.; Aug. 19, 1987, Susp.	do	Do.
Minimal Conversions—Region VII				
Iowa: Anamosa, city of, Jones County	190174	July 25, 1975, Emerg.; Aug. 19, 1987, Reg.; Aug. 19, 1987, Susp.	do	Do.
Nebraska: Brock, village of, Nemaha County	310155	Dec. 26, 1975, Emerg.; Aug. 19, 1987, Reg.; Aug. 19, 1987, Susp.	do	Do.

Code for reading third column: Emerg:—Emergency, Reg.—Regular, Susp.—Suspension.

Harold T. Duryee,
Administrator, Federal Insurance Administration.

[FR Doc. 87-17857 Filed 8-5-87; 8:45 am]

BILLING CODE 6718-03-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 22

[CC Docket No. 85-388]

Amendment Rules Concerning Rural Cellular Service; Correction

AGENCY: Federal Communications Commission.

ACTION: Final rule; correction.

SUMMARY: This document corrects inadvertent errors in the *Order on Reconsideration* (FCC-87-178) in CC Docket No. 85-388 concerning the amendment of the Commission's Rules For Rural Cellular Radio Service (published on June 12, 1987, 52 FR 22461). Appendices D and E are corrected.

FOR FURTHER INFORMATION CONTACT: Gerald Mark Goldstein, Mobile Services Division, Common Carrier Bureau; TELE: 202-632-6450.

SUPPLEMENTARY INFORMATION: This is a summary of corrected portions of the *Order on Reconsideration*, CC Docket 85-388, Adopted May 5, 1987 and Released June 8, 1987. The Complete text of Commission Decisions are available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, (202) 857-3800, 2100 M Street NW., Suite 140, Washington, DC 20037.

In Appendices D and E of the June 12, 1987, document, the following entries are corrected:

Appendix D

State:	Market No.
ALASKA	
RSA 1	315
Wade Hampton	
Yukon-Koyukuk	
RSA 2	316
Aleutian Islands	
RSA 3	317
Ketchikan Gateway	
ARIZONA	
RSA 1	318
Mohave	

Appendix D—Continued

State:	Market No.
CALIFORNIA	
RSA 1	336
Del Norte	
RSA 10	345
Sierra	
COLORADO	
RSA 7	354
Conejos	
FLORIDA	
RSA 3	362
Charlotte	
GEORGIA	
RSA 4	373
Taliaferro	
ILLINOIS	
RSA 2	394
Stark	
RSA 3	395
Knox	
INDIANA	
RSA 1	402
Starke	
DELETE Benton.	
RSA 5	406
Putnam	
Benton is now in RSA 5.	
KANSAS	
RSA 13	439
Comanche	
RSA 15	441
Elk	
DELETE Caldwell, Lyon and Trigg. These counties are in Kentucky RSA 2.	
KENTUCKY	
RSA 1	442
Hickman	
RSA 2	443
ADD Caldwell, Lyon, Trigg.	
These counties were inadvertently placed in Kansas 15.	
RSA 4	445
Larue	
RSA 5	446
Metcalfe	
LOUISIANA	
RSA 5	457
Vermilion	
MAINE	
RSA 3	464
DELETE Sagodaahoc (Sagodaahoo)	
MARYLAND	
RSA 2	467
Worcester	
MINNESOTA	
RSA 6	486
Crow Wing	
Morrison	
RSA 8	488
Lac qui Parle	
MISSOURI	
RSA 1	503
DELETE Andrew	
RSA 7	509
ADD Lafeyette	
RSA 13	515
Ste. Genevieve	

Appendix D—Continued

State:	Market No.
MONTANA	
RSA 5	526
Lewis and Clark	
NEBRASKA	
RSA 1	532
Scotts Bluff	
RSA 4	535
Arthur	
NEW HAMPSHIRE	
RSA 1	547
Cheshire	
NEW MEXICO	
RSA 2	553
Colfax	
NEW YORK	
ADD RSA 6	
RSA 6	729*
Columbia	
Greene	
***This will be Market No. 729.**	
NORTH CAROLINA	
RSA 15	577
Stanly	
OKLAHOMA	
RSA 6	599
Pittsburg	
RSA 8	601
Jackson	
Tillman	
These are separate counties.	
SOUTH DAKOTA	
RSA 7	637
Sully should not have a 6 after it, it is Market No. 637	
TEXAS	
RSA 18	666
Uvalde	
La Salle	
RSA 19	667
Kenedy	
RSA 20	668
De Witt	
Aransas	
VERMONT	
RSA 1	676
Lamoille	
VIRGINIA	
RSA 6	688
Staunton City	
RSA 12	689
King and Queen	
WASHINGTON	
RSA 1	690
Jefferson	
Island	
These are separate counties.	
WEST VIRGINIA	
RSA 5	702
Pocahontas	
WISCONSIN	
RSA 9	713
Fond du Lac	

APPENDIX E—RSA BLOCKS

Block 1	No. of RSAs
Alabama	8
Florida	10
Georgia	14
Mississippi	11
North Carolina	15
South Carolina	8
Tennessee	9
Puerto Rico	7
U.S. Virgin Islands	2
Guam	1
All Other U.S. Territories & Possessions	
Total	85

Block 2	No. of RSAs
Alaska	3
Arizona	6
California	12
Colorado	9
Hawaii	3
Idaho	6
Montana	10
Nevada	5
New Mexico	6
Oregon	6
Utah	6
Washington	8
Wyoming	5
Total	85

Block 3	No. of RSAs
Arkansas	12
Kansas	15
Louisiana	9
Missouri	19
Oklahoma	10
Texas	21
Total	86

Block 4	No. of RSAs
Connecticut	2
Delaware	1
Kentucky	11
Maine	4
Maryland	3
Massachusetts	2
Michigan	10
New Hampshire	2
New Jersey	3
New York	6
Ohio	11
Pennsylvania	12
Rhode Island	1
Vermont	2
Virginia	12
West Virginia	7
Total	89

Block 5	No. of RSAs
Illinois	9
Inndiana	9
Iowa	16
Minnesota	11
Nebraska	10
North Dakota	5
South Dakota	9
Wisconsin	9
Total	78
Overall Total	423

Order of Blocks Scheduled for Lottery	
1. Block 2.	
2. Block 5.	
3. Block 3.	
4. Block 1.	
5. Block 4.	

Federal Communications Commission.

William J. Tricarico,

Secretary.

[FR Doc. 87-17545 Filed 8-5-87; 8:45 am]

BILLING CODE 6712-01-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 20

Migratory Bird Hunting; Final Frameworks for Selecting Early Hunting Seasons on Certain Migratory Game Birds in the United States for the 1987-88 Season

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: This rule prescribes final frameworks (i.e., the outer limits for dates and times when shooting may begin and end, hunting areas, and the numbers of birds which may be taken and possessed) for early-season migratory bird hunting regulations from which States may select season dates and daily bag and possession limits for the 1987-88 season. These seasons may open prior to October 1, 1987, and apply to mourning doves; white-winged and white-tipped doves; band-tailed pigeons; rails: woodcock; snipe; common moorhens and purple gallinules; teal (September only, in designated States); sea ducks (Atlantic Flyway only); experimental September duck seasons in Florida, Iowa, Kentucky and Tennessee; experimental early September Canada goose seasons in parts of Illinois, Michigan and Minnesota; sandhill cranes in the Central and Pacific Flyways; sandhill cranes and Canada geese in southwestern Wyoming; and extended falconry seasons.

DATES: Effective on August 6, 1987. Selected season dates are to be transmitted to the U.S. Fish and Wildlife Service (hereinafter the Service) for publication in the **Federal Register** as amendments to §§ 20.103 through 20.106 and 20.109 of 50 CFR Part 20.

ADDRESSES: Season selections from States are to be mailed to: Director (FWS/MBMO U.S. Fish and Wildlife Service, Department of the Interior, Matomic Building—Room 536, Washington, DC 20240. Comments received are available for public inspection during normal business hours at the Service's Office in Room 536, Matomic Building, 1717 H Street, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Rollin D. Sparrowe, Chief, Office of Migratory Bird Management, Department of the Interior, Washington, DC 20240, telephone (202) 254-3207.

SUPPLEMENTARY INFORMATION: On March 13, 1987, the U.S. Fish and Wildlife Service published for public comment in the **Federal Register** (52 FR 7900) initial proposals to amend 50 CFR Part 20, with comment periods ending June 18, 1987, for Alaska, Hawaii, Puerto Rico and the Virgin Islands frameworks; July 14, 1987, for other early-season frameworks; and August 25, 1987, for late-season frameworks. The March 13, 1987, document dealt with establishment of seasons, limits and shooting hours for migratory game birds under §§ 20.101 through 20.107, 20.109, and 20.110 of Subpart K. A supplemental proposed rulemaking for both the early and late hunting season frameworks appeared in the **Federal Register** dated June 3, 1987 (52 FR 20757).

On June 18, 1987, a public hearing was held in Washington, DC., to review the status of mourning doves, woodcock, band-tailed pigeons, white-winged and white-tipped doves, sanchill cranes and other species. The meeting was announced in the **Federal Register** on March 13, 1987, (52 FR 7900) and June 3, 1987, (52 FR 20757). Proposed hunting regulations were discussed for these species and for common snipe; rails; common moorhens and purple gallinules; September teal seasons in the Mississippi and Central Flyways; experimental early duck seasons in Florida, Iowa, Kentucky and Tennessee; experimental early September Canada goose seasons in parts of Illinois, Michigan and Minnesota; special sea duck seasons in the Atlantic Flyway; sandhill cranes in the Central and Pacific Flyways; sandhill cranes and Canada geese in southwestern Wyoming; extended falconry seasons and hunting regulations for Alaska, Puerto Rico and the Virgin Islands.

Public comments on these matters were received.

On July 2, 1987, the Service published in the **Federal Register** (52 FR 25170) a third document in the series of proposed and final rulemaking documents dealing specifically with proposed frameworks for the 1987–88 season from which, when finalized, wildlife conservation agency officials may select season dates and bag limits for hunting certain migratory birds in their respective jurisdictions during the 1987–88 season. On August 3, 1987, the Service published in the **Federal Register** (52 FR 28717) a fourth document in the series which dealt specifically with final frameworks for Alaska, Puerto Rico and the Virgin Islands.

This rulemaking is the fifth in the series and deals specifically with final frameworks for other early-season migratory game bird hunting regulations from which State wildlife conservation agency officials may select season dates and daily bag and possession limits for the 1987–88 season. These seasons may open prior to October 1, 1987, and apply to mourning doves; white-winged and white-tipped doves; band-tailed pigeons; rails; woodcock; snipe; common moorhens and purple gallinules; teal; (September only, in designated States); sea ducks (Atlantic Flyway only); experimental September duck seasons in Florida, Iowa, Kentucky and Tennessee; experimental early September Canada goose seasons in parts of Illinois, Michigan and Minnesota; sandhill cranes in the Central and Pacific Flyways; sandhill cranes and Canada geese in southwestern Wyoming; and extended falconry seasons.

Review of Public Comments

The Service has already responded to earlier comments on proposed regulations published in the **Federal Register** on March 13, 1987 (52 FR 7900) and June 3, 1987 (52 FR 20757), and discussed at the June 18, 1987, public hearing in Washington, DC. These responses appeared in the **Federal Register** of June 3, 1987 (52 FR 20757) July 2, 1987 (52 FR 25170), and August 3, 1987 (52 FR 28717). Fifty-seven additional comments relating to proposed early season frameworks have been received and are discussed here.

One individual expressed his support of the proposed early season frameworks as they appeared in the July 2, 1987, **Federal Register** (52 FR 25176). The remaining comments are discussed in the same order as the specific numbered items to which they apply are listed in previous 1987 **Federal Register** publications.

6. September Teal Season

An Indiana waterfowl biologist requested that the Service consider permitting eligible States to split their 9-day September teal season. He indicated the option to split the teal season would provide the State flexibility to solve a public relations problem and it would not negatively impact the resource.

Response. The frameworks for September teal seasons specify that such seasons be 9 consecutive days. Further, States may not zone or split the September teal seasons. The request to allow a split season is viewed as a liberalization. The blue-winged teal population has been generally depressed during the 1980s, therefore the Service believes liberalizations are not appropriate. In addition, it may be time to examine current harvest management strategies for blue-winged teal in the event that the decline in this species continues in subsequent years. For these reasons the Service believes the current frameworks for September teal seasons should be continued during the 1987 season.

8. Experimental September Duck Seasons

In the July 2, 1987, **Federal Register** (52 FR 25172), the Service reviewed and responded to the comments presented at the June 18, 1987, public hearing by Mr. Frank Montalbano, III, representing the Florida Game and Fresh Water Fish Commission, who urged the Service to support Florida's request for operational status of their experimental September duck season. By letter dated June 23, 1987, Florida submitted additional information in support of their request foroperational status of their experimental September duck season. The State asserts that existing banding data (1961-85) showing low recovery rates for Florida wood ducks are sufficient to justify the additional hunting opportunities associated with the September season. The State pointed out that while wood duck harvest has not increased with implementation of the special September season, harvest per hunter per day has, which they believe suggests that wood duck populations have expanded. Also, based on the estimate size of the resident wood duck population in Florida and the estimated annual harvest, they maintain that harvest rates do not exceed 10 percent, which is not excessive. In addition, they believe by means of a recent parasite-tag study, the evaluation of the October liberalized harvest regulations (Johnson et al. 1986) and the final report of Florida's September duck season, that sufficient information exists to satisfy the Service's expression of need for more cooperative studies that are flyway-oriented to better manage wood ducks.

Response. In the **Federal Register** of July 2, 1987 (52 FR 25172), June 3, 1987 (52 FR 20759) and August 13, 1986 (51 FR 28948), the Service responded to Florida's request that their experimental September season become operational by citing that results of wood duck banding information provided in Florida's final report were not adequate to evaluate the impact of the season. The Service recognizes the difficulty in obtaining these banding samples but again, reiterates its position. Problems associated with September duck seasons and the need for a full and complete evaluation were presented in the July 3, 1986, **Federal Register** (51 FR 24420). The Service notes the various studies conducted in the Atlantic Flyway and recognizes the contribution they provide to better management of wood ducks. However, the Service has repeatedly stated its intent to review September seasons and their suitability for widespread application before authorizing existing experimental seasons to become operational.

14. Frameworks For Geese And Brant in the Conterminous United States—Outside Dates, Season Length, and Bag Limits

Mississippi Flyway. (a) By letter dated June 29, 1987, a Michigan wildlife official transmitted the following requests relative to early September Canada goose hunting seasons: (1) The large areas outside the posted boundaries of the Shiawassee River State Game Area, the Shiawassee National Wildlife Refuge (NWR) and the Fish Point Wildife Area that were closed during the 1986 experimental September Canada goose hunting season be opened for the 1987 experimental season because significant movements of migrant Canada geese do not occur in Michigan until after September 10; (2) the daily bag limit during the experimental September Canada goose hunting season be increased to 5 Canada geese daily, and the season length be increased to 10 days between September 1 and 10; (3) the State be permitted to incorporate portions of its Upper Peninsula in an early September Canada goose hunting season in 1987 because hunting is the only practical way to address crop damages by geese there; and (4) the opening date for the regular Canada goose hunting season in the Saginaw County Goose Management Area be liberalized to September 26 to

act as a control against crop damage by geese in the vicinity of the Shiawassee NWR and the State Game Area.

In a subsequent letter dated July 10, 1987, another Michigan wildlife official reiterated the preceding requests and emphasized the following points: (1) The closed areas adjacent to the Shiawassee State and Federal wildlife areas and the Fish Point and Allegan State Game and Wildlife Areas be opened; and (2) that the Upper Peninsula (UP) or limited portions of the same be included in the early September hunt because of reports of serious crop damage problems. It was noted that an early September hunt in the UP was denied in 1986 for reasons not fully explained and that the State supplied the Service with information from the Baraga Plains Area and Seney NWR concerning peak migration periods for Canada geese. It was reported that no apparent migration (i.e., arrival of migrating Canada geese) occurs before September 12 at Seney NWR. Additional information was offered for the UP and northern Lower Peninsula to the effect that 89 percent of the neck-collar reports received from these areas were of Michigan collars during the May-October period, but the State indicated that there were too few collar observations during the September 1–10 period to draw specific conclusions about the relative numbers of migrant versus resident Canada geese.

Response. The Service addressed the issue of removing the area closures for the 1987 experimental September Canada goose hunting season in Michigan in the June 3, 1987, **Federal Register** (52 FR 20760), by indicating that the closed-areas provision of the experimental season should not be changed until after the initial experimental period (3-years) has been completed and the results evaluated. The Service notes the closed areas were identified and described by Michigan in 1986. Based on 1-year's experience with a 6-day early season and a 2-goose daily bag limit the State now believes these closed areas should be opened to hunting. The Service has reconsidered this situation and agrees that removal of the closed areas outside the posted boundaries of the Shiawassee, Fish Point and Allegan State Game and Wildlife Areas and the Shiawassee NWR is appropriate to aid in control of depredation complaints. The Service's understanding is that all lands within the posted boundaries of those four wildlife management areas will remain closed to hunting during the experimental September hunting season. The final frameworks presented later in this document reflect a 10-day experimental Canada goose season between September 1 and 10 and a daily bag limit of 5 Canada geese for Michigan's Lower Peninsula. Should the removal of the hunting closure in the four areas above, in combination with the longer season and larger bag limit, result in an unacceptable harvest of migrant Canada geese, the Service hereby gives notice that these seasons may be more restrictive in 1988.

In regard to the request for an early season in a limited portion of the UP, the Service notes the migration information provided by Michigan for the Baraga Plains and Seney NWR and the limited neck collar sightings support the State's claim that little or no migration of Canada geese occurs during early September in the UP. The Service agrees an experimental early September season for resident Canada geese is warranted. The final frameworks that follow provide for a 10-day experimental season between September 1 and 10 and a daily bag limit of 5 Canada geese for certain designated areas in the UP. For both the Lower Peninsula and Upper Peninsula experimental September Canada goose seasons are offered provided the following conditions are met and a Memoranda of Agreement governing the experimental seasons is concluded by the Service and Michigan.

1. Outside dates for the seasons are September 1 and September 10.

2. The State must conduct neck-collar observations and population surveys during these hunt periods.

3. The State must collect sufficient data to ascertain the probable source population of the Canada geese harvested.

4. The State must report in writing on the results of these early seasons prior to the Service's June 1988 early-season regulations meeting.

Michigan's desire to open the 1987 goose hunting season in its Saginaw County Goose Management Area on September 26 was addressed by the Service in the June 3, 1987, **Federal Register** (52 FR 20760) wherein the Service noted the request required an extension of the regular framework opening date and that present frameworks are adequate and no further changes should be made at this time.

(b) Three hunting groups and 45 individuals from Michigan submitted comments supporting Michigan's request that the large areas outside the posted boundaries of the Shiawassee, Fish Point and Allegan State Game and Wildlife Areas and the Shiawassee NWR that were closed to hunting during the 1986 experimental September Canada goose season be opened for the 1987 experimental season.

Response. See the response in 14a above concerning these areas.

(c) Minnesota's request for an experimental 9-day September Canada goose hunting season between September 1 and 15 was noted in the June 3, 1987, **Federal Register** (52 FR 20760). Minnesota later amended its request by changing the dates for the season to September 12 through 20. In the July 2, 1987, **Federal Register** (52 FR 25174) the Service indicated that Minnesota's request would be considered pending receipt of supplemental data from the State supporting its request. Minnesota subsequently submitted additional information relative to the neck-collar observation data it had previously supplied.

Response. In view of the data provided by Minnesota, the Service believes an experimental September hunting season on Canada geese is warranted. However, there are still concerns that the population data and neck-collar observations of Canada geese in the proposed hunt area in mid-September are limited. Therefore, the regulatory frameworks presented later in this document provide for an experimental September Canada goose season in Minnesota not to exceed 10 days, provided a Memorandum of Agreement governing the experimental season is concluded by the Service and Minnesota and the numbered conditions outlined in 14a above for Michigan are met by Minnesota.

16. Sandhill Cranes

The National Wildlife Federation submitted comments endorsing the proposed regulatory frameworks for hunting sandhill cranes. The endorsement is made because the frameworks are such that excellent sandhill crane hunting opportunities are provided, crop depredations by sandhill cranes can be reduced and the potential conflicts between sandhill crane hunters and whooping cranes are minimized.

Response. The Service notes and appreciates the National Wildlife Federation's comments.

22. Band-tailed Pigeons.

The National Wildlife Federation expressed its endorsement of the proposed regulatory frameworks restrictions for the Pacific Coast Population of band-tailed pigeons.

Response. The Service notes and appreciates the support of the National Wildlife Federation.

23. Mourning Doves

Western Management Unit. (a) In a July 1, 1987, letter, Arizona reaffirmed the comments presented at the June 18, 1987, public hearing by its representative Mr. Dave Brown, objecting to the Service's proposed frameworks for mourning doves in the Western Management Unit. The State reiterated its request for a 70-day season, the first 20 days from September 1 through 20, the remainder of the season to occur after November 1.

Response. The Service reviewed and addressed Mr. Brown's comments in the July 2, 1987, **Federal Register** (52 FR 25172). In view of the significant long-term downward trend in mourning doves throughout the Western Management Unit, the Service continues to believe that harvest opportunity for this species should be reduced commensurate with lower population levels. The Service does not favor establishing separate regulatory frameworks which attempt to address population segments that have not yet been adequately defined and therefore has established frameworks that will regulate mourning dove harvest throughout the Western Management Unit.

(b) The Tucson Rod and Gun Club expressed its support of Arizona's request for a 70-day mourning dove hunting season.

Response. See the Service's response given to item 23a above.

(c) The National Wildlife Federation submitted comments indicating that it agreed that available data on long-term mourning dove population trends support the Service's 3-year experimental harvest reduction of the species in the Western Management Unit. The Federation indicated that while the data do not suggest the population decline is due to excessive harvest, the causes and possible remedies for the decline need to be determined.

Response. The Service notes and appreciates the National Wildlife Federation's comments.

(d) The Wildlife Legislative Fund of America questioned the Service's basis for reduction of the season length and bag limits for mourning doves in the Western Management Unit. They indicated it is highly questionable whether restrictions on hunting will have any affect on dove populations in the Unit because the decreased dove population is not the result of hunting, but rather is the result of loss of habitat due to changing agricultural and horticultural practices.

Response. In the June 2, 1987, **Federal Register** (52 FR 20762) it was noted that the factors that are suspected of causing the long-term downward trend in dove populations in the Western Management Unit are loss of nesting habitat, agricultural changes and overharvest. In light of this, the Service concurred with the Pacific Flyway Council's recommendation that regulations restrictions be imposed to decrease harvest opportunity to a level commensurate with the reduced dove populations.

24. White-winged Doves

The National Wildlife Federation expressed its endorsement of the proposed regulatory frameworks for white-winged doves.

Response. The Service notes and appreciates the National Wildlife Federation's support.

NEPA Consideration

The "Final Environmental Statement for the Issuance of Annual Regulations Permitting the Sport Hunting of Migratory Birds (FES 75–54)" was filed with the Council on Environmental Quality on June 6, 1975, and notice of availability was published in the **Federal Register** on June 13, 1975 (40 FR 25241). In addition, several environmental assessments have been prepared on specific matters which serve to supplement the material in the Final Environmental Statement. Copies of the environmental assessments are available from the Service at the address indicated under the caption **ADDRESS.** As a noted in the March 13, 1987, **Federal Register** (52 FR 7905), the Service is preparing a supplemental environmental impact statement (SEIS) on the FES. The Service indicated a mid-July 1987 publication date for a draft SEIS to be followed by public meetings prior to preparation of the final SEIS was anticipated; however, it is now unlikely that the draft SEIS will be available before early September.

Endangered Species Act Consideration

Section 7 of the Endangered Species Act provides that, "The Secretary shall review other programs administered by him and utilize such programs in furtherance of the purposes of this Act" [and shall] "insure that any action authorized, funded, or carried out * * * is not likely to jeopardize the continued existence of such endangered or threatened species or result in the destruction or modification of [critical] habitat * * * ". The Service therefore initiated section 7 consultation under the Endangered Species Act for the proposed hunting season frameworks.

On June 15, 1987, the Chief, Office of Endangered Species, concluded that the proposed actions were not likely to jeopardize the continued existence of listed species.

As in the past, hunting regulations this year are designed, among other things, to remove or alleviate chances of conflict between seasons for migratory game birds and the protection and conservation of endangered and threatened species.

The Service's biological opinions resulting from its consultation under section 7 are considered public documents and are available for inspection in the Office of Endangered Species and the Office of Migratory Bird Management, U.S. Fish and Wildlife Service, Department of the Interior, Washington, DC 20240.

Regulatory Flexibility Act, Executive Order 12291 and the Paperwork Reduction Act

In the **Federal Register** dated March 13, 1987 (52 FR 7900), the Service reported measures it had undertaken to comply with requirements of the Regulatory Flexibility Act and the Executive Order. These included preparing a Determination of Effects and an updated Final Regulatory Impact Analysis, and publication of a summary of the latter. These regulations have been determined to be major under Executive Order 12291 and they have a significant economic impact on substantial numbers of small entities under the Regulatory Flexibility Act. This determination is detailed in the aforementioned documents which are available upon request from the Office of Migratory Bird Management, U.S. Fish and Wildlife Service, Department of the Interior, Washington, DC 20240. These regulations contain no information collections subject to Office of Management and Budget review under the Paperwork Reduction Act of 1980.

Memorandum of Law

The Service published its Memorandum of Law, as required by section 4 of Executive Order 12291, in the **Federal Register** dated August 3, 1987 (52 FR 28717).

Authorship

The primary author of this final rulemaking is Morton M. Smith, Office of Migratory Bird Management, working under the direction of Rollin D. Sparrowe, Chief.

Regulations Promulgation

The rulemaking process for migratory bird hunting must, by its nature, operate under severe time constraints. However, the Service is of the view that every attempt should be made to give the public the greatest possible opportunity to comment on the regulations. Thus, when the proposed rules were published March 13, June 3, and July 2, the Service established what it believed were the longest periods possible for public comment. In doing this, the Service recognized that at the periods' close, time would be of the essence. That is, if there were a delay in the effective date of these regulations after this final rulemaking, the Service is of the opinion that States would have insufficient time to select their season dates, shooting hours and limits; to communicate those selections to the Service; and finally establish and publicize the necessary regulations and procedures to implement their decisions.

Therefore, the Service under authority of the Migratory Bird Treaty Act of July 3, 1918, as amended, (40 Stat. 755; 16 U.S.C. 701 through 708h), prescribes final frameworks setting forth the species to be hunted, the daily bag and possession limits, the shooting hours, the season lengths, the earliest opening and latest closing season dates, and hunting areas, from which State conservation agency officials may select hunting season dates and other options. Upon receipt of season and option selections from State officials, the Service will publish in the **Federal Register** a final rulemaking amending 50 CFR Part 20 to reflect seasons, limits, and shooting hours for the contiguous United States, Alaska, Puerto Rico and the Virgin Islands for the 1987–88 season.

The Service therefore finds that "good cause" exists, within the terms of 5 U.S.C. 553(d)(3) of the Administrative Procedure Act and these frameworks will, therefore, take effect immediately upon publication.

List of Subjects in 50 CFR Part 20

Exports, Hunting, Imports, Transportation, Wildlife.

The rules that eventually will be promulgated for the 1987–88 hunting season are authorized under the Migratory Bird Treaty Act of July 3, 1918 (40 Stat. 755; 16 U.S.C. 701–708h); the Fish and Wildlife Improvement Act of 1978 (92 Stat. 3112; 16 U.S.C. 712); and the Alaska Game Act of 1925 (43 Stat. 739, as amended, 54 Stat. 1103–04).

Final Regulations Frameworks for 1987–88 Early Hunting Seasons on Certain Migratory Birds

Pursuant to the Migratory Bird Treaty Act, the Service of Interior has approved final frameworks which prescribe season lengths, bag limits, shooting hours and outside dates within which States may select seasons for mourning doves; white-winged and white-tipped doves; band-tailed pigeons; rails; woodcock; snipe; common moorhens and purple gallinules; teal in September; experimental September duck season in Iowa, Florida, Kentucky and Tennessee; experimental September Canada goose seasons in Illinois, Michigan and Minnesota; sea ducks (scoters, eiders, and oldsquaw) in certain defined areas of the Atlantic Flyway; sandhill cranes; sandhill cranes-Canada geese in southwestern Wyoming; and extended falconry seasons. For the guidance of State conservation agencies, these frameworks are summarized below.

Notice

Any State desiring its hunting seasons for mourning doves, white-winged doves, white-tipped doves; band-tailed pigeons; rails; woodcock; common snipe; common moorhens and purple gallinules, sandhill cranes or extended falconry seasons to open in September must make its selection no later than August 7, 1987. States desiring these seasons to open after Septemer 30 may make their selections at the time they select regular waterfowl seasons. Season selections for the seven States offered experimental September waterfowl seasons and Wyoming's special sandhill crane-Canada goose season must also be made by August 7, 1987.

Atlantic Flyway coastal States desiring their seasons on sea ducks in certain defined areas to open in September must make their selection no later than August 7, 1987. Those desiring this season to open after September may make their selections when they select their regular waterfowl seasons.

Outside Dates; All dates noted are inclusive.

Shooting Hours: Between ½ hour before sunrise and sunset daily for all species except as noted below. The hours noted here and elsewhere also apply to hawking (taking by falconry).

Mourning Doves

Outside Dates: Between September 1, 1987, and January 15, 1988, except as otherwise provided, States may select hunting seasons and bag limits as follows:

Eastern Management Unit

(All States east of the Mississippi River and Louisiana)

Hunting seasons, and daily bag and possession limits: Not more than 70 days with bag and possession limits of 12 and 24, respectively,

or

Not more than 60 days with bag and possession limits of 15 and 30, respectively.

Hunting seasons may be split into not more than 3 periods under either option.

Shooting Hours: Between ½ hour before sunrise and sunset daily.

Zoning: Alabama, Georgia, Illinois, Louisiana and *Mississippi*, may elect to zone their States as follows:

A. Two zones per State having the following descriptions or division lines:

Alabama—South Zone: Mobile, Baldwin, Escambia, Covington, Coffee, Geneva, Dale, Houston and Henry Counties. North Zone: Remainder of the State.

Georgia—The Northern Zone shall be that portion of the State lying north of a line running west to east along U.S. Highway 280 from Columbus to Wilcox County, thence southward along the western border of Wilcox County, thence east along the southern border of Wilcox County to the Ocmulgee River, thence north along Ocmulgee River to Highway 280, thence east along Highway 280 to the Little Ocmulgee River; thence southward along the Little Ocmulgee River to the Ocmulgee River; thence southwesterly along the Ocmulgee River to the western border of Jeff Davis County; thence south along the western border of Jeff Davis County; thence east along the southern border of Jeff Davis and Appling Counties; thence north along the eastern border of Appling County to the Altamaha River; thence east to the eastern border of Tattnall County; thence north along the eastern border of Tattnall County; thence north along the western border of Evans to Candler County; thence east along the northern border of Evans to Bulloch County; thence north along the western border of Bulloch County to Highway 301; thence northeast along Highway 301 to the South Carolina line.

Illinois—U.S. Highway 36.

Louisiana—Interstate Highway 10 from the Texas State line to Baton Rouge, Interstate Highway 12 from Baton Rouge to Slidell and Interstate Highway 10 from Slidell to the Mississippi State line.

Mississippi—U.S. Highway 84.

B. Within each zone, these States may select hunting seasons of not more than

70 days (or 60 under the alternative) which may be split into not more than 3 periods.

C. The hunting seasons in the South Zones of Alabama, Georgia, Louisiana and Mississippi may commence no earlier than September 20, 1987.

D. Regulations for bag and possession limits, season length, and shooting hours must be uniform within specific hunting zones.

Central Management Unit

(Arkansas, Colorado, Iowa, Kansas, Minnesota, Missouri, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas and Wyoming)

Hunting seasons and daily bag and possession limits: Not more than 70 days with bag and possession limits of 12 and 24, respectively,

or

Not more than 60 days with bag and possession limits of 15 and 30, respectively.

Hunting seasons may be split into not more than 3 periods under either option.

Texas zoning:—In addition to the basic framework and the alternative, Texas may select hunting seasons for each of 3 zones described below.

North zone—That portion of the State north of a line beginning at the International Bridge south of Fort Hancock; north along FM 1088 to State Highway 20; west along State Highway 20 to State Highway 148; north along State Highway 148 to Interstate Highway 10 at Fort Hancock; east along Interstate Highway 10 to Interstate Highway 20; northeast along Interstate Highway 20 to Interstate Highway 30 at Fort Worth; northeast along Interstate Highway 30 to the Texas-Arkansas State line

South zone—That portion of the State south and west of a line beginning at the International Bridge south of Fort Hancock; north along FM 1088 to State Highway 20; west along State Highway 20 to State Highway 148; north along State Highway 148 to Interstate Highway 10 at Fort Hancock; east along Interstate Highway 10 to Van Horn, south and east on U.S. 90 to San Antonio; then east on Interstate 10 to Orange, Texas.

Special white-winged dove area in the south zone—That portion of the State south and west of a line beginning at the International Bridge south of Fort Hancock; north along FM 1088 to State Highway 20; west along State Highway 20 to State Highway 148; north along State Highway 148 to Interstate Highway 10 at Fort Hancock; east along Interstate Highway 10 to Van Horn, south and east on U.S. Highway 90 to Uvalde, south on U.S. Highway 83 to State Highway 44; east along State Highway 44 to State Highway 16 at Freer; south along State Highway 16 to State Highway 285 at Hebbronville; east along State Highway 285 to FM 1017; southeast along FM 1017 to State Highway 186 at Linn; east along State Highway 186 to the Mansfield Channel at Port Mansfield; east along the Mansfield Channel to the Gulf of Mexico.

Central zone—That portion of the State lying between the North and South Zones.

Hunting seasons in these zones are subject to the following conditions:

A. The hunting season may be split into not more than 2 periods, except that, in that portion of Texas where the special 4-day white-winged dove season is allowed, a limited mourning dove season may be held concurrently with the white-winged dove season and with shooting hours coinciding with those for white-winged doves (see white-winged dove frameworks).

B. Each zone may have a season of not more than 70 days (or 60 under the alternative). The North and Central zones may select a season between September 1, 1987 and January 25, 1988; the South zone between September 20, 1987 and January 25, 1988.

C. Except during the special 4-day white-winged dove season in the South Zone, each zone may have an aggregate daily bag limit of 12 doves, (or 15 under the alternative), no more than 2 of which may be white-winged doves and no more than 2 of which may be white-tipped doves. The possession limit is double the daily bag limit.

D. Regulations for bag and possession limits, season length, and shooting hours must be uniform within each hunting zone.

Western Management Unit

(Arizona, California, Idaho, Nevada, Oregon, Utah and Washington)

Hunting seasons, and daily bag and possession limits: Not more than 30 consecutive days between September 1, 1987 and Janaury 15, 1988.

Not more than 45 days to be split between two periods, September 1–15, 1987, and November 1, 1987–January 15, 1988.

In all States, the bag and possession limits are 10 and 20, respectively.

White-Winged Doves

Outside dates: Arizona, California, Nevada, New Mexico, and *Texas* (except as shown below) may select hunting seasons between September 1 and December 31, 1987. *Florida* may select hunting seasons between September 1, 1987 and January 15, 1988.

Arizona may select a hunting season of not more than 15 consecutive days running concurrently with the mourning dove season. The daily bag limit may not exceed 10 mourning and white-winged doves in the aggregate, no more than 6 of which may be white-winged doves, and a possession limit twice the daily bag limit after the opening day.

In the *Nevada* counties of Clark and Nye, and in the *California* counties of Imperial, Riverside and San Bernardino, the aggregate daily bag and possession limits of mourning and white-winged doves may not exceed 10 and 20, respectively, and run concurrently with the season on mourning doves.

New Mexico may select a hunting season with daily bag and possession limits not to exceed 12 and 24 (or 15 and 30 if the 60-day option for mourning doves is selected) white-winged and mourning doves, respectively, singly or in the aggregate of the 2 species. Dates, limits, and hours are to conform with those for mourning doves.

Texas may select a hunting season of not more than 4 days for the special white-winged dove area of the South Zone. The daily bag limit may not exceed 10 white-winged, mourning, and white-tipped doves in the aggregate including no more than two mourning doves and two white-tipped doves per day; and the possession limit may not exceed 20 white-winged, mourning and white-tipped doves in the aggregate including no more than four mourning doves and four white-tipped doves in possession.

and

In addition, *Texas* may also select a white-winged dove season of not more than 70 days (or 60 under the alternative for mourning doves) to be held between September 1, 1987, and January 25, 1988, and coinciding with the mourning dove season. The daily bag limit may not exceed 12 white-winged, mourning and white-tipped doves (or 15 under the alternative) in the aggregate, of which not more than 2 may be white-winged doves and not more than 2 of which may be white-tipped doves. The possession limit may not exceed 24 white-winged, mourning and white-tipped doves (or 30 under the alternative) in the aggregate, of which not more than 4 may be white-winged doves and not more than 4 of which may be white-tipped doves.

Florida may select a white-winged dove season of not more than 70 days (or 60 under the alternative for mourning doves) to be held between September 1, 1987, and January 15, 1988, and

coinciding with the mourning dove season. The aggregate daily bag and possession limits of mourning and white-winged doves may not exceed 12 and 24 (or 15 and 30 if the 60-day option for mourning doves is selected); however, for either option, the bag and possession limits of white-winged doves may not exceed 4 and 8, respectively.

Band-Tailed Pigeons

Pacific Coast States and Nevada: California, Oregon, Washington and the Nevada counties of Carson City, Douglas, Lyon, Washoe, Humboldt, Pershing, Churchill, Mineral and Storey.

Outside dates: Between September 7, 1987, and January 3, 1988 (Sunday closest to January 1).

Hunting seasons, and daily bag and possession limits: Not more than 16 consecutive days, with a bag and possession limit of 4.

Zoning: California may select hunting seasons of 16 consecutive days in each of the following two zones:

1. In the counties of Alpine, Butte, Del Norte, Glenn, Humboldt, Lassen, Mendocino, Modoc, Plumas, Shasta, Sierra, Siskiyou, Tehama and Trinity; and

2. The remainder of the State.

Four-corners states: Arizona, Colorado, New Mexico and Utah.

Outside dates: Between September 1, 1987, and November 30, 1987.

Hunting seasons, and daily bag and possession limits: Not more than 30 consecutive days, with bag and possession limits of 5 and 10, respectively.

Areas: These seasons shall be open only in the areas delineated by the respective States in their hunting regulations.

Zoning: New Mexico may be divided into North and South Zones along a line following U.S. Highway 60 from the Arizona State line east to Interstate Highway 25 at Socorro and south along Interstate Highway 25 from Socorro to the Texas State line. Hunting seasons not to exceed 20 consecutive days may be selected between September 1 and November 30, 1987, in the North Zone and October 1 and November 30, 1987, in the South Zone.

Rails (Clapper, King, Sora and Virginia)

Outside dates: States included herein may select seasons between September 1, 1987, and January 20, 1988, on clapper, king, sora and Virginia rails as follows:

Hunting seasons: The season may not exceed 70 days. Any State may split its season into two segments.

Clapper and King Rails

Daily bag and possession limits: In *Rhode Island, Connecticut, New Jersey, Delaware,* and *Maryland,* 10 and 20 respectively, singly or in the aggregate of these two species. In *Texas, Louisiana, Mississippi, Alabama, Georgia, Florida, South Carolina, North Carolina,* and *Virginia,* 15 and 30, respectively, singly or in the aggregate of the two species.

Sora and Virginia Rails

Daily bag and possession limits: In the Atlantic, Mississippi and Central [1] Flyways and portions of Colorado, Montana, New Mexico and Wyoming in the Pacific Flyway,[2] 25 daily and 25 in possession, singly or in the aggregate of the two species.

Woodcock

Outside dates: States in the Atlantic Flyway may select hunting seasons between October 1, 1987, and January 31, 1988. States in the Central and Mississippi Flyways may select hunting seasons between September 1, 1987, and February 28, 1988.

Hunting seasons, and daily bag and possession limits: In the Atlantic Flyway, seasons may not exceed 45 days, with bag and possession limits of 3 and 6, respectively; in the Central and Mississippi Flyways, seasons may not exceed 65 days, with bag and possession limits of 5 and 10, respectively. Seasons may be split into two segments.

Zoning: New Jersey may select seasons by north and south zones divided by State Highway 70. The season in each zone may not exceed 35 days.

Common Snipe

Outside dates: Between September 1, 1987, and February 28, 1988. In *Maine, Vermont, New Hampshire, Massachusetts, Rhode Island, Connecticut, New York, New Jersey, Delaware, Maryland* and *Virginia* the season must end no later than January 31.

Hunting seasons, and daily bag and possession limits: Seasons may not exceed 107 days in the Atlantic, Mississippi and Central Flyways and 93 days in Pacific Flyway portions of Montana, Wyoming, Colorado and New Mexico. In the remainder of the Pacific Flyway the season shall coincide with the duck seasons. Seasons may be split into two segments. Bag and possession limits are 8 and 16, respectively.

Common Moorhens and Purple Gallinules

Outside dates: September 1, 1987, through January 20, 1988, in the Atlantic and Mississippi Flyways and September 1, 1987, through January 17, 1988, in the Central Flyway. States in the Pacific Flyway must select their hunting seasons to coincide with their duck seasons.

Hunting seasons, and daily bag and possession limits: Seasons may not exceed 70 days in the Atlantic, Mississippi and Central Flyways; in the Pacific Flyway seasons must be the same as the duck seasons. Seasons may be split. Bag and possession limits are 15 and 30 common moorhens and purple gallinules, singly or in the aggregate of the two species respectively; except the daily bag and possession limits in the Pacific Flyway may not exceed 25 coots and common moorhens, singly or in the aggregate of the two species.

Sandhill Cranes

Regulation Seasons in the Central Flyway

Seasons not to exceed 58 days between September 1, 1987, and February 28, 1988, may be selected in the following States: *Colorado* (the Central Flyway portion except the San Luis Valley); *Kansas; Montana* (the Central Flyway portion except that area south of I–90 and west of the Bighorn River); *North Dakota* (west of U.S. 281); *South Dakota*; and *Wyoming* (in the counties of Campbell, Converse, Crook, Goshen, Laramie, Niobrara, Platte and Weston).

For the remainder of the flyway, seasons not to exceed 93 days between September 1, 1987 and February 28, 1988, may be selected in the following States: *New Mexico* (the counties of Chaves, Curry, DeBaca, Eddy, Lea, Quay and Roosevelt); *Oklahoma* (that portion west of I–35); and *Texas* (that portion west of a line from Brownsville along U.S. 77 to Victoria; U.S. 87 to Placedo; Farm Road 616 to Blessing; State 35 to Alvin; State 6 to U.S. 290; U.S. 290 to Sonora; U.S. 277 to Abilene; Texas 351 to Albany; U.S. 283 to Vernon; and U.S. 183 to the Texas-Oklahoma boundary).

[1] The Central Flyway is defined as follows: Colorado (east of the Continental Divide), Kansas, Montana (east of Hill, Chouteau, Cascade, Meagher, and Park Counties), Nebraska, New Mexico (east of the Continental Divide but outside the Jicarilla Apache Indian Reservation), North Dakota, Oklahoma, South Dakota, Texas and Wyoming (east of the Continental Divide).

[2] The Pacific Flyway is defined as follows: Arizona, California, Idaho, Nevada, Oregon, Utah, and Washington; those portions of Colorado and Wyoming lying west of the Continental Divide; New Mexico west of the Continental Divide plus the entire Jicarilla Apache Indian Reservation; and in Montana, the counties of Hill, Chouteau, Cascade, Meagher and Park, and all counties west thereof.

Bag and possession limits: 3 and 6, respectively.

Permits: Each person participating in the regular sandhill crane seasons must obtain and have in his possession while hunting, a valid Federal sandhill crane hunting permit.

Special Seasons in the Central and Pacific Flyways

Arizona, Colorado, Idaho, Montana, New Mexico, Utah and Wyoming may select seasons for hunting sandhill cranes within the range of the Rocky Mountain Population (as described in a management plan approved March 22, 1987, by the Central and Pacific Flyway Councils) subject to the following conditions:

1. Outside dates are September 1–November 30, 1987.

2. Season(s) in any State may not exceed 30 days.

3. Daily bag limits may not exceed 3 and season limits may not exceed 9.

4. Participants must have in their possession while hunting a valid permit issued by the appropriate State.

5. Numbers of permits, areas open and season dates, protection plans for other species, and other provisions of seasons are consistent with the management plan and approved by the Central and Pacific Flyway Councils.

Specific restrictions are:

Arizona

1. The hunting area is confined to Game Management Units 30A, 30B, 31 and 32.

2. No more than 500 permits may be issued.

3. Emergency closures for all crane hunting may be invoked as necessary.

Wyoming

1. Outside dates for the season(s) are September 1–22, 1987.

2. No more than 60 permits may be issued for the Bear River drainage and 60 permits issued for the Salt River area all in Lincoln County; no more than 75 permits may be issued for the Eden-Farson Agricultural Project in Sweetwater and Sublette Counties and the season may not exceed 14 days; and no more than 75 permits may be issued for the Bureau of Reclamation Riverton-Boysen Units in Fremont County.

3. Each permittee may take 2 sandhill cranes per season.

4. Emergency closures for all crane hunting may be invoked as necessary.

New Mexico

1. Two experimental seasons, not to exceed 8 days each, may be selected during the period October 10–31, 1987, in the Middle Rio Grande Valley Crane Hunt Area bounded by the south boundary of Isleta Pueblo; on the west by Interstate 25 and including all of Sevilleta and Bosque del Apache National Wildlife Refuges; on the east by a dirt road from the northeast corner of Bosque del Apache NWR to the western boundary of the White Sands Missile Range Extension Co-Use (WSMREC) area, by the western WSMREC boundary and the eastern boundary of the Sevilleta NWR to U.S. Highway 60, U.S. 60 to NM Highway 47, and NM 47 to the south boundary of Isleta Pueblo; under the following conditions:

2. Not more than 500 special permits may be issued for each season. Permittees must possess valid Bosque del Apache NWR Hunt Cards or pass a hunter qualification course to be eligible to participate.

3. Shooting hours shall be sunrise to sunset and non-toxic shot is required.

4. All special provisions of an annual operational hunt plan, cooperatively prepared by the New Mexico Department of Game and Fish and the U.S. Fish and Wildlife Service Region 2, must be in effect to assure protection of whooping cranes that might occur in the hunting area.

Special Sandhill Crane-Canada Goose Season

Wyoming may select a concurrent season(s) on sandhill cranes, subject to conditions listed under "Sandhill Cranes, Special Seasons in the Central and Pacific Flyways" above, and Canada geese subject to the following conditions:

1. Outside dates for the season(s) are September 1–22, 1987.

2. Hunting will be by State permit.

3. No more than 60 permits may be issued for the Salt River (Star Valley) area in Lincoln County. Each permittee may take 2 Canada geese per season.

4. No more than 75 permits may be issued in the Eden-Farson Agricultural Project in Sweetwater and Sublette Counties, each permittee may take no more than 1 goose per season, and the season may not exceed 14 days.

Scoter, Eider, and Oldsquaw Ducks (Atlantic Flyway)

Outside dates: Between September 15, 1987, and January 20, 1988.

Hunting seasons, and daily bag and possession limits: Not to exceed 107 days, with bag and possession limits of 7 and 14, respectively, singly or in the aggregate of these species.

Bag and possession limits during regular duck season: Within the special sea duck areas, during the regular duck season in the Atlantic Flyway, States may set, in addition to the limits applying to other ducks during the regular duck season, a daily limit of 7 and a possession limit of 14 scoter, eider and oldsquaw ducks, singly or in the aggregate of these species.

Areas: In all coastal waters and all waters of rivers and streams seaward from the first upstream bridge in *Maine, New Hampshire, Massachusetts, Rhode Island, Connecticut* and *New York;* in any waters of the Atlantic Ocean and in any tidal waters of any bay which are separated by at least 1 mile of open water from any shore, island and emergent vegetation in *New Jersey, South Carolina,* and *Georgia;* and in any waters of the Atlantic Ocean and in any tidal waters of any bay which are separated by at least 800 yards of open water from any shore, island and emegent vegetation in *Delaware, Maryland, North Carolina* and *Virginia;* and provided that any such areas have been described, delineated and designated as special sea duck hunting areas under the hunting regulations adopted by the respective States. In all other areas of these States and in all other States in the Atlantic Flyway, sea ducks may be taken only during the regular open season for ducks and they must be included in the regular duck season conventional or point-system daily bag and possession limits.

Deferred selection: Any State desiring its sea duck season to open in September must make its selection no later than August 7, 1987. Any State desiring its sea duck season to open after September may make its selection at the time it selects its waterfowl season.

September Teal Season

Outside Dates: Between September 1 and September 30, 1987, an open season on all species of teal may be selected by *Alabama, Arkansas, Colorado* (Central Flyway portion only), *Illinois, Indiana, Kansas, Kentucky, Louisiana, Mississippi, Missouri, New Mexico,* (Central Flyway portion only), *Ohio, Oklahoma, Tennessee* and *Texas* in areas delineated by State regulations.

Hunting seasons, and bag and possession limits: Not to exceed 9 consecutive days, with bag and possession limits of 4 and 8, respectively.

Shooting hours: From sunrise to sunset daily.

Deadline: States must advise the Service of season dates and special provisions to protect non-target species by August 7, 1987.

Special September Duck Seasons

Iowa September duck season: Iowa may experimentally hold a portion of its regular duck hunting season in September. All ducks which are legal during the regular duck season may be taken during the September segment of the season. In 1987, the 5-day season segment may commence no earlier than September 19, with daily bag and possession limits being the same as those in effect during the 1987 regular duck season.

Florida September duck season: An experimental 5-consecutive-day duck season may be selected in September subject to the following conditions:

1. The season will be in lieu of the extra teal option.

2. The daily bag limit will be 4 ducks, no more than one of which may be a species other than teal or wood duck, and the possession limit will be double the daily bag limit.

Tennessee and Kentucky September duck seasons: Experimental 5-consecutive-day duck seasons may be selected in September by *Tennessee* and *Kentucky* subject to the following conditions:

1. The seasons will be in lieu of September teal seasons.

2. The daily bag limit will be 4 ducks, no more than 2 of which may be wood ducks, and no more than 1 of which may be a species other than teal or wood duck. The possession limit will be double the daily bag limit.

Special Early-September Canada Goose Seasons

Experimental Canada goose seasons of up to 10 consecutive days may be selected in September by *Michigan, Illinois,* and *Minnesota* subject to the following conditions:

1. Outside dates for the season are September 1–10, 1987.

2. The daily bag and possession limits will be no more than 5 and 10 Canada geese, respectively.

3. Areas open to the hunting of Canada geese are as follows:

Michigan—The Lower Peninsula, exclusive of the major goose migration/concentration areas that remained closed during the 1986 early-September season, except for the areas outside the posted boundaries of the Fish Point, Shiawassee and Allegan State Game and Wildlife Areas and the Shiawassee National Wildlife Refuge. On the Upper Peninsula the areas open to hunting are limited to the Garden Peninsula, that area south of US Highway 2 but east of Escanaba, Michigan, that area east of Interstate Highway 75, and that area west of Interstate Highway 75 bounded by Highways M–28 and M–221.

Illinois: McHenry, Lake, Kane, DuPage, Cook, Kendall, Grundy, Will, and Kankakee Counties.

Minnesota: All or portions of Anoka, Washington, Ramsey, Hennepin, Carver, Scott and Dakota Counties.

4. Areas open to hunting must be described, delineated and designated as such in each State's hunting regulations.

Special Falconry Regulations

Extended Seasons: Falconry is a permitted means of taking migratory game birds in any State meeting Federal faconry standards in 50 CFR 21.29(k). These States may select an extended season for taking migratory game birds in accordance with the following:

Framework dates: Seasons must fall within the regular season framework dates and, if offered and accepted, other special season framework dates for hunting.

Daily bag and possession limits: Falconry daily bag and possession limits for all permitted migratory game birds shall not exceed 3 and 6 birds, respectively, singly or in the aggregate, during both regular hunting seasons and extended falconry seasons.

Regulations publication: Each State selecting the special season must inform the Service of the season dates and publish said regulations.

Regular seasons: General hunting regulations, including seasons, hours, and limits, apply to falconry in each State listed in 50 CFR 21.29(k) which does not select an extended falconry season.

Note: In no instance shall the total number of days in any combination of duck seasons (regular duck season, sea duck season, September seasons, special scaup season, special scaup and goldeneye season or falconry season) exceed 107 days for a species in one geographical area.

Dated: July 27, 1987.

Susan Recce,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 87–17855 Filed 8–5–87; 8:45 am]

BILLING CODE 4310-55-M

Proposed Rules

Federal Register
Vol. 52, No. 151
Thursday, August 6, 1987

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

Agricultural Marketing Service

7 CFR Part 1030

[Docket No. AO-361-A25]

Milk in the Chicago Regional Marketing Area; Extension of Time for Filing Briefs

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Extension of time for filing briefs.

SUMMARY: This notice extends the time for filing briefs on the record of the hearing held June 2–4, 1987, at Madison, Wisconsin, concerning proposals six through ten to amend the Chicago Regional marketing order. Counsel for proponent cooperatives requested more time to review the hearing record and to prepare a brief.

DATE: Briefs are now due on or before August 6, 1987.

ADDRESS: Briefs (4 copies) should be filed with the Hearing Clerk, Room 1079, South Building, U. S. Department of Agriculture, Washington, DC 20250.

FOR FURTHER INFORMATION CONTACT: Richard A. Glandt, Marketing Specialist, Dairy Division, Agricultural Marketing Service, U. S. Department of Agriculture, Washington, DC 20250 (202) 447–4829.

SUPPLEMENTARY INFORMATION: Prior document in this proceeding:

Notice of Hearing: Issued May 15, 1987; published May 19, 1987.

Notice is hereby given that the time for filing briefs, proposed findings and conclusions on the record of the public hearing held June 2–4 1987, at Madison, Wisconsin, on proposals six through ten with respect to the tentative marketing agreement and to the order regulating the handling of milk in the Chicago Regional marketing area pursuant to notice of hearing issued May 15, 1987, (52 FR 18894, May 19, 1987) is hereby further extended to August 6, 1987.

This notice is issued pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and the applicable rules of practice and procedure governing the formulation of marketing agreements and marketing orders (7 CFR Part 900).

List of Subjects in 7 CFR Part 1030

Milk marketing orders, Milk, Dairy products.

Signed at Washington, DC, on: July 31, 1987.

William T. Manley

Acting Administrator.

[FR Doc. 87–17861 Filed 8–5–87; 8:45 am]

BILLING CODE 3410-02-M

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 2 and 9

Revision of Freedom of Information Act Regulations; Conforming Amendments

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations pertaining to Public Records in order to conform its Freedom of Information Act (FOIA) regulations to the Freedom of Information Reform Act of 1986 and to reflect current NRC organizational structure and current agency practice and delegation.These amendments will also reduce the repetition of statutory requirements. These amendments are necessary to inform the public about the procedural changes to the FOIA regulations.

DATES: The comment period expires on August 26, 1987. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Send written comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Comments may also be delivered to Room 1121, 1717 H Street, NW., Washington, DC between 7:30 a.m. and 4:15 p.m. Copies of any comments received may be examined at the NRC Public Document Room, 1717 H Street, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Donnie H. Grimsley, Director, Division of Rules and Records, Office of Administration and Resources Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 301–492–7211.

SUPPLEMENTARY INFORMATION: The Freedom of Information Reform Act of 1986 (Pub. L. 99–570) was signed by the President on October 27, 1986. The Act provides for broader exemption protection for law enforcement information (Exemption 7 of the FOIA) and new law enforcement record exclusions.The new exemption provisions became effective immediately. The amendments changed the threshold of records encompassed under Exemption 7 from "investigatory records" to all records or information compiled for law enforcement purposes.

The OMB guidelines containing a uniform schedule of fees for all agencies were published on March 27, 1987 (52 FR 10012) and became effective on April 25, 1987. Important features of the new fee structure involve substantial changes that relate to agency charges for search, review, and duplication of records. In addition, the new guidelines set forth procedures for conducting searches without charge, duplicating records without charge, waiving or reducing a fee, and the provisions for assessing interest on unpaid bills that are more than 30 days delinquent. Moreover, the OMB guidelines set forth the exclusions to the Act which require the agency to provide the first 100 pages of requested records free of charge. The Act requires affected agencies to use the March 27, 1987 OMB guidelines in structuring their implementing regulations. The new fee structure provisions of the Act became effective on April 25, 1987.

Currently, the NRC is undergoing a major consolidation effort, affecting the entire organizational structure of the agency. While finalization of the total reorganization has not yet been completed, Part 9 has been revised to reflect certain organizational changes that have been completed.

In revising Subpart A, the NRC has renumbered most of the sections to conform to the Office of the Federal Register guidelines which will allow

greater flexibility and ease in making future amendments.

The proposed rule also contains several changes to Part 9, Subpart A, that were proposed by the NRC's Office of the General Counsel. Among the recommended changes included in the proposed rule are four exclusions from the definition of "agency record," a provision that FOIA requests cover only agency records in existence on the date the request is received, and reflection of the delegations made in NRC Manual Chapter 0211.

Conforming amendments are also being made to Part 2 and Part 9, Subparts B, C, and D, to conform cross references to the renumbered sections of Part 9, Subpart A, and to reflect the changes to Exemption 7 of the Freedom of Information Act.

Environmental Impact: Categorical Exclusion

The NRC has determined that this proposed rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(1). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed rule.

Paperwork Reduction Act Statement

This proposed rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget approval numbers 3150-0136 (Part 2) and 3150-0043 (Part 9).

Regulatory Analysis

The proposed rule implements the provisions of the Freedom of Information Reform Act of 1986 and brings Part 9 into conformance with current agency practice and several of the major recommendations of the Office of the General Counsel.

The Freedom of Information Reform Act of 1986 established (1) three levels of fees, (2) new standards for waiving or reducing fees, and (3) an exclusion from providing records without charge. Basically, the NRC will not charge fees for the first two hours of search and the first 100 pages duplicated for all requesters, except commercial-use requesters. Any requester may also seek a waiver or reduction of fees for records in excess of 100 pages. The NRC will not charge fees if the cost of collecting the fee is equal to or greater than the fee itself.

There will be an economic impact on all requesters. However, the most significant economic impact will fall on commercial-use requesters. In keeping with the intent of the Federal user fee concept, the NRC will charge commercial-use requesters full direct cost fees for all search for, review, and duplication of requested records. Commercial-use requesters are not considered to be "small entities," and the NRC believes that assessment of the fees will not cause a significant economic burden on them.

Estimated Annual Costs for Commercial-Use Requesters

[Figure of 350 commercial-use requesters based on actual 1986 statistics]

Search costs (⅓ clerical + ⅔ Professional)	$14,000
Review costs (Professional)	17,000
Total estimated costs	31,000

For the remaining three categories of requesters, the Freedom of Information Reform Act requires agencies to provide 100 pages and two hours of search time free of charge. In addition, these requesters may request a waiver or reduction of fees, which would normally be charged for duplication and search time in excess of the initially waived amounts, if they can show that their request for agency records is in the public interest and is not primarily in their commercial interest.

As a result of the amendments, several principal economic impacts on the NRC are expected. Additional administrative effort will be required by the staff to record time spent in processing FOIA requests, time spent in recording staff processing reports, and time spent in determining the amount requesters will be billed. Also, additional staff duplication effort will be required to provide requesters copies that must be provided without charge.

Estimated Annual Costs for NRC to Process FOIA Requests

[Figures based on estimated 833 hours]

Staff recording of time (⅓ Clerical + ⅔ Professional)	$17,000
Division of Rules and Records Billing Costs	3,000
Duplication of first 100 free pages (23,000 sheets x $.20 per page)	5,000
Total estimated costs	25,000

Regulatory Flexibility Certification

As required by the Regulatory flexibility Act, 5 U.S.C. 605(b), the Commission certifies that this rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. This proposed rule implements the Freedom of Information Reform Act of 1986 (Pub. L. 99-570) which includes the establishment of three levels of fees and specific provisions regarding waiver or assessment of fees for search, review, and duplication of records. Because the Freedom of Information Reform Act of 1986 provides relief for all requesters, except for commercial-use requesters, through waiver or reductions of fees, the NRC does not believe that the majority of potential requesters would fall under the definition of "small entities" set forth in the Regulatory flexibility Act or the Small Business Size Standards issued by the Small Business Administration at 13 CFR Part 121.

Backfit analysis

This proposed rule pertains to the implementation of the Freedom of Information Reform Act of 1986; therefore, no backfit analysis has been prepared.

List of Subjects

10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalty, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 9

Freedom of information, Penalty, Privacy, Reporting and recordkeeping requirements, Sunshine Act.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Parts 2 and 9.

PART 2—RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

1. The authority citation for Part 2 continues to read as follows:

Authority: Sec. 161, 68 Stat. 948, as amended (42 U.S.C. 2201); Sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

2. In § 2.790, paragraphs (a)(7), (b)(1)(ii), and (d) are revised to read as follows:

§ 2.790 Public inspections, exemptions, requests for withholding.

(a) * * *

(7) Records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information—

(i) Could reasonably be expected to interfere with enforcement proceedings;

(ii) Would deprive a person of a right to a fair trial or an impartial adjudication;

(iii) Could reasonably be expected to constitute an unwarranted invasion of personal privacy;

(iv) Could reasonably be expected to disclose the identity of a confidential source, including a State, local, or foreign agency or authority, or any private institution which furnished information on a confidential basis, and, in the case of a record or information compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, information furnished by a confidential source;

(v) Would disclose techniques and procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law; or

(vi) Could reasonably be expected to endanger the life or physical safety of any individual;

* * * * *

(b)(1) * * *

(ii) Contains a full statement of the reasons on the basis of which it is claimed that the information should be withheld from public disclosure. Such statement shall address with specificity the considerations listed in paragraph (b)(4) of this section. In the case of an affidavit submitted by a company, the affidavit shall be executed by an officer or upper-level management official who has been specifically delegated the function of reviewing the information sought to be withheld and authorized to apply for its withholding on behalf of the Company. The affidavit shall be executed by the owner of the information, even though the information sought to be withheld is submitted to the Commission by another person. The application and affidavit shall be submitted at the time of filing the information sought to be withheld. The information sought to be withheld shall be incorporated, as far as possible, into a separate paper. The affiant may designate with appropriate markings information submitted in the affidavit as a trade secret or confidential or privileged commercial or financial information within the meaning of § 9.17(a)(4) of this chapter and such information shall be subject to disclosure only in accordance with the provisions of § 9.19 of this chapter.

* * * * *

(d) The following information shall be deemed to be commerical or financial information within the meaning of § 9.17(a)(4) of this chapter and shall be subject to disclosure only in accordance with the provisions of § 9.19 of this chapter.

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PART 9—PUBLIC RECORDS

3. The authority citation for Part 9 is revised to read as follows:

Authority: Sec. 161, 68 Stat. 948, as amended (42 U.S.C. 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

Subpart A also issued under 5 U.S.C. 552; 31 U.S.C. 9701; Pub. L. 99–570. Subpart B also issued under 5 U.S.C. 552a. Subpart C also issued under 5 U.S.C. 552b.

4. Section 9.1 is revised to read as follows:

§ 9.1 Scope and purpose.

(a) Subpart A implements the provisions of the Freedom of Information Act, 5 U.S.C. 552, concerning the availability to the public of Nuclear Regulatory Commission records for inspection and copying.

(b) Subpart B implements the provisions of the Privacy Act of 1974, 5 U.S.C. 552a, concerning disclosure and availability of certain Nuclear Regulatory commission records maintained on individuals.

(c) Subpart C implements the provisions of the Government in the Sunshine Act, 5 U.S.C. 552b, concerning the opening of Commission meetings to public observation.

(d) Subpart D describes procedures governing the production of agency records, information, or testimony in response to subpoenas or demands of courts or other judicial or quasi-judicial authorities in State and Federal proceedings.

§ 9.1a, 9.3, 9.5, and 9.8 [Removed]

5. Sections 9.1a, 9.3, 9.5 and 9.8 are removed.

6. Section 9.2 is redesignated § 9.3 and revised to read as follows:

§ 9.3 Definitions.

As used in this part:

"Commission" means the Commission of five members of a quorum thereof sitting as a body, as provided by section 201 of the Energy Reorganization Act of 1974.

"Government agency" means any executive department, military department, Government corporation, Government-controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency.

"NRC" means the Nuclear Regulatory Commission, established by the Energy Reorganization Act of 1974.

"NRC personnel" means employees, consultants, and members of advisory boards, committees, and panels of the NRC; members of boards designated by the Commission to preside at adjudicatory proceedings; and officers or employees of Government agencies, including military personnel, assigned to duty at the NRC.

"Working days" means Monday through Friday, except legal holidays.

7. Section 9.2a is redesignated § 9.5 and is republished to read as follows:

§ 9.5 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by an officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized as binding upon the Commission.

8. Section 9.2b is redesignated § 9.8 and revised to read as follows:

§ 9.8 Information collection requirements: OMB approval.

(a) The NRC has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.) OMB has approved the information collection requirements contained in this part under control number 3150–0043.

(b) The approved information collection requirements contained in this part appear in §§ 9.29, 9.41, 9.54, 9.55, and 9.202.

9. Subpart A currently consists of §§ 9.3–9.16. New §§ 9.3, 9.5, and 9.8 are redesignated to precede Subpart A and the remaining sections in Subpart A are renumbered and revised to read as follows (new §§ 9.11 through 9.45):

Subpart A—Freedom of Information Act Regulations

Sec.
9.11 Scope of subpart.
9.13 Definitions.
9.15 Availability of records.
9.17 Agency records exempt from public disclosure.
9.19 Segregation of exempt information and deletion of identifying details.
9.23 Requests for records.
9.21 Publicly available records.

Sec.
9.23 Requests for records.
9.25 Initial disclosure determination.
9.27 Form and content of responses.
9.29 Appeal from initial determination.
9.31 Extension of time for response.
9.33 Search, review, and special service fees.
9.34 Assessment of interest and debt collection.
9.35 Duplication fees.
9.37 Fees for search, review, and duplication of records by NRC personnel.
9.39 Search and duplication provided without charge.
9.41 Requests for waiver or reduction of fees.
9.43 Processing of requests for a waiver or reduction of fees.
9.45 Annual Report to Congress.

Subpart A—Freedom of Information Act Regulations

§ 9.11 Scope of subpart.

This subpart prescribes procedures for making NRC agency records available to the public for inspection and copying pursuant to the provisions of the Freedom of Information Act (5 U.S.C. 552) and provides notice of procedures for obtaining NRC records otherwise publicly available. This subpart does not affect the dissemination or distribution of NRC-originated, or NRC contractor-originated, information to the public under any other NRC public, technical, or other information program or policy.

§ 9.13 Definitions.

As used in this subpart:

"Agency record" is a record in the possession and control of the NRC that is associated with Government business. Agency record does not include records such as—

(1) Publicly available books, periodicals, or other publications that are owned or copyrighted by non-Federal sources;

(2) Records solely in the possession and control of NRC contractors;

(3) Personal records in possession of NRC personnel that have not been circulated, were not required to be created or retained by the NRC, and can be retained or discarded at the author's sole discretion, or records of a personal nature that are not associated with any Government business; and

(4) Non-substantive information in logs or schedule books of the Chairman or Commissioners, uncirculated except for typing or recording purposes.

"Commercial-use request" means a request made under § 9.23(b) for a use or purpose that furthers the commercial, trade, or profit interests of the requester or the person on whose behalf the request is made.

"Direct costs" mean the expenditures that an agency incurs in searching for and duplicating agency records. For a commercial-use request, direct costs include the expenditures involved in reviewing records to respond to the request. Direct costs include the salary of the employee category performing the work based on that basic rate of pay plus 16 percent of that rate to cover fringe benefits and the cost of operating duplicating machinery.

"Duplication" means the process of making a copy of a record necessary to respond to a request made under § 9.23. Copies may take the form of paper copy, microform, audio-visual materials, disk, magnetic tape, or machine readable documentation, among others.

"Educational institution" means an institution which operates a program or programs of scholarly research. Educational institution refers to a preschool, a public or private elementary or secondary school, an institution or graduate higher education, an institution of undergraduate higher education, an institution of professional education, or an institution of vocational education.

"News" means information that is about current events or that would be of current interest to the public.

"Noncommercial scientific institution" means an institution that is not operated on a commercial basis, as the term "commecial" is referred to in the defintion of "commercial-use request," and is operated solely for the purpose of conducting scientific research, the results of which are not intended to promote any particualr product or industry.

"Office", unless otherwise indicated, means all offices, boards, panels, and advisory committees of the NRC.

"Record" means any book, paper, map photograph, brochure, punch card, magnetic tape, paper tape, sound recording, pamphlet, slide, motion picture, or other documentary material regardless of form or characteristics. Record does not include an object or article such as a structure, furniture, a tangible exhibit or model, or a vehicle or piece of equipment.

"Representative of the news media" means any person actively gathering news for an entity that is organized and operated to publish or broadcast news to the public.

"Review" means the process of examining records identified as responsive to a commercial-use request to determine whether they are exempted from disclosure in whole or in part. Also, review includes examining records to determine which Freedom of Information Act exemptions are applicable, identifying records or portions thereof to be disclosed, and excising from the records those portions which are to be withheld.

"Search" means all time spent looking for records, either by manual search or search using existing computer programs, that respond to a request including a page-by-page or line-by-line identification or responsive information within the records.

"Unusual circumstances" mean—

(1) The need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request;

(2) The need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request; or

(3) The need for consultation, which will be conducted with all practicable speed, with another agency having substantial interested in the determination of the request or among two or more components of the NRC having substantial subject-matter interest therein.

§ 9.15 Availability of records.

The NRC will make available for public inspection and copying any reasonably described agency record in the possession and control of the NRC under the provisions of this subpart, and upon request by any person. Records that the NRC routinely makes publicly available are described in § 9.21. Procedures and conditions governing requests for records are set forth in § 9.23.

§ 9.17 Agency records exempt from public disclosure.

(a) The following types of agency records are exempt from pubilc disclosure under § 9.15:

(1) Records (i) which are specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy, and (ii) which are in fact properly classified pursuant to such Executive order;

(2) Records related solely to the internal personnel rules and practices of the agency;

(3) Records specifically exempted from disclosure by stature (other than 5 U.S.C. 552b), provided that such statute (i) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (ii) establishes particular criteria for withholding or refers to particular types of matters to be withheld;

(4) Trade secrets and commercial or financial information obtained from a person and privileged or confidential;

(5) Interagency or intraagency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency;

(6) Personnel and medical files and similar files, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

(7) Records or information complied for law enforcement purpose, but only to the extent that the production of such law enforcement records or information—

(i) Could reasonably be expected to interfere with enforcement proceedings;

(ii) Would deprive a person of a right to fair trail or an impartial adjudication;

(iii) Could reasonably be expected to consitute an unwarranted invasion of personal privacy;

(iv) Could reasonably be expected to disclose the identity of a confidential sources, including a State, local, or foreign agency or authority, or any private institution which furnished information on a confidential basis, and, in the case of a record or information complied by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, information furnished by a confidential source;

(v) Would disclose techniques and procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law; or

(vi) Could reasonably be expected to endanger the life or physical safety of any individual;

(8) Matters contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of any agency responsible for the regulations or supervision of financial institutions; or

(9) Geological and geophysical information and data, including maps, concerning wells.

(b) Nothing in this subpart authorizes withholding of information of limiting the availability or records to the public, except as specifically provided in this part, nor it this subpart authority to withhold information from Congress.

(c) Whenever a request is made which involves access to agency records described in paragraph (a)(7) of this section, the NRC may, during only such time as that circumstance continues, treat the records as not subject to the requirements of this subpart when—

(1) The investigation or proceeding involves a possible violation of criminal law; and

(2) There is reason to believe that—

(i) The subject of the investigation or proceeding is not aware of its pendency; and

(ii) Disclosure of the existence of the records could reasonably be expected to interfere with enforcement proceedings.

§ 9.19 Segregation of exempt information and deletion of identifying details.

(a) For records required to be made availalble under 5 U.S.C. 552(a)(2), the NRC shall delete the name with any identifying details, if the release of the name or other identifying details of, or relating to, a private party will constitute a clearly unwarranted invasion of personal privacy. The NRC shall provide notification that names of parties and certain other identifying details have been removed in order to prevent a clearly unwarranted invasion of the personal privacy of the individuals involved.

(b) In responding to a request for information submitted under § 9.23, in which it has been determined to withhold exempt information, the NRC shall segregate—

(1) Information that is exempt from public disclosure under § 9.17(a) from nonexempt information; and

(2) Factual information from advice, opinions, and recommendations in predecisional records unless the information is inextricably intertwined, or is contained in drafts, legal work products, and records covered by the lawyer-client privilege, or is otherwise exempt from disclosure.

§ 9.21 Publicly available records.

(a) Publicly available records of NRC activities described in paragraphs (c) and (d) of this section are available through the National Technical Information Service. Subcriptions to these records are available on 48× michrofiche and may be ordered from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. Single copies of NRC publications in the NUREG series, NRC Regulatory Guides, and Standard Review Plans are also available from the National Technical Information Service.

(b) For the convenience of persons who may wish to inspect without charge or purchase copies of a records or a limited category of records for a fee, publicly available records of the NRC's activities described in paragraph (c) of this section are also made available at the NRC Public Document Room. The NRC Public Document Room is located at 1717 H Street, NW, Washington, DC, and is open between 7:45 a.m. and 4:15 p.m. on Mondays through Friday, except legal holidays.

(c) The following records of NRC activities are publicly available at the NRC Public Document Room For public inspection and copying:

(1) Final opinions including concurring and dissenting opinions as well as orders of the NRC issued as a result of adjudication of cases.

(2) Statements of policy and interpretations which have been adopted by the NRC and have not been published in the **Federal Register.**

(3) Nuclear Regulatory Commission rules and regulations.

(4) Nuclear Regulatory Commission Manual and instructions to NRC personnel that affect any member of the public.

(5) Records made available for public inspection and copying under this chapter and the NRC Manual. (NRC Bulletin 3203–15 describes the "NRC Policy for Routinely Making NRC Records Publicly Available.")

(6) Current indexes to records made available under 5 U.S.C. 552 (a)(2) and that are made publicly available are listed in NUREG–0550, "Title of List of Documents Made Publicly Available," which is published monthly.

(d) Records made publicly available under paragraphs (c)(1), (2), and (5) of this section are also available for purchase through the National Technical Information Service.

§ 9.23 Requests for records.

(a)(1) A person may request access to records routinely made available by the NRC under § 9.21 in person or in writing at the NRC Public Document Room, 1717 H. Street NW., Washington, DC 20555.

(i) Each record requested must be described in sufficient detail to enable the Public Document Room to locate the record. If the description of the records is not sufficient to allow the Public Document Room staff to identify the record, the Public Document Room shall advise the requester to select the record from the indexes published under § 9.21(c)(6).

(ii) In order to obtain copies of records expeditiously, a person may open an account at the Public Document Room with the private contracting firm that is responsible for duplicating NRC records.

(2) A person may also order records routinely made available by the NRC under § 9.21 from the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia, 22168.

(b) A person may request agency records by submitting a request

authorized by 5 U.S.C. 552(a)(3) to the Director, Division of Rules and Records, Office of Administration and Resources Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555. The request must be in writing and clearly state on the envelope and in the letter that it is a "Freedom of Information Act request." The NRC does not consider a request as received until it has been received and logged in by the Director, Division of Rules and Records, Office of Administration and Resources Management.

(1) A Freedom of Information request covers only agency records that are in existence on the date the Director, Division of Rules and Records, receives the request. A request does not cover agency records destroyed or discarded before receipt of a request or which are created after the date of the request.

(2) All Freedom of Information Act requests for copies of agency records must reasonably describe the agency records sought in sufficient detail to permit the NRC to identify the requested records. Where possible, the requester should provide specific information regarding dates, titles, docket numbers, file designations, and other information which may help identify the records. If a requested record is not described in sufficient detail to permit its identification, the Director, Division of Rules and Records, shall inform the requester of the deficiency within 10 working days after receipt of the request and ask the requester to submit additional information regarding the request or meet with appropriate NRC personnel in order to clarify the request.

(3) Upon receipt of a request made under paragraph (b) of this section, the NRC shall provide written notification to the requester that indicates the request has been received, the name of the individual and telephone number to contact to find out the status of the request, and other pertinent matters regarding the processing of the request.

(4)(i) The NRC shall advise a requester that fees will be assessed if—

(A) A request involves anticipated costs in excess of the minimum specified in § 9.39; and

(B) Search and duplication is not provided without charge under § 9.39; or

(C) The requester does not specifically state that the cost involved is acceptable or acceptable up to a specified limit.

(ii) The NRC has discretion to discontinue processing for records responsive to a request made under paragraph (b) until—

(A) A required advance payment has been received;

(B) The requester has agreed to bear the estimated costs;

(C) A determination has been made on a request for waiver or reduction of fees; or

(D) The requester meets the requirements of § 9.39.

(c) If a requested agency record that has been reasonably described is located at a place other than the NRC Public Document Room or NRC headquarters, the NRC may, at its discretion, make the record available for inspection and copying at the other location.

(d) Except as provided in § 9.39, if the record requested under paragraph (b) of this section is a record available through the National Technical Information Service, the NRC shall refer the requester to the National Technical Information Service. If the requested record has been placed in the NRC Public Document Room under § 9.21, the NRC shall inform the requester that the record is in the PDR, and that the record may be obtained in accordance with the procedures set forth in paragraph (a) of this section.

(e) The Director, Division of Rules and Records, shall promptly forward a Freedom of Information Act request made under § 9.23(b) for an agency record which is not publicly available in the NRC Public Document Room under § 9.21 to the head of the office primarily concerned with the records requested and to the General Counsel, as appropriate. The responsible office will conduct a search for the records responsive to the request and compile those records to be reviewed for initial disclosure determination under §§ 9.25 and 9.27.

§ 9.25 Initial disclosure determination.

(a) The head of the responsible office shall review agency records located in a search under § 9.23(b) to determine whether the agency records are exempt from disclosure under § 9.17(a). If the head of the office determines that, although exempt, the disclosure of the agency records will not be contrary to the public interest and will not affect the rights of any person, the head of the office may authorize disclosure of the agency records. If the head of the office authorizes disclosure of the agency records, the head of the office shall furnish the agency records to the Director, Division of Rules and Records, who shall notify the requester of the determination in the manner provided in § 9.27.

(b) Except as provided in paragarph (c) of this section, if, as a result of the review specified in paragraph (a) of this section, the head of the responsible office finds that agency records should be denied in whole or in part, the head of the office will submit that finding to the Director, Division of Rules and Records, who will, in consultation with the General Counsel, make an independent determination whether the agency records should be denied in whole or in part. If the Director, Division of Rules and Records, determines that the agency records sought are exempt from disclosure and disclosure of the records is contrary to the public interest and will adversely affect the rights of any person, the Director, Division of Rules and Records, shall notify the requester of the determination in the manner provided in § 9.27.

(c) For agency records located in the office of a Commissioner or in the Office of the Secretary of the Commission, the Assistant Secretary of the Commission shall make the initial determination to deny agency records in whole or in part under § 917(a) instead of the Director, Division of Rules and Records. For agency records located in the Office of the General Counsel, the General Counsel shall make the initial determination to deny agency records in whole or in part instead of the Director, Division of Rules and Records. If the Assistant Secretary of the Commission or the General Counsel determines that the agency records sought are exempt from disclosure and that their disclosure is contrary to the public interest and will adversely affect the rights of any person, the Assistant Secretary of the Commission or the General Counsel shall furnish that determination to the Director, Division of Rules and Records, who shall notify the requester of the determination in the manner provided in § 9.27.

(d) If a requested record that is located is one of another Government agency or deals with subject matter over which an agency other than the NRC has exclusive or primary responsibility, the NRC shall promptly refer the record to that Government agency for disposition or for guidance regarding disposition.

(e) The 10-working day period for response to a request for records provided in paragraphs (a), (b), and (c) of this section may be extended for unusual circumstances as provided in § 9.31.

(f) In exceptional circumstances where it does not appear possible to complete action on a request within the maximum 20 working-day limit as provided in § 9.31, the Director, Division of Rules and Records, may seek an agreement with the requester for a specified extension of time in which to

act upon the request. The NRC shall confirm the agreement for an extension of time in writing.

(g) If the NRC does not respond to a request within the 10-working-day period, or within the extended periods described in paragraph (c) of this section, the requester may treat that delay as a denial of the request and immediately appeal to the Executive Director for Operations as provided in § 9.29(a) or to a district court as provided in § 9.29(c).

§ 9.27 Form and content of responses.

(a) When the NRC has located a requested record and has determined to disclose the record, the Director, Division of Rules and Records, shall promptly furnish the record or notify the requester where and when the record will be available for inspection and copying. The NRC will normally place copies of records disclosed in response to Freedom of Information Act requests in the NRC Public Document Room and, for records relating to a specific nuclear power facility, in the Local Public Document Room established for that facility. The NRC shall also advise the requester of any applicable fees under § 9.35.

(b) When the NRC denies access to a requested agency record or denies a request for a waiver or reduction of fees, the Director, Division of Rules and Records, shall notify the requester in writing. The denial includes as appropirate—

(1) The reason for the denial;

(2) A reference to the specific exemption under the Freedom of Information Act and the Commission's regulations authorizing the withholding of the record or portions of it;

(3) The name and title or position of each person responsible for the denial of the request, including the head of the office recommending denial of a record;

(4) A statement stating why the request does not meet the requirements of § 9.41 if the request is for a waiver or reduction of fees; and

(5) A statement that the denial may be appealed within 30 days from the receipt of the denial to the Executive Director for Operations or to the Commission, as appropriate.

(c) The Director, Division of Rules and Records, shall maintain a copy of each letter granting or denying requested records or denying a request for waiver or reduction of fees in accordance with the NRC Comprehensive Records Disposition Schedule.

§ 9.29 Appeal from initial determination.

(a) A requester may appeal a notice of denial of a Freedom of Information Act request for agency records or a request for waiver or reduction of fees under this subpart within 30 days of the date of the NRC's denial. For records denied by an Office Director reporting to the Executive Director for Operations or for a denial of a request for a waiver or reduction of fees, the appeal must be in writing and addressed to the Executive Director for Operations, U.S. Nuclear Regulatory Commission, Washington, DC 20555. For record denied by an Office Director reporting to the Commission, the Assistant Secretary of the Commission, or by the Advisory Committee Management Officer, the appeal must be in writing and addressed to the Secretary of the Commission. The appeal should clearly state on the envelope and in the letter that it is an "Appeal from Initial FOIA Decision." The NRC does not consider an appeal that is not marked as indicated in this paragraph as received until it is actually received by the Executive Director for Operations or Secretary of the Commission.

(b) The NRC shall make determination on any appeal made under this section within 20 working days after the receipt of the appeal.

(c)(1) If the appeal of the denial of the request for record is upheld in whole or in part, the Executive Director for Operations or the Secretary of the Commission shall notify the requester of the denial, specifying—

(i) The exemptions relied upon;

(ii) An explanation of how the exemption applies to the records withheld; and

(iii) The reasons for asserting the exemption.

(2) If, on appeal, the denial of a request for waiver or reduction of fees for locating and reproducing records is upheld in whole or in part, the Executive Director for Operations shall notify the person making the request of his decision to sustain the denial, including a statement explaining why the request does not meet the requirements of § 9.41.

(3) The Executive Director for Operations or the Secretary of the Commission shall inform the requester that the denial is final agency action and that judicial review is available in a district court of the United States in the district in which the requester resides, has a principal place of business, or in which the agency records are situated, or in the District of Columbia.

(d) The Executive Director for Operations or the Secretary of the Commission shall furnish copies of all appeals and written determinations on appeals to the Director, Division of Rules and Records.

§ 9.31 Extension of time for response.

(a) In unusual circumstances defined in § 9.13, the NRC may extend the time limits prescribed in § 9.25 or § 9.29 by not more than 10 working days. The extension may be made by written notice to the person making the request to explain the reasons for the extension and indicate the date on which a determination is expected to be dispatched.

(b) An extension of the time limits prescribed in §§ 9.25 and 9.29 may not exceed a combined total of 10 working days per request.

§ 9.33 Search, review, and special service fees.

(a) The NRC charges fees for—

(1) Search, duplication, and review, when records are requested for commercial use;

(2) Duplication of records provided in excess of 100 pages when records are not sought for commercial use and the request is made by an educational, noncommercial scientific institution, or a representative of the news media;

(3) Search and duplication of records in excess of 100 pages for any request not described in paragraph (a) (1) and (2) of this section;

(4) The direct costs of searching for records. The NRC will assess fees even when no records are located as a result of the search or when records that are located as a result of the search are not disclosed; and

(5) Computer searches which include the cost of operating the Central Processing Unit for that portion of operating time that is directly attributable to searching for records plus the operator/programmer salary apportionable to the search.

(b) The NRC may charge requesters who request the following services for the direct costs of the service:

(1) Certifying that records are true copies; or

(2) Sending records by special methods, such as express mail, package delivery service, etc.

§ 9.34 Assessment of interest and debt collection.

(a) The NRC shall assess interest on the fee amount billed starting on the 31st day following the day on which the billing was sent in accordance with NRC's regulations set out in § 15.37 of this chapter. Interest is at the rate prescribed in 21 U.S.C. 3717.

(b) The NRC will use its debt collection procedures under Part 15 of this chapter for any overdue fees.

§ 9.35 Duplication fees.

(a)(1) Charges for the duplication of records made available under § 9.21 at the NRC Public Document Room, 1717 H Street NW., Washington, DC 20555 by the duplicating service contractor are as follows:

(i) Six cents per page for paper copy to paper copy, except for engineering drawings and any other records larger than 17 x 11 inches for which the charges vary as follows depending on the reproduction process that is used:

(A) Xerographic process—$1.50 per square foot for large documents or engineering drawings (random size up to 24 inches in width and with variable length) reduced or full size;

(B) Photographic process—$7.00 per square foot for large documents or engineering drawings (random size exceeding 24 inches in width up to a maximum size of 42 inches in length) full size only.

(ii) Six cents per page for microform to paper copy, except for engineering drawings and any other records larger than 17 x 11 inches for which the charge is $1.25 per square foot or $3.00 for a reduced size print (18 x 24 inches).

(iii) One dollar per microfiche to microfiche.

(iv) One dollar per aperture card to aperture card.

(2) Self-service, coin-operated, duplicating machines are available at the PDR for the use of the public. Paper to paper is $0.10 per page. Microform to paper is $0.10 per page on the reader printers.

(3) A requester may submit mail-order requests for contractor duplication of NRC records made by writing to the NRC Public Document Room. The charges for mail-order duplication of records are the same as those set out in paragraph (a)(1) of this section, plus mailing or shipping charges.

(4) A requester may open an account with the duplicating service contractor. A requester may obtain the name and address and billing policy of the contractor from the NRC Public Document Room.

(5) Any change in the costs specified in this section will become effective immediately pending completion of the Commission's rulemaking that amends this section to reflect the new charges. The Commission shall post the charges that will be in effect for the interim period in the Public Document Room. The Commission shall complete the rulemaking necessary to reflect the new charges within 15 working days from the beginning of the interim period.

(b) The NRC shall assess the following charges for copies of records to be duplicated by the NRC at locations other than the NRC Public Document Room located in Washington, DC or at Local Public Document Rooms:

(1) Sizes up to 8½ x 14 inches made on office copying machines—$0.20 per page of copy; and

(2) The charge for duplicating records other than those specified in paragraphs (a) and (b) of this section is computed on the basis of NRC's direct costs.

(c) In compliance with the Federal Advisory Committee Act, a requester may purchase copies of transcripts of testimony in NRC Advisory Committee proceedings, which are transcribed by a reporting firm under contract with the NRC directly from the reporting firm at the cost of reproduction as provided for in the contract with the reporting firm. A requester may also purchase transcripts from the NRC at the cost of reproduction as set out in paragraphs (a) and (b) of this section.

(d) Copyrighted material may not be reproduced in violation of the copyright laws.

(e) Charges for the duplication of NRC documents located in NRC Local Public Document Rooms are those costs that the institutions maintaining the NRC Local Public Document Room collections establish.

§ 9.37 Fees for search, review, and duplication of records by NRC personnel.

The NRC shall charge the following hourly rates for search, review, and duplication of records by NRC personnel:

(a) Clerical search, review, and duplication at a salary rate that is equivalent to a GG–7, Step 5 plus 16 percent fringe benefits;

(b)Professional/managerial search, review, and duplication at a salary rate that is equivalent to a GG–13, Step 5 plus 16 percent fringe benefits; and

(c) Senior executive or Commissioner search, review, and duplication at a salary rate that is equivalent to an ES–3 plus 16 percent fringe benefits.

§ 9.39 Search and duplication provided without charge.

(a) The NRC shall search for records requested under § 9.23(b), without charges:

(1) If the requester is a representative of the news media;

(2) If the requester is an educational institution.

(3) If the requester is a noncommercial scientific institution; and

(4) For the first two hours of search if the requester is not a commercial-use requester;

(b) The NRC shall duplicate records requested under § 9.23(b) without charge for the first 100 pages of standard paper copies, or equivalent pages on microfiche, computer, disks, etc., if the requester is not a commercial-use requester.

(c) The NRC may not bill any requester for fees if the cost of collecting the fee would be equal to or greater than the fee itself.

(d) The NRC may aggregate requests in determining search and duplication to be provided without charge as provided in paragraphs (a) and (b) of this section, if the NRC finds a requester has filed multiple requests for only portions of a document or similar documents for the purpose of avoiding charges.

§ 9.41 Requests for waiver or reduction of fees.

(a)(1) The NRC shall collect fees for searching for, reviewing, and duplicating agency records, except as provided in § 9.39, unless a requester submits a request in writing for a waiver or reduction of fees. To assure that there will be no delay in the processing of Freedom of Information Act requests, the request for a waiver or reduction of fees should be included in the initial Freedom of Information Act request letter.

(2) Each request for a waiver or reduction of fees must be addressed to the Director, Division of Rules and Records, Office of Administration and Resources Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

(b) A person requesting the NRC to waive or reduce search, review, or duplication fees shall:

(1) Describe the purpose for which the requester intends to use the requested information;

(2) Explain the extent to which the requester will extract and analyze the substantive content of the record;

(3) Describe the nature of the specific activity or research in which the records will be used and the specific qualifications the requester possesses to utilize information for the intended use in such a way that it will contribute to public understanding;

(4) Describe the likely impact on the public's understanding of the subject as compared to the level of understanding of the subject existing prior to disclosure;

(5) Describe the size and nature of the public to whose understanding a contribution will be made;

(6) Describe the intended means of dissemination to the general public;

(7) Indicate if public access to information will be provided free of charge or provided for an access fee or publication fee; and

(8) Describe any commercial interest the requester has in the records sought.

(c) The NRC will waive or reduce fees, without further specific information from the requester if, from information provided with the request for records made under § 9.23(b), it can determine that disclosure of the information in records is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the Government and is not primarily in the commercial interest of the requester.

(d) In making a determination regarding a request for a waiver or reduction of fees, the NRC shall consider the following factors:

(1) How the subject of the requested records concerns the operations or activities of the Government;

(2) How the disclosure of the information is likely to contribute to an understanding of Government operations or activities;

(3) If disclosure of the requested information is likely to contribute to public understanding;

(4) If disclosure is likely to contribute significantly to public understanding of Government operations or activities;

(5) If, and the extent to which, the requester has a commercial interest that would be furthered by the disclosure of the requested records;

(6) If the magnitude of the identified commercial interest of the requester is sufficiently large, in comparison with the public interest in disclosure, that disclosure is primarily in the commercial interest of the requester;

(7) If the request involves search fees, to what extent the search is likely to identify records which will be disclosed;

(8) If a concurrent request for the same or similar records has been made under Subpart D of this part or under § 2.720 of this chapter; and

(9) If the requested records are already publicly available or will not add appreciably to the substance of information already available to the public in the NRC Public Document Room, a Local Public Document Room, the National Technical Information Service, or from other public sources.

(d) If the written request for a waiver or reduction of fees does not meet the requirements of this section, the NRC will inform the requester that the request for waiver or reduction of fees is being denied and set forth the appeal rights under § 9.29 to the requester.

§ 9.43 Processing of requests for a waiver or reduction of fees.

(a)(1) Within 10 working days after receipt of a request for access to records for which the NRC agrees to waive fees under § 9.39(a)–(d) or § 9.41(c), the NRC shall respond to the request as provided in § 9.25.

(2) If the request is expected to require the NRC to assess fees in excess of $25 for search and/or duplication, the NRC shall notify the requester that fees will be assessed unless the requester has indicated in advance his or her willingness to pay fees as high as estimated.

(3) In the notification, the NRC shall include the estimated cost of search fees and the nature of the search required and estimated cost of duplicating fees.

(4) The NRC will encourage requesters to discuss with the NRC the possibility of narrowing the scope of the request with the goal of reducing the cost while retaining the requester's original objective.

(5) If the fee is determined to be in excess of $250, the NRC shall require an advance payment. If the fee is determined to be $250 or less, the NRC may not begin to process the request until the requester agrees to bear the estimated costs.

(b) If the NRC receives a new request and determines that the requester has failed to pay a fee charged within 30 days of receipt of the bill on a previous request, the NRC may not accept the new request for processing until payment of the full amount owed on the prior request, plus any applicable interest assessed as provided in § 9.34, is made.

(c)(1) Within 10 working days of the receipt of NRC's notice that fees will be assessed, the requester shall provide advance payment if required, notify the NRC in writing that the requester agrees to bear the estimated costs, or submit a request for a waiver or reduction of fees pursuant to § 9.41.

(2) In making a request for a waiver or reduction of fees, a requester shall provide the information required by § 9.41(b).

(d) Within 10 working days after receipt of a request for the waiver or reduction of fees made in accordance with § 9.41, the NRC shall either waive or reduce the fees and notify the requester of the NRC's intent to promptly provide the records or deny the request and provide a statement to the requester explaining why the request does not meet the requirements of § 9.41(b).

(e) As provided in § 9.29, a requester may appeal a denial of a request to waive or reduce fees within 30 days to the Executive Director for Operations.

§ 9.45 Annual Report to Congress.

(a) On or before March 1 of each calendar year, the Chairman of the NRC will submit a report covering the preceding calendar year to the Speaker of the House of Representatives and President of the Senate for referral to the appropriate committees of the Congress. The report includes—

(1) The number of determinations made by the NRC to deny requests for records made to the NRC under this part and the reasons for each determination;

(2) The number of appeals made by persons under § 9.29, the results of the appeals, and the reason for the action taken on each appeal that results in a denial of information;

(3) The names and titles or positions of each person responsible for the denial of records requested under this section, and the number of instances of participation for each;

(4) The results of each proceeding conducted pursuant to 5 U.S.C. 552(a)(4)(F), including a report of the disciplinary action taken against the officer or employee who was primarily responsible for improperly withholding records, or an explanation of why disciplinary action was not taken;

(5) A copy of every rule the NRC published affecting this part;

(6) A copy of the fee schedule and the total amount of fees collected by the NRC for making records available under this part; and

(7) Any other information that indicates efforts to administer fully the provisions of 5 U.S.C. 552.

(b) The NRC shall make a copy of each report submitted to the Congress under paragraph (a) of this section available for public inspection and copying in the NRC Public Document Room.

10. Section 9.85 is revised to read as follows:

§ 9.85 Fees.

Fees shall not be charged for search for or review of records requested pursuant to this subpart or for making copies or extracts of records in order to make them available for review. Fees established pursuant to 31 U.S.C. 483c and 5 U.S.C. 552a(f)(5) shall be charged according to the schedule contained in § 9.35 of this part for actual copies of records requested by individuals, pursuant to the Privacy Act of 1974, unless the Director, Division of Rules and Records, waives the fee because of the inability of the individual to pay or because making the records available without cost, or at a reduction in cost, is otherwise in the public interest.

11. Section 9.100 is revised to read as follows:

§ 9.100 Scope of subpart.

This subpart prescribes procedures pursuant to which NRC meetings shall be open to public observation pursuant to the provisions of 5 U.S.C. Sec. 552b. This subpart does not affect the procedures pursuant to which NRC records are made available to the public for inspection and copying which remain governed by Subpart A, except that the exemptions set forth in § 9.104(a) shall govern in the case of any request made pursuant to § 9.23 to copy or inspect the transcripts, recordings, or minutes described in § 9.108. Access to documents considered at NRC meetings shall continue to be governed by Subpart A of this part.

12. In § 9.200, paragraph (b) is revised to read as follows:

§ 9.200 Scope of subpart.

* * * * *

(b) For purposes of this subpart, the term "employee of the NRC" includes all NRC personnel as that term is defined in § 9.3 of this part, including NRC contractors.

* * * * *

Dated at Washington, DC, this 27th day of July 1987.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 87-17564 Filed 8-5-87; 8:45 am]

BILLING CODE 7590-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 61, 71, and 91

[Docket No 25304; Notice N 87-7]

Terminal Control Area (TCA) Classification and Pilot and Equipment Requirements

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Proposed Rulemaking (NPRM); extension of comment period.

SUMMARY: This notice announces extension of the comment period of an NPRM which proposes to establish a single-class TCA and to revise the associated pilot and equipment requirements. Under this proposal, the separate classifications of TCA's, which are currently Group I, Group II, and Group III, would be eliminated. Existing and future TCA's would be designated simply as "terminal control areas." This notice also proposes expanded pilot and equipment requirements for operation in and near TCA's as follows: (a) The pilot-in-command of a civil aircraft operating within a TCA would be required to hold at least a private pilot certificate, with a limited exception for student pilots with certain training; (b) automatic pressure altitude reporting equipment (Mode C) would be required in all airspace from the surface to and including 12,500 feet above mean sea level (MSL) within 30 miles of the primary TCA airport; and (c) helicopters would be required to operate under the same equipment requirements as fixed-wing aircraft. Student pilots would not be allowed to operate at certain primary airports and would require specific training and an instructor's endorsement for all other TCA operations.

DATES: Comments must be received on or or before September 16, 1987.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attention: Rules Docket (AGC-204) Docket No. 25304, 800 Independence Avenue, SW., Washington, DC 20591.

The official docket may be examined in the Rules Docket, weekdays, except Federal holidays, between 8:30 a.m. and 5:00 p.m. The FAA Rules Docket is located in the Office of the Chief Counsel, Room 916, 800 Independence Avenue, SW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Burns, Air Traffic Rules Branch (ATO-230), Airspace—Rules and Aeronautical Information Division, Air Traffic Operations Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267-8783.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposals. Communications should identify the regulatory docket and be submitted in duplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on the NPRM must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 25304." The postcard will be date/time stamped and returned to the commenter. All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal may be changed in the light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of the Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA-200, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267-3484. Communications must identify the notice number of the document. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11-2 which describes the application procedure.

Background

Docket No. 25304, published on June 16, 1987 (52 FR 22918) proposed to establish a single-class TCA and to revise the associated pilot and equipment requirements. Under this proposal, the separate classifications of TCA's, which are currently Group I, Group II, and Group III, would be eliminated. Existing and future TCA's would be designated simply as "terminal control areas." This notice also proposes expanded pilot and equipment requirements for operation in and near TCA's as follows: (a) The pilot-in-command of a civil aircraft operating within a TCA would be required to hold at least a private pilot certificate, with a limited exception for student pilots with certain training; (b) automatic pressure altitude reporting equipment (Mode C) would be required in all airspace from the surface to and including 12,500 feet above mean sea level (MSL) within 30 miles of the primary TCA airport; and (c) helicopters would be required to operate under the same equipment requirements as fixed-wing aircraft. Student pilots would not be allowed to operate at certain primary airports and would require specific training and an instructor's endorsement for all other TCA operations.

On June 28, 1987, the Experimental Aircraft Association (EAA) petitioned the FAA for a 60-day extension to the comment period in order to circularize the notice to the organization's members. The FAA is aware that many general aviation pilots receive

notification of proposed rulemaking only through user organizations. However, due to the urgent need to implement safety improvements, we are reluctant to extend the original comment period beyond an additional 30 days.

Due to the vast numbers of responses received to date (700 responses to the docket in less than 40 days), the FAA believes that a 60-day extension of the comment period is unwarranted. However, the FAA believes that a shorter extension of the comment period will not jeopardize the ability of the agency to reach a timely final rule action.

For the reasons stated, the FAA will extend the comment period on Docket Number 25304 to September 16, 1987, to allow for a 92-day comment period instead of the existing 62-day comment period.

Issued in Washington, DC, on July 31, 1987.

John R. Ryan,

Director, Air Traffic Operations Service.

[FR Doc. 87-17809 Filed 8-5-87; 8:45 am]

BILLING CODE 4910-13-M

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 230

[Release No. 33-6727; IC-15902 File No. S7-29-87]

Prospectus Delivery Requirements in Firm Commitment; Underwritten Offerings of Securities Made for Cash

AGENCY: Securities and Exchange Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Securities and Exchange Commission ("Commission") today is publishing for comment two alternative proposals for a new Rule 433 concerning the timing of delivery to investors of a prospectus meeting the requirements of section 10(a) of the Securities Act of 1933. The proposals would permit, if all conditions are satisfied, the sending of a final prospectus no later than five business days after a confirmation of sale is sent to a purchaser in a registered firm commitment offering of securities for cash.

DATE: Comments should be received on or before October 5, 1987.

ADDRESS: Comments should be submitted in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, DC 20549. All comment letters should refer to File No. S7-29-87. Comment letters received will be available for public inspection and copying in the Commission's Public Reference Room, 450 Fifth Street, NW., Washington, DC 20549.

FOR FURTHER INFORMATION CONTACT: Mauri L. Osheroff, Deputy Chief Counsel, (202) 272-2573 or Gerard S. DiFiore, (202) 272-2589, Division of Corporation Finance, Securities and Exchange Commission, 450 Fifth Street, NW., 20549.

SUPPLEMENTARY INFORMATION: The Commission today is publishing for comment two alternative proposals for a new Rule 433 that would provide a safe harbor for sending a confirmation of sale prior to sending a prospectus meeting the requirements of section 10(a) [1] ("final prospectus") of the Securities Act of 1933 (the "Securities Act") [2] for a security sold for cash in a firm commitment underwritten offering.

I. Executive Summary

On January 21, 1986, as supplemented on April 18, 1986, the Commission received a rulemaking petition [3] from the Securities Industry Association ("SIA") [4] requesting amendment of certain prospectus delivery requirements under the Securities Act. Citing serious logistical problems in providing a final prospectus prior to or contemporaneously with delivery of a confirmation in syndicated offerings, the SIA sought promulgation of a rule that would permit the delivery of the final prospectus after the confirmation was sent. The Commission, appreciative of the problems cited in the SIA's petition, is proposing two alternative versions of a new Rule 433 that would allow, under specified conditions, delayed delivery [5] of the final prospectus in a firm commitment underwritten offering made for cash. Both proposal require that the final prospectus be sent no later than five business days after the confirmation is sent to the investor. Each proposal contains provisions limiting the availability of the Rule to offerings where specified information about the securities being offered is available. Each proposal also contains specific provisions for offerings registered on Form S-3 or F-3 [6] and those registered on other Forms.

Proposal I would permit delayed delivery of the final prospectus for an offering not registered on Form S-3 or F-3 if a prospectus subject to completion [7] is delivered to the investor before or with the confirmation ("prior delivery"). Delivery of any subsequent prospectus containing a material change also would be required, and the final prospectus could not differ materially from the latest prospectus so delivered, except for the inclusion of the type of information permitted to be omitted pursuant to Rule 430A.[8]

For an offering registered on Form S-3 or F-3, Proposal I would not require prior delivery of a prospectus. Rather, delayed delivery of the final prospectus would be permitted if any material change in Item 11 information [9] between effectiveness and the sending of the confirmation is filed in a Form 8-K (or Form 6-K for a foreign issuer). [10] Such filing would have to be made no later than two business days after the date that the confirmation is sent to the investor, whether or not such information also is physically included in the final prospectus. If, however, a prospectus had been delivered to an investor and the information contained

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[1] 15 U.S.C. 77j(a).

[2] 15 U.S.C. 77a *et seq.*

[3] The petition (File No. 4-287), which was submitted pursuant to Rule 4(a) of the Commission's Rules of Practice (17 CFR 201.4(a)), is available for public inspection in the Commission's Public Reference Room, 450 Fifth St., NW. Washington, DC 20549.

[4] The SIA is a trade association representing over 500 securities firms in the United States and Canada, which collectively account for approximately 90% of the securities business transacted in North America.

[5] "Delayed delivery" is used in this release to mean sending of the final prospectus no later than five business days after the confirmation is sent to the investor, rather than before or with the confirmation, as currently required.

[6] 17 CFR 239.13 and 17 CFR 239.33, respectively.

[7] The term "prospectus subject to completion" refers either to a preliminary prospectus used in reliance on Rule 430 (17 CFR 230.430), or a prospectus used after the effective date of a registration statement that omits certain information and accordingly cannot substitute for the final prospectus (*i.e.*, a prospectus omitting information in reliance on Rule 430A (17 CFR 230.430A), or a prospectus omitting information not yet known concerning a delayed offering under Rule 415 (17 CFR 230.415)). *See* Item 501(c)(8) of Regulation S-K (17 CFR 229.501(c)(8)). When the word "prospectus" is used unmodified in this release, it means a prospectus subject to completion and not a final prospectus.

[8] If specified conditions are met, Rule 430A permits a registration statement to be declared effective without including information as to the offering price, underwriting syndicate and other specified information related to the offering price and date in the registration statement must be included either in a prospectus filed pursuant to Rule 424(b) or 497 (17 CFR 230.424(b) or 497) (which will be deemed part of the registration statement) or in a post-effective amendment. This type of information is referred to in this release as "430A-type information" in connection with prospectuses that may or may not be filed in reliance on Rule 430A. *See* Release 33-6714 (June 5, 1987) (52 FR 21252).

[9] Item 11 of both Forms requires disclosure of material changes in the registrant's affairs that have occurred since the end of the latest fiscal year, as well as specified financial information necessitated by an acquisition, disposition or restatement of financial statements.

[10] 17 CFR 249.308 and 17 CFR 249.308, respectively.

in it changed materially (except for 430A-type information), the Rule 433 safe harbor would not be available unless a revised, updated prospectus was delivered to the investor prior to or with the confirmation.

Proposal I would not be available for delayed shelf offerings if the description of the securities (except for 430A-type information) were not contained in a prospectus, supplemented as necessary, which is delivered to investors prior to or with the confirmation (or, for offerings on Form S-3 or F-3, in the effective registration statement or post-effective amendment).

In contrast to Proposal I, Proposal II would not require prior delivery of a prospectus as a condition to the availability of the safe harbor, except for initial public offerings. If, however, a prospectus were delivered and there were material changes to the information contained in it (except for 430A-type information), delivery of a revised, updated prospectus would be required, as in Proposal I.

Proposal II would permit delayed delivery of the final prospectus in an offering not registered on Form S-3 or F-3 where: (i) There were no material differences (except for inclusion of the securities description and 430A-type information) between the final prospectus and the prospectus included in the effective registration statement or latest effective post-effective amendment (and the latest prospectus delivered to the investor, if any); and (ii) the final prospectus was sent on an expedited basis to any prospective purchaser who so requested.

Proposal II, like Proposal I, would permit delayed delivery in an offering registered on Form S-3 or F-3 without prior delivery of a prospectus. A Form 8-K or 6-K would be required to be filed no later than two business days after the date the confirmation of sale was sent to an investor to report any material change in Item 11 information between effectiveness of the registration statement and the sending of the confirmation. Expedited delivery would not be required for such offerings. For a delayed shelf offering on Form S-3 or F-3 that did not provide a specific description of the securities, the proposed Rule would require either (i) prior delivery of a prospectus, supplemented to contain the securities information, (ii) inclusion of such information in a post-effective amendment, or (iii) expedited delivery of the final prospectus upon request (comparable to that required in a non-Form S-3 or F-3 offering).

Proposal I is based on the premise that the delivery of a prospectus that does not differ materially from the final prospectus except for the inclusion of 430A-type information, together with the confirmation, is substantially equivalent to delivery of the final prospectus. While a prospectus subject to completion ordinarily does not contain the price and many specific terms of the security related to the price and offering date, the principal elements of such information generally will be in the confirmation.[11] The lack of a prior delivery requirement for offerings registered on Form S-3 or F-3 reflects the fact that most, if not all, substantive issuer information is incorporated by reference to Securities Exchange Act of 1934 ("Exchange Act")[12] reports disseminated into the marketplace.

Proposal II, on the other hand, relies on the assurance of access to the information contained in the final prospectus to meet the investor protection information needs served by section 5(b)(1) of the Securities Act.[13] Proposal II is intended to assure that any investor who wants to review that information prior to payment has an opportunity to do so. Expedited access to the final prospectus through expedited delivery upon investor request would be required for offerings not registered on Form S-3 or F-3. For offerings registered on Form S-3 or F-3, there would be access to information in the Commission's files that is materially equivalent to the information in the final prospectus or, for certain delayed offerings, expedited prospectus delivery. As in Proposal I, the treatment of offerings on Form S-3 or F-3 reflects the incorporation by reference of Exchange Act reports for substantive issuer information.

While the Commission specifically requests commentators to address whether Proposal I or Proposal II is preferable, it also is interested in comment on a rule that would include both proposals as alternative safe harbors, or a rule combining various features of each proposal.

II. Background

Under section 5(b)(1) of the Securities Act, it is unlawful to use a prospectus after a registration statement has been filed unless it meets the requirements of section 10 of the Securities Act.[14] The term "prospectus," as defined in section 2(10) of the Securities Act,[15] includes any written communication that "offers a security for sale or confirms the sale of any security; except that * * * a communication provided after the effective date of the registration statement (other than a prospectus permitted under subsection (b) of section 10) shall not be deemed a prospectus if it is proved that prior to or at the same time with such communication a written prospectus meeting the requirements of subsection (a) of section 10" is provided. Accordingly, a confirmation must be preceded or accompanied by a final prospectus meeting the requirements of section 10(a),[16] because the confirmation itself would not meet these requirements.[17]

The SIA stated in its petition that the current prospectus delivery requirements under the Securities Act result in a burdensome and costly confirmation process in syndicated public offerings. Existing requirements prevent syndicate members from confirming trades until the final prospectus has been received from the syndicate manager. Regional firms must await receipt of the final prospectus and only thereafter mail the confirmation with the prospectus.

Additionally, such delays may interfere with the process whereby brokerage firms mail confirmations from regional operational centers or branch offices. While, in other contexts, such as ordinary exchange or over-the-counter trading transactions, this regional confirmation mailing process ordinarily enables customers to receive confirmations promptly, for syndicate trades the delay in receiving copies of the final prospectus can result in disruptive delays in the mailing of confirmations.

The SIA stated that such mailing delays may result in delays in the payment of the purchase price to the underwriter, increasing underwriter carrying costs, and may create uncertainty on the part of investors.

[11] Exchange Act Rule 10b-10 [17 CFR 240.10b-10] contains requirements regarding the timing and content of a confirmation sent by a broker or dealer in effecting a transaction for a customer.

[12] 15 U.S.C. 78a *et seq.*

[13] 15 U.S.C. 77e(b)(1).

[14] 15 U.S.C. 77j.

[15] 15 U.S.C. 77b(10).

[16] 15 U.S.C. 77j(a).

[17] Delivery of a prospectus to investors in advance of the final prospectus is not required by the Securities Act. The Commission has, however, imposed such a requirement for all initial public offerings. *See* Exchange Act Rule 15c2-8(b) [17 CFR 240.15c2-8(b)], which requires brokers and dealers participating in an offering of securities by an issuer not previously required to file reports pursuant to section 13(a) or 15(d) of the Exchange Act (15 U.S.C. 78m(a) or 78o(d)) to deliver a copy of a preliminary prospectus to any person who is expected to receive a confirmation of sale at least 48 hours prior to the mailing of such confirmation.

Although a purchase of a new issue [18] can be effected only in a cash account,[19] margin regulations effectively allow purchasers to defer payment for securities until the underwriters have paid for and received the securities from the issuer.[20] For firm commitment offerings, this closing process ordinarily occurs seven to ten days after effectiveness of the registration statement.

After considering the petition submitted by the SIA, and the application of existing prospectus delivery requirements in the context of firm commitment underwritten offerings, the Commission has determined that it may be appropriate to permit alternative means of compliance that conform more closely to the needs of issuers, underwriters and dealers in light of modern distribution practices, while assuring that investors continue to have timely access to information required to be disclosed by rules and regulations under the Securities Act.

III. Features Common To Both Proposals

1. Operation of the Rule

Each proposal specifies a set of conditions under which the requirements of section 5(b)(1) of the Securities Act will be deemed to have been met if a confirmation of purchase is sent prior to sending a final prospectus. Failure to meet any condition would preclude reliance on the safe harbor of proposed Rule 433 and would require compliance with existing Securities Act requirements governing the timing of delivery of the final prospectus. Both proposals would be available to any issuer, including one engaged in an initial public offering, except an investment company.[21] Both proposals are, however, conditioned on compliance with the prospectus delivery requirement of Exchange Act Rule 15c2–8(b) [22] applicable to an offering by an issuer not previously required to file reports pursuant to section 13(a) or 15(d) of the Exchange Act.[23] Reliance on the proposed Rule would not, of course, excuse compliance with the other provisions of Rule 15c2–8 [24] or other requirements relating to the filing, delivery or content of prospectuses.[25]

As discussed more specifically below, the proposals would either require or permit delivery of a prospectus in advance of the final prospectus. Accordingly, both proposals would permit delivery after the registration statement has been declared effective of prospectus that met the requirements of Rule 430 or 430A.[26]

Both proposals would require that the final prospectus meeting the requirements of section 10(a) of the Securities Act be sent to a purchaser of securities registered by the registration statement no later than five business days after a confirmation is sent to that person.[27] In this context, sending of the prospectus means placing into the mails or otherwise beginning transmission. First class mail or an equally prompt means is required. The Commission solicits comment on whether this five business day time period should be shortened or extended. Finally, both proposals would require that the confirmation incorporate the final prospectus by reference.[28]

2. Limitation to Firm Commitment Underwritten Offerings for Cash

The Commission is proposing to make this safe harbor available only for firm commitment underwritten offerings[29] of securities offered for cash.[30]

The problems described by the SIA appear to be limited to firm commitment underwritings where the underwriter must make payment with its own funds to the issuer on a specified date, whether or not its customers have purchased and paid for the securities. In contrast, in a best efforts offering,[31] Exchange Act Rule 15c2–4 requires that the broker-dealer pay customers' funds promptly to the issuer upon receipt or, if payment is not to be made to the issuer until some future event or contingency occurs, to a separate bank account or escrow account. While the prompt payment requirement calls for diligent efforts to settle customer transactions and prompt forwarding of funds received, it does not contemplate that a broker-dealer pay out funds it has not received, or use its own funds to pay for securities that have not been sold.

Firm commitment underwriting arrangements thus appear to impose the greatest pressure on the distribution process regarding delivery of the final prospectus. Nonetheless, the Commission specifically seeks comment on whether other types of offerings cause comparable logistical and timing pressures. Comment also is solicited on whether non-syndicated firm commitment underwriting arrangements are subject to these pressures, and if not, whether the Rule should be available for such offerings.

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[18] A new issue of securities in this context is intended to cover both initial public offerings and offerings of additional debt or equity issues by reporting companies.

[19] *See* section 11(d) of the Exchange Act (15 U.S.C. 78k(d)).

[20] The cash account provisions of Regulation T (12 CFR 220.8(b)(1)(ii)) require full cash payment for customer purchases within seven business days after the date an unissued security is made available for delivery to purchasers. For purposes of this section, the securities are not available for delivery to purchasers until the underwriter or underwriters have closed with the issuer. While Regulation T establishes a maximum time during which credit can be extended, brokers may require payment from their customers sooner. The customary settlement period is five business days after the sale, but not earlier than the date of the closing.

[21] *See* Part VII, 3, "Applicability to Investment Companies," *infra*.

[22] *See* n. 17, *supra*.

[23] *See* paragraph (a)(7) of Proposal I and paragraph (a)(6) of Proposal II.

[24] 17 CFR 240.15c2–8. *See* n. 46, *infra*, for certain of these requirements.

[25] *See, e.g.*, Rule 424 (17 CFR 230.424). *See also* Rules 460 and 461(b)(2) (17 CFR 230.460 and 461(b)(2)), which provide that the Commission, in responding to requests for acceleration of the effective date of a registration statement, may consider the extent to which a preliminary prospectus has been distributed to underwriters and dealers, and whether appropriate correcting material has been sent if a distributed preliminary prospectus has been found to be materially inaccurate or inadequate.

Use of the proposed Rule would not limit any existing cause of action available to investors based on the content of the registration statement or prospectus used after effectiveness. *See* sections 11, 12(2) and 17(a) of the Securities Act (15 U.S.C. 77k, 77*l*, and 77q respectively). *See also* section 10(b) of the Exchange Act (15 U.S.C. 78j(b)) and Rule 10b-5 thereunder (17 CFR 240.10b-5).

[26] Rule 430 by its terms is limited to prospectuses used before effectiveness. Rule 430A allows the use after effectiveness of the registration statement, but before pricing, of the prospectus contained in the registration statement when declared effective. Both proposals would extend the time during which Rule 430 and 430A prospectuses may be used so that they could be delivered, for purposes of the proposed Rule, at any time before or with the confirmation. *See* paragraph (b) of both proposals.

[27] *See* paragraph (a)(5) of Proposal I and paragraph (a)(4) of Proposal II.

[28] *See* paragraph (a)(6) of Proposal I and paragraph (a)(5) of Proposal II.

[29] For purposes of the proposed Rule, all offerings that are not subject to Exchange Act Rule 10b–9 (17 CFR 240.10b–9) or 15c2–4 (17 CFR 240.15c2–4) would be deemed firm commitment underwritings. In a firm commitment underwriting, the underwriter(s) purchases the securities from the issuer for a fixed price and then re-sells the securities to the public, thereby assuming the risk of market fluctuations in the price of the securities.

[30] *See* paragraph (a)(1) of each proposal. The proposed Rule would be available only when cash is the sole form of consideration given in exchange for the securities. This requirement is intended to limit the use of the Rule to the conventional firm commitment public offerings associated with the logistical problems intended to be alleviated by the proposed Rule, rather than including transactions such as issuer exchange offers or business combinations.

[31] In a best efforts arrangement, the underwriter acts as an agent for the issuer. It agrees to use its best efforts to sell the securities on behalf of the issuer, and acts as a conduit for funds paid to it by the purchasers of the security being offered.

3. Securities Description Limitation

Both proposals contain provisions conditioning use of the Rule on the availability to investors of the description of the securities being offered in accordance with Item 202 of Regulation S-K,[32] except for 430A-type information. While these provisions operate differently in each proposal, they are intended to assure that investors have an adequate opportunity to review the basic features and terms of the securities prior to payment. These securities description conditions would restrict the availability of the Rule for certain delayed offerings. The Commission solicits comment on whether the proposed approaches, described more fully below,[33] achieve their purpose without unnecessarily restricting registrants' flexibility.

4. The Confirmation

The term "confirmation" would be defined in both versions of the proposed Rule to include electronic confirmations.[34] This will facilitate the use of a no-action position granted by the Division of Market Regulation to The Depository Trust Company ("DTC") regarding its automated interdealer settlement system (the "ID System"),[35] as well as anticipated subsequent developments in this area. This no-action position permits, for purposes of Rule 10b–10 under the Exchange Act, confirmations to institutional customers in DTC's ID System to be delivered by DTC on behalf of its broker-dealer participants through the use of automated electronic methods rather than by providing "hard copy." [36]

IV. Proposal I [37]

1. Offering Not Registered on Form S–3 or F–3

Proposal I would permit the mailing of a final prospectus to an investor no more than five business days after the confirmation is sent to him in an offering registered on a Form other than Form S–3 or F–3, if the following conditions are satisfied.

First, the investor would have to receive a prospectus omitting no more than 430A-type information,[38] as well as any subsequent prospectus that contains a material change other than inclusion of 430A-type information, before or with the confirmation. Second, there could be no material change, other than inclusion of 430A-type information, between the information contained in the latest prospectus delivered to the investor and the information contained in the final prospectus.

The Commission seeks comment on the impact of proposed Rule 433 on the procedures followed by managing underwriters, syndicate members, and selling dealers in firm commitment offerings when material unforeseen events occur after effectiveness of the registration statement and before confirmation, and also when such events occur during the confirmation process or immediately after completion of the confirmation process. Commentators should focus on the effect of the proposed Rule on the manner in which updated information is provided to investors during these time periods and the circumstances under which investors would have an opportunity to disaffirm their investment decision after receiving disclosure of the impact of such events on the company.

The proposed Rule would be available to non-syndicate non-selling group broker-dealers effecting transactions in the immediate aftermarket for initial public offerings where they have a prospectus delivery obligation.[39] Comment is solicited on whether use of the proposed Rule would be needed for such broker-dealers, whether such use would be practicable in light of potential redelivery obligations, and if not, how the Rule should be modified to accommodate their transactions.

2. Offering Registered on Form S–3 or F–3

For an offering registered on Form S–3 or F–3, Proposal I would not require any prospectus to be delivered before or with a confirmation, given the comprehensive incorporation by reference of issuer information in such a prospectus. If such a prospectus were delivered, however, material changes to the information in it would require delivery of a revised, updated prospectus.[40] Material changes to the information required by Item 11 [41] of Form S–3 or F–3 between effectiveness and the sending of the confirmation would have to be filed with the Commission in a Current Report on Form 8–K or 6–K,[42] whether or not such information was physically contained in the final prospectus, unless a prospectus containing such information had been delivered to the investor before or with the confirmation. The filing would alert the market place to the new information, and quickly disseminate it to the public. The Form 8–K or 6–K would disclose information as of the date a confirmation is sent to a purchaser and be filed with the Commission no later than two business days after the date the confirmation is sent.

V. Proposal II [43]

1. Offering Not Registered on Form S–3 or F–3

Proposal II is premised primarily upon access to information rather than delivery of it. It would require, for an offering not registered on Form S–3 or F–3, that the information contained in the prospectus included in the effective registration statement or effective post-effective amendment not be materially different from the information contained in the final prospectus (except for the inclusion of the securities description and 430A-type information); [44] and that the person confirming the sale deliver the final prospectus on an expedited basis after a prospective purchaser's request.[45] Although Proposal II, unlike

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[32] 17 CFR 229.202, "Description of Registration's Securities."

[33] *See* Part VI, "Applicability of Securities Description Limitation to Delayed Offerings," *infra*.

[34] *See* paragraph (c) of both proposals.

[35] The ID System allows confirmation of trades between a broker-dealer and its institutional customers or the institution's agent bank through DTC's facilities.

[36] Under this arrangement, broker-dealers in the ID System provide DTC with all data necessary to generate a confirmation in accordance with Rule 10b-10. DTC in turn provides electronic confirmation to the broker-dealer's ID System customer. *See* Letter from Edward A. Kwalwasser, Associate Director, Division of Market Regulation, to Edward J. McGuire, Jr., Secretary, DTC, dated February 28, 1983.

[37] *See also* Part VI, "Applicability of Securities Description Limitation to Delayed Offerings," *infra*, for a discussion of the securities description limitation in Proposal I.

[38] The proposed Rule refers to "the type of information permitted to be omitted pursuant to Rule 430A" in order not to limit the prospectuses described to those filed in reliance on that Rule. For example, a delayed offering shelf filing made pursuant to Rule 415 could be included in that category, depending on the information omitted. *See* n. 8, *supra*.

[39] Under the Securities Act, there would be no such obligation for transactions exempt pursuant to section 4(3) (15 U.S.C. 77d(3)) and Rule 174 thereunder (17 CFR 230.174) or section 4(4) (15 U.S.C. 77d(4)).

[40] *See* paragraph (a)(4)(ii) of Proposal I.

[41] *See* paragraph (a)(4)(i) of Proposal I, and n. 9, *supra*.

[42] The Form 8–K or 6–K would be incorporated by reference into the prospectus. *See* Item 12(b) of Forms S–3 and F–3.

[43] *See also* Part VI, "Applicability of Securities Description Limitation to Delayed Offerings," *infra*, for a discussion of the securities description limitation in Proposal II.

[44] *See* paragraph (a)(2)(i) of Proposal II. The inclusion of a securities description would not trigger a requirement under the proposed Rule to file a post-effective amendment. *See also* section VI, "Applicability of Securities Description Limitation to Delayed Offerings," *infra*.

[45] If no such request was made, the final prospectus would have to be sent no later than five business days after the confirmation, as required by paragraph (a)(4) of Proposal II.

Proposal I, would not require prior delivery for non-Form S–3 or F–3 offerings,[46] if a prospectus were so delivered, the final prospectus could not differ materially (except for inclusion of 430A-type information) from the latest prospectus delivered to the investor.[47]

To facilitate expedited access to the information in the final prospectus, Proposal II would require that the confirmation in an offering not registered on Form S–3 or F–3 be sent no later than one business day after the date on which the investor agrees to purchase the security. Use of first class mail or equally prompt means reasonably calculated to cause delivery no more than three business days later would be required.[48] Comment is solicited on whether the ability to mail confirmations regionally would reasonably assure delivery within three business days.

Proposal II also would require [49] that the confirmation specifically and prominently set forth a telephone number that the investor may call toll-free to request the final prospectus, and state that the final prospectus will be delivered to a requesting investor within one business day.[50] Since a confirmation is a standardized pre-printed "fill in the blank" form that is completed by computer, modifications would have to be made to the confirmation to accommodate this proposed legend. It is anticipated that the above language would be added to the other information customarily contained in the confirmation.

Investors would be permitted to request expedited delivery of the final prospectus until the fifth business day after the confirmation is sent, the date the final prospectus is required to be sent pursuant to paragraph (a)(4) of Proposal II.[51] Upon receipt of such a request, the person confirming the sale would be required to deliver the final prospectus in a manner reasonably calculated to result in delivery no later than one business day after the request. This would require overnight mail or equally prompt means.

Prospective investors would be able to request expedited delivery of the final prospectus before receiving the confirmation, perhaps as early as the first contact with a broker-dealer regarding that securities offering. At the time of the request, of course, the final prospectus might not yet be available. In such case, paragraph (a)(2)(v) would require delivery of the final prospectus no later than the second business day following the determination of the offering price of the security.[52]

As proposed, the Rule would not provide a specific method, other than a statement in the confirmation, of informing prospective investors of their right to request expedited delivery of the final prospectus. In order to notify persons of this right at an earlier time, the Commission is considering requiring that prospectuses contain a legend on the cover or back page stating that the final prospectus, if not furnished with the confirmation, may be obtained on an expedited basis by calling the toll-free number. Comment is solicited on this approach and on alternative means of accomplishing this purpose.

The provisions of Proposal II are intended to provide investors with an opportunity to request and review the final prospectus before settlement date, customarily five business days after the sale. Comment is sought on the impact of the proposed Rule's requirements on the current timing and procedures for the settlement of securities purchases. The Commission is concerned that Proposal II's time frame might not provide an adequate opportunity for investor review of the final prospectus prior to payment. The Commission solicits specific suggestions on alternative means to provide a meaningful time frame for investors to review the final prospectus before settlement date, taking into account the point in the transaction at which investors are obligated, practically speaking, to purchase and pay for the securities.

As in Proposal I, Proposal II requires that the final prospectus be sent, by first-class mail or other equally prompt means, to each person who purchased securities registered by the registration statement no later than five business days after a confirmation is sent to that purchaser. Expedited delivery of a final prospectus to an investor pursuant to paragraph (a)(2)(iii) of Proposal II for an offering not registered on Form S-3 or F-3 would satisfy the delivery obligation pursuant to paragraph (a)(4) for that investor.

2. Offering Registered on Form S–3 or F–3

As in Proposal I, for an offering registered on Form S–3 or F–3, Proposal II would not require prior delivery of a prospectus. In the absence of such delivery, any material changes in Item 11 information between effectiveness and the sending of the confirmation must be included in a Current Report on Form 8–K or Form 6–K [53] filed within two business days after the date a confirmation is sent to the investor.

Although Proposal II would not impose prior delivery of a prospectus as a condition to the availability of the safe harbor, if a person delivered a prospectus before confirmation, he also would be required to deliver a revised, updated prospectus, if there were material changes in the information contained in the prospectus.[54]

As proposed, offerings on Form S–3 or F–3 would not be subject to the expedited delivery procedures required for offerings on other Forms, although such procedures would be available as an optional means of providing the securities description.[55] Comment is, however, solicited on whether expedited delivery upon request should be required as a condition to the use of the Rule regardless of the Form on which the securities are registered.

VI. Applicability of Securities Description Limitation to Delayed Offerings

1. General Effect of Limitation

As noted above,[56] both Proposals would require that the terms of the securities offered be described in accordance with Item 202 of Regulation S–K, except for omission of 430A-type information.[57] For example, terms such

[46] Initial public offerings, however, still would require delivery of a preliminary prospectus to investors pursuant to Exchange Act Rule 15c2–8(b) and paragraph (a)(6) of Proposal II, discussed in Part III, "Features Common to Both Proposals," *supra*. Nor would proposed Rule 433 affect the current requirements to furnish the latest preliminary prospectus to any person who so requests and to distribute the preliminary prospectus to brokers and dealers participating in an offering if such brokers and dealers are expected to solicit customers' orders to buy the security. *See* Exchange Act Rule 15c2–8 (c) and (e) (17 CFR 240.15c2–8 (c) and (e)).

[47] *See* paragraph (a)(2)(ii) of Proposal II.

[48] *See* paragraph (a)(2)(iii) of Proposal II.

[49] *See* paragraph (a)(2)(iv) of Proposal II. These requirements would be in addition to those under other Commission rules governing the content of confirmations. *See, e.g.*, Rule 10b–10 under the Exchange Act.

[50] The provision for delivery of the prospectus upon request would be in addition to any applicable requirements for delivery of a prospectus upon request pursuant to Exchange Act Rule 15c2–8. *See* n. 46, *supra*.

[51] *See* paragraph (a)(2)(v) of Proposal II.

[52] The final prospectus should be available and on file with the Commission by the second business day after the determination of the offering price. *See* Rule 424(b) (1), (2), (4) and (5) (17 CFR 230.424(b) (1), (2), (4) and (5)).

[53] *See* paragraph (a)(3)(i) of Proposal II and discussionin Part IV.2, "Offering Registered on Form S–3 or F–3," *supra*.

[54] *See* paragraph (a)(3)(ii) of Proposal II.

[55] *See* Part VI, "Applicability of Securities Description Limitation to Delayed Offerings," *infra*.

[56] *See* Part III.3, "Securities Description Limitation," *supra*.

[57] A registrant need not be relying on Rule 430A to omit 430A-type information. Instead, the

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as the price, interest rate, discount or premium, maturity and redemption dates of debt securities could be omitted, but the basic characteristics of the securities, such as the presence of a put or convertibility feature, the index by which interest will be calculated, the nature of the collateral, subordination provisions, and the existence of sinking fund and redemption provisions, could not.

Under current rules, at the time a registration statement for an offering not made on a delayed basis becomes effective, it must contain an Item 202 description of securities, omitting only narrowly specified terms related to the offering price and date if Rule 430A is used. Thus, the securities description limitation in the proposed Rule is a limiting factor only with respect to delayed offerings under Rule 415, since only such registration statements may omit a broader range of information than would be permitted under Rule 430A.

While some registrants eligible to make delayed offerings [58] are able to specify the nature of the security in advance, and thus include in the prospectus at effectiveness all of the required information except for 430A-type information, many registrants prefer to preserve their flexibility to tailor securities to be offered in the future to then-prevailing market conditions. Such registrants will register a "generic" security, such as debt or preferred stock, with the principal features of the security disclosed by prospectus supplement each time a tranche is offered. In such case, the securities description limitation generally would condition the availability of proposed Rule 433 on providing the securities information, as described below.

2. Proposal I

Under Proposal I, for offerings not registered on Form S-3 or F-3, a prospectus containing a complete description of the securities (except for omission of 430A-type information) must be delivered to the investor.[59] For an offering registered on Form S-3 or F-3, the securities description either could be delivered in an appropriately supplemented prospectus or, alternatively, included in a prospectus contained in an effective registration statement or post-effective amendment.

Under the current Form requirements, the description of the securities must be included in the prospectus itself, not incorporated by reference, except for the description of capital stock in a Form S-3 or F-3 registration statement.[60] However, the Commission solicits comment on whether a Form S-3 or F-3 registrant should be permitted to file the description of certain types of securities with which investors generally are familiar, such as conventional debt or preferred stock, in a Form 8-K or 6-K, which would be incorporated by reference into the prospectus. The report would be required to be filed no later than two business days after the determination of the offering price. This could substitute for the requirement to file a post-effective amendment or deliver a prospectus before or with the confirmation.

The principal elements of the securities description also would be in the confirmation. The Commission recognizes, however, that certain provisions of standard senior securities, such as optional redemption prices and extraordinary call provisions, are not necessarily reflected in a confirmation. If incorporation by reference of the securities description is to be permitted, it would appear appropriate to require the confirmation to indicate that the securities are subject to an extraordinary call at a stated price, and to optional redemption starting in a stated year at a stated price. The Commission recognizes the physical limitations of confirmations, but believes the information could be streamlined to be so accommodated.

Other features of conventional debt securities not found in the confirmation include the ranking of the debt, along with provisions governing collateral or subordination, and restrictive covenants. Comment is solicited on whether the availability of the incorporation by reference approach for debt should be limited to rated senior securities, as the securities rating would reflect an assessment of ranking and security provisions.

The incorporation by reference approach would not extend to novel or complex securities that are not widely known and readily understood throughout the investment community, such as currency exchange warrants, stripped or synthetic securities, hybrids, and notes with yields based on a stock or commodity price index. The principal difficulty in adopting this approach is developing an appropriate definition of the securities permitted to be described by incorporation by reference. One possible approach would be to focus on securities as to which the confirmation provides basic financial terms, such as maturity, yield, calls, sinking fund provisions, and convertibility and exchange prices. Commentators supporting an incorporation by reference approach should address the parameters of such a definition.

3. Proposal II

Proposal II, unlike Proposal I, does not have an across-the-board securities description limitation. Under the access-based approach of Proposal II, no such limitation would attach to offerings not on Form S-3 or F-3, because expedited delivery of the final prospectus would be available upon investor request for all such offerings.[61] Accordingly, an investor purchasing securities in a delayed offering, e.g., on Form S-11, would have the opportunity to review the prospectus, including the complete description of securities, before payment.[62]

Proposal II does include a securities description limitation for filings on Form S-3 or F-3, because expedited delivery generally would not be required under Proposal II for such offerings.[63] As

registrant may be relying on Rule 430 or, in the case of a delayed shelf offering under Rule 415, may be omitting information because it is not yet known at the time of effectiveness of the registration statement or use of the prospectus.

[58] Registrants using Rule 415 to make delayed offerings are generally those eligible to use Form S-3 or F-3 (*see* Rule 415(a)(1)(x) (17 CFR 230.415(a)(1)(x))), but Rule 415 also provides that several kinds of traditional delayed offerings may be made on other Forms. *See, e.g.*, Rule 415(a)(1)(vii) (17 CFR 230.415(a)(1)(vii)), which permits offerings of mortgage related securities to be made on a delayed basis; such offerings may be registered on Form S-11 (17 CFR 239.18).

[59] *See* paragraph (a)(2) of Proposal I. Such a prospectus still would be subject to completion since it could omit 430A-type information, which would be provided in the final prospectus required to be sent pursuant to paragraph (a)(5) of Proposal I and paragraph (a)(4) of Proposal II. If the prospectus contained all required information, including the 430A-type information, it presumably would be a final prospectus. If a final prospectus were furnished before or with the confirmation, the safe harbor afforded by proposed Rule 433 would not, of course, be needed.

[60] *See* Item 12(a) of such Forms, which permits incorporation by reference when the capital stock is registered under section 12 of the Exchange Act (15 U.S.C. 78*l*).

[61] *See* paragraph (a)(2) (iii)-(v) of Proposal II and discussion in Part V, "Proposal II," *Supra*.

[62] In general, a material change in the prospectus from that included in the registration statement would preclude availability of the proposed Rule under Proposal II unless a post-effective amendment were filed and declared effective, but the addition of a securities description or 430A-type information would not trigger this requirement. *See* paragraph (a)(2)(i) of Proposal II. Accordingly, Proposal II would not limit the current practice for delayed offerings on Form S-11, such as those of collateralized mortgage obligations, which typically do not require a post-effective amendment to describe each offering under the registration statement.

[63] *See* paragraph (a)(3)(iii) of Proposal II.

noted above, this limitation would affect only delayed offerings. In such case, the Rule would be available if the securities description were included in a supplemented prospectus delivered to investors in advance of the final, or in a prospectus contained in an effective post-effective amendment. Alternatively, expedited delivery of the final prospectus could be provided in the same manner as for offerings not registered on Form S-3 or F-3. Issuers making delayed offerings would therefore have the flexibility to tailor their securities to market-sensitive conditions without having to file a post-effective amendment or have a prospectus delivered to investors in advance of the final prospectus. Comment is solicited on whether expedited delivery of the final prospectus is a useful approach for providing information regarding the principal characteristics of the securities offered, and if so, whether this option should be available only for conventional securities.

VII. Additional Specific Issues of Concern to the Commission

In addition to other topics noted throughout this release, the Commission seeks comment on the following questions and concerns.

1. Alternative Safe Harbors

The Commission has proposed Rule 433 in two distinct versions, which take different approaches to providing a means of satisfying the requirements of section 5(b)(1) of the Securities Act. The Commission seeks comment on whether proposed Rule 433 should instead provide alternative safe harbors for compliance with section 5(b)(1), allowing persons wishing to rely on the Rule, particularly those persons not otherwise required to deliver a preliminary prospectus,[64] greater flexibility.

2. Registrant Eligibility Criteria

As proposed, Rule 433 would be available for all non-investment company registrants complying with the limitations of the Rule, including those engaged in initial public offerings. The Commission seeks comment on whether the proposed Rule should impose any registrant eligibility requirements, such as a limitation to registrants subject to the provisions of section 13(a) or 15(d) of the Exchange Act immediately prior to the filing of the registration statement.

3. Applicability to Investment Companies

The Rule as proposed would not apply to offerings by investment companies regulated under the Investment Company Act of 1940.[65] The SIA petition does not discuss them, and the Commission does not have independent evidence that similar relief is required for them. (In any event, the firm commitment underwriting condition would preclude use of the Rule in most offerings by open-end investment companies.)

The Commission seeks comment on whether a similar rule should be proposed for offerings of investment company securities, and, if so, whether a different approach is necessary or appropriate with respect to them. In addition, the Commission seeks comment on how, if at all, the current confirmation process for registered offerings by open-end investment companies, unit investment trusts, or closed-end investment companies (including business development companies) creates the need for a rule of this type or raises concerns discussed by the SIA in its petition.

VIII. Cost-Benefit Analysis

To evaluate fully the benefits and costs associated with each alternative rule proposal, the Commission requests commentators to provide views and data as to the costs and benefits associated with the proposals. In this regard, the Commission notes that adoption of either proposal should expedite the confirmation process associated with purchases of securities offered in a firm commitment underwriting solely for cash, substantially eliminating the payment delays previously affecting underwriters and concurrently reducing underwriter carrying costs and investor uncertainty. The Commission believes the proposals would permit alternative means of compliance with the requirements of section 5(b)(1) of the Securities Act that conform more closely to the needs of investors, issuers, underwriters, and dealers in light of modern distribution practices. The Commission believes both alternatives address the problems resulting from delays in the confirmation process, while assuring timely access by investors and others to mandated disclosure relating to the investment decision. In addition, use of the proposed Rule would be optional, so persons not wishing to rely on the Rule would be able to continue selling under current procedures.

In order to use the safe harbor that would be afforded by Proposal I, a person may have to deliver a prospectus subject to completion (as well as a final prospectus) who otherwise only would have been required to deliver a final prospectus. This also would be true for certain delayed offering filings under Proposal II. The Commission believes that any increased costs would be offset by the logistical advantages of being able to rely on the proposed Rule, but solicits comment on this aspect of the proposals.

Although the expedited delivery requirements applicable to offerings not registered on Form S-3 or F-3 under Proposal II would be more expensive than those used under current prospectus delivery requirements, the Commission believes that the proposed Rule would reduce the total delivery costs since expedited delivery need only be made to those requesting the prospectus. Potential related costs would include those associated with establishing record-keeping procedures sufficient to demonstrate compliance with the conditions set forth in the proposals, and the additional costs of distribution of the preliminary prospectus where otherwise not required by the Commission's Rules. Such potential costs also would include any costs associated with establishing and operating the toll-free telephone service which would be available to those requesting prospectuses for offerings not made on Form S-3 or F-3 pursuant to Proposal II. The Commission specifically requests comments on the respective costs and benefits of these aspects of the rule proposals.

Finally, comments also are sought concerning costs and benefits to investors resulting from the prospectus delivery procedures and timing that would be permitted by the proposals.

IX. Initial Regulatory Flexibility Analysis

This initial regulatory flexibility analysis, which relates to two alternative rule proposals concerning prospectus delivery requirements, has been prepared in accordance with the Regulatory Flexibility Act ("RFA").[66]

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[64] For example, an issuer having an obligation to file reports pursuant to Exchange Act section 13(a) or 15(d) who makes an offering pursuant to Proposal I must deliver a prospectus to the investor prior to the final prospectus. If such an issuer were not relying upon the proposed Rule, only the final prospectus would be required to be delivered since Exchange Act Rule 15c2-8(b) would be inapplicable to such an issuer. *See n. 17, supra.*

[65] 15 U.S.C. 80a-1 *et seq.* as amended. *See* paragraph (d) of both proposals.

[66] 5 U.S.C. 601 *et seq.*

1. Reasons for and Objectives of the Proposed Action

The alternative rule proposals would allow, if specified conditions are satisfied, the delivery to investors of a confirmation of a purchase of securities in a firm commitment offering prior to delivery of the final prospectus. The proposals respond to concerns raised by the SIA in its rulemaking petition filed with the Commission on January 2, 1986, as supplemented on April 18, 1986. The SIA stated in its petition that the current prospectus delivery requirements under the Securities Act result in a burdensome and costly confirmation process in syndicated public offerings. The alternative rule proposals are designed to address these concerns, reducing the administrative burdens associated with the requirement to mail the final prospectus with the confirmation of purchase, reducing payment delays, and enhancing timely access to such prospectus by investors who wish to review its contents before compliance with their settlement obligation. Under both proposals, existing requirements governing the delivery of the final prospectus would continue to be available.

2. Legal Basis

The alternative rule proposals are being proposed by the Commission pursuant to sections 2(10), 10(a)(4), 10(d), and 19(a) of the Securities Act.[67]

3. Small Entities Subject to the Rule

The Commission has adopted definitions of the term "small entity" for the various entities subject to Commission rulemaking. When used with reference to an "issuer," other than an investment company, the term is defined by Rule 157 [68] under the Securities Act as an issuer whose total assets on the last day of its most recent fiscal year were $5,000,000 or less and that is engaged or proposing to engage in an offering of securities which does not exceed $5,000,000. In the recent experience of the Commission, several hundred registration statements a year may be filed with the Commission by small issuers.

When used with reference to a broker or dealer, the term is defined by Rule 0–10 [69] of the Exchange Act as a broker or dealer that: (1) Had total capital (net worth plus subordinated liabilities) of less than $500,000 on the date in the prior fiscal year as of which its audited financial statements were prepared pursuant to Rule 17a–5(d)[70] under the Exchange Act or, if not required to file such statements, a broker or dealer that had total capital (net worth plus subordinated liabilities) of less than $500,000 on the last business day of the preceding fiscal year (or in the time that it has been in business, if shorter); and (2) is not affiliated with any person (other than a natural person) that is not a small business or small organization as defined by Rule 0–10. As many as 5,000 brokers and dealers may be considered small entities under this definition. Of these, approximately 600 are involved in underwriting activity.

The Commission believes that the proposals would reduce regulatory burdens associated with satisfying the prospectus delivery requirements for those small issuers, brokers and dealers (including underwriters) covered by each of the proposals. Although the delivery requirements of Proposal I and the expedited delivery available under Proposal II would be more expensive than those used under current prospectus delivery requirements, the Commission believes that the proposals would reduce the total delivery costs since delivery under Proposal I would reduce carrying costs associated with mailing and payment delays, and under Proposal II delivery prior to expiration of a five business day period following the sending of confirmations need only be made to those requesting the prospectus.

4. Reporting, Record-Keeping and Other Compliance Requirements

Since existing requirements governing the delivery of the final prospectus would continue to be available, the Commission believes that neither proposal would impose additional reporting or record-keeping requirements on small entities, nor increase their regulatory compliance costs. Potential costs for those entities opting to use either proposal, however, would include those associated with establishing record-keeping procedures sufficient to demonstrate compliance with the conditions set forth in the proposals. Such potential costs also would include any costs associated with establishing and operating the toll-free telephone service which would be available to those requesting the prospectus for offerings not registered on Form S–3 or F–3 pursuant to Proposal II.

5. Overlapping or Conflicting Federal Rules

The Commission does not believe that the proposals duplicate, overlap, or conflict with any existing rule provisions, although they do condition availability of the safe harbor on compliance with one existing rule, Rule 15c2–8(b).

6. Significant Alternatives

Since proposed Rule 433 is a voluntary safe harbor, satisfaction of existing prospectus delivery requirements would make compliance with the proposed Rule's provisions unnecessary.

The Rule's safe harbor is intended to benefit all issuers and broker-dealers engaging in firm commitment underwritten offerings solely for cash. In this regard, the rule proposals represent alternative approaches to reducing the regulatory burdens associated with prospectus delivery.

The Commission has requested comment on whether registrant eligibility requirements should be included in proposed Rule 433. specifically, the Commission has requested whether the proposed Rule should be available to registrants not subject to the reporting provisions of section 13(a) or 15(d) of the Exchange Act immediately prior to the filing of a registration statement. If not, such an alternative would essentially exempt small issuers from the proposed rule since no more than 2,000 of the 12,000 companies reporting to the Commission pursuant to section 13(a) or 15(d) of the Exchange Act are small issuers.

The Commission has also requested comment on whether the security description limitations and the firm commitment condition in the proposals are appropriate. Specifically, comment has been requested on alternative approaches to the securities description limitation, and also whether other types of offerings impose pressure on the distribution process similar to those posed by firm commitment underwritten offerings subject to the Rule. If the firm commitment underwriting condition were removed, the Rule would be applicable to all small entities engaging in small registered financings whether made on a firm commitment basis or on a best efforts basis. As currently proposed, the Rule's impact on small entities engaged in small business financings is limited to those entities involved in firm commitment registered offerings not exceeding $5,000,000.

Another significant alternative to the proposed Rule could be different or

[67] 15 U.S.C. 77b(10, 77j(a)(4), 77j(d), and 77s(a) respectively.

[68] 17 CFR 230.157.

[69] 17 CFR 240.0–10.

[70] 17 CFR 240.17a–5(d).

simplified compliance or reporting requirements for small entities, such an alternative could include the elimination or modification of various prerequisites for use of the proposed Rule for small entities. Such an approach would not be consistent with the Commission's mandate under section 5 of the Securities Act as it relates to registered offerings by small issuers. Another alternative could be the adoption of performance rather than design standards with respect to prospectus delivery requirements. Use of performance standards in a safe harbor context would frustrate the ability of persons subject to the Rule to ascertain whether all the conditions for meeting the safe harbor were satisfied.

7. Solicitation of Comments

The Commission encourages the submission of written comments with respect to any aspect of this initial regulatory flexibility analysis. Such written comments will be considered in the preparation of the final regulatory flexibility analysis if either proposal is adopted. Persons wishing to submit written comments should file four copies with Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. All submissions should refer to File No. S7- -87 and will be available for public inspection and copying at the Commission's Public Reference Room.

X. Request for Comments

Any interested persons wishing to submit written comments on the alternative rule proposals, as well as other matters that might have an impact on the proposals, are requested to do so. In addition to the specific requests for comments appearing elsewhere in this release, the Commission generally seeks comment on the necessity for or desirability of Commission action relating to the prospectus delivery requirements under the Securities Act, the potential benefits or disadvantages of such a rule to investors, issuers, underwriters, brokers, dealers, and others, and the extent of hardship experienced by underwriters operating under the current prospectus delivery requirements. The Commission also solicits comment on whether the operation of the proposed Rule could have an adverse impact upon investor's rights and remedies, both legal and practical, in the purchase of securities offered in reliance on the Rule. The Commission also invites all interested persons to comment on any other possible alternative resolutions to the issuers raised by the SIA's petition.

Written statements must be received on or before October 5, 1987 and should be submitted in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Such communications should refer to File No. S7-29-87 and will be available for public inspection and copying at the Commission's Public Reference Room.

XI. Statutory Basis of Alternative Rule Proposals

These alternative rules are being proposed pursuant to sections 2(10), 10(a)(4), 10(d) and 19(a) of the Securities Act of 1933.

List of Subjects in 17 CFR Part 230

Prospectus delivery requirements, Reporting and record keeping requirements, Securities.

XII. Text of Alternative Rule Proposals

In accordance with the foregoing Title 17, Chapter II of the Code of Federal Regulations is proposed to be amended as follows:

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

1. The authority citation for Part 230 continues to read: (citations before * * * indicate general rulemaking authority).

Authority: Sec. 19, 48 Stat. 85, as amended; 15 U.S.C. 77s * * * Section 230.433 also issued under Section 2, 15 U.S.C. 77b, and 10, 15 U.S.C. 77j.

* * * * *

2. By adding § 230.433 to read in one of the following ways:

Proposal I

§ 230.433 Prospectus delivery requirements in firm commitment underwritten offerings of securities for cash.

(a) Where each of the following conditions has been met, the prospectus meeting the requirements of section 10(a) of the Securities Act of 1933 (15 U.S.C. 77j(a)) shall be deemed to have been sent to a person prior to or at the same time that a confirmation is sent to that person:

(1) The securities are offered for cash in a firm commitment underwriting;

(2) The terms of the securities offered are described in accordance with Item 202 of Regulation S-K (17 CFR 229.202 of this chapter), except for the omission of the type of information that may be omitted pursuant to Rule 430A (17 CFR 230.430A of this chapter), in a prospectus delivered to that person prior to or with the confirmation; *Provided, however,* that with respect to an offering registered on Form S-3 or F-3, such information need not be delivered if the information is included in the prospectus contained in the effective registration statement or effective post-effective amendment thereto;

(3) With respect to an offering not registered on Form S-3 or F-3:

(i) A prospectus omitting no more than the type of information that may be omitted pursuant to Rule 430A, and any subsequent prospectus that contains a material change (other than inclusion of information of the type that may be omitted pursuant to Rule 430A) from that previously delivered, is delivered to that person prior to or with the confirmation; and

(ii) There is no material change (other than inclusion of the type of information that may be omitted pursuant to Rule 430A) between the information contained in the latest prospectus delivered to that person pursuant to paragraph (a)(3)(i) of this section and the information contained in the prospectus required to be sent to that person pursuant to paragraph (a)(5) of this section;

(4) With respect to an offering registered on Form S-3 or F-3:

(i) Any material change in the information required by Item 11 of such Form between effectiveness of the registration statement or post-effective amendment and the sending of the confirmation shall, whether or not such information is contained in the prospectus required to be sent to that person pursuant to paragraph (a)(5) of this section, be included in a Current Report on Form 8-K or 6-K (17 CFR 249.308 and 249.306 of this chapter, respectively) filed no later than two business days after the sending of the confirmation; *Provided, however,* that no such filing shall be required if such information is contained in a prospectus delivered to that person prior to or with the confirmation; and

(ii) There is no material change (other than inclusion of the type of information that may be omitted pursuant to Rule 430A) between the information contained in the latest prospectus delivered to that person, if any, and the information contained in the prospectus required to be sent to that person pursuant to paragraph (a)(5) of this section;

(5) A prospectus meeting the requirements of section 10(a) of the Securities Act is sent by first class mail or other equally prompt means to that person no later than five business days after the date the confirmation is sent to that person;

(6) The confirmation sent to that person incorporates by reference the prospectus required to be sent pursuant to paragraph (a)(5) of this section; and

(7) That person receives a prospectus in accordance with the prospectus delivery requirements of Rule 15c2–8(b) (17 CFR 240.15c2–8(b) of this chapter) under the Securities Exchange Act of 1934, if applicable.

(b) Notwithstanding any provision of Rule 430 (17 CFR 230.430 of this chapter) or Rule 430A to the contrary, and solely for purposes of use under paragraphs (a)(3)(i) and (a)(4)(ii) of this section, a prospectus that omits no more than the information permitted to be omitted pursuant to Rule 430 or Rule 430A may be used after the effective date of the registration statement; *Provided, however,* that such prospectus otherwise complies with the requirements of Section 10 of the Act (15 U.S.C. 77j) at the time of delivery under paragraph (a)(3)(i) or (a)(4)(ii) of this section.

(c) For purposes of this rule, confirmation shall mean any written or electronic data communication confirming the sale of securities.

(d) This section shall not apply to the offering of any securities of any company registered under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.* as amended) or any company that is exempt from the requirement to register under that Act through filing either a notification of election or a notice of intent to file a notification of election to be treated as a business development company under that Act.

Proposal II

§ 230.433 Prospectus delivery requirements in firm commitment underwritten offerings of securities for cash.

(a) Where each of the following conditions has been met, the prospectus meeting the requirements of section 10(a) of the Securities Act of 1933 (15 U.S.C. 77j(a)) shall be deemed to have been sent to a person prior to or at the same time that a confirmation is sent to that person:

(1) The securities are offered for cash in a firm commitment underwriting;

(2) With respect to an offering not registered on Form S–3 or F–3:

(i) There is no material change between the information contained in the prospectus included in the effective registration statement or effective post-effective amendment thereto (other than inclusion of the description of the securities and the type of information that may be omitted pursuant to Rule 430A (17 CFR 230.430A of this chapter)) and the information contained in the prospectus required to be sent to that person pursuant to paragraph (a)(4) of this section;

(ii) There is no material change (other than inclusion of the type of information that may be omitted pursuant to Rule 430A) between the information contained in the latest prospectus delivered to that person, if any, and the information contained in the prospectus required to be sent to that person pursuant to paragraph (a)(4) of this section;

(iii) The confirmation is sent, no later than one business day after the date on which that person agrees to purchase the security, by first class mail or equally prompt means reasonably calculated to result in delivery no later than three business days after the date the confirmation is sent;

(iv) The confirmation specifically and prominently sets forth a telephone number that may be called toll-free to request expedited delivery of the prospectus required to be sent pursuant to paragraph (a)(4) of this section, and states that such prospectus will be delivered no later than one business day after such a request is made; and

(v) If that person requests expedited delivery of a prospectus no later than the sending date for prospectus required to be sent pursuant to paragraph (a)(4) of this section, that prospectus is sent to that person by means reasonably calculated to result in delivery no later than (1) two business days after the date of determination of the offering price or (2) one business day after the date on which such request is made, whichever is later;

(3) With respect to an offering registered on Form S–3 or F–3:

(i) Any material change in the information required by Item 11 of such Form between effectiveness of the registration statement or post-effective amendment and the sending of the confirmation shall, whether or not such information is contained in the prospectus required to be sent to that person pursuant to paragraph (a)(4) of this section, be included in a Current Report on Form 8–K or 6–K [17 CFR 249.308 and 249.306 of this chapter, respectively] filed no later than two business days after the sending of the confirmation; *Provided, however,* that no such filing shall be required if such information is contained in a prospectus delivered to that person prior to or with the confirmation;

(ii) There is no material change (other than inclusion of the type of information that may be omitted pursuant to Rule 430A) between the information contained in the latest prospectus delivered to that person, if any, and the information contained in the prospectus required to be sent to that person pursuant to paragraph (a)(4); and

(iii)(A) Except for the omission of the type of information that may be omitted pursuant to Rule 430A, the terms of the securities offered are described in accordance with Item 202 of Regulation S–K (17 CFR 229.202 of this chapter):

(*1*) In the prospectus contained in the effective registration statement or effective post-effective amendment thereto; or

(*2*) In a prospectus delivered to that person prior to or with the confirmation; or

(B) The confirmation requirements of paragraphs (a)(2) (iii) and (iv) of this section and the expedited delivery provisions of paragraph (a)(2)(v) of this section are complied with;

(4) A prospectus meeting the requirements of section 10(a) of the Securities Act is sent to that person by first class mail or other equally prompt means no later than five business days after the date the confirmation is sent to that person;

(5) The confirmation sent to that person incorporates by reference the prospectus required to be sent pursuant to paragraph (a)(4) of this section; and

(6) That person receives a prospectus in accordance with the prospectus delivery requirements of Rule 15c2–8(b) (17 CFR 240.15c2–8(b) of this chapter) under the Securities Exchange Act of 1934, if applicable.

(b) Notwithstanding any provision of Rule 430 (17 CFR 230.430 of ths chapter) or Rule 430A to the contrary, and solely for purposes of use under paragraphs (a)(2)(ii) and (a)(3)(ii) of this sction, a prospectus that omits no more than the information permitted to be omitted pursuant to Rule 430 or Rule 430A may be used after the effective date of the registration statement; *Provided, however,* that such prospectus otherwise complies with the requirements of Section 10 of the Act (15 U.S.C. 77j) at the time of delivery under paragraph (a)(2)(ii) or (a)(3)(ii) of this section.

(c) For purposes of this rule, confirmation shall mean any written or electronic data communication confirming the sale of securities.

(d) This section shall not apply to the offering of any security of any company registered under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.* as amended) or any company that is exempt from the requirement to register under that Act through filing either a notification of election or a notice of intent to file a notification of

election to be treated as a business development company under that Act.

July 31, 1987.

Jonathan G. Katz,

Secretary.

[FR Doc. 87-17880 Filed 8-5-87; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 385

[Docket No. RM87-24-000]

Procedures for the Assessment of Civil Penalties under Section 31 of the Federal Power Act

August 3, 1987.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is issuing a notice of proposed rulemaking establishing procedures for the assessment of civil penalties pursuant to section 12 of the Electric Consumers Protection Act of 1986, which amended and added a new section 31 to the Federal Power Act.

DATE: Comments must be in writing and received by the Secretary of the Commission prior to 4:30 p.m. E.D.T. on October 5, 1987. An original and fourteen copies should be filed.

ADDRESS: All filings should refer to Docket No. RM87-24-000 and should be addressed to: Office of the Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426.

FOR FURTHER INFORMATION CONTACT: Richard Meyer, Office of the General Counsel, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, Phone: (202) 357-5228.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Federal Energy Regulatory Commission (Commission) is proposing to adopt new regulations for the assessment of civil penalties pursuant to section 12 of the Electric Consumers Protection Act of 1986 (ECPA) [1].

II. Background

ECPA was enacted on October 16, 1986. Section 12 of ECPA amended the Federal Power Act (FPA) by adding a new section 31.[2] Section 31 of the Federal Power Act, among other things, authorizes the Commission to assess civil penalties in certain circumstances. It does not lessen or repeal any authority the Commission possessed prior to the enactment of ECPA to issue compliance orders or to take other remedial action.

Section 31 of the Federal Power Act has four subsections. Subsection (a) affirms the Commission's authority to monitor and investigate compliance with licenses, permits and exemptions issued for hydroelectric projects.[3] This subsection also sets forth the Commission's authority to issue certain compliance orders which, if violated, provide a basis for enforcement action under subsection (b) or (c). Subsection (b) states the conditions under which the Commission may issue an order revoling a license or exemption.[4] Subsection (c) forth the persons subject to a civil penalty, the conduct which may subject those persons to a civil penalty, and factors which the Commission must take into account in determining the amount of a proposed penalty.[5] Subsection (c) also provides that no civil penalty shall be assessed where revocation is ordered. Subsection (d) establishes alternative civil penalty assessment procedures.[6]

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[1] Pub. L. No. 99-495, 100 Stat. 1243 (1986).

[2] To be codified as 16 U.S.C. 823b.

[3] Section 31(a) of the FPA states:

MONITORING AND INVESTIGATION.—The Commission shall monitor and investigate compliance with each license and permit issued under this Part and with each exemption granted from any requirement of this Part. The Commission shall conduct such investigations as may be necessary and proper in accordance with this Act. After notice and opportunity for public hearing, the Commission may issue such orders as necessary to require compliance with the terms and conditions of licenses and permits issued under this Part and with the terms and conditions of exemptions granted from any requirement of this Part.

[4] Section 31(b) of the FPA states:

REVOCATION ORDERS.—After notice and opportunity for an evidentiary hearing, the Commission may also issue an order revoking any license issued under this Part or any exemption granted from any requirement of this Part where any licensee or exemptee is found by the Commission:

(1) to have knowingly violated a final order issued under subsection (a) after completion of judicial review (or the opportunity for judicial review); and

(2) to have been given reasonable time to comply fully with such order prior to commencing any revocation proceeding.

In any such proceeding, the order issued under subsection (a) shall be subject to de novo review by the Commission. No order shall be issued under this subsection until after the Commission has taken into consideration the nature and seriousness of the violation and the efforts of the licensee to remedy the violation.

[5] Section 31(c) of the FPA states:

CIVIL PENALTY.—Any licensee, permittee, or exemptee who violates or fails or refuses to comply with any rule or regulation under this Part, any term, or condition of a license, permit, or exemption under this Part, or any order issued under subsection (a) shall be subject to a civil penalty in an amount not to exceed $10,000 for each day that such violation or failure or refusal continues. Such penalty shall be assessed by the Commission after notice and opportunity for public hearing. In determining the amount of a proposed penalty, the Commission shall take into consideration the nature and seriousness of the violation, failure, or refusal and the efforts to the licensee to remedy the violation, failure, or refusal in a timely manner. No civil penalty shall be assessed where revocation is ordered.

[6] Section 31(d) of the FPA states:

ASSESSMENT.—(1) Before issuing an order assessing a civil penalty against any person under this section, the Commission shall provide to such person notice of the proposed penalty. Such notice shall, except in the case of a violation of a final order issued under subsection (a), inform such person of his opportunity to elect in writing within 30 days after the date of receipt of such notice to have the procedures of paragraph (3) (in lieu of those of paragraph (2)) apply with respect to such assessment.

(2)(A) In the case of the violation of a final order issued under subsection (a), or unless an election is made within 30 calendar days after receipt of notice under paragraph (1) to have paragraph (3) apply with respect to such penalty, the Commission shall assess the penalty, by order, after a determination of violation has been made on the record after an opportunity for an agency hearing pursuant to section 554 of title 5, United States Code, before an administrative law judge appointed under section 3105 of such title 5. Such assessment order shall include the administrative law judge's findings and the basis for such assessment.

(B) Any person against whom a penalty is assessed under this paragraph may, within 60 calendar days after the date of the order of the Commission assessing such penalty, institute an action in the United States court of appeals for the appropriate judicial circuit for judicial review of such order in accordance with chapter 7 of title 5, United States Code. The court shall have jurisdiction to enter a judgment affirming, modifying, or setting aside in whole or in part, the order of the Commission, or the court may remand the proceeding to the Commission for such further action as the court may direct.

(3)(A) In the case of any civil penalty with respect to which the procedures of this paragraph have been elected, the Commission shall promptly assess such penalty, by order, after the date of the receipt of the notice under paragraph (1) of the proposed penalty.

(B) If the civil penalty has not been paid within 60 calendar days after the assessment order has been made under subparagraph (A), the Commission shall institute an action in the appropriate district court of the United States for an order affirming the assessment of the civil penalty. The court shall have authority to review de novo the law and the facts involved, and shall have jurisdiction to enter a judgment enforcing, modifying, and enforcing as so modified, or setting aside in whole or in part, such assessment.

(C) Any election to have this paragraph apply may not be revoked except with the consent of the Commission.

(4) The Commission may compromise, modify, or remit, with or without conditions, any civil penalty which may be imposed under this subsection, taking into consideration the nature and seriousness of the

Continued

In this notice of proposed rulemaking, the Commission is proposing rules to implement subsections (c) and (d) of FPA section 31.

The civil penalty provisions enacted in those subsections may be summarized as follows.

Licensees, permittees and exemptees are subject to civil penalties of up to $10,000 per day for each violation of, or failure or refusal to comply with, any rule or regulation issued under Part I of the FPA, any term or condition of a license, permit, or exemption issued under Part I of the FPA, or a compliance order issued under subsection (a)(1). The amount of the proposed penalty must reflect the nature and seriousness of the violation and the timely remedial efforts of the person against whom the penalty is proposed. No penalty may be assessed where a license or exemption is revoked.

The Commission must provide notice of the proposed penalty and, where applicable, of the person's right to make an election between the administrative hearing procedures of FPA section 31(d)(2) and trail in United States district court under FPA section 31(d)(3) procedures. The person then has 30 days to elect in writing the procedural course to be followed. An election may be revoked only with the consent of the Commission.

If an election is not made, or if an election is not applicable, then administrative procedures apply. The Commission must then provide the opportunity for an adjudicatory hearing under section 554 of the Administrative Procedure Act, 5 U.S.C. 554 (1982). After the hearing, the Commission may issue an assessment order, and the person against whom the penalty is assessed may appeal to the appropriate United States Court of Appeals within 60 days. If the penalty is not paid within 60 days after a final and unappealable order has been issued, the Commission must institute a collection action in United States District Court.

If an election is made in favor of the alternate trial court procedures, the Commission must promptly assess the penalty and, if the penalty is not paid within 60 days, must initiate an action in United States District Court for an order affirming the penalty. If the penalty is not paid within 60 days after the District Court has entered a final judgment in favor of the Commission, the Commission must institute a collection action in United States District Court.

In certain circumstances, the Commission may modify a civil penalty.

A detailed analysis of the civil penalty provisions and the proposed regulations follows below.

III. Discussion

A. Scope of Proposed Rule and Persons Subject to Civil Penalties (§§ 385.1501 and 1502)

Section 385.1501 of the proposed rules provides that the rules apply to proceedings to assess civil penalties pursuant to section 31 of the FPA. Section 385.1502 states that any licensee or permittee under the FPA, and any exemptee from any requirement of Part I of the FPA, may be subject to civil penalties. Any person who should have a license or exemption, but does not, would also be subject to civil penalties. The Commission interprets the statutory phrase, "licensee, permittee or exemptee" to include a person who engages in conduct requiring a license or exemption but fails to obtain one. Congress was clearly concerned about unlicensed projects when it enacted this law: "The Committee . . . expects FERC to locate projects that are being operated without legal authority and to enforce the law." [7]

In the Commission's view, Congress could not have meant to insulate from civil penalties persons who have ignored licensing requirements, while penalizing only those who have taken the trouble to obtain the necessary authority. Under such a reading, an unlicensed person would be immune from a civil penalty even if he operated in exactly the same way as a penalized licensee. There is no reason to ascribe to Congress such an irrational intent. Accordingly, the Commission proposes in new § 385.1502 to apply the civil penalty provisions to those persons who should have a license or exemption for constructing, maintaining or operating a project, but do not.

Similarly, section 31(c) of the FPA does not explicitly state that the Commission may assess civil penalties for violations of exemptions that are issued pursuant to section 405 of the Public Utility Regulatory Policies Act of 1978, as amended, 16 U.S.C. 2705 (1982) (PURPA). The Commission, however, reads the civil penalty provisions to apply to violations of such exemptions for two reasons. First, EPA section 31(c) makes "any exemptee" subject to a civil penalty, not just the small percentage of exemptees who hold conduit exemptions issued under section 30 of the FPA. Second, FPA section 31(b) explicitly provides authority to the Commission to revoke any exemption, regardless of whether it is grounded on PURPA or section 30 of the FPA. The legislative history shows that Congress intended the Commission to use its revocation authority "quite sparingly." [8] It is doubtful Congress intended to permit the use of the more severe remedy—revocation—against the holder of any exemption while limiting the use of a less severe remedy—civil penalties—to holders of conduit exemptions. Therefore, proposed § 385.1502 provides that any exemptee is subject to civil penalties. The Commission also notes that FPA section 31(c) provides for civil penalties for violations of orders issued under FPA section 31(a). FPA section 31(a) covers the terms and conditions of exemptions granted from any requirement of Part I of the FPA. This would include exemptions issued pursuant to section 405 of PURPA. Thus, the Commission clearly has the authority to assess a civil penalty for violations of any order issued pursuant to FPA section 31(a) requiring compliance with the terms and conditions of an exemption under section 405 of PURPA.

B. Actions Subjecting Persons to Civil Penalties (§ 385.1503)

Section 385.1503 of the proposed rules sets forth the actions that would subject persons to civil penalties. Those actions are violations of, or failures or refusals to comply with: (1) Any rule or regulation issued under Part I of the

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violation and the efforts of the licensee to remedy the violation in a timely manner at any time prior to a final decision by the court of appeals under paragraph (2) or by the district court under paragraph (3).

(5) If any person fails to pay an assessment of a civil penalty after it has become a final and unappealable order under paragraph (2), or after the appropriate district court has entered final judgment in favor of the Commission under paragraph (3), the Commission shall institute an action to recover the amount of such penalty in any appropriate district court of the United States. In such action, the validity and appropriateness of such final assessment order or judgment shall not be subject to review.

(6)(A) Notwithstanding the provisions of title 28, United States Code, or of this Act, the Commission may be represented by the general counsel of the Commission (or any attorney or attorneys within the Commission designated by the Chairman) who shall supervise, conduct, and argue any civil litigation to which paragraph (3) of this subsection applies (including any related collection action under paragraph (5)) in a court of the United States or in any other court, except the Supreme Court. However, the Commission or the general counsel shall consult with the Attorney General concerning such litigation, and the Attorney General shall provide, on request, such assistance in the conduct of such litigation as may be appropriate.

(B) The Commission shall be represented by the Attorney General, or the Solicitor General, as appropriate, in actions under this subsection, except to the extent provided in subparagraph (A) of this paragraph.

[7] H.R. Rep. No. 507, 99th Cong., 2d Sess. 40 (1986).

[8] *Id.* at 41.

Federal Power Act; (2) any term or condition of a license, permit or exemption; or (3) any order issued pursuant to section 31(a) of the FPA to require compliance with terms and conditions of licenses, permits or exemptions issued under Part I of the Federal Power Act. As noted above, the Commission also interprets the statutory civil penalty provisions to apply to those persons who construct or operate a jurisdictional project without a license or exemption.

There is no requirement in section 31 of the FPA that the actions subjecting persons to civil penalties be either knowing or willful, nor does the Commission propose such a requirement in this regulation. Where Congress has intended such a requirement as a condition for assessing a civil penalty it has said so.[9] However, the Commission will take these factors into account in considering the "nature" of any violation.

FPA section 31(c) is silent as to whether Congress intended to give the Commission authority to assess a civil penalty for improper conduct occurring prior to enactment of ECPA on October 16, 1986. Absent clear congressional intent favoring retroactive application, a statute is presumed to be applied prospectively only.[10] Accordingly, the Commission proposes in the new § 385.1503 to apply the civil penalty provisions of FPA section 31 prospectively. The proposed rules would apply to conduct occurring on or after October 16, 1986, even if that conduct began before October 16, 1986.[11]

C. Maximum Amount of Civil Penalty (§ 385.1504)

Under section 31(c) of the FPA, the Commission may not assess a civil penalty of more than $10,000 for each day that such violation or failure or refusal continues, and no civil penalty may be assessed where a license or exemption is ordered revoked. Section 385.1504 of the proposed rules reflects these limitations.

The Commission proposes to utilize a civil penalty as a supplement to other appropriate sanctions, such as criminal penalties and nonpenal remedies authorized by sections 4(g) and 309 of the FPA.[12] Although the Commission may not assess a penalty where a license is ordered revoked, an unsuccessful criminal prosecution would not foreclose an action for civil penalties.[13]

D. Determination of Proposed Penalty Amount (§ 385.1505)

In determining the amount of a proposed penalty, section 31(c) of the FPA requires the Commission to consider (1) the nature and seriousness of the violation, failure or refusal, and (2) the efforts of the licensee to remedy the violation, failure, or refusal in a timely manner. These factors are set forth in §385.1505(a) of the proposed rules.

In considering the "nature" of the violation, the Commission proposes in the new § 385.1505(b) (1), (2) and (3) to consider the violator's compliance history, and whether the violator had actural knowledge or the constructive knowledge deemed to be possessed by a reasonable individual acting under similar circumstances. Other factors being equal, a knowing violation will subject a person to a higher civil penalty than a violation which is not knowing

In considering the "seriousness" of the violation, the Commission proposes in § 385.1505 (b)(4) through (b)(6) to consider whether the violation resulted in loss of life, whether and to what extent persons were injured or property or the environment was damaged, and whether persons, property or the environment were endangered but not damaged. For example, a violation which results in loss of human life will subject a person to a higher civil penalty than a violation that solely endangers property, other factors being equal.

In considering the remedial efforts of the violator, the Commission proposes in § 385.1505 (b)(7) through (b)(9) to consider whether the violator remedied the violation in a timely manner, in an untimely manner, or failed to remedy the violation. A violation followed by untimely remedial efforts will subject a person to a higher civil penalty than a violation followed by timely remedial efforts, other factors being equal.

The Commission does not propose to state in the proposed regulations specific dollar amounts for every hypothetical violation that may occur. Because the Commission lacks experience assessing civil penalties pursuant to FPA section 31, it would be premature to allocate precise or even approximate numerical weights to the factors to be considered or to establish fixed formulae for penalty assessment at this time. Moreover, FPA section 31 does not require the Commission to publish criteria for calculating the dollar amount at which to propose or assess a penalty, and it has been historically rare for federal agencies in general to publish such criteria.[14] In most variable penalty statutes, Congress has imposed few constraints on the discretion of the penalty-imposing authority to determine the penalty amount. Its most common restraint has been the enumeration of standards to be considered in determining the penalty amount.[15] While the Commission is not proposing fixed formulae for assessing penalties, the proposed rule enumerates factors that will influence the determination of penalty amounts.

Read literally, section 31(c) of the FPA requires the Commission to consider timely remedial efforts only of licensees. It does not expressly require the Commission to consider timely remedial efforts of permittees or exemptees. However, since there is no logical reason to require a consideration of remedial efforts when the violator is a licensee but not when it is a permittee or exemptee, the Commission, in § 385.1505(a), proposes to consider the remedial efforts of all persons subject to civil penalties. When interpreting a statute, words may be inserted to carry out legislative intent and to avoid absurd results.[16] In any event, in the absence of contrary statutory language, the Commission has the inherent discretion to consider the remedial efforts of a violator when it assesses a civil penalty.

E. Requirement of Notice of Proposed Penalty (§ 385.1506)

FPA section 31(d)(1) requires the Commission to provide notice of the proposed penalty to the person against whom the penalty is to be assessed. The new § 385.1506(a) embodies this requirement.

Section 31(d)(1) of the FPA does not expressly state that the notice of proposed penalty must specify the exact amount of the proposed penalty. It also does not expressly state that the notice must articulate the basis for the amount of the proposed penalty. Nevertheless, because section 31(c) of the FPA states how the Commission is to determine the amount of a proposed penalty, it can be argued that the amount, and the basis

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[9] *See* section 504(b) of the Natural Gas Policy Act of 1978, 15 U.S.C. 3414(b)(6) (1982).

[10] *See 2 Sutherland Stat. Const.* section 41.04 (4th ed. 1984).

[11] *See Samuels v. McCurdy*, 267 U.S. 188, 193 (1925) (criminal penalty upheld for possession of liquor, where possession began before statutory prohibition and continued thereafter).

[12] *See e.g., Niagara Mohawk Power Corp. v. FPC*, 379 F. 2d 153 (D.C. Cir. 1967); Administrative Conference of the United States, *Recommendations and Reports* 220 (1979).

[13] *See U.S. v. Ward*, 448 U.S. 242, 248, 253 (1980).

[14] *See* Administrative Conference of the United States, *Recommendations and Reports* 221 (1979).

[15] *Id.* at 214, 289.

[16] 2A *Sutherland Stat. Const.* section 47.38 (4th ed. 1984).

for such amount, should be articulated in the notice of proposed penalty to provide a person receiving a notice with a rational basis on which to exercise his election rights.[17] This is consistent with the procedures used by other agencies.[18] The Administrative Conference of the United States recommends that agencies should give notice of the factual and legal basis for, and the amount of, the initial assessment.[19] Accordingly, the Commission proposes in the new § 385.1506(b) to include, in the notice, a statement of the amount of the proposed penalty, and the factual and legal basis of the proposed penalty. In the instance of a continuing violation, the proposed penalty could be expressed in terms of a daily amount.

Where there is a right to an election, the Commission must inform the person against whom the penalty is to be assessed of that person's opportunity to elect the procedures to be followed, *i.e*, the administrative evidentiary hearing of FPA section 31(d)(2) or the United States District Court procedures of FPA section 31(d)(3). This notice would be provided under § 385.1506(b)(iii) of the proposed regulations.

F. Election of Procedures and Answer (§ 385.1507(a))

Under section 31(d)(1) of the FPA, a person to whom a notice of proposed penalty is issued has thirty days from receipt of such notice to elect in writing between the procedures of FPA section 31(d)(2) and section 31(d)(3). The administrative hearing procedures of FPA sction 31(d)(2) automatically apply unless the person has the right to an election and exercises that right within 30 days of receipt of the notice of proposed penalty, new § 385.1507(a). The notification may include an answer contesting the proposed assessment. If the person fails to file such as anser in a timely manner, all material facts alleged by the Commission shall be deemed admitted. General denials unsupported by specific factual allegations may provide a basis for summary disposition.

Sections 31(d)(1) and 31(d)(2)(A) of the FPA provide that there is no right to an election where the proposed penalty is based on a violation of a final order issued under FPA section 31(a) requiring compliance with the terms and conditions of licenses, permits and exemptions. The violation of a nonfinal compliance order would not, in itself, eliminate the right to an election.

Read literally, FPA section 31(d)(2)(A) refers only to a *violation* of a final compliance order. By contrast, section 31(c) of the FPA makes violations, refusals and failures all actions which may subject a person to civil penalties. However, whether a person has a right to an election cannot reasonably depend on whether he violates a compliance order or refuses or fails to comply with a compliance order. A refusal or a failure to comply with a lawful order is a violation of the order, and a violation is a refusal or failure to comply. It therefore makes no sense to argue that Congress meant to remove the right to an election of procedures in one case but not in the other. Absent a reasonable distinction between violations, on one, hand, and refusals and failures, on the other, the Commission proposes to interpret "violation" under FPA section 31(d)(2)(A) to include failures and refusals.

The Commission proposes to treat as "final," compliance orders issued by staff pursuant to delegated authority and from which no appeal has been filed.[20] For example, such actions could include letters issued by FERC regional offices ordering a licensee, exemptee, or permittee to file specific information. Such a letter order would become a final FPA section 31(a) order where the licensee, exemptee or permittee did not file a timely appeal from staff action pursuant to the procedures set forth in §§ 12.4(c), 385.207 and 385.1902 of the Commission's regulations.

The Commission does not propose to interpret the notice and opportunity for public hearing requirement of section 31(a) as requiring a formal evidentiary hearing. Where Congress has intended such a hearing in FPA section 31 it has said so. (FPA section 31(d)(2)(A)). Morever, since Congress has clearly provided an opportunity for a formal evidentiary proceeding before a civil penalty may be assessed, the Commission does not propose to require an additional formal evidentiary hearing prior to issuing an FPA section 31(a) compliance order. In the Commission's judgment, Congress did not intend cumbersome procedures at this perliminary stage of the civil penalty assessment process. Notice of noncompliance, issued by the Commission or its delegate, coupled with an opportunity to respond in writing, with written submissions placed into the public record, satisfy the notice and hearing requirement of the preliminary stage of the penalty process.[21] Moreover, the right to appeal from staff action, and the right to seek rehearing, provide further assurances that procedural due process will not be denied.[22]

G. Revocation of Election (§ 385.1507(b))

FPA section 31(d)(3)(C) provides that a person may revoke an election to require FPA section 31(d)(3) District Court procedures only with the consent of the Commission. The Commission proposes in the new § 385.1507(b) to require consent only after the 30-day election period has ended. Where a person elects the procedures of section 31(d)(3) of the FPA and subsequently files to revoke that election within the 30-day election period, the Commission's consent will not be required.

H. Description of Section 31(d)(2) Procedures (§ 385.1508)

There are four phases to the assessment process under FPA section 31(d)(2).

In the first phase the Commission would provide an opportunity for a hearing under 5 U.S.C. 554, and would utilize, as appropriate, the hearing procedures set forth in 18 CFR part 385, Subpart E (1986). The Commission does not propose to institute a hearing before an Administrative Law Judge (ALJ) If there are no disputed issues of material fact. Even where an adjudicative proceeding is provided by statute, an evidentiary hearing before an ALJ is unnecessary where it will serve no purpose, such as when material facts are not in dispute.[23]

In the second phase, the Commission would issue an assessment order which would include the ALJ's initial decision, if any, and the Commission's basis for the assessment.

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[17] This is distinguished from the civil penalty provision of the Natural Gas Policy Act of 1978, which neither specifies how the Commission is to determine the amount of the penalty nor provides for an election. *See* section 504(b) of the NGPA 15 U.S.C. 3414(b)(6) (1982).

[18] *See* 16 CFR 1.93 (1987) (Federal Trade Commission implementation of civil penalty notice requirements of the Energy Policy and Conservation Act, 42 U.S.C. 6303(d)(1982).

[19] 1 CFR 305.79–3 (1987).

[20] *See* FERC Stats. & Regs., [Regulations Preambles 1982–1985] ¶ 30,568 at 30,941 (1984) ("Staff actions are final in the absence of any appeal.").

[21] *See Goss v. Lopez*, 419 U.S. 565, 581–84 (1975).

[22] *See Boddie v. Connecticut*, 401 U.S. 371, 378 (1970) ("The formality and procedural requisites for the hearing can vary, depending upon the importance of the interests involved and the nature of the subsequent proceedings."); *DOE v. Casey*, 796 F. 2d 1508, 1524 (D.C. Cir. 1986) ("A hearing demands that a person have the right to support his allegations by argument, however brief, and if necessary, by proof, however informal.").

[23] *See Cerro Wire & Cable Co. v. FERC*, 677 F.2d 124 (D.C. Cir. 1982); *Citizens for Allegan County v. FPC*, 414 F.2d 1125 (D.C. Cir. 1969).

In the third phase, the person against whom the penalty is assessed could appeal to an appropriate United States Court of Appeals within 60 calendar days after the date of the order of the Commission assessing such penalty.

In the fourth phase, the Court of Appeals may affirm, modify, set aside in whole or in part, or remand the matter to the Commission.

I. Description of Section 31(d)(3) Procedures (§ 385.1509)

There are two phases to the assessment process under FPA section 31(d)(3) procedures.

In the first phase, FPA section 31(d)(3)(A) provides that the Commission shall *promptly* assess the penalty, by order, after the notice of election is received by the Commission.

In the second phase, if the penalty has not been paid within 60 days of the date of issuance of the assessment order, the Commission shall institute an action in United States District Court for an order affirming the civil penalty.

J. Commission Authority to Modify a Civil Penalty (§ 385.1510)

Section 31(d)(4) of the FPA gives the Commission the authority to compromise, modify, or remit, with or without conditions, any civil penalty. Section 385.1510(a) of the proposed rules implements this authority. The Commission would allow increases in the proposed penalty amount only if it issued a new notice proposing an increase.

In determining whether to compromise, modify or remit a civil penalty, FPA section 31(d)(4) provides that the Commission may consider the nature and seriousness of the *violation* and the efforts of the *licensee* to remedy the violation in a timely manner. Although licensees, permittees and exemptees are referred to elsewhere in FPA section 31, only licensees are referred to in FPA section 31(d)(4). Absent a reasonable distinction between these three classes of persons in terms of the purpose of the statute, the Commission concludes that Congress used the term "licensee" in this context as a shorthand for holders of all forms of jurisdictional authority, whether a licensee, permittee, or exemptee, or one who should possess appropriate authority but does not.

Likewise, FPA section 31(d)(4) specifically refers only to violations. It does not refer to failures or refusals. The Commission nevertheless proposes in § 385.1510(b) of the proposed rules interpret to "violations" to include "failures" or "refusals" for the purpose of exercising its authority to compromise, modify or remit any civil penalty.[24]

Section 385.1510(c) of the proposed rules provides that the Commission's authority to compromise, modify or remit a civil penalty may be exercised at any time prior to a final decision by the United States Court of Appeals under FPA section 31(d)(2) procedures or a final decision by the United States District Court under FPA's section 31(d)(3) procedures.

K. Collection of Civil Penalties (§ 385.1511)

As provided in section 31(d)(5) of the FPA, § 385.1510(c) of the proposed rules proposes that the Commission institute an action to recover an unpaid civil penalty in an appropriate United States District Court. The validity and appropriateness of the final assessment order or judgment are not subject to review in such actions.

Where the administrative hearing procedures set forth in FPA's section 31(d)(2) are used to assess the penalty, the Commission will take any necessary collection action after a final and unappealable order has been issued.

Where the procedures set forth in section 31(d)(3) of the FPA are used to assess the penalty, the Commission proposes to include a collection action in its pleading at the same time it institutes its action in the United States District Court to affirm the civil penalty.

IV. Regulatory Flexibility Act Certification

The Regulatory Flexibility Act of 1980 (RFA) requires a description and analysis of final rules that will have a "significant economic impact on a substantial number of small entities."[25] An agency is not required to make an RFA analysis, however, if it certifies that rule will not have such an impact.

In accordance with the Regulatory FLexibility Act, the Commission certifies that this rule, if adopted, will not have a significant economic impact on a substantial number of small entities. Although many of the licensees, permittees, and exemptees that may be assessed civil penalties under this regulation are likely to be small entities, the Commission expects that the total number of small entities assessed civil penalties will not be substantial. The Commission notes that other agencies implementing civil penalty provisions have similarly found that no regulatory flexibility analysis is required when the number of small entities that will be assessed civil penalties is not substantial. *See* 46 FR 25321 (1981) (Civil Aeronautics Board Proposed Revision of 14 CFR Part 374) and 51 FR 30501 (1986) (Department of Labor Proposed Revision of 29 CFR Part 2560).

V. Paperwork Reduction Act Statement

This notice of proposed rulemaking does not propose any new information collection provisions. Thus, this notice of proposed rulemaking is not being submitted to the Office of Management and Budget (OMB) for its approval under the Paperwork Reduction Act[26] and OMB's regulations.[27]

VI. Public Comment Procedures

The Commission invites interested persons to submit written comments, data, views, and other information concerning the matters set out in this notice.

An original and 14 copies of such comments should be filed with the Commission by October 5, 1987. Comments should be submitted to the Office of the Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, and should refer to to Docket No. RM87-24-000. All written submissions will be placed in the Commission's public files and will be available for public inspection through the Commission's Division of Public Information, Room 1000, 825 North Capitol Street, NE., Washington, DC 20426 during regular business hours.

List of Subjects in 18 CFR Part 385

Administrative practice and procedure, Pipelines, Reporting and recordkeeping requirements.

In consideration of the foregoing, the Commission proposes to amend Part 385, Title 18, Code of Federal Regulations, as set forth below.

By direction of the Commission.

Kenneth F. Plumb,

Secretary.

PART 385—RULES OF PRACTICE AND PROCEDURE

1. The authority citation for Part 385 continues to read as follows:

Authority: Department of Energy Organization Act, 42 U.S.C. 7101-7352 (1982); E.O. 12009, 3 CFR 1978 Comp., p 142; Administrative Procedure Act, 5 U.S.C. 551-557 (1982); Independent Offices Appropriations Act, 31 U.S.C. 9701 (1982); Federal Power Act, 16 U.S.C. 791-825r (1982); Natural Gas Act, 15 U.S.C. 717-717w (1982); Natural Gas Policy Act, 15 U.S.C. 3301-3432

[24] *See Election of procedures and answer, supra.*

[25] U.S.C. 601-612 (1982).

[26] 5 U.S.C. 601(6) (1982).

[27] 44 U.S.C. 3501-3520 (1982).

(1982); Public Utilities Regulatory Policies Act of 1978, 16 U.S.C. 2601–2645 (1982); Interstate Commerce Act, 49 U.S.C. 1–27 (1976), unless otherwise noted.

2. Subpart O is added to Part 385 to read as follows:

Subpart O—Procedures for the Assessment of Civil Penalties Under Section 31 of the Federal Power Act

Sec.
385.1501 Scope (Rule 1501).
385.1502 Persons subject to civil penalties (Rule 1502).
385.1503 Actions subjecting persons to civil penalties (Rule 1503)..
385.1504 Maximum civil penalty (Rule 1504).
385.1505 Determination of proposed penalty amount (Rule 1505).
385.1506 Notice of proposed penalty (Rule 1506).
385.1507 Election of procedures and answer (Rule 1507).
385.1508 Commission proceeding to assess a civil penalty (Rule 1508).
385.1509 Procedures upon election (Rule 1509).
385.1510 Modifications of civil penalty (Rule 1510).
385.1511 Collection of civil penalties (Rule 1511).

Subpart O—Procedures for the Assessment of Civil Penalties Under Section 31 of the Federal Power Act

§ 385.1501 Scope (Rule 1501).

The rules in this subpart apply to and govern proceedings for the assessment of civil penalties pursuant to section 31 of the Federal Power Act, 16 U.S.C. 823b.

§ 385.1502 Persons subject to civil penalties (Rule 1502).

(a) Any licensee or permittee under the Federal Power Act, or exemptee from any requirement of Part I of the Federal Power Act, may be subject to civil penalties; and

(b) Any person who should have a license under, or exemption from, the Federal Power Act, but does not, may be subject to civil penalties.

§ 385.1503 Actions subjecting persons to civil penalties (Rule 1503).

(a) The actions that subject persons to civil penalties are violations of, or failures or refusals to comply with: any rule of regulation issued under Part I of the Federal Power Act; any term or condition of a license, permit or exemption; any Commission order or order issued pursuant to delegated authority issued under section 31(a) of the Federal Power Act requiring compliance with terms and conditions of a license, permit or exemption; or any requirement of Part I of the Federal Power Act.

(b) Only actions occurring on or after October 16, 1986, may subject a person to civil penalties.

§ 385.1504 Maximum civil penalty (Rule 1504).

(a) Except as provided in paragraph (b) of this section, the Commission may assess a civil penalty of up to $10,000 for each day that such violation, failure, or refusal continues.

(b) No civil penalty may be assessed where a license or exemption is ordered revoked.

§ 385.1505 Determination of proposed penalty amount (Rule 1505).

(a) In determining the amount of a proposed penalty, the Commission will consider the nature and seriousness of the violation, failure or refusal, and the efforts of the licensee, exemptee or permittee to remedy the violation, failure, or refusal in a timely manner.

(b) In making its determination under paragraph (a) of this section, the Commission will consider, among other things, the following factors:

(1) Whether the person had actual knowledge;

(2) Whether the person had constructive knowledge deemed to be possessed by a reasonable individual acting under similar circumstances;

(3) Whether the person has a history of previous violations;

(4) Whether the violations caused, in whole or in part, loss of life or injury to persons;

(5) Whether the violation caused, in whole or in part, damage to property or the environment;

(6) Whether the violation endangered persons, property or the environment;

(7) Timely remedial efforts;

(8) Untimely remedial efforts; and

(9) No remedial efforts.

(c) In considering the factors in paragraph (b) of this section:

(1) An affirmative finding under paragraphs (b)(1), (2), or (3) of this section will subject a person to a higher penalty than if the findings under those paragraphs are negative, other factors being equal;

(2) A person will be subject to a higher penalty if any of the situations described in paragraphs (b)(4) through (b)(6) of this section are present. The amount of the penalty will be increased most by presence of the situation described in paragraph (b)(4) of this section. The amount of the penalty will be increased least by the presence of the situation described in paragraph (b)(6) of this section, other factors being equal; and

(3) A violation followed by untimely remedial efforts will subject a person to a higher civil penalty than a violation followed by timely remedial efforts, other factors being equal.

§ 385.1506 Notice of proposed penalty (Rule 1506).

(a) Before issuing an order assessing a civil penalty under this subpart against any person, the Commission will provide to such person notice of the proposed penalty.

(b) The notice referred to in paragraph (a) of this section will:

(1) Include the amount of the proposed penalty;

(2) Include a statement of the material facts constituting the alleged violation, failure, or refusal; and

(3) Inform such person of the opportunity to elect in writing within 30 days of receipt of the notice to have the procedures of Rule 1509 (in lieu of those of Rule 1508) apply with respect to such assessment, except that no notice of election shall be provided for a violation of, or a failure or refusal to comply with, a final order issued under section 31(a) of the Federal Power Act requiring compliance with the terms and conditions of a license, permit or exemption.

§ 385.1507 Election of procedures and answer (Rule 1507).

(a) Within 30 days of receipt of the notice of proposed penalty, the respondent receiving such notice must, if he wishes to have the procedures of Rule 1509 apply, file a notification of such election with the Commission in accordance with Subpart T of this subchapter. The notification may include an answer setting forth factual or legal reasons why the proposed assessment order should not issue, should be reduced in amount, or should otherwise be modified. If a person fails to file an answer within the 30-day time limit, all material facts stated in the Commission's notice will be deemed admitted. General denials which are unsupported by specific factual allegations will provide a basis for summary disposition.

(b) Any election to have the procedures of Rule 1509 apply may not be revoked after the 30-day election period in paragraph (a) of this section, except with the consent of the Commission.

§ 385.1508 Commission proceeding to assess a civil penalty (Rule 1508).

(a) If the respondent fails to elect to have the procedures of Rule 1509 apply, the Commission will determine whether to commence a proceeding in accordance with the provisions of Subpart E of this chapter. The

Commission will not commence such an evidentiary proceeding if it would serve no purpose, such as if no material facts are in dispute, in which event the Commission may summarily act on the assessment.

(b) The Commission's Rules of Practice and Procedure, Part 385 of Subchapter X of this chapter, will apply, as appropriated, to a proceeding to assess a civil penalty.

§ 385.1509 Procedures upon election (Rule 1509).

(a) After receipt of the notification of election to apply the provisions of this section pursuant to Rule 1507, the Commission will promptly assess such penalty as it deems appropriate, in accordance with Rule 1505(b).

(b) If the civil penalty has not been paid within 60 calendar days after the assessment order has been issued under paragraph (a) of this section, the General Counsel, unless otherwise directed by the Commission, shall institute an action in the appropriate United States District Court for an order enforcing the assessment of the civil penalty.

§ 385.1510 Modification of civil penalty (Rule 1510).

(a) The Commission may compromise, modify, or remit, with or without conditions, any civil penalty (with leave of court if necessary).

(b) In exercising its authority under paragraph (a) of this section, the Commission may consider the nature and seriousness of the violation, failure, or refusal, and the efforts of the licensee, exemptee, permittee, or one who should possess appropriate authority but does not, to remedy the violation in a timely manner.

(c) The Commission's authority to compromise, modify or remit a civil penalty may be exercised at any time prior to a final decision by the United States Court of Appeals if Rule 1508 procedures are utilized, or a final decision by the United States District Court if Rule 1509 procedures are utilized.

§ 385.1511 Collection of civil penalties (Rule 1511).

If any person fails to pay an assessment of a civil penalty after it has become a final and unappealable order under Rule 1508, or after the appropriate District Court has entered final judgment in favor of the Commission under Rule 1509, the Commission shall seek to recover the amount of such penalty in any appropriate District Court of the United States. In such action, the validity and appropriateness of such final assessment order or judgment shall not be subject to review.

[FR Doc. 87-17902 Filed 8-5-87; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 256

Outer Continental Shelf Minerals and Rights-of-Way Management; General

AGENCY: Minerals Management Service, Interior.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: This notice reopens the comment period for the proposed rulemaking concerning amendments to the Outer Continental Shelf (OCS) leasing regulations to authorize the Minerals Management Service (MMS) to conduct supplemental sales. The reopening extends the time for submission of comments on this proposed rule and permits MMS to consider those which were not submitted during the original comment period.

DATE: Comments must be hand-delivered or postmarked not later than August 20, 1987.

ADDRESS: Written comments must be mailed or hand-delivered to the Department of the Interior; Minerals Management Service; 12203 Sunrise Valley Drive; Mail Stop 646, Room 6A110; Reston, Virginia 22091.

FOR FURTHER INFORMATION CONTACT: Mary B. McDonald, Telephone: (703) 648-7817, (FTS) 959-7817.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 28, 1987 (52 FR 9672), MMS issued a Notice of Proposed Rulemaking to authorize supplemental sales in addition to regular lease sales scheduled in the 5-year leasing plan. This action will enable the Department of the Interior to respond to new geological and geophysical data by making available for lease a limited number of additional blocks which new data may indicate to be critical for the development of an area. The proposed regulation excluded the Central and Western Gulf of Mexico OCS Planning Areas where sales are conducted annually, precluding the need for supplemental sales.

The comment period was orginally open through April 27, 1987. Several comments were received after the closing date. The elimination of late comments from consideration might require MMS to disregard important and unique observations and suggestions. Given the restricted scope of the rule and its importance to the areas affected by it, MMS wishes to have the benefit of as many comments as possible and, therefore, is reopening the comment period. All comments previously submitted and received to date will be considered and should not be resubmitted. Any additional comments should be submitted so as to ensure that they are postmarked or received by the date specified above.

Date: July 27, 1987.

Bruce G. Weetman,

Acting Associate Director for Offshore Minerals Management.

[FR Doc. 87-17818 Filed 8-5-87; 8:45 am]

BILLING CODE 4310-MR-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 22 and 24

[FRL-3198-8]

Issuance of and Administrative Hearings on RCRA Section 3008(h) Corrective Action Orders for Hazardous Waste Management Facilities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Rule.

SUMMARY: The rule proposed here establishes procedures governing the conduct of administrative hearings requested, pursuant to section 3008(b) of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act (RCRA), by recipients of administrative enforcement orders issued under the interim status corrective action authority contained in Section 3008(h) of RCRA.

DATE: Comments on this proposed rule will be accepted if received on or before September 8, 1987.

ADDRESS: Interested members of the public must submit an original and two copies of their comments to: Steve Botts, mail code LE-134S, Office of Enforcement and Compliance Monitoring, Waste Enforcement Division, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Steve Botts at (202) 382-5787.

SUPPLEMENTARY INFORMATION:

I. Authority

The rule we propose today has been issued under authority of sections 2002 and 3008 of RCRA, as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), 42 U.S.C. sections 6912 and 6928.

II. Background

On November 8, 1984, the President signed HSWA into law. Among the changes in RCRA effected by this legislation was the addition of new authority under section 3008(h) of RCRA for EPA to issue administrative enforcement orders to owner/operators of interim status treatment, storage, and disposal facilities, requiring corrective action or other measures necessary to respond to releases of hazardous waste from such facilities. Such orders may also revoke or suspend authority to operate under section 3005(e) of RCRA and/or assess penalties of up to $25,000 a day for noncompliance with a previous corrective action order.

Section 3008(b) of RCRA provides that an administrative enforcement order issued pursuant to section 3008 of RCRA becomes final, unless, within 30 days of service of such order, the person or persons named therein request a public hearing. The rules currently appearing at 40 CFR Part 22 establish procedures to be followed in administrative hearings requested by recipients of orders issued pursuant to section 3008(a) of RCRA, which require compliance or assess penalties for violations of Subtitle C of RCRA.

III. Purpose of Today's Proposed Rule

The rule proposed here is designed to supplement those appearing at 40 CFR Part 22. It would establish new procedures for the conduct of administrative hearings requested by recipients of section 3008(h) orders, which require corrective action or other response measures necessary to address releases of hazardous waste or constituents from interim status facilities. It would also amend 40 CFR Part 22 as necessary to insure that Part 22 procedures would be employed for hearings on section 3008(h) orders which (1) include counts under section 3008(a) of RCRA, (2) assess penalties for non-compliance with a previous section 3008(h) order, or (3) revoke or suspend authority to operate under section 3005(e) of RCRA.

Prior to the enactment of HSWA, the language in section 3008(b) of RCRA offering the recipient of an order the opportunity to request a hearing applied only to section 3008(a) orders. In enacting HSWA, Congress amended section 3008(b) so as to make it applicable to any order "issued under this section." The clear intent of Congress in adding this language, as borne out by the legislative history of this amendment, was to extend the right to request a hearing to recipients of orders issued under the new section 3008(h) corrective action authority. However, there is no indication in the language of the statute or the legislative history as to what kind of "public hearing" on corrective action orders is required or contemplated by section 3008(b).

In the absence of Congressional guidance on the question of what kind of public hearing is required, we believe that the Agency has the discretion, circumscribed only by constitutional due process considerations, to decide what kind of hearings are appropriate. The range of options considered by the Agency in developing the procedures we propose today for use in hearings on RCRA section 3008(h) corrective action orders extends from formal evidentiary hearings of the kind now required by 40 CFR Part 22 for hearings on SWDA section 3008(a) orders to informal conferences of the type employed by the Agency pursuant to guidance (see, "Guidance Memorandum on Use and Issuance of Administrative Orders under section 106(a) of CERCLA," September 8, 1983) to afford due process to recipients of orders issued pursuant to section 106(a) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA).

Under the Supreme Court decision in *Mathews* v. *Eldridge*, 424 U.S. 319 (1976), in order to satisfy the requirements of procedural due process, an Agency decision as to whether evidentiary hearings or less formal hearings are required for a given class of proceedings should be based on consideration of three factors: (1) The private interest that will be affected by the official action, (2) the risk of an erroneous deprivation of such interest through the procedures used, and probable value, if any, of additional procedural safeguards, and (3) the Government's interest, including the fiscal and administrative burdens that the additional or substitute procedures would entail. Accordingly, the procedures proposed today by the Agency attempt to balance EPA's interest in expediting clean-up and minimizing the resource outlay required to prepare for and participate in hearings against (1) the cost of corrective action incurred by the respondent and (2) the risk that the Agency might mistakenly require unwarranted expenditures by respondent through reliance on hearing procedures containing inadequate mechanisms for the resolution of those factual disputes which might reasonably be expected to arise.

In the preamble to the proposed rule adopting 40 CFR Part 22 procedures for public hearings on RCRA section 3008(a) orders (43 FR 34738), the Agency noted that the language of RCRA section 3008(b) did not specifically compel use of formal adjudicatory hearing procedures but nevertheless opted for full adjudicatory hearings because of the nature of the section 3008(a) proceedings. The Agency observed that in such proceedings EPA would be accusing respondents of violations of "established legal standards" and that the decisionmaker would be called upon to adjudicate specific factual issues relating to the violations in question. In other words, the Agency concluded that, without full adjudicatory hearings, there was a significant risk that EPA might be vulnerable to arguments that the Agency lacked the means to properly resolve disputed factual matters upon which respondent's property interests were dependent.

It should be noted that the Part 22 procedures were designed for use not just in hearings on RCRA section 3008(a) compliance orders but also hearings on orders which assessed penalties and revoked or suspended operating authority. The rule proposed today requires that Part 22 procedures be employed for hearings on corrective action orders which assess penalties or revoke or suspend interim status operating authority.

However, we believe that the nature of the typical hearing on a RCRA section 3008(h) order will differ significantly from the type of hearing held on a RCRA section 3008(a) compliance order. Hearings on corrective action orders are less apt to present the kind of specific factual issues, which case law identifies as being uniquely susceptible to resolution in a formal evidentiary hearing. Corrective action orders generally will not seek injunctive relief for specific regulatory violations but will rather seek to compel respondent to undertake studies of identified releases of hazardous waste or implement measures designed to remediate such releases. The only jurisdictional prerequisite to obtaining relief under RCRA section 3008(h) is that the Agency establish that a release of hazardous waste or constituents from an interim status facility has occurred. It will generally be a simple and straightforward matter to make the

threshold demonstration that a release has occurred. Where the issue is in dispute the Presiding Officer can typically resolve the dispute through analysis of the written affidavits and arguments of the parties' technical experts. The risk of an erroneous deprivation of respondent's rights in deciding this issue is accordingly very low.

The issues posed in proceedings on disputed corrective action orders will typically relate to legal, policy, or technical matters, which are most appropriately addressed in informal hearings. The primary issue in a hearing on a corrective action order is not likely to be whether a violation occurred (as is generally true in the case of a RCRA section 3008(a) order) but how a respondent should study and remediate a release. This kind of issue is apt to be wide-ranging and complex and is more susceptible to resolution through analysis of a full documentary record than through examination and cross-examination of witnesses. The goal should then be to compile a full and fair documentary record upon which EPA can base its decision. These procedures allow the respondent and the Agency every opportunity to develop just such a record.

Since (1) proceedings on corrective action orders will generally not involve adjudication of factual issues for which formal evidentiary hearings are best suited, and (2) the Agency has a strong interest in conserving the resources which would be required for formal adjudication of disputed factual matters and in expediting the owner/operator's response to releases of hazardous waste or constituents from his facility, the proposed procedures for hearings on RCRA section 3008(h) orders have been designed to eliminate formalities and time-consuming features contained in the Part 22 procedures which are unnecessary for section 3008(h) orders.

The hearing procedures here proposed employ a two-track approach. Hearings on corrective action orders requiring respondent to undertake investigative studies, either alone or in conjunction with certain limited interim corrective measures, would be subject to the relatively informal procedures set forth in Subpart B of Part 24. Hearings on corrective action orders directing respondent to implement more permanent corrective measures, either alone or in conjunction with investigative studies, would be governed by the somewhat more formal procedures contained in Subpart C of Part 24. The Agency's rationale for employing this two-track system is essentially an extension of its rationale for adopting something less formal than full adjudicatory hearings on corrective action orders. Hearings on orders requiring investigative studies (with or without interim corrective measures) are expected to present fewer issues of material fact and, accordingly, fewer opportunities for the Agency to commit a prejudicial error in reaching its decision. It is also expected that the extent of respondent's property interests placed at risk will be more limited where the order seeks to compel studies or interim measures as opposed to permanent corrective measures.

It should be noted that, although the Agency has opted in this proposed rule not to require full evidentiary hearings on corrective action orders for the reason, among others, that proceedings on such orders typically will not present issues of material fact for resolution, the proposed procedures do allow respondents (subject to the Presiding Officer's approval) the opportunity to pose either oral or written questions to EPA on those factual matters which are in dispute. EPA believes that such procedures will provide additional protection against factual error, while ensuring that hearings do not require the unnecessary expenditure of Agency or respondent's resources or interfere with the timely selection and implementation of appropriate corrective measures.

IV. Regulatory Analysis

A. Regulatory Impact Analysis

Inasmuch as this proposed rule is procedural in nature, will not have any important economic impacts, and will not significantly affect the operations of Regional or other program offices, it is not deemed to be "major" within the meaning of Executive Order No. 12291 and, accordingly, does not trigger the requirement in said executive order that a regulatory impact analysis be prepared.

B. Regulatory Flexibility Act

Since this proposed rule merely establishes hearing procedures and has no significant economic impact on a substantial number of small entities, it does not trigger the requirement in the Regulatory Flexibility Act, 5 U.S.C. section 601 *et seq.*, that a regulatory flexibility analysis be prepared.

C. Paperwork Reduction Act

This regulation contains no information collection requirements and thus will not increase the paperwork burden on the regulated community in contravention of the purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq.

List of Subjects

40 CFR Part 22

Administrative practice and procedure, Hazardous materials, Penalties, Waste treatment disposal.

40 CFR Part 24

Administrative practice and procedure, Corrective action, Hazardous materials, Penalties, Revocation of operating authority.

Lee M. Thomas,

Administrator.

July 24, 1987.

For the reasons set out in the Preamble, Title 40 of the Code of Federal Regulations is proposed to be amended as follows:

PART 22—CONSOLIDATED RULES OF PRACTICE GOVERNING THE ADMINISTRATIVE ASSESSMENT OF CIVIL PENALTIES AND THE REVOCATION OR SUSPENSION OF PERMITS

1. The authority citation for Part 22 is revised to read as follows:

Authority: 15 U.S.C. sec. 2615; 42 U.S.C. secs. 7545 and 7601; 7 U.S.C. secs. 136(1) and (w); 33 U.S.C. secs. 1415 and 1418; 42 U.S.C. secs. 6912, 6928.

2. Section 22.01 is amended by revising paragraph (a)(4) to read as follows:

§ 22.01 Scope of these rules.

(a) * * *

(4) The issuance of a compliance order, the issuance of a corrective action order, the suspension or revocation of authority to operate pursuant to section 3005(e) of the Solid Waste Disposal Act, or the assessment of any civil penalty under section 3008 of the Solid Waste Disposal Act, as amended, except as provided in 40 CFR Parts 24 and 124.

* * * * *

3. New Part 24 is added as follows:

PART 24—RULES GOVERNING ISSUANCE OF AND ADMINISTRATIVE HEARINGS ON INTERIM STATUS CORRECTIVE ACTION ORDERS

Subpart A—General

Sec.
24.01 Scope of these rules.
24.02 Issuance of initial orders; definition of final orders and orders on consent.
24.03 Maintenance of docket and official record.
24.04 Filing and service of orders, decisions, and documents.

Sec.
24.05 Response to the initial order; request for hearing.
24.06 Designation of Presiding Officer.
24.07 Informal settlement conference.
24.08 Selection of appropriate hearing procedures.

Subpart B—Hearings on Orders Requiring Investigations or Studies

24.09 Qualifications of Presiding Officer; ex parte discussion of the proceeding.
24.10 Scheduling the hearing; pre-hearing submissions by respondent.
24.11 Hearing; oral presentations and written submissions by the parties.
24.12 Summary of hearing; Presiding Officer's recommendation.

Subpart C—Hearings on Orders Requiring Corrective Measures

24.13 Qualifications of Presiding Officer; ex parte discussion of the proceeding.
24.14 Scheduling the hearing; pre-hearing submissions by the parties.
24.15 Hearing; oral presentations and written submissions by the parties.
24.16 Transcript or recording of hearing.
24.17 Presiding Officer's recommendation.

Subpart D—Post-Hearing Procedures

24.18 Final decision.
24.19 Final order.
24.20 Final agency action.

Authority: 42 U.S.C. sections 6912, 6928.

Subpart A—General

§ 24.01 Scope of these rules.

(a) These rules establish procedures governing issuance of administrative orders for corrective action pursuant to section 3008(h) of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act (the Act), and conduct of administrative hearings on such orders, except as specified in § 24.01(b) below.

(b) The hearing procedures appearing at 40 CFR Part 22 govern administrative hearings on any order issued pursuant to section 3008(h) of the Act which:

(1) Is contained within an administrative order that includes claims under section 3008(a) of the Act; or

(2) Includes a suspension or revocation of authorization to operate under section 3005(e) of the Act; or

(3) Seeks penalties under section 3008(h)(2) of the Act for non-compliance with a section 3008(h) order.

(c) Questions arising at any stage of the proceeding which are not addressed in these rules shall be resolved at the discretion of the Regional Administrator or Presiding Officer, as appropriate.

§ 24.02 Issuance of initial orders; definition of final orders and orders on consent.

(a) An administrative action under section 3008(n) of the Act shall be commenced by issuance of an administrative order. When the order is issued unilaterally, the order shall be referred to as an initial administrative order and may be referenced as a proceeding under section 3008(h). When the order has become effective, either after issuance of a final order following a final decision by the Regional Administrator, or after thirty days from issuance if no hearing is requested, the order shall be referred to as a final administrative order. Where the order is agreed to by the parties, the order shall be denominated as a final administrative order on consent.

(b) The initial administrative order shall be executed by an authorized official of EPA (petitioner), other than the Regional Administrator or the Assistant Administrator for the Office of Solid Waste and Emergency Response. For orders issued by EPA Headquarters, rather than by a Regional office, all references in these procedures to the Regional Administrator shall be understood to be to the Assistant Administrator for the Office of Solid Waste and Emergency Response or his delegatee.

§ 24.03 Maintenance of docket and official record.

A Clerk shall be designated by the Regional Administrator to receive all initial orders, final orders, responses, memoranda, and documents regarding the order and to maintain the official record and docket.

§ 24.04 Filing and service of orders, decisions, and documents.

(a) *Filing of orders, decisions, and documents.* The original and one copy of the initial administrative order, the final decision and the final administrative order, and one copy of the administrative record and an index thereto must be filed with the Clerk designated for section 3008(h) orders. In addition, all memoranda and documents submitted in the proceeding shall be filed with the Clerk.

(b) *Service of orders, decisions, and rulings.* The Clerk (or in the case of the initial administrative order, any other designated EPA employee) shall arrange for the effectuation of service of the initial administrative order, the final decision, and final administrative order. Service of a copy of the initial administrative order together with a copy of these procedures, the final decision, or a final administrative order, shall be made personally or by certified mail, return receipt requested, or, if personal service cannot be effectuated or certified mail is returned refused or unsigned, by regular mail, on the respondent or his representative. The Clerk shall serve other documents from the Presiding Officer by regular mail.

(c) *Service of documents filed by the parties.* Service of all documents, filed by the parties, shall be made by the parties or their representatives on other parties or their representatives and may be made by regular mail, with the original filed with the Clerk.

(d) *Effective date of service.* Service of the initial administrative order and final administrative order is complete upon receipt by respondent (or the respondent's agent, attorney, representative or other person employed by respondent and receiving such service), personally or by certified mail, or upon mailing by regular mail if personal service or certified mail cannot be accomplished, in accordance with § 24.04(b). Service of all other pleadings and documents is complete upon mailing, except as provided in §§ 24.10(b) and 24.14(e).

§ 24.05 Response to the initial order; request for hearing.

(a) The initial administrative order becomes a final administrative order thirty (30) days after service of the order, unless the respondent files with the Clerk within thirty (30) days after service of the order, a response to the initial order and requests a hearing.

(b) The response to the initial order and request for a hearing must be in writing and mailed to, or personally served on, the Clerk of the Region which issued the order.

(c) The response to the initial order shall specify each factual, or legal determination, or relief provision in the initial order the respondent disputes.

§ 24.06 Designation of Presiding Officer.

Upon receipt of a request for a hearing, the Regional Administrator shall designate a Presiding Officer to conduct the hearing and preside over the proceedings.

§ 24.07 Informal settlement conference.

The respondent may request an informal settlement conference at any time by contacting the appropriate EPA employee, as specified in the initial administrative order. A request for an informal conference will not affect the respondent's obligation to timely request a hearing. Whether or not the respondent requests a hearing, the parties may confer informally concerning any aspect of the order. The respondent and respondent's representatives shall generally be allowed the opportunity at an informal conference to discuss with the

appropriate Agency technical and legal personnel all aspects of the order, in particular the basis for the determination that a release has occurred and the appropriateness of the ordered corrective action.

§ 24.08 Selection of appropriate hearing procedures.

If the initial order directs the respondent (a) to undertake only a RCRA Facility Investigation and/or Corrective Measures Study, which may include monitoring, surveys, testing, information gathering, analyses, and/or studies (including studies designed to develop recommendations for appropriate corrective measures), or (b) to undertake such investigations and/or studies and interim corrective measures, and if such interim corrective measures are neither costly nor technically complex and are necessary to protect human health and the environment prior to development of a permanent remedy, the hearing procedures set forth in Subpart B of this part shall be employed for any requested hearing. If the respondent seeks a hearing on an order directing that corrective measures or such corrective measures together with investigations/studies be undertaken, the hearing procedures set forth in Subpart C of this part shall be employed. The procedures contained in Subparts A and D of this part shall be followed regardless of whether the initial order directs respondent to undertake an investigation or implement corrective measures.

Subpart B—Hearings on Orders Requiring Investigations or Studies

§ 24.09 Qualifications of Presiding Officer; ex parte discussion of the proceeding.

The Presiding Officer shall be any employee of the Agency designated by the Regional Administrator other than a person who drafted or participated in drafting the order in question. If, after issuance of the initial order and prior to issuance of the final order, the Regional Administrator, Presiding Officer, or any person who will advise these officials in the decision on the case receives from or on behalf of any party in an ex parte communication information which is relevant to the decision on the case and to which other parties have not had an opportunity to respond, a summary of such information shall be served on all other parties, who shall have an opportunity to reply to same within ten (10) days of service of the summary.

§ 24.10 Scheduling the hearing; pre-hearing submissions by respondent.

(a) *Date and time for hearing.* The Presiding Officer shall establish the date and time for the requested public hearing. Subject to § 24.10(c), the hearing shall be scheduled and held within thirty (30) days of the Agency's receipt of the request for a public hearing.

(b) *Pre-hearing submissions by respondent.* At any time up to five (5) business days before the hearing respondent may, but is not required to, submit for inclusion in the administrative record information and argument supporting respondent's positions on the facts, law, and relief, as each relates to the order in question. All factual representations made by respondent must be by affidavit. A copy of any information or argument submitted by respondent shall be served such that the Clerk and petitioner receive same at least five (5) business days before hearing.

(c) *Postponement of hearing.* The Presiding Officer may grant an extension of time for the conduct of the hearing, upon written request of either party, for good cause shown, and after consideration of any prejudice to other parties. The Presiding Officer may not extend the date by which the request for hearing is due under § 24.05(a).

(d) *Location of hearing.* The hearing shall be held in the city in which the relevant EPA Regional Office is located, unless the Presiding Officer determines that there is good cause to hold it in another location.

§ 24.11 Hearing; oral presentations and written submissions by the parties.

The Presiding Officer shall establish the agenda for the hearing and conduct the hearing in a fair and impartial way, taking action as needed to avoid unnecessary delay, exclude redundant material, and maintain order during the proceedings. Representatives of EPA shall introduce the administrative record and be prepared to summarize the basis for the order. The respondent shall have a reasonable opportunity to address relevant issues and present its views through legal counsel or technical advisors. The Presiding Officer may also allow technical and legal discussions and interchanges between the parties, including responses to questions to the extent deemed appropriate. It is not the Agency's intent to provide EPA or respondent an opportunity to engage in direct or cross-examination of witnesses. Where respondent can demonstrate that, through no fault of its own, certain documents supportive of its position could not have been submitted before hearing in accordance with the requirements of § 24.10(b), it may submit such documents at the hearing. Otherwise no new documentary support may be submitted at hearing. Unless otherwise directed by the Presiding Officer, factual representations made by respondent shall be by affidavit. The Presiding Officer may upon request grant petitioner leave to respond to submissions made by respondent pursuant to this section or § 24.10(b).

§ 24.12 Summary of hearing; Presiding Officer's recommendation.

(a) As soon as practicable after the conclusion of the hearing, a written summary of the proceeding shall be prepared. This summary shall, at a minimum, identify:

(1) The dates of and known attendees at the hearing; and,

(2) the bases upon which the respondent contested the terms of the order.

The summary must be signed by the Presiding Officer.

(b) The Presiding Officer will evaluate the entire administrative record and, on the basis of that review and the representations of EPA and respondent at the hearing, shall prepare and file a statement recommending to the Regional Administrator that the initial order be modified, withdrawn, or issued without modification. The statement must address all significant arguments raised by respondent and provide support, through citation to material contained in the record or adduced at the hearing, for any decision to modify a term of the order, withdraw the order, or issue the order without change.

(c) The statement shall be based on the administrative record, including the hearing and supplemental submissions. If the Presiding Officer finds that there is not adequate support in the record for the initial order, the Presiding Officer may recommend that the order be modified and issued on terms that are supported by the record, or withdrawn.

Subpart C—Hearings on Orders Requiring Corrective Measures

§ 24.13 Qualifications of Presiding Officer; ex parte discussion of the proceeding.

(a) *Qualifications of Presiding Officer.* The Presiding Officer shall be either the Regional Judicial Officer, or another attorney employed by the Agency who did not draft or in any way assist in drafting the section 3008(h) initial order that is the subject of the proceeding.

(b) *Ex parte discussion of the proceeding.* If, after issuance of the initial order and prior to issuance of the

final order, the Regional Administrator, Presiding Officer, or any person who will advise these officials in the decision on the case receives from or on behalf of any party in an ex parte communication information which is relevant to the decision on the case and to which other parties have not had an opportunity to respond, a summary of such information shall be served on all other parties, who shall have an opportunity to reply to same within ten (10) days of service of the summary.

§ 24.14 Scheduling the hearing; pre-hearing submissions by the parties.

(a) The Presiding Officer shall establish an expeditious schedule for—

(1) The submission by respondent of a memorandum, with appropriate affidavits and exhibits, stating and supporting respondent's position on the facts, law and relief, specifying the bases upon and manner in which such determinations or relief provisions, if erroneous, require modification or withdrawal or the order;

(2) Submission of a response by EPA; and

(3) A public hearing.

Subject to § 24.14(b), a hearing shall be scheduled within 45 days of the order setting the schedule.

(b) *Postponement of the hearing.* The Presiding Officer, as appropriate, may grant an extension of time for the filing of any document, other than a request for a hearing under § 24.05(a), or may grant an extension of time for the conduct of the hearing, upon written request of either party, for good cause shown and after consideration of any prejudice to other parties.

(c) *Respondent's pre-hearing submission.* In accordance with the schedule set by the Presiding Officer, the respondent shall file a memorandum stating and supporting respondent's position on the facts, law and relief. The memorandum must identify each factual allegation and all issues regarding appropriateness of the terms of the relief in the initial order that respondent contests and for which respondent requests a hearing. The memorandum must clearly state respondent's position with respect to each such issue. Respondent must also include any proposals for modification of the order. Respondent must submit affidavits and exhibits which support any of its factual contentions on relief and defenses. The memorandum shall also present any arguments on the legal conclusions contained in the order.

(d) *Written questions to EPA.* The respondent may file a request with the Presiding Officer for permission to submit written questions to the EPA Regional Office issuing the order concerning issues of material fact in the order.

(1) Requests shall be accompanied by the proposed questions. In most instances, no more than twenty-five (25) questions, including subquestions and subparts, may be posed. The request and questions must be submitted to the Presiding Officer at least twenty-one (21) days before the hearing.

(2) The Presiding Officer may direct EPA to respond to such questions as he designates, if he determines that such questions are required for full disclosure and adequate resolution of the facts. No questions shall be allowed regarding matters of policy or privileged internal communications. The Presiding Officer shall grant, deny, or modify such requests expeditiously. If a request is granted, the Presiding Officer may revise questions and may limit the number and scope of questions. Questions may be deleted or revised in the discretion of the Presiding Officer for reasons, which may include the fact that he finds the questions to be irrelevant, redundant, unneccessary, or an undue burden on the Agency. The Presiding Officer shall transmit the questions as submitted or as modified to EPA. EPA shall respond to the questions within fourteen (14) calendar days of service of the questions by the Presiding Officer, unless an extension is granted.

(e) *Submission of additional information.* The Presiding Officer shall have the discretion to order either party to submit additional information in whatever form he deems appropriate. The Presiding Officer may issue subpoenas for the attendance and testimony of persons and the production of relevant papers, books, and documents. Since these hearing procedures provide elsewhere that the parties are not to engage in direct or cross-examination of witnesses and must make any factual representations in writing by affidavit, the subpoena power is to serve only as an adjunct to the Presiding Officer's authority to ask questions and otherwise take steps to clarify factual matters which are in dispute. Upon request of the respondent, the Presiding Officer may, in his discretion, allow submittal by the respondent of additional information in support of its claim, if it is received by the Clerk and petitioner at least five (5) business days before the hearing.

(f) *Location of hearing.* The hearing shall be held in the city in which the relevant EPA Regional Office is located, unless the Presiding Officer determines that there is good cause to hold it in another location.

§ 24.15 Hearing; oral presentations and written submissions by the parties.

(a) The Presiding Officer shall establish the agenda for the hearing and conduct the hearing in a fair and impartial manner, take action to avoid unnecessary delay in the disposition of the proceedings, and maintain order. The Presiding Officer shall permit oral statements on behalf of the respondent and EPA. The Presiding Officer may address questions to the respondent or the EPA representative during the hearing. Although oral statements will be permitted at the hearing, unless otherwise directed by the Presiding Officer, all factual matters to be presented by respondent must be in writing by affidavit. Apart from questions by the Presiding Officer, no direct examination or cross-examination shall be allowed.

(b) Upon commencement of the hearing, a representative of EPA shall introduce the order and the record supporting issuance of the order, and summarize the basis for the order. The respondent may respond to the administrative record and offer any facts, statements, explanations or documents which bear on any issue for which the hearing has been requested. Any such presentation by respondent may include new documents only to the extent that respondent can demonstrate that, through no fault of its own, such documents could not have been submitted before hearing in accordance with the requirements of § 24.14 (c) and (e). The Agency may then present matters solely in rebuttal to matters previously presented by the respondent. The Presiding Officer may allow the respondent to respond to any such rebuttal submitted. The Presiding Officer may exclude repetitive or irrelevant matter. The Presiding Officer may upon request grant petitioner leave to respond to submissions made by respondent pursuant to this paragraph or § 24.14(e).

§ 24.16 Transcript or recording of hearing.

(a) The hearing shall be either transcribed stenographically or tape recorded. Upon written request, such transcript or tape recording shall be made available for inspection or copying.

(b) The transcript or recording of the hearing and all written submittals filed with the Clerk by the parties subsequent to initial issuance of the order including post-hearing submissions will become part of the administrative record for the proceeding, for consideration by the Presiding Officer and Regional Administrator.

§ 24.17 Presiding Officer's recommendation.

The Presiding Officer will, as soon as practicable after the conclusion of the hearing, evaluate the entire administrative record and, on the basis of the administrative record, prepare and file a recommended decision with the Regional Administrator. The recommended decision must address all material issues of fact or law properly raised by respondent, and must recommend that the order be modified, withdrawn or issued without modification. The recommended decision must provide an explanation, with citation to material contained in the record, for any decision to modify a term of the order, to issue the order without change or to withdraw the order. The recommended decision shall be based on the administrative record. If the Presiding Officer finds that there is not adequate support in the record for any contested required action, the Presiding Officer may recommend that the order be modified and issued on terms that are supported by the record, or withdrawn.

Subpart D—Post-Hearing Procedures

§ 24.18 Final decision.

As soon as practicable after receipt of either the summary and statement or the recommended decision, the Regional Administrator will either sign, or modify such statement or recommended decision, and issue it as a final decision. The Regional Administrator's decision shall be based on the administrative record.

§ 24.19 Final order.

If the Regional Administrator does not adopt portions of the initial order, or finds that modification of the order is necessary, the signatory official on the initial administrative order shall modify the order in accordance with the terms of the final decision and file and serve a copy of the final administrative order. If the Regional Administrator finds the initial order appropriate as originally issued, the final decision shall declare the initial administrative order to be a final order, effective upon service of the final decision. If the Regional Administrator declares that the initial order must be withdrawn, the signatory official on the initial administrative order will file and serve a withdrawal of the initial administrative order. This may be done without prejudice.

§ 24.20 Final agency action.

The final decision and the final administrative order are final agency actions that are effective on filing and service. These actions are not appealable to the Administrator.

[FR Doc. 87-17739 Filed 8-5-87; 8:45 am]

BILLING CODE 6560-50-M

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40 CFR Part 763

[OPTS-62048D; FRL-3242-3]

Asbestos-Containing Materials in Schools; Public Hearing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Public Hearing.

SUMMARY: EPA has scheduled a public hearing to hear comments on the proposed rule to require all Local Education Agencies to identify asbestos-containing materials in their school buildings, develop asbestos management plans, and take appropriate actions to control release of asbestos fibers.

DATES: The hearing will be held on Tuesday, August 25, and Wednesday, August 26, 1987, from 9 a.m. to 5 p.m.

ADDRESS: The hearing will be held at: Holiday Inn, Columbia South Room, 550 C St., SW., Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Room E-543, 401 M St., SW., Washington, DC 20460, Telephone: (202-554-1404).

SUPPLEMENTARY INFORMATION: EPA has proposed a rule to require all Local Education Agencies to identify asbestos-containing materials in their school buildings, develop asbestos management plans, and take appropriate actions to control release of asbestos fibers. The proposed rule was published in the **Federal Register** of April 30, 1987 (52 FR 15820). The proposal allowed 60 days for public comment, with comments due by June 29, 1987. Seven state attorneys general, two city boards of education, and other persons have requested a public hearing. Requests to testify at the hearing should be submitted by August 20, 1987, to Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St., SW., Washington, DC 20460.

Dated: July 30, 1987.

John W. Melone,

Director, Chemical Control Division.

[FR Doc. 87-17740 Filed 7-31-87; 3:54 am]

BILLING CODE 6560-50-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 65

[Docket No. FEMA-6915]

Proposed Flood Elevation Determinations; Arizona et al.

AGENCY: Federal Emergency Management Agency.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are solicited on the proposed base (100-year) flood elevations and proposed modified base flood elevations listed below for selected locations in the nation. These base (100-year) flood elevations are the basis for the floodplain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program.

DATES: The period for comment will be ninety (90) days following the second publication of the proposed rule in a newspaper of local circulation in each community.

ADDRESSES: See table below.

FOR FURTHER INFORMATION CONTACT: Mr. John L Matticks, Chief, Risk Studies Division, Federal Insurance Administration, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-2768.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency gives notice of the proposed determinations of base (100-year) flood elevations and modified base flood elevations for selected locations in the nation, in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448)), 42 U.S.C. 4001-4128, and 44 CFR 67.4(a).

These elevations, together with the floodplain management measures required by § 60.3 of the program regulations, are the minimum that are required. They should not be construed to mean the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements on its own, or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations will also be used to calculate the appropriate flood insurance

premimum rates for new buildings and their contents and for the second layer of insurance on existing buildings and their contents.

Pursuant to the provisions of 5 U.S.C. 605(b), the Administrator, to whom authority has been delegated by the Director, Federal Emergency Management Agency, hereby certifies that the proposed flood elevation determinations, if promulgated, will not have a significant economic impact on a substantial number of small entities. A flood elevation determination under section 1363 forms the basis for new local ordinances, which, if adopted by a local community, will govern future construction within the floodplain area. The elevation determinations, however, impose no restriction unless and until the local community voluntarily adopts floodplain ordinances in accord with these elevations. Even if ordinances are adopted in compliance with Federal standards, the elevations prescribe how high to build in the floodplain and do not proscribe development. Thus, this action only forms the basis for future local actions. It imposes no new requirement; of itself it has no economic impact.

List of Subjects in 44 CFR Part 67

Flood insurance, Floodplains.

PART 67—[AMENDED]

1. The authority citation for Part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 et seq., Reorganization Plan No. 3 of 1978, E.O. 12127.

2. The proposed modified base flood elevations for selected locations are:

PROPOSED MODIFIED BASE FLOOD ELEVATIONS

State	City/town/county	Source of flooding	Location	# Depth in feet above ground. *Elevation in feet (NGVD)	
				Existing	Modified
Arizona	Town of Eagar, Apache County	Water Canyon	At the confluence with Little Colorado River	None	*7,012
			At Highway 260	None	*7,035
			At the confluence of Dry Canyon	None	*7,045
			At 4th Street	None	*7,107
			At River Road	None	*7,112
			At 6th Street	None	*7,142
			At School Bus Road	None	*7,194
			At Burk Street	None	*7,204
			At Big Ditch	None	*7,215
			At 10th Street	None	*7,219
			Approximately 3,000 feet upstream of 10th Street	None	*7,294
			Approximately 4,600 feet upstream of 10th Street (limit of detailed study).	None	*7,332
		Dry Canyon	At 4th Street	None	*7,082
			At Farm Road	None	*7,104
			At Amity Ditch	None	*7,113
			At School Bus Road	None	*7,139
			At River Road	None	*7,173
			At Spanish Trail Road	None	*7,218
			Approximately 3,100 feet upstream of Spanish Trail Road (limit of detailed study).	None	*7,280
		Robertson Hollow	At Big Ditch (limit of detailed study)	None	*7,210
			Approximately 1,000 feet upstream of Big Ditch	None	*7,231
			Approximately 2,000 feet upstream of Big Ditch	None	*7,246
			At Flat Top Road	None	*7,278
			Approximately 220 feet upstream of Flat Top Road (limit of detailed study).	None	*7,281
Maps are available for inspection at the Town Hall, Town of Eagar, Eagar, Arizona.					
Send comments to The Honorable George R. Pena, Mayor, Town of Eagar, Box 78, Eagar, Arizona 85925.					
	Graham County (unincorporated areas).	Frye Creek	At the Town of Thatcher western corporate limits	*3,087	*3,086
			Approximately 1,000 feet upstream of Town of Thatcher western corporate limits.	*3,105	*3,104
			Approximately 2,000 feet upstream of Town of Thatcher western corporate limits.	*3,126	*3,128
			Approximately 3,000 feet upstream of Town of Thatcher western corporate limits.	*3,151	*3,148
			Approximately 4,000 feet upstream of Town of Thatcher western corporate limits.	None	*3,177
			Approximately 4,600 feet upstream of Town of Thatcher western corporate limits (limit of detailed study).	None	*3,191
		Frye Creek Tributary	At the Town of Thatcher southern corporate limits	*3,089	*3,090
			Approximately 1,000 feet upstream of Town of Thatcher southern corporate limits.	*3,102	*3,103
			Approximately 2,000 feet upstream of Town of Thatcher southern corporate limits.	*3,115	*3,115
			Approximately 3,000 feet upstream of Town of Thatcher southern corporate limits.	*3,131	*3,132
			Approximately 3,600 feet upstream of Town of Thatcher southern corporate limits (limit of detailed study).	None	*3,141
		School District Wash	Approximately 4,200 feet upstream of Frye Creek Dam (downstream limit of detailed study).	None	*3,002
			Approximately 6,400 feet upstream of Frye Creek Dam	None	*3,027
			At Golf Course Road	None	*3,048
			Approximately 2,000 feet upstream of Golf Course Road.	None	*3,072
			Approximately 4,000 feet upstream of Golf Course Road.	None	*3,096
			Approximately 5,900 feet upstream of Golf Course Road (limit of detailed study).	None	*3,123
		Spring Canyon	At the Town of Thatcher western corporate limits	None	*3,005
			Confluence of Frye Creek	None	*3,013
			Confluence of Spring Canyon Tributary	None	*3,028

PROPOSED MODIFIED BASE FLOOD ELEVATIONS—Continued

State	City/town/county	Source of flooding	Location	# Depth in feet above ground. *Elevation in feet (NGVD)	
				Existing	Modified
			Approximately 2,000 feet upstream of confluence of Spring Canyon.	None	*3,049
			Approximately 4,000 feet upstream of confluence of Spring Canyon.	None	*3,074
			Approximately 6,400 feet upstream of confluence of Spring Canyon.	None	*3,110
			Approximately 8,800 feet upstream of confluence of Spring Canyon Tributary.	None	*3,146
		Spring Canyon Tributary	Confluence with Spring Canyon	None	*3,027
			Approximately 2,000 feet upstream of confluence with Spring Canyon.	None	*3,040
			Approximately 4,000 feet upstream of confluence with Spring Canyon.	None	*3,060
			Approximately 6,000 feet upstream of confluence with Spring Canyon.	None	*3,085
			Approximately 8,000 feet upstream of confluence with Spring Canyon.	None	*3,118
			Approximately 10,000 feet upstream of confluence with Spring Canyon.	None	*3,161
			Approximately 11,100 feet upstream of confluence with Spring Canyon (limit of detailed study).	None	*3,192

Maps are available for inspection at the County Courthouse, 800 Main Street, Safford, Arizona.

Send comments to The Honorable Ben L. Smith, Chairman, Graham County Board of Supervisors, 800 Main Street, Safford, Arizona 85546.

California	City of Chula Vista San Diego County.	San Diego Bay	At Chula Vista	*5	*6
		Telegraph Canyon Creek	Approximately 3,250 feet southwest of the intersection of Telegraph Canyon Road and Otay Lakes Road.	None	*377
			Approximately 1,150 feet northeast of the intersection of Rutgers Avenue and Telegraph Canyon Road.	None	*456
			Approximately 1,400 feet southwest of the intersection of Otay Lakes Road and Janal Drive.	None	*499
			Approximately 425 feet northeast of the intersection of Otay Lakes Road and Rancho Janal Drive.	None	*530

Maps are available for inspection at the City of Chula Vista Engineering Department, 276 Fourth Avenue, Chula Vista, California.

Send comments to The Honorable Gregory R. Cox, Mayor, City of Chula Vista, 276 Fourth Avenue, Chula Vista, California 92010.

	City of Foster City, San Mateo County.	San Francisco Bay	At Foster City	*6	*7

Maps are available for inspection at the City Hall, 610 Foster City Boulevard, Foster City, California.

Send comments to The Honorable John Oliver, Mayor, City of Foster City,10 Foster City Boulevard, Foster City, California 94404.

	City of Milpitas, Santa Clara County.	Upper Penitencia Creek Overflow	From a point approximately 5,100 feet north of Redwood Avenue to a point approximately 100 feet north of Redwood Avenue between Nimitz Freeway to the west and lower Penitencia Creek to the east.	*10	*12
			At Chestnut Avenue	#1	*14
			At Serra Way	#1	*17
			Approximately 100 feet south of Sylvia Avenue	*17	*20
			From a point approximately 200 feet south of Sylvia Avenue to a point approximately 150 feet north of Capital Avenue between Nimitz Freeway to the west and lower Penitencia Creek to the east.	#1	#2
			From a point approximately 150 feet north of Capital Avenue to Lower Penitencia Creek.	*26	#1
			From lower Penitencia Creek to the southern corporate limits between the Southern Pacific Railroad and the Union Pacific Railroad.	*33	#1
		San Francisco Bay	At shoreline	*7	*9
		Scott Creek Overflow	Along Union Pacific Railroad on eastern side, between northern corporate limits and Dixon Landing Road.	None	17

Maps are available for inspection at 455 East Calaveras Boulevard, Milpitas, California.

Send comments to The Honorable Robert Livengood, Mayor, City of Milpitas, 455 East Calaveras Boulevard, Milpitas, California 95035.

	City of San Jacinto, Riverside County.	Bautista Wash	At Seventh Street (downstream corporate limits)	None	*1,522
			At Palm Avenue	None	*1,525
			At Grand Avenue	None	*1,526
			At State Street	None	*1,532
			At Atchison Topeka and Santa Fe Railroad	None	*1,536
			At Santa Fe Avenue	*1,546	*1,546

Maps are available for inspection at the City Hall, 201 East Main Street, San Jacinto, California.

Send comments to The Honorable Wayne Stuart, Mayor, City of San Jacinto, P.O. Box 488, San Jacinto, California 92383

Colorado	City of Wheat Ridge, Jefferson County.	Lena Gulch	Downstream of Kipling Street	*5,361	*5,361
			Upstream of Kipling Street	*5,367	(**)
			Downstream of Parfet Street	*5,403	(**)
			Upstream of Parfet Street	*5,408	5,406
			Approximately 1,500 feet downstream from Simms Street.	*5,416	*5,416

PROPOSED MODIFIED BASE FLOOD ELEVATIONS—Continued

State	City/town/county	Source of flooding	Location	# Depth in feet above ground. *Elevation in feet (NGVD)	
				Existing	Modified
100-Year Flood Contained in Channel					
Maps are available for inspection at the City Hall, 7500 West 29th Avenue, Wheat Ridge, California.					
Send comments to The Honorable Frank Stites, Mayor, City of Wheat Ridge, P.O. Box 638, Wheat Ridge, California 0034.					
Connecticut	South Windsor, Town, Hartford County.	Farm Brook	Downstream side of Oakland Road Bridge	*126	*127
Maps available for inspection at the Town Clerk's Office, Town Hall, South Windsor, Connecticut.					
Send comments to The Honorable Richard Sartor, Manager of the Town of South Windsor, Hartford County, 1209 Sullivan Avenue, South Windsor, Connecticut 06074.					
Georgia	City of Darien, McIntosh County	Atlantic Ocean/Altamaha River/ Darien River.	About 500 feet west of the intersection of Broad Street and Screven Street.	*11	*12
			About 0.56 miles south of the intersection of Wayne Street and Second Street.	*11	*14
Maps available for inspection at the City Hall, Darien, Georgia.					
Send comments to The Honorable George Scotty Rogers, Mayor, City of Darien, City Hall, P.O. Box 452, Darien, Georgia 31305.					
Idaho	Benewah County, unincorporated areas.	St. Joe River	Approximately 8.8 miles downstream of U.S. Highway 95A Bridge.	None	*2,136
			Approximately 4.9 miles downstream of U.S. Highway 95A Bridge.	None	*2,136
			Approximately 3.4 miles downstream of U.S. Highway 95A Bridge.	None	*2,137
			Approximately 2.7 miles downstream of U.S. Highway 95A Bridge.	None	*2,138
			Approximately 0.4 mile downstream of U.S. Highway 95A Bridge.	*2,139	*2,139
Maps are available for inspection at the Building Inspector's Office, Benewah County Courthouse, St. Maries, Idaho 83861.					
Send comments to Mr. Jack A. Buell, Chairman, Benewah County Board of Commissioners, Benewah County Courthouse, St. Maries, Idaho 83861.					
Illinois	City of Cairo, Alexander County	Upper Mississippi River	About 0.85 mile downstream of U.S. Route 60	*329	*331
			About 1,700 feet upstream of Interstate 57	*334	*335
		Ohio River	About 1 mile downstream of U.S. Route 60	*329	*331
			About 1,200 feet upstream of Illinois Central Gulf Railroad.	*332	*331
		Ponding from Interior Drainage	At Goose Pond Pumping Station	*312	*307
Maps available for inspection at the City Hall, 1501 Washington Avenue, Cairo, Illinois.					
Send comments to The Honorable Allen E. Moss, Mayor, City of Cairo, City Hall, 1501 Washington Avenue, P.O. Box 393, Cairo, Illinois 62914.					
	Unincorporated Areas of Monroe County.	Carr Creek	About 0.26 mile downstream of Bluff Road	None	*420
			About 550 feet upstream of Bluff Road	None	*423
			About 0.92 mile upstream of Bluff Road	None	*431
		Palmer Creek	About 1.45 miles downstream of Bluff Road	None	*403
			Just downstream of Bluff Road	None	*421
			Just upstream of Bluff Road	None	*424
			Just downstream of Illinois Central Gulf Railroad	None	*430
			Just upstream of Illinois Central Gulf Railroad	None	*435
			About 0.26 mile upstream of Rueck Road	None	*460
		Palmer Creek Tributary	At confluence with Palmer Creek	None	*435
			About 0.2 mile downstream of Rueck Road	None	*446
			Just downstream of Abandoned Railroad	None	*461
			Just upstream of Abandoned Railroad	None	*474
Maps available for inspection at the County Courthouse, Planning Department, 100 South Main Street, Waterloo, Illinois.					
Send comments to The Honorable Carl Upchurch, Chairman, Monroe County Board, County Courthouse, 100 South Main Street, Waterloo, Illinois 62298.					
Indiana	City of Indianapolis, Marion County.	State Ditch	At mouth	None	*672
			About 400 feet upstream of Bradbury Avenue	None	*702
		Seerley Creek	At confluence with State Ditch	None	*693
			About 0.66 mile upstream of Lynhurst Drive	None	*732
		Mars Ditch-Drexel Run	At confluence with State Ditch	None	*697
			Just upstream of Lynhurst Drive	None	*724
			About 1,500 feet upstream of Lynhurst Drive	None	*732
		Howland Ditch	Just upstream of Allison Road	*760	*760
			About 0.84 mile upstream of 82nd Street	None	*806
		Neeld Ditch	At confluence with Eagle Creek	*692	*692
			Just downstream of Mickley Avenue	None	*752
		East Fork White Lick Creek	About 0.67 mile downstream of U.S. Route 40	None	*736
			Just downstream of Raceway Road	None	*805
		Pleasant Run Creek	About 0.37 mile downstream of State Route 37	None	*666
			Just downstream of County Line Road	None	*678
Maps available for inspection at 2501 City County Building, Indianapolis, Indiana.					
Send comments to The Honorable William Hudnutt III, Mayor, City of Indianapolis, 2501 City County Building, Indianapolis, Indiana 46402.					
Louisiana	West Monroe, City, Ouachita Parish.	Black Bayou	Downstream side of Glenwood Drive	*74	*73
			Approximately 3,000 feet upstream of Glenwood Drive.	*83	*80
		Gravel Pit Branch	Approximately 100 feet upstream of confluence with Black Bayou.	*81	*80
			Approximately 150 feet upstream of Interstate Route 20.	*87	*86

PROPOSED MODIFIED BASE FLOOD ELEVATIONS—Continued

State	City/town/county	Source of flooding	Location	# Depth in feet above ground. *Elevation in feet (NGVD)	
				Existing	Modified
		Highland School Branch	At confluence with Black Bayou	*77	*76
			Approximately 3,050 feet upstream of McMillan Road	*97	*96
		Black Bayou Tributary	Approximately 50 feet upstream of confluence with Black Bayou.	*81	*80
			Approximately 50 feet downstream of corporate limits	*93	*92

Maps available for inspection at the City Engineer's Office, P.O. Box 2105, Monroe, Louisiana.

Send comments to The Honorable Dave Norris, Mayor of the City of West Monroe, Ouachita Parish, 2305 North Seventh Street, West Monroe, Louisiana 71291.

Maryland	Frederick, City, Frederick County	Monocacy River Tributary No. 8	Approximately 340 feet downstream of Fairview Avenue.	*312	*313
			Downstream side of Fairview Avenue	*317	*321
			Upstream side of Fairview Avenue	None	*322
			Approximately 650 feet upstream of Fairview Avenue	None	*333

Maps available for inspection at the City Hall, 101 N. Court Street, Frederick, Maryland.

Send comments to The Honorable Ronald N. Young, Mayor of the City of Frederick, Frederick County, 101 N. Court Street, Frederick, Maryland 21701.

Massachusetts	Ludlow, Town, Hampden County	Chicopee River	380 feet upstream of Cottage Avenue	*226	*229
			Approximately 500 feet upstream of Cottage Avenue	*228	*229

Maps available for inspection at 488 Chapin Street, Ludlow, Massachusetts.

Send comments to The Honorable John B. Randall, Chairman of the Board of Selectmen of the Town of Ludlow, Hampden County, 488 Chapin Street, Ludlow, Massachusetts 01056.

	Wilbraham, Town, Hampden County.	Chicopee River	Approximately 380 feet upstream of Cottage Avenue	*226	*229
			Approximately 500 feet upstream of Cottage Avenue	*228	*229

Maps available for inspection at the Town Office Building, 240 Springfield Street, Wilbraham, Massachusetts.

Send comments to The Honorable Melvin Kleckner, Executive Secretary of theTown of Wilbraham, Hampden County, Town Office Building, 240 Springfield Street, Wilbraham, Massachusetts 01095.

New Jersey	Bergenfield, Borough, Bergen County.	Hirschfeld	Brook Downstream side of North Prospect Avenue	*44	*45
			Upstream side of Coopers Pond Dam	*49	*50
			Approximately 80 feet upstream of West Church Street	*55	*54
			Approximately 40 feet upstream of West Main Street	*58	*55
			Approximately 70 feet upstream of Roosevelt Avenue	*64	*58
			Approximately 300 feet upstream of downstream CONRAIL bridge.	*68	*69
		Hirschfeld Brook Tributary	Approximately 140 feet downstream of downstream side of culvert.	*56	*57
			Approximately 30 feet downstream of Dick Street	*73	*70
			Upstream side of New Jersey Avenue	*86	*88

Maps available for inspection at the Borough Clerk's Office, 198 North Washington Avenue, Bergenfield, New Jersey.

Send comments to The Honorable Louis C. Goetting, IV, Administrator of the Borough of Bergenfield, Bergen County, 198 North Washington Avenue, Bergenfield, New Jersey 07621.

	Dumont, Borough, Bergen County.	Hirschfeld Brook	Approximately 600 feet downstream of Lafayette Avenue.	*22	*23
			Approximately 230 feet downstream of West Madison Avenue.	*34	*35
		Hirschfeld Brook Tributary	Downstream corporate limits	None	*88
			Upstream side of Rucereto Avenue	None	*115

Maps available for inspection at 50 Washington Avenue, Dumont, New Jersey.

Send comments to The Honorable William Dochicchio, Mayor of the Borough of Dumont, Bergen County, 50 Washington Avenue, Dumont, New Jersey 07628.

	Garwood, Borough, Union County.	Garwood Brook	Upstream side of Oak Street	*79	*78
			At upstream corporate limits	*96	*94

Maps available for inspection at the Construction Department, Municipal Building, 403 South Avenue, Garwood, New Jersey.

Send comments to The Honorable Georgiana Gurrieri, Mayor of the Borough of Garwood, Union County, Municipal Building, 403 South Avenue, Garwood, New Jersey 07027.

	Livingston, Township, Essex County.	Canoe Brook	Approximately 520 feet upstream of confluence with Bear Brook.	*225	*224
			Upstream side of West Oakwood Avenue	*277	*276
			Upstream side of Mount Pleasant Avenue	*318	*317
			Approximately 0.5 mile upstream of Laurel Avenue	*440	*435

*Mean Sea Level.

Maps available for inspection at the Township Engineer's Office, 357 South Livingston Avenue, Livingston, New Jersey.

Send comments to The Honorable Charles Tahaney, Manager of the Township of Livingston, Essex County, 357 South Livingston Avenue, Livingston, New Jersey 07039.

Oklahoma	Catoosa, City, Rogers County	Bird Creek	Most downstream corporate limit	None	*572
			Approximately 630 feet upstream of Burlington Northern Railroad.	None	*575
		Spunky Creek	Confluence with Verdigris River	*575	*571
			Approximately 600 feet downstream of U.S. Highway 66.	*575	*572

Maps available for inspection at the City Hall, P.O. Box 190, Catoosa, Oklahoma.

Send comments to The Honorable Terry Whiteley, Mayor of the City of Catoosa, Rogers County, P.O. Box 190, Catoosa, Oklahoma 74015.

	Oklahoma City, City, Oklahoma County.	Tributary 1 of Canadian River	Approximately 0.6 mile downstream of S.W. 122nd Street.	*1,190	*1,189
			At upstream side of S.W. 119th	1,204	*1,202
			Approximately 550 feet downstream of S.W. 112th	*1,213	*1,212

PROPOSED MODIFIED BASE FLOOD ELEVATIONS—Continued

State	City/town/county	Source of flooding	Location	# Depth in feet above ground. *Elevation in feet (NGVD)	
				Existing	Modified
		Tributary 4 of Tributary 1 of Canadian River.	At confluence with Tributary 1 of N. Canadian River	*1,198	*1,194
			Approximately 2,300 feet upstream of S.W. 119th Street bridge.	*1,211	*1,212
			Approximately 0.65 mile upstream of S.W. 119th Street bridge.	*1,219	*1,220
Maps available for inspection at the City Engineer's Office, 200 N. Walker, Oklahoma City, Oklahoma.					
Send comments to The Honorable Andrew Coats, Mayor of the City of Oklahoma City, Oklahoma County, 200 N. Walker, Suite 102, Oklahoma City, Oklahoma 73102.					
Oregon	Unincorporated Areas, Lane County.	Coast Fork, Willamette River	Approximately 5,830 feet downstream of State Highway 99.	*616	*616
			Approximately 3,175 feet downstream of State Highway 99.	*620	*621
			Approximately 825 feet downstream of State Highway 99.	*631	*629
			Downstream of Woodson Place	*635	*635
			Downstream of Main Street	*642	*641
			Approximately 170 feet downstream of Harrison Avenue.	*647	*647
			Downstream of State Highway 99	*653	*651
			Downstream of the Southern Pacific Railroad	*653	*652
			Approximately 2,550 feet upstream of the Southern Pacific Railroad.	*663	*663
			Downstream of London Road	*680	*680
		Long Tom River	Approximately 2,400 feet upstream of State Highway 126.	*385	*385
			Approximately 3,600 feet upstream of State Highway 126.	*386	*385
			Approximately 9,000 feet upstream of State Highway 126.	*387	*387
Maps are available for inspection at the Department of Public Works, 125 East 8th Street, Eugene, Oregon.					
Send comments to The Honorable Chuck Ivey, Chairman, Lane County Board of Commissioners, Eugene, Oregon 97401.					
Pennsylvania	Caln, Township, Chester County	Valley Run	Approximately 1,340 feet upstream of Bondsville Road	*285	*284
			Downstream side of Barley Sheaf Road	*318	*319
Maps available for inspection at the Municipal Building, 253 Municipal Drive, Thorndale, Pennsylvania.					
Send comments to Mr. Charles O'Donnell, President of the Township of Caln Board of Supervisors, P.O. Box 147, Thorndale, Pennsylvania 19372.					
Texas	Cedar Hill, (City), Dallas and Ellis Counties.	Bee Branch	At downstream side of Duncanville Road	None	*667
			At downstream side of dam	None	*706
			Approximately 500 feet upstream of Calvert Drive	None	*740
Maps available for inspection at the City Manager's Office, Cedar Hill, Texas.					
Send comments to The Honorable Kenneth Lander, Mayor of the City of Cedar Hill, Dallas and Ellis Counties, P.O. Box 96, Cedar Hill, Texas 75104.					
	Fort Bend County, unincorporated areas.	Dry Creek	At Berdett Road	None	*74
			Approximately 650 feet upstream of FM 2977	None	*83
			At County boundary	*91	*92
Maps available for inspection at the Fort Bend County Judge's Office, County Courthouse, Richmond, Texas.					
Send comments to The Honorable Jodie Stavinoha, Fort Bend County Judge, P.O. Box 368, Richmond, Texas 77469.					
	Friendswood, City, Galveston County.	Mary's Creek	At confluence with Clear Creek	*25	*23
			Approximately 300 feet downstream of Dunbar Estates Drive.	*30	*23
			At upstream corporate limits	*32	*26
		Cowart Creek	At confluence with Clear Creek	*22	*19
			Approximately 320 feet upstream of Sunset Drive	*24	*20
			At upstream corporate limits	*31	*30
		Chigger Creek	At confluence with Clear Creek	*16	*15
			Approximately 4,000 feet downstream of Windwood Drive.	*28	*25
			At upstream corporate limits	*38	*37
		Clear Creek (A100-00-00)	At downstream corporate limits	*15	*14
			Upstream side of Whispering Pines	*23	*20
			At confluence of Mary's Creek	*25	*23
			At upstream corporate limits	*33	*32
		Turkey Creek (A119-00-00)	At confluence with Clear Creek	None	*26
			At upstream corporate limits	None	*26
		Tributary 0.16 to Turkey Creek (A119-02-00).	At confluence with Turkey Creek	None	*26
			At upstream corporate limits	None	*29
		Halls Road Ditch (A120-00-00)	At confluence with Clear Creek	None	*27
			At upstream corporate limits	None	*30
		Cedar Gully (A118-00-00)	At confluence with Clear Creek	None	*22
			At upstream corporate limits	None	*22
Maps available for inspection at the Public Works Building, 1306 Deepwood, Friendswood, Texas.					
Send comments to The Honorable Ralph L. Lowe, Mayor of the City of Friendswood, Galveston County, 109 Willowick, Friendswood, Texas 77546.					
	Montgomery County, unincorporated areas.	Bens Branch	At County boundary	*74	*72

PROPOSED MODIFIED BASE FLOOD ELEVATIONS—Continued

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)	
				Existing	Modified
			Approximately 3,000 feet downstream of Sorters Road	*89	*90
		Bens Branch Tributary No. 1	At confluence with Bens Branch	*78	*77
		Bens Branch Tributary No. 2	At confluence with Bens Branch	*84	*81
			Approximately 700 feet upstream of Martin Drive	*84	*83
Maps available for inspection at J.D. Blanton's office, 326½ North Main, Conroe, Texas.					
Send comments to The Honorable Al Stahl, Montgomery County Judge, County Courthouse, Conroe, Texas 77301.					
	Ovilla (City), Dallas and Ellis Counties (FEMA Docket No. 6901).	Red Oak Creek	At downstream corporate limits	*593	
			Upstream side of State Route 664	*604	
			Upstream side of Water Street	*619	
			At upstream corporate limits	*651	
		Shiloh Branch	At confluence with Red Oak Creek	*605	
			Upstream side of Stock Tank Dam	*634	
			At upstream corporate limits	*637	
		Little Creek	Approximately 520 feet downstream of downstream corporate limits.	*590	
			At upstream corporate limits	*596	
Maps available for inspection at the City Hall, Cocker Hill and Main, Ovilla, Texas.					
Virginia	Waynesboro, City, Independent City.	Pratt's Run	At confluence with South River	None	*1,307
			Approximately 1.1 miles upstream of confluence with South River.	None	*1,340
			At upstream corporate limits	None	*1,385
		Jones Hollow	At confluence with South River	*1,283	*1,284
			Approximately 0.9 mile upstream of confluence with South River.	*1,315	*1,320
			Approximately 1,200 feet upstream of Kirby Avenue	*1,327	*1,336
			Approximately 0.5 mile upstream of Kirby Avenue	None	*1356
		South River	Approximately 1.1 miles downstream of corporate limits.	None	*1,255
			Approximately 200 feet downstream of Second Street	*1,273	*1,272
			At upstream corporate limits	*1,314	*1,332
Maps available for inspection at 250 South Wayne Avenue, Waynesboro, Virginia.					
Send comments to The Honorable Thomas L. Gorsuch, Mayor of the City of Waynesboro, P.O. Box 1028, Waynesboro, Virginia 22980.					
Wisconsin	Unincorporated Areas of Fond du Lac County.	De Neveu Creek	About 420 feet downstream of County Highway V	*784	*783
			About 370 feet upstream of U.S. Highway 45	*818	*820
			About 0.7 mile upstream of U.S. Highway 45	*828	*829
Maps available for inspection at the Planning Department, 160 South Macy Street, Fond du Lac, Wisconsin.					
Send comments to The Honorable Anita Anderegg, County Executive, Fond du Lac County, 160 South Macy Street, Fond du Lac, Wisconsin 54935.					
	Unincorporated Areas of Sheboygan County.	Fisherman's Creek	At confluence with Black River	*584	*584
			About 640 feet upstream of U.S. Highway 141	None	*635
Maps available for inspection at the Planning Department, 615 North Sixth Street, Sheboygan, Wisconsin.					
Send comments to The Honorable Harold Lindemann, Chairman, Sheboygan County Board, 615 North Sixth Street, Sheboygan, Wisconsin 53081.					
Wyoming	City of Gillette, Campbell County	Stonepile Creek	Approximately 100 feet downstream of Interstate Highway 90.	*4,504	*4,504
			Approximately 50 feet upstream of Interstate Highway 90.	*4,506	(**)
			Approximately 100 feet upstream of Stanley Avenue	*4,516	(**)
			Approximately 150 feet downstream of Gurley Avenue	*4,520	(**)
			Just upstream of N. Brooks Avenue	*4,534	(**)
			Approximately 50 feet upstream of N. Gillette Avenue	*4,540	(**)
			Just upstream of Burma Avenue	*4,558	(**)
			Approximately 220 feet downstream of Highway 14/16	*4,573	(**)
			Approximately 300 feet upstream of Highway 14/16	*4,578	*4,578

** 100-year flood contained in the channel.

Maps are available for inspection at the City Hall, 201 East 5th Street, Gillette, Wyoming 82716.

Send comments to The Honorable Herbert A. Carter, City of Gillette, P.O. Box 3003, Gillette, Wyoming 82716.

Issued: July 29, 1987.

Harold T. Duryee,

Administrator, Federal Insurance Administration.

[FR Doc. 87-17714 Filed 8-5-87; 8:45 am]

BILLING CODE 6718-03-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 87-259, RM-5693]

Radio Broadcasting Services; Steamboat Springs, CO

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition by KBCR, Inc., proposing the substitution of FM Channel 245C2 for Channel 244A at Steamboat Springs, Colorado, and modification of the license of Station KSBT(FM) accordingly, to provide that community with its first wide-coverage area FM service.

DATES: Comments must be filed on or before September 21, 1987, and reply comments on or before October 6, 1987.

ADDRESS: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, as follows: John G. Gayer, KBCR, Inc., P.O. Box 881720, Steamboat Springs, CO 80488.

FOR FURTHER INFORMATION CONTACT: Nancy V. Joyner, Mass Media Bureau, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rule Making, MM Docket No. 87-259, adopted July 9, 1987, and released July 30, 1987. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, (202) 857-3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1231 for rules governing permissible *ex parte* contact.

For information regarding proper filing procedures for comments, See 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Mark N. Lipp,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 87-17816 Filed 8-5-87; 8:45 am]

BILLING CODE 6712-01-M

Notices

Federal Register
Vol. 52, No. 151
Thursday, August 6, 1987

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.

ADMINISTRATIVE COMMITTEE OF THE FEDERAL REGISTER

Sale of Magnetic Tapes by the Superintendent of Documents, Government Printing Office

AGENCY: Administrative Committee of the Federal Register (ACFR).

ACTION: Notice.

SUMMARY: The sale of magnetic tapes produced by the Government Printing Office to photocompose the daily **Federal Register** and the annual Code of Federal Regulations, ACFR publications, has been transferred to the Superintendent of Documents at GPO. New prices for the tapes have been established.

FOR FURTHER INFORMATION CONTACT: Sarah S. Wilson, Government Printing Office, telephone 202-275-3328.

SUPPLEMENTARY INFORMATION: GPO has transferred to the Superintendent of Documents the sale of all publication data tapes previously available through its Customer Service Staff. The ACFR, which in 1979 had authorized sale of the **Federal Register** and Code of Federal Regulations tapes by the Customer Service Staff, has now approved sale of the tapes by the Superintendent of Documents at the new prices.

Each daily issue of the **Federal Register** on magnetic tape is available three working days after the issue is published. The price is $175 for a daily tape, $18,750 for a six month subscription and $37,500 for an annual subscription.

Each magnetic tape for the Code of Federal Regulations will be available after the paper edition is published. The price is $125 for a tape and $21,750 for an annual subscription. The number of tapes necessary to print one volume or title of the *Code* will vary with the length of the volume or title. Payment must be made in advance.

The magnetic tapes include the printing instructions or codes used to print the **Federal Register** as well as text. The tapes do not include all the material appearing in the **Federal Register** or CFR. Illustrations, graphic designs, and certain documents that were photographed in order to be published are not on the tapes and certain last-minute corrections may not be on the tapes.

John E. Byrne,
Secretary, Administrative Committee of the Federal Register.

[FR Doc. 87-17831 Filed 8-5-87; 8:45 am]

BILLING CODE 1505-02-M

COMMISSION ON CIVIL RIGHTS

Alaska Advisory Committee; Public 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 Alaska Advisory Committee to the Commission will convene at 1:00 p.m. and adjourn at 4:00 p.m., on August 26, 1987, at the Federal Building, 701 C Street (Room C-105), Anchorage, Alaska 99513. The purpose of the meeting is to develop program plans and to receive a briefing on the status of the U.S. Commission on Civil Rights and its regional operations.

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson, Daniel Alex or Philip Montez, Director of the Western Regional Division, (213) 894-3437 (TDD 213/894-0508). Hearing impaired persons who will attend the meeting and require the services of a sign language interpreter, should contact the Regional Office at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, July 31, 1987.

Susan J. Prado,
Acting Staff Director.

[FR Doc. 87-17832 Filed 8-5-87; 8:45 am]

BILLING CODE 6335-01-M

New Jersey Advisory Committee; Public 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 New Jersey Advisory Committee to the Commission will convene at 7:00 p.m. and adjourn at 9:30 p.m. on August 25, 1987, at the Quality Inn Conference Center, U.S. Route 1, South, North Brunswick, New Jersey. The purpose of the meeting is to present an administrative orientation for new members, report on the 1987 Regional Conference, discuss a synopsis of the forum on racial harassment in Essex County, and to plan activities for FY 87-88.

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson Stephen Balch or John I. Binkley, Director of the Eastern Regional Division at (202) 523-5264, (TDD 202/376-8117). Hearing impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Division at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, July 28, 1987.

Susan J. Prado,
Acting Staff Director.

[FR Doc. 87-17833 Filed 8-5-87; 8:45 am]

BILLING CODE 6335-01-M

DEPARTMENT OF COMMERCE

International Trade Administration

Computer Systems Technical Advisory Committee; Partially Closed Meeting

A meeting of the Computer Systems Technical Advisory Committee will be held August 26, 1987, 9:30 a.m., in the Herbert C. Hoover Building, Room 6802, 14th Street & Constitution Avenue, NW., Washington, DC. The Committee advises the Office of Technology & Policy Analysis with respect to technical questions which affect the level of export controls applicable to computer systems or technology.

Open Session

1. Opening Remarks by the Chairman.
2. Presentation of papers or comments by the public.
3. Presentation on multi data stream processing.
4. Reports from Hardware and Software Subcommittees.

Executive Session

5. Discussion of matters properly classified under Executive Order 12356, dealing with the U.S. and COCOM control program and strategic criteria thereto.

The General Session of the meeting will be open to the public and a limited number of seats will be available. To the extent time permits, members of the public may present oral statements to the Committee. Written statements may be submitted at any time before or after the meeting.

The Assistant Secretary for Administration, with the concurrencies of the delegate of the General Counsel, formally determined on January 10, 1986, pursuant to section 10(d) of the Federal Advisory Committee Act, as amended by section 5(c) of the Government in the Sunshine Act, Pub. L. 94–409, that the matters to be discussed in the Executive Session should be exempt from the provisions of the Federal Advisory Committee Act relating to open meetings and public participation therein, because the Executive Session will be concerned with matters listed in 5 U.S.C. 552b(c)(1) and are properly classified under Executive Order 12356.

A copy of the Notice of Determination to close meetings or portions thereof is available for public inspection and copying in the Central Reference and Records Inspection Facility, Room 6628, U.S. Department of Commerce, Telephone: 202/377–4127. For further information or copies of the minutes, call Betty Ferrell at 202/377–2583.

Date: August 3, 1987.

Betty A. Ferrell,

Acting Director, Technical Support Staff, Office of Technology & Policy Analysis.

[FR Doc. 87–17893 Filed 8–5–87; 8:45 am]

BILLING CODE 3510-DT-M

Hardware Subcommittee of the Computer Systems Technical Advisory Committee; Partially Closed Meeting

A meeting of the Hardware Subcommittee of the Computer Systems Technical Advisory Committee will be held August 25, 1987, 1:30 p.m. in the Herbert C. Hoover Building, Room 6802, 14th Street & Constitution Avenue, NW., Washington, DC 20230.

The Hardware Subcommittee was formed to study computer hardware with the goal of making recommendations to the Department of Commerce relating to the appropriate parameters for controlling exports for reasons of national security.

Open Session

1. Opening remarks by the Chairman.
2. Presentation of papers or comments by the public.
3. Review of NEMA evaluation of proposals on programmable controllers.

Executive Session

4. Discussion of matters properly classified under Executive Order 12356, dealing with the U.S. and COCOM control program and strategic criteria related thereto.

The General Session of the meeting will be open to the public and a limited number of seats will be available. To the extent time permits, members of the public may present oral statements to the Committee. Written statements may be submitted at any time before or after the meeting.

The Assistant Secretary for Administration, with the concurrence of the General Counsel, formally determined on January 10, 1986, pursuant to section 10(d) of the Federal Advisory Committee Act, as amended by section 5(c) of the Government in the Sunshine Act, Pub. L. 94–409, that the matters to be discussed in the Executive Session should be exempt from the provisions of the Federal Advisory Committee Act relating to open meetings and public participation therein, because the Executive Session will be concerned with matters listed in 5 U.S.C. 552b(c)(1) and are properly classified under Executive Order 12356.

A copy of the Notice of Determination to close meetings or portions thereof is available for public inspection and copying in the Central Reference and Records Inspection Facility, Room 6628, U.S. Department of Commerce, Telephone: 202/377–4127. For further information or copies of the minutes, call Betty Ferrell at 202/377–2583.

Date: August 3, 1987.

Betty A. Ferrell,

Acting Director, Technical Support Staff, Office of Technology & Policy Analysis.

[FR Doc. 87–17892 Filed 8–5–87; 8:45 am]

BILLING CODE 3510-DT-M

Software Subcommittee of the Computer Systems Technical Advisory Committee; Partially Closed Meeting

A meeting of the Software Subcommittee of the Computer Systems Technical Advisory Committee will be held August 25, 1987, 9:30 a.m. in the Herbert C. Hoover Building, Room 6802, 14th Street & Constitution Avenue, NW., Washington, DC. The Software committee was formed to study computer software with the goal of making recommendations to the Department of Commerce relating to the appropriate parameters for controlling exports for reasons of national security.

General Session

1. Opening remarks by the Chairman.
2. Presentation of papers or comments by the public.

Executive Session

3. Discussion of matters properly classified under Executive Order 12356, dealing with the U.S. and COCOM control program and strategic criteria related thereto.

The General session of the meeting will be open to the public and a limited number of seats will be available. To the extent time permits members of the public may present oral statements to the Committee. Written statements may be submitted at any time before or after the meeting.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on January 10, 1986, pursuant to section 10(d) of the Federal Advisory Committee Act, as amended by section 5(c) of the Government in the Sunshine Act, Pub. L. 94–409, that the matters to be discussed in the Executive Session should be exempt from the provisions of the Federal Advisory Committee Act relating to open meetings and public participation therein, because the Executive Session will be concerned with matters listed in 5 U.S.C. 552b(c)(1) and are properly classified under Executive Order 12356.

A copy of the Notice of Determination to close meetings or portions thereof is available for public inspection and copying in the Central Reference and Records Inspection Facility, Room 6628, U.S. Department of Commerce, Telephone: 202/377–4127. For further information or copies of the minutes, call Betty Ferrell at 202/377–2583.

Dated: August 3, 1987.

Betty A. Ferrell,

Acting Director, Technical Support Staff Office of Technolog & Policy Analysis.

[FR Doc. 87–17891 Filed 8–5–87; 8:45 am]

BILLING CODE 3510-DT-M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Establishment and Amendment of Import Limits for Certain Cotton and Man-Made Fiber Textile Products Produced or Manufactured in the Socialist Republic of Romania

August 4, 1987.

The Chairman of the Committee for the Implementation of Textile Agreements (CITA), under the authority contained in E.O. 11651 of March 3, 1972, as amended, has issued the directive published below to the Commissioner of Customs to be effective on August 7, 1987.

For further information contact Chris Lozano, Assistant International Trade Specialist (202) 377–4212. For information on the quota status of these limits, please refer to the Quota Status Reports which are posted on the bulletin boards of each Customs port or call (202) 682–3072. For information on embargoes and quota re-openings, please call (202) 377–3715.

Summary

In the letter published below, the Chairman of the Committee for the Implementation of Textile Agreements directs the Commissioner of Customs to establish new limits for cotton and wool textile products in the Categories 360 and 465, and to amend the previously established import restraint limits for cotton, wool and man-made fiber textile products in Categories 315, 333, 339, 361, 442, 448, 640 and 641, produced or manufactured in the Socialist Republic of Romania and exported during the twelve-month period which began on January 1, 1987 and extends through December 31, 1987. In addition, the Commissioner is directed to exclude tank tops from the current limit for sublevel 338pt. They will continue to be charged to the limit of Category 338. Also, goods exported in 1986 in Categories 448 and 641, but charged to the 1987 limits are to be deducted from the 1987 limits and charged back to the limits established for 1986. The Commissioner is directed to charge imports, for the period beginning January 1, 1987, to the newly established limits for Categories 333/833, 360, 465, as indicated.

As a result of the above actions, the limits for Categories 338pt., 339 and 641, which are currently filled, will re-open.

Background

CITA directives dated December 23, 1986 established import restraint limits for certain cotton textile products, including Categories 315, 333, 339, 361, 338 and 338pt. (51 FR 47050) and wool and man-made fiber textile products, including Categories 442, 448, 640 and 641 (51 FR 47280), produced or manufactured in the Socialist Republic of Romania and exported during the twelve-month period which began on January 1, 1987 and extends through December 31, 1987.

On March 18, 1987, a notice was published in the **Federal Register** (52 FR 8498) which announced that the United States Government had requested the Government of Socialist Republic of Romania to enter into consultations concerning certain silk blend and other vegetable fiber textiles and textile products in Category 833, produced or manufactured in Romania.

A CITA directive dated April 3, 1987 (52 FR 11305) established an import restraint limit for certain man-made fiber textile products in Category 641, produced or manufactured in Romania and exported during the twelve-month period which began on January 1, 1987 and extends through December 31, 1987.

Under the terms of the Bilateral Cotton Textile Agreement, effected by exchange of notes dated January 28 and March 31, 1983, as amended, and the Bilateral Wool and Man-Made Fiber Textile Agreement, effected by exchange of notes dated November 7 and 16, 1984, as amended, between the Governments of the United States and the Socialist Republic of Romania, the two governments have reached agreement, effected by exchange of notes dated June 16, 1987 and July 7, 1987, to further amend the bilateral agreements.

The bilateral agreements are amended to increase the existing designated consultation levels for Categories 315, 339, 360, 361, 465 and 640 for the 1987 agreement year. In addition, agreement was reached to exclude tank tops from the current sublevel for Category 338pt. They will continue to be charged to the designated consultation level for Category 338. The current level for Category 338 and the sublevel for 338pt. will remain the same.

The bilateral agreements are further amended to include new designate consultation levels for the newly merged Category 333/833, including a sublevel for Category 833, and Categories 361 and 465. The level for 333/833 is for the 1987 agreement year only. Category 333 is currently controlled under the Group II limit and shall remain subject to the group limit, as merged Category 333/833. The conversion factor for converting Category 333/833 to square yards is 36.2.

The Bilateral Wool and Man-Made Fiber Textile Agreement is further amended to convert the existing minimum consultation levels for Categories 448 and 641 to designated consultation levels for the agreement years 1986 through 1989. The existing minimum consultation level for Category 442 is being converted to a designated consultation level for the agreement years 1987 through 1989.

Imports of 1986 overshipments charged to the 1987 restraint limits for Categories 448 and 641 will be deducted and charged back to the adjusted 1986 limits for those categories.

A description of the textile categories in terms of T.S.U.S.A. numbers was published in the **Federal Register** on December 13, 1982 (47 FR 55709), as amended on April 7, 1983 (48 FR 15175), May 3, 1983 (48 FR 19924), December 14, 1983, (48 FR 55607), December 30, 1983 (48 FR 57584), April 4, 1984 (49 FR 13397), June 28, 1984 (49 FR 26622), July 16, 1984 (49 FR 28754), November 9, 1984 (49 FR 44782), July 14, 1986 (49 FR 25386), July 29, 1986 (51 FR 27068) and in Statistical Headnote 5, Schedule 3 of the Tariff Schedules of the United States Annotated (1987).

Adoption by the United States of the Harmonized Commodity Code (HCC) may result in some changes in the categorization of textile products covered by this notice. Notice of any necessary adjustments to the limits affected by adoption of the HCC will be published in the **Federal Register.**

This letter and the actions taken pursuant to it are not designed to implement all of the provisions of the bilateral agreements, but are designed to assist only in the implementation of certain of its provisions.

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

August 4, 1987.

Committee for the Implementation of Textile Agreements

Commissioner of Customs,
Department of the Treasury, Washington, D.C. 20229

Dear Mr. Commissioner: This directive amends, but does not cancel, the directives of December 23, 1986, as amended on April 3, 1987, issued to you by the Chairman, Committee for the Implementation of Textile Agreements, which directed you to prohibit entry for consumption or withdrawal from warehouse for consumption of cotton, wool and man-made fiber textile products, produced or manufactured in Romania and exported during the twelve-month period which began on January 1, 1987 and extends through December 31, 1987.

Effective on August 7, 1987, the directives of December 23, 1986, as amended, are hereby further amended to create the merged Category 333/833 and to include amended

limits for cotton, wool, silk blend and other vegetable fiber textiles and textile products in the newly merged Category 333/833 and Categories 315, 339, 361, 442, 448, 640 and 641; and new limits for cotton and wool textile products in Categories 360 and 465, produced or manufactured in Romania and exported during the twelve-month period which began on January 1, 1987 and extends through December 31, 1987. Category 333/833 shall be subject to the Group II limit. Categories 442, 448, 640 and 641 are currently controlled under the Group III limit and shall remain subject to the group.

Category	Twelve-month adjusted limit [1]
315	1,750,000 square yards.
333/833 [2]	66,298 dozen of which not more than 13,260 dozen shall be in Category 833.
339	150,000 dozen.
360	1,030,000 numbers.
361	515,000 numbers.
442	6,500 dozen.
448	6,500 dozen.
465	2,100,000 square feet.
640	62,500 dozen.
641	65,000 dozen.

[1] The limits have not been adjusted to account for any imports exported after December 31, 1986.

[2] The conversion factor for converting to square yards is 36.2.

In addition, you are directed to exclude tank tops (TSUSA numbers 381.0230 and 381.4120) from the current limit for sublevel 338pt. TSUSAs 381.0230 and 381.4120 are to be included in the current limit of 256,000 dozen for Category 338, as a whole, of which not more than 97,222 dozen shall be in TSUSA numbers 381.0240, 382.0425, 381.3516, 381.4130, 381.4337, 381.6610, 381.8506, and 381.9924.

Effective on August 7, 1987, you are directed to deduct 61,225 dozen from the charges made to the 1987 import restraint limit for Category 338pt. for tank tops only (TSUSA numbers 381.0230 and 381.4120). In addition, you are to charge 61,225 dozen to the 1987 restraint limit for Category 338, as a whole. These charges are for goods imported during the period January 1, 1987 through April 30, 1987.

Textile products in Categories 360, 465 and 833 which have been exported to the United States prior to January 1, 1987 shall not be subject to this directive.

Textile products in Categories 360, 465 and 833 which have been released from the custody of the U.S. Customs Service under the provisions of 19 U.S.C. 1448(b) or 1484(a)(1)(A) prior to the effective date of this directive shall not be denied entry under this directive.

Also effective on August 7, 1987, you are directed to deduct the following amounts from the 1987 import restraint limits established in the directive of December 23, 1986, as amended, for Categories 448 and 641. These same amounts are to be charged to the 1986 limits established for these categories.

Category	Amount to be deducted/charged
448	944 dozen.
641	16,724 dozen.

Charges already made to Group II limit for Category 333 shall be applied to the newly merged Category 333/833. In addition, the following amounts are to be charged to the import restraint limits established by this directive for Categories 360, 465 and 333/833. These charges are for the period January 1, 1987 through May 30, 1987.

Category	Amount to be charged
360	214,290 numbers.
465	483,790 square feet.
833	533 dozen.

In carrying out the above directions, the Commissioner of Customs should construe entry into the United States for consumption to include entry for consumption into the Commonwealth of Puerto Rico.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553.

Sincerely,

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 87-17984 Filed 8-5-87; 8:45 am]

BILLING CODE 3510-DR-M

Amendment of an Import Limit for Certain Cotton and Man-Made Fiber Textiles and Textile Products Produced or Manufactured in Thailand

August 3, 1987.

The Chairman of the Committee for the Implementation of Textile Agreements (CITA), under the authority contained in E.O. 11651 of March 3, 1972, as amended, has issued the directive published below to the Commissioner of Customs to be effective on August 3, 1987. For further information contact Ross Arnold, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377-4212. For information on the quota status of these limits, please refer to the Quota Status Reports which are posted on the bulletin boards of each Customs port or call (202) 343-6580. For information on embargoes and quota reopenings, please call (202) 377-3715.

Summary

In the letter published below, the Chairman of the Committee for the Implementation of Textile Agreements directs the Commissioner of Customs to cancel the previously established ninety-day import restraint limit and establish a six-month limit for cotton and man-made fiber textile products in Category 342/642, produced or manufactured in Thailand and exported during the period which began on July 1, 1987 and extends through December 31, 1987.

Background

A CITA directive dated June 5, 1987 (52 FR 22515) established an import restraint limit for cotton and man-made fiber textile products in Category 342/642, produced or manufactured in Thailand and exported during the ninety-day period which began on May 22, 1987 and extends through August 19, 1987.

The Governments of the United States and Thailand have agreed in consultations to further amend their Bilateral Cotton, Wool and Man-Made Fiber Textile Agreement of July 27 and August 8, 1983, as previously amended and extended, to establish a new specific limit for cotton and man-made fiber skirts in Category 342/642, during the six-month period which began on July 1, 1987 and extends through December 31, 1987.

A description of the textile categories in terms of T.S.U.S.A. numbers was published in the **Federal Register** on December 13, 1982 (47 FR 55709), as amended on April 7, 1983 (48 FR 15175), May 3, 1983 (48 FR 19924), December 14, 1983, (48 FR 55607), December 30, 1983 (48 FR 57584), April 4, 1984 (49 FR 13397), June 28, 1984 (49 FR 26622), July 16, 1984 (49 FR 28754), November 9, 1984 (49 FR 44782), July 14, 1986 (51 FR 25386), July 29, 1986 (51 FR 27068) and in Statistical Headnote 5, Schedule 3 of the Tariff Schedules of the United States Annotated (1987).

Adoption by the United States of the Harmonized Commodity Code (HCC) may result in some changes in the categorization of textile products covered by this notice. Notice of any necessary adjustments to the limits affected by adoption of the HCC will be published in the **Federal Register.**

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

August 3, 1987.

Committee for the Implementation of Textile Agreements

Commissioner of Customs,

Department of the Treasury, Washington, DC 20229

Dear Mr. Commissioner: This directive cancels and supersedes the directive of June 5, 1987 from the Chairman of the Committee for the Implementation of Textile Agreements, which established a restraint limit for certain cotton and man-made fiber textile products in Category 342/642, produced or manufactured in Thailand and exported during the ninety-day period which began on May 22, 1987 and extends through August 19, 1987.

Under the terms of Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854), and the Arrangement Regarding International Trade in Textiles done at Geneva on December 20, 1973, as further extended on July 31, 1986; pursuant to the Bilateral Cotton, Wool and Man-Made fiber Textile Agreement of July 27 and August 8, 1983, as amended, and extended, between the Governments of the United States and Thailand; and in accordance with the provisions of Executive Order 11651 of March 3, 1972, as amended, you are directed to prohibit, effective on August 3, 1987, entry into the United States for consumption and withdrawal from warehouse for consumption of cotton and man-made fiber textile products in Category 342/642, produced or manufactured in Thailand and exported during the six-month period which began on July 1, 1987 and extends through December 31, 1987, in excess of 137,000 dozen.[1]

Textile products in Category 342/642 which have been exported to the United States prior to July 1, 1987 shall not be subject to this directive. Those exports remain, however, subject to the Group limit established in the directive of December 23, 1986, as are imports of Category 342/642 exported during the July 1–December 31, 1987 period.

In carrying out the above directions, the Commissioner of Customs should construe entry into the United States for consumption to include entry for consumption into the Commonwealth of Puerto Rico.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553.

Sincerely,

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 87–17890 Filed 8–5–87; 8:45 am]

BILLING CODE 3510-DR-M

[1] The limit has not been adjusted to account for any imports exported after June 30, 1987.

DEPARTMENT OF DEFENSE

Office of the Secretary of Defense

DOD Advisory Group on Electron Devices; Meeting

SUMMARY: Working Group A (Mainly Microwave Devices) of the DoD Advisory Group on Electron Devices (AGED) announces a closed session meeting.

DATE: The meeting will be held at 0900, Thursday and Friday, 27 & 28 August 1987.

ADDRESS: The meeting will be held at Palisades Institute for Research Services, Inc., 2011 S. Crystal Drive, Suite 307, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Harold Summer, AGED Secretariat, 201 Varick Street, New York, 10014.

SUPPLEMENTARY INFORMATION: The mission of the Advisory Group is to provide the Under Secretary of Defense for Acquisition, the Director, Defense Advanced Research Projects Agency and the Military Departments with technical advice on the conduct of economical and effective research and development programs in the area of electron devices.

The Working Group A meeting will be limited to review of research and development programs which the military propose to initiate with industry, universities or in their laboratories. This microwave device area includes programs on developments and research related to microwave tubes, solid state microwave, electronic warfare devices, millimeter wave devices, and passive devices. The review will include classified program details throughout.

In accordance with section 10(d) of Pub. L. No. 92–463, as amended, (5 U.S.C. App. II § 10(d) (1982)), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. 552b(c)(1) (1982), and that accordingly, this meeting will be closed to the public.

Linda M. Lawson,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

July 31, 1987.

[FR Doc. 87–17872 Filed 8–5–87; 8:45 am]

BILLING CODE 3810-01-M

DOD Advisory Group on Electron Devices; Meeting

SUMMARY: The DoD Advisory Group on Electron Devices (AGED) announces a closed session meeting.

DATE: The meeting will be held at 0900, Wednesday, 26 August 1987.

ADDRESS: The meeting will be held at Palisades Institute for Research Services, Inc., 2011 S. Crystal Drive, Suite 307, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: David Slater, AGED Secretariat, 201 Varick Street, New York, NY 10014.

SUPPLEMENTARY INFORMATION: The mission of the Advisory Group is to provide the Under Secretary of Defense for Acquisition, the Director, Defense Advanced Research Projects Agency and the Military Departments with technical advice on the conduct of economical and effective research and development programs in the area of electron devices.

The AGED meeting will be limited to review of research and development programs which the Military Departments propose to initiate with industry, universities or in their laboratories. The agenda for this meeting will include programs on Radiation Hardened Devices, Microwave Tubes, Displays and Lasers. The review will include details of classified defense programs throughout.

In accordance with section 10(d) of Pub. L. No. 92–463, as amended (5 U.S.C. App. II 10(d) (1982)), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. 552b(c)(1) (1982), and that accordingly, this meeting will be closed to the public.

Linda M. Lawson,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

July 31, 1987.

[FR Doc. 87–17873 Filed 8–5–87; 8:45 am]

BILLING CODE 3810-01-M

Department of the Air Force

Performance Review Boards; List of Members

Below is a list of additional individuals who are eligible to serve on the Performance Review Boards for the Department of the Air Force in accordance with the Air Force Senior Executive Appraisal and Award System.

Air Staff

BG Joseph A. Ahearn
Earl A. Aler
L. Denny Crouch
BG William P. Hallin
BG John E. Jackson, Jr.

Air Force Systems Command

LG Spence M. Armstrong

Air Force Logistics Command

W. Edward Daley
L. Keith Dumas
BG Robert F. Swarts

Patsy J. Conner,

Air Force Federal Register Liaison Officer.

[FR Doc. 87–17834 Filed 8–5–87; 8:45 am]

BILLING CODE 3910-01-M

USAF Scientific Advisory Board; Meeting

August 3rd, 1987.

The USAF Scientific Advisory Board Ad Hoc Committee on Peacekeeper IMU Testing and Production will meet on August 21st, 27th and 28th, and September 3rd and 4th and 10th through 15th, 1987, at the Pentagon, Washington, DC from 8:00 a.m. to 5:00 p.m. each day. The purpose of the meeting is to review and assess the testing and production of the Inertial Measurement Unit for the Peacekeeper weapon system.

This meeting will involve discussions of classified defense matters listed in section 552b(c) of Title 5, United States Code, specifically subparagraph (1) thereof, and accordingly will be closed to the public.

For further information, contact the Scientific Advisory Board Secretariat at 202–697–4811.

Norita C. Koritko,

Air Force Federal Register Liaison Officer.

[FR Doc. 87–17943 Filed 8–5–87; 8:45 am]

BILLING CODE 3910-01-M

Corps of Engineers, Department of the Army

Intention To Prepare a Draft Environmental Impact Statement (Draft EIS); Norfolk Harbor and Channels, VA

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice of intent to prepare a draft environmental impact statement, Norfolk Harbor and Channels, Virginia, Long-Term Disposal (Draft EIS).

SUMMARY: 1. The proposed action involves investigating the long-term dredged material disposal needs of Hampton Roads and developing the most suitable plan to meet those needs. These investigations will be in the depth and detail needed to adequately evaluate all possible long-range disposal alternatives and to select the optimum plan. This investigation is authorized by Congressional Resolutions adopted by the Senate Committee on Public Works on 20 June 1969 and 24 June 1974, and by the House Committee on Public Works on 3 Ocotber 1968 and 10 October 1974. The authority for continuing this investigation is contained in the Water Resources Development Act of 1986. The Draft EIS will focus on the impacts to the environment that may occur as a result of implementing the recommended plan and would also consider the impacts of alternative measures.

2. The study will be a comprehensive effort and will consider all possible alternatives for dealing with the long-range dredged material disposal needs in Hampton Roads. Alternative plans which will be considered include the expansion of Craney Island Disposal Area, confined sites at Willoughby Bay, Ocean View, Hampton Flats, Horseshoe Area off Buckroe Beach, Ragged Island, Suffolk, and Chesapeake Bay, open water disposal at the Dam Neck Ocean Disposal Site and Norfolk Disposal Site, and truck and rail haul. The study will reflect a sound planning approach in which all alternatives will be appropriately considered in order to reach conclusions that can be supported throughout the implementation process.

3a. The scoping process is a method of soliciting public or agency input which could include perception of the action, identification of major issues and environmental concerns, and development of alternatives and mitigation plans. The scoping process for this Draft EIS will take place during the 90 days following the date of this notice of intent. The written comments of interested Federal, State, and local agencies as well as organized groups and private individuals are requested before this time limit so that scheduling of studies needed for this Draft EIS can be done.

3b. Some preliminary investigations are currently underway which will identify and evaluate impacts of the alternatives. Impacts of the considered plans on the environmental, social, historical, and cultural resources of the study area will be investigated. Significant issues to be considered in the Draft EIS include impacts to commercial and non-commercial benthos and finfish, navigation, cultural resources, aesthetics, wetlands and water quality. Alternatives which have less long term adverse effects on the local environment with a lower economic cost will be considered more favorably over alternatives with higher environmental and economic costs.

3c. Requests will be made of the following Federal and State agencies for assistance within their areas of expertise during the scoping portion of the Draft EIS's preparation:

The U.S. Fish and Wildlife Service
The National Marine Fisheries Service
The U.S. Environmental Protection Agency
The Virginia State Water Control Board
The Virginia Department of Health
The Virginia Marine Resources Commission
The Virginia Institute of Marine Science
The Virginia Port Authority

Other Federal and State agencies may be requested to provide information for the draft document if necessary.

3d. Further environmental review and consultation may be required for site-specific evaluations but the preparation and evaluation of the Draft and Final EIS is expected to fulfill all immediate environmental coordination.

4. One or more public scoping meetings will be held within 90 days of the date of this notice to give all interested parties an opportunity to express concerns related to this study and the preparation of this Draft EIS. An interagency meeting involving Federal and State environmental agencies will also be held to obtain specific environmental concerns which should be addressed in this document. This meeting is expected to be held at the Norfolk District Corps of Engineers within 60 days of the date of this notice.

5. It is estimated that the Draft EIS will be available for public review approximately two years following the date of this notice.

ADDRESS: Questions about the proposed action and Draft EIS can be answered by:

Craig L. Seltzer, Oceanographer, CENAO–PL–R, Norfolk District Corps of Engineers, 803 Front Street, Norfolk, VA 23510–1096.

Dated: July 6, 1987.

J.J. Thomas,

District Engineer, Corps of Engineers, Norfolk District.

[FR Doc. 87–17835 Filed 8–5–87; 8:45 am]

BILLING CODE 3710-EN-M

Department of the Navy

Chief of Naval Operations Executive Panel Advisory Committee; Closed Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. app.), notice is hereby given that the Chief of Naval Operations (CNC) Executive Panel Advisory Committee Mine Warfare Capabilities Task Force will meet September 9–10, 1987 from 9 a.m. to 5 p.m. each day, at 4401 Ford Avenue, Alexandria, Virginia. All sessions will be closed to the public.

The purpose of this meeting is to review current and projected U.S. and Allied Mine Warfare capabilities and potential U.S. vulnerabilities in the broad context of maritime operations and related intelligence. These matters constitute classified information that is specifically authorized by Executive order to be kept secret in the interest of national defense and is, in fact, properly

classified pursuant to such Executive order. Accordingly, the Secretary of the Navy has determined in writing that the public interest requires that all sessions of the meeting be closed to the public because they will be concerned with matters listed in section 552b(c)(1) of title 5, United States Code.

For further information concerning this meeting, contact Lieutenant Paul G. Butler, Executive Secretary of the CNO Executive Panel Advisory Committee, 4401 Ford Avenue, Room 601, Alexandria, Virginia 22302-0268. Phone (703) 756-1205.

Dated: August 3, 1987.

Jane M. Virga,

Lieutenant, JAGC, U.S. Naval Reserve, Federal Register Liaison Officer.

[FR Doc. 87-17830 Filed 8-5-87; 8:45 am]

BILLING CODE 3810-AE-M

Intent to Prepare a Draft Environmental Impact Statement (DEIS) for the Establishment of an AV-8B (Harrier Jet) Forward Training Facility Within North Carolina

Pursuant to section 102(2)(c) of the National Environmental Policy Act (NEPA) of 1969 and the Council on Environmental Quality Guidelines (40 CFR part 1500), the Department of the Navy (DON), U.S. Marine Corps is preparing a Draft Environmental Impact Statement for the establishment of an AV-8B (Harrier Jet) Forward Training Facility (FTF) in the eastern region of North Carolina.

The primary purpose of the proposed facility is to provide a site to exercise the Harrier's forward basing capability. Facility operations will expose aircrews and squadron ground-support personnel to a remote environment that is difficult to see and locate (a type environment that may be experienced in a real battle situation). The facility is intended to be austere in nature and will be logistically dependent upon the Marine Corps Air Station, Cherry Point.

Training at the facility will have a maximum of 200 aircraft operations per day and will occur primarily during daylight hours, five days a week, with infrequent weekend and nighttime operations.

To support proposed facility operations, the following infrastructure is required:

—1,800 foot runway constructed of steel/aluminum matting (interlocking sections) sufficient to support the AV-8B at gross weight of 26,000 pounds,
—Ramp sufficient to support six AV-8B aircraft,
—Areas (hides) sufficient to conceal six AV-8B aircraft,
—Taxiway sufficient to taxi to/from ramp and hides,
—Berms sufficient to install six fuel bladders, and contain any leaks therefrom,
—Refueling capability on ramp and hides from fuel bladder,
—Arming and de-arming area sufficient to accommodate two AV-8B aircraft simultaneously, and
—Utilities consisting of potable water (well with treatment system) expeditionary electrical power, expeditionary lighting, and commercial telephone lines.

Additional facilities will include a crash/fire/rescue pad, security perimeter fencing, a support facilities building (9,000 sq. ft.), a caretakers post (400 sq. ft.), toilets (150 person maximum), septic system (possible batch treatment system unless soil condition will permit septic tanks system), and road improvements.

The perferred location of the facility was selected on the basis of recommendations provided by a Navy-contracted siting study. Three basic alternatives were examined under this analysis:

a. Develop the AV-8B training facility at MCAS Cherry Point, from which such operations are currently conducted.

b. Choose an existing outlying military airfield on which to develop the facility.

c. Locate a new site on which to develop the facility.

In view of these alternatives, a methodology was developed to identify and evaluate possible training facility locations. Identified locations included five existing military facilities (MCAS Cherry Point, MCOLF Atlantic, MCALF Bogue, MCALF Camp Davis, and MCOLF Oak Grove) as well as five new undeveloped "generic" areas which were selected on the basis of compatibility with mission requirements.

Scoping for this DEIS was initiated on December 22, 1986, by a letter to potentially affected entities. The letter described the proposed action and requested formal input which would identify environmental issues warranting in-depth analysis. MCOLF Oak Grove has now been determined to be an appropriate site, and is currently being considered as the preferred FTF location. The Marine Corps wishes to ensure all interested parties have the opportunity to participate in the environmental analysis and requests comments be addressed to: Atlantic Division, Naval Facilities, Engineering Command, Norfolk, VA 23511-6287, Attn. Mr. H. Eacho (Code 2032E3).

In order that comments be considered in a timely fashion, all scoping correspondence should be received not later than three (3) weeks after the publication date of this notice. When the DEIS is completed, a public notice of its availability will be made which will request review and comments by all interested parties. A final Environmental Impact Statement (FEIS) will then be prepared to respond to the review comments.

Date: August 3, 1987.

Jane M. Virga,

LT, JAGC, USNR Federal Register Liaison Officer.

[FR Doc. 87-17827 Filed 8-5-87; 8:45 am]

BILLING CODE 3810-AE-M

DEPARTMENT OF EDUCATION

National Advisory and Coordinating Council on Bilingual Education; Cancellation of Meeting

AGENCY: Department of Education, National Advisory and Coordinating Council on Bilingual Education.

ACTION: Notice of cancellation of meeting.

SUMMARY: The notice is hereby given of the cancellation of the National Advisory and Coordinating Council on Bilingual Education meeting scheduled at the Holiday Inn, 480 King Street, Alexandria, Virginia for August 10 and 11, 1987 that was published in the **Federal Register** of July 23, 1987, Vol. 52, No. 141, page 27704.

FOR FURTHER INFORMATION CONTACT: Anna Maria Farias, Designated Federal Official, 421 Reporters Building, 400 Maryland Avenue SW., Washington, DC 20202 (202-732-5063).

Dated: August 3, 1987

Anna Maria Farias,

Acting Director, Office of Bilingual Education.

[FR Doc. 87-17879 Filed 8-5-87; 8:45 am]

BILLING CODE 4000-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Preliminary Findings; Oklahoma Corporation Commission et al.

July 29, 1987.

In the matter of Oklahoma Corporation Commission, Cherokee Group, Roger Mills County, JD No. 87-16490T, Docket No. GP87-65-000, (formerly RM79-76-248 (Oklahoma-8)); Colorado Oil and Gas Conservation Commission, Niobrara Formation, Weld County, JD No. 87-16489T, Docket No. GP87-66-000, (formerly RM79-76-239 (Colorado-39

Addition)); Commonwealth of Kentucky, "Big Lime" Formation, Harlan, Leslie, Letcher and Perry Counties, JD No. 87-16488T, Docket No. GP87-67-000, (formerly RM79-76-225 (Kentucky-3)); Virginia Department of Mines, Minerals and Energy, "Big Lime" Formation, Buchanan, Dickenson, Lee, Scott, Wise, Russell and Tazewell Counties, JD No. 87-16491T, Docket No. GP87-68-000, (formerly RM79-76-249 (Virginia-4)) and Colorado Oil and Gas Conservation Commission, Niobrara Formation, Larimer, Boulder and Weld Counties, JD No. 87-16492T, Docket No. GP87-69-000, (formerly RM79-76-255 (Colorado-38 Addition)).

Introduction

Under section 107(b) of the Natural Gas Policy Act of 1978, (NGPA) the Federal Energy Regulatory Commission (Commission) is authorized to prescribe incentive prices for high-cost natural gas.[1] High-cost gas is produced under conditions which present extraordinary risks or costs and once designated may receive an incentive price. The Commission determined that natural gas produced from tight formations is high-cost natural gas under section 107(c)(5).[2] Under the Commission's rule, jurisdictional agencies may submit for Commission review recommendations of areas for designation as tight formations.

The five tight formation recommendations listed above were submitted to the Commission by state jurisdictional agencies pursuant to § 271.703(c) of the Commission's regulations, and are still pending before the Commission. Under § 271.703(c) the Commission in the past has reviewed tight formation recommendations received from jurisdictional agencies under its general rulemaking authority of NGPA section 501. However, the United States Court of Appeals for the District of Columbia Circuit recently held in *Williston Basin Interstate Pipeline Co.* v. *FERC*, 816 F.2d 777 (D.C. Cir. 1987) (*Williston Basin*) that the Commission must review jurisdictional agency tight formation recommendations as determinations under NGPA section 503.

A review of section 503 reveals that if there is not substantial evidence to support a jurisdictional agency's determination, the Commission may issue a preliminary finding reversing such determination.

The Commission is issuing a notice of preliminary finding that the subject jurisdictional agency recommendations are not supported by substantial evidence in the record. In addition, the Commission will treat the issuance of the court mandate in *Williston Basin* on July 15, 1987, as triggering the 45 day review period of section 503(b)(1)(B). The Commission believes the preliminary finding issued herewith satisfies the 45 day period. Within 120 days of the notice of preliminary finding, the Commission may issue a final finding reversing the jurisdictional agencies' determination.

Background

Five state jurisdictional agencies submitted recommendations that the respective areas be designated as tight formations pursuant to § 271.703(c)(2)(i) of the Commission's regulations and section 501 of the NGPA.[3] These recommendations if approved by the Commission would entitle gas produced from these properties to receive section 107(c) incentive pricing.

In all five of the above-captioned cases the Commission staff found that additional information was needed before the formations could be designated as tight formations under § 271.703. The Commission staff sent out deficiency letters in the five cases detailing the particular information missing in the jurisdictional agencies' original recommendations. A report of the specific deficiencies is attached hereto as Appendix A. In four cases there was no response to the deficiency letters. In the fifth case (Kentucky-3) the jurisdictional agency provided the explanation and information requested. However, as discussed in Appendix A, the Commission believes there is not substantial evidence in the record even with the response. Accordingly, the Commission is issuing a notice of preliminary findings in the above-captioned cases reversing the tight formation determinations of Oklahoma, Kentucky, Virginia and Colorado (38-Addition and 39-Addition) since there is not substantial evidence to support the determinations. The Commission notes that Virginia's determination will satisfy the guidelines of § 271.703, provided Virginia resubmits its recommendation without the "Big Lime" formation in Buchanan County.

Discussion

The Commission used NGPA section 501 rulemaking procedures for evaluating jurisdictional agency recommendations up until the recent *Williston Basin* decision. In implementing its authority under section 107(c)(5) of the NGPA, the Commission issued Order Nos. 99 and 99-A establishing incentive pricing for natural gas produced from designated tight formations. Section 271.703(c) of the Commission's regulations provides that upon written recommendation by a jurisdictional agency, the Commission may approve a recommendation that a natural gas formation be designated as a tight formation if it meets the following guidelines:

(A) The estimated average in situ gas permeability, throughout the pay section, is expected to be 0.1 millidarcy or less.

(B) The stabilized production rate, against atmospheric pressure, of wells, completed for production in the formation, without stimulation, is not expected to exceed [certain specified] production rate[s]. . . .

(C) No well drilled into the recommended tight formation is expected to produce, without stimulation, more than five barrels of crude oil per day.

The court in *Williston Basin*, contrary to the Commission's past practice, held that the Commission, in passing on local jurisdictional agencies' recommendations for tight formation designations, was actually reviewing determinations under NGPA section 503. Under section 503, the Commission's orders and thus the determinations were not judicially reviewable when the Commission adopts the jurisdictional agency's recommendation. As a result of *Williston Basin* the Commission must reevaluate the appropriate treatment of the seven tight formation recommendations which are currently pending before it.[4]

[1] 15 U.S.C. 3317(c)(5) (1986).

[2] Order No. 99, Regulations Covering High-Cost Natural Gas Produced from Tight Formations, 45 FR 56034 (Aug. 22, 1980), FERC Stats. and Regs. [Regulations Preambles 1977-1987] ¶30,183 (1980). 18 CFR 271.703 (1987).

[3] 18 CFR 271.703(c)(2)(i) (1986); *see also*, 15 U.S.C. 3317(c) (1986) (To encourage exploration for high-cost natural gas, Congress in the NGPA provided the Commission with authority to establish incentive prices for certain classifications for high-cost gas).

[4] Concurrently with this order, the Commission is issuing a final rule in Docket No. RM87-31-000 regarding procedures for determining high-cost natural gas produced from tight formations eligible for incentive prices pursuant to section 107(c)(5) of the NGPA. The rule will, among other things, incorporate tight formation designations under NGPA section 503 regulations rather than section 501 under Title 18 of the Code of Federal Regulations. The Commission is also issuing a notice of preliminary finding and order terminating hearing in Docket No. JD87-16493T (formerly Docket No. RM79-76-250) remanding the jurisdictional agency tight formation determination of the Texas Railroad Commission as not supported by substantial evidence in the record on which the determination was made. In addition, the Commission is issuing an order permitting a jurisdictional agency determination of tight formation to become final in Docket No. RM79-76-101 (Colorado 23). This order specifically approves the jurisdictional agency's recommendation that the subject areas be designated as tight formations.

The Commission staff reviewed the five of the seven pending tight formation recommendations herein and found that additional information was required for the formations to be designated as tight formations under § 271.703. The Commission staff sent out deficiency letters to each of the five jurisdictional agencies requesting more detailed information. A report of the specific deficiencies is attached hereto as Appendix A. Four of the five jurisdictional agencies did not respond to the deficiency letters. Kentucky did provide a response; however, the staff determined the data in such response was still incomplete. Based on currently available information, the Commission finds that the five jurisdictional agency determinations are not supported by substantial evidence in the record upon which such determinations were made pursuant to NGPA section 503(b)(1)(A). Therefore, the Commission will reverse the jurisdictional agency tight formation determinations under NGPA section 503(b)(1).

Accordingly, the Commission herewith issues a notice of preliminary findings under § 275.202(a)(1)(i) (1986) that the determinations submited by the five jurisdictional agencies are not supported by substantial evidence in the record on which the determinations were made.

Pursuant to section 503(b)(2)(B), the Commission must make its preliminary finding and notice thereof within 45 days after the date on which the Commission received notice of such determination under subsection (a)(2). However, since there was no notice prior to the *Williston Basin* decision that the Commission's review was under section 503 of the NGPA, and to avoid the untoward result of retroactive effectiveness of tight formation determinations, some of which have been pending at the Commission for years, the Commission concludes as the date of notification of the jurisdictional agency's tight formation determination.[5] Thus, the 45 day review period will run from the date of the *Williston Basin* mandate. The Commission is acting within the 45 days by issuing this notice of preliminary findings. Pursuant to section 553(d) of the Administrative Procedure Act, the Commission's new rule concurrently issued in Docket No. RM87-31-000 will be effective immediately except for the information collection provisions in §§ 271.703 (c)(3) and (c)(4) which have been submitted to the Office of Management and Budget for approval. When these information collection provisions are approved by the Office of Management and Budget, the Commission will issue a notice in the **Federal Register** with the effective date for these information collection provisions.

The Commission Orders

(A) Pursuant to section 18 CFR 275.202 (a)(1)(i) (1986) and section 503(b)(2)(A) of the NGPA, the Commission makes a preliminary finding that the determinations of the five jurisdictional agencies are not supported by substantial evidence in the record on which the determinations were made and issues this notice under 18 CFR 275.202(a)(ii) (1987).

(B) Pursuant to section 18 CFR 2375.202(f) (1987), jurisdictional agencies, interested parties or any person may, within 30 days after issuance of the preliminary finding, submit written comments and request an informal conference with the Commission staff.

By the Commission.

Kenneth F. Plumb,

Secretary.

Appendix A

Oklahoma-8 (JD87-1649OT, Formerly RM79-76-248)

On December 6, 1985, the Oklahoma Corporation Commission (OCC) found that the information presented by Diamond Shamrock Exploration Company in its application to designate a tight formation complied fully with the guidelines of section 271.703(c) of the Commission's regulations. The OCC ruled that the Cherokee Group common source of supply underlying sections 19, 20, 21, 22, 23, 28, 29, 31, 32, and 33, all in Township 15 North, Range 22 West, Roger Mills County, Oklahoma should be designated as a tight formation pursuant to section 107 of the NGPA in accordance with the provisions of 18 CFR § 271.703(c)(2)(i)(1985).

By letter dated October 27, 1986, the staff of the Federal Energy Regulatory Commission (Commission) advised the OCC that additional information was required in order for the Commission to designate the Cherokee Group in a portion of Roger Mills County as a tight formation. Specifically, the staff requested the OCC to provide the formula used to calculate the predicted rates of the test wells and to furnish examples of how variation of one of the four variables in the formula affected the others. Staff also requested the OCC to explain why the permeability and stabilized flow rates of the Upper Cherokee are adequately represented when only one or two of the test wells is completed in the Upper Cherokee. To date, the Commission has received no response from the OCC.

Virginia-4 (JD87-16491T, Formerly RM79-76-249)

On May 12, 1986, Virginia's Department of Mines, Minerals and Energy (Virginia) recommended that the "Big Lime" formation in southwest Virginia (in portions of Buchanan, Dickenson, Lee, Scott, Wise, Russell, and Tazewell Counties) be designated a tight formation. By letter dated September 29, 1986, Commission staff advised Virginia that its recommendation, as it pertains to the "Big Lime" formation in Buchanan County, is not supported by substantial evidence and that the Buchanan portion should be deleted from the recommendation. The staff's letter was based on its review which revealed that 32% of the data wells in Buchanan County were excluded as anomalous and that 62% of the data wells which were completed in the "Big Lime" formation were also excluded an anomalous. The Commission staff noted that the exclusions are, in effect, a suggestion that 62% of the wells drilled and completed in the "Big Lime" are anomalous when attempting to satisfy the expected production rate in the Commission's regulations, and that the flow rates attributable to the excluded wells are not representative of the expected production rates of wells completed in the "Big Lime" formation although these wells account for 74% of the cumulative open flow for all available data wells in Buchanan County. To date, the Commission has received no response from Virginia.

Kentucky-3 (JD87-16488T, formerly RM79-76-225)

On January 16, 1984, the Commonwealth of Kentucky (Kentucky) submitted to the Commission its

[5] Although the general rule is to apply court decisions retroatively, the Supreme Court in *Chevron Oil Co. v. Huson*, 404 U.S. 97 (1971) enumerated three factors which should be weighed in determining whether a particular judicial construction prospectively. First, any decision which establishes a new principle of law may be prospectively applied. The second factor is whether retroactive operation of the rule will further or retard the purpose and effect of the rule. The third factor involves equitable considerations. Using this test, the Commission concludes that the *Williston Basin* decision should be applied prospectively only. The decision establishes a new principle of law; retroactive application of the decision would retard the purpose of the rule because unsupported jurisdictional agency determinations which have been pending before the Commission for more than 45 days would otherwise be considered final; and such a result would be inequitable.

recommendation that the "Big Lime" formation of the Newman Group (located in Harlan, Leslie, Letcher and Perry Counties) be designated as a tight formation. On May 17, 1984, the Commission staff sent a letter to Kentucky requesting that additional information or explanations be submitted to support its recommendation. Specifically, staff requested Kentucky to submit a more precise geographic delineation of the recommended area, a list of wells within the recommended area which produce from the recommended formation, additional permeability data for the recommended area, and an explanation, in light of statistical evidence, of how permeability in the area was determined to meet the guideline in § 271.703(c) of the Commission's regulations.

By letter dated October 6, 1986, Kentucky furnished the requested information and explanation. Kentucky stated that it believes the "Big Lime" formation exhibits a linear relationship between permeability and porosity and, therefore, that permeability can be calculated for wells which have a measured porosity. Using this method, Kentucky states that the average calculated permeability in the recommended area is less than the Commission's guideline of 0.1 md.

A review of Kentucky's data reveals that deficiencies still exist, and that the method Kentucky uses to determine the "average in-situ" permeability for the recommended area does not appear to be based on sound statistical methodology. Therefore, the Commission finds there is insufficient evidence on which to base a recommendation that the "Big Lime" formation of the Newman Group in Harlan, Leslie, Letcher and Perry Counties meets the Commission's guidelines as a tight formation.

Colorado-39 Addition (JD87-16489T, Formerly RM79-76-239)

On November 15, 1984, the Colorado Oil and Gas Conservation Commission (Colorado) submitted to the Commission a recommendation pursuant to § 271.703 of the Commission's its regulations, that the Niobrara formation located in Weld County, Colorado, be designated as a tight formation. The recommended acreage is an extension of an area in which the Niobrara formation had been previously approved as a tight formation by the Commission in Docket No. RM79-76-235 (Colorado-39).

The Commission staff advised Colorado by letter dated April 18, 1985, that further explanation and information was required in order for staff to complete its review of Colorado's recommendation that the Niobrara formation in Weld County be designated as a tight formation. Specifically, staff noted that the record contained no permeability data for wells in the recommended area and requested Colorado to furnish such permeability data. If no data was available, staff requested that Colorado explain why data from five wells outside the recommended area was adequate to support its recommendation. Staff also requested Colorado to provide additional information (such as well completion reports, post-stimulation production data, etc.) to substantiate Colorado's recommendation that the prestimulation flow rate is not expected to exceed the rate in the regulations. To date the Commission has received no response from Colorado to the deficiency letter.

Colorado-38 Addition (JD87-16492T, Formerly RM79-76-255)

On February 9, 1987, the Colorado Oil and Gas Conservation Commission (Colorado) submitted to the Commission a recommendation that the area in which the Niobrara Formation had previously been recommended as a "Tight Formation" by Order No. 43-1, and approved by the Commission in Order No. 386, be extended to include additional lands in Larimer, Boulder and Weld Counties under § 271.703(c) of the Commission's regulations.

On June 4, 1987, the Commission staff advised Colorado that more information was needed for its recommendation that an additional area of the Niobrara formation in Larimer, Boulder, and Weld Counties be designated as a tight formation. Since a majority of the wells in the recommended area appear to be oil wells, staff requested Colorado to clarify whether the recommended area contains designated oil fields and, if so, why Colorado believes the oil areas should be designated a natural gas tight formation. Staff also requested additional information (such as well completion reports, prestimulation production or additional post-stimulation production data) to substantiate Colorado's finding that the pre-stimulation flow rate of oil and gas was not expected to exceed the rate in the regulations. To date the Commission has received no response from Colorado.

[FR Doc. 87-17844 Filed 8-5-87; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. GP87-27-000 (Formerly RM79-76-250)]

Preliminary Finding and Order Terminating Hearing; Texas Railroad Commission, Travis Peak Formation JD87-16493T

Issued July 29, 1987.

Before Commissioners: Martha O. Hesse, Chairman; Anthony G. Sousa, Charles G. Stalon, Charles A. Trabandt and C. M. Naeve.

Introduction

Under section 107(c)(5) of the Natural Gas Policy Act of 1978 (NGPA), the Federal Energy Regulatory Commission (Commission) designates certain types of natural gas as high-cost gas.[1] High-cost gas is produced under conditions which present extraordinary risks or costs, and once designated may receive an incentive price. The Commission issued a rule establishing that natural gas produced from tight formations is high-cost natural gas under NGPA section 107(c)(5).[2] Under the Commission's rule, jurisdictional agencies may submit recommendations of areas for designation as tight formations for Commission approval. In the instant case, the Texas Railroad Commission (Texas) recommended designation of the Travis Peak formation (Travis Peak) as a tight formation. For the reasons stated below the Commission is issuing this notice of preliminary finding under NGPA section 503(b)(2) that the determination by Texas that Travis Peak qualifies as a tight formation is not consistent with information contained in the public records of the Commission and therefore should be remanded to Texas for such further action as it deems appropriate. The Commission's preliminary finding under section 503 is made in light of the recent decision of the United States Court of Appeals for the District of Columbia Circuit *Williston Basin Interstate Pipeline Co. v. FERC*, 816 F.2d 777 (D.C. Cir. 1987) (*Williston Basin*) which held that the Commission in reviewing jurisdictional agency tight formation recommendations must treat them as determinations under NGPA section 503, rather than recommendations for rulemakings under NGPA section 501 as the Commission has done in the past.

[1] 15 U.S.C. 3317(c)(5) (1986).

[2] Order No. 99, Regulations Covering High-Cost Natural Gas Produced from Tight Formations, 45 FR 56034 (August 22, 1980), FERC Stats. and Regs. [Regulations Preambles 1977-1981] ¶ 30,183 (1980); 18 CFR 271.703 (1987).

Background

On November 2, 1981, the Commission received a recommendation from Texas that Travis Peak be designated a tight formation pursuant to § 271.703(c)(2)(i) of the Commission's regulations.[3] Travis Peak underlies 47 counties in northeastern Texas. After reviewing the record and supplemental material the Commission on May 23, 1986, issued Order No. 450 [4] that modified and adopted Texas' recommendation that Travis Peak be designated a tight formation under NGPA section 107(c)(5) but excluded certain "sweet spots" from the designation.[5]

On June 19, 1986, Delhi Gas Pipeline Corporation (Delhi) filed an application for rehearing which was later supplemented on October 6, 1986, complaining that Texas' recommendation contained stale information which was limited to fewer than half of the wells drilled into the formation. The data submitted by Delhi suggest that the average permeability and flow rates in Travis Peak may exceed the maximum permissible level for the formation to qualify as a tight formation under the Commission's regulations.[6] The Commission concluded that Delhi's supplemental information raised legitimate doubts as to whether Travis Peak should be designated a tight formation. On January 9, 1987, the Commission granted Delhi's request for rehearing, vacated Order No. 450, reopened the record, and initiated a formal hearing to determine whether, in light of additional evidence presented by Delhi and other interested parties, Travis Peak meets the Commission's standards for designation as a tight formation.[7]

Discussion

The Commission used section 501 rulemaking procedures for evaluating jurisdictional agency recommendations up until the recent *Williston Basin* decision. In implementing its authority under section 107(c)(5) of the NGPA, the Commission issued Order Nos. 99 and 99–A establishing incentive pricing for natural gas produced from designated tight formations. Section 271.703(c) of the Commission's regulations provides that, upon written recommendation by a jurisdictional agency, the Commission may approve a recommendation that a natural gas formation be designated as a tight formation if it meets the following guidelines:

(A) The estimated average in situ gas permeability, throughout the pay section, is expected to be 0.1 millidarcy or less.

(B) The stabilized production rate, against atmospheric pressure, of wells completed for production in the formation, without stimulation, is not expected to exceed [certain specified] production rate[s]. . . .

(C) No well drilled into the recommended tight formation is expected to produce, without stimulation, more than five barrels of crude oil per day.

Pursuant to § 271.703(c) of the regulations, the Commission has reviewed tight formation recommendations received from jurisdictional agencies under its general rulemaking authority in section 501 of the NGPA, which authorizes the Commission to perform any and all acts and to prescribe, issue, amend and rescind such rules and orders as it may find necessary. The section 501 rulemaking procedure is subject to judicial review under sections 502 and 506 of the NGPA.

The court in *Williston Basin*, contrary to the Commission's past practice, held that the Commission, in passing on local jurisdictional agencies' recommendations for tight formation designations, was actually reviewing determinations under NGPA section 503. Under section 503, the Commission's orders and thus the determinations were not judicially reviewable when the Commission adopts the jurisdictional agency's view. As a result of *Williston Basin* the Commission must reevaluate the appropriate treatment of the seven tight formation recommendations which are currently pending before it.[8]

In Travis Peak, which was in hearing when the court issued its opinion in *Williston Basin*, the Commission originally approved the jurisdictional agency's determination in Order No. 450. As noted above, however, supplemental information submitted by Delhi which contradicted this finding caused the Commission to vacate Order No. 450, grant Delhi's request for rehearing, and establish procedures for determining the character of the formation. Since the Commission's Order granting rehearing, interested parties have submitted copious information both challenging and supporting designation of Travis Peak as a tight formation. Section 503 of the NGPA [9] establishes a procedure whereby state and federal agencies with jurisdiction with respect to the production of natural gas determine whether natural gas qualifies under various NGPA price categories upon application. Once a jurisdictional agency notifies the Commission of its determination, such determination becomes final by operation of law within 45 days unless it is reversed or remanded by the Commission during that period. Section 503(b) sets the standards for Commission review of these determinations and states, in pertinent part, that if, "the Commission finds that a state or federal agency determination if not consistent with information contained in the public records of the Commission, and which is not part of the record upon which such determination was made, * * * it may remand the matter to such state or federal agency for consideration of the information. If such agency, after consideration of the information transmitted to it by the Commission, affirms its previous determination, such determination, as affirmed, shall be subject to review in accordance with this subsection (other than this paragraph)."

A review of section 503 reveals that the Commission's options in dealing with Travis Peak are either to reverse or remand the case to the state jurisdictional agency. In light of information in the Commission's files submitted by Delhi which is inconsistent with Texas' recommendation, and which is not part of the record upon which such tight formation determination was made, the Commission under section 503(b)(2)(A) hereby remands Travis Peak to the Texas Railroad Commission. Section 503 provides no basis for

[3] 18 CFR 271.703(c)(2)(i) (1986).

[4] Docket No. RM79–76–090, 51 FR 19164 (May 28, 1986), FERC Stats. & Regs. ¶ 30,698.

[5] The sweet spots excluded in Order No. 450 were the Bethany and the Carthage fields in Panola County. Also excluded were 31 additional gas wells which had high permeability values.

[6] 18 CFR 271.703(c)(2) (1986).

[7] Docket No. RM79–76–250, 52 FR 2401 (January 22, 1987), FERC Stats. & Regs. ¶ 30724.

[8] Concurrently with this order, the Commission is issuing a final rule in Docket No. RM87–31–000 regarding procedures for determining high-cost natural gas produced from tight formations eligible for incentive prices pursuant to section 107(c)(5) of the NGPA. The rule will, among other things, incorporate tight formation designations under UGPA section 503 regulations rather than section 501 under Title 18 of the Code of Federal Regulations. The Commission is also issuing a notice of preliminary findings in Docket Nos. JD87–16490T, JD87–16489T, JD87–16488T, JD87–16491T, and JD87–16492T reversing the jurisdictional agency tight formation recommendations as not supported by substantial evidence in the records, pursuant to NGPA section 503 and § 275.202 of the Commission's regulations. In addition, the Commission is issuing an order permitting a jurisdictional agency determination of tight formation to become final in Docket No. RM79–76101 (Colorado 23). This order specifically approves the jurisdictional agency's recommendation that the subject areas be designated as tight formations.

[9] 15 U.S.C. 3413 (198s).

holding hearings on tight formations. Therefore, the hearing previously ordered will be terminated as having no further force under NGPA section 503 and *Williston Basin* and Docket No. GP87-27-000 is hereby cancelled.

Accordingly, the Commission herewith issues notice of its preliminary finding under § 275.202(a)(1)(ii)(1986) that the determination submitted by the Texas Railroad Commission is not consistent with information which is contained in the public records of the Commission and which was not part of the record on which the jurisdictional agency made the determination. The Commission issues this notice of preliminary finding under § 275.202(a)(2)(1986), remanding Travis Peak to the jurisdictional agency.

The Commission notes that numerous motions are pending in this case requesting that the hearing be remanded to the state jurisdictional agency. In light of the *Williston Basin* decision and the new procedures under section 503, the Commission hereby dismisses all pending motions in this case. Comments may be submitted prior to the Commission's final finding pursuant to section 503.

Pursuant to section 503(b)(2)(B), the Commission must make its preliminary finding and notice thereof within 45 days after the date on which the Commission received notice of such determination under subsection (a)(2). However, since there was no notice prior to the *Williston Basin* decision that the Commission review was under section 503 of the NGPA, and to avoid the untoward result of retroactive effectiveness of tight formation determinations, some of which have been pending at the Commission for years, the Commission concludes that the court's mandate on July 15, 1987, will be treated as the date of notification of the jurisdictional agency's tight formation determination.[10] Thus the 45 day period will run from the date of the *Williston Basin* mandate. The Commission is hereby acting within the 45 days by issuing this notice of preliminary finding.[11]

The Commission Orders

(A) Pursuant to section 18 CFR 275.202(a)(i)(ii) (1987) and section 503(b)(2)(A) of the NGPA the Commission issues notice of a preliminary finding that the determination is not consistent with information which is contained in the public recording of the Commission and which was not part of the record on which the jurisdictional agency made its determination.

(B) Pursuant to section 18 CFR 275.202(f) (1987), jurisdictional agencies, interested parties, or any person may, within 30 days after issuance of the preliminary finding, submit written comments and request an informal conference with the Commission staff.

By the Commission.

Kenneth F. Plumb,

Secretary.

[FR Doc. 87-17845 Filed 8-5-87; 8:45 am]

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[10] Although the general rule is to apply court decisions retroactively, the Supreme Court in *Chevron Oil Co. v. Huson*, 404 U.S. 97 (1971) enumerated three factors which should be weighed in determining whether to apply a particular judicial construction prospectively. First, any decision which establishes a new principle of law may be prospectively applied. The second factor is whether retroactive operation of the rule will further or retard the purpose and effect of the rule. The third factor involves equitable considerations. Using this test, the Commission concludes that the *Williston Basin* decision should be applied prospectively only. The decision established a new principle of law; retroactive application of the decision would retard the purpose of the rule because unsupported jurisdictional agency determinations which have been pending before the Commission for more than 45 days would otherwise be considered final; and such a result would be inequitable.

[11] Pursuant to section 553(d) of the Administrative Procedure Act, the Commission's new rule concurrently issued in Docket No. RM87-31-000 will be effective immediately except for the information collection provisions in § 271.703(c)(3) and (c)(4) which have been submitted to the Office of Management and Budget for approval. When these information collection provisions are approved by the office of Management and Budget, the Commission will issue a notice in the **Federal Register** with the effective date for these information.

[Docket Nos. CP87-443-000 et al.]

Natural Gas Certificate Filings; Southern Natural Gas Co. et al.

July 31, 1987.

Take notice that the following filings have been made with the Commission:

1. Southern Natural Gas Co.

[Docket No. CP87-443-000]

Take notice that on July 14, 1987, Southern Natural Gas Company (Southern), P.O. Box 2563, Birmingham, Alabama 35202-2563, filed in Docket No. CP87-443-000 an application pursuant to section 7(c) of the Natural Gas Act for a limited-term certificate of public convenience and necessity for a term expiring on October 2, 1988, authorizing the transportation of natural gas for the City of Cartersville, Georgia (Cartersville), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Southern proposes, to transport gas on an interruptible basis, for Cartersville in accordance with the terms and conditions of a tranportation agreement between Cartersville and Southern dated June 29, 1987.

Subject to the receipt of all necessary governmental authorizations, Southern states that it has agreed to transport on an interruptible basis up to 10,800 MMBtu of gas per day purchased by Cartersville from SNG Trading Inc., and Exxon Corporation, U.S.A. Southern requests that the Commission issue a limited-term certificate for a term expiring October 31, 1988.

Southern states that the agreement provides for gas to be delivered to Southern for transportation at the various existing points on Southern's contiguous pipeline system specified in Exhibit A to the agreement. Southern states that it will redeliver to Cartersville at the City of Cartersville Meter Station located in Floyd County, Georgia, an equivalent quantity of gas less 3.25 per cent of such amount which shall be deemed to be used as compressor fuel and company-use gas (including system unaccounted-for gas losses), less and all shrinkage, fuel or loss resulting from or consumed in the processing of gas and less Cartersville's pro-rate share of any gas delivered for Cartersville's account which is lost or vented for any reason.

Southern states that Cartersville has agreed to pay Southern each month the following transportation rates:

(a) Where the aggregate of the volumes transported and redelivered by Southern on any day to Cartersville under any and all transportation agreements with Southern, when added to the volumes of gas delivered under Southern's Rate Schedule OCD on such day to Cartersville does not exceed the daily contract demand of Cartersville, the transportation rate would be 48.2 cents per MMBtu; and

(b) Where the aggregate of the volumes transported and redelivered by Southern on any day to Cartersville under any and all transportation agreements with Southern, when added to the volumes of gas delivered under Southern's Rate Schedule OCD on such day to Cartersville exceeds the daily contract demand of Cartersville, the transportation rate for the excess volumes would be 77.6 cents per MMBtu.

Southern proposes to collect from Cartersville the GRI surcharge of 1.52 cents per Mcf or any such other GRI funding unit or surcharge as hereafter prescribed.

Southern states that the transportation arrangement would enable Cartersville to diversify its natural gas supply sources and to obtain gas at competitive prices. In addition, Southern states that it would obtain take-or-pay relief on gas that Cartersville may obtain from its suppliers.

Comment Date: August 21, 1987, in accordance with Standard Paragraph F at the end of this notice.

2. Consolidated Gas Transmission Corp.

[Docket No. CP87-447-000]

Take notice that on July 15, 1987, Consolidated Gas Transmission Corporation (Consolidated), 445 West Main Street, Clarksburg, West Virginia 26301, filed in Docket No. CP87-447-000 an application pursuant to section 7(c) of the Natural Gas Act, for a certificate of public convenience and necessity authorizing the rendition of a long-term storage service for Tennessee Gas Pipeline Company, a Division of Tenneco, Inc. (Tennessee), as more fully set out in the application which is on file with the Commission and open to public inspection.

Consolidated states that the proposed storage service consists of a storage capacity quantity of 12,000,000 dt and a storage demand quantity of 80,000 dt. Consolidated further states that the storage service proposed is to be rendered on a firm basis under and in accordance with Consolidated's Rate Schedule GSS contained in its effective FERC Gas Tariff or any effective superseding rate schedule. Consolidated indicated that the proposed service would be rendered under a contract the term of which commences April 1, 1988, and continues for a term of twenty years.

Consolidated states that no additional facilities are proposed or required to be constructed in connection with the service proposed in this application. Consolidated states further that deliveries of Gas to Consolidated for Tennessee's account for injection, and by Consolidated for Tennessee's account upon withdrawal would be made at an existing interconnection between the pipeline facilities of Consolidated and Tennessee in Kanawha County, West Virginia, known as the Broad Run Measuring Station.

Comment Date: August 21, 1987, in accordance with Standard Paragraph F at the end of this notice.

3. Northwest Pipeline Co.

[Docket No. CP86-166-002]

Take notice that on July 21, 1987, Northwest Pipeline Corporation (Northwest), 295 Chipeta Way, Salt Lake City, Utah 84108, filed in Docket No. CP86-166-002, its petition to amend the Commission's December 24, 1985, order in Docket No. CP86-166-000 to extend the term of the limited-term certificate of public convenience and necessity authorizing Northwest to transport natural gas for the account of J. R. Simplot Company (Simplot); all as more fully set forth in the petition on file with the Commission and open to public inspection.

It is stated that the Commission's order issued December 24, 1985 in Docket No. CP86-166-000 (33 FERC ¶62,464) authorized Northwest to transport, on an interruptible basis, up to 30,000 MMBtu's of natural gas per day for the account of Simplot pursuant to a gas transportation agreement (transportation agreement) dated October 30, 1985, for a term of two years commencing with initial delivery. Northwest states that since service commenced thereunder on June 8, 1986, certificate authority expires June 8, 1988. It is stated that under the transportation agreement, Northwest would transport Simplot's gas supplies and redeliver the gas for Simplot's account to either Intermountain Gas Company (Intermountain) at existing interconnections in Idaho or to Cascade Natural Gas Company (Cascade) at an existing interconnection in Oregon. Northwest indicates that Intermountain and Cascade would then redeliver the gas to various Simplot fertilizer and potato processing plants in Idaho and Oregon.

It is said that, by an amendment dated June 25, 1987, to the transportation agreement, Northwest and Simplot agreed to extend the term of the transportation agreement for an additional term, expiring June 11, 1991.

Northwest requests the Commission to amend its December 24, 1985, order to authorize Northwest to continue to transport natural gas for Simplot under the transportation agreement, as amended, for an additional term expiring June 11, 1991.

Other than the extension of term, Northwest proposes no change in the above-described existing transportation service. Northwest indicates it would continue to charge its previously-approved interruptible incremental on-system transportation rate (T-4) and its interruptible replacement on-system transportation rate (T-5) under Volume No. 2 of its tariff.

Comment date: August 21, 1987, in accordance with the first subparagraph of Standard Paragraph F at the end of this notice.

4. Northwest Pipeline Corp.

[Docket No. CP87-449-000]

Take notice that on July 16, 1987, Northwest Pipeline Corporation (Northwest), P.O. Box 8900, Salt Lake City, Utah 84108, filed in Docket No. CP87-449-000 an application pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the transportation of natural gas for the account of Washington Natural Gas Company (Washington Natural), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

It is stated that Washington Natural has acquired Canadian and domestic supplies of natural gas which it desires to have transported by Northwest pursuant to a transportation agreement dated June 2, 1987, providing for transportation service under Rate Schedules T-4 and T-5 of Northwest's FERC Gas Tariff Volume 1-A. Northwest states that it would transport up to 100,000 MMBtu's per day of natural gas for a term commencing with initial delivery and terminating October 31, 1989.

Northwest states that the Canadian gas supplies would be tendered to it for transportation at its interconnection with Westcoast Transmission Company Limited at the international boundary near Sumas, Washington or at its interconnection with Pacific Gas Transmission Company near Stanfield, Oregon.

It is stated that the domestic gas supplies would be tendered to Northwest for transportation at the following points: interconnections with Mountain Fuel Resources Inc. at Crossover 16 in Sweetwater County, Wyoming and Red Wash in Uintah County, Utah; the interconnection with Utah Gas Service Company near Jensen, Utah; the interconnections with Rocky Mountain Natural Gas Company at South Canyon in Mesa County, Colorado and Piceance in Rio Blanco County, Colorado; the Papoose Canyon mainline receipt point from Santa Fe Energy in Delores County, Colorado; the interconnections between Northwest's gathering facilities and Northwest's mainline at North Douglas Creek and Foundation Creek in Rio Blanco County, Colorado and at Corcoran Point in Garfield County, Colorado; and the outlets of Northwest's Opal Gasoline Plant in Lincoln County, Colorado and Ignacio Gasoline Plant in LaPlata County, Colorado.

Northwest proposes to transport and deliver the natural gas, on an

interruptible basis, for the account of Washington Natural, to the existing meter stations in the State of Washington where Northwest states it is presently authorized to make deliveries to Washington Natural under Northwest's ODL-1 sales rate schedule. Northwest further proposes to provide the transportation service for a limited-term expiring on October 31, 1989. Also, Northwest requests authorization to allow Washington Natural the flexibility to switch to new suppliers behind any of the authorized transportation receipts points.

Northwest states that Washington Natural, as a local distribution company subject to the jurisdiction of the Washington Utilities and Transportation Commission, would deliver the subject natural gas to 86 specific end-users.

Comment date: August 21, 1987, in accordance with Standard Paragraph F at the end of this notice.

5. Southern Natural Gas Co.

[Docket No. CP86-306-002]

Take notice that on July 9, 1987, Southern Natural Gas Company (Southern), P.O. Box 2563, Birmingham, Alabama 35202-2563 filed in Docket No. CP86-306-002 a petition to amend the order issued June 13, 1986, as extended by order issued September 11, 1986, pursuant to section 7(c) of the Natural Gas Act, all as more fully set forth in the petition to amend which is on file with Commission and open to public inspection.

By its Order Issuing Limited-Term Certificates issued June 13, 1986, and its Order Extending Certificates issued September 11, 1986, in this proceeding, the Commission authorized Southern to provide interruptible transportation of up to 310 billion Btu equivalent of natural gas per day for Atlanta Gas Light Company (Atlanta) for a term expiring June 13, 1988.

In its petition to amend which is the subject of the present filing, Southern, in accordance with an amended agreement with Atlanta, requests that the Commission authorize the addition of 37 redelivery points or areas in Georgia. According to Southern the addition of these redelivery points would allow the gas that is transported by Southern for Atlanta to be accessible at all points on Atlanta's distribution system.

Comment date: August 21, 1987, in accordance with the first subparagraph of Standard Paragraph F at the end of this notice.

6. Southern Natural Gas Co.

[Docket No. CP86-318-002]

Take notice that on July 14, 1987, Southern Natural Gas Company (Southern), P.O. Box 2563, Birmingham, Alabama 35202-2563, filed in Docket No. CP86-318-002 a petition to amend the order issued June 13, 1986, as extended by order issued September 11, 1986, and June 5, 1987, pursuant to section 7(c) of the Natural Gas Act, all as more fully set forth in the petition to amend which is on file with the Commission and open to public inspection.

By its Order Issuing Limited-Term Certificates issued June 13, 1986, and its Order Extending Certificates issued September 11, 1986, and June 5, 1987 in this proceeding, the Commission authorized Southern to provide interruptible transportation of up to 80 billion Btu equivalent of natural gas per day for South Carolina Pipeline Corporation (South Carolina) for a term expiring October 31, 1988.

In its petition to amend which is the subject of the present filing, Southern, in accordance with an amended agreement with South Carolina, requests that the transportation quantity authorized in the certificate be increased to 160 billion Btu equivalent per day. Southern states that South Carolina has arranged to obtain additional sources of supply of natural gas, and that the amended transportation is proposed to transport these additional supplies.

Comment date: August 21, 1987, in accordance with the first subparagraph of Standard Paragraph F at the end of this notice.

7. Trunkline Gas Co.

[Docket No. CP87-441-000]

Take notice that on July 13, 1987, Trunkline Gas Company (Trunkline), P.O. Box 1642, Houston, Texas 77251-1642, filed in Docket No. CP87-441-000, an application pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the sale of natural gas to the Hardeman-Fayette Utility District (Hardeman) for distribution and resale in Fayette County, Tennessee, as well as the construction and operation of facilities necessary to provide such sale, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Trunkline proposes to sell a maximum of 3,800 Mcf of natural gas per day to Hardeman under its Rate Schedule SG-1 for Small General Service Customers in its FERC Gas Tariff, Original Volume No. 1. It is stated that Hardeman is a public utility district which serves industrial and residential end-users and is expanding its current service into a new area in Fayette County, Tennessee.

Trunkline proposes to deliver the gas to Hardeman at two points of delivery referred to as the Piperton point and the Canadaville point. Trunkline states that the authorization to establish the Piperton point is requested in Docket No. CP87-413-000 under the blanket certificate authorization; however, Trunkline requests authorization in the subject filing to construct and operate additional facilities necessary to provide the sale of gas to Hardeman at the Piperton point. In addition, Trunkline requests authorization to establish the Canadaville point as well as to construct and operate the necessary facilities in order to also deliver the sale gas to Hardeman at the new Canadaville point. Trunkline states that the cost of facilities would be $223,000 which would be financed from funds on hand.

Trunkline projects that the distribution of the maximum daily quantity of 3,800 Mcf per day between the delivery points would be approximately 2,300 Mcf per day to the Piperton point and 1,500 Mcf per day to the Canadaville point. Trunkline states that the sale of natural gas to Hardeman for resale would be for a primary term through November 1, 1993 and for successive terms of twelve months thereafter, subject to termination by either party upon 18 months prior notice.

Comment date: August 21, 1987, in accordance with Standard Paragraph F at the end of this notice.

Standard Paragraphs

F. Any person desiring to be heard or make any protest with reference to said filing should on or before the comment date file with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceedings. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal

Energy Regulatory Commission by sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this filing if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for the applicant to appear or be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 87-17846 Filed 8-5-87; 8:45 am]

BILLING CODE 6717-01-M

[Project Nos. 9642-001 et al.]

Surrender of Preliminary Permits; Hydrodynamics, Inc., et al.

July 31, 1987.

Take notice that the following prelimiary permits have been surrendered effective as described in Standard Paragraph I at the end of this notice.

1. Hydrodynamics, Inc.

[Project No. 9642-001]

Take notice that Hydrodynamics, Inc., permittee for the proposed East Bench Project, has requested that its preliminary permit be terminated. The permit was issued on April 28, 1986, and would have expired on March 31, 1989. The project would have been located on Rock Creek Clear Ditch near the town of Red Lodge, in Carbon County, Montana.

The permitted filed the request on June 23, 1987.

2. Hydrodynamics, Inc.

[Project No. 9644.001]

Take notice that Hydrodynamics, Inc., permittee for the proposed Scotch Coulee Project, has requested that its preliminary permit to be terminated. The permit was issued on April 28, 1986, and would have expired on March 31, 1989. The project would have been located on Rock Creek Clear Creek Ditch near the town of Red Lodge, in Carbon County, Montana.

The permittee filed the request on June 25, 1987.

3. Tongue River Limited Partnership

[Project No. 9536.001]

Take notice that Tongue River Limited Partnership, Permittee for the Tongue River Project No. 9536, has requested that its preliminary permit to be terminated. The preliminary permit for Project No. 9536 was issued April 14, 1986, and would have expired on March 31, 1989. The project would have been located on Tongue River at the State of Montana owned Tongue River Dam in Big Horn County, Montana.

The permittee filed the request on July 6, 1987.

4. River Street Associates

[Project No. 9559.001]

Take notice that River Street Associates, permittee for the Gurnsey Dam Project No. 9559, has requested the preliminary permit to be terminated. The preliminary permit for Project No. 9559 was issued on April 28, 1986, and would have expired on March 31, 1989. The project would have been located on the Nubanusit River, In Hillsboro County, New Hampshre.

The permitted filed the request on May 4, 1987.

Standard Paragraphs

I. The preliminary permit shall remain in effect through the thirtieth day after issuance of this notice unless that day is a Saturday, Sunday or holiday as described in 18 CFR 385.2007 in which case the permit shall remain in effect through the first business day following that day. New applications involving this project site, to the extent provided for under 18 CFR Part 4, may be filed on the next business day.

Kenneth F. Plumb,

Secretary.

[FR Doc. 87-17847 Filed 8-5-87; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. QF87-529-000]

Application for Commission Certification of Qualifying Status of a Cogeneration Facility; Ada Cogeneration

July 30, 1987.

On July 14, 1987, Ada Cogeneration (Applicant), of 320 Lennon Lane, Walnut Creek, California 94598 submitted for filing an application for certification of a facility as a qualifying cogeneration facility pursuant to § 292.207 of the Commission's regulations. No determination has been made that the submittal constitutes a complete filing.

The topping-cycle cogeneration facility will be located in Ada, Michigan and will consist of a combustion turbine generator, a heat recovery steam generator, and an extraction/condensing steam turbine generator. Thermal energy recovered from the facility in the form of steam will be used for space heating, hot water production and various manufacturing, chemical processing and packaging by Amway Corporation. The electric power production capacity of the facility is 20.6 MW. The primary energy source will be natural gas. Construction of the facility is expected to commence in mid-1988.

Any person desiring to be heard or objecting to the granting of qualifying status should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure. All such petitions or protests must be filed within 30 days after the date of publication of this notice and must be served on the applicant. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 87-17848 Filed 8-5-87; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. QF85-621-001]

Application for Commission Certification of Qualifying Status of a Small Power Production Facility; Pennsylvania Renewable Resources Associates

July 30, 1987.

On July 16, 1987, Pennsylvania Renewable Resources Associates (Applicant), of c/o United American Energy Corp., 50 Tice Boulevard, Woodcliff Lake, New Jersey 07675 submitted for filing an application for certification of a facility as a qualifying small power production facility pursuant to § 292.207 of the Commission's regulations. No determination has been made that the submittal constitutes a complete filing.

The 15 MW hydroelectric facility (FERC P. 3207) is located near the Conemaugh River and Lake in Westmoreland County, Pennsylvania.

Recertification is requested due to a change in ownership of the facility. Under the instant application, the

ownership of the facility will be transferred from Borough of Saltsburg, Pennsylvania and Pennsylvania Renewable Resources Associates to Pennsylvania Renewable Resources Associates.

Any person desiring to be heard or objecting to the granting of qualifying status should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure. All such petitions or protests must be filed within 30 days after the date of publication of this notice and must be served on the applicant. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

A separate application is required for a hydroelectric project license, preliminary permit or exemption from licensing. Comments on such applications are requested by separate public notice. Qualifying status serves only to establish eligibility for benefits provided by PURPA, as implemented by the Commission's regulations, 18 CFR Part 292. It does not relieve a facility of any other requirements of local, State or Federal law, including those regarding siting, construction, operation, licensing and pollution abatement.

Kenneth F. Plumb,

Secretary.

[FR Doc. 87-17849 Filed 8-15-87; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TA87-3-46-006]

PGA Rate Change Filing; ANR Pipeline Co.

July 31, 1987.

Take notice that on July 28, 1987 ANR Pipeline Company ("ANR"), pursuant to Section 15 of the General Terms and Conditions of its F.E.R.C. Gas Tariff, Original Volume No. 1, tendered for filing with the Federal Energy Regulatory Commission ("Commission") the following tariff sheets:

Tenth Revised Sheet No. 18

Tenth Revised Sheet No. 18 reflects a 8.56¢ per dekatherm ("dth") increase in the gas cost component of the commodity rate of ANR's CD-1 and MC-1 Rate Schedules, a decrease of $0.408 in the monthly demand rate of CD-1 and MC-1 Rate Schedules and an increase of ANR's one-part rates applicable to Rate Schedules SGS-1 and LVS-1 of 2.09¢ and 6.60¢ respectively, per dth.

In this tariff filing, ANR is revising its demand and commodity rates to reflect cost functionalization and classification consistent with Opinion Nos. 256 and 256A with respect to ANR's Canadian gas costs. In the absence of specific guidance from the Commission, ANR has undertaken to estimate such cost functionalization and classification, with the benefit of only limited information from its Canadian suppliers.

ANR states that copies of the filing were served upon all of its jurisdictional customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before August 7, 1987. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 87-11850 Filed 8-5-87; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. TA87-2-23-005, 006 and RE87-61-001]

Tariff Filing; Eastern Shore Natural Gas Co.

July 30, 1987.

Take notice that Eastern Shore Natural Gas Company (Eastern Shore) on July 22, 1987, tendered for filing the following tariff sheets to Original Volume No. 1 of its FERC Gas Tariff:

Revised Tariff Sheets—Docket No. TA87-2-23-000, et al.

Third Substitute Second Alternate Thirty-Third Revised Sheet No. 5
Third Substitute Second Alternate Thirty-Third Revised Sheet No. 6
Third Substitute Second Alternate Thirty-Third Revised Sheet No. 10
Third Substitute Second Alternate Thirty-Third Revised Sheet No. 11
Third Substitute Second Alternate Thirty-Third Revised Sheet No. 12
Third Substitute Second Alternate Tenth Revised Sheet No. 13
Substitute Second Alternate Fourth Revised Sheet No. 14
Substitute Thirty-Fifth Revised Sheet No. 5
Substitute Thirty-Fifth Revised Sheet No. 6
Substitute Thirty-Fifth Revised Sheet No. 10
Substitute Thirty-Fifth Revised Sheet No. 11
Substitute Thirty-Sixth Revised Sheet No. 12
Substitute Twelfth Revised Sheet No. 13
Substitue Sixth Revised Sheet No. 14

Substitute Revised Tariff Sheets in Docket No. RP87-61-000

Substitute Thirty-Fourth Revised Sheet No. 5
Substitute Thirty-Fourth Revised Sheet No. 6
Substitute Thirty-Fourth Revised Sheet No. 10
Substitute Thirty-Fourth Revised Sheet No. 11
Substitute Thirty-Fifth Revised Sheet No. 12
Substitute Eleventh Revised Sheet No. 13
Substitute Fifth Revised Sheet No. 14

Eastern Shore states that the purpose of the tariff sheets is to (1) revise certain tariff sheets in compliance with the Commission's June 19, 1987 order in Docket No. TA87-2-23-000, *et al.*, and (2) re-submit its June 4, 1987 filing in compliance with the Commission's May 22, 1987 order in Docket No. RP87-61-000.

On July 27, 1987, Eastern Shore filed the following tariff sheets to its FERC Gas Tariff, Original Volume No. 1:

Docket No. TA87-2-23-000 et al.

Fourth Substitute Second Alternate Thirty-Third Revised Sheet No. 11

Docket No. RP87-61-000

Second Substitute Thirty-Fourth Revised Sheet No. 5
Second Substitute Thirty-Fifth Revised Sheet No. 12

Eastern Shore states that the purpose of the July 27th filing was to correct mathematical calculations on the tariff sheets previously filed on July 22, 1987.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 214 and 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.214,

385.211). All such motions or protests should be filed on or before August 7, 1987. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 87-17851 Filed 8-5-87; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CI87-554-000]

Application for Limited-Term Abandonment with Pregranted Abandonment for Sales Under Small Producer Certificate; Horace F. McKay, Jr.

July 30, 1987.

Take notice that on May 1, 1987, as supplemented on May 11, 1987, June 1, 1987, and June 23, 1987, Horace F. McKay, Jr. (McKay) filed an application pursuant to Section 7(b) of the Natural Gas Act (NGA) and § 2.77 of the Commission's rules for a three-year limited-term abandonment of his sale of gas to El Paso Natural Gas Company (El Paso) from the McKay #1 Well, located in the Bloomfield Field, San Juan County, New Mexico. McKay also requests a three-year pregranted abandonment for sales of such gas under his small producer certificate in Docket No. CS71-969.

In support of his application McKay states the well has been shut-in due to market conditions for the majority of 1986 and 1987, and he is subject to substantially reduced takes without payment.[1] By letter agreement dated May 1, 1987, El Paso agreed to release the subject gas upon receipt by McKay of appropriate abandonment authority from the Commission. McKay proposes to sell instead to Sunshine Energy Company under a February 1, 1987, contract, as amended by letter agreement dated April 24, 1987. The estimated deliverability is 40 Mcf/d. The gas is NGPA section 104 post-1974 gas.

Since McKay indicates his well is shut-in without payment and has requested that his application be considered on an expedited basis, all as more fully described in the application which is on file with the Commission and open to public inspection, any person desiring to be heard or to make any protest with reference to said application should on or before 15 days after the date of publication of this notice in the **Federal Register**, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party in a proceeding must file a petition to intervene in accordance with the Commission's rules.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for McKay to appear or to be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 87-17852 Filed 8-5-87; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. CI87-555-000 and CI87-572-000]

Applications for Limited-Term Partial Abandonment, Blanket Limited-Term Certificate with Pregranted Abandonment and Limited-Term Pregranted Abandonment for Sales Under Small Producer Certificate; SPG Exploration Corp., et al., Kerr-McGee Corp.

July 30, 1987.

Take notice that on May 21, 1987, as supplemented on June 2 and July 17, 1987, SPG Exploration Corp. and Kerr-McGee Corporation (Applicants) filed an application in Docket No. CI87-555-000 requesting limited-term partial abandonment through January 1, 1989, of sales of excess gas owned by Applicants and their co-owners[1] to Northern Natural Gas Company, Division of Enron Corp. (Northern). The application also requests that for sales of the released gas to other purchasers, SPG Exploration Corp. receive pregranted abandonment authorization through January 1, 1989, under the small producer certificate in Docket No. CS75-396, and in Docket No. CI87-572-000, Kerr-McGee Corporation receive a blanket limited-term certificate through January 1, 1989, with pregranted abandonment.

Applicants state expedited relief is sought for the reason that takes of gas under the terms of the Gas Purchase Contracts have been substantially reduced below the deliverability test amounts as filed with the Texas Railroad Commission. Applicants have not received any take-or-pay payments as a result of reduced takes, and Northern disputes Applicants' claim that such payments should be made as a result of the reduced takes. Applicants request that their application be considered on an expedited basis under procedures established by Order No. 436, Docket No. RM85-1-000, at 18 CFR 2.77.[2] Deliverability is approximately 15,449 Mcf/d. The gas is NGPA section 104 flowing (66%), certain Permian Basin gas (6%), 1973-1974 biennium (7%) and post 1974 gas (8%), 107 (c)(5) (6%) and 108 (7%) gas.

Since SPG states that it is subject to substantially reduced takes without payment and has requested that its applications be considered on an expedited basis, all as more fully described in the attached tabulation and in the applications which are on file with the Commission and open to public inspection, any person desiring to be heard or to make any protest with reference to said application should on or before 15 days after the date of publication of this notice in the **Federal Register**, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All protests filed with the Commission will be considered by it in determining the appropriate action to

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[1] The United States Court of Appeals for the District of Columbia vacated the Commission's Order No. 436 on June 23, 1987. In vacating Order No. 436, the Court rejected challenges to the Commission's statement of policy in § 2.77 of its Regulations. Section 2.77 states that the Commission will consider on an expedited basis applications for certificate and abandonment authority where the producers assert they are subject to substantially reduced takes without payment.

[1] Applicants state that the gas is produced from various interests and attributable to other owners having interests in the same wells as either or both of Applicants to the extent that such other owners agree to same.

[2] The United States Court of Appeals for the District of Columbia vacated the Commission's Order No. 436 on June 23, 1987. In vacating Order No. 436, the Court rejected challenges to the Commission's statement of policy in § 2.77 of its Regulations. Section 2.77 states that the Commission will consider on an expedited basis applications for certificate and abandonment authority where the producers assert they are subject to substantially reduced takes without payment.

be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party in any proceeding herein must file a petition to intervene in accordance with the Commission's rules.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for SPG to appear or to be represented at the hearing.

Kenneth F. Plumb,
Secretary.

Docket No. and date filed	Applicant	Purchaser and location	Price per Mcf	Pressure base
CI87-555-000	SPG Exploration Corp, et al.[2] 100 NE. Loop 410, Suite 1400, One International Centre, San Antonio, Texas 72816-4797.	Northern Natural Gas Company, Division of Enron Corp.[3], Sawyer Canyon Field, Sutton County, Texas.		
		Hunt Baggett Strawn, Ozona Canyon and Thomason Strawn Fields.		
(CI86-546-000)	Kerr McGee Corporation, P.O. Box 25861, Oklahoma City, Okla. 73125.	Ozona Canyon, Ozona SW. Strawn, Ozona E. Ellenberger and Penn 7890 Fields.		
(CI86-547-000)		Penn 7890 and Canyon 6200 Fields		
(CI86-553-000)		Penn 7890 Field		
(CI86-554-000)		Hunt Baggett Strawn and Ozona Canyon Fields, Crockett County, Texas.		
B, May 1, 1987 [1]				
CI87-572-000, A, May 21, 1987 [5].	Kerr-McGee Corporation, P.O. Box 25861, Oklahoma City, Okla. 73125.	Various Purchasers [4], Various Fields, Sutton and Crockett Counties, Texas.		

[1] Additional material received June 2 and July 17, 1987.

[2] Applicants state that the gas is produced from various interests and attributable to other owners having interests in the same wells as either or both of Applicants to the extent that such other owners agree to same.

[3] Applicants request limited-term partial abandonment through January 1, 1989, of sales of gas in excess of Northern's requirements. SPG requests limited-term pregranted abandonment through January 1, 1989, for sales under the small producer certificate in Docket No. CS75-396. The purpose of the abandonment is to maximize production of the wells involved by entering into alternate marketing arrangements to sell this excess gas. In support of their application, Applicants state that they are subject to reduced takes without payment.

[4] Kerr-McGee requests a blanket limited-term certificate with pregranted abandonment through January 1, 1989 to make sales for resale in interstate commerce of the gas attributable to its interest which is released in Docket No. CI87-555-000.

[5] The application was received May 1, 1987. The filing date is the date the filing fee was received.

Filing Code: A—Initial Service; B—Abandonment; C—Amendment to add acreage; D—Amendment to delete acreage; E—Total Succession; F—Partial Succession.

[FR Doc. 87-17853 Filed 8-5-87; 8:45 am]
BILLING CODE 6717-01-M

[Docket Nos. RP87-26-007 and RP87-26-008]

Filing of Revised Tariff Sheets; Tennessee Gas Pipeline Co., a Division of Tenneco, Inc.

July 30, 1987.

Take notice that on July 22, 1987, Tennessee Gas Pipeline Company (Tennessee) tendered for filing the following revised tariff sheets to Second Revised Volume No. 1 of its FERC Gas Tariff, to be effective as indicated:

Tariff Sheets and Effective Date

First Revised Sheet No. 46, August 21, 1987
First Revised Sheet Nos. 106-112, 116, August 21, 1987
Original Sheet Nos. 117-199, August 21, 1987
First Revised Sheet Nos. 205-207, August 21, 1987
First Revised Sheet No. 208, December 10, 1986
Original Sheet Nos. 208A and 208B, December 10, 1986
First Revised Sheet No. 211, August 21, 1987
First Revised Sheet Nos. 247-252, August 21, 1987
Original Sheet Nos. 253-299, August 21, 1987
First Revised Sheet Nos. 333-348, August 21, 1987
Original Sheet No. 349, August 21, 1987

Tennessee states that it is filing these revised tariff sheets in response to comments and concerns raised at the informal technical conference in this proceeding on February 19, 1987, and to operational situations that have arisen during the six months Tennessee has been an open-access transporter under the terms of Order No. 436. On July 27, 1987, Tennessee filed First Revised Sheet Nos. 113, 114, 115, which had been inadvertently omitted from the July 22nd filing.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 214 and 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.214, 385.211). All such motions or protests should be filed on or before August 7, 1987. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file

with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 87-77854 Filed 8-5-87; 8:45 am]

BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL-3243-4]

Ambient Air Monitoring Reference and Equivalent Methods; Receipt of Application for a Reference Method Determination

Notice is hereby given that on July 14, 1987, the Environmental Protection Agency received an application from Wedding & Associates, Inc., P.O. Box 1756, Fort Collins, Colorado 80522, to determine if its PM_{10} Critical Flow High-Volume Sampler should be designated by the Administrator of the EPA as a reference method under 40 CFR Part 53 (40 FR 7049, 41 FR 11255, 52 FR 24727). If, after appropriate technical study, the Administrator determines that this method should be so designated, notice thereof will be given in a subsequent issue of the **Federal Register.**

Vaun A. Newill,

Assistant Administrator for Research and Development.

[FR Doc. 87-17883 Filed 8-5-87; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL COMMUNICATIONS COMMISSION

Information Collection Requirement Approval by Office of Management and Budget

July 31, 1987.

The following information collection requirements have been approved by the Office of Management and Budget under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507). For further information contact Terry Johnson, Federal Communications Commission, telephone (202) 632-7513.

OMB No.: 3060-0113.

Title: Equal Employment Opportunity Program—10 Point Model Program and Guidelines.

Form No.: FCC 396.

OMB No.: 3060-0120.

Title: Equal Employment Opportunity Program—5 Point Model Program and Guidelines.

Form No.: FCC 396-A.

OMB No.: 3060-0212.

Title: Section 73.2080—Equal Employment Opportunity Program.

The approval on the above three information collections has been extended through 1/31/88 and they will remain in effect until that time, or until superseded by revised EEO program requirements which are currently under review at OMB.

Federal Communications Commission.

William J. Tricarico,

Secretary.

[FR Doc. 87-17896 Filed 8-5-87; 8:45 am]

BILLING CODE 6712-01-M

Public Information Collection Requirement Submitted to Office of Management and Budget for Review

July 31, 1987.

The Federal Communications Commission has submitted the following information collection requirement to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act (44 U.S.C. 3501 et seq.).

Copies of the submission may be purchased from the Commission's copy contractor, International Transcription Service, (202) 857-3800, 2100 M Street NW., Suite 140, Washington, DC 20037. For further information on this submission contact Jerry Cowden, Federal Communications Commission, (202) 632-7513. Persons wishing to comment on this information collection should contact J. Timothy Sprehe, Office of Management and Budget, Room 3235 NEOB, Washington, DC 20503, (202) 395-4814.

OMB Number: None.

Title: Monitoring Program for Impact of Federal-State Joint Board Decisions.

Action: New collection.

Respondents: Telephone companies and state utility regulatory commissions.

Frequency of Response: Quarterly and annual reporting requirements.

Estimated Annual Burden: 890 Responses; 3,650 Hours.

Needs and Uses: The Commission is proposing to collect from telephone companies and state utility regulatory commissions information on: (1) Lifeline assistance programs, (2) telephone network usage and growth, (3) rate cases brought by large telephone companies before state regulatory commissions, and (4) jurisdictional shifts in revenue requirements. This information will be used by the Commission, Joint Board, Congress, and the public to assess the impact of several Federal-State Joint Board decisions.

Federal Communications Commission.

William J. Tricarico,

Secretary.

[FR Doc. 87-17897 Filed 8-5-87; 8:45 am]

BILLING CODE 6712-01-M

Specialized Mobile Radio Service Frequencies To Be Available for Reassignment

July 22, 1987.

The following channels were recently recovered from licensees who failed to meet the Commission's loading or construction requirements and will be available for reassignment to trunked Specialized Mobile Radio (SMR) applicants. They were previously licensed at the coordinates indicated and are available at any location within the geographic area which will protect existing SMR systems pursuant to Rules 90.362 and 90.621.

864.1375, 864.5875, 865.0375, 865.4875, 865.9375 MHz, Buffalo, NY

864.1375, 864.5875, 865.0375, 865.4875, 865.9375 MHz, Rochester, NY

864.0625, 864.5125, 864.9625, 865.4125, 865.8625 MHz, Grand Island, NY

864.0625, 864.5125, 864.9625, 865.4125, 865.8625 MHz, Brighton, NY

864.0875, 864.5375, 864.9875, 865.4375, 865.8875 MHz, Buffalo, NY

863.9875, 864.4375, 864.8875, 865.3375, 865.7875 MHz, Buffalo, NY

863.9875, 864.4375, 864.8875, 865.3375, 865.7875 MHz, Rochester, NY

856/860.5625 MHz, San Antonio, TX, 29-30-28 North, 98-34-09 West

856/860.9000 MHz, Tucson, AZ, 32-08-56 North, 110-52-54 West

856/860.8250 MHz, Tucson, AZ, 32-13-20 North, 110-58-14 West

856/860.7500 MHz, Tucson, AZ, 32-11-45 North, 110-54-28 West

851/854.9375 MHz, Ontario, OH, 40-45-36 North, 82-39-02 West

856/860.1625 MHz, Denver, CO, 39-23-17 North, 105-01-56 West

856/860.1375 MHz, Denver, CO, 39-45-55 North, 105-22-07 West

863.9375, 864.3875, 864.8375, 865.2875, 865.7375 MHz, Erie, PA, 42-02-24 North, 80-04-08 West

Pursuant to the Public Notice of January 6, 1986, Mimeo No. 1805, these channels will be available for reassignment on August 21, 1987. All applications received before August 21, 1987 will be dismissed. The first application received after the channels become available for reassignment opens the filing window. The window stays open only for the day on which the first application is received. *All applications MUST reference the date and DA number of this Public Notice in*

order to be considered for these frequencies.

There is a $30.00 fee required for each application filed. All checks should be made payable to the FCC. Applications should be mailed to: Federal Communications Commission, 800 Megahertz Service, P.O. Box 360416M, Pittsburgh, PA 15251-6416. Applications may also be filed in person between 9:00 AM and 3:00 PM at the following address: Federal Communications Commission, c/o Mellon Bank, Three Mellon Bank Center, 525 William Penn Way, 27th Floor, Room 153-2713, Pittsburgh, PA 15259, Attention: (Wholesale Lockbox Shift Supervisor).

For further information, refer to Public Notice of January 6, 1986 or contact Riley Hollingsworth or Betty Woolford, (202) 632-7125 of the Private Radio Bureau's Land Mobile and Microwave Division.

Federal Communications Commission.

William J. Tricarico,

Secretary.

[FR Doc. 87-17899 Filed 8-5-87; 8:45 am]

BILLING CODE 6712-01-M

Applications for Consolidated Hearing; B&F Broadcasting, Inc., et al.

1. The Commission has before it the following mutually exclusive. applications for a new FM station:

Applicant, city and State	File No.	MM Docket No.
A. B&F Broadcasting, Inc., Clinton, Missouri.	BPH-850617MI	87-270
B. Bott Communications, Inc., Clinton, Missouri.	BPH-850702ME	
C. Progressive Media, Inc., Clinton, Missouri.	BPH-850712XL	
D. Lucile Faye Stevens, Clinton, Missouri.	BPH-850712XM	
E. Cal Broadcasting, Inc., Clinton, Missouri.	BPH-850712CI	
F. Clinton Radio Partnership, Clinton, Missouri.	BPH-850712Z5	

2. Pursuant to section 309(e) of the Communications Act of 1934, as amended, the above applications have been designated for hearing in a consolidated proceeding upon the issues whose headings are set forth below. The text of each of these issues has been standardized and is set forth in its entirety under the corresponding headings at 51 FR 19347, May 29, 1986. The letter shown before each applicant's name, above, is used below to signify whether the issue in question applies to that particular applicant.

Issue Heading and Applicant(s)

1. Air Hazard, A, C
2. Comparative, A, B, C, D, E, F
3. Ultimate, A, B, C, D, E, F

3. If there is any non-standardized issue(s) in this proceeding, the full text of the issue and the applicant(s) to which it applies are set forth in an Appendix to this Notice. A copy of the complete HDO in this proceeding is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street NW., Washington, DC. The complete text may also be purchased from the Commission's duplicating contractor, International Transcription Services, Inc., 2100 M Street NW., Washington, DC 20037. (Telephone (202) 857-3800).

W. Jan Gay,

Assistant Chief, Audio Services Division, Mass Media Bureau.

[FR Doc. 87-17817 Filed 8-5-87; 8:45 am]

BILLING CODE 6712-01-M

Filing of Proposed Revisions to the Average Schedules; National Exchange Carrier Association, Inc. (NECA)

On June 30, 1987, the National Exchange Carrier Association, Inc. ("NECA") filed revisions with supporting documentation to the 1987 average schedules with a proposed effective date of January 1, 1988.

Persons wishing to examine NECA's June 30, 1987 filing may do so at the Commission's Public Reference Room, Room 239, 1919 M St., NW., Washington, DC in CC Docket No. 78-72, Phase I—Average Schedule Companies. Copies of the filing may also be ordered from the International Transcription Service ("ITS"), Room 246, 1919 M St., NW., Washington, DC. ITS may be reached by telephone at 202-857-3800.

Persons wishing to file comments may do so on or before September 15, 1987. Reply comments may be filed on or before October 8, 1987.

For further information contact Kent Nilsson at (202)-632-6363.

Federal Communications Commission.

William J. Tricarico,

Secretary.

[FR Doc. 87-17898 Filed 8-5-87; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL MARITIME COMMISSION

Security for the Protection of the Public Indemnification of Passengers for Nonperformance of Transportation; Issuance of Certificate (Performance)

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation pursuant to the provisions of section 3, Pub. L. 89-777 (80 Stat. 1357, 1358) and Federal Maritime Commission General Order 20, as amended (46 CFR Part 540): Sea Venture Cruises, Inc., 5233 NW., 79th Avenue, Miami, Florida 33166.

Date: August 3, 1987.

Joseph C. Polking,

Secretary.

[FR Doc. 87-17887 Filed 8-5-87; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

[Docket No. R-0607]

Interim Policy Statement Regarding Risks on Large-Dollar Wire Transfer Systems

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Interim policy statement.

SUMMARY: The Board has adopted a statement of an interim policy regarding risks on large-dollar wire transfer systems pending reevaluation of the Board's risk reduction program. This interim policy statement supersedes the policy statement adopted by the Board on May 17, 1985. 50 FR 21120 (May 22, 1985). In addition to matters covered in the earlier statement, the interim policy statement:

- Reduces in two stages the current sender net debit cap by 25 per cent.
- Exempts depository institutions from self-evaluation guidelines if their boards of directors approve a *de minimis* net debit cap of the lesser of 20 per cent of adjusted primary capital or $500,000.
- Imposes a $50 million limit on book-entry securities transfers over Fedwire.
- Provides for review by the Federal Reserve Bank of New York of the clearing procedures of primary dealers.
- Permits inter-affiliate Fedwire transfers resulting in daylight overdrafts, provided certain safeguards are observed, and permits depository institution holding companies to centralize their wire transfer operations at one or more of their subsidiaries, again, provided certain safeguards are observed.

EFFECTIVE DATE: The component parts of the interim policy will take effect as follows:

Cap Reduction: 15 per cent reduction on January 14, 1988; the remainder of the 25 per cent cap reduction on May 19, 1988.

De Minimis Cap: Implementation no later than December 3, 1987; earlier at the discretion of Reserve Banks. Board of director certification required by March 31, 1988.

$50 million Book-Entry Transfer Limit: January 14, 1988.

Inter-affiliate Transfers: No later than June 30, 1988.

FOR FURTHER INFORMATION CONTACT: Edward C. Ettin, Deputy Director (202–452–3368), Division of Research and Statistics; Elliott C. McEntee, Associate Director (202–452–2231), Division of Federal Reserve Bank Operations; Joseph R. Alexander, Senior Attorney (202–452–2489), Legal Division; for the hearing impaired only, Telecommunications Device for the Deaf (202–452–3544), Earnestine Hill or Dorothea Thompson.

SUPPLEMENTARY INFORMATION: The Board of Governors of The Federal Reserve System has issued the following interim policy statement concerning risks on large-dollar electronic funds transfer systems:

Interim Policy Statement Regarding Risks on Large-Dollar Payment Systems [1]

The Board has been concerned for some time about the risks associated with large-dollar payment systems.[2] The Federal Reserve Banks face direct risks of loss should depository institutions [3] be unable to settle their intra-day overdrafts on Fedwire before the end of the day. Moreover, the inability or unwillingness of a participant to settle its net debit position on a private large-dollar network—one that permits its participants to transmit payment messages throughout the day with settlement of net positions at the end of the day—would expose the banking system to systemic risk. The Federal Reserve would bear an indirect risk if it sought to avoid or limit this systemic risk. Systemic risk occurs when institutions unable to settle on private large-dollar payments networks cause their creditors on those networks, in turn, to be unable to settle their own commitments. Serious repercussions could, as a result, spread to other participants in the network, to other depository institutions not even participating in the private network, and to the nonfinancial economy generally. Finally, on either private wire systems or Fedwire, depository institutions create risk by permitting their customers, including other depository institutions, to transfer uncollected balances over wire systems in anticipation of their coverage before the end of the day.

The Board first began to address these risks in 1982 by permitting same-day net settlement at the Federal Reserve Bank of New York by participants in the CHIPS [4] network. In 1985, it adopted the next step in its effort to reduce risk on large-dollar networks by:

(1) Requiring participants in private networks using the Federal Reserve's net settlement service to establish maximum net credit limits they would establish for each other network participant (bilateral net credit limits).

(2) Requiring such networks to establish maximum limits on the net credit positions that all participants could have with any one participant (network net debit caps).

(3) Establishing guidelines by which institutions could evaluate their own ability to settle intra-day payments over Fedwire and private large-dollar wire systems combined; using these guidelines, institutions adopt voluntary limits on their maximum intra-day net debit funds positions across all large-dollar payments systems (cross-system sender net debit caps), approved annually by each institution's board of directors and subject to the primary supervisor's review as part of the examination process.

These and related steps were effective March 27, 1986.

In its 1985 policy statement, the Board indicated its intention to review its policy in late 1986, and to adopt modifications as required. In December, 1986, it published for public comment proposed modifications.[5] After reviewing the public comments and the progress of its risk reduction program to date, the Board has determined to adopt several modifications to its policy on an interim basis while the Board reconsiders the whole of its risk reduction program (see below). The interim policy changes the previous risk reduction policy in the following ways:

- The sender net debit cap multiples will be reduced by 25 per cent in two steps; a 15 per cent reduction will be effective on January 14, 1988, and the balance to 25 per cent below the original cap multiples will take place on May 19, 1988, unless subsequent events suggest the second step would be too disruptive to the payments mechanism or financial markets.
- A Fedwire transfer limit of $50 million on secondary market book-entry securities transfer (effective January 14, 1988) has been adopted. It will be unacceptable to send multiple transfers of $50 million or less with the express purpose of avoiding the limits or intentionally substitute book-entry for funds transfers in order to avoid quantitative limits on overdrafts.
- The Federal Reserve Bank of New York will continue to monitor clearing patterns and policies of primary dealers and will encourage these dealers to adopt practices designed to minimize book-entry overdrafts.
- With board of director approval, depository institutions may exempt themselves from self-evaluation to determine their sender net debit cap if they limit their cross-system funds overdrafts to the lesser of 20 per cent of adjusted primary capital or $500,000. Institutions that chronically exceed this *de minimis* cap, or incur overdrafts without filing a cap, will not be permitted to incur any Fedwire overdrafts. The *de minimis* cap is intended for use by depository institutions incurring only occasional overdrafts. Institutions that incur overdrafts under the *de minimis* policy on a regular basis will be counseled to reduce their frequency of overdrafts or to file a regular cap. Institutions that have not filed any cap by March 31, 1988, will be assigned a cap of zero.
- Depository institutions may transfer funds over Fedwire to affiliates, even when the sending institution incurs an overdraft, so long as the sender's total overdrafts stay within its cap, and provided that the sending institution's

[1] This policy statement supercedes an earlier one issued by the Board on May 17, 1985. 50 FR 21120 (May 22, 1985).

[2] In a changing technological and regulatory environment, it is not possible or desirable to adopt an all inclusive and permanent definition of a "large-dollar payment system" for the purposes of Federal Reserve risk control policy. In determining whether any particular system is a "large-dollar" system, the Board will consider any of the following four factors: (1) The employment of multilateral netting arrangements, (2) the use of same-day settlement, (3) the routine processing of a significant number of individual payments larger than $50,000, and (4) the possibility that any one participant could be exposed to a net debit position at the time of settlement in excess of its capital.

[3] In this policy statement, the terms "depository institution" or "institution" will be used to refer not only to institutions defined as "depository institutions" by 12 U.S.C. 461(b)(1)(A), but also to U.S. branches and agencies of foreign banks and Edge and agreement corporations, unless the context indicates a different reading.

[4] CHIPS (Clearing House Inter-bank Payments System) is a large-dollar network owned and operated by the New York Clearing House.

[5] On December 10, 1986, the Board issued the following six proposals for public comment: book-entry securities transfers (Docket No. R–0587, 51 FR 45046); cap level reductions (Docket No. R–0588, 51 FR 45050); *"de minimis"* caps (Docket No. 0589, 51 FR 45053); limits on inter-affiliate Fedwire transfers (Docket No. R–0590, 51 FR 45054); automated clearing house transactions (Docket No. 0591, 51 FR 45043); and pricing of daylight overdrafts (Docket No. R–0592, 51 FR 45052). All these proposals were published in the December 16, 1986, edition of the Federal Register.

board of directors approves and the primary supervisor finds the arrangement acceptable. (FSLIC-insured institutions are not permitted by the Federal Home Loan Bank Board to adopt such practices.)

• Depository institutions may arrange to send and receive Fedwire transfers for affiliated depository institutions with board of director approval, provided certain safeguards are met.

The Board is well aware that large-dollar networks are an integral part of the payments and clearing mechanism and that it is of vital importance to keep the payments mechanism operating without significant disruption. Indeed, it is precisely because of the importance of avoiding such disruptions that the Board continues to seek to reduce the risks of settlement failures that could cause these disruptions. The Board is also aware, however, that some intra-day credit may be necessary to keep the payments mechanism running smoothly and efficiently. While it is essential to reduce and control intra-day credit risks, this must be done in a manner that will minimize disruptions to the payments mechanism. The Board anticipates that in relying largely on the efforts of individual institutions to identify, control, and reduce their own exposures, and by establishing guidelines for use by institutions, the goal of reducing and controlling risks will not unduly disrupt the smooth operation of the payments mechanism—even with the additional steps the Board has taken.

The Board reemphasizes that it is not condoning daylight overdrafts. While, as noted, some intra-day credit may be necessary, the Board anticipates that, as a result of its policy, there will continue to be a reduction in the number of institutions consistently relying on daylight overdrafts or other intra-day credit to conduct their business. The Board also expects to continue observing, over time, a reduction in the volume of intra-day credit at those institutions with a pattern of substantial reliance on such credit. The Board will continue to monitor the effect of its policy on the payments system and financial markets and anticipates that its Large-Dollar Payments System Advisory Group will advise it if significant disruptions occur from its daylight overdraft policy.

The Board believes that its policy to date has been successful in alerting senior management of depository institutions to the risks involved in extending daylight credit to their customers and in the exposure presented by other depository institutions on private networks. The evidence suggests that most depository institutions have improved operational and credit controls and have been successful in reducing their daylight overdrafts relative to their transactions volume. The Board has taken the additional modest steps described above in order to induce a further reduction. The Board believes that these steps will not result in any disruptions to the payments mechanism.

The additional steps taken by the Board are considerably less stringent than those published for public comment in December, 1986.[6] In view of public comments, the Board has determined that, before it considers further steps to reduce payment system risk it will first review:

• Its long-run goals for this policy;

• The applicablity to, and relationship between, caps and collateral for book-entry overdrafts;

• The role of collateral for funds and book-entry overdrafts;

• The applicability of caps to book-entry overdrafts;

• The benefits and costs of future cap reductions;

• The benefits and costs of Reserve Bank pricing of Fedwire funds and book-entry overdrafts, in lieu of, or in addition to, cap reduction;

• The benefits and costs of requiring larger clearing balances for active participants in the payment system in lieu of, or in addition to, cap reduction and/or pricing of Fedwire overdrafts; and

• Other related issues.

The Board will be requesting its Large-Dollar Payment System Advisory Group to review these issues in consultation with other interested private-sector parties and to present its views to the Federal Reserve Payment System Policy Committee [7] by the first quarter of 1988. At the same time, it has asked the Payment System Policy Committee to create a joint Reserve Bank-Board staff task force to review these issues as well and to present its analysis by early 1988. Subsequent to the reports of the private sector Advisory Group and the staff task force, the Payment System Policy Committee will review the analyses and present its views to the Board. The Board intends that the Committee report will highlight the Board's options and the implications of each of them for both risk reduction and possible market disruption.

In the interim, the Board's revised risk reduction policy is set out below:

I. Bilateral Net Credit Limits

In earlier statements of its risk-reduction policy,[8] the Board stated that any large-dollar network obtaining net settlement services from a Federal Reserve Bank would have to require each of its participants to establish bilateral net credit limits vis-a-vis each other participant on that network. In setting bilateral net credit limits, each participant on a network determines for itself the maximum dollar amount of net transfers (i.e., the value of receives in excess of the value of sends) that it is willing to accept from each other participant on that network. The Board believes that bilateral net credit limits reduce risk by enabling an institution to identify and control the exposure it could face in the event of a settlement failure. Accordingly, the Board has decided to continue this requirement.

Under the Board's policy, no private large-dollar payment network is eligible for Reserve Bank net settlement services unless it (1) requires each participant to establish bilateral net credit limits vis-a-vis each other participant on that network, and (2) establishes a system to reject or hold any payment that would exceed such a limit.[9]

The federal bank examiners will continue, during regular examinations, to review and comment on the procedures used by each institution in establishing, monitoring, reviewing, and modifying bilateral net credit limits, and ensure that institutions understand their potential exposures with each other participant over more than one network and in more than one market.

II. Sender Net Debit Caps

Bilateral net credit limits are not sufficient by themselves to reduce aggregate risk on large-dollar payment networks. The volume of daylight exposure that each institution is willing to accept from each other institution is likely to be quite large when aggregated across all receivers. Moreover, each institution is unaware of the credit made available to a given sender by other potential receivers. For this reason, the Board believes that bilateral net credit limits must be supplemented by a limit

[6] The Board anticipates that it will consider in the fall of 1987 proposals to reduce risks on automated clearing houses (ACHs), but does not expect that it will, at that time, modify the treatment of ACH payments in its ex post monitoring system.

[7] The Payment System Policy Committee is chaired by Vice Chairman Johnson. Other members are Governor Angell and Presidents Corrigan and Melzer and First Vice President Monhollon.

[8] 49 FR 13191; 50 FR 21121.

[9] Bilateral net credit limits do not apply to Fedwire because the Federal Reserve provides final credit to the receiver when advice of credit is given for the transfer. 12 CFR 210.36. Reserve Banks, however, may take action to reduce their credit exposure.

on the aggregate amount of risk that an institution can present to the payments system. Accordingly, the Board strongly urges that each institution either participating on a large-dollar network or incurring daylight overdrafts on Fedwire adopt a sender net debit cap (a ceiling or "cap" on the aggregate net debit position—the value of all sends in excess of the value of all receives—that it can incur during a given interval).

Sender net debit caps—expressed as multiples of capital—should be applied across all large-dollar systems, i.e., to the aggregate position of an institution at a moment in time on all large-dollar transfer systems combined. With this "cross-system" sender net debit cap, net debit positions on one system can be offset by credit positions on other systems.[10] In addition to the cross-system sender net debit cap, the Board requires, as a condition for access to the Federal Reserve net settlement service, that each private network develop and impose on its participants a network sender net debit cap designed to reduce individual institution risk exposure on that network to reasonable levels. Further, each network is required to implement a mechanism for rejecting or holding those transfers that would cause an institution to exceed its cap.

The Board's policy calls for a voluntary cross-system sender net debit cap based on a specific set of guidelines and some degree of examiner oversight.[11] The Board's policy has no regulatory dimension except (1) potential responses to an actual level of aggregate daylight credit exposure at an individual institution deemed by the institution's examiner to be unsafe or unsound, (2) elimination of access to daylight overdrafts on Fedwire by institutions not engaging in the self-evaluation process or filing a board of directors approved *de minimis* cap, and (3) control of Fedwire overdrafts of individual institutions determined by a Reserve Bank to expose it to excessive risk. Events since March, 1986, have demonstrated that senior management and the boards of directors of depository institutions generally have followed the proposed guidelines and procedures closely. If further events demonstrate the contrary, the Board will reconsider its options, including the adoption of regulations designed to impose explicit limits on daylight credit exposure.

A. Determining Cap Category

The first step for an institution in establishing its cross-system sender net debit cap is to determine its own cap category by evaluating its creditworthiness, credit policies, and operational controls and procedures.[12] The guidelines to be used by each institution in establishing its cap category are detailed in an Appendix to the Board's this policy statement.

Determination of cap category should be made by an institution's board of directors. A cap determination may be reviewed and approved by the board of directors of a holding company parent of a depository institution, or the parent of an Edge or agreement corporation, provided that (1) the self-evaluation is performed by each entity incurring daylight overdrafts or participating on a private large-dollar network, (2) the entity's cap is based on the entity's own capital (adjusted as noted below to avoid double counting), and (3) each entity maintains for its primary supervisor's review its own file with supporting documents for its self-evaluation and a record of the parent's board of directors' review, as noted below.[13]

In applying these guidelines, each institution is expected to maintain a confidential file for examiner review that includes (1) worksheets and supporting analysis developed in its self-evaluation of its own risk category, (2) copies of senior management reports to the board of directors of the institution or its parent (as appropriate) regarding that self-evaluation, and (3) copies of the minutes of the discussion of the appropriate board of directors concerning the institution's adoption of a cap category.[14] The process of self-evaluation, with board of director review, should be conducted at least once in each 12-month period.

As part of its normal examination, the depository institution's examiners will review the contents of the self-evaluation file.[15] The objective of this review will be to assure that the institution has seriously and diligently applied the guidelines, that the underlying analysis and methodology were reasonable, and that the resultant self-evaluation was generally consistent with the examination report. Examiner comments, if any, would be expected to be forwarded to the board of directors of the institution. Consistent with the voluntary nature of the Board's policy with regard to sender net debit caps, however, it should be emphasized that the examiner cannot require a modification of the self-evaluation cap category unless the level of daylight credit used by the institution constitutes an unsafe or unsound banking practice.

B. Establishing Sender Net Debit Cap

The cap category resulting from the self-evaluation process should be used by each institution to establish its cross-system net debit cap. The cap levels, set as multiples of adjusted primary capital.[16] would be as follows:

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[10] As noted below, however, Reserve Banks will not permit daylight overdrafts on Fedwire to exceed the cross-system cap established by an institution; i.e., net credits on private wire systems will not be able to be used to increase the Fedwire cap. A similar arrangement will exist for private network participants where net credits on Fedwire and other private networks cannot be used to increase a participant's cap on a given private network.

[11] The Board acknowledges with appreciation that its policy draws heavily on the *Final Report of the Risk Control Task Force, Payments System Committee, Association of Reserve City Bankers*, prepared with the assistance of the Bank Administration Institute and Robert Morris Associates (October, 1984).

[12] This evaluation should be done on an individual institution basis—treating as separate entities each commercial bank, each Edge (and its branches), each thrift institution, etc. While the Board realizes that depository institution holding companies may act as integrated entities and that performing the self-evaluation on an individual institution basis may result in some increased costs, permitting holding company organizations to consolidate their funds transfer activities for daylight overdraft monitoring purposes would increase Federal Reserve Bank credit risk or systemic risk to depository institutions.

An exception is made in the case of U.S. agencies and branches of foreign banks. Since these entities have no existence separate from the foreign bank, all the U.S. offices of foreign banks (excluding U.S. chartered bank subsidiaries and U.S. chartered Edge subsidiaries) should be treated as a consolidated family relying on the foreign bank's capital.

[13] The Board believes that in determining a sender net debit cap for its U.S. branches and agencies, a foreign bank should undergo the same self-evaluation process as domestic banks. Many foreign banks, however, do not have the same management structure as U.S. depository institutions, and adjustments should be made as appropriate. Where a foreign bank's board of directors has a more limited role to play in the bank's management than a U.S. board, the self-evaluation and cap level should be reviewed by senior management at the foreign bank's head office that exercises authority over the foreign bank that is equivalent to that exercised by a board of directors over a U.S. depository institution. In those cases where the board of directors does exercise authority equivalent to that of a U.S. board, cap determination should be done by the board.

[14] In most cases it may not be possible for the U.S. examiners to review the minutes of the meeting a foreign bank's board of directors or other appropriate management group at which the self-evaluation was discussed. In lieu of this, the file on the self-evaluation that is made available for examiner review by the U.S. offices of a foreign bank should contain the report on the self-evaluation made to the foreign bank's senior management by the management of U.S. operations. In addition, the file should also contain a record of the appropriate senior management's response. As in the case of U.S. institutions, this review and confirmation should be completed every year.

[15] In the interim between examinations, examiners may contact an institution about its cap if statistical or supervisory reports or ad hoc information suggest that there may have been a change in the institution's position.

[16] See Section II C on capital, *infra*.

1. MARCH 27, 1986 THROUGH JANUARY 13, 1988

Cap class	Net debit cap	
	2-week avg. plus	Single day
High	2.0	3.0
Above average	1.5	2.5
Average	1.0	1.5
Limited [17]	0.5	0.5
No cap	0.0	0.0

[17] The "Limited Cap" is described in Section II C, infra. It will remain in effect only until January 1, 1989.

2. JANUARY 14, 1988 THROUGH MAY 18, 1988

Cap class	Net debit cap	
	2-week avg. plus	Single day
High	1.70	2.55
Above average	1.275	2.125
Average	0.85	1.275
Limited	0.425	0.425
No Cap	0.0	0.0

3. MAY 19, 1988 AND AFTER

Cap class	Net debit cap	
	2-week avg. plus	Single day
High	1.50	2.25
Above average	1.125	1.875
Average	0.75	1.125
Limited	0.375	0.375
No Cap	0.0	0.0

An institution is expected to avoid incurring cross-system net debits that, on average over a two-week period, exceed the two-week average cap, *and*, on any day, exceed the single-day cap. The two-week average cap provides some flexibility for institutions and recognizes that fluctuations in payments can occur from day-to-day. The purpose of the higher single-day cap is to limit excessive daylight overdrafts on any day, and to assure that institutions develop internal controls that focus on the exposures each day, as well as over time.

The two-week average overdraft volume to be measured against the cap is the average over a two-week reserve maintenance period of an institution's daily maximum net debit position across all networks. In calculating the two-week average, individual days on which an institution is in an aggregate net credit position across all systems throughout the day are treated as if the institution was in a net position of zero. The number of days to be used in calculating the average is the number of business days the institution's Reserve Bank is open during the reserve maintenance period.

C. Capital

Sender net debit caps are multiples applied to "adjusted primary capital." Primary capital includes common stock, perpetual-preferred stock, surplus, undivided profits, contingency and other capital reserves, qualifying mandatory convertible instruments, allowances for possible loan and lease losses (exclusive of any allocated transfer risk reserves),[18] and minority interests in equity accounts of consolidated subsidiaries, but excludes limited-life preferred stock. "Adjusted primary capital" is defined as the sum of these primary capital components less all intangible assets and deferred net losses on loans and other assets sold. Adjusted primary capital for thrift institutions would include any capital assistance provided by the Federal Deposit Insurance Corporation or the Federal Savings and Loan Insurance Corporation in the form of net worth certificates pursuant to 12 U.S.C. 1729(f) or 1823(i).

Any institution with negative adjusted primary capital may incur daylight overdrafts on Fedwire only with the permission of its Reserve Bank; all such overdrafts are to be collateralized and be subjected to "limited" sender net debit cap levels. An institution that has improved its position from negative to positive adjusted primary capital, but whose intangible assets and deferred loan and other asset losses still equal one-half or more of its adjusted primary capital, may continue to incur daylight overdrafts on Fedwire up to the limited cap for two years after it has achieved a positive adjusted primary capital position, but only with the permission of its Reserve Bank. All such overdrafts must be collateralized. Reserve Banks decide whether to allow institutions with negative capital and improving institutions to incur daylight overdrafts on a case-by-case basis and in no case permit an institution to incur daylight overdrafts on Fedwire unless the institution has undergone the self-assessment process outlined in the self-assessment guidelines and rated itself as having satisfactory credit policies and procedures and adequate creditworthiness. This limited cap policy will remain in effect until January 1, 1989, after which time all institutions must adopt another appropriate sender net debit cap.

In some instances, further adjustments to capital will be required. For example, virtually all Edge and agreement corporations are subsidiaries of depository institutions that may themselves use intra-day credit. The same capital would be double-counted if both the parent and the Edge or agreement corporation subsidiary used such credit based on their own capital bases. Accordingly, if a parent elects to permit its Edge or agreement corporation subsidiary to use daylight credit, any adjusted primary capital attributable to its Edge or agreement corporation subsidiary that is reflected on the parent's balance sheet must be subtracted from the parent's capital. The parent could choose, however, not to permit its Edge or agreement corporation subsidiary to use intra-day credit, and use all of its (the parent's) capital for its own cap.

In determining cross-system sender net debit cap levels, U.S. branches and agencies of a foreign bank should use the world-wide consolidated capital of that foreign bank[19] not that bank's parent. Furthermore, the adjusted primary capital of any U.S. bank subsidiary of the foreign bank should be subtracted from the foreign bank's adjusted primary capital to avoid double counting.

D. "De Minimis" Caps

Many depository institutions incur insignificant amounts of overdrafts and thus impose little risk to the payments system. In order to ease for these small overdrafters the burden of engaging in the self-evaluation process, and to ease the burden on the Federal Reserve of administering caps and monitoring these institutions, the Board has adopted its proposal to allow those institutions that meet reasonable safety standards to incur *"de minimis"* amounts of daylight overdrafts. The *de minimis* cap policy will take effect on December 3, 1987, or earlier at the option of each Reserve Bank.

Under this policy, any institution, including an Edge or agreement corporation or a "family" of U.S. offices of a foreign bank, may incur daylight overdrafts up to the lesser of 20 per cent of its adjusted primary capital (or U.S. "capital equivalency" for foreign banks' overdrafts on Fedwire) or $500,000.

This *de minimis* cap will be available to any institution, even though the institution has not conducted the self-evaluation normally required under Board guidelines. Nevertheless, an institution choosing to use a *de minimis* cap must submit to its Reserve Bank at least once each year a copy of the

[18] Allocated transfer risk reserves ("ATRR") are reserves against certain assets whose value has been found by the federal bank regulatory agencies to have been significantly impaired by protracted transfer risk problems. Such reserves are not considered capital by the agencies.

[19] As reported on Form FR 2225, the daylight overdraft capital report for U.S. branches and agencies of foreign banks.

resolution of its board of directors (or its holding company's board) approving the depository institution's use of daylight credit up to the *de minimis* level. Of course, if an institution's primary supervisor or Reserve Bank believes that the institution is not creditworthy, it will not be permitted to incur daylight overdrafts on Fedwire.

Depository institutions using a *de minimis* cap will not be permitted to have daylight overdrafts on a regular basis. Each Reserve Bank will counsel institutions that have a *de minimis* cap but continue to use daylight overdrafts habitually; those institutions that continue to incur overdrafts on a regular basis within the *de minimis* cap will be asked to file a regular cap or reduce their frequency of overdrafts. Institutions that exceed their *de minimis* caps on a chronic basis will be counseled vigorously to file a regular cap or to eliminate overdrafts. Institutions that fail to respond to counseling will be prohibited from incurring overdrafts on Fedwire by being assigned a zero cap and by either having their transfers monitored on a real-time basis or handled manually.

E. Additional Considerations

The contents of the self-evaluation cap category file will be considered confidential by the institution's examiner. Similarly, the actual cap level selected by the institution will be held confidential by the Federal Reserve and the institution's examiner. Finally, the Board notes that exceptional circumstances may require an institution to incur overdrafts in excess of its cap. Such a pattern of overdrafts should be discussed with its the Reserve Bank, with specific plans developed to reduce the intra-day credit positions as soon as possible to a level within the institution's cap.

III. Other Components of the Board's Policy

A. Daylight Overdrafts on Fedwire

The Fedwire cap for depository institutions is equal to the voluntary cross-system cap adopted by the institution, reduced by the institution's actual net debits on other networks as determined in an after-the-fact measurement process. This cap is thus to be monitored on an ex post basis.[20] The Fedwire cap is not increased by the institution's net credits on other networks. Each Reserve Bank, of course, retains the right to protect its risk exposure from individual institutions by reducing unilaterally Fedwire caps, imposing collateralization or clearing balance requirements, holding or rejecting Fedwire transfers during the day until the institution has collected balances in its Federal Reserve account, or—in extreme cases—taking the problem institution off-line or prohibiting it from using Fedwire.

Institutions that incur Fedwire overdrafts for the first time will be subjected to the *de minimis* cap of the lesser of 20 per cent of adjusted primary capital or $500,000. After 90 days, this provisional cap will be reduced to zero unless the institution either submits the appropriate board of directors approval of the *de minimis* cap or files a self-assessment rating and regular cap.[21]

B. Inter—Affiliate Transfers

The Board's prior policy statement provided for sender net debit caps to be established for each individual depository institution regardless of whether an institution was part of a holding company. Recognizing that depository institution subsidiaries of holding companies often seek to operate their funds transfers as if they were a single consolidated entity, the Board requested the private sector Large-Dollar Payments System Advisory Group to study whether institutions affiliated through common holding company ownership should be allowed to consolidate their wire transfer activity and capital for the purpose of monitoring compliance with the Board's payments system risk policy. The matter was also studied by a Federal Reserve task force.

After considering the recommendation of the Advisory Group and the Federal Reserve task force, the Board determined to continue its prior policy and not permit the consolidation of affiliates' capital and funds transfer activity for daylight overdraft monitoring purposes. The Board did, however, in December, 1986, request the public's comments on whether to permit or forbid holding companies to simulate consolidation through inter-affiliate transfers. After considering the public comments and the staff's recommendations, the Board has determined to permit transfers of funds over Fedwire among affiliated depository institutions that are intended to simulate consolidation and which create a pattern of daylight overdrafts up to the sending institution's sender net debit cap, provided the following conditions are met:

1. Each of the individual sending depository institutions' boards of directors approve, at least once each year, the intra-day extension of credit to the specified affiliate(s),[22] and sends a copy of the directors' resolution to its Reserve Bank.

2. During the regular examination, the individual's primary federal supervisor reviews the timeliness of board of directors resolutions, the establishment by the institution of limits on credit extensions to each affiliate, the establishment by the institution of controls to assure that credit extensions stay within such limits, and notes whether credit extensions have in fact stayed within those limits.

The Federal Home Loan Bank Board has advised that federal law prohibits any extension of credit between affiliated institutions insured by the Federal Savings and Loan Insurance Corporation. Accordingly, FSLIC-insured institutions may not enter into such "consolidation" arrangements. The federal bank regulatory agencies have indicated that they will scrutinize inter-affiliate transfers carefully, with particular emphasis on any indications of concentrations of credit beyond the sending bank's usual limits.

The Board notes that the adoption of this policy regarding transfers among depository institution affiliates does not in any way change the treatment of depository institutions and their Edge and agreement corporation *subsidiaries*. The ability of a parent institution to fund its Edge or ageement subsidiaries on an intra-day basis remains unchanged, so long as the parent remains within its own cap.

The Board has also adopted a proposal to allow arrangements whereby a depository institution or other entity ("the service provider") could initiate Fedwire transfers from the Federal Reserve account of another depository institution. Such arrangements will be permitted provided:

1. The institution whose account is being charged (the "institution") retains

[20] Reserve Banks, however, monitor an institution's Fedwire positions on a real-time basis when they believe that the institution is exposing the Federal Reserve to excessive risk. Real-time monitors permit a Reserve Bank to take action when a transaction exposes the Reserve Bank to excessive risk.

[21] Under the self-policing policy adopted by the Board, an institution that does not adopt a cap for itself would be able to use without limit all credit available to it over any private network, unless use of such credit is found to constitute an unsafe or unsound banking practice by the institution's examiner. Such behavior, however, would not be consistent with the spirit of the Board's policy.

[22] The provision of this policy statement that allows a holding company to establish caps for its depository institution subsidiaries does not apply to this requirement.

control of the credit granting process by individually approving each transfer or establishing credit limits within which the service provider can act.

2. The service provider must be an affiliate of the institution, or, if the institution approves each individual transaction, an unaffiliated company. All service providers must be subject to examination.

3. The service provider must not permit or initiate transfers that would exceed individual customer credit limits without first obtaining the institution's permission.

4. The service provider must have the operational ability to ensure that the aggregate funds transfer activity of the institution does not result in daylight overdrafts in excess of the institution's cap.

5. All funds transfer activity must be posted to the institution's account, and the institution will remain responsible for its account.

6. The institution's board of directors must approve the specifics of the arrangement, including: (a) The operational transfer of its funds transfer activity to the service provider; (b) the net debit cap for the activity to be processed by the service provider; (c) the credit limits for any inter-affiliate funds transfers.

7. The institution and the service provider must execute an agreement with the relevant Reserve Banks delineating the terms of the agreement.

8. The institution must have adequate backup procedures and facilities to cover equipment failure or other developments affecting the adequacy of the service being provided. This back-up must provide the Reserve Bank with the ability to terminate a service provider arrangement.

9. The institution must have the ability to monitor transfers being made on its behalf.

10. The institution must provide an opinion of counsel that the arrangement is consistent with corporate separateness and does not violate branching restrictions.

11. The primary supervisor must not object to the arrangement.

12. No individual with decision-making responsibilities relating to the funds transfer area may hold such a position in more than one affiliated institution participating in an approved arrangement.

13. The institution must have in place an adequate audit program to review the arrangements at least annually to confirm that these requirements are being met.

Any existing third-party access arrangements that do not conform to these requirements should be phased out as soon as possible, but in no event later than June 30, 1990. In order to assure consistency with the Board's policy, each new arrangement should be reviewed by the Director of the Division of Federal Reserve Bank Operations prior to approval by the Reserve Bank.

C. Book-entry Securities Transfers

In formulating its daylight overdraft policies, the Board has been concerned about the effect that overdraft restrictions could have on the U.S. government securities market and on the Federal Reserve's ability to conduct monetary policy through open market operations. Accordingly, the Board, pending adoption of procedures for reducing the Reserve Banks' risk exposure, had provisionally exempted from quantitative overdraft controls those Fedwire daylight overdrafts resulting from the transfer of book-entry securities against payment.[23]

In May, 1985, and again in December, 1986, the Board requested public comment on options that would collateralize part or all of book-entry securities overdrafts and subject the uncollateralized portion to the sender net debit cap. The Board has determined that, in light of the adverse public comments and the changes and potential changes in Treasury regulations governing the government securities market and the transfer and pledge of Treasury securities,[24] the collateralization of book-entry overdrafts and the inclusion of some or all of these overdrafts under the sender net debit cap warrants further review. The Board has thus determined to continue to exempt book-entry overdrafts from explicit quantitative limitations and delay its consideration of the collateralization of such overdrafts in normal circumstances pending the outcome of this review process, which will be part of the general review of longer-run goals, collateral, caps, pricing, etc., discussed above. Of course, as is now the case, Reserve Banks will continue to take steps to protect themselves against the risks posed by weak organizations or other special cases. For these high-risk situations, a Reserve Bank will take whatever steps it deems necessary, including requiring additional or specific collateral to be posted for funds *and* book-entry overdrafts, or, in extreme cases, even denying direct access to the funds and book-entry Fedwire system.

Nevertheless, the Board has adopted the following measures:

1. The operating circulars of the Reserve Banks will be revised to impose, effective January 14, 1988, a $50 million par value transfer size limit on secondary market book-entry Fedwire transfers. This limit is intended to induce multiple deliveries to reduce position building by dealers, a major cause of book-entry overdrafts; participants may choose to limit their trade size as well. New issue allocations to dealers and transfers of Treasury STRIPS would be exempt from the transfer limit. The Federal Reserve will work with the Public Securities Association and others to establish market practices and policies consistent with the intent of this policy modification, and the Board will monitor the effects of this policy on overdraft levels.

2. It will not be acceptable for institutions to use Fedwire to avoid the Board's risk reduction policy. Among other things, institutions should not:

(a) Send multiple deliveries of $50 million or less in succession for the account of the same customer for the purpose of avoiding the $50 million transfer limit;

(b) Intentionally substitute book-entry transfers for funds transfers in order to avoid quantitative limits; or

(c) Establish multilateral netting arrangements which settle net differences at the end of the day on Fedwire in order to reduce measured daylight overdrafts without reducing the gross obligations among participants. (This policy applies both to funds and book-entry Fedwire transfers.)

3. Staff in the surveillance and open market units of the Federal Reserve Bank of New York will continue to monitor primary dealers' clearing patterns and policies and review their findings with senior officials of those dealers. The Reserve Bank will seek to persuade dealers to adopt practices designed to minimize book-entry overdrafts.

4. After review by the Federal Reserve's Payments System Policy Committee of the work of a System task force, Reserve Banks are to develop and

[23] Such overdrafts occur when the institution receiving book-entry securities has received book-entry securities against payment at a point in time of a greater value than the securities it has sent. Because receipt of a book-entry security and Fedwire payment to the sender of the security are simultaneous, the sender of the security receives Fedwire payment regardless of the securities overdraft position of the receiver. The definition used for a book-entry securities overdraft means that such an overdraft could occur even while the receiver's funds account was in credit balance.

[24] *See*, Treasury regulations implementing the Government Securities Act of 1986, 17 CFR Ch. IV, 52 FR 19,642 (May 28, 1987), and proposed regulations governing the Treasury-Reserve Automated Debt Entry System, 31 CFR Part 357, 51 FR 43027 (Nov. 28, 1986).

implement book-entry real-time monitoring capabilities as soon as possible, but not later than the first quarter of 1989.

5. Reserve Banks will review the book-entry clearing and settlement activities of institutions incurring sizable book-entry daylight overdrafts or conducting large-scale book-entry securities operations to assure themselves that such institutions have developed acceptable procedures to control the associated risk. In the event that an institution's controls are found to be inadequate, the Reserve Bank will take whatever steps it deems necessary to cover its risk exposure.

D. Automated Clearing Houses Transactions

In the past, automated clearing houses (ACHs) have generally been regarded as small-dollar systems. Recently, however, the ACHs have been evolving in such a way that they appear to be taking on many of the characteristics of large-dollar transfer systems, and they therefore present many of the same risks.

Accordingly, the Board directed its staff to undertake a study of ACH risk and sought comment on ACH risk issues.[25] Based upon the comments received and further study of the issues, the Board proposed certain changes in the Federal Reserve's treatment of ACH transactions.[26]

The Board has now determined to postpone any changes to the treatment of ACH transactions pending the review of the Federal Reserve's payments system risk policy. Pending completion of this review, the present treatment of ACH transactions on the ex post monitoring system will remain in place. Specifically, for purposes of ex post monitoring, net debits and credits resulting from ACH transactions will continue to be posted at the Reserve Bank's opening of business on the settlement date.[27] In addition, pending completion of the payment system risk study, the Board has suspended consideration of providing same-day ACH settlement service by Reserve Banks.

E. Edge and Agreement Corporations, U.S. Branches and Agencies of Foreign Banks, and New York Article XII Investment Companies [28]

Special risks are presented by the participation on large-dollar transfer systems of these institutions. Some of them are major participants in those networks, often making and receiving a large volume of payments on behalf of affiliates and their parent organizations. The size of their payment activities is generally quite large relative to their U.S. capital (or for branches and agencies of foreign banks, measures derived from their U.S. financial statements), and thus sender net debit caps would tend to constrain severely the ability of many of these institutions to participate directly in the U.S. dollar payments mechanism, forcing them to deal either through their U.S. parent (in the case of Edges) or through U.S. correspondents or affiliates (in the case of U.S. agencies and branches and Edge subsidiaries of foreign banks, and some New York investment companies).

In developing its policy for these institutions, the Board has sought to balance the goal of reducing and managing risk in the payments system, including risk to the Federal Reserve, with that of minimizing the adverse effects on the payments operations of these institutions. In addition, the principle of fair and equitable treatment embodied in the U.S. policy of national treatment for foreign banks was given explicit consideration.

1. *Edge and Agreement Corporations.* Under current Board policy, all Fedwire overdrafts of Edge and agreement corporations must be fully collateralized. This policy reflects the lack of access of these institutions to the discount window and the possibility that the parent of an Edge or agreement corporation may be unable or unwilling to cover its subsidiary's overdraft on a timely basis.

The Board believes that Edge and agreement corporation subsidiaries of U.S. banks can, together with their parents, arrange their affairs in a way that would allow them to continue to service their customers at the same time that risk exposures are reduced. Specifically, the Board notes that the parent of an Edge or agreement corporation could fund its subsidiary during the day over Fedwire and/or the parent could substitute itself for its subsidiary on private networks. Indeed, data suggest that, in virtually all cases, the consolidated Edge and parent overdraft position would be within the cap limits of the parent if it were evaluated as an above average cap institution, even though the Edge's overdrafts are very large in relation to the Edge's own capital. This suggests that such an approach by the parent could both reduce systemic risk exposure and permit the Edge corporation to continue to service its customers.[29]

With respect to Edge and agreement subsidiaries of foreign banks, the Board believes that because they lack access to the discount window and ready access to a U.S. affiliate that can provide support, these institutions should be treated in the same manner as their domestically owned counterparts.

Accordingly, the Board has determined that all Edge and agreement corporations will continue to be required to collateralize Fedwire daylight overdrafts, and strongly urges that each such corporation restrain its use of intra-day credit by establishing sender net debit caps based on its own capital in the same manner as any other domestic depository institution. In addition, the Board urges parents of Edge and agreement corporations to substitute themselves for their Edge or agreement subsidiaries on private large-dollar networks.

For purposes of sender net debit caps, the Board suggests that all branches of these same Edge or agreement corporations be consolidated. The consolidated entity's overdraft position will be monitored by the Reserve Bank of the Edge or agreement corporation's head office.[30] The monitoring Reserve Bank, in consultation with those Reserve Banks in which the Edge or agreement branches operate and the management of the consolidated entity, can either (1) determine that Edge or agreement branches outside its District will not be permitted to run Fedwire overdrafts, or (2) allocate part or all of the Edge or agreement corporation's Fedwire cap (and the responsibility of administering part or all of the collateral requirement) to a Reserve Bank in which one or more of the branches operate.

[25] 50 FR 21130 (May 22, 1985).

[26] 51 FR 45043 (Dec. 16, 1986).

[27] This posting procedure is for ex post monitoring purposes and will in no way change when actual settlement entries are made or when ACH transactions become final.

[28] This section excludes discussion of foreign-owned U.S. depository institutions, including U.S. depository institutions that are either subsidiaries of foreign banks or of foreign bank holding companies. These entities have U.S. depository institution charters and capital in the U.S., and are treated the same as any other U.S. depository institution.

[29] The Board's action to place certain restrictions on inter-affiliate transactions has not changed the existing policy with respect to the treatment of depository institutions and their Edge or agreement subsidiaries.

[30] With the consent of the parties, a Reserve Bank other than that of an Edge head office can assume the management of these responsibilities.

2. *U.S Branches and Agencies of Foreign Banks.* As noted previously, the Board believes that U.S. branches and agencies of foreign banks should undergo the same self-evaluation process as domestic depository institutions, but that it be done on the basis of all U.S. branch and agency operations, rather than on an office-by-office basis. In setting a cross-system sender net debit cap, the Board believes that it is appropriate the cap be based on the world-wide consolidated capital of the foreign bank (less any adjusted primary capital attributable to subsidiary U.S. banks and Edge or agreement corporations reflected in the foreign bank's world-wide capital). The Board has reached this conclusion because public comments and other data indicate that private market participants view the intra-day credit risk associated with U.S. offices of foreign banks in terms of the world-wide creditworthiness of the entire foreign bank.

In assessing the Federal Reserve's own risk, however, the Board is still concerned about the lack of timely information filed with Reserve Banks, and the Federal Reserve's inability to monitor developments concerning each foreign bank's non-U.S. operations. Accordingly, the Board has determined that, only for purposes of determining the volume of a foreign bank family's uncollateralized Fedwire overdrafts, the multiples developed from the self-evaluation process (Section II–B, above) will be multiplied by the consolidated "U.S. Capital equivalency" of its U.S. agencies and branches.[31] (The term "U.S. capital equivalency" has been chosen merely as the most convenient term of art. While "U.S. capital equivalency" is to continue to be used in connection with "sender net debit cap multiples," developed from the foreign bank's self-evaluation, to determine foreign banks' maximum uncollateralized daylight overdrafts on Fedwire, the Board's use of the term is not meant to suggest that the Board presently intends that this measure necessarily should be used to measure a foreign bank's capital position in the United States for prudential or other purposes.) Any Fedwire overdrafts in excess of that amount will have to be collateralized. Any use of intra-day credit on private large-dollar networks will be treated as any other use of intra-day credit, and, as noted above, the total cross-system cap of a foreign bank's U.S. agencies and branches will be based on the world-wide capital of the foreign bank (less the noted adjustments).

The cross-system sender net debit cap for families of branches and agencies of the same foreign bank will be monitored by the Reserve Bank which exercises the Federal Reserve's oversight responsibilities under the International Banking Act. The administering Reserve Bank can, in consultation with Reserve Banks in which other U.S. agencies and/or branches of the same foreign bank are located and the management of the foreign bank's U.S. operations, determine that branches and agencies outside its District either will not be permitted to incur Fedwire overdrafts or will allocate part or all of the foreign family's Fedwire cap (and the responsibility for administering part or all of the collateral requirement) to a Reserve Bank in which one or more of the foreign offices operate.[32]

The Board believes that this approach will limit the Federal Reserve's risk while giving foreign banks with U.S. branches and agencies open access to the U.S. payments mechanism in keeping with the policy of national treatment.

3. *New York Investment Companies.* Investment companies chartered under Article XII of the New York Banking Law are not subject to reserve requirements and do not have access to the discount window. Because they do not maintain accounts with the Federal Reserve, they cannot use Fedwire. Some are, however, active participants on private networks, and therefore introduce risk in the payments system much like other participants. Accordingly, the Board urges that investment companies that participate on private large-dollar networks establish for themselves a cross-system sender net debit cap using the procedures and guidelines the Board has established for depository institutions.

F. Bankers' Banks

Bankers' banks are exempt from reserve requirements and do not have regular access to the discount window. They do, however, have access to Federal Reserve payment services. To protect Reserve Banks from potential loss resulting from daylight overdrafts incurred by bankers' banks, the Board adopted, in 1982, a policy that bankers' banks should refrain from incurring overdrafts and post collateral to cover any overdrafts they do incur. Bankers' banks may voluntarily give up their exemption from reserve requirements, thus gaining access to the discount window and avoid having to post collateral.

The Board has determined to continue the present policy.

G. Monitoring

The Board believes that ex-post monitoring is consistent with the voluntary, flexible approach it has adopted. Under ex-post monitoring, an institution with a cross-system net debit position in excess of its cap will be contacted by its Reserve Bank.[33] The Reserve Bank will counsel the institution, discussing ways to reduce its excessive use of intra-day credit. No regulatory action will be taken, but the Reserve Bank may

- Advise the appropriate examiner, who may recommend supervisory action if the volume of cross-system overdrafts are deemed unsafe or unsound, and/or
- Take appropriate action to limit its own risk exposure on Fedwire.

A Federal Reserve Bank will apply real-time monitoring to an individual institution's Fedwire position when the Reserve Bank believes that it faces excessive risk exposure, e.g., for problem banks or from institutions with chronic overdrafts in excess of what the Reserve Bank thinks is prudent. In such a case, the Reserve Bank will control its risk exposures by monitoring the institution's position on a real-time basis, and taking other prudential actions.

In order that Reserve Banks may properly monitor the use of intra-day credit, no future or existing large-dollar network will be permitted to settle on the books of a Reserve Bank unless its members authorize the network to provide position data to the Reserve Bank on request.

[31] "Capital equivalency" is defined as: the greater of (1) the sum of the amount of capital (but not surplus) which would be required of a national bank being organized at each branch or agency location, or (2) the sum of 5 per cent of the total liabilities of each branch or agency, including acceptances, but excluding (A) accrued expenses and (B) amounts due and other liabilities to offices, branches, and subsidiaries of the foreign bank.

[32] As in the case of Edge and agreement corporations and their branches, with the approval of the designated administering Reserve Bank, a second Reserve Bank may assume the responsibility of managing and monitoring the cross-system sender net debit cap of particular foreign branch and agency families. This would often be the case when the payments activity and national administrative office of the foreign branch and agency family is located in one District, while the oversight responsibility under the International Banking Act is in another District. If a second Reserve Bank assumes management responsibility, monitoring data will be forwarded to the designated administrator for use in the supervisory process.

[33] Even if the institution is not a state member bank, the Reserve Bank can make this contact because an overdraft is occurring on Fedwire or because the institution is in a net debit position on a wire system settling on the books of the Federal Reserve.

H. Avoidance of Risk Reduction Measures

In its March 29, 1984, policy statement, the Board stated that "use of Fedwire for the avoidance of Federal Reserve or private sector risk reduction measures is not appropriate." The Board adopted this policy to prevent institutions from participating in bilateral netting arrangements whereby they would exchange gross payment messages during that day and settle at the end of the day by using Fedwire to adjust net positions bilaterally. Such arrangements would be difficult for Reserve Banks to detect and would be outside of Federal Reserve and private-sector risk control measures. They still, however, present the same risks to the payments mechanism that other net settlement arrangements present because settlement failures are still possible, and such failures would have the same deleterious consequences as any other settlement failures.

The Board, therefore, reaffirms its policy that institutions may not use Fedwire or other payments networks as a method of avoiding risk reduction measures.

The Board realizes, however, that certain netting arrangements are not intended to avoid risk reduction measures. Indeed, they can themselves reduce risk. For example, institutions may by means of novation, net transactions prior to settlement, with each participant legally obligated only for the resultant net position. This arrangement reduces risk because it replaces gross transactions with the smaller net obligation, and failures to settle would almost always involve smaller exposures (and less systemic risk) than with bilateral net settlement. The Board's policy on limiting avoidance techniques is not intended to restrict this kind of netting arrangement.

I. Large-Dollar Payment Systems Advisory Group

In July, 1985, the Board appointed a Large-Dollar Payment Systems Advisory Group composed of knowledgeable representatives of institutions active in the large-dollar payments market. Although the Board has not adopted all of the recommendations that the Advisory Group has made, it has found the Group an invaluable source of information on industry practices and industry views. Indeed it has asked the Advisory Group to aid in the Board's continued evaluation of its daylight overdraft policy. The Advisory Group will report directly to the Board through the Payment System Policy Committee and will be free to study any and all matters associated with the Board's policy of reducing risks on large-dollar payment systems.

By order of the Board of Governors of the Federal Reserve System, July 30, 1987.

James McAfee,

Associate Secretary of the Board.

Appendix—Guidelines for Establishing Risk Categories

This appendix presents the Board's guidelines to be used by institutions in determining their own classifications for purposes of setting their own sender net debit caps. The Board policy recognizes that individual institutions may perceive that special or unusual circumstances not adequately captured in these guidelines may, in the view of the institution's management and board of directors, be consistent with a higher grade classification and higher sender net debit cap. Such a position should be fully supported by analysis and evidence included in the file for examiner review. Examiners will be critical if such special factors are not fully documented, and will be especially sensitive to evidence that special positive factors are being emphasized and adverse factors ignored or downplayed.

The guidelines address creditworthiness; operational controls, policies, and procedures; and credit policies and procedures. The last section suggests how the self-evaluation in each of these three areas is to be combined into an overall assessment, which is then to be the basis for determining a sender net debit cap.

I. Creditworthiness

Self-assessment of creditworthiness should begin by reference to an institution's most recent examination report and, where applicable, to peer group statistics contained in the most recent Uniform Bank Performance Report (UBPR) and to the most recent Bank Holding Company Performance Report (BHCPR). Additional data from other reports and analyses should, of course, be used.

Major emphasis should be placed on asset quality, capital, and earnings where an institution's relative standing can be determined based upon quantifiable measures. Liquidity and holding company strength should be added in as modifying factors which, if strongly positive or negative, could influence the overall assessment of creditiworthiness. For each of the characteristics that become the primary determinants of the initial benchmark assessment of creditworthiness, each institution should rank itself using a four part scale from "Excellent" to "Below Standard."[1] The institution's files maintained for examiner review of cap determination should provide supporting analysis for the self-ranking assigned for each of the characteristics.

a. *Asset quality.* Asset quality should be graded "Excellent" through "Below Standard" in relation to

(a) The level, distribution, and severity of classified assets; (b) the level and composition of non-accrual and reduced rate assets; (c) the adequacy of valuation reserves; and (d) demonstrated ability to administer and correct problem credits. The self-analysis should take peer group statistics into consideration.[2] Obviously, adequate valuation reserves and a proven capacity to police and collect problem credits mitigate to some degree the weaknesses inherent in a given level of classified assets. In evaluating asset quality, consideration should also be given to any undue degree of concentration of credits or investments, the nature and volume of credits specially mentioned or classified, lending policies, and the adequacy of credit administration procedures. Evaluations of asset quality significantly different from the last examination report should be highlighted and supported in the cap determination file.

b. *Capital.* In the self-evaluation of capital, institutions should, as a starting point, note that the federal guidelines call for a minimum primary capital-to-asset ratio of 5.5 per cent for commercial banks. In assigning a specific rating for its capital position, adjustments should be made for the volume of risk assets; the level of off-balance sheet risk; the volume of classified assets; and bank growth experience, plans, prospects, and peer group capital levels. Asset quality should receive particular weight. Any institution that ranks its capital more than one grade above its asset quality has a significant burden of proof to justify such a grade, and its cap file should contain specific documentation.

c. *Earnings.* Earnings should also be graded "Excellent" to "Below Standard" with respect to (a) the ability to cover losses and provide for adequate capital, (b) earnings trends, (c) peer group comparisons, and (d) quality and composition of earnings. Consideration must also be given to the inter-relationships that exist between the dividend payout ratio, the rate of growth

[1] The full scale is as follows: "Excellent," "Very Good," "Adequate," and "Below Standard."

[2] In the case of classified assets, reference should be made to nonperforming assets of peer group institutions.

of retained earnings, and the adequacy of bank capital. A dividend payout rate that is excessive in this context, would warrant a lower grade despite a level of earnings that might otherwise result in a more favorable appraisal. Quality is also an important factor in evaluating this dimension of an institution's performance. Consideration should be given to the adequacy of transfers to the valuation reserve and the extent to which extraordinary or nonrecurring items, securities transactions, and tax effects contribute to net income.

The self-grading for asset quality, capital, and earnings should be combined into a single preliminary grade of creditworthiness based on an average of the three components. This preliminary grade would be affected by two final considerations, which are graded positive (+), neutral (o), or negative (−).

d. *Liquidity.* In most instances, an analysis of liquidity will indicate a stable funding base with a reasonable cushion of assets or untapped funding sources available to meet contingencies. In such instances, liquidity should be regarded as a neutral (o) factor in assessing creditworthiness. Evidence of frequent, unplanned borrowing from the Federal Reserve's discount window or deterioration in the normal funding base would be regarded as negative (−), and, depending upon the severity of the situation, the preliminary grade might be downgraded. Extremely liquid findings (+) could cause an upgrading of the preliminary rating, but such findings would usually need to demonstrate asset liquidity as well as sound liability management practices.

e. *Holding company and affiliates.* The relative strength of other depository institutions within the holding company, the parent company itself, and nondepository institution subsidiaries within the company can also marginally affect the preliminary grade. In general, if the regulators have characterized the consolidated holding company as in satisfactory condition in its most recent inspection, the influence should be regarded as neutral (o). If it was regarded as less than satisfactory, the influence should be regarded as negative (−). Downgrading of the preliminary grade would be expected if significant losses were being incurred or anticipated at the parent or nondepository institution subsidiary level, if consolidated capital was materially less than that of the subsidiary institution(s), or if holding company debt service necessitated excessive dividends from the depository institution subsidiaries. If the parent had a demonstrated record of capital contributions and other support for the depository institution subsidiary, its influence would be regarded as positive (+) and could raise the preliminary grade upward.

These five factors become the initial and minimum benchmark for the self-assessment. Other considerations, such as major changes in management or pending litigation that is material, may be significant when evaluating an institution. Further, in using any ratio in the analysis of the first three factors, the limitations of using a single ratio or even a few ratios must be recognized. To the extent that other factors or mitigating circumstances are factored into the final grade on creditworthiness, the reasoning for special consideration should be clearly laid out for the examiner's review. Also, in a voluntary self-assessment program, management should recognize its own natural predisposition to identify and emphasize positive factors while downplaying adverse ones. To the extent that files do not document balanced analyses, examiners should be critical.

U.S. Branches and Agencies of Foreign Banks

U.S. branches and agencies of foreign banks pose special problems for assessing creditworthiness because they do not have a corporate identity in the United States separate from that of the world-wide institution. Conceptually, however, the same analytical approach is appropriate, although special considerations are necessary to address data limitations.

In many cases, branches and/or agencies belonging to a single family will be found in several different geographic regions and subject to different supervisory authorities. Because the strength of the foreign bank, including all of its parts, will largely determine the strength of each branch or agency in the United States, a single overall assessment is necessary. Thus, branches and agencies of foreign banks should assess creditworthiness on the basis of the entire family—excluding any subsidiary U.S. chartered banks or Edge corporations of the foreign bank—rather than on an individual branch or agency basis.

For capital and earnings, the same approach and standards used for domestic depository institutions are appropriate. In general, the analysis should be done using available data on the foreign parent. Branches and agencies may restate their data to identify undisclosed reserves that are functionally equivalent to capital and to adjust earnings to reflect additions to such reserves. To the extent that the self-assessment relies on these factors, the file available to the examiner should provide supporting documentation.

For assessment of asset quality, additional difficulties are encountered. While information on the overall organization is clearly the data that should be used, asset quality information on the foreign bank or on the consolidated organization is generally not available to either the manager of U.S. operations or U.S. supervisory authorities. Instead, only U.S. asset quality information is available. Even then, organizations with multiple branches or agencies will typically have examinations of individual entities conducted on different dates and by different supervisors. Combining these results into a single meaningful composite of U.S. operations is therefore not easily accomplished. Recognizing these imperfections, the only practical approach available in most cases is to extrapolate for the overall family from whatever information is available in the U.S. operations.

Recognition should be given to the distortions that can arise when a single international credit becomes problemtic and is booked entirely in or outside the U.S. for control purposes. In instances where it is booked in the U.S., the credit may unduly overstate the severity of asset problems in the U.S. by attributing it entirely to the U.S. when it should more properly be attributed to the overall family. Judgment is therefore clearly appropriate in assessing asset quality.

As in the case for domestic depository institutions, asset quality, capital, and earnings provide a benchmark for the assessment of creditworthiness of the branch or agency. Other factors, like liquidity or the effect of affiliates, should be factored in as appropriate. Nevertheless, because the assessment has already included the strength of the foreign bank in measuring capital and earnings, extra care should be taken to avoid double counting the foreign bank in the assessment of its U.S. branches and agencies.

II. Operational Controls, Policies and Procedures

Two distinct components require analysis in the operational area if an institution is to be able to monitor its payments system risk effectively. These components are:

- Monitoring of the position of the institution on *each* payments system on which it operates and *across* all systems as an overall net position; and

• Monitoring of individual customers and the extent to which the institution extends credit by making funds available before they are collected, both when the institution is a sender and a receiver of funds.

Both components are important to any institution in its efforts to manage its payments system risk. The significance of monitoring the debit and credit flows to determine one's overall position and the position of individual customers does not decrease for smaller institutions. For both components, the business activity is first defined, areas of significant risk identified, and the adequacy of controls reviewed.

Factors such as automation or the size of the institution are not relevant except as they affect the ability to monitor risks. References to "real-time," therefore, address the timeliness of information, and not the degree of automation. Indeed, a manual system in a small institution that records every transaction may be far more effective as a real-time monitor than a fully automated and integrated system in a major operation that has yet to bring one area with substantial risk exposure in the institution into the monitored environment.

Based upon the analysis of the business activities and the identification of existing monitoring capabilities, each component is graded "strong," "satisfactory," or unsatisfactory," using specific standards. These two separate ratings of overall activity and individual customers should then be combined into an overall rating of operational controls, policies, and procedures.

a. Monitoring Institution Positions Relative to Net Debit Caps

Before evaluating its wire transfer operation, each institution needs to define the magnitude and relative importance of each payment system in which it participates.

The table below seeks to define the institution's funds transfer environment.[3]

AVERAGE DAILY VOLUME

System	Dollars sent	Percent of total	Dollars received	Percent of total
1. CHIPS				
2. Fedwire				
3. Other				
Total		100		100

For each system in which the institution participates, an acceptable level of risk exposure needs to be identified against which its position will be monitored. The monitoring of each system should then be identified as being: (1) On a real-time basis; (2) on a periodic basis and at what periodicity; or (3) not currently monitored or monitored only at the end of the day. Completing the following table summarizes the type of monitoring activity for each system:

INDIVIDUAL SYSTEM MONITORING CAPABILITY

System	Real time	Periodic	(Frequency)	No interim-monitoring
1. CHIPS			( )	
2. Fedwire			( )	
3. Other			( )	

For systems that are monitored, the extent of cross-system monitoring can then be determined. For example, a real-time, cross-system monitor on Fedwire might be combined with a periodic monitor on CHIPS (or other networks that might develop in the future) to give a periodic cross-system on all systems. By identifying which systems used by the institution are monitored on a cross-system basis to determine a net exposure, an overall risk exposure can be obtained. As with the individual system, a summary table of cross-system monitoring capability can be completed like the one below.[4]

CROSS-SYSTEM MONITORING CAPABILITY

Systems monitored together	Real time	Periodic	(Frequency)	No interim monitoring
			( )	
			( )	
			( )	

Based on the cross-system monitoring capability and the volume of business handled by each system, a rating for the institution's controls for its cross-system exposure can be obtained as follows:

Rating for Monitoring Institution Positions

Strong

a. 95% of total dollars sent and received are monitored on a real-time basis or at 15 minute intervals or less *and*

b. a cross-system calculation of the institution's net debit/credit positions is computed and compared to established limits on a real-time basis or at 15 minute intervals or less.

Satisfactory

a. 80% of the total average daily dollar volume sent is monitored on a real-time basis or at 30 minute intervals or less; *and*

b. a cross-system calculation of the institution's net debit/credit position, utilizing these data, is computed and compared to established limits on a real-time basis or at 30 minute intervals or less.

Unsatisfactory—Any other condition.

b. Montoring Customer Positions

Each institution should have the capability of monitoring the effect of all significant transactions on the funds positions of customers as the transactions occur during the business day. At a minimum, the institution should be aware of the positions of customers that have a high-dollar volume of funds transfer activity in relation to each customer's funds position or to the institution's capital. Customer position should reflect the collected status of funds sent and received over payments systems, as well as the effect of other activities, such as loan advances, loan payments, and book transfers (transfers between customers on the institution's own books) which may result from instructions developed internally or received over message systems, such as S.W.I.F.T. Some customers require frequent monitoring because the volume of their daily transactions is large. Others need to be monitored only as a result of particularly large and unusual transactions.

For customers that are significant users of the payments system, three questions are important:

	Yes	No
1. Has the institution isolated its customers which participate to a significant degree in funds transfer systems as either senders or receivers of funds?		
2. Can the institution monitor the positions of these customers taking into account the source of significant transactions?		
3. Does the monitoring system include the opening collected balance?		

In monitoring customers for compliance with intra-day overdraft position limits established by credit policy and/or in approving over-limit payments, transactions other than those being transmitted and received over payments systems need to be considered as they directly affect the intra-day position. Among the transaction sources that should be

[3] To the extent that an institution uses other payments systems with same-day settlement, the list should be expanded to include them.

[4] Systems may often be listed on more than one line. For example, a real-time cross-system monitor on Fedwire and CHIPS might be combined with a periodic monitor on other systems to give a periodic cross-system monitor on all four systems.

considered are message systems such as S.W.I.F.T. and Telex; internal book transfers; and the institution's own lending, investment, and check processing operations. While it may not be feasible or reasonable to monitor all transactions from all areas, material thresholds should be established by the institution as criteria for monitoring individual transactions or aggregate transactions for a single customer that could put the institution at risk. The files should clearly document the reasons for including or excluding other areas and justify threshold limits sets.

Once customers have been identified and individual transaction limits set, the institution's ability to monitor and control the funds positions of its customers can be determined. The following checklist identifies the adequacy of controls:

	Yes	No
1. Does the system for monitoring positions of customers cover:		
a. All significant sources generating customer account entries?		
b. Total dollar volume of transactions over an established dollar limit?		
c. Overdraft limits?		
d. Single transfer limits?		
2. Does the system halt any transaction in excess of established limits from further processing until appropriate action is taken?		
3. If documentation of action taken with regard to over-limit transactions reflects consistent exceptions attributed to a customer, is analysis of those accounts intensified?		
4. Are reviews of the funds transactions environment conducted by internal or external auditors at least annually? (These reviews should conform to the standards established by the Bank Administration Institute and the Federal Financial Institutions Examination Council.)		

Institutions must be able to respond positively to all questions in this section on monitoring customer positions if they are to evaluate their control as satisfactory or strong. These ratings should be obtained as follows:

Rating for Customer Monitoring System and Controls

1. *Strong*—Responses to all of the above are positive and comprehensive customer monitoring is in force *for both debits and credits* on a real-time basis or at intervals of 15 minutes of or less.[5]

2. *Satisfactory*—Responses to all of the above are positive and comprehensive customer monitoring is in force for all debit transactions greater than or equal to the monitoring threshold on a real-time basis or at intervals of 30 minutes or less.

3. *Unsatisfactory*—Any other condition.

Overall Rating for Operational Controls, Policies, and Procedures

The two separate ratings for monitoring capability are combined into a single rating by taking the lower of the two ratings as follows:

Monitoring institutition positions	Monitoring customer and controls	Overall rating
Strong	Strong	Strong.
Strong	Satisfactory	Satisfactory.
Satisfactory	Strong	Satisfactory.
Satisfactory	Satisfactory	Satisfactory.
—Either Rated Unsatisfactory—		Unsatisfactory.

III. Credit Policies and Procedures

A simple two-way classification system for credit policies and procedures should be used. All institutions should have explicit, written credit policies and the necessary internal procedures in place to implement these policies. Failure to have such policies and procedures puts all participants in the payments system at risk, and should preclude a satisfactory overall rating and its associated debit cap limit regardless of the ratings for creditworthiness or monitoring capabilities.

The following checklist identifies the adequacy of credit policies and procedures:

	Yes	No
1. Does the institution have a written credit policy detailing normal and exception approval and reporting procedures for all loans and credit commitments, including daylight overdraft and bilateral limits and other special facilities?		
2. Are all facilities and exposures approved as part of acknowledged aggregate exposure to individual bank and commercial customers?		
3. Does the institution use monitoring systems which identify usage in excess of approved facilities and provide adequate information for review and evaluation of such usage on a timely basis?		
4. Does the institution have exception identification and approval systems which are tailored to the speed, volume, and size of credit approvals required by its payment system generated exposures?		
5. Are the institution's review systems geared to single out and take action on deteriorating risk situations?		
6. Does senior management periodically review and take action on aggregate exposures over a finite limit?		
7. Are all controls and procedures reviewed and tested by the institution's internal auditors?		
8. Is adequate training available and required for operations, credit, and account officer staff responsible for monitoring the intra-day overdraft exposure system of the institution?		

In completing the checklist, negative responses should not be explained away in order to obtain a satisfactory self-assessment except under extremely unusual circumstances. Institutions that attempt to explain shortcomings will be scrutinized very closely by the examiners.

IV. Overall Assessment

The three component evaluations can be combined into a single overall assessment using the following table:

Credit policies and procedures	Operational controls policies and procedures	Credit worthiness	Overall assessment
Satisfactory	Strong	Excellent	High cap
		Very good	Above average cap
		Adequate	Average cap
		Below standard	No cap
Satisfactory	Satisfactory	Excellent or very good.	Above average cap
		Adequate	Average cap
		Below standard	No cap
Satisfactory	Unsatisfactory	Any	No cap
Unsatisfactory	Any	Any	No cap

In completing the assignment for U.S. branches and agencies of foreign banks that are part of a single family operating in more than one state, a single assessment for the family should be conducted. If more than one branch or agency has access to a large-dollar system, the adequacy of operational controls for each access point should be assessed separately and combined into a single assessment. A single cap should then be determined and divided among the entities having access. The file documenting the assessment and its division among the separate entities should be available to examiners in a designated office in the District of the Administrative Federal Reserve Bank.

[FR Doc. 87-17694 Filed 8-5-87; 8:45 am]

BILLING CODE 6210-01-M

[5] If an institution monitors on a worst case basis, that is, debits only, a strong rating may still be justified if the limits established are no higher than those appropratie for monitoring a net position.

Application To Engage de Novo in Nonbanking Activities; Midlantic Corp.

Midlantic Corporation and Midlantic

Banks Inc., both of Edison, New Jersey, have filed an application under § 225.23(a)(3) of the Board's Regulation Y, 12 CFR 225.23(a)(3), for the Board's approval under section 4(c)(8), 12 U.S.C. 1843(c)(8) and § 225.21(a) of Regulation Y, 12 CFR 225.21(a), to engage through a national bank subsidiary in making loans to individuals for personal, family, household, or charitable purposes, and in taking deposits, including savings, time, and demand deposits. The national bank subsidiary will not make commercial loans or engage in any transactions defined by applicable law or regulation to be commercial loans for purposes of the definition of "Bank" in the Bank Holding Company Act. The activities will be engaged in by Midlantic National Bank Trust Company of Florida, Fort Lauderdale, Florida. The Board has previously determined by order that such activities are closely related to banking. *U.S. Trust Company*, 70 Federal Reserve Bulletin 371 (1984).

The application is available for immediate inspection at the Federal Reserve Bank of New York. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors.

Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of facts 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 the proposal.

Comments regarding the application must be received at the Federal Reserve Bank of New York or the offices of the Board of Governors not later than August 28, 1987.

Board of Governors of the Federal Reserve System, July 31, 1987.

Barbara Lowrey,

Associate Secretary of the Board.

[FR Doc. 87-17819 Filed 8-5-87; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Interest Rate on Overdue Debts

Section 30.13 of the Department of Health and Human Service's claims collection regulations (45 CFR Part 30) provides that the Secretary shall charge an annual rate of interest as fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date that HHS becomes entitled to recovery. The rate generally cannot be lower than the Department of the Treasury's current value of Certified Interest Rates with Range of Maturities. This rate may be revised quarterly by the Secretary of the Treasury and shall be published quarterly by the Department of Health and Human Services in the **Federal Register.**

The Secretary of the Treasury has certified a rate of 14% for the quarter ended June 30, 1987. This interest rate will remain in effect until such time as the Secretary of the Treasury notifies HHS of any change.

Date: August 3, 1987.

Dennis Fischer,

Deputy Assistant Secretary, Finance.

[FR Doc. 87-17901 Filed 8-5-87; 8:45 am]

BILLING CODE 4150-04-M

Centers for Disease Control

National Institute for Occupational Safety and Health; Cooperative Agreement to Enhance the Preparation of Graduates of Schools of Business in the Areas of Occupational Safety and Health; Availability of Funds for Fiscal Year 1987

The National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control (CDC) announces the availability of funds in Fiscal Year 1987 for a cooperative agreement to assist the Nation's schools of business by influencing the academic curriculum of schools of business, to enhance skill/knowledge in the development and preparation of graduates in the areas of occupational safety and health, and to enhance their ability to understand that workplace safety and health must be managed as any other function. The Catalog of Federal Domestic Assistance number is 13.263.

Program Objectives

Long-term objectives of the agreement are:

A. To enhance the integration of occupational safety and health into the existing curriculum of schools of business.

B. To expand the number of schools of business which are promoting the goals of Project Minerva. The purpose of Project Minerva is to assist schools of business to improve the knowledge and skills of their graduates to understand the importance of occupational safety and health and provide them with the necessary ability to manage this area of responsibility as they will all other areas of business.

C. To assist the recipient in providing leadership and direction in this activity.

Authority

This program is authorized under section 21(a) of the Occupational Safety and Health Act (Pub. L. 91-596) as amended.

Eligibility Requirements

Eligible applicants are public or private non-profit organizations which have demonstrated that a major part of their organizational function is to promote occupational safety and health within the academic programs of schools of business.

Availability of Funds and Period of Support

It is expected that approximately $100,000 will be available during Fiscal Year 1987 to support one cooperative agreement award. It is anticipated that the cooperative agreement will be funded initially for a 12-month budget period.

Continuation award within a 5-year project period will be made on the basis of satisfactory progress in meeting project objectives and on the availability of funds. The funding estimate is subject to change.

Purpose and Cooperative Activities

A. Purpose

The purpose of this cooperative agreement is to enhance the education and practice of graduates of schools of business in the area of occupational safety and health.

B. Cooperative Activities

To achieve the purpose and objectives, the following activities should be performed.

1. Recipient Activities

a. Build a consensus among the academic community regarding essential skills and knowledge in occupational safety and health which all graduates of business schools should possess.

b. Make available information regarding those essential skills and knowledge in occupational safety and health to all faculty and students in business schools affiliated with Project Minerva.

c. Identify new educational activities and instructional methods to provide necessary skills and knowledge.

d. Develop and evaluate new educational activities and instructional methods.

e. Identify and develop new approaches and opportunities for field experiences and internships in which faculty can participate in industry programs where occupational safety and health practice is applied to assist the instructor in providing more meaningful curricular for their students.

f. Conduct workshops and conferences of interested private, academic, and public organizations to exchange current information, opinions and findings in the area of occupational safety and health. Utilize the result of such workshops and conferences to help further the Minerva concept.

g. Conduct faculty workshops to enhance their ability to provide OS&H content to their students.

h. Establish regional speakers bureaus to assist new schools of business to introduce the program into its curriculum.

2. NIOSH Activities

a. Collaborate in building consensus among the business school community regarding essential skills and knowledge on occupational safety and health which all graduates of business schools should possess.

b. Collaborate regarding methods to disseminate information concerning those essential skills and knowledge.

c. Collaborate in developing new and unique methods to integrate occupational safety and health into existing curriculum.

d. Collaborate in developing new educational activities and instructional methods to provide necessary skills and knowledge.

e. Provide technical assistance on the design, development and testing of educational activities and instructional packages.

f. Collaborate in identifying new approaches and opportunities for field experiences and internships in which faculty can participate in industry programs emphasizing the importance of occupational safety and health practice.

g. Participate in workshops and conferences to exchange current information, opinions and findings in the area of management of occupational safety and health.

h. Provide information on experts in the field to serve as members of regional speakers bureaus.

Scheduling and Reporting

Annual progress and financial status reports shall be prepared and submitted in accordance with the requirements of 45 CFR 74, subparts I and J, respectively.

Applications Submission and Deadline

The original and two copies of the application should be submitted on Form PHS 5161-1 (revised 3-86) on or before September 8, 1987, to: Leo A. Sanders, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 E. Paces Ferry Rd., Room 321, Atlanta, Georgia 30305.

A. *Deadline:* Applications shall be considered as meeting the deadline if they are either:

1. Received on or before the deadline date, or

2. Sent on or before the deadline date and received in time for submission to the independent review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly-dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

B. *Late applications:* Applications which do not meet the criteria in A. 1. or 2. above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Other Submission and Review Requirements

Applications are not subject to review as governed by Executive Order 12372, Intergovernmental Review of Federal Programs.

Application Content

Applications must include a narrative which includes the following:

A. Briefly states the applicant's understanding of the need or problem to be addressed and the purpose of this cooperative agreement.

B. Documents the applicant's ability to provide staff, knowledge, and other resources required to perform the responsibilities in this project, and describe the approach to be used in carrying out those responsibilities.

C. Describes clearly the objectives of the project, the steps to be taken in planning and implementing this project, and the respective responsibilities of the applicant, CDC, and any other entities for carrying out those steps.

D. Provides a proposed schedule for accomplishing each of the activities to be carried out in this project, and a method for evaluating the accomplishments.

E. Describes the names, qualifications, and time allocations of the professional staff to be assigned to this project; the support staff available for performance of this project; and the facilities, space, and equipment available for performance of this project.

F. Specifies a proposed plan for administering this project, and the name, qualifications, and time allocations of the individual whom the applicant proposes to make responsible for its administration.

G. Provides a detailed budget which indicates (1) anticipated costs for personnel, travel, communications and postage, equipment, and supplies and (2) the sources of funds to meet those needs.

Review and Evaluation Criteria

The application will be reviewed in accordance with PHS Grants Administration Manual Chapter PHS 1-507, Objective Review of Grant Applications. An ad hoc committee will be convened to determine the merit of the application which will be based on the following:

A. The applicant's understanding of the need or problem to be addressed in this program and its approach to perform the project.

B. The plan and schedule for accomplishing each of the activities to be carried out in this project, and the method for evaluating the accomplishments.

C. The qualifications, time allocations of the professional staff, the support staff; the adequacy of facilities, space, and equipment available for performance of this project.

D. The adequacy of the plan for administering this project, including the qualifications and time allocations of the individual whom the applicant proposes to make responsible for its administration.

E. The adequacy of the budget as it relates to the proposed activities.

Information

Information on application procedures, copies of application forms, and other material may be obtained from: Nancy Bridger, Grants Management Specialist, Procurement and Grants Office, Centers for Disease

Control, 255 E. Paces Ferry Road, NE., Room 231, Atlanta, Georgia 30305, Telephone (404) 262-6575.

Technical assistance may be obtained from: Norbert J. Berberich, Jr., Ph.D., Chief, Curriculum Development Branch, Division of Training and Manpower Development, National Institute for Occupational Safety and Health, Robert A.Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226, Telephone (513) 533-8231.

Dated: July 31, 1987.

Larry W. Sparks,

Executive Officer, National Institute for Occupational Safety and Health.

[FR Doc. 87-17811 Filed 8-5-87; 8:45 am]

BILLING CODE 4160-19-M

Hearing Protector Effects on Communication; Open Meeting

The following meeting will be convened by the National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control (CDC) and will be open to the public for observation and participation, limited only by the space available:

Date: August 20, 1987.

Time: 9 a.m.-4 p.m.

Place: Auditorium, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

Purpose: To review and discuss the scientific merit of an experimental investigation designed to evaluate the effect of hearing protectors on normal and hearing-impaired listeners as a function of background noise level. Viewpoints and suggestions from industry, organized labor, academia, other government agencies, and the public are invited.

Additional information may be obtained from: Barry L. Lempert, Division of Biomedical and Behavioral Sciences, NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226, Telephones: FTS: 684-8281; Commercial: 513/533-8281.

Dated: July 30, 1987.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control.

[FR Doc. 87-17812 Filed 8-5-87 8:45 am]

BILLING CODE 4160-19-M

Revision of the NIOSH Work Practices Guide for Manual Lifting Workplace Protection Factor Study of Negative Pressure Respirators; Open Meetings; Correction

In the **Federal Register**, Vol. 52, No. 130, Wednesday, July 8, 1987, page 25636, the above titles were listed as one meeting. Titles should have read "Revision of the NIOSH Work Practices Guide for Manual Lifting; Workplace Protection Factor Study of Negative Pressure Respirators; Open Meetings."

The word "Respirators" was omitted in the narrative title for the open meeting, "Workplace Protection Factor Study of Negative Pressure Respirators."

All other portions of this Notice remain as printed.

Dated: July 30, 1987.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control.

[FR Doc. 87-17813 Filed 8-5-87; 8:45 am]

BILLING CODE 4160-19-M

Cooperative Agreements for Pilot Demonstration Projects for the Prevention of Perinatal Infections With Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS); Program Announcement and Notice of Availability of Funds for Fiscal Year 1987

Introduction

The Centers for Disease Control (CDC) announces the availability of funds for Fiscal Year 1987 for cooperative agreements for pilot demonstration projects for the prevention of perinatal infection with human immunodeficiency virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS).

Authority

These projects are authorized under section 301(a) of the Public Health Service Act (42 U.S.C. 241(a)), as amended, section 311)(b) of the Public Health Service Act (42 U.S.C. 243(b)), as amended, and section 318 of the Public Health Service Act (42 U.S.C. 247c), as amended. The Catalog of Federal Domestic Assistance Number is 13.118.

Eligible Applicants

Eligible applicants are official health departments of any State or local government, including the District of Columbia, the Commonwealth of Puerto Rico, and any territory or possession of the United States. Applicants are encouraged to have health care providers or research groups participate in the program. The proposed program must be located within, or include a Standard Metropolitan Statistical Area, with a minimum of 10 cases of AIDS among adult women meeting the CDC case definition and reported to CDC during calendar year 1986.

Program Background and Objectives

The incidence of AIDS in women is increasing markedly. To date (July 20, 1987) there have been 2,623 cases of AIDS in women, 50 percent of which were intravenous (IV) drug abusers, 24 percent had heterosexual exposure to an AIDS case or AIDS risk group member, 11 percent had been transfused or had other exposure to blood components, 5 percent were born in a country with high AIDS case rates, and 10 percent had HIV infection of other or undetermined origin. A much larger number of women have HIV infection without the manifestations of AIDS. Each of these HIV infectionss, apart from its effect on the women herself, represents a risk of perinatal transmission. Between 30 and 50 percent of children born to infected mothers are themselves infected. Most of the 423 cases of AIDS that have occurred in children were acquired perinatally from infected women. Infections in women represent only 7 percent of all AIDS cases. However, this proportion is increasing. Heterosexual propagation of the epidemic is a serious possibility. These infections in women and the resulting perinatal transmission to children are potentially preventable.

AIDS has disproportionable affected minorities, especially AIDS not involving homosexual transmission. Seventy-one percent of non-homosexual AIDS cases are Black or Hispanic whereas 18 percent of the U.S. population is Black or Hispanic. Seventy-one percent of all AIDS cases among women and 76 percent of female IV drug abuse-related cases have been Black or Hispanic. Eighty-seven percent of childen with perinatally-acquired AIDS in children have been Black or Hispanic.

Current State and local AIDS Prevention Projects are designed to prevent infections among women and children by (1) expanding health education and risk reduction efforts among IV drug abusers, (2) promoting less risky sex practices among non-monogomous women of reproductive age, (3) developing approaches to reach female sex partners of infected males, and (4) expanding efforts to involve minority communities at increased risk of HIV infection. This program's objective is to meet an urgent need to develop additional programs to prevent pregnancies among HIV-infected women, and women at high risk of HIV infection.

Purpose

The purpose of this program is to assist selected areas experiencing

substantial numbers of HIV infections in women and children (perinatal) to demonstrate an effective program to (1) identify women with HIV Infection or women at high risk of infection; (2) provide them with information concerning the effects of infection on the mother and fetus during pregnancy and on the infant following birth; (3) assess the adequacy of their current and past contraception practices and their attitudes toward contraception and pregnancy; (4) activley educate such women about the need to take steps to avoid pregnancy; and (5) provide those desiring to avoid pregnancy with the medical and counseling support to practice adequate contraception. These efforts to prevent perinatal infections should be integrated with other education efforts to promote less risky sex practices and to reduce drug dependency and needle sharing. Program effort should also insure that infected pregnant women are referred to health care providers with appropriate medical and social service expertise. Since the program is a demonstration, it is intended that grantees will identify and develop a rationale for promising and different approaches, and conduct evaluation studies to demonstrate which of the approaches is most effective.

Cooperative Activities

1. Recipient Activities

a. Obtain Community Participation

Community input should be obtained during planning, implementation, and evaluation of the program. Participation by members of black, Hispanic, and immigrant communities affected by the program should, in particular, be obtained.

b. Define the Target Population

The population of women considered to be at risk for HIV infection and pregnancy should be defined. Suitable populations may be as broad as a entire community or may be narrower such as the catchment population for an obstetric service experiencing perinatal infections or a set of clinics (drug abuse treatment centers, family planning clinics, sexually transmitted diseases clinics, etc.) attended by women with an elevated prevalence of infection.

c. Develop Methods to Identify Infected Women

Methods must be devised to screen the target population for HIV infection and for HIV risk factors. Alternative approaches should be considered for their relative merits. For example, if the target population is defined as a set of clinics or is served by clinics, the clinic attendees might be serologically screened. If the target population is not restricted to clinic attendees, outreach workers might be considered to identify IV drug abusers who are not affiliated with clinics. Sex partner referral would be appropriate if the target population includes sex partners of high risk males; e.g., bisexuals or IV drug abusers.

d. Develop Education and Counseling Methods

Education and counseling activities should be developed based on existing information or on an assessment of the women in the target population who have HIV Infection or are at high risk of infection. Alternative approaches should be considered for their relative merits. Consideration should be given to the several factors that may influence behaviors including: (1) knowledge of HIV Infection and its effects on the mother and fetus during pregnancy and on the infant after birth, (2) knowledge of contraceptive methods, (3) attitudes toward infection, pregnancy, and contraception, (4) normative values in the community and among peers regarding HIV infection, pregnancy, and contraceptive practices, and (5) social skills to negotiate adequate contraception and HIV risk reduction behaviors with sex partners.

e. Develop Referral Systems

Education and counseling activities may not be most efficiently or effectively conducted at sites where women at high risk are identified. Where indicated, methods should be developed to refer women with HIV infection or at high risk of infection for education and counseling. Alternative approaches should be considered for their relative merits.

f. Evaluate the Effectiveness of the Program by Developing and Implementing

(1) *Systems to monitor program activities and the outcomes of interest.* Systems should be developed to monitor women in the target population who have HIV infection or are at high risk of infection for trends in perinatal HIV infections, pregnancies, adequate contraception, and those psychological and social factors that influence contracepting behaviors. Systems should be developed to monitor program activities and to devise methods to relate trends in outcomes of interest to the level and quality of activities.

(2) *Evaluation studies to determine the best education and counseling methods and referral systems.* At a minimum, a program should convey basic information concerning HIV infection, the serologic test, the risks of pregnancy, the risks to the infant, and methods to prevent transmission perinatally or otherwise, and to provide psychological support. Wherever feasible, more intensive efforts should be evaluated to justify the effort by comparing the intensive and minimum efforts with regard to their efforts on perinatal infection rates, pregnancy rates, knowledge, attitudes, and contraceptive practices. Inclusion of controls, randomization, and other research methods to permit unambiguous comparison of results are desirable, where ethical and feasible. To the extent that the recipient engages in information collection through questionnaires, survey forms, or any related means, there shall be no review of such forms or the information collection design by CDC or another federal agency. However, recipients may request technical consultation from CDC.

g. Participate in the Transfer of Perinatal Prevention Information and Methods Developed in This Program to Other States and Communities

2. CDC Activities

a. Provide consultation and technical assistance in planning, operating, and evaluating activities for preventing the perinatal transmission of HIV infection and AIDS.

b. Provide current scientific information relevant to program strategies for such prevention.

c. Participate in the analysis of data gathered from program activities and the reporting of results.

d. Participate in transfer of perinatal prevention information and methods developed in this program to other States and communities.

Availability of Funds

Approximately $1,484,000 will be available in Fiscal Year 1987 to fund 1 to 3 new cooperative agreements ranging from $350,000 to $1,484,000 with an average award of $495,000. It is expected that new cooperative agreements will begin on or about September 1, 1987, and will be funded for 12 months in a 1 to 5-year project period. Continuation awards within the project period will be made on the basis of satisfactory progress in meeting project objectives and on the availability of funds. Funding estimates outlined above may vary and are subject to change.

Use of Funds

Funds may be expended for the written materials, pictorials, audiovisuals, questionnaires or survey

instruments, and educational group sessions related to AIDS risk reduction if approved in accordance with guidance provided in this announcement under the heading *Content of Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions.*

Funds may be used to support personnel and purchase supplies and services directly related to planning, organizing, and conducting the program described in this announcement. Requests for direct assistance (i.e., "in lieu of cash") for personnel, supplies, and other forms of direct assistance will be considered.

Funds may not be used to pay for clinical treatment costs.

Confidentiality

In accordance with section 318(e)(5) of the Public Health Service Act (42 U.S.C. 247c(e)(5)), all information obtained in connection with the examination, care, or services provided to any individual under any program which is being carried out with a cooperative agreement made under this announcement shall not, without such individual's consent, be disclosed except as may be necessary to provide services to him/her or as may be required by a law of a State or political subdivision of a State. Information derived from any such program may be disclosed (A) in summary, statistical, or other form, or (B) for clinical or research purposes, but only if the identity of the individuals diagnosed or provided care under such program is not disclosed.

Reporting Requirements

Progress reports are required on a quarterly basis and are due 30 days after the end of each quarter. The fourth quarter report will include a summary of the year's activities. Annual financial status reports are required no later than 90 days after the end of each budget period. Final financial status and performance reports are required 90 days after the end of a project period.

Recipient Financial Participation

This program has no statutory cost sharing formula.

Guidance—Content of Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions

The current lack of therapeutic or vaccine methods to control the spread of HIV infection and AIDS requires the promotion of sexual and lifestyle behaviors for individuals which will reduce their risk of acquiring and spreading the virus. Behavioral science research suggests that expecting people to permanently alter any set of behaviors affecting their health is unrealistic unless the educational message provides acceptable alternatives to the behaviors creating the risk. Consequently, AIDS risk reduction efforts have focused on the promotion of responsible sex practices for individuals for whom sexual activity is an important factor of risk in acquiring or spreading HIV.

The adoption of less risky sex practices is a practical concept of AIDS risk reduction and is being suggested as a strategy intended to minimize the spread of HIV infection among sexually active individuals, including homosexual and bisexual men. The promotion of this risk reduction strategy may involve supporting the communication of suggestions using candid terms, some of which may be offensive to society at large or to local community standards. The Centers for Disease Control (CDC) is answerable for the use of Federal funds and broad support is vital to its public health mission. CDC also has an obligation to take actions designed to control the spread of HIV. This guidance is meant to promote such actions, and to require local review panels to consider the bounds of explicitness believed needed to communicate an effective message to those for whom it is intended.

1. Basic Principles

a. Language use in written materials (i.e., pamphlets, brochures, fliers), audiovisual materials (i.e., motion pictures and video tapes), and pictorials (i.e., posters and similar educational materials using photographs, slides, drawings, or paintings) to explain less risky sex practices and/or to contrast them with "unsafe sex" practices concerning AIDS should use terms or descriptors necessary for the target audience to understand the messages.

B. Such terms or descriptors used should be those which a reasonabale person would conclude should be understood by a boad cross-section of educated adults in society, or which, when used to communicate with a specific group, such as homosexual men, about high risk sexual practices, would be judged by a reasonable person to be unoffensive to most educated adults beyond that group.

c. The language of items in questionnaires or survey instruments which will be administered in any fashion to any persons should use terms to communicate the information needed which would be understood by a broad cross-section of educated adults in society but which a reasonable person would not judge to be offensive to such people.

d. Educational group sessions of any size should avoid activities in which attendees participate in sexually suggestive physical contact or actual sexual practices.

2. Program Review Panel

a. Prospective cooperative agreement recipients will be required to establish a program review panel whether the applicant plans to conduct the total program activities or plans to have part of them conducted through subvention to nongovernmental organization(s). This panel, guided by the CDC Basic Principles in conjunction with prevailing community standards, will review and approve all written materials, pictorials, audiovisuals, questionnaires or survey instruments, and proposed educational group session activities to be used under the project plan. This panel is intended to review materials only and should not be empowered either to evaluate the proposal as a whole or to replace any other internal review panel or procedure of the local governmental jurisdiction. Specifically, applicants for cooperative agreements will be required to include in the application the following:

(1) Identification of a panel of no less than five persons representing a reasonable cross-section for the general community, which might include members of existing AIDS service groups, but which is not drawn predominantly from the target group or groups to whom the written materials, pictorials, audiovisuals, questionnaires, survey instruments, or educational group sessions are directed; and

(2) A letter or memorandum from the proposed project director, countersigned by the business office, which includes:

(a) Concurrence with this guidance and assurance that its provisions will be observed;

(b) The identity of proposed members of the Program Review Panel, including their names, occupations, and any organizational affiliations that were considered in their selection for the Panel;

b. When a cooperative agreement is awarded, the recipient will:

(1) Convene the Program Review Panel and Present for its assessment actual copies of written materials, pictorials, and audiovisuals to be used;

(2) Provide for assessment by the Program Review Panel draft text, scripts, or detailed descriptions for written materials, pictorials, or audiovisuals to be used;

(3) Prior to expenditure of funds related to the ultimate program use of

these materials, assure that their project files are documented with a statement(s) signed by the Program Review Panel which itemizes their majority vote of approval or disapproval of all proposed written materials, audiovisual materials and pictorials submitted to them for assessment as part of the project plan.

(4) Provide to CDC in progress reports the statement(s) of all members of the program review panel itemizing their majority vote of approval or disapproval of all proposed written materials, audiovisual materials and pictorials signed during the quarter.

Application Content

1. *Compliance with program review panel requirement*—Applications which include written materials, pictorials, audiovisuals, questionnaires or survey instruments, or group educational sessions related to AIDS risk reduction must contain the documentation required in paragraph 2.a under the subpart of this announcement entitled *Content of Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments and Education Sessions;*

2. *Competing applications*—Competing applications, including the initial application for a new project period, must include a narrative which details the following:

a. The background and need for project support, including:

(1) A description of the problem;

(2) Evidence of the administrative capability and experience of the applicant to conduct the activities of the project; and

(3) The applicant's contribution to overall program costs;

b. Objectives which address the recipient activities and a time schedule for conducting the activities. These should include specific quantifiable objectives;

c. A plan of operation which describes the methods and activities which will be undertaken to accomplish the recipient activities described above. In addition, the plan should include:

(1) The proposed organization and the qualifications and training of the project staff;

(2) A description of how the project will be coordinated with other AIDS prevention and surveillance activities, the efforts of comprehensive hemophilia treatment centers to provide education and support to hemophiliacs and their families, and the "look back" programs of blood plasma donation services to identify people at risk through transfusion; and

(3) A description of how clinical care will be coordinated with counseling activities;

d. A plan of evaluation which describes how program activities and the outcomes of interest will be monitored and how studies to determine the best education and counseling methods and referral systems will be conducted. In addition, the plan should include information about how statistical and data processing support will be obtained;

e. A budget and accompanying justification consistent with the purpose and objectives of the project; and

f. Any other information that will support the request for assistance.

3. *Noncompeting continuation applications*—An application for continuation funding of these activities within an approved project period should contain the following information:

a. Progress report on activities performed and results achieved during the prior budget period;

b. Short-term, numerically measurable objectives for the new budget period;

c. A description of the method of operation that will be used to accomplish any new or signficantly revised objectives;

d. A description of any other changes in the need for support, long-term objectives, methods of operation, and the evaluation procedures compared to information provided in the previous application;

e. A budget and accompanying justification consistent with the purpose and objectives of the project.

4. *Related projects*—If the applicant has current projects in perinatal HIV surveillance, epidemiology, or prevention, these should be described and the relationship to this demonstration project should be made clear, to avoid duplication of efffort. A copy of related project applications should be submitted.

Review and Evaluation Criteria

1. *Competing applications*—Competing applications, including the initial application for a project period, will be reviewed and evaluated for technical merit according to the following criteria.

a. *Understanding the problem.* The extent to which the applicant's statement of background and need and objectives demonstrates an understanding of the risks of perinatal transmission of HIV, methods of prevention, and an understanding of the purpose of the cooperative agreement.

b. *Administrative capabilities and experience.* The degree to which the applicant provides evidence that demonstrates the capability and experience to manage the planning, implementation, and coordination of HIV perinatal infection prevention activities.

c. *Plan of operation.* The extent to which the applicant's proposal indicates that the following will be accomplished:

(1) Participation by the community;

(2) Selection of an appropriate target population;

(3) Effective methods will be developed and implemented to identify women in the target population who have HIV infection and/or are at high risk of infection;

(4) Effective methods will be developed and implemented to educate and counsel women with HIV infection or at high risk of HIV infection to prevent pregnancy and perinatal HIV infection;

(5) Referral systems will be developed and implemented to bring high risk women into the education and counseling program to prevent perinatal HIV infection.

d. *Plan of evaluation.* Evaluation systems will be designed and implemented to monitor outcomes of interest and to include (where feasible) controlled studies to determine the relative and abosolute effectiveness of proposed activities.

e. *Personnel.* The extent to which the staff to be assigned to this project are demonstrated to be adequate in number and to have the qualifications appropriate for this project.

f. *Coordination with other AIDS prevention activities.* The degree to which evidence is provided that the applicant (1) understands existing State and local health department surveillance, health education, and risk reduction activities for HIV infection and AIDS and (2) plans to coordinate activities supported by this grant with other AIDS and HIV surveillance, health education, and risk reduction activities.

g. The extent to which the budget is reasonable and consistent with the intended use of cooperative agreement funds.

2. *Noncompeting continuation applications*—Continuation awards within the project period will be made on the basis of the following criteria:

a. The degree to which the accomplishments of the prior budget period demonstrate that the applicant is meeting its objectives;

b. The extent to which the objectives for the new budget period are realistic, specific, numerically measurable, and time-phased;

c. The extent to which the methods described will clearly lead to achievement of the objectives;

d. The extent to which the evaluation plan will allow management to monitor whether individual and organizational performance is of acceptable quality, the methods are effective, and the activities are having an impact; and

e. The extent to which the budget request is clearly explained, adequately justified, reasonable, and consistent with the intended use of cooperative agreement funds.

Application Submission

The original and two copies of the application must be submitted to Leo A. Sanders, Chief, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, N.E., Room 321, Mailstop E14, Atlanta, Georgia 30305, on or before August 19, 1987.

1. *Deadline:* Applications shall be considered as meeting the deadline if they are either:

a. Received on or before the deadline date, or

b. Sent on or before the deadline date and received in time for submission to the independent review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

2. *Late applications:* Applications which do not meet the criteria in 1. a. or b. above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Other Submission and Review Requirements

Applications are not subject to review as governed by Executive Order 12372, Intergovernmental Review of Federal Programs.

Where to Obtain Additional Information

Information on application procedures, copies of application forms, and other material may be obtained from Marsha Driggans, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, N.E., Room 321, Mailstop E14, Atlanta, Georgia 30305, or by calling (404) 262-6575 or FTS 236-6575. Technical information may be obtained by calling Dr. Robert E. Johnson, Division of Sexually Transmitted Diseases, Centers for Disease Control, (404) 329-2580 or FTS 236-2580.

Dated: August 3, 1987.

Glenda S. Cowart,

Acting Director, Office of Program Support, Centers for Disease Control.

[FR Doc. 87-17916 Filed 8-5-87; 8:45 am]

BILLING CODE 4160-18-M

Food and Drug Administration

[Docket No. 87N-0078]

Denial of Hearing and Withdrawal of Approval of New Drug Applications and New Animal Drug Applications for Sterile Injectable Products; Final Order; J.D. Copanos and Sons, Inc. and Kanasco Ltd.

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Commissioner of Food and Drugs denies a hearing and withdraws approval of the New Drug Applications (NDA's) and New Animal Drug Applications (NADA's) for sterile injectable products manufactured by John D. Copanos and Sons, Inc. and Kanasco, Ltd. (hereinafter Kanasco or Copanos) on the grounds that the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the sterile injectable drugs are inadequate to assure their identity, strength, quality, and purity, and were not made adequate within a reasonable time after receipt of written notice specifying the inadequacies.

EFFECTIVE DATE: September 8, 1987.

FOR FURTHER INFORMATION CONTACT:

For Human Drugs: Steven A. Masiello, Division of Manufacturing and Product Quality (HFN-320), Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8095.

For Veterinary Drugs: Philip J. Frappaolo, Division of Voluntary Compliance and Hearings Development (HFV-240), Office of Surveillance and Compliance, Center for Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4940.

For general information: Douglas I. Ellsworth, Center for Drugs and Biologics (HFN-366), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8041.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 10, 1987 (52 FR 7311), the Acting Director of the Center for Drugs and Biologics and the Director of the Center for Veterinary Medicine (hereinafter the Directors) published a notice of opportunity for hearing (NOOH) proposing to issue an order under sections 505(e) and 512(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e) and 360b(e)) (the FDC Act) withdrawing approval of specifically listed NDA's and NADA's for sterile injectable products manufactured by Kanasco. The basis for the proposal was that new information, evaluated together with the evidence when the applications were approved, showed that the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drugs were inadequate to assure their identity, strength, quality, and purity, and were not made adequate within a reasonable time after receipt of written notice from the Food and Drug Administration (FDA) specifying the matters complained of.

Interested persons were advised in the **Federal Register** of March 10, 1987 (52 FR 7318), that hearing requests "may not rest upon mere allegations or denials, but must present *specific facts* showing that there is a genuine and substantial issue of fact that requires a hearing," and that failure to provide such a response would result in the denial of a hearing and entry of summary judgment against the person(s) who requested a hearing (emphasis in original). Interested persons were asked to file hearing requests by April 9, 1987, and to file the data, information, and analysis relied on to justify the hearing by May 11, 1987. *Id.*

In addition to the applications held by Copanos, the NOOH listed applications held by Elkins-Sinn, Inc., 2 Esterbrook Lane., P.O. Box 5483, Cherry Hill, NJ 08034 (Elkins-Sinn) and E.R. Squibb & Sons, Inc., P.O. Box 191, New Brunswick, NJ 08903 (Squibb). By letter dated March 18, 1987, Elkins-Sinn advised FDA that the inclusion of its application in the notice was in error and that it never had any business relationship with Copanos. In the **Federal Register** of March 31, 1987 (52 FR 17477), the Director of the Center for Drugs and Biologics rescinded the NOOH with respect to Elkins-Sinn's applications. By letters dated March 20, 1987, Squibb advised FDA that it was supplementing its NDA's to delete Kanasco as a manufacturing site for its products. In the **Federal Register** of May 8, 1987 (52 FR 17477), the Director of the Center for Drugs and Biologics rescinded the NOOH insofar as it related to the Squibb products.

On May 18, 1987, Kanasco submitted a Motion for Summary Judgment and a memorandum in support of its Request for Hearing and Motion for Summary Judgment (hereinafter "Kanasco Memo."). In support of its motion and

hearing request, the firm submitted four declarations (two from its employees and two from experts in the field of current good manufacturing practice (CGMP)) and various written responses which the firm had contemporaneously made to the Lists of Observations (Form FD–483's) that FDA investigators had issued to Kanasco representatives during the 2½ years that preceded the NOOH.

The Commissioner has reviewed Kanasco's response to the NOOH and the data on file with the Dockets Management Branch filed by the Directors in support of the NOOH, and concludes that Kanasco's motion for summary judgment should be denied, that Kanasco has failed to raise a genuine and substantial issue of fact requiring a hearing under 21 CFR 314.200, and that summary judgment should be granted in favor of the agency. The reasons for this decision are described below.

I. Statutory and Regulatory Framework

The FDC Act provides that the Secretary and by delegation of authority, the Commissioner of Food and Drugs may withdraw approval of a manufacturer's NDA's or NADA's if he finds:

> * * * that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the [Commissioner] specifying the matter complained of * * *.

21 U.S.C. secs. 355(e), 360b(e)(2)(B).

In turn, the current good manufacturing practice provision of the FDC Act, 21 U.S.C. 351(a)(2)(B), provides that a drug is deemed to be adulterated if:

> * * * the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess * * *.

Congress added this provision to the FDC Act in 1962 to improve the quality and reliability of drugs and to assure their integrity from the beginning of the manufacturing process until their delivery to the ultimate consumer. Congress intended to require that all phases of drug production be rigorously controlled to achieve the desired end:

> The manufacturing of drugs is a business that requires highly qualified and trained personnel, and special laboratory and other facilities and most careful internal manufacturing, packaging, and labeling controls. These requirements are necessary to the assurance that the drugs will be safe for the user and will have, and so far as possible retain, the identity, strength, quality, purity, and effectiveness that they purport to have. * * * People with inadequate experience, equipment, and technical competence can, and do, enter the business of making drugs. * * * The phrase "operated or administered in conformity with current good manufacturing practice" [in the law] encompasses key technical and professional personnel responsible for the safety of the drug, and its identity, strength, quality, and purity characteristics.

H. Rept. No. 2464, 87th Cong., 2d Sess., pp. 1 and 2 (1962).

To show that a manufacturer has failed to conform to CGMP, the FDA need not establish that the drugs it has produced are actually contaminated. As one court explained:

> the purpose of section 351(a)(2)(B) was to attack commerce in unsafe and unreliable drugs in its incipiency by giving the Food and Drug Administration (FDA) " * * additional authority to require that sound methods, facilities, and controls be used in all phases of drug manufacturing and distribution.' Thus, under the subject section a drug is *deemed* to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to . . . current good manufacturing practice to assure that such drug is safe and reliable, *regardless of whether the drug actually is deficient in some respect.* [footnotes omitted]?

United States v. *Bel-Mar Laboratories, Inc.*, 284 F. Supp. 875, 880–81 (E.D.N.Y. 1968) (emphasis added). *Accord, United States* v. *Lit Drug Co.*, 333 F. Supp. 990, 998 (D.N.J. 1971) ("Thus a drug may be pharmaceutically perfect in content but still be regarded as adulterated under the law").

The CGMP regulations, 21 CFR Part 211, were promulgated pursuant to 21 U.S.C. 351(a)(2)(B) and FDA's general rulemaking authority, 21 U.S.C. 371(a). These regulations establish the minimum requirements in determining whether production methods, facilities, and controls are in compliance with the FDC Act. 21 CFR 211.1(a). The CGMP regulations are binding and have the force and effect of law. *National Ass'n of Pharmaceutical Manufacturers* v. *FDA*, 637 F.2d 877, 880–81 and 889 (2d Cir. 1981); *see* also *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 621–24 (1973); *National Nutritional Foods Assn.* v. *Weinberger*, 512 F.2d 688, 696–97 (2d Cir.), *cert. denied*, 423 U.S. 827 (1975). A broad-based challenge to the content of the CGMP regulations has been rejected. *National Ass'n of Pharmaceutical Manufacturers* v. *Department of Health and Human Services*, 586 F. Supp. 740 (S.D.N.Y. 1984).

II. Kanasco's Motion for Summary Judgment

A. The Vindictiveness Claim

Kanasco's first contention is that this proceeding is another example of "vindictive abuse" of FDA's regulatory power and a "misguided obsession" on the part of the agency to force its president out of the pharmaceutical business. Kanasco Memo., p. 1.

Kanasco does not point to any facts to support this contention. Instead, the firm turns only to further arguments. For example, Kanasco argues that FDA is attempting to use its resources to "wage a war of attrition against John D. Copanos," the owner of Kanasco, and cites *Southeastern Minerals, Inc.* v. *Harris*, 622 F.2d 758 (5th Cir. 1980), to buttress its claim. Kanasco does not provide any explanation as to how the facts in *Southeastern Minerals*, an unrelated case, are in any way related to this proceeding. Hence, the agency has not been provided with the information it would need to give this contention any further consideration.

In further support of its vindictiveness claim, Kanasco also argues that, because it has been closed since late 1986 as the result of previous CGMP violations which led to a consent decree of permanent injunction filed in the district court (Civil No. K–85–3356 (D. Md.)), "the only possible explanation" for FDA's institution of this proceeding is to "emasculate" any order which the firm might obtain from the district court to reopen its facility. Kanasco Memo., p. 2 and 3.[1] This argument is unpersuasive. As Kanasco itself points out, if the firm were to petition the district court to reopen, and if the court agreed to hear the matter while it was being actively considered by the FDA, and if the court granted Kanasco's petition, then the FDA would take whatever action is appropriate in this proceeding, which could include abating or terminating this proceeding.

More importantly, however, there are compelling reasons to go forward with this proceeding, notwithstanding the current status of the permanent injunction. As the history of Kanasco described in the NOOH and amplified in

[1] By letter dated March 10, 1987, with a copy to Kanasco counsel, FDA advised the district court of this proceeding.

this order shows, an enormous amount of judicial and administrative time and resources has been expended in an effort to achieve compliance by the Kanasco firm with the law during the last 10 years. These efforts have included seizures of adulterated and misbranded products, recalls, Regulatory Letters and other similar warning correspondence from FDA, inspections at the Kanasco facility and elsewhere, complaints for injunction, numerous motions filed with the district court to enforce the injunctions, telephone conferences and meetings with the district court to discuss the motions and other case-related matters, a voluntary agreement, consent decrees and other court orders, a prior FDA proceeding in which 23 lots of Kanasco-manufactured products were declared adulterated, execution of a criminal search warrant, laboratory testing by FDA, meetings with the firm's personnel and counsel, and appeals to the United States Court of Appeals for the Fourth Circuit. 52 FR 7311 to 7318; *See also*, the record in this docket number, *passim*. These efforts have required the courts and the agency to devote thousands of hours to resolve a problem which appears intractable.

As noted in the NOOH, Kanasco made the vindictiveness argument in a lawsuit which it filed in 1985. *John D. Copanos & Sons, Inc.* v. *Heckler* Civil No. K-85-2905 (D. Md.). At a May 12, 1986 hearing in that case, the district court (the same judge who presided over the FDA's suit for injunctive relief) observed, "[t]he violations in this case, that clearly, without controversy took place on the part of [Kanasco] * * * are egregious. They are established beyond controversy. They are far beyond a question in terms of fact, and * * * [Kanasco] leave[s] all that out when [it claims] that there was no call for what the [FDA] did." *See* this Docket Number, FDA Ex. 32 (hereinafter "FDA Ex._____"), Transcript of May 12, 1986 hearing in Civil No. K-85-2905, at 116-17. The district court also observed that "if there ever was a case for summary judgment, this is it." *Id.*, pp. 20 and 21. On July 8, 1986, the district court granted summary judgment for the government and dismissed all counts with prejudice. FDA Ex. 32, Order dated July 9, 1986, filed in Civil No. K-85-2905 (D. Md.).

Kanasco appealed the decision of the district court. In an unpublished opinion dated April 24, 1987, the United States Court of Appeals for the Fourth Circuit summarily affirmed the district court's decision characterizing Kanasco's appeal as "meritless". *See John D. Copanos & Sons, Inc.* v. *Bowen*, No. 86-2186, slip op. at 5 and 7 (4th Cir. April 24, 1987) (*per curiam*).

On January 13, 1986, Kanasco filed a similar suit in the United States Claims Court alleging that FDA had unfairly administered the 1984 Agreement which the firm and FDA entered in settlement of the agency's 1984 injunction action. 52 FR 7315. After the Government moved to dismiss the complaint and for summary judgment, Kanasco withdrew its complaint. That case also was dismissed with prejudice. *See* July 2, 1986 Order, No. 22-86C, U.S. Claims Court.[2]

Moreover, Kanasco's claim of vindictiveness is not supported by the 1984 Agreement pursuant to which the FDA gave the company an additional, and very rare, opportunity to voluntarily comply with the law without being subjected to an injunction.

Congress specifically empowered FDA both to seek injunctive relief from the district courts (21 U.S.C. 332) and to withdraw NDA's and NADA's when a manufacturer cannot comply with CGMP. *See* 21 U.S.C. 355(e) and 360b(e). There is nothing in the FDC Act that suggests that these remedies may only be used in the alternative.

In conclusion, Kanasco has not provided any factual basis to support its claim of unfair treatment by FDA. If anything, the record in this case shows an unusual amount of forbearance by the agency.

B. The Improper Notice Claim

Kanasco next argues that the FDA, "in its zeal to punish Kanasco," has failed to provide the proper written notice required under the FDC Act to initiate this withdrawal proceeding. Kanasco Memo., p. 3. Specifically, the company contends that sections 355(e) and 360b(e)(2)(B) of the statute provide that the Secretary may withdraw approval of an NDA or NADA if he finds that the methods used for the manufacture of drugs are inadequate, *"and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of * * *"* (emphasis in Kanasco Memo.). And, Kanasco's argument continues, since FDA's regulations, 21 CFR 5.10, have only delegated the authority to issue such notice to the Commissioner of Food and Drugs, not to subordinate agency officials, and it has not received any notice from the Commissioner, the statutorily required notice has not been given in this proceeding. *Id.*, pp. 5 and 6.

This argument is also without factual or legal merit. Kanasco does not claim that it lacked actual notice of the CGMP violations that precipitated this proceeding. Nor does Kanasco argue that the predicate notice, which it claims is absent, must be issued in a specific format or have a specific content. Rather, its argument is premised on the assumption that the Commissioner's authority has not been redelegated by FDA's regulations. The assumption is wrong.

Under FDA's regulations, the agency's chief compliance official, the Associate Commissioner for Regulatory Affairs, is authorized to perform "all of the functions of the Commissioner of Food and Drugs." 21 CFR 5.20. In this very proceeding, the Associate Commissioner for Regulatory Affairs gave Kanasco the requisite written notice on several occasions. The Associate Commissioner for Regulatory Affairs signed the November 1984 Agreement with Kanasco which was entered to settle the complaint for injunctive relief filed by the government in Civil No. JH-84-3957 (D. Md.). *See* FDA Ex. 19. The 1984 Agreement explicitly told Kanasco that the company was not in compliance with CGMP, and that the company could not resume the manufacture and distribution of drugs unless and until FDA advised the firm in writing that it was in compliance with CGMP. *See* FDA Ex. 19, 1984 Agreement, paras. 1 and 2. The 1984 Agreement also referenced the 1984 complaint for injunctive relief and the 1984 Consent Decree both of which listed numerous violations of specific CGMP regulations. *Compare* 1984 Agreement, FDA Ex. 19 paras. 1 and 2, *with* government's Motion for Preliminary Injunction in Civil No. JH-84-3957 (D. Md.), pp. 2 to 6 and the Form FD-483 and declarations of Thomas L. Hooker and Salvatore J. Turco attached thereto, FDA Ex. 18; *See also*, 1984 Consent Decree, exhibit C attached to Government's Request to Enter Consent Decree of Permanent Injunction, FDA Ex. 33.

The Associate Commissioner for Regulatory Affairs also signed the November 1985 Consent Decree which, like its 1984 predecessor, specified many violations of CGMP that had not been corrected by Kanasco. *See* FDA Ex. 39. In fact, the 1985 Consent Decree also stated that Kanasco would be required to correct "all deficiencies brought to [its] attention in writing subsequent to November 2, 1984," including those listed in the 1985 Consent Decree. *See*

[2] Recently, Kanasco appealed another order of the district court awarding inspectional fees to the FDA incurred under the 1985 consent decree entered in Civil No. K-85-3356 (D. Md.). That matter has been briefed by the parties and a decision is expected in the near future. No. 86-2180 (4th Cir.)

FDA Ex. 39, p. 2; *See also* FDA Ex. 35, October 22, 1985, Declaration of J. Paul Hile, Associate Commissioner for Regulatory Affairs (filed in support of Government's Reply to Defendant's Response to Order to Show Cause, Civil No. K-85-3356 (D. Md.)) in which Mr. Hile advised the district court and Kanasco that he had signed the 1984 Agreement with the expectation "that there would be no further proceedings in this case" and that "defendants would bring their drug manufacturing operations into compliance with the law." As the Associate Commissioner for Regulatory Affairs also advised the district court, "[s]ubsequent events have shown that this decision was ill advised." *Id.*

Finally, in a 15-page letter dated June 24, 1986, the Acting Associate Commissioner for Regulatory Affairs, James Swanson, advised Kanasco's counsel that numerous lots of veterinary injectable drugs produced by Kanasco between April 1984 and June 1985 were adulterated because they had not been produced in compliance with CGMP. *See* FDA Ex. 45, *passim*. Mr. Swanson's letter was based upon, and discussed in detail, the observations made by FDA investigators during inspections conducted at the Kanasco facility in 1984 and February–March, May, July, and November 1985; declarations, exhibits, and other documents filed by Kanasco and the agency in the injunction actions against Kanasco, and by Kanasco's suit against the FDA (K-85-2905 (D. Md.)); Kanasco's test data, media fill results, and batch records; and the declarations of two independent experts in CGMP retained by FDA, Drs. Salvatore Turco and Kenneth E. Avis. The Associate Commissioner's letter and FDA's exhibits attached thereto provided a comprehensive discussion of Kanasco's CGMP violations, including an explanation of the significance of those violations and citation to CGMP regulations and particular Form FD-483's.

In addition to these notifications from the Associate Commissioner for Regulatory Affairs, Kanasco also received written notice of the CGMP deficiencies at its facility from numerous other appropriate sources. For example, Kanasco received two Regulatory Letters from the Director of FDA's Baltimore District. The first such letter, dated April 26, 1977, warned Kanasco and its president that the company had used an uncertified bulk ingredient in one of its antibiotic drugs. *See* FDA Ex. 5. The second Regulatory Letter, dated January 2, 1980, advised Kanasco and its president that the steam autoclave which the firm used to sterilize various packaging components and equipment used to manufacture injectable drugs had not been adequately validated. *See* FDA Ex. 13.

Kanasco also received two Notice of Adverse Findings (NAF) letters from FDA. The first NAF letter, dated June 9, 1980, again warned Kanasco and its president that the company had used another uncertified bulk antibiotic in one of its injectable products. *See* FDA Ex. 14. The second NAF letter, dated July 31, 1981, warned Kanasco and its president about "serious inadequacies" in the firm's stability program for oral products. *See* FDA Ex. 15.

The authority to issue these NAF and Regulatory Letters was specifically delegated to the persons who sent them or approved them (*See* 21 CFR 5.37 (1978)), and there is no authority that such warnings cannot serve as a predicate to initiate this proceeding. This is particularly true where, as here, neither section 355(e) nor section 360b(e) contain any suggestion that the predicate notice must be given in any particular form. *Compare*, e.g., section 355(g) describing the manner of service of an order issued under section 355, *with* 355(e) which is silent about the form of predicate notice. The issuance of such warning letters is more than adequate to provide the requisite notice and to give reasonable assurance of a responsible executive determination of the fairness of the sanction imposed.

Kanasco received yet further written notice of its CGMP deficiencies by means of the various complaints filed in the district courts requesting statutory injunctions under the FDC Act for violations of CGMP. *See* FDA Exs. 18 and 33. These complaints, together with the Form FD-483s, declarations, and other exhibits attached thereto and the numerous ancillary motions filed with the district court (also with attached and referenced Form FD-483s, declarations, and exhibits), discussed Kanasco's CGMP violations at great length and in extensive detail. *See* e.g., FDA Ex. 35, Government's Supplemental Request to Enter Consent Decree of Permanent Injunction, filed August 7, 1985 (supported by Second Declaration of Carl I. Turner); Government's Reply to Defendants' Response to Order to Show Cause, filed October 22, 1985 (supported, *inter alia*, by Fourth Declaration of Carl I. Turner, Declaration of Kenneth E. Avis (CGMP expert), and Second Declaration of Salvatore J. Turco (CGMP expert)); FDA Ex. 42, Government's Motion to Enforce Consent Decree of Permanent Injunction, filed December 12, 1985 (supported, *inter alia*, by Declarations of FDA investigators Henry L. Avallone and Bruce W. Hartman and Form FD-483 dated November 25 and 26, 1985); FDA Ex. 48, Government's Motion for Expedited Enforcement of Consent Decree of Permanent Injunction, filed on October 16, 1985 (supported, *inter alia*, by declarations of FDA investigators David Pulham and Ronald Tetzlaff, and Declarations of Dr. Kenneth E. Avis and Salvatore Turco).

In short, there has been an overwhelming amount of appropriate predicate notice to Kanasco prior to initiating this proceeding. Where, as here, a manufacturer has received such a longstanding and continuous stream of notice and refused to make substantial corrections of CGMP, the Commissioner is fully warranted in withdrawing approval of its NDA's and NADA's.

For the foregoing reasons, Kanasco's motion for summary judgment is denied.

III. Kanasco's Hearing Request

A. Legal Arguments

Kanasco contends that it is entitled to a full evidentiary hearing because FDA has failed to issue "precise regulations that apply to withdrawal of NDA's on the grounds set forth in the notice of opportunity for hearing". Kanasco Memo., p. 11. Kanasco also argues that FDA's hearing regulations, 21 CFR 314.200, do not apply to the current case. The only cases which Kanasco cites in support of this contention are *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973), and *American Cyanamid Co.* v. *FDA*, 606 F.2d 1307 (D.C. Cir. 1979).

For the reasons set forth below, this argument is without merit.

In *Hynson*, the Supreme Court not only sustained the propriety of FDA's umbrella hearing regulations, 21 CFR 130.14 (now 314.200), but also the agency's regulations defining adequate and well-controlled clinical investigations, 21 CFR 130.12 (now 314.126). Even with respect to the latter regulations, the Court did not rule, as Kanasco suggests, that FDA could never grant itself summary judgment based on regulations which were less than precise. To the contrary, the Court stated that regulations which use

> qualitative standards [such as] 'adequate' and 'suitable' do not lend themselves to clear-cut definition, and it *may* not be possible to tell from the face of a study whether the standards have been met. Thus it *might* not be proper to deny a hearing on the ground that the study did not comply with this regulation.

412 U.S. at 621 n. 17 (emphasis added).

As courts have subsequently pointed out, whether or not a particular regulation is sufficiently precise to provide a basis for denying a hearing request "will vary with the context in which it is invoked. * * * [A] regulatory provision which seems vague in the abstract may nonetheless be conclusively at odds with a peculiarly deficient item of evidence." *Cooper Laboratories, Inc.* v. *Commissioner, Federal Food & Drug Admin.*, 501 F.2d 772, 780 (D.C. Cir. 1974); *American Cyanamid Co.* v. *FDA*, 606 F.2d at 1312.

Nor does *American Cyanamid* support Kanasco's argument. In that case, the manufacturer sought FDA's approval of a supplemental NADA to market a new animal drug over-the-counter (OTC). The FDA denied the supplement on the grounds that the manufacturer had failed to show that the product could be used safely, and published an NOOH particularizing, for the first time, the reasons for its denial. *Id.*, at 1309. The court noted that since the FDC Act did not delineate the type of evidence needed to prove the safety of a product and since the agency had not promulgated detailed regulations defining either the kinds of safety tests FDA would consider adequate or the margin of safety that would be sufficient to market an OTC product, summary judgment should not have been granted; FDA had not given the applicant notice of the safety standards and of the manner in which its data failed to meet those standards. *Id.*, pp. 1313 and 14.

This proceeding bears no resemblance to the situation described in American Cyanamid. Here, FDA has promulgated extensive regulations particularizing the requirements of CGMP. *See* 21 CFR Parts 210 and 211. These regulations, while somewhat broadened since their initial promulgation in 1967 (*See* 21 CFR 133.1 *et seq.* (January 1, 1967)), have remained virtually unchanged in principle, scope, and detail since 1978. *Compare* 21 CFR Part 211 (1978), *with* 21 CFR Parts 210 and 211 (1987).

In fact, Kanasco overlooks critical language in the *American Cyanamid* decision. The court in that case also observed that *"summary action may likewise be taken on the basis of manifest noncompliance with general statutory or regulatory provisions*, or even on the basis of obvious noncompliance with an undisputed particularization of general statutory mandates, so long as the regulated party is afforded ample opportunity to question or meet the newly-adopted standards". *Id.*, p. 1323 (emphasis added). *See also Hess & Clark, Division of Rhodia, Inc.* v. *FDA*, 495 F.2d 975, 983 (D.C. Cir. 1974) (an NOOH which specifies the nature of the facts and evidence on which the agency proposes to take action and gives the affected party enough information to provide a general opportunity to identify material issues of fact, satisfies the notice and opportunity for hearing required by the FDC Act and may serve as a predicate for summary judgment).

Moreover, in this and earlier proceedings, FDA has provided Kanasco with numerous declarations, consent decrees, motions filed in the district court, letters from agency officials, and even scientific treatises describing in extensive detail precisely how the firm's manufacturing methods, processes, and controls ran afoul of the CGMP provision of the FDC Act, 21 U.S.C. 351(a)(2)(B), and the implementing CGMP regulations, 21 CFR Parts 210 and 211. These materials have not only been continuously furnished to the Kanasco firm, its employees and counsel since 1976, but also, and for the most part, the materials have been furnished to Kanasco in the context of adversarial proceedings in which the company had a strong incentive to focus carefully on the documents' contents.

FDA has provided Kanasco with notice of the facts, the evidence which supports the notice, an explanation of the basis for the proposed action, and a genuine and meaningful opportunity to prepare a response. Nothing more is required. *See* 21 CFR 314.200(a)(1); *See also*, 21 CFR Part 12, subpart B describing the proceedings which may or may not lead to a formal hearing.

Objections to a notice must raise issues material to the question involved. *See Pineapple Growers Ass'n* v. *Food and Drug Admin.*, 673 F.2d 1083, 1085 (9th Cir. 1982). Objections may not be frivolous or inconsequential—Congress did not intend governmental agencies created by it to perform useless or unfruitful tasks. *Id.* Moreover, it is well established that the law does not require a hearing in every case in which an adversely affected person files an objection, particularly where the issues have already been aired in a previous proceeding. *See Community Nutrition Inst.* v. *Young*, 773 F.2d 1356, 1364 (D.C. Cir. 1985). Thus, in this proceeding, it will not suffice for Kanasco to point to a few improvements in its CGMP. Rather, Kanasco must raise a material issue of fact concerning whether its manufacturing methods are adequate to assure and preserve the identity, strength, quality, and purity of its drug products and whether efforts to render such methods adequate have been successful within a reasonable time period. 21 U.S.C. 355(e), 360(e)(2)(B). In short, Kanasco must submit specific facts showing that there is a genuine and substantial issue of fact concerning whether the statutory standards for the withdrawal of the approvals of Kanasco's new drug and new animal drug applications have been met. Unless Kanasco submits such facts, the Commissioner may deny a hearing and enter summary judgment in this proceeding. 21 CFR 314.200(g). As discussed below, Kanasco has failed to come forward with such facts.

B. Kanasco's Evidence—An Overview

In response to the NOOH and underlying evidentiary documents, Kanasco submitted 14 exhibits consisting of 4 declarations, 8 letters constituting Kanasco's contemporaneous responses to the Form FD–483's which FDA investigators had left at the firm following the inspections conducted between August–October 1984 and September 1986, a 2-page letter to FDA transmitting validation studies which Kanasco conducted in October and November 1986, and a letter responding to a meeting which the firm had with FDA representatives in December 1986. Kanasco also incorporated by reference the reports of its 1986 validation studies.

The declarations, which will be discussed in greater detail below, may be briefly summarized as follows. Two of the declarations were submitted by experts in CGMP. For the most part, these experts did not directly refute any of the specific contentions in the NOOH. Nor did they attempt to rebut, the numerous declarations filed by the Directors in support of the NOOH. Instead, in a conclusory fashion, the experts stated that the methods, procedures, records, and employees of the firm were either in compliance with CGMP (*See* Kanasco Ex. 2, Declaration of Theodore E. Byers, *passim*) or that the deficiencies noted in the NOOH were "correctable." *See* Kanasco Ex. 1, Declaration of Angel Arambulo, p. 5. One of Kanasco's experts, Mr. Byers, adopted by reference each of Kanasco's letter responses to the Form FD–483's stating that he helped prepare the letters and that they "reflect [his] position concerning the investigators' observations." *See* Kanasco Ex. 2, Declaration of Theodore E. Byers, pp. 2 and 3. The other two declarations were submitted by the two Kanasco employees whose qualifications to serve in key supervisory roles at Kanasco were challenged in the NOOH. These employees recounted their background and experience, took issue with several

of the statements made about the interviews in the NOOH, and stated that the interviews had been conducted in an unfair manner. Although both of these employees were present during, and in one case supervised, the day-to-day operations of Kanasco, neither challenged any of the CGMP findings stated in the NOOH or the underlying FDA exhibits. *See* Kanasco Exs. 3 and 4, Declarations of Ian Chester and John Wanner.

IV. Kanasco's Response to the NOOH

A. Regulatory History of Kanasco

1. Prior to 1984

The NOOH stated the following with respect to Kanasco's regulatory history prior to 1984:

In 1976, a large number of vials of antibiotic that FDA found to be nonsterile was destroyed, and one lot of veterinary oral dosage form antibiotics that FDA found to be subpotent was recalled. During the same year, FDA decertified a batch of antibiotic that the Agency found to be subpotent. The batch was subsequently recalled by the consignee. FDA refused to certify yet another batch of human oral dosage form antibiotic because of excessive variance in moisture content and inadequate batch records.

In 1977, FDA issued a Regulatory letter to Kanasco regarding the firm's use of uncertified bulk antibiotic in the production of two lots of human oral dosage form drug products. The two lots were ultimately seized, condemned, and destroyed (Civil No. B-78-322 D. Md.).

In 1978, FDA conducted an inspection and found that the firm had not validated its autoclave or sterilization-depyrogenation heat tunnel and that its manufacturing and control records were incomplete. A List of Inspectional Observations (FDA-483) was left [at] the firm reflecting these and other CGMP deficiencies. Later that year, tests showed that one lot of veterinary drug product was not sterile. The product was recalled and destroyed. Thereafter, as a result of a limited followup inspection, the agency provided Kanasco with [an] FDA-483, which reflected that the firm's autoclave, depyrogenation tunnel, and manufacturing (gel) tanks used to sterilize and depyrogenate products and product containers had not been adequately validated to assure that pharmaceuticals intended to be sterile would in fact be sterile. FDA also advised Kanasco that the firm's manufacturing and testing records were incomplete.

In 1979, one lot of a human oral dosage form drug product was decertified and recalled because its moisture content exceeded established specifications. During the same year, Kanasco produced and distributed several batches of an injectable veterinary product which lacked an approved new animal drug application. Also during the same year, Kanasco recalled a lot of a human oral dosage form antibiotic which was misbranded.

In 1980, FDA issued a Regulatory Letter to Kanasco advising the firm that one of its autoclaves used to sterilize manufacturing equipment had not been validated. During this period, the agency also issued a Notice of Adverse Findings to Kanasco regarding the firm's use of an uncertified sterile bulk antibiotic in the production of finished pharmaceuticals.

In 1981, FDA issued a Notice of Adverse Findings to Kanasco regarding the firm's inadequate stability data for two oral dosage form penicillin products that it had produced.

52 FR 7312; *See also*, FDA Exs. 1 to 15.

Kanasco did not submit any factual response to these observations. Rather, in its legal memorandum, the company argued that the recitation of the history prior to 1984 was "wholly irrelevant" because the items discussed therein related "almost solely" to oral dosage form drugs which the NOOH specifically stated were not affected by this proceeding. Kanasco Memo., p. 12 n. 8.

This argument raises no factual issues which require an evidentiary hearing. Contrary to Kanasco's assertion, many of the deficiencies cited in this section of the NOOH pertain exclusively to the sterile injectable facility (i.e., the nonsterile vials produced in 1976, FDA Ex. 1; the decertified, subpotent batch of antibiotic drug which had to be recalled in 1976, FDA Ex. 3; the failure to validate the autoclave and sterilization-depyrogenation heat tunnel and incomplete manufacturing and control records in April 1978, FDA Ex. 7; [3] the nonsterile lot of veterinary drug that was recalled and destroyed in 1978, FDA Ex. B; the firm's continued failures to validate the autoclave and sterilization-depyrogenation heat tunnel and to have complete manufacturing records in June 1978, FDA Ex. 9; [4] the distribution in 1979 of an injectable drug product which lacked an approved new animal drug application, FDA Ex. 11; the still-continuing failure to validate the autoclave in 1980, FDA Ex. 13; and the use of an uncertified antibiotic ingredient in the production of an injectable product in 1980, FDA Ex. 14.

Nor can the Commissioner agree that the findings related to the manufacture of oral dosage form drugs are "irrelevant" to this proceeding. Both types of drugs were made in the same facility. The company primarily responsible for making the oral drugs and injectable drugs is owned, operated, and controlled by the same individual; the FDA's observations regarding both operations were, in many cases, brought directly to his attention. *See* e.g., FDA Exs. 1, 3, 4, 5, 11, and 13 to 15. There is no reason why a CGMP deficiency brought to management's attention relating to one type of product should not cause a company to take corrective action to prevent the same violation from occurring with respect to another product made in the same (or indeed, even a different) facility. (In fact, Kanasco management was again reminded of the applicability of the foregoing events to its injectable manufacturing operation when FDA recounted the firm's pre-1984 regulatory history in a declaration filed with the district court in October 1985. *See* FDA Ex. 35, Fourth Declaration of Carl Turner, pp. 9 to 11, filed in Civil No. K-85-3356 (D. Md.)).

The Commissioner concludes that the findings related to oral dosage form drugs are relevant to this proceeding and that the events described in this section should have caused Kanasco management to take corrective and preventive action with respect to the firm's manufacturing practices generally.

2. The August–October 1984 Inspection

The NOOH charged:

A partial inspection of the Kanasco oral dosage form manufacturing facility conducted by FDA in August through October 1984 revealed that Kanasco's processing and quality control procedures were not adequate to provide reasonable assurance that the firm's products would have the identity, strength, quality, and purity characteristics that they were purported or represented to have. At the conclusion of the inspection, FDA left an FDA-483 with Kanasco and discussed the observations with the firm's management. Some of the observations were as follows:

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[3] Among other things, FDA Ex. 7 also pointed out that (a) the autoclave validation data were inadequate because "heat distribution, heat penetration and microbial destruction tests have not been performed for each load and configuration * * *"; (b) the firm used a lower temperature and shorter time cyle than called for by its own SOP for sterilizing various materials; (c) actual weights of active ingredients were not recorded in writing at the time of weighing; (d) the company had not followed its own manufacturing instructions with respect to the temperature of water that was used in a batch of product; (e) products had been distributed prior to determination of actual yield, review, and approval of batch records and release of the lot; (f) Kanasco failed to properly store laboratory reference standards; (g) employees had not properly calculated the potency of a product; (h) the company lacked a written quality assurance program to assure that laboratory equipment was and had been working properly; (i) Kanasco's laboratory procedures failed to specify which tests were required for active ingredients and raw materials; and (j) the company did not have the manufacturing instructions contained in master records signed and dated to reflect management approval.

[4] Among other things, FDA Ex. 9 pointed out that Kanasco's (a) master production records had not been updated to reference current laboratory test procedures, (b) batch records contained inadequate manufacturing directions, and (c) laboratory reports did not adequately describe the sample being tested or the particular analytical method used.

• A consultant then employed by Kanasco stated that he had prepared batch production records for six lots of a prescription antibiotic intended for human use to reflect that certain manufacturing steps had been completed when in fact the steps had not been performed. The consultant also stated that he had persuaded other employees to countersign these records.

• Batch records for several lots of drugs showed that the lots had been prepared in final form and shipped in interstate commerce whereas FDA investigators observed the same lots of drugs in the process of being manufactured at the Kanasco facility.

• Batch records for a specified raw material showed that the material had been used in making a product whereas the same material was actually located, unused, in Kanasco's storage area.

• Production records showed that a particular lot of raw material had been used in a product whereas the firm's inventory and receipt records showed that the same lot of material had not yet been received by Kanasco at the time the product was supposed to have been made.

• Various pieces of basic analytical equipment used in Kanasco's quality control laboratory to test the quality of its products and ingredients had not been regularly and routinely calibrated or standardized.

• On the ceiling support in a room used to compound drugs for human use, FDA investigators observed dust, used cigarettes, and other unidentified materials.

• Laboratory records for samples of a drug did not include the location from which the sample was taken, the quantity of sample taken, or the date the sample was taken.

In addition to the above observations, FDA analyses revealed that one lot of a veterinary injectable dosage form antibiotic produced by Kanasco contained only 45.7 to 53.1 percent of the amount of active ingredient declared by the product's label. The analyses also showed that the product contained gross amounts of particulate matter.

52 FR 7312 and 7313; *See also* FDA Ex. 18, Form FD–483 attached to Government's Motion for Temporary Restraining Order, filed on October 26, 1984 (Civil No. JH–84–3957 (D. Md.)). The Director of FDA's Baltimore District described these deficiencies in greater detail in a declaration filed with the district court and in this docket number. He stated:

8. The FDA inspection of Copanos conducted between August 23 through October 3, 1984, by the Baltimore District Office revealed serious deviations from the Current Good Manufacturing Practice (CGMP) Regulations 21 CFR 210.3 and 211.1 through 211.108. At the conclusion of this inspection, FDA investigators provided Dr. Ellerton [the firm's director of quality control and quality assurance] with a list of observed deficiencies (FD–483). This list and an addendum thereto (which was hand-carried to Dr. Ellerton on October 10, 1984) are attached to this declaration as exhibits 1 and 2, respectively [attached to FDA Ex. 18]. The CGMP deviations observed at Copanos include the following:

(a) The batch production and control records for six lots of Amoxicillin for Oral Suspension (Amoxicillin), a prescription antibiotic drug intended for human use, were falsified in that they were created before the drugs were manufactured. Mr. Greenspun, who was identified by Mr. Copanos as a consultant to Copanos, admitted to two FDA investigators that he had falsified these documents and that he had persuaded two other Copanos employees to counter-sign these records. As a result, although Copanos' batch records indicated that each of the six lots had been blended, reconciled, and each placed into 18 drums, in fact, the lots had not been blended, and had been placed in only three to four drums each. *See* [FD–483] Exhibit 1, item 4 [attached to FDA Ex. 18].

(b) Twelve drums of in-process Amoxicillin (eleven drums with lot number 122H214 written over the original lot number 122H234, and one drum identified as lot 122H234) were observed in the Copanos plant. The batch records for both of these lots showed that the lots had already been packaged and shipped to Pennsylvania. When asked to investigate this discrepancy, Dr. Ellerton replied that the drums must actually represent a third lot number, 123H284.

However, the batch record for lot 123H284 indicate that there should have been 18 drums, not 12. Dr. Ellerton was unable to explain these discrepancies. [*Id.*], item 1.

(c) A similar situation existed with respect to three drums of what appeared to be unblended Amoxicillin (with lot number 122H274 written over the original lot number 123J064). When the FDA investigators looked at the batch records for these lots, the records showed that the batches had been blended and placed into 18 and 19 drums, respectively. Although the FDA investigators later found 11 blended drums of lot 122H274, Dr. Ellerton was unable to account for the missing drums of both lots. [*Id.*], Exhibits 1 and 2, item 5.

(d) There are several instances in which Copanos' raw materials inventory and batch records indicated that a certain quantity of a specified raw material had been used in batches of drug, when, in fact, the same raw material was found in a Copanos storage area. [*Id.*], Exhibit 1, items 6 and 7; Exhibit 2, item 7.

(e) On several occasions, Copanos' records showed that raw materials had been used in a product, whereas other records showed that the raw materials had not yet arrived at the plant. [*Id.*], Exhibit 1, items 8, 9, 24 and 26; Exhibit 2, item 9.

(f) In one instance, the firm cannot account for 71.1 kg (approximately 243 pounds) of Pen V Potassium raw material. [*Id.*], Exhibit 1, item 10.

(g) Copanos' raw material records and batch records do not always agree with respect to what lot numbers of raw material were actually used in particular batches of drugs. [*Id.*], Exhibit 1, item 11.

(h) Raw material inventory/use records are written in pencil with numerous missing dates, crossouts, erasures, and write-overs, with no identification as to who made the changes. [*Id.*], Exhibit 1, items 13 and 15.

(i) The gross, tare, and net weights of in-process materials (tablets, capsules) recorded (to the hundredth of a kilogram) on many weight sheets are suspicious in that the entries on each weight sheet appear to have been made at one sitting and the net weights of bulk drums of raw material (each weighing approximately 50 pounds) are identical. [*Id.*], Exhibit 1, item 17.

(j) Records do not show whether drums of raw material are weighed before being used in production. [*Id.*], Exhibit 1, item 17.

(k) Copanos does not keep logs to show whether laboratory equipment and instruments have been calibrated or standardized. This equipment includes dissolution measuring devices, automatic titrators, an autoanalyzer, pH meter, polarimeter, and thermometers. Laboratory employees could not state with certainty when various pieces of equipment had been calibrated. [*Id.*], Exhibit 1, items 17 to 21.

(l) Copanos does not control intermediate carton labeling and cannot account for thousands of labels. [*Id.*], Exhibit 1, items 29 to 32.

(m) Cleaning and maintenance logs do not exist for some manufacturing equipment such as blenders, compactor, fitzmill, and tableting equipment. [*Id.*], Exhibit 1, items 38 and 39.

(n) Various batches of in-process products were observed in the plant which were not identified as to their stage of processing, and in one instance, an active ingredient was not identified as to its status (e.g., released for use, quarantined, or rejected). [*Id.*], Exhibit 1, items 43 and 44.

(o) Items of manufacturing equipment were observed without identification as to their stage of operation (e.g., in use, cleaned, not cleaned). [*Id.*], Exhibit 1, item 37.

(p) Records required by the GMP regulations under 21 CFR Part 211, Subpart J, are not readily available at Copanos for authorized inspection by the FDA. *See* FDA Ex. 18, October 18, 1984, Declaration of Thomas L. Hooker, Director, FDA Baltimore District Office, exhibit A attached to Motion for Temporary Restraining Order.

9. Mr. Copanos used a variety of tactics during the FDA inspection to interfere with the investigators' ability to conduct a complete and timely investigation of the Copanos and Kanasco plants. These tactics included closing the plants on three occasions when the investigators appeared, delaying ready access to manufacturing records, requiring the investigators to inspect the plant as a team instead of allowing them to contemporaneously and individually inspect several departments, and subjecting the investigators to lengthy and sometimes unseemly tirades. As a result of the actions, I decided that a complete FDA inspection of defendants' plants could not be conducted within a reasonable time, and I terminated the inspection before it was completed. *Id.*

10. FDA analyses of one lot of a veterinary drug, Oxytetracycline Hydrochloride Injection, produced by Copanos show that this drug was subpotent in that it contained between 64.0 and 83.6% of the amount of active ingredient declared on label (*See* exhibit 4) [*in* FDA Ex. 18], and had large amounts of particulate matter. This product is

not recognized in the official drug compendia (e.g., United States Pharmacopeia and National Formulary). This product had been shipped by Copanos to a customer in Sioux Falls, South Dakota, in October 1983. The customer complained, and Dr. Ellerton, by letter dated August 13, 1984, advised the firm to return the product to Copanos. On September 25, 1984, FDA investigators found a portion of the returned product stored at Kanasco. When Dr. Ellerton was asked about the material, he denied any knowledge about it. [FD–483] Exhibit 3, item 2. *Id.*

An expert who testified on behalf of FDA, both in the district court and in this proceeding, Dr. Salvatore J. Turco, explained the significance of the foregoing CGMP deficiencies. Dr. Turco stated:

2. In the pharmaceutical industry, it has been understood for many years that product deficiencies such as incorrect formulation, subpotency, and improper dissolution characteristics cannot always be accurately detected by laboratory analysis of the product itself. The purpose of the good manufacturing practice (GMP) regulations is to so carefully control the process of manufacturing that product defects will be prevented from occurring. This concept is frequently expressed as 'quality must be built into each batch of drug product.' *See* FDA Ex. 18, Declaration of Salvatore Turco, Pharm D., exhibit B attached to Government's Motion for Temporary Restraining Order (Civil No. JH–84–3957 (D. Md.)).

3. I have reviewed the Lists of Observations (FD–483) issued to John D. Copanos & Sons, Inc. (the Copanos firm) following the August-October 1984 inspection and have talked with employees of the United States Food and Drug Administration (FDA) who are familiar with the details of the investigation. Based upon my education, training, and experience, I believe that there are a number of poor manufacturing practices occurring at the Copanos firm. Although there is not enough time to address each of the deficiencies, my views with respect to the more serious deficiencies are as follows:

a. I understand that records have been falsified (*See* FD–483, item 4) for six batches of Amoxicillin for Oral Suspension.

The science of manufacturing pharmaceuticals and the GMP regulations are premised on the presumption that all manufacturing records will be maintained honestly, accurately, and completely. While no system of records can be entirely free of error, drug manufacturing records must reflect the best efforts of the manufacturer to prepare accurate and complete records; records which have been fabricated are wholly unacceptable. The purpose of careful recordkeeping in a drug manufacturing plant is two-fold: First, it serves as a prospective control mechanism to assure that products are properly formulated and manufactured at each step of the process. Second, scrupulous recordkeeping also serves as a means to reconstruct the manufacturing history of a product in the event any problem occurs. For example, if a harmful ingredient has inadvertently been placed in the product, the best way to trace the source of the problem (and prevent recurrence in other batches of drug which contain the safe ingredient) is to examine these records to determine which ingredients were used in the product. In view of the alleged falsification of records referred to above and the uncertain nature and extent of such falsifications, I am unable to place any reliance on the integrity of the recordkeeping practices at the Copanos firm. Consequently, I can have no confidence in the integrity, safety, purity, or quality of the firm's products. My lack of confidence in the products made by the Copanos firm is underscored by the appalling number of serious discrepancies with respect to precisely which raw materials were used in which batches of product. (*See* FD–483, items 6 to 12, 24 and 46).

The alleged record falsifications raise serious questions which extend beyond the involvement of the consultant who acknowledged the fabrications. Thus, other employees at the firm were persuaded by the consultant to counter sign the fictitious batch and control records prepared by the consultant. At a minimum their agreement to sign records which could not have been genuine demonstrates a lack of appreciation of the importance of such records. Moreover, these employees either failed to notify the firm's management about this situation, or did notify management, and no action was taken to correct the problem (e.g., investigating the extent of the problem, terminating employment of the individual employees, recalling the product, notifying the FDA). *Id.*

b. The raw material inventory/use records are kept in pencil, and at least 25 of these records contained one or more missing dates, crossouts, erasures, and erasures with changes and write-overs. None of these changes reflect which person or persons made the changes. (*See* FD–483, item 13).

These records are clerical and should be easy to keep. Generally, they are kept in ink or typed, rather than in pencil. It would appear that the preparation of these records is not very well supervised, because the lack of identification of persons making changes in records is a poor practice which should have been detected and corrected. Further, I cannot understand why the number of omissions and crossouts is so extensive. Errors and changes in production records do occur, but not to this extent. The manner in which these records are kept increases my lack of confidence in the firm's entire manufacturing procedures. *Id.*

c. The investigators found many drums of Amoxicillin for Oral Suspension on hand (not from the falsified batches) that could not be reconciled with the number of drums shown in the batch records. (*See* FDA 483, items 1, 2, 3 and 5). The firm could not account for these discrepancies.

A batch number is any combination of letters, numbers, or symbols from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch of drug product can be determined.

In modern drug manufacturing it is virtually unheard of that drugs or specific in-process or finished material cannot be traced back to batch records with precision. While occasional mistakes in identification of in-process and finished product can occur, the extent of write-overs and the frequent inability to reconcile amounts on hand with batch records is very troubling. At the least, these discrepancies indicate a manufacturing operation that is not adequately controlled. At worst, it suggests a manufacturing operation which lacks integrity. *Id.*

d. There are no records to show whether and, if so, when, laboratory instruments and equipment, including the dissolution equipment, have been calibrated. (*See* FD 483, item 19). (I understand that laboratory personnel interviewed during the inspection had no idea when, if ever, calibration had been done. They stated that it had not been done for the last year or so.) Dissolution testing thermometers have not been calibrated against a National Bureau of Standards (NBS) thermometer as required by the firm's own standard operating procedures (SOP); the firm does not have an NBS thermometer on the premises. (*See* FD 483, item 20).

Sound manufacturing techniques and the GMP regulations (21 CFR 211.194(d)) require that these records be kept because they provide a basis upon which management can be sure that the laboratory equipment is being properly maintained. Proper practice also requires that laboratory control mechanisms used to test the products and their ingredients for identity, purity, and quality must be scientifically sound and appropriate. (*See* 21 CFR 211.160(a)). Laboratory controls include the calibration of instruments, recording devices, and other equipment at suitable intervals in accordance with an established written program. (*See* 21 CFR 211.160(b)(4)).

A specific example of the importance of the foregoing precaution will illustrate my point. Dissolution is the rate at which a drug's active ingredient(s) is (are) released into solution. It is a very important measurement for all oral, solid dosage form drugs such as tablets and capsules and such drugs manufactured by Copanos must pass dissolution testing prior to release. Without proper calibration of the dissolution equipment, little reliance can be placed on the test results obtained. Dissolution equipment is normally calibrated at intervals of at least once every 6 months.

Although I understand that the firm's dissolution equipment has now been calibrated, the fact that this situation was permitted to persist as long as it did indicates that inadequate supervision was provided to the laboratory recordkeeping and equipment maintenance practices.

I would not comfortably rely on any of the results reported from this laboratory that involved the use of the uncalibrated equipment or equipment for which there is no record of calibration. *Id.*

e. Other deficiencies which should be promptly addressed and corrected by the firm include the failure to identify the status of raw materials (e.g., released for use, quarantined, rejected) (*See* FD 483, item 44), the failure to control the labeling with a consequent inability to account for very large numbers of labels (*See* FD 483, items 25 to 36), the failure to identify the status of in-

process materials (*See* FD 483, item 43), and the failure to keep maintenance logs for production equipment. (*See* FD 483, items 38 and 39). *Id*

f. All of the deficiencies discussed above and listed in the FD 483s indicate to me that there are an inadequate number of properly trained personnel to perform and supervise the day-to-day operation of the Copanos firm. *Id.*

4. In conclusion, I share the FDA's concern with respect to the continuing operation of this firm. If I were a consultant to management of the Copanos company, I would recommend that all operations of the firm be suspended until such time as additional employees have been hired; all employees have been properly trained; all production records have been reviewed; all raw materials, in-process and final products have been examined, inventoried and reconciled; and the other aspects of production have been brought under control. *Id.*

The only response in Kanasco's hearing request to this evidence was in the form of a letter to FDA dated November 30, 1984, signed by Kanasco counsel (*See* Kanasco Ex. 14) and subsequently adopted by Kanasco's CGMP expert Mr. Byers. *See* Kanasco Ex. 2, pp. 2 and 3.[5] In this letter (which was dated 1 month after Mr. Hooker's and Dr. Turco's declarations, FDA Ex. 18, had been filed with the district court and served on Kanasco counsel), Kanasco did not deny any of the FDA observations regarding improper recordkeeping. *See* Kanasco Ex. 14, pp. 1 to 13. Instead, the firm offered a wide-ranging variety of excuses and assurances of corrective measures. For example, the firm stated that the consultant (who admitted to FDA that he and other employees had falsified the records), had been seeking "to devise a new and more efficient system" and his "[i]nexperience . . . with the Company numbering and paperwork systems resulted in several problems." *See* Kanasco Ex. 14, November 30, 1984, letter to J.D. Sherry, p. 4. The firm also stated that "an adequate identification protocol for drums in this intermediate stage had not been established, and production personnel had not adequately described the processing status of material on these drum labels (*Id.*, p. 5); * * * batch records * * * were defaced or misplaced * * * and reconstructed [and] [d]uring the process of reconstruction [information] was erroneously inserted into the record." *Id.*, p. 8.

Kanasco's letter assured FDA that the company was "committed to maintaining its good reputation" and "dedicated" to operating in compliance with CGMP regulations. *Id.*, p. 1. The firm also promised that its lot numbering system would be changed, personnel would receive additional training in how to detect batch record errors, a person would be hired to prevent such errors from occurring on line, the inventory records procedure had been changed, a materials management department had been established and would be staffed, and the consultant's contract had been terminated while other employees involved "in the incident" were severly reprimanded. *Id.*, pp. 6 and 7.

While Kanasco offered explanations for its failure to calibrate and/or standardize several pieces of its equipment, no explanations were proferred for its failure to calibrate or standardize dissolution equipment, thermometers, and the polarimeter. Nor did Kanasco offer any explanation for its failure to maintain records to show that calibration and standardization had in fact been performed. *Id.*, pp. 13 and 14. Again, the firm promised correction by ordering the necessary equipment for calibration and standardization. *Id.*, p. 14.

Finally, Kanasco did not deny that a lot of drug product was subpotent and contained particulate matter. *See* FDA Ex. 17.

Kanasco has not presented any specific facts which require an evidentiary hearing on the events described in this section. The uncontested violations which were observed by FDA in 1984, in many cases, not only bore a striking resemblance to those observed in the preceding section (e.g., employees not following company procedures, inadequate recordkeeping, poor maintenance of laboratory equipment, inadequate supervision, production of adulterated and non-sterile products), but also reflected an operation that was not sufficiently controlled and lacked an adequate "number of properly trained personnel to perform and supervise the day-to-day operation of the [Kanasco] firm." *See* FDA Ex. 18, Turco Declaration, paras. 3f and 4. As shown by the ensuing discussion, these and similar CGMP problems have continued at Kanasco.

3. The October 1984 Injunction Suit and November 1984 Agreement

Kanasco does not dispute that after the 1984 inspection, the Government filed a complaint for injunctive relief in the district court (Civil No. JH-84-3957 (D. Md.)). Nor does Kanasco dispute that as a result of that suit, the company and FDA entered into the 1984 Agreement, which, *inter alia*, prohibited Kanasco from manufacturing or shipping any drugs without FDA's prior written authorization. *See* FDA Ex. 19.

4. The Aspartame Products

The NOOH charged:

> In December 1984, FDA learned that during the previous year Kanasco had manufactured numerous batches of oral dosage form products intended for human use using aspartame, a sweetener which at the time had not been approved for use in drugs. Kanasco's batch records did not reflect that aspartame had been used in the products. Instead, the records showed that sodium saccharin, an approved sweetener, had been used in the products. By letter dated January 4, 1985, FDA requested that these lots be recalled to the retail level.

52 FR 7313.

An FDA official explained the background of these events more fully. He stated:

> During the period November 8, 1984 through February 20, 1985, FDA investigated the use of [a]spartame in Penicillin V Potassium for Oral Solution products manufactured by Copanos. The investigation revealed that the firm had manufactured at least 25 batches of such products in which [a]spartame was used. However, Copanos' batch production and control records for these batches do not declare the use of [a]spartame in the batches. Rather, they showed that sodium saccharin had been used in the products. FDA analyses of samples collected from five of the lots (Copanos lot numbers 904D3JA, 90764JA, 90534JA, 91984JA, and 90964JA) confirmed the presence of [A]spartame in the batches. Because Copanos' batch production and control records for these batches do not declare the use of [A]spartame in the batches, they are false documents. [Three persons] signed the relevant part of these records * * *".

FDA Ex. 35, Second Declaration of Carl I. Turner, p. 6.

When FDA's Baltimore District Office learned of this matter, it sought an opinion regarding the potential health consequences of the substituted sweetener. The agency's Office of Drugs reported as follows:

> Patients with phenylketonuria have a decreased ability to metabolize the amino acid phenylalanine [present in aspartame].

[5] Mr. Byers' declaration does not refer to the 1984 inspection, to any of the specific batches of product with which FDA noted problems, to any of the specific findings in the Form FD 483, or to Mr. Hooker's and Dr. Turco's declarations. *Compare* Kanasco Ex. 2, *with* FDA Exs. 17 and 18. Mr. Byers states only that from time to time he certified various batches of product for release, and that FDA "released most batches he certified." Kanasco Ex. 2, p. 1. While Mr. Byers' declaration does not so reflect, FDA refused to release many of the products which Kanasco produced in 1984, including but not limited to those for which false batch records had been prepared. *See* FDA. Ex. 45 discussing the "partial lots". Nor does Mr. Byers' declaration reflect the fact that even he was unable to certify that two of these 1984 batches had been produced in compliance with CGMP. *See* FDA Ex. 20, p. 2; 52 FR 7313.

Infants and children with this disorder who are not treated with a special diet low in phenylalanine frequently develop severe mental retardation. Taking into consideration the amounts of aspartame reported to be in the oral penicillin solution of up to 10 mg per 5 mg and the usual dosage of penicillin, it is estimated that patients with phenylketonuria would receive an amount of phenylalanine that is about 5% of their recommended dietary intake. The degree of risk posed by this additional intake of phenylalanine over the two or perhaps four week period these patients might receive the penicillin is not known, but there is a potential for some degree of central nervous system damage.

FDA Ex. 22, January 4, 1985 letter to John D. Copanos from Janice F. Oliver. As a result of that information, FDA asked Kanasco to recall the lots in question. *Id.*

Kanasco has not offered any evidence in this proceeding to controvert the events described in this section. The record shows that on December 18, 1984, the firm's president advised FDA that the unapproved ingredient had been added to the lots "inadvertently". FDA Ex. 21. Although it is not necessary to determine in this proceeding whether these occurrences were intentional or inadvertent, the views of the agency's CGMP expert who responded to this same argument when it was presented by Kanasco to the district court, place Kanasco's argument in the proper perspective. He stated:

In a properly run manufacturing facility, these aspartame incidents would not happen because the identity and lot number of each ingredient or mixture of ingredients must be clearly identified on the container. *See* 21 CFR 211.80(d), 211.101 (b) and (c). Also, I do not understand how this error was not discovered until after numerous lots of product had been produced by the firm.

FDA Ex. 35, Declaration of Kenneth E. Avis, p. 6; *See also* FDA Ex. 35, Declaration of Salvatore Turco, p. 5. It is worth noting that two of the persons involved in the aspartame incidents were also involved in the admitted record falsifications during the 1984 inspection. *Compare* FDA Ex. 35, Second Declaration of Carl Turner, paras. 7 and 8, *with Id.*, para. 10(b).

There is no reason to have an evidentiary hearing on this issue. The events are undisputed. These ingredient-substitution incidents are virtually identical to those brought to Kanasco's attention in 1977, 1979, and 1980. *See* FDA Exs. 5, 11, and 14.

5. The February-March 1985 Inspection

With respect to this inspection, the NOOH stated as follows:

In January 1985, a consultant retained by Kanasco certified to FDA that the firm's injectable drug manufacturing operation was in compliance with CGMP. However, when FDA conducted an inspection between February 15 and March 15, 1985, to verify the certification, the agency concluded that the injectable operation was not in compliance with CGMP. The written list of deficiencies, which FDA gave to the firm and discussed with the firm's management, included:

- Failure to validate aseptic processing procedures, sterilization equipment and procedures, gowning procedures, and the water for injection system.
- Failure to have primary barriers, e.g., laminar flow hoods, to control the flow of microbiologically filtered air in critical manufacturing areas such as the sterile filling room (where sterilized products are placed into the pre-sterilized product containers) and the mixing area (where sterilized powders are placed into mixing tanks).
- Failure to assure that positive air pressure was maintained between the aseptic filling room and adjacent areas. Temperature and humidity were not recorded for the filling area, and no limits had been set for these parameters.
- Environmental monitoring of aseptic manufacturing environment was inadequate. Rodac plates were used to monitor surfaces only on a weekly basis. No quantitative microbiological air sampling had been performed. Isolates and flora found in the manufacturing area were not identified. Non viable particulate counts were only conducted under static conditions which did not reflect the actual manufacturing situation.
- Procedures for cleaning and sterilizing manufacturing equipment omitted important steps.
- Microbiological and other testing procedures were inadequate, were not carefully reviewed by supervisory personnel, and failed to follow recognized compendial standards (e.g., sterility test procedures failed to include a control to assure that the firm's analysts could recover low level contaminants; endotoxin test procedures used a control that was 1000 times higher than the compendial standard).

By letter dated March 20, 1985, FDA advised Kanasco that the agency would not authorize the distribution of any injectable drug products which had been made under manufacturing conditions reflected by the February-March 1985 inspection.

52 FR 7313.

One of FDA's CGMP experts in this proceeding made the following observations regarding several of the foregoing deficiencies:

(a) *Processing procedures for the manufacture of aseptically processed sterile drug products were not validated.* (*See* February-March FD 483; items 1, 4, 5, 6, 7 and 14; . . . and 21 CFR 211.113.)

5. There are two ways to make a drug product sterile: by terminal sterilization and by aseptic processing. Terminal sterilization is the sterilization of a product after the components have been placed in the final container. Aseptic processing, the method used by the Copanos company, is the processing and filling of previously sterilized drug powders or liquids into previously sterilized containers, under aseptic, i.e., virtually microorganism-free conditions. The environment in which aseptically processed products are handled and filled must be designed and rigorously controlled to assure that the final products will not become contaminated during the filling process. FDA Ex. 45, June 19, 1986, Declaration of Kenneth E. Avis.

6. It is *essential* that an aseptic process be validated. An aseptic fill process is validated only when it has been *documented* by reliable, technological means to be capable of *consistently* producing a sterile product. Because of inherent statistical limitations (which I will explain more fully below), end-product testing of a portion of a batch cannot provide assurance that each and every vial in the batch is sterile. Accordingly, CGMP practitioners universally recognize that quality must be built into the product at each and every step of its manufacture; quality assurance cannot be "tested into" the product. Validation is the way to assure that the process will consistently do what it is supposed to do. *Id.*

7. Although the Copanos firm aseptically processes its sterile products, the company had not conducted adequate process validation to assure that [products] would consistently be sterile. *Id.*

* * * * *

(b) *The manufacturing environment was not adequately monitored.* (*See* February–March FD 483, item 3; * * * and 21 CFR 211.42(c)(10)(iv)).

15. In conjunction with validation, it is also necessary to determine the level and nature of contamination present in the manufacturing environment when and where products are being aseptically filled. This type of monitoring is accomplished by taking microbiological samples of the air and surfaces in manufacturing areas, including the aseptic fill area. Only by determining the quantity and type of contamination present in the aseptic area, and by concurrently making every effort to achieve and maintain an ultra clean environment, can a baseline for judging and accepting future production be established. Without such a baseline, there is no proper way to determine whether products were filled in a suitably clean environment. To the extent products are filled in an unclean environment or in an environment whose quality has not been ascertained and documented, assurance of product purity is lacking. *Id.*

16. Prior to the February–March 1985 FDA inspection, the firm had failed to adequately monitor the manufacturing environment for microbiological contamination. The firm's monitoring was inadequate because it was not done under actual manufacturing conditions, surface sampling was not performed, microorganisms were not identified, and volumetric air sampling was not performed to determine the quantity of microorganisms present. Also, the firm's monitoring did not take into account the possible inhibitory effect that ambient penicillin (used in some of the firm's products) would have on the detection of contamination in the manufacturing area if any microorganisms were present . . . In light of these deficiencies, there can be no

adequate assurance that products were produced in an acceptably clean environment. *Id.* * * *

(e) *The aseptic fill area was not suitably designed and maintained to provide adequate protection against contamination. (See* February–March 1985 FD 483, item 2, and 21 CFR 211.42(c)(10) (ii) and (iii).

40. For aseptic processing to be effective, filtered, virtually microorganism-free, air must be provided to the area immediately surrounding the exposed drug components and containers. The filtered air must be supplied directly to the aseptic fill area in a manner that prevents movement of the air from personnel and other potential sources of contamination to the product. Proper environmental control of this filtered air depends upon the use of the primary and secondary microbiological barriers. Design features that make use of the double barrier include hoods, cabinets, or other types of enclosures that serve as the primary barrier around the process, and the room itself, which serves as a secondary barrier. For many years, laminar air flow hoods have been commonly used in the aseptic process to provide this essential protective primary barrier. *Id.*

41. The Copanos firm did not employ laminar flow hoods or any other primary barrier system in the aseptic processing area until early March 1985.

Accordingly, * * * any * * * lots which were produced without a primary barrier were even more likely to be exposed to contamination * * *. *Id.*

(f) *The sterilization procedures for the manufacturing tanks, mixing tanks, hoses and holding tanks were inadequate. (See* February–March 1985 FD 483, item 5, and 21 CFR 211.67).

42. Aseptic processing is predicated not only on the cleanliness of the surrounding manufacturing environment, but also on the sterility of the various components (including the bulk drug product) and containers used to manufacture the finished drug. The sterilization of the delivery system used to transport the sterile bulk drug product to the filling operation can be highly complex. The written standard operating procedure relating to the cleaning and sterilization of equipment (e.g., manufacturing tanks and connecting hoses) which the firm used prior to March 20, 1985 was vague and did not provide adequate guidance to assure that critical components would be properly cleaned or sterilized. Inadequate sterilization of delivery equipment provides a potential additional avenue by which products may become contaminated.

Id.; See also FDA Ex. 33, July 29, 1985, Declaration of Edmund Fry, *passim.*

With few exceptions, Kanasco has not contested either the accuracy or the significance of the findings made by the FDA investigators during the February–March 1985 inspection. None of the observations were challenged as being outside the bounds of CGMP. For example, in its March 1985 response to FDA's observations, Kanasco stated as follows:

Aseptic processing procedures [for manufacturing tanks and hoses] were validated by water fills every six months at the same time as environmental testing was performed by an outside consulting firm. Kanasco Ex. 14, March 20, 1985 letter, pp. 1 and 5. * * *[6]

The observation that media fill validation should be performed as an additional stringent test to assure the integrity of aseptic processing procedures was readily accepted. Aseptic processing procedures now have been validated through a media fill, results of which are reported in Attachment 1 * * *. One or more additional media fills will be conducted within the next three months to build a validation history * * * *Id.*, p. 2.

Particle counting under dynamic conditions will be conducted during manufacturing to obtain meaningful "in use" data. A validation history using this parameter will be generated. *Id.* * * *

Laminar flow hoods were reinstalled in the sterile filling room and validated during the course of the inspection. Primary barrier systems for the mixing area are being evaluated to determine their feasibility and suitability. *Id.*, pp. 2 and 3.

Magnahelic gauges have been ordered and will be installed to monitor the positive air pressure in the filling room and to measure pressure differentials among rooms used to manufacture parenteral products * * *. [T]emperature and humidity levels have been established for the powder filling operation, and temperature limits have been set for the liquid filling operation * * * Appropriate temperature and humidity recording devices have been installed. *Id.*, p. 3. * * *

Environmental sampling procedures have been revised. Settling plates and Rodac plates will be used on a daily basis. Plates were checked for their growth-promoting properties. As of February 26, 1985, Penase has been used to assess the inhibitory effect of penicillin on test results * * *. *Id.*, p. 4.

Quantitative microbiological air sampling will be performed using a quantitative air sampler (centralfugal) [sic]. Criteria to identify isolates and flora will be established and incorporated into a revised SOP. *Id.* * * *

The sterilization procedures for the tanks and hoses have been validated . . . . Additionally, the SOP for the sterilization of the system has been revised to particularize the essential steps that must be performed during the sanitizing process . . . . Piping on the gel (manufacturing) tanks has been altered to remove the "dead leg." Filters now fit directly on the manufacturing tanks, thus eliminating the need for a more complex sterilization procedure for piping. * * * *Id.*, p. 5.

Validation of the distilled water (closed system) was not performed at frequent intervals because the constant (daily) testing of the water did not indicate any problems. The SOP did not call for revalidation until daily testing revealed a problem. The system was validated and, because no changes were made to it, revalidation was not regarded as necessary. The Sterile Water for Injection System now has been revalidated. As an additional safeguard, the system will be validated on a regular periodic basis. *Id.*, pp. 5 and 6 * * *

The two drops in the Sterile Water for Injection System in the holding tank room have been removed. A revised SOP provides for a daily flush of the line to the lab and stopper washer. *Id.*, p. 6 * * *

Water directly from the still and feed water to the still will be sampled and tested on a regular periodic basis . . . . The test procedure for determining sterility of water from the Sterile Water for Injection System has been revised to provide for a 100 mL sample. Additionally, LAL testing procedures have been revised to assure that the appropriate positive control is employed. *Id.* * * *

Sterility test procedures have been amended to provide for a periodic positive system control to assure that analysts can recover low level contaminants. *Id.*, p. 7.

At the conclusion of the letter, the company's counsel again assured FDA of Kanasco's desire and ability to comply with CGMP, and asked to be permitted to resume manufacturing injectable drugs. *Id.*, p. 12.

By letter dated April 12, 1985, the Director of the FDA Baltimore District declined Kanasco's request to resume manufacturing injectable drugs. *See* FDA Ex. 26, April 26, 1985 letter to John D. Copanos. Among other things, FDA advised the firm that the single media fill which it had performed in February 1985 had an unacceptable failure rate; that three consecutive, successful media fills were necessary to validate aseptic processing procedures; the firm had not performed any monitoring for particulates during the media fill; the firm's media fill data failed to show that penase had been added to the media (to counteract the inhibitory effect that penicillin might have on the growth of any microorganisms in the media); data submitted by the firm failed to show that quantitative air sampling had been performed, that criteria had not been established to identify isolates and flora found in the facility, or that the agency's observations in the laboratory had been corrected. *Id.*, 2. Moreover, and more importantly, the letter also told Mr. Copanos:

Of far greater importance to us than any particular CGMP observation is the underlying cause of deficiencies that were observed in the laboratory area of your operation. These deficiencies and the ones described in paragraph 12 of the FD 483 lead the agency to conclude that your firm does not have an adequate number of individuals with sufficient training and experience to perform the necessary quality control, quality assurance, and laboratory activities. Indeed, viewed as a whole, the FD 483 underscores

[6] No documentation to support the "water fill" data were ever provided to FDA by the firm. Nor has FDA ever accepted such data from any other firm to validate an aseptic process.

our concerns regarding one of the basic problems which led the agency to pursue regulatory action in the first place: the inadequate number, training and experience of both operating and supervisory personnel associated with manufacture and control of drug products. *Id.*, p. 3.

Kanasco also has not offered any specific facts to counter the agency's assessment of the underlying cause of the observations made by FDA in February and March of 1985. *See* Kanasco Exs. 13 and 14. It is again worth noting that several previously observed deficiencies reappeared during the February–March 1985 inspection (e.g., failure to validate equipment used to aseptically process drugs, failure to establish and record manufacturing parameters, failure to maintain equipment, and failure of management to review and approve manufacturing and testing procedures). *Compare* sections A and B, *supra, with* this section.

In view of the foregoing evidence and Kanasco's response, there is no genuine, substantial dispute requiring an evidentiary hearing with respect to the findings of this inspection.

6. The May 1985 Inspection

The NOOH stated the following with regard to this visit to the Kanasco facility:

In May 1985, FDA returned to Kanasco to evaluate the results of media fills that had been conducted by the firm in April and to inspect the procedures used by the firm's microbiological laboratory. The inspection revealed that the media fills were unsatisfactory and that the firm's microbiological test procedures were inadequate. The FDA–483, which FDA left with the firm, included the following observations:

- Kanasco's sterility test procedures did not include proper controls to assure that low-level contamination would be detected.
- There was no standard test procedure available which reflected the test procedures currently used by the firm.
- A control test used in conjunction with sterility testing did not follow recognized compendial standards.
- Environmental contaminants found in the manufacturing area were not identified.
- Followup investigations had not been conducted to determine the nature or cause of quality control test failures.

52 FR 7314; *See also* FDA Ex. 27, Form FD 483 dated May 8 and 9, 1985.

By letter dated May 10, 1985, FDA again advised Kanasco management that in the agency's opinion the "underlying cause" of the deficiencies which had been observed at the firm appeared to be related to the number, training, and supervision of personnel. After commenting that "[s]ome of these deviations [observed in May 1985] occurred after training had been provided to plant personnel," the letter concluded, FDA is "also concerned about the people who work at the Copanos plant and the adverse impact these past several months may have had on them and their families. However, [the agency] must balance our concerns for them with an equal concern for people who will consume the product produced by the firm." FDA Ex. 28, May 10, 1985 letter to counsel for Kanasco, p. 2.

The FDA expert who reviewed the observations made during the May 1985 inspection and similar observations of Kanasco's laboratory practices had the following to say:

(c) *Laboratory procedures for testing were inadequate and/or not accurately reviewed; laboratory personnel were not adequately trained and supervised.* (*See*, e.g., February-March FD 483, item 12; May 1985 FD 483, items 1 to 4; and 21 CFR 211.192 and 211.194).

17. The laboratory is a critical aspect in making pharmaceutical products. It is supposed to provide a check on the safety, purity, strength, and quality of all components used in making a product, the environment in which the product is assembled, and the finished product itself. The assurance that a product has these characteristics is no better than (but not necessarily as good as) the laboratory procedures and personnel who test the products, their ingredients, and manufacturing environment. *See* FDA Ex. 45, June 19, 1986, Declaration of Kenneth Avis.

18. The deficiencies observed at the Copanos laboratory during the March and May 1985 inspections and uncovered during the Summer of 1985 (e.g., the unavailability of a standard sterility test procedure, failure to periodically test employees' ability to conduct the tests they perform, the use of proper control organisms in test procedures, the practice of the firm's microbiologist not to have her tests independently checked and verified by a second person, the missing and false sterility and pyrogen tests discovered by FDA investigators, and the inability of the firm's microbiologists to follow standard test procedures * * * reflected a lack of supervision and training of the firm's laboratory employees. In view of these deficiencies, I have little confidence in any of the tests performed by this laboratory. *Id.*

The firm has not provided any specific facts to dispute the accuracy or CGMP significance of the FDA's observations made during this inspection. By letter dated May 14, 1985, Kanasco's counsel responded to the observations as follows:

An SOP is being written to include periodic positive system controls employing the foregoing organisms, and the procedure will be instituted upon resumption of manufacture. Kanasco Ex. 13, May 14, 1985 letter from Kanasco to Mr. Thomas Hooker, p. 2. * * *

The SOP for sterility testing has been in the process of revision to conform it to current laboratory procedures. It will be finished and in effect prior to resumption of manufacture. *Id.* * * *

The revised sterility test SOP will eliminate use of other organisms and provide for use of Staphyloccocus aureus as the exclusive positive penase control. *Id.* * * *

As noted above the three bottles of [media] the company found "hazy" have been sent to a laboratory for testing, and the one bottle that visibly displayed growth was determined to contain gram positive rods. Speciation is being conducted on the organism in the bottle that displayed growth. The other three (3) bottles will be speciated if they are contaminated. *Id.*, p. 3 * * *

Speciation has not been performed on a regular periodic basis. The Company will establish an SOP for periodic testing of environmental contaminants, including their speciation. This additional environmental monitoring will go into effect upon resumption of manufacture. Appropriate modifications of cleaning, gowning and other procedures will be made, as may be necessary or desirable, based upon these and other environmental monitoring results. *Id.*

Procedures to investigate distillate water and product samples when a test result exceeds [the specification] for water or is positive for product are being written. *Id.* * * *

In the case of product, retest procedures will be written to conform to official standards. *Id.* * * *

There were typographical errors in SOP 1.3, . . . In actual use the directions received from the supplier of the standard . . . were followed . . . SOP 1.3 has been rewritten to correct the typographical errors. . . . *Id.*, p. 4.

There is no genuine and substantial dispute with respect to these observations which require a hearing. Not only are these deficiencies uncontested, but also they demonstrate the continuing inability or unwillingness of the firm to correct its CGMP deficiencies. As before, many of the problems found in this inspection had been pointed out to the firm during the earlier inspections (e.g., the failure to identify microorganisms found in the facility and the absence of a periodic system control were observed during the February-March 1985 inspection; the failure to follow current official testing procedures was noted in the 1978 and February-March 1985 inspections; the failure to follow company SOPs was noted in the 1978 inspection). In addition, several of the problems observed during this inspection represented unfulfilled promises made during earlier inspections (e.g., in March 1985, Kanasco had promised to institute a periodic systems control and a program to identify plant isolates (*See* Kanasco Ex. 14, pp. 4 to 7)).

Finally, the significance of the problems has not and cannot be

disputed. If the causes of test failures are not investigated, they will almost inevitably be repeated. *See* 21 CFR 211.192. If laboratory employees do not follow current official methodologies and are not supervised to determine that they are following appropriate procedures, assurance of product quality, purity, and identity is diminished.

7. Unauthorized Shipment and Manufacture of Injectable Drugs

The NOOH stated:

In June 1985, FDA learned that Kanasco had shipped several thousand vials of an injectable product to one of its customers in New Jersey. This shipment had not been authorized by FDA and was in violation of the Agreement. Kanasco personnel provided FDA investigators with manufacturing and shipping records which, although Kanasco represented them as being complete, did not reflect the violative shipment.

In July 1985, FDA investigators learned that between January and June 1985, Kanasco had manufactured 23 lots of injectable drug comprising more than one million vials. FDA had only authorized Kanasco to manufacture one batch of injectable product on a "pilot" basis to test the firm's manufacturing process.

52 FR 7314.

The FDA's evidence regarding the circumstances surrounding the unauthorized shipment is as follows:

14. Paragraph 4(a) of the 1984 Agreement prohibits the defendants from shipping in interstate commerce any lot of veterinary drug unless and until they receive written authorization from the FDA to do so. Investigations conducted by FDA investigators have documented that on February 6, 1985, the defendants shipped 2,688 vials of a veterinary injectable drug, dihydrostreptomycin solution (100 mL) lot number 4H314, in interstate commerce before the FDA released the lot for interstate shipment. In fact, by letter that was hand-delivered to the defendants on February 4, 1985, FDA advised the defendants that lot 4H314 'may not be distributed in interstate commerce at this time.' The lot was not released by the FDA until March 1, 1985. *See* FDA Ex. 33, July 29, 1985, Declaration of Carl I. Turner.

15. Documents obtained by FDA from sources independent of the defendants show that 2688 vials of lot 4H314 were labeled with the defendants' Veticare label and shipped on February 6, 1985, to Newark Refrigeration Company, Newark, New Jersey, to the account of Sussex Drug Products Company, Middlesex, New Jersey. *Id.*

16. Further FDA investigation at defendants' plant has documented that in order to cover up the February 6, 1985 shipment of the 2688 vials of lot 4H314, the defendants have withheld from FDA several documents relating to the foregoing shipment (*e.g.*, sales invoice and shipping records) other distribution and labeling records which are required to be maintained by the CGMP regulations. *Id.*

17. Labeling records supplied to FDA investigators by defendants Ellerton and McGraw purport to show that no vials of lot 4H413 were labeled by the defendants with the Veticare label until March 8, 1985, four weeks after the February 6, 1985 shipment actually occurred. These records (which were signed by several of the defendants' employees) were represented by the defendants as covering all labeling operations relating to lot 4H314. *Id.*

18. When requested by FDA investigators to provide documentation of all shipments of lot 4H314, defendants Ellerton and McGraw provided documentation of four shipments, all of which occurred on or after March 8, 1985. The defendants Ellerton and McGraw also provided FDA investigators with a distribution summary which was supposed to record all shipments of lot 4H314. This record did not reflect the February 6, 1985 shipment of lot 4H314. In fact, no record was provided to the investigators which covered the February 6, 1985 shipment. *Id.*

The circumstances surrounding the unauthorized manufacture were as follows:

3. * * * Paragraph 3(c) of the 1984 Agreement prohibits the defendants from manufacturing any veterinary drug products unless and until defendants have received written notification from the FDA that they are in compliance with current good manufacturing practice (CGMP) regulations and may resume the manufacture of veterinary drugs. *Id.*

At a recent meeting which I attended [on July 16, 1985] the defendants and their counsel were told that FDA would authorize resumption of the manufacture of injectable drugs as soon as they had conducted three consecutive successful media fills (to validate their sterile fill process) and provided FDA with scientifically documented explanations as to why previous media fills had been unsuccessful. *Id.*

5. To date, neither of the foregoing events has occurred and the FDA has not notified the defendants that their operations relating to the manufacture of injectable veterinary drugs are in compliance with CGMP requirements. Neither has the FDA authorized the defendants to resume the manufacture of injectable veterinary drugs. *Id.*

6. In a letter dated January 11, 1985, Mr. Thomas L. Hooker, FDA's Baltimore District Director, authorized the defendants to manufacture 'a pilot batch of a veterinary drug' for the limited purpose of allowing the defendants' consultant an opportunity to evaluate defendants' degree of compliance with CGMP requirements. [Exhibit citation omitted.] *Id.*

7. In letters dated February 8 and March 6, 1985, the Baltimore District was notified by the defendants that several lots of veterinary parenteral drug products had been manufactured for evaluation purposes. *Id.* * * *

9. By letter dated March 20, 1985, Mr. Hooker warned defendant John D. Copanos that defendants' manufacture of veterinary drugs without FDA approval was a violation of paragraph 3 of the agreement and warned him to cease the manufacture of veterinary drugs. See [FDA Ex. 25]. *Id.* * * *

11. By letter dated April 12, 1985, Mr. Hooker again advised the defendants that 'the agency does not agree that the facilities, controls, and procedures used by your firm in the production of sterile veterinary drug products are in compliance with CGMP regulations. Accordingly, we are unable at this time to authorize resumption of the manufacture of sterile veterinary drug products.' *See* [FDA Ex. 26]. *Id.* * * *

13. As shown by the declaration of FDA investigator Bruce W. Hartman [FDA Ex. 33], between January 11 and June 15, 1985, the defendants manufactured 23 veterinary parenteral drugs. The only batch which the FDA authorized the defendants to manufacture, the 'pilot' batch, was lot 2A115 produced on January 11, 1985. Although FDA was advised— after the fact—that defendants had produced two other pilot batches, the agency was never told about or authorized any additional production.

Id.; See also FDA Ex. 33, July 1985 Declaration of Bruce Hartman who observed the 23 lots of drug at the Kanasco facility.

Kanasco, in its response to the NOOH, has not offered any specific facts to rebut the foregoing.[7] In fact, a review of the firm's hearing request would not indicate that the events described in this section had ever occurred. These events are not only a clear violation of CGMP which require the maintenance of accurate and complete records (*See*. e.g., 21 CFR 211.25, 211.188 and 211.196), but also are irreconcilable with the entire philosophy of CGMP which presumes that the regulations will be honestly and faithfully followed. As one of the agency's CGMP experts stated:

Although obvious, it is worth recalling that the quality of drug product which a firm

[7] The conclusory, unsubstantiated, and unexplained assurance of Kanasco's expert, Mr. Byers, "[d]uring the two and one-half years I have been involved with Mr. Copanos and the firm, I have found him and his personnel to be trustworthy and honest in all their dealings with me, notwithstanding certain allegations by FDA concerning the integrity of the records in the past" (Kanasco Ex. 2, p. 6), is plainly not sufficient to create a genuine and substantial issue of fact on these issues. 21 CFR 314.200(g); Rule 56(e), F. R. Civ. P.; *Evers* v. *General Motors Corp.*, 770 F.2d 984, 986 (11th Cir. 1985) (expert's affidavit which purports to be based on a review of the evidence but which fails to provide specific facts to back up conclusory allegations, inadequate to defeat summary judgment); *United States* v. *Various Slot Machines on Guam* 658 F.2d 697, 700–01 (9th Cir. 1981) ("in the context of a motion for summary judgment, an expert must back up his opinions with specific facts. * * * It would be an imposition on the trial judge, and make a mockery of summary judgment to hold otherwise"); *See also, Merit Motors* v. *Chrysler Corp.*, 569 F.2d 666, 673 (D.C. Cir. 1977). Moreover, in view of Kanasco's failure to specifically rebut any of the evidence regarding its recordkeeping practices, these items are no longer allegations, but established facts. 52 FR 7311 to 7317.

produces is almost entirely dependant upon the extent to which its employees understand and scrupulously follow CGMP. This is clearly implied in the first substantive section of the CGMP regulations which require that personnel shall 'perform assigned functions in such a manner as to provide assurance that the drug product has the safety, identity, strength, quality, and purity that it purports or is represented to possess.' *See* 21 CFR 211.25.

FDA Ex. 35, October 21, 1985 Second Declaration of Salvatore Turco, para. 6.

In light of the foregoing, it is clear that there are no genuine and substantial issues that require a hearing with respect to the events described in this section.

8. The July 1985 Inspection and Media Fills

The NOOH stated:

In early July 1985, Kanasco conducted three media fills which were either abandoned prematurely by the firm and/or had excessive failure rates. On July 10, while FDA was monitoring two of these media fills, FDA observed several CGMP violations and provided Kanasco with a written list of deficiencies (FDA-483). These observations included:

• Flexible tubing used in the morning fill was reused in the afternoon fill without aseptic storage or proper resterilization.

• Personnel in the aseptic fill room touched exposed portions of their faces with gloved hands.

• Personnel reached across the conveyor which was holding previously sterilized bottles.

52 FR 7314; *See also* FDA Ex. 30, Form FD 483 dated July 12, 1985.

With respect to these and other poor employee practices observed later at Kanasco one of FDA's CGMP experts observed:

(d) *Employees were not adequately trained in aseptic technique.* (*See* e.g., July 12, 1985 FD 483, items 7 to 12; July 15 to 17, 1985 FD 483, items 3 to 6 on p. 1 and items 1 and 2, p. 2; November 1985 FD-483, items 1 and 3; and 21 CFR 211.25. *See* FDA Ex. 45, June 19, 1986 Declaration of Kenneth E. Avis.

20. The FDA's observations in July 1985 show that this firm's employees were not trained in aseptic technique. * * *

21. Because there are countless ways in which an employee can inadvertently cause a product to be contaminated (e.g., by touching exposed portions of the body and then touching the product, placing any portion of the body between the product and the filtered air, not scrupulously following sterilization procedures, or not properly gowning up), it is essential for employees who are involved in making sterile drugs to understand the significance of what they are doing and be able to perform manufacturing operations properly. In fact, employees are perhaps the principal source of product contamination. *See* e.g., Tetzlaff R. F., 'Regulatory aspects of aseptic processing, *in* Pharmaceutical Technology, November 1984, 38, 40, exhibit 1 attached hereto. ("Because employees are a major source of microbial contamination, thorough and continuous training in aseptic techniques is necessary and should be systematically documented as well.") The Parenteral Drug Association regards aseptic technique sufficiently important that it makes and distributes films and other training materials to its members. In fact, many firms make their own films and have specialized programs to train employees in aseptic technique. *Id.*

Kanasco has not come forward with any specific facts to rebut the occurrence or CGMP significance of these observations, and there is no genuine and substantial controversy requiring an evidentiary hearing.

9. FDA Refiles Complaint for Injunctive Relief

As noted in the NOOH, based on the foregoing events, on August 7, 1985, the Government filed its second complaint for injunctive relief in the district court. Civil No. K-85-3356 (D. Md.). *See* FDA Ex. 33, Government's Request to Enter Consent Decree of Permanent Injunction, and attachments thereto. On August 15, 1985, the court entered a show cause order against Kanasco. *See* FDA Ex. 34, 52 FR at 7314.

10. Further Recordkeeping Irregularities

The NOOH stated:

While the [August 15, 1985 show cause order] was pending, and based upon information provided by several Kanasco employees, FDA obtained a criminal search warrant. The evidence obtained from the firm's employees as well as that obtained from the search warrant was presented to the court on August 19, 1985. Among other things, the evidence showed the following:

• Copies of manufacturing batch records for the same lot of product (which should have been identical) were significantly different.

• Sterility and pyrogen test results which were positive (indicating product contamination) obtained under the search warrant were not filed in Kanasco's batch records although test results which were negative (indicating that the products were not contaminated) were filed in the firm's batch records.

• Pyrogen test samples had been sent by Kanasco to a testing facility in New Jersey before product filling had begun at Kanasco (Pyrogen tests can properly be done only on finished product).

• Recording charts used to monitor processing temperatures were not authentic.

52 FR 7314.

The FDA's evidence with respect to these events is as follows:

[Batch Record Discrepancies]

12. (a) On May 1, 1985, the FDA informed Copanos that the agency had tested a sample of Procaine Penicillin G Aqueous Suspension, an injectable antibiotic (Copanos lot number 2A115) for sterility and found it grossly contaminated with bacteria. In various discussions with FDA personnel, and in a letter from his attorney dated June 7, 1985, Mr. Copanos stated that he suspected that the contamination came from raw material active ingredients, Procaine Penicillin G. *See* FDA Ex. 35, August 19, 1985 Declaration of Carl I. Turner.

(b) In August 1985, a Copanos employee gave FDA investigators records which he/she said were copies of original batch records that had been changed. I have compared the records given to the FDA investigators by the Copanos employees with the corresponding pages in the batch production and control records given to FDA by Dr. Ellerton during the course of FDA inspections conducted between June 12 and August 1, 1985. Both sets of records relate to 23 batches of product produced in violation of the [1984] Agreement. (The products reflected in these records are: Procaine Penicillin G Aqueous Suspension (Copanos lot numbers 2A115, 2SC195, 2D045 and 2C205), Penicillin G Benzathine Penicillin G Procaine Aqueous Suspension (Copanos lot numbers 21C225 and 21A185) and Penicillin G Procaine with Dihydrostreptomycin Sulfate Solution (Copanos lot number 1C275)). Although the records given to the FDA investigator by the Copanos employee are identified with the same finished product lot numbers as the records provided to FDA by Dr. Ellerton (and should therefore be identical in all respects), they are significantly different than the batch production and control records given to FDA investigators by Dr. Ellerton. *Id.*

(c) The records from the employee show that one of the active ingredient raw materials which Mr. Copanos had identified as being the possible cause of the contamination in Copanos lot number 2A115 (*See* paragraph 12(a) above), lot number G34032, was used in the manufacture of *five* other lots (Copanos lot numbers 2SC195, 2C205, 21C225, 1C275, 2D045). However, the records received from Dr. Ellerton show that *other* active ingredient raw materials were used in the manufacture of lots 2SC195, 2C205, 21C225, 1C275, and 2D045. Portions of the batch production and control records given to FDA investigators by Dr. Ellerton appear to have been prepared to conceal from the FDA the fact that an active ingredient raw material (lot number G34032) had been used in the manufacture of the above described five lots. [Four] Copanos employees * * * signed the relevant part of the records which Dr. Ellerton provided FDA * * *. *Id.*

13. The records received from the Copanos employee for Penicillin G Procaine Penicillin G Benzathine in Aqueous Suspension (Copanos lot number 21A185) also are different than the batch production and control records for lot 21A185 that FDA received from Dr. Ellerton. The records received from the employee show that specific lots of raw material active ingredients (Copanos lot numbers D674, D687, 70063V2 and 70065V1) were used to

manufacture lot number 21A185, whereas the batch production and control records received from Dr. Ellerton show that *another* lot of raw material (Copanos lot number G34032) was used to manufacture this product. The batch production and control record for lot 21A185 given to FDA investigators by Dr. Ellerton appears to have been prepared to show that the raw material (Copanos lot number G34032) was used in only *one* other lot (Copanos lot number 21A185) rather than *five* other lots (Copanos lot numbers 2SC195, 2C205, 21C225, lC275, and 2D045). [Three] Copanos employees * * * signed the relevant portions of the records which Dr. Ellerton gave to FDA * * *.

Id.; See also FDA Ex. 35, October 22, 1985 Fourth Declaration of Carl I. Turner.

[Sterility Test Record Discrepancies]

16. Partially as the result of a Search Warrant executed at Copanos on August 13, 1985, FDA has obtained copies of sterility tests performed on some of the 23 lots that were manufactured in violation of the [1984] Agreement. These sterility test records show that Copanos' employees tested these lots and found some of them to be contaminated. These results are summarized in the following chart:

Date lot manufactured	copanos lot No.	Sterility test results obtained from Copanos employees and/or search warrant	See exchange No. 7	Sterility test results in batch records	See exchange No. 7
1/11/85	2A115	3/5/85 (−)	a	1/16/85 (−)	i
		3/5/85 (+)	b	1/16/85 (−)	j
		3/7/85 (+)*	c		
		3/21/85 (−)	d		
		5/6/85 (−)	e		
		5/6/85 (−)	f		
		6/5/85 (+)*	g		
		6/5/85 (+)*	h		
1/17/85	51A175	3/5/85 (+)	k	1/21/85 (−)	m
		3/21/85 (+)	l		
1/19/85	21A185	3/5/85 (+)	n	2/4/85 (−)	p
		3/27/85 (−)	o	3/5/85 (−)	q
4/1/85	lC215	3/22/85 (+)	r	4/8/85 (+)	t
		3/25/85 (−)	s	4/22/85 (−)	u
4/22/85	2D045	5/17/85 (+)	v	4/24/85 (−)	y
		5/21/85 (+)	w	6/5/85 (−)	z
		5/23/85 (+)	x	6/5/85 (−)	aa
4/26/85	lE035	5/1/85 (+)	bb	4/29/85 (−)	ee
		5/10/85 (+)	cc		
		5/15/85 (+)	dd		
5/31/85	lE135 (5A550) (lE095)	5/15/85 (+Bulk)	ff	6/5/85 (−)	hh
		5/22/85 (−Bulk)	gg	6/5/85 (−)	ii

See FDA. Ex. 35, October 22, 1985 Fourth Declaration of Carl I. Turner, and exhibit 7 attached thereto. (*Indicates a sterility test in which results are not identified with the customary '+' or '−' but are marked with a dot ('.'). However, the microbiologist's notes which accompany these records indicate that something was observed in the tubes on particular dates during the incubation period); *See also, Id.*, August 19, 1985 Declaration of Carl I. Turner.

17. Copanos' batch records for the above listed lots fail to contain many of the sterility test results that were conducted on these products, including (with one exception) all of the positive test results which indicate that the product is contaminated. Under the CGMP regulations, batch records must include complete information relating to laboratory control results. *See* 21 CFR 211.188. Moreover, where, as here, the laboratory test results indicate that a product failed to meet a required specification, the CGMP regulations require the manufacturer to conduct a thorough investigation and make a written report thereof. *See* 21 CFR 211.192. None of the batches listed above contained a record that such an investigation had been conducted. FDA Ex. 35, October 22, 1985 Declaration of Carl I. Turner.

18. Finally, in several instances the finished product sterility test results for lots of product are dated *before* the lots were manufactured. This indicates either that these sterility tests were not conducted on the date indicated on the firm's record or that lots other than the indicated lot (i.e., 'spiked' samples) were actually tested. *Compare* sterility test results for lots 2A295, 1C215 (2 tests), 2SC195, and 2C205, exhibits 8, 9, 10, and 11 [attached to FDA Ex. 35], *with* relevant portion of batch records which show date manufacture was completed, exhibits 8a, 9a, 10a, and 11a. [attached to FDA Ex. 35]. *Id.*

[Pyrogen Test Record Discrepancies]

16. (a). It is the practice of Copanos to send samples of all lots of sterile drugs to Leberco Testing, Inc., Roselle Park, New Jersey (Leberco), an independent laboratory, to be tested for pyrogens. (Pyrogens are the waste product of bacteria which may cause a fever in humans and animals.)

(b). FDA investigators have recently obtained from Leberco copies of records which document the testing of pyrogen samples for particular lots of Copanos products. The dates the pyrogen samples were received in New Jersey have been compared with the dates the lots were filled at Copanos in Maryland. Such tests can properly be done only on finished (filled) product. As shown by the chart below, in at least three instances, the pyrogen samples were received by Leberco *before* Copanos' batch production and control records document the lots had been filled:

Copanos lot No.	Date filling of lot began at Copanos	Date Pyrogen sample was received as Leberco
2C205	4/2/85	3/28/85
2D095	4/26/85	4/24/85
2A295	3/29/85	3/28/85

See FDA Ex. 35, August 19, 1985 Declaration of Carl I. Turner.

17. In one instance, a sample of Iron Dextran, a sterile veterinary drug (Copanos lot number 70F135), was tested on June 18, 1985, and found positive by Leberco (indicating the presence of pyrogens in the product). However, the batch production and control record received from Dr. Ellerton has a pyrogen test result dated July 16, 1985, which is negative. The positive pyrogen test result is not in Copanos' batch record given to FDA. *Id.*

[Recording Chart Record Discrepancies]

18. (a). During the course of FDA investigations at the firm, FDA investigators have reviewed the batch production and control records associated with the manufacture of seven lots of Penicillin G with Dihydrostreptomycin (Copanos lot numbers 1G244, 1G264, 1H224, 1H294, 1K234, 1K264, 1K294). Within these batch production and control records were Taylor temperature recording charts which purportedly documented either the sterilization of the products during their manufacture or the cooling down of the products preparatory to further processing. These Taylor temperature recording charts are graphs in a circular format which are designed to be mounted on a device known as a temperature recording thermometer. The device mechanically records a tracing on a chart which documents the temperatures occurring in the tank over a period of time. Sterilization is a critical stage in the manufacture of these products because the products must be sterile to be used safely.

(b). FDA investigators examined the pen tracings on the temperature recording charts in the batch records for the seven lots cited above. Because the tracings are created by a mechanical arm within the temperature recording box, and reflect temperature changes over time, such tracings are typically smooth and continuous. The tracings on the subject charts are angular and non-continuous. The configurations of the tracings on the charts suggested to the FDA that the tracings on the charts were false and were created by the human hand rather than a mechanical device.

(c). Accordingly, on March 6, 1985, FDA investigators gave photocopies of these Taylor temperature recording charts to an expert in thermal processing to evaluate their authenticity. The expert has stated that, in his opinion, the ink tracings on certain of the temperature recording charts associated with all of the above lots did not appear to be authentic.

Id.; See also Id., October 22, 1985 Declaration of Carl I. Turner, para. 20, discussing additional evidence of these charts.

FDA's expert testimony on these events was as follows:

c. [The Batch Record Discrepancies] This series of incidents reflects an attitude toward drug manufacturing that is virtually serendipitous. The mixing of ingredients for use in a product is a process which must be documented contemporaneously with its occurrence. If, as the firm suggests, [in a legal memorandum, not supported by declarations or other competent evidence], different ingredients were in the manufacturing area when the mixing took place (Defendants' memorandum, 10–13), the batch production records should have reflected the precise ingredients that were in fact used in the product. *See* 21 CFR 211.101(c) and 211.188(b)(4). In my opinion, there can be no reasonable explanation that is consistent with CGMP for the existence of two different sets of batch records relating to the same lot of product. If an error in production is made and detected during the course of production, it must be immediately noted in the batch record and explained subsequently in a written follow-up investigation. *See* 21 CFR 211.192.

In any event, the firm's 'pre-allocation system' explanation for these events is inconsistent with its own batch records and inventory records which show that the ingredients could not properly have been pre-allocated for use in these lots. *See* [FDA Ex. 35] Fourth Declaration of Carl Turner, paras. 12–15. Finally, these lots were manufactured between January and April 1985, long after the substantially similar Amoxicillin problem was brought to the firm's attention. That the problem was not promptly corrected reflects a casual attitude that is inappropriate for a manufacturer of pharmaceutical products. FDA Ex. 35, October 21, 1985, Declaration of Salvatore Turco, para. 4.

d. [The Sterility Test Record Discrepancies] I have reviewed the sterility test results for lots 2D045, 1E035, 1G264, and 1E095 (1E135). I have also read the firm's statement that these tests were not sterility tests, but rather preservative effectiveness checks (*See* Defendants' memorandum, 13–15). Based upon my experience in the parenteral manufacturing industry, I do not believe that these tests represent preservative effectiveness tests. My reasons are the same as those set forth in [FDA Ex. 35] Dr. Avis' Declaration, 10–11. Indeed, if by some remote chance these tests are preservative effectiveness tests, they are wholly inadequate for this purpose and demonstrate a fundamental lack of understanding on the part of the person who conducted the tests and on the part of the supervisors who failed to note, record, and correct the numerous deficiencies in the test methodology.

Another very serious problem is reflected by the firm's records which reflect *finished* product sterility test results that were initiated *before* the lot was manufactured. *See* [FDA Ex. 35] Carl Turner's Fourth Declaration, para. 18. There is no reasonable explanation which comports with CGMP for these discrepancies between the sterility test dates and manufacturing dates. These records coupled with the fact that these tests were not physically incorporated in the batch records suggest to me either that the lots were not manufactured on the dates reflected in the batch records or that the sterility tests were conducted on other lots of drug. In either case, there is an extremely significant problem that must be addressed and corrected before the firm should be allowed to resume making parenteral drugs. *Id.*

e. [Pyrogen Test Record Discrepancies] I have reviewed the pyrogen tests referred to in Mr. Turner's second and fourth declarations [FDA Ex. 35] and compared them with the batch records to which they purport to relate. These pyrogen tests appear to have been conducted before the lots in question were filled and manufacturing was completed. The purpose of the pyrogen test is to determine the level of febrile reaction that will be produced when the product is given to the patient. A pyrogen test is meaningful only if conducted on the finished product. Accordingly, I do not see how it is possible to reconcile the dates of manufacture shown on Copanos batch records for lots 2C205, 2D095 and 2A295 with the pyrogen test dates shown on the Leberco records. This is virtually the identical problem described in the preceding paragraph and represents an equally serious deviation from CGMP. *Id.*

5. * * * I have no confidence in the integrity of the products which have been produced by [this firm] under the conditions described above. Moreover, the explanations provided by the firm for these occurrences reflects a lack of familiarity with CGMP requirements for making injectable drugs.

The firm has gone to great lengths attempting to assure the Court that the CGMP violations were inadvertent. However, in their efforts, the firm has entirely overlooked the fact that its procedures are significant CGMP deficiencies and that the deficiencies have continued long after FDA has brought similar violations to its attention. Indeed, the practices are so egregious that they should not have occurred in the first instance. The history of this firm, including the incomprehensible decision to continue manufacturing drugs after it had agreed in writing with FDA not to do so and after FDA had advised the firm that it was not in compliance with CGMP, persuades me that stronger measures are necessary to bring about and maintain the substantial changes necessary to assure that this firm complies with CGMP. For the reasons stated in Dr. Avis' Declaration, pp. 13 & 14 [FDA Ex. 35], my opinion is not affected by the firms representations with regard to the absence of consumer complaints. Such data, if relevant at all, is far outweighed by the clear evidence which shows that this firm has not followed CGMP in the manufacturing of injectable drugs.

Id.; See also FDA Ex. 35, October 21, 1985 Declaration of Kenneth E. Avis, pp. 7 to 12.

Copanos has not offered any specific facts (or even legal argument) to rebut the occurrence or significance of these facts. These practices constitute violations of CGMP. *See* e.g., 21 CFR 211.180(d) (requiring accurate copies of batch records), 21 CFR 211.188 (requiring complete and accurate batch records), 21 CFR 211.167(a) (requiring appropriate pyrogen and sterility testing), 21 CFR 211.194 (requiring complete laboratory records to be kept with batch records), and 21 CFR 211.100(b) (requiring contemporaneous documentation of process control procedures).

11. The Interim Order of Injunction

On September 5, 1985, the district court entered an agreed-to interim order of injunction. Among other things, the order prohibited Kanasco from making or distributing injectable drugs without prior judicial authorization. The order also required that all oral dosage form drug products be manufactured and tested under the direct supervision of Parke-Davis. FDA Ex. 36, Interim Order dated September 5, 1985 (Civil No. K–85–3356 (D. Md.)). On September 14, 1985, the district court issued a second order requiring Kanasco to show cause why a permanent injunction should not be entered against the firm. FDA Ex. 37, Order to Show Cause dated September 14, 1985.

12. The October 1985 Inspection

The NOOH stated:

In October 1985, FDA investigators visited Kanasco to observe media fills that were being conducted and to collect samples of filled media. During this time, the following observations were made and documented with an FDA–483 which FDA left with the firm:

- There was no backup temperature measuring system for the manufacturing gel tank used to sterilize media and products or for the heat tunnel used to sterilize product containers.
- There was no documentation to validate the sterilization of the delivery system (hoses and filters) used to make suspension-type products.
- The firm's alert limit for monitoring the microbiological quality of the air in sterile manufacturing areas was 10 times too high.

52 FR 7314; *See also* FDA Ex. 38, Form FD–483 dated October 9 to 11, 1985.

In its hearing request, Kanasco did not contest the observations. The firm stated, "A thermometer will be installed on the tank not currently having such a device. Recording temperature measuring devices have been installed on the tunnel used for sterilization/depyrogenation of glassware." Kanasco Ex. 11, p. 1. Kanasco also stated that it "has obtained a slit to agar sampler and will reevaluate this environment, and reissue the SOP as needed prior to manufacture." *Id.*, p. 2. With respect to the lack of documentation to substantiate the validation of the delivery tanks, the firm merely stated

that the test had been done by the water fill method in March of 1985. *Id.* Kanasco neither responded to the allegation regarding missing documentation to support the test it claimed had been done nor supplied the data.

Each of the observations is a violation of CGMP. *See* e.g., 21 CFR 211.94(c) (requiring sterilization and depyrogenation in aseptic processing), 21 CFR 211.113(b) and 211.194(a) (requiring, respectively, validation of procedures and complete laboratory records), 21 CFR 211.42(c)(10)(iv) and 211.113 (requiring, respectively, a system for monitoring environmental conditions and appropriate written procedures to prevent objectionable microorganisms in drug products). The absence of a backup temperature measuring system in the heat tunnel had been noted by FDA in the February-March 1985 inspection. *See* FDA Ex. 24, item 7. At that time Kanasco promised, "[a]dditional temperature sensors have been purchased and a recorder has been ordered; they will be installed within the next few days." Kanasco Ex. 14, p. 7. The firm had also previously been advised that its SOPs needed to be carefully reviewed for errors and completeness. *See* e.g., FDA Ex. 24, items 5, 6, 9, and 12; FDA Ex. 27, items 1, 2, 3, and 6; FDA Ex. 9, items 3 and 4).

13. The November 4, 1985 Consent Decree

The events following the October 1985 inspection described in the NOOH are also not in dispute. On November 4, 1985, Kanasco consented to a Decree of Permanent Injunction. *See* FDA Ex. 39. This decree was substantially similar to the 1984 Agreement. However, it also required that Kanasco obtain FDA's written approval before placing personnel in supervisory positions.

Upon receipt of a certification from the firm's consultant that validation had been successfully accomplished (including completion of additional successful media fills), that a program for revalidation would be established and implemented, that adequately trained supervisory personnel had been hired and reported for duty, and that the Kanasco injectable plant, processes, and personnel were in substantial compliance with CGMP (*See* FDA Ex. 40), FDA allowed the plant to reopen. FDA did not, however, conduct an inspection to verify the consultant's certification prior to the reopening of the plant.

14. The November 25–26, 1985 Inspection and Followup Action

The NOOH stated:

On November 25–26, 1985, FDA conducted a brief inspection of Kanasco to verify the consultant's certification. The FDA inspection disclosed a number of deficiencies which were reduced to writing and provided to the firm. Among other things, the deficiencies included the following:

- No primary barrier or laminar flow hood had been installed at the site where sterile powders are placed into the sterile mixing tank.
- Personnel working in the aseptic compounding area had not been adequately trained. An employee was observed sampling sterile powder without sanitizing his hands, allowing sterilized bags to touch the floor and then placing the bags directly over sterile product mixing tanks, and failing to remove the outer bags for the sterile powder before placing the bags over the sterile product mixing tanks.
- The firm had no system to evaluate the aseptic training of employees.
- Inadequate microbiological test procedures were being used in environmental monitoring of aseptic areas. Surface sampling was not performed during the manufacture of each batch; microorganisms and flora found in the manufacturing area were not identified; the alert limit for monitoring the microbiological quality of the air in sterile manufacturing areas was 10 times too high; the firm failed to investigate a sterility test failure and a negative control contamination; no report had been prepared for a sterility test which had been initiated; and levels of inoculum used at the time of growth-promotion testing were not verified.
- The firm's batch records were signed off to show that a piece of manufacturing equipment had been sterilized when in fact the equipment had not been sterilized.
- Kanasco employees were not following the firm's written standard operating procedures. An in-line filter had not been installed prior to processing product. Other filters, which were used on tanks that hold sterilized product ingredient, had not been sterilized before being put in place and were not tested for integrity after their removal.
- One product had been heated for 15 hours instead of the 1 hour called for in the firm's batch record. This product was later tested by FDA and shown to be subpotent.

52 FR 7314 and 15; *See also* FDA Ex. 44, Form FD–483's for November 25 and 26 and December 3 to 19, 1985 inspections.

The FDA investigators who conducted this inspection testified as follows:

2. On November 25, 26, 1985, I, along with Bruce Hartman, Baltimore District Investigator, and Kevin O'Brien, Baltimore District Microbiologist, conducted an inspection of Kanasco, Ltd./John D. Copanos & Sons, Inc. With respect to the firm's failure to provide adequate training in aseptic techniques to the two operating personnel who compounded sterile suspensions, Mr. Rene J. Barresi, production supervisor, and the individual responsible for directing the aseptic compounding personnel, stated to me that Mr. Carl Allen and Mr. Paul Sturgis, the two operators, are new to the aseptic compounding department and had not received any formal training by him in aseptic techniques. Mr. Byers stated that he had not trained Mr. Allen and Mr. Sturgis in aseptic procedures and that he did not know what training they had received. Mr. Byers also stated that the firm had no system in place to evaluate the performance of these employees. Dr. Ellerton stated that the firm had ordered training materials from the Parenteral Drug Association and that these would be used to train employees. The only evidence which the firm provided for training of Carl Allen consisted of a training summary for training of the SOPs for the sterile distilled water system (SPR 1.1 to 1.6) and the SOPs for sterile production cleaning procedures (SPR 2.1 to 2.13). *See* FDA Ex. 42, December 12, 1985 Declaration of Henry Avallone.

3. During the course of the inspection I noted that the production record for Sterile Procaine Penicillin G Suspension lot 2L185, showed that the solution was supposed to be filtered during transfer to a sterile mixing tank through two sterile Cuno in-line filters. I noted that these Cuno filters were not in the systems and pointed it out to Mr. Barresi. *Id.*

4. On the afternoon of November 26, 1985, we discussed our findings at the conclusion of the inspection. Among those present were John Wanner, Vice President of Operations, Dr. Kenneth Dunlap, Director of Quality Control, Ted Byers, Consultant, and Jerald Oppel, Attorney. I commented that I have seen an improvement in the manufacture of sterile solutions since my initial inspection on February 5, 1985. Also, I commented that documentation and records seem more complete. However, I also stated that I had serious concerns with the procedures employed in the manufacture of sterile suspensions. At no time did I say that the firm's suspension operation was in substantial compliance with CGMP. [The manufacture of solutions is relatively straightforward. Solutions are compounded, filter-sterilized and aseptically filled, similar to the processing of sterile media. However, in the manufacture of suspensions, there is considerable aseptic manipulation involved in the transfer of sterile powder to the sterile vehicle or solution in the tank.] *Id.*

5. In my view, the manufacture of sterile suspensions by this firm should have been halted at the conclusion of my inspection and should remain halted until such time as it can be demonstrated that all employees engaged in the production and control of such products have been thoroughly trained in their jobs (i.e., aseptic technique, following company SOPs, and accurate and complete record-keeping), and the aseptic manufacturing environment has a primary barrier (laminar flow) in place, or it has been demonstrated (by historical documentation of surfaces and air monitoring and on-site verification by FDA) that this critical processing area is suitable for its intended purpose. *Id.*

Another investigator testified as follows:

2. On November 25 and 26, 1985, I, along with Investigator Henry Avallone and Microbiologist Kevin O'Brien, conducted an

inspection of the injectable drug manufacturing processes, procedures, and controls of John D. Copanos & Sons, Inc. (Copanos). At the conclusion of the inspection a list (FD-483) of CGMP deviations was given to and discussed with Mr. John Wanner, Vice President. A true and accurate copy of the FD-483 is attached hereto as [FDA Ex. 41]. The observations were also discussed with Dr. Kenneth Dunlap, Director of Quality Control, Mr. Theodore Byers, consultant for Copanos, and Mr. Jerald Oppel, attorney. The individuals did not deny or refute the factual accuracy of the inspectional observations. *See* FDA Ex. 42, December 12, 1985 Declaration of Bruce Hartman.

3. With respect to the firm's failure to have a primary barrier or laminar flow at the site where sterile penicillin powders are added to the mixing tank (*See* [FDA Ex. 41] FD-483, item 2), Mr. Byers stated that he was aware that the same CGMP deviation was listed on a previous FD-483 given to the firm on March 15, 1985. Mr. Byers said the firm is actively working on a solution to the problem. *Id.*

4. The firm was previously notified on a FD-483 issued on March 15, 1985, of their failure to adequately monitor the environment in the firm's aseptic processing areas by performing surface sampling on a daily basis, and their failure to identify isolates or flora found during environmental monitoring. In response to those observations, the firm advised FDA that they would perform surface sampling on a daily basis and would establish written procedures to identify isolates and flora. These same CGMP deviations were observed during the current inspection (*See* [FDA Ex. 41] FD-483, item 5). *Id.*

5. During the inspection, we reviewed the firm's sterility testing procedures and reports. During a discussion with Mr. Philip Magno, Microbiology Supervisor, Mr. Magno stated that he had observed contamination during a sterility test of a sample of Iron Dextran Injection lot number 70L085. Mr. Magno said he had not conducted an investigation into the test failure. Dr. Dunlap stated that he was unaware of the test failure prior to our discussion of it during the inspection. *Id.*

6. During the inspection, I reviewed the batch production and control record for Iron Dextran Injection lot number 70L115. The record requires that the product be mixed for 1 hour at 180 °F to 185 °F during its manufacture. However, the record had been changed to reflect that part 2 of the batch had been mixed for 15 hours at 180 °F to 185 °F. There was no explanation given in the record for the extended mixing time. *Id.*

7. During the inspection we observed the manufacture of Procaine Penicillin G Suspension lot number 2L185. The firm's written procedure for the assembly and sanitation of the gel tank system requires a hose connection between the tanks. Further, the batch record for the lot bears the initials of the individuals who purportedly assembled and sanitized the system, including all hose connections, prior to beginning the manufacture of the batch. Despite what these records indicated, we observed that the firm's personnel had failed to connect and sanitize a hose from gel tank number 1 to the mixing tank in use. *Id.*

8. At the conclusion of the inspection, we advised the firm's management that, in our opinion, the firm continued to have serious CGMP deficiencies with respect to the manufacture of sterile penicillin suspensions. *Id.*

With few exceptions, the firm did not deny most of these inspectional observations. Instead, in a letter dated December 6, 1985, it offered explanations and promised yet additional corrective measures. For example, with respect to the observation of poor aseptic practices in the compounding area, Kanasco did not deny that the employee had failed to sanitize his gloved hands before sampling sterile powder. In response to the observation regarding placing sterilized bags on the floor, Kanasco stated that the "floor was sanitized". Kanasco Ex. 10, p. 1. The firm also stated that employees had been trained, additional training would be carried out, and that observations as to one employee should not be the basis for concluding that training was inadequate.

With respect to the absence of a primary barrier or laminar flow in the mixing area, Kanasco stated it believed the environment and environmental controls were adequate since air flow had been increased significantly (but to an unspecified rate). Once again, the company stated it was "considering" installation of a primary barrier and when "evaluation" is completed, the equipment would be installed. *Id.*, p. 2.

The firm did not, however, deny that it still had not instituted a system to evaluate the effectiveness of its employee training. In its response, the firm promised to implement such a system.

Nor did Kanasco deny its failure to sterilize vent filters. To the contrary, Kanasco stated, "Procedures for sterilization of the vent filters were in place * * *. In this instance they were not followed * * *. We are reemphasizing the necessity for following our established procedures." *Id.*

Regarding the observation that the batch records reflected that a hose had been sterilized when in fact the hose had not been sterilized, Kanasco stated: "[b]ecause of damage to one flexible hose, it was necessary in this instance, to use only one hose. Since that time, additional hoses have been obtained. Since only one sterilized hose was available, the procedure was temporarily modified to use only one sterilized hose, and thus the sterility of the product was not compromised." *Id.* In short, the firm refused to acknowledge the improper record.

With respect to its continued failure to conduct daily surface monitoring and to identify microorganisms and flora, the firm stated that while such information was "useful," it was not required by CGMP. Nevertheless, the firm promised to initiate such procedures. *Id.*

Kanasco did not deny that its alert limit for monitoring quantitative air sampling was 10 times too high. Nor did it deny that it had failed to conduct an investigation into the sterility test failure and negative control contamination that had occurred. *Id.*, p. 3.

As for the failure to contemporaneously prepare a sterility test report at the time the test was initiated and the failure to verify the level of inoculum at the time of the sterility test, Kanasco stated:

> . . . the initiation of this sterility test was recorded on the sterility test tubes themselves, as observed by the inspectors, but the analyst had not yet transferred the information to the test sheets. The analyst was advised in the future to initiate the test sheet at the same time as labeling the tubes. *Id.*
>
> With regard to the observation that the level of inoculum at the time of inoculation for growth promotion testing was not verified, such practice will not have an adverse effect on the outcome of USP sterility testing since a decrease in numbers would lead to a false negative growth promotion test. This means no growth and that the sterility test would have to be repeated unnecessarily. We wish to point out that the level of inoculum was determined at the time of preparation and could only have decreased. *Id.*

Kanasco did not deny that it had heated one product for a period of 15 hours (at a temperature of 180 °F) even though the manufacturing instructions provided that such heating was to last only 1 hour. *See* FDA Ex. 42, December 6, 1985 letter to John D. Copanos, p. 2.

Finally, Kanasco did not offer any evidence to rebut FDA's finding that, upon analysis, the product was shown to be subpotent. *Id.; See also.* FDA Ex. 41, analytical report.

In short, Kanasco's response does not raise any genuine and substantial issue which warrants a hearing regarding either the observations made by FDA during the November 1985 inspection or subsequent events. The employee practices were conceded to be improper. Kanasco's argument that the sterility of product was not compromised because the floor was "sanitized" is immaterial and incorrect. The argument is not material because the theory of CGMP is that each step of the manufacturing process will provide cumulative assurance of product sterility. *See* e.g., FDA Ex. 18, Turco Declaration, para. 2;

FDA Ex. 45, Avis Declaration, p. 3. ("CGMP practitioners universally recognize that quality must be built into the product at each and every step of its manufacture * * *"); *See also* 21 CFR Part 211, *passim*. It is therefore no answer to say that one deficiency may be ignored because it may, possibly, be mitigated by another precautionary measure.

Moreover, this deficiency has not been shown to have been mitigated. Aside from the employees themselves, the floor is the least clean area in an aseptic facility. It is not only subject to constant traffic of personnel and equipment, but is also the ultimate repository for any contamination which may be present in the surrounding environment. Thus, whether or not the floor in the Kanasco facility may have been sanitized at some unspecified time by an unidentified Kanasco employee using unidentified cleaning materials whose effectiveness has not been demonstrated by documented results, is not a substantial issue which requires an evidentiary hearing.

Kanasco's explanation with respect to the failure to contemporaneously prepare reports of sterility test results also does not raise a genuine or material factual issue. CGMP requires that laboratory "records" include complete and specific data relating to the test. *See* 21 CFR 211.194. This requirement is not met by writing the date the test was begun on a test tube. *See also*, 21 CFR 211.100(b) and 211.160 (requiring documentation at the time of performance).

Kanasco's response with respect to its failure to verify the level of inoculum used in its sterility test procedure is neither responsive nor correct. Kanasco did not contest that the level of inoculum had not been verified or that proper laboratory practice requires verification. *See* 21 CFR 211.165(e). Instead, the firm claimed that the level of inoculum could only have decreased and that a decrease would not have adversely affected the sterility test. First, in the absence of any facts to show when the inoculum was prepared in relation to the sterility test and the conditions under which it was stored, there is no factual basis to assume that the level could only have decreased. Second, the argument misses the point of CGMP. The firm has not followed proper procedures. If its employees cannot be relied upon to routinely and consistently follow procedures (*See* 21 CFR 211.160(e)), there can be no assurance that tests will be conducted so as to prevent problems before they occur.

The only possible factual issues raised in this response are Kanasco's claims that the absence of primary barriers or laminar flow hoods in the mixing area, daily surface monitoring, and identification of organisms and flora in the plant, are not required by CGMP. In light of Kanasco's many uncontroverted violations of CGMP, these issues are neither material nor substantial. Moreover, the Commissioner believes that such measures are required by CGMP. Indeed, in its response to the February-March 1985 inspection, Kanasco stated it had "reinstalled" laminar air flow hoods in the aseptic filling area and claimed it was evaluating the use of laminar flow hoods in the mixing area. Kanasco Ex. 14, p. 2. The firm did not suggest at that time that laminar flow hoods were not required by CGMP. In fact, as noted above, during the November 1985 inspection, Kanasco's consultant, Mr. Byers, characterized the absence of a primary barrier over the mixing area as a CGMP violation. *See* FDA Ex. 42, Declaration of Bruce Hartman, para. 3. *See also* FDA Ex. 33, Declaration of Edmund Fry quoting from the "United States Pharmacopoeia" (1970) ("* * * Proper environmental control depends upon microbiological barriers. Design features that make use of the double barrier include * * * laminar air flow hoods."); FDA Ex. 45, Declaration of Kenneth Avis ("For many years, laminar flow hoods have been commonly used in the aseptic process to provide this essential protective primary barrier.").

Following the February-March 1985 inspection, Kanasco also stated it would revise its SOP's to include surface sampling on a daily basis and identification of microorganisms found in the plant. *See* Kanasco Ex. 14, p. 2. In addition, Kanasco's own SOP's required daily monitoring (dynamic) of the air for microbial contamination. *See* FDA Ex. 42, Kanasco SOP QC 116 dated April 11, 1985. Kanasco has not provided any logical reason why the air should be monitored on a daily basis and the equally critical surface areas, which come in direct contact with product containers and personnel, should not be so monitored. *See also*, FDA Ex. 45, Declaration of Kenneth E. Avis, pp. 7 and 8:

> It is also necessary to determine the level and nature of contamination present in the manufacturing environment when and where products are being aseptically filled. This type of monitoring is accomplished by taking microbiological samples of the air and surfaces in manufacturing areas, including the aseptic fill area. Only by determining the quantity and type of contamination present in the aseptic area, and by concurrently making every effort to achieve and maintain an ultra clean environment, can a baseline for judging and accepting future production be established. Without such a baseline, there is no proper way to determine whether products were filled in a suitably clean environment. To the extent products are filled in an unclean environment or in an environment whose quality has not been ascertained and documented, assurance of product purity is lacking.

In opposition to all of the foregoing, Kanasco, without any explanation or supporting facts, merely alleges that such measures do not fall within CGMP. Such a conclusory allegation is not a specific fact which raises a genuine and substantial issue requiring a hearing. *See* 21 CFR 314.200(g); Rule 56(e), F.R. Civ. P.; *Evers* v. *General Motors Corp.*, 770 F.2d at 986 (expert's conclusions not supported by facts will not defeat summary judgment); *Merit Motors* v. *Chrysler Corp.*, 569 F.2d at 673; *Anderson* v. *Liberty Lobby, Inc.*, ____U.S.____, 106 S.Ct. 2505 (1986) (summary judgment cannot be thwarted by presentation of a scintilla of evidence).

Moreover, the Commissioner finds that the undisputed observations made during this inspection constitute serious violations of CGMP. To this end, several additional points are worth noting. First, despite countless and dramatic warnings about the need to adequately train employees in aseptic technique (*See*, e.g., FDA Exs. 18 and 33, complaints filed in JH-84-3957 and K-85-3356, pp. 12 and 13, and Declaration of Salvatore Turco attached thereto, paras. 3 (b) and (4)); FDA Ex. 26, April 12, 1985 letter from Thomas L. Hooker to John D. Copanos, p. 3; FDA Ex. 28; May 10, 1985 letter from Thomas L. Hooker to counsel for Kanasco), the firm allowed two employees to participate in aseptic compounding of drugs without any apparent training in this process. *See* FDA Ex. 42, Hartman Declaration, para. 2. The CGMP regulations clearly require that personnel be trained "in the particular operations" that they perform. *See* 21 CFR 211.25.

Second, although Kanasco's consultant, Mr. Byers, had certified to FDA on October 31, 1985 that he had "reviewed the personnel" and found them to be "in substantial compliance with CGMP" (*See* FDA Ex. 40, October 31, 1985 Certification of Theodore Byers), on November 25 and 26, 1985, he advised FDA investigators that he had not trained the two employees involved in aseptic compounding, he did not know what training they had received, and that Kanasco had no system in place to evaluate the performance of its

employees. *See* FDA Ex. 42, Avallone Declaration, para. 2. In fact, the lack of adequate training was specifically raised in the Consent Decree of Permanent Injunction which Kanasco had signed just 3 weeks prior to this November 1985 inspection. *See* FDA Ex. 39, p. 5.

Third, as noted above, the need for daily surface sampling and identification of plant isolates had been specifically brought to Kanasco's attention during the February-March 1985 inspection. *See* FDA Ex. 24. Although the firm in its response (and Mr. Byers' by his subsequent adoption thereof) promised that "Rodac plates will be used on a daily basis" and that "criteria to identify isolates and flora will be established and incorporated into a revised SOP" (*See* Kanasco Ex. 14, March 20, 1985 letter to Thomas Hooker, p. 4.), no such action had been taken in the ensuing 8 months. Instead, the firm reversed its earlier position and, without any explanation or documentation, claimed that such procedures were not required by CGMP. *See* 21 CFR 211.42(c)(10)(iv) and 211.113.

Fourth, Kanasco's failures to conduct followup investigations of test failures was cited in the October 1984 Complaint for Injunction (FDA Ex. 18, p. 11), discussed in declarations filed with the district court (*See* e.g., FDA Ex. 35, October 22, 1985 Fourth Declaration of Carl I. Turner, p. 8) and expressly required by the November 1985 Consent Decree. FDA Ex. 39, p. 4. Nevertheless, Kanasco had not conducted an investigation to learn the cause of a sterility test failure that had occurred (with an iron dextran product). *See* FDA Ex. 42, Hartman Declaration, p. 2. In fact, the employee who discovered the test failure did not even advise the quality control director that the test had failed. *Id.; See also,* 21 CFR 211.192 (requiring documented followup investigation of discrepancies).

Fifth, Kanasco's failure to contemporaneously prepare records to reflect all manufacturing and/or testing events was one of the CGMP deficiencies which precipitated the filing of the October 1984 and August 7, 1985 complaints for injunction (*See* FDA Exs. 18 and 33, complaints, *passim*), formed a substantial part of the declarations filed with the district court (*See* e.g., FDA Ex. 18 (Hooker and Turco Declarations), FDA Ex. 33 (Turner Declaration), and FDA Ex. 35 (Second Turner Declaration, Avis Declaration, and Second Turco Declaration), and was explicitly prohibited by the 1985 Consent Decree (*See* FDA Ex. 39, Consent Decree, p. 2.). Nevertheless, Kanasco's manufacturing records continued to reflect the occurrence of events which did not in fact occur (e.g., the production record for a product was signed off to indicate that connecting hosing for two tanks had been sterilized, when in fact only one hose had been sterilized. *See* FDA Ex. 42 Hartman Declaration, para 7; *See also* 21 CFR 211.100 (requiring contemporaneous preparation of batch records).

Finally, the failure of Kanasco employees to follow the firm's SOP's had also been repeatedly brought to the company's attention. *See* e.g., FDA Ex. 7, Form FD–483, items 11 and 12; Ex. 18, 1984 Complaint for Injunction (Civil No. JH–84–3957 (D. Md.)), *passim;* Ex. 35, Second Turner Declaration discussing the 1984 batch record failures, including the aspartame events. Again, however, Kanasco employees failed to follow the firm's own written SOP's (e.g., a product had been heated 15 times longer than called for by the batch record with the result that it was rendered subpotent; air vent filters on the gel tanks had not been tested for integrity when removed nor were the new filters sterilized before being used; another type of filter, used to screen product ingredients, had not been put in place until FDA pointed it out to defendants). *See* FDA Ex. 42, Declarations of Bruce Hartman (paras. 6 and 7) and Henry Avallone, (para. 3.).

Based upon the above inspectional findings, the FDA filed a motion to enforce the 1985 consent decree, asking the district court to order that Kanasco cease the manufacture of all injectable drugs. FDA Ex. 42. On December 17 and 18, 1985, FDA met with Kanasco, at which time the firm provided the agency with assurance that the foregoing deficiencies either had been or were being corrected. Based upon these assurances and without conducting an on-site followup inspection, FDA allowed the firm to resume the manufacture of injectable drugs on December 20, 1985. FDA Ex. 43.

In the spring of 1986, Kanasco submitted a proposal to FDA to release for distribution the 23 lots of product that had been made between January and June of 1985 in violation of the 1984 Agreement. The firm asked that the products be released based upon additional sterility and other tests. In June of 1986, FDA denied Kanasco's request on the ground, *inter alia,* that finished product sterility testing could not provide adequate assurance of product purity. *See* FDA Ex. 45.

Kanasco's response regarding the 23 lots also does not raise a genuine or substantial issue which requires a hearing. Mr. Byers states that he believes the 23 lots of drug produced in violation of the 1984 Agreement are "suitable for sale." Kanasco Ex. 2, p. 5. The issue of whether or not these lots may be distributed is not addressed in this proceeding. The Associate Commissioner for Regulatory Affairs has already decided that issue adversely to Kanasco more than 1 year ago, and the firm has not appealed that ruling to the district court. *See* FDA Ex. 45, June 24, 1986 letter from J.W. Swanson, and exhibits attached thereto. The issue in this proceeding is whether Kanasco has raised a genuine, substantial issue of fact as to whether it was in compliance with CGMP. As shown above, Kanasco has failed to do so with respect to the period of time (January–June 1985) when the 23 lots were manufactured. *See* section E above.

Even if the issue were not addressed for the first time, it would still not involve a genuine or substantial issue of fact. Mr. Byers' conclusion with respect to the 23 lots is based upon the results of finished product sterility testing and his review of production records. Kanasco Ex. 2, p. 5. On many previous occasions and in public fora, Mr. Byers has squarely rejected the notion that finished product sterility testing provides any reliable evidence of the sterility of an entire batch of product. *See* e.g., Byers, T.E., "Is This Trip Really Necessary?", Drug and Cosmetic Industry, January 1982, p. 19 exhibit K attached to FDA Ex. 45 ("[c]ertainly it doesn't take a great statistician to recognize the limitations of the USP sterility test in assaying microbiological quality of the product represented to be sterile"); "Validation—an Essential for Quality Assurance," remarks presented by T.E. Byers at the Parenteral Drug Association's 1978 Annual Convention, New York, New York, pp. 1 and 2, exhibit L attached to FDA Ex. 45 ("[i]t should be obvious to all of you that in * * * [parenteral] products, finished product testing is not minimally sufficient to assure the quality of the products involved, specifically, the sterility attribute. * * * [A]s * * * quality assurance people have known for years * * * quality is not tested into a product, but rather built into a product"); "Validation—Not the Ultimate But an Alternative Approach to Quality Assurance," presented by T.E. Byers at the Annual Convention of The Parenteral Drug Association, New York, New York, November 8, 1979, exhibit E attached to FDA Ex. 45 ("a satisfactory result [in a sterility test] only indicates that no contaminating microorganism has been found in the sample examined in the conditions of the test. The

extension of this result to the whole of a batch of a product requires the assurance that every unit in the batch has been prepared in such a manner that it would also have passed the test with a high degree of probability. Clearly, this depends on the precautions taken during manufacture," *quoting* the European Pharmacopeia).

In view of Mr. Byers' numerous previous public statements which are contrary to his current testimony and the otherwise universally accepted principle that finished product sterility testing provides little or no assurance of the sterility of an entire batch (*See* e.g., FDA Ex. 45, June 18, 1986 Declaration of Salvatore Turco, p. 8 ("[s]terility * * * tests are a notoriously unreliable means to detect low-level product contamination * * * ."), *Id.*, U.S.P. (XXI) (1985) at 1351 ("[T]he referee sterility test might not detect microbial contamination if present in only a small percentage of the finished articles in the lot because [of] * * * a significant statistical limitation on the utility of the test results"); *Id.*, June 19, 1986 Declaration of Kenneth E. Avis ("the probability that microorganisms will be detected by sterility testing is extremely low. Many scientists have commented on this fact in published works [citations and additional explanation omitted]")), the Commissioner does not accept Mr. Byers' views as sufficient to justify a hearing. A proposition which is so plainly irreconcilable with many previous statements made under circumstances which indicate a degree of reliability at least as high as testimony, is not adequate to thwart summary judgment. *See United States* v. *Various Slot Machines on Guam*, 658 F.2d at 701 ("[e]ven on a motion for summary judgment, a court is not compelled to give weight to an allegation that is incontrovertibly demonstrated to be false"); *Radobenko* v. *Automated Equipment Corp.*, 520 F.2d 540, 544 (9th Cir. 1975) (party should not be allowed to create genuine issue of fact simply by submitting an affidavit contradicting prior testimony); *Barwick* v. *Delotex Corp.* 736 F.2d 946, 960 (4th Cir. 1984) (affidavit contradicting prior testimony given under circumstances where importance of issue was understood found not sufficient to defeat summary judgment which is designed to screen out sham issues of fact).

Nor does Mr. Byers' reliance upon a review of Kanasco's production records sufficiently enhance his testimony to create a genuine issue of fact relating to the 23 lots. Given the history of record falsification at the Kanasco facility, any reliance upon the firm's records is totally unfounded. *See* e.g., FDA Ex. 45, June 19, 1986 Declaration of Kenneth E. Avis, p. 13 ("[w]here, as here, the evidence shows that batch records were not kept honestly, there can be little, if any, confidence that the contents of the products are ascertainable. For example, it is impossible to rely on the firm's manufacturing records [even] to learn the lot numbers and suppliers of each active and inactive ingredient, or, as in the case of the 1984 aspartame lots (where batch records concealed that aspartame had been substituted for sodium saccharin), to determine whether the products even contain the proper inactive ingredients. Nor, in view of the many discrepancies in the dates and signatures on the sterility, pyrogen, shipping, labeling and other records, can the firm's batch records provide any assurance that the various manufacturing steps were performed at the times, by the persons, and/or under the conditions reflected in this company's records. In short, the entire manufacturing history of these products is shrouded in doubt"); and June 18, 1986 Declaration of Salvatore Turco p. 11 ("* * * the batch production records which the firm kept in 1984 and 1985 are wholly unreliable. Given the firm's apparent practice of omitting unsatisfactory results, changing the weight calculations sheets and altering manufacturing, labeling, and shipping records (*See* Turner Declaration [FDA Exs. 33 and 35]), it would not be surprising if the batch records failed to reveal any manufacturing problems.").

As noted above, *See* notes 5 and 7, Mr. Byers has not meaningfully addressed the overwhelming evidence as to the unreliability of this firm's records. For example, Mr. Byers' declaration fails to take into account any of the positive sterility test results (showing product contamination) which Kanasco employees found in these lots but failed to include in the firm's batch records. *See* FDA Ex. 35, October 22, 1985, Declaration of Carl Turner, pp. 6 and 7. Although this and other omissions on Mr. Byers' part were brought to Kanasco's attention in June 1986 by the Associate Commissioner of Regulatory Affairs (*See* FDA Ex. 45, June 18, 1986, Declaration of Salvatore Turco, p. 9; June 19, 1986, Declaration of Kenneth Avis, p. 18), Mr. Byers continues to ignore the firm's own positive sterility test reports or otherwise present specific facts to create a genuine and substantial issue for hearing.

15. The September 1986 Inspection and Response by Kanasco

The NOOH stated:

On September 15 to 29, 1986, FDA inspected the Kanasco injectable manufacturing facility. FDA again found numerous violations of CGMP requirements, including the following:

- Inadequate number and training of operating and supervisory personnel. The firm had no quality assurance director, no quality control director, no microbiological laboratory supervisor, no materials control manager, no formulation supervisor, and no second shift production supervisor.
- Inadequate validation of aseptic facilities and equipment (steam autoclave, sterilization and depyrogenation heat tunnel, homogenizer, and one filling machine). Inadequate validation of gowning procedures. Failure to have a validation procedure or revalidation schedule established for critical manufacturing areas and equipment.
- Failure to have a primary barrier over the mixing tanks where sterile powders are added to sterile liquid.
- A floor drain in the aseptic fill area, which had been stopped up for 3 weeks, contained stagnant water. Stagnant water was observed over the drain during the filling of a product.
- A drug product for human use which was required to be penicillin-free was manufactured in the same area and with the same equipment used to make penicillin-containing product.
- Veterinary drug products which are required to be penicillin-free were manufactured in the same equipment used to make penicillin products and distributed without testing for penicillin cross-contamination.
- Open product containers which had gone through the sterilization depyrogeneration heat tunnel were directed into an inappropriately classified, unvalidated, and inadequately monitored area en route to the aseptic fill area.
- A cover was missing from equipment in the aseptic fill area exposing moving parts, grease deposits, and other debris.
- Wall and floor surface in the aseptic fill area and adjoining areas, which are supposed to be smooth and cleanable, were chipped and broken.
- During a routine clean-up of the aseptic fill area, FDA investigators observed Kanasco employees (ungowned and improperly gowned) entering and exiting clean areas after touching walls, floors, and trash bags in non-clean areas; mopping up stagnant floor drain water with rags and then, with the same rags, cleaning equipment used to fill sterile product and filters used to purify air at the aseptic filling line; and using unapproved, unsterilized, and unvalidated retail cleaning materials (e.g., "Ajax All Purpose Cleaner" and "SOS" steel wool pads) to clean critical equipment in the aseptic fill area.
- Manufacturing and testing equipment were not properly maintained or calibrated (e.g., equipment used to monitor the air quality in manufacturing areas was not calibrated and components were broken; laboratory thermometers were not calibrated and the laboratory autoclave was neither validated nor monitored with a reference

thermometer; sterilization and depyrogenation heat tunnel belt speed (which determines the time vials are exposed to heat) was neither calibrated nor monitored; and magnahelic gauges used to measure pressure differentials between rooms were not calibrated).

• Air flow patterns were not mapped and air quality in aseptic manufacturing areas was not adequately monitored (e.g., floor and wall surfaces were not being monitored at all; sample locations of other monitored surfaces were not adequately identified; there was virtually no environmental monitoring during second or third shifts; no records were kept to show that appropriate pressure differentials were either monitored or maintained throughout the clean area; monitoring of non viable particulates was not done at all in some months, incompletely done in other months, and exceeded specifications without comment or correction in still other months; during the inspection, actual air flow patterns in the aseptic area were the reverse of what they should have been).

• Environmental monitoring data were unreliable (e.g., there were no logs documenting how media, which Kanasco used to monitor the microbiological quality of the environment, were prepared; the firm did not use positive controls to assure that the media employed to monitor the environment would support growth; and the temperature of the incubator used to culture environmental samples had been out of specification for 4 months).

• Failure to adequately monitor and control water for injection, a component of injectable drug products (e.g., water for injection was not monitored for particulates; a stagnant water line to the bottle washer was not drained before use or on a regular basis, nor had it been sampled for bacteria for 5 months; and end use water quality monitoring records were not signed and dated as reviewed).

• Cleaning procedures for critical manufacturing equipment did not provide for draining or rinsing of dead leg valves which could harbor bacteria and contaminate product. One holding tank valve was opened (after the tank had been cleaned by Kanasco) and found to contain a white suspension.

52 FR 7315 and 7316; *See also* FDA Exs. 47 and 48, Form FD–483 dated September 15 to 29, 1986.

One of the FDA investigators who conducted this inspection testified as follows:

3. During the period of September 15 through September 29, 1986, I, along with FDA Investigator Donald J. Vasbinder, FDA Microbiologist Linda C. English, and FDA Chemist Helen Naviasky, conducted an inspection of the injectable and oral drug manufacturing facilities, equipment, processes, procedures, and controls of Kanasco, Ltd. (formerly trading as John D. Copanos & Sons, Inc.). At the conclusion of the inspection, a list (FD–483) of deviations from FDA's regulations for current good manufacturing practice for finished pharmaceuticals (CGMP) was given to and discussed with Mr. John D. Wanner (Executive Vice President), Dr. Norman V. Ellerton, Mr. Rathi Sethi (a Parke-Davis employee), Mr. Rene Barresi (Production Manager), Dr. Ian Chester (Bulk Plant Manager), and Mr. Jerald Oppel (attorney). A true and accurate copy of the FD–483 is attached hereto [as FDA Ex. 48] * * *. Except for two items on the FD–483, which I deleted during the discussion, the individuals did not deny or refute the factual accuracy or significance of any of the inspectional observations. Also, in a telephone conversation with me on October 1, 1986, Mr. Copanos did not dispute the FD–483 items. Mr. Wanner said that the firm would respond to the FD–483 in writing within thirty days. *Id. See* FDA Ex. 48, October 9, 1986 Declaration of David Pulham.

4. Based upon the inspectional findings and statements from company personnel, it is evident to me that Kanasco, Ltd. (Kanasco) has neither an adequate number of qualified personnel to perform the necessary and critical sterile drug manufacturing operations and testing, nor an adequate number of personnel to supervise those operations. During the inspection, Mr. Wanner and Mr. Byers told me that Kanasco is operating with four critical positions vacant at the company, a quality control/quality assurance director, a formulation supervisor for the day shift, a night shift production supervisor, and a materials control supervisor. In addition there does not appear to be supervisors for the microbiology and chemistry laboratories. Finally, on September 25, 1986, Mr. Copanos told me that both Mr. Wanner and Mr. Byers may not be with the company much longer. *Id.*

5. On September 17, 1986, both Mr. Wanner and Mr. Theodore Byers, consultant for Kanasco told me that the company has been planning to shut down the injectable operation and make major re-construction and equipment improvements since April 1986. On September 17, 1986, Mr. Wanner, Mr. Byers, Mr. Barresi, and I discussed the firm's plans to renovate its clean room. Mr. Wanner stated that Mr. Copanos had promised him repeatedly over the past five months that the clean room would be completely renovated and re-validated. However, Mr. Wanner said that each attempt to begin such a project was thwarted by a production order from Mr. Copanos. *Id.*

6. During my inspection, I was unable to properly inspect the actual manufacturing of injectable drugs by Kanasco. When the FDA inspection team first entered the plant at 1:25 p.m., the firm was manufacturing an injectable product. However, within five minutes of our arrival, the firm ceased all manufacturing of injectable drugs; after finishing the batch in process late that evening, the firm did not resume manufacturing injectable drugs for the duration of our inspection. When I asked Mr. Wanner what generated a production order, he said that Mr. Copanos decides what to make and when to make it. *Id.*

7. On September 17, 1986, at approximately 7:00 p.m., Mr. Wanner and I agreed that I would inspect the clean room with Ms. M. Araquel, one of the firm's microbiologists, at 9:00 a.m. the next morning. The purpose of this inspection was to observe Ms. Araquel while she was monitoring the microbiological environment in the clean room, and to assess the aseptic conditions of the area. Mr. Wanner, Mr. Byers, and Mr. Barresi all assured me explicitly that, absent an emergency, no one would be entering the clean room until the next morning. However later that evening at 10:30 p.m., I visited Kanasco to assess operations on the second shift. To my surprise, I found an entire crew of six in the clean room cleaning up and carrying out bags full of trash and miscellaneous debris. *Id.*

8. On September 17, 1986, I asked Mr. Wanner and Mr. Barresi for all gel tank and fill time use logs covering the period January 1, 1986 to the present. There were no non-penicillin human injectable products listed in those logs. Subsequently, Mr. Vasbinder observed a label for a non-penicillin human injectable drug product in a trash can in the print shop. When I asked Mr. Wanner and Mr. Barresi about this non-penicillin product (which was made in the same gel tanks on the same fill line as penicillin-containing products) they said those products were logged in a separate file. Mr. Barresi then gave me the logs in which production of this non-penicillin human injectable drug product was recorded. *Id.*

9. Insofar as I could determine, the firm intends to continue manufacturing injectable drugs despite the violative condition of its facility. On September 17, 1986, Mr. Byers told me that the clean room was closed for renovation. Mr. Wanner, however, disageed Mr. Byers then left the room to call Mr. Copanos. When he returned, he said that Mr. Copanos had committed himself to the renovation plan. A few minutes later, Mr. Byers was called from the meeting for a second telephone call. When he returned, he said Mr. Copanos had changed his mind; the clean room was to be kept ready for manufacturing so that production could begin at anytime. *Id.*

10. In my opinion, the manufacture of sterile injectable drugs by Kanasco should cease and remain halted until such time as it can be demonstrated that all equipment and processes have been properly validated, that all equipment and facilities have been properly repaired, that all employees engaged in the production and control of injectable products have been thoroughly and effectively trained in their jobs and responsibilities (e.g., aseptic technique, following company SOP's and CGMP regulations, and maintaining accurate, concurrent and complete records), that proper procedures and practices are implemented in the microbiological monitoring of the manufacturing environment and testing of product, and an adequate number of properly qualified supervisory personnel are hired to fill critical vacancies at the company. The above deficiencies will require weeks, if not months, to correct. *Id.*

An FDA expert who reviewed the inspectional observations, testified as follows:

3. The observations in this FD–483 [FDA Ex. 48] are extensive, serious and constitute

clear violations of current good manufacturing practice. There can be no assurance that products produced under the conditions listed in this FD–483 are either sterile or have the quality, strength and identity characteristics which they purport to possess. In my opinion, this firm should be immediately required to stop all further manufacturing and shipping of injectable drug products until the deficiencies described in the FD–483 have been corrected and FDA. has, by on-site inspection, verified that they have been corrected. *See* FDA Ex. 48, October 9, 1986 Declaration of Kenneth E. Avis.

4. This firm has manufactured and distributed a non-penicillin drug product for human use with the same equipment used to manufacture penicillin-containing products. Also, using the same equipment, the firm has manufactured, released and distributed veterinary non-penicillin products without testing for penicillin contamination. These products are in direct violation of CGMP, *See* 21 CFR 211.42(d) and 211.176, and could result in serious harm or even death to persons or animals who are sensitive to penicillin. *Id.*

5. Because the violations described in this recent FD–483 are virtually identical to those which FDA has repeatedly encountered in the past and since I have already explained the practical significance of these violations, I will not re-explain their significance here. Suffice it to say that I regard the following areas as *some* of the critical matters which must be corrected before manufacturing operations resume:

a. The lack of sufficiently trained operating and supervisory personnel. There are four positions which are currently vacant at the firm: The quality control/quality assurance director, formulation supervisor, night shift supervisor, and materials control supervisor. These are key positions. In fact, the absence of a knowledgeable quality control/quality assurance director who is committed to comply with the law is clearly reflected by the many obviously critical deficiencies listed in the FD–483. This is not to suggest, however, that these vacancies are the only personnel problems at the firm. The firm's operating level employees still have not been adequately trained and still do not understand and practice the most fundamental principles of basic sanitation, much less the more rigorous principles of aseptic technique. The firm's management also appears unknowledgeable and/or unconcerned as to how to establish processes and procedures for aseptic manufacturing. Finally, in the single instance in which employees did recognize the need to stop manufacturing to revalidate an area, they were apparently overruled by Mr. Copanos. In the final analysis, most of the problems at the firm can be traced directly to inadequate training and management.

b. The failure to validate aseptic processes and procedures following major alterations to the manufacturing area. As much time as the firm and FDA have spent discussing the need for regular validation and revalidation, I do not see how this failure was allowed to occur. It could only have been the result of a calculated decision by firm management. It is an inexcuseable and gross departure of CGMP. (While the firm apparently has attempted partial validations, by media fill, of two pieces of equipment, these efforts were grossly inadequate since, among other reasons, they were not conducted under normal manufacturing conditions.)

c. The firm continues to neglect to complete batch records contemporaneously with production, still does not conduct followup investigations when manufacturing errors occur, and still fails to record all data on laboratory test records. Such omissions may be significant even when they occur as isolated events. This firm has been repeatedly cited for these errors since the Summer of 1984.

d. Apparently, the firm continues to view environemtal monitoring of critical manufacturing areas as an inconvenience which it may dispense with as it sees fit. Monitoring is omitted entirely for several months and is incomplete for other months. When excessive contamination is found in the manufacturing area, followup is not routinely performed. As explained previously to this firm and to the Court, monitoring is an essential component of properly made sterile drugs.

e. The firm does not regularly maintain and calibrate important manufacturing and testing equipment. For example, there is no record that equipment used to microbiologically cleanse the air (HEPA filters) is tested or periodically changed.

f. Both the chemistry and microbiology laboratories are deficient. Laboratory personnel do not follow recognized test and control procedures, do not keep adequate records, and do not maintain testing equipment or supplies in a satisfactory condition.

g. Employees continue to disregard the firm's own standard operating procedures.

h. Components used in drugs remain unidentified or improperly identified. In several cases, the same released and quarantined.

i. Sterilized, depyrogenated vials which will contain the actual drug product are held in an ante room area which is not environmentally monitored, has not been validated, and is not classified as to its degree of aseptic cleanliness. This procedure may result in contaminating product containers after they have been sterilized.

j. Basic sanitation is lacking. Employees do not understand how to properly clean an aseptic area. The investigator observed a large pool of stagnant water in a manufacturing area after employees had cleaned the area and while product was being made. Employees were observed wiping the floor and stagnant water with rags and then, without even an intermediate rinse with a disinfectant, wiping equipment used to process sterile drugs. *Id.*

6. In my opinion, the nature and extent of these conditions is such that it would take dedicated and knowledgeable firm many weeks to bring this operation into compliance with CGMP. Qualified people have to be interviewed, hired, familiarized with the firm's procedures and equipment and trained in CGMP and aseptic technique. Many new procedures have to be written; old procedures have to be revised. Operations and equipment have to be validated individually and collectively. Finally, if all these measures are completed, steps must be taken to assure that the firm is and will remain in compliance with CGMP. *Id.*

Another FDA expert, Dr. Turco, shared Dr. Avis' concerns. Dr. Turco testified:

In my opinion, the observations in this most recent FD–483 are *extremely* serious. There can be no assurance that products made under these conditions have the sterility and other characteristics which they must have if they are to be safe and effective for their intended uses. I agree with FDA's evaluation and fully support the agency's request that all injectable operations be halted *immediately* and stay halted until such time as there can be adequate assurance that this operation and its employees have been brought into and will remain in compliance with CGMP. *See* FDA Ex. 48, October 8, 1986 Declaration of Salvatore I. Turco. * * *

4. Because I have explained the importance of the CGMP violations seen at this firm previously and the present violations are essentially the same, I will only summarize some of the matters which I believe are most important. They are as follows:

a. Inadequate number and training of operating and supervising personnel. As the history of this firm so clearly shows, one cannot properly make injectable drugs without the necessary number of qualified personnel.

b. Failure to validate aseptic facilities, equipment, systems and processes. Only regular validation assures that drugs will routinely be made in accordance with CGMP and company specifications. Although this firm apparently conducted successful media fills in October 1985, it has failed to conduct followup validations after significant modifications (e.g., lowering the ceiling in its manufacturing area) were made to its aseptic process. This is inexcusable.

c. Failure to follow elementary rules of sanitation and orderliness. It is impossible to properly make sterile drugs in an environment which is not clean, not cleanable, disorganized and overcrowded. Stagnant water, broken tiles, and improperly identified in-process materials and components are examples of the firm's failure to heed the most basic elements of any manufacturing environment.

d. Failure to regularly maintain and calibrate manufacturing and testing equipment. Self explanatory.

e. Failure to complete manufacturing records concurrently with manufacturing procedures.

f. Failure to regularly and properly monitor the patterns of air flow and microbiological environment in aseptic manufacturing areas.

g. Failure to adequately monitor and control the system used to make water for injection. Water for injection, the vehicle in which the other drug ingredients are mixed, is a critical component of the injectable drugs in which it is used. Without adequate assurance of its sterility, there can be no assurance that the finished product is sterile.

h. Failure to follow basic laboratory procedures for testing of products and control of test apparatus and media. The deficiencies observed in the laboratory reflect that this part of the firm's operation is also understaffed, and inadequately trained and supervised.

i. Cleaning procedures for critical manufacturing equipment do not provide for draining or rinsing valves which may harbor bacteria.

5. There is an additional serious matter about which this Court should be aware. The firm is manufacturing non-penicillin containing products for *human* use in the same area and with the same equipment as penicillin-containing products. This is not only a violation of the regulations, 21 CFR 211.42(d), but also a serious health hazard. If a penicillin sensitive person is inadvertently exposed to even a minute amount of penicillin, the result may be fatal. The same problem is presented by the firm's manufacturing of non-penicillin veterinary products in equipment used to make penicillin products without testing the products for penicillin cross-contamination. *See* 21 CFR 211.176. *Id.*

Finally, an FDA employee who serves as a consultant to the agency's Center for Drugs and Biologics in the development of national and international inspectional programs, regulations, and guidelines for injectable drug manufacturing, testified as follows:

2. I have been employed by the FDA as an investigator for twenty years, during which time I have conducted well over one hundred inspections of sterile product manufacturers located all over the United States and the world. I have read the FD–483 list of inspectional observations issued to Kanasco, Ltd. At the conclusion of the September 15 to 29, 1986, inspection conducted by FDA Investigator David C. Pulham, et al. I have also talked to the investigator and microbiologist who were on the inspectional team. *See* FDA Ex. 48, October 9, 1986 Declaration of Ronald Tetzlaff.

3. In my opinion, the observations on the FD–483 are extremely serious deviations from current good manufacturing practice (CGMP) for an injectable drug manufacturer. * * * *Id.*

4. I regard the following areas to be some of the most critical CGMP deficiencies.

a. * * * It was quite apparent to me, just from reading the FD–483, and before I was advised of the vacant positions at the firm, that there must be a very serious lack of adequate supervision at the firm. Deviations of the magnitude as those listed on this FD–483 are not just isolated instances of failure to adhere to CGMP requirements, but are evidence of a plantwide lack of understanding of the rigorous controls and commitments necessary for making sterile drug products by aseptic processes.

b. The aseptic facilities, equipment, systems, and processes are not in validation * * * Although the firm apparently conducted successful media fills in October 1985 to validate the aseptic filling operation, there were major changes made since that time which would completely destroy the aseptic condition of the filling room. Following the lowering of the ceiling and HEPA filters in the aseptic filling room in November 1985 there was inadequate validation to demonstrate that aseptic conditions had been re-established before resuming production. Since the ceiling was lowered, there has been no integrity testing of HEPA filters to show absence of leaks, no air flow pattern testing, and no pressure differential testing. In fact, during the inspection the flow of air was observed to be from non-aseptic areas, such as a corridor and holding room, into the aseptic room.

c. Furthermore, the firm's attempts to validate other specific pieces of equipment and processes, e.g. the Cozzoli and Diehl Mateer fillers, were insufficient in number and design to validate even these pieces of equipment.

d. It is impossible to assure sterility of drugs made in an environment which is neither clean nor readily cleanable such as was found during the current inspection. For example, the stagnant water on the floor and broken tiles and grout illustrate the firm's failure to adhere to the most basic elements of any drug manufacturing environment * * * The pool of water, with HEPA filtered air blowing over it, is a potential source of microbial contamination of the sterile product.

e. The filling line had a 300 liter surge tank which was located in the filling room which is used for holding sterile product before it is placed in the vial. This tank was not sealed to preclude microorganisms or other contaminants from being drawn into the tank around the unsealed lid. Such a deficiency is, in my opinion, inexcusable in this type of manufacturing facility, and is a very real potential source for the introduction of microbial and particulate contamination into the sterile product.

f. The failure to integrity test the HEPA filters and determine air velocities or air flow patterns in the aseptic areas and the failure to monitor and maintain proper pressure differentials between classified and unclassified areas of manufacturing and the aseptic processing environments are violations of fundamental aseptic processing requirements. The routine failure to monitor the environment during aseptic processing (40% of first shift batches reviewed) and the absence of any environmental testing during the second and third shifts is a blatant violation of CGMP.

g. The firm's cleaning procedures for critical manufacturing equipment used to hold sterile product during filling do not provide for draining or rinsing valves which may harbor microorganisms.

h. The firm does not adequately monitor and control the system used to make water for injection.

i. The firm does not follow basic accepted laboratory procedures for testing environmental and validation samples or drug product sterility. The deficiencies associated with the microbiology laboratory not only reflect inadequate training and supervision, but make it virtually impossible to have confidence that laboratory results are reliable or meaningful. Especially significant are the failures to maintain incubators at suitable temperatures, excessive (by a factor of 200) microbiological challenge levels for media fill growth-promotion tests, insufficient concentration of neutralizing agents to inactivate residual antibiotics in media for media fills, sterility test samples which fail to conform to USP XXI, and the failure to perform bacteriostasis or fungistasis testing for membrane filtration sterility test as specified by USP XXI. *Id.*

In its written response to the Form FD–483, Kanasco conceded the accuracy of many of the investigators' observations. *See* Kanasco Ex. 7. For example, Kanasco did not offer any specific facts to rebut the evidence that key supervisory positions (quality assurance director, microbiological laboratory supervisor, materials control manager, formulation supervisor, and second shift supervisor) had been vacant for some time prior to the September 1986 inspection. Nor did the firm offer any factual rebuttal to the finding that its employee training and evaluation were inadequate. Instead, the firm again promised that "[t]raining of personnel will be further increased and individual performance reviewed * * *. [W]e will continue our efforts to hire additional qualified personnel." Kanasco Ex. 7, October 10, 1986, response to FD–483, pp. 2 and 3. (*See* 21 CFR 211.25 (requiring training and adequate number of qualified supervisory personnel).)

Kanasco admitted that a primary barrier had not yet been installed over the mixing area, and again stated it has been unable to come up with a satisfactory solution to the problem. The firm also suggested that part of the reason for this problem was *FDA's* failure to offer advice on how the problems could be rectified. *Id.*, p. 6. (*See* 21 CFR 211.46 (requiring equipment for adequate control over air pressure, microorganisms, etc.).)

Kanasco admitted that the Manton-Gaulin homogenizer had not been validated, but promised that "this will be done". *Id.*, p. 4. Kanasco conceded that its gowning procedures had not been entirely validated and claimed that the procedures relating to the use of rubber boots in the clean room area "is in progress". *Id.*, p. 8. Kanasco also conceded that "it is true, there is, in some cases, no written revalidation schedule". *Id.* (*See* 21 CFR 211.100 and 211.113(b) (requiring written procedures for process control and validation).)

The firm also did not deny that the floor drain in the aseptic fill area had been stopped up for (at least) 3 weeks and contained stagnant water. Nor did it deny that product was being manufactured while this condition existed. Indeed, Kanasco agreed that the

condition was "undesirable," but suggested that the problem was minimized, *inter alia*, because the water had initially been sterile and "the standing pools are periodically removed by the operators". The firm also promised to replace and regrade the floor. *Id.*, p. 10. (*See* 21 CFR 211.42 and 211.48 (requiring systems and controls to maintain aseptic conditions and adequate plumbing) and 21 CFR 211.22(a) and 211.25 (discussing, respectively, the responsibilities of the quality control unit and the necessity for adequately trained and supervised personnel).)

Kanasco did not deny that it had manufactured a drug product for human use which was required to be penicillin-free in the same area and with the same equipment used to make penicillin-containing products. *Id.*, p. 3. Nor did it deny that it had made veterinary drug products which are required to be penicillin-free in the same equipment used to make penicillin-containing products, and then distributed the products in commerce without having tested for penicillin cross-contamination. *Id.*, p. 3 (*See* 21 CFR 211.42(d) and 211.176 (prohibiting such practices which may cause cross-contamination) and 21 CFR 211.22 and 211.25 (responsibilities of quality control unit, training and supervision of personnel).)

Kanasco did not deny that the bottles which had been sterilized and depyrogenated in the heat tunnel were directed into an inappropriately classified area en route to the aseptic fill area. The firm's response that the room has a HEPA filter over the tunnel outlet and that environmental data show the room to be "satisfactory" (*Id.*, p. 9) does not address the question of whether sterilized and depyrogenated product containers should, as FDA stated, be maintained under class 100 conditions. *Compare* FDA Ex. 47, p. 3, item III A–2, *with* Kanasco Ex. 7, p. 9. (*See* 21 CFR 211.46(b), 211.63, 211.80, and 211.113(b) (requiring equipment and procedures to prevent microbiological contamination).)

Kanasco did not deny that a cover was missing from equipment in the aseptic fill area exposing moving parts, grease deposits, and other debris to products. Instead, it stated that "[t]he back cover for the Cozzoli filler has been replaced." *Id.*, p. 10. (*See* 21 CFR 211.67 (requiring equipment maintenance).)

The firm did not deny that floor and wall titles and grout in the aseptic filling room were chipped, broken or missing, and not readily cleanable. Nor did it deny that surface samples in this area had not been taken since January of 1986. Rather, Kanasco's rejoinder was that "new personnel in the microbiology laboratory during 1986 did not realize that Rodac plates on the walls should have been taken." *Id.*, p. 10. (*See* 21 CFR 211.42(c)(10)(i) (requiring smooth and easily cleanable floors and walls), 21 CFR 211.25 (training and supervision of personnel), and 21 CFR 211.100 (requiring adherence to written process controls).)

Kanasco did not deny any of the objectionable practices observed by the investigators during their unannounced visit on the evening of September 17, 1986. *See* FDA Ex. 47, p. 4. To the contrary, its response served only to underscore what FDA had been pointing out to the firm all along. Kanasco's response was as follows:

> The clean-up crew observed in the clean room on the evening of 9/17/86 was not the normal clean room clean-up crew. They had been labeling a previously filled batch and experienced mechanical problems with the labeler. The supervisor did not have any other work for them to perform and told them to go in the room to clean. The supervisor *has been reprimanded for allowing untrained personnel to go into the clean room.* She was also reprimanded for allowing *them to use unauthorized cleaning agents. We will perform additional GMP training on proper clean-up procedures and proper gowning techniques.* All supervisors have been *told to strictly adhere to our existing policy that only properly trained personnel are to be allowed in the clean room.*

Id., p. 13 (emphasis added). (*See* 21 CFR 211.25 (training and supervision of personnel).)

Kanasco did not deny that the equipment it used to monitor the air quality in manufacturing areas (i.e., the RCS sampler) had not been calibrated, and contained broken parts. Instead, it stated that it was "our intention to eliminate the RCS as our primary method of collecting viable particulate data * * *". *Id.*, p. 17. (*See* 21 CFR 211.67) (requiring maintenance of equipment).)

Kanasco did not deny that its laboratory autoclave had not been validated or monitored with a reference thermometer. *Id.*, p. 31. (*See* 21 CFR 211.160(b)(4) (requiring calibration of laboratory equipment).)

While the firm claimed that it monitored the heat tunnel belt speed, it did not deny that it had not been calibrated. *Id.*, p. 24. Nor did the firm deny that the magnehelic gauges used to measure pressure differentials between rooms had not been calibrated. *Id.*, pp. 18 and 19. (*See* 21 CFR 211.68 (requiring calibration of equipment).)

With respect to environmental monitoring and related practices, Kanasco did not deny that air flow patterns had not been mapped since it lowered the ceiling in aseptic fill areas, the autoclave storage area, and corridor. Instead, the firm promised "air pattern studies will be conducted". Kanasco Ex. 7, p. 19. Kanasco did not deny that its records failed to identify the exact locations where surface samples were taken so that there could be effective followup if a sample were found to be positive. Kanasco Ex. 7, pp. 18 and 10. (*See* 21 CFR 211.42(c)(10)(iv) and 211.194(a)(1) (requiring, respectively, a system for environmental monitoring and laboratory records which identify the source of the sample).) Nor did the firm deny that there was virtually no environmental monitoring during the second or third shifts. In fact, it admitted that such monitoring existing only for 6 days of second shift operations between January and August 1986, and even this monitoring was only for the first 2 hours of an 8-hour shift. *Id.*, p. 16. The firm promised to conduct monitoring during the third shift "in the future". *Id.* (*See* 21 CFR 211.42(c)(10)(iv).)

Kanasco did not deny that there was no record of air pressure differentials throughout the clean room area. *Id.*, p. 18. The firm did not deny that actual air flow patterns in the aseptic area were the reverse of what they should have been. *Id.*, pp. 10 and 11. (*See* 21 CFR 211.46(b).) Nor did Kanasco deny that monitoring for non-viable particulates was not done at all in some months, and incompletely done in others or, that when high counts were recorded, there was no record of comment or correction. Instead, Kanasco argued that its SOP only called for nonviable counts to be conducted "approximately monthly and that it regards the viable counts as more important". *Id.*, p. 18. (*See* 21 CFR 211.42(c)(10(iv), 211.100(a), 211.100(b), and 211.192.) The firm's explanation for the missing data was that they "may have been misplaced due to a change in personnel and disruption of the record filing system immediately after the EPA raid." *Id.* Although 9 months have elapsed since this explanation was made, no further data have been supplied by the firm. (*See* 21 CFR 211.180(c) and 211.194(a)(4) (requiring complete records).)

The firm did not dispute that its environmental monitoring data were unreliable, *inter alia*, because there were no logs kept to document how media, which Kanasco used to monitor the environment, were prepared. Kanasco Ex. 7, p. 30. Nor did the firm deny that it failed to conduct growth-promotion tests to assure that its environmental monitoring media would support growth if any microorganisms

were present in the manufacturing environment. *Id.* Finally, Kanasco did not deny that the temperature of its laboratory incubator used to store the environmental monitoring media had been out of specification for 4 months. *Id.*, p. 17. With respect to all of the foregoing matters, Kanasco claimed (as it had previously when faced with similar criticisms) that "the microbiology laboratory and systems were in the process of review," and that it would "institute a log book for media preparation". *Id.* (*See* 21 CFR 211.160 and 211.194.)

While Kanasco claimed that it had tested two types of media (TSB and fluid thioglycollate broth) for growth-promotion properties when the media were delivered to the firm (Kanasco Ex. 7, p. 30), these media are used by Kanasco only in its sterility test procedures, not to monitor the environment. (*See* 21 CFR 211.194.)

With respect to its water for injection (WFI) system, Kanasco did not deny that it lacked records to document testing for particulates. Instead, the firm claimed that particulate monitoring had been done "by visual inspection" and as an unwritten and unrecorded part of its sterility test procedure; the firm promised to modify its procedure to conform to the USP requirement and record it as a separate test. Kanasco Ex. 7, p. 21. (The USP "test calls for the use of an electronic liquid-borne particle counter system utilizing a light obscuration based sensor or equivalent". USP XXI (1985), p. 1257.) (*See* 21 CFR 211.194.)

Kanasco did not deny that the line in the WFI system to the bottle washer was not drained either before use or on a regular basis. The firm stated, "[a] drain port has been added to the bottle washer and this leg is now being drained daily." Kanasco Ex. 7, p. 22. (*See* 21 CFR 211.63 and 211.67.)

Nor did the firm deny that it had not monitored bottle washer WFI for the past 5 months proceeding the inspection. Instead, the firm argued that this was not necessary because subsequent processing in the heat tunnel would "handle a very high microbial load". Kanasco Ex. 7, p. 22. This response not only demonstrates the fundamental lack of appreciation for the underlying principle of CGMP—quality must be built into the product at each step of its manufacture—but this response also is neither scientific nor specific. Unless Kanasco has monitored and measured the microbial load of its undrained and untested water source, and subjected those specific loads to the specific time and temperature parameters of the heat tunnel used in processing, there is no sound basis for determining whether the system will or will not remove the pyrogens. (*See* 21 CFR 211.110 (control of in-process materials).)

Kanasco did not deny that WFI quality monitoring records had not been signed and dated as reviewed by a second person. Instead, the firm stated that these steps were now being taken. Kanasco Ex. 7, p. 23. (*See* 21 CFR 211.188 and 211.192 (requiring double sign off on production and control records).)

Kanasco did not deny that its written cleaning procedures for critical manufacturing equipment such as formulation, mixing, and holding tanks did not provide a procedure for, or record of, the draining or rinsing of dead leg valves that could harbor bacteria and contaminate the product. The firm promised to revise the procedure to make it more explicit. Kanasco Ex. 7, p. 15. In response to the FDA observation that one tank valve contained a white, unidentified substance after it had been cleaned by the firm, Kanasco argued that the tank had only been "rinsed" after completion of a previous batch and not yet subjected to "pre-manufacturing clean up and sterilization procedure which involves opening all valves." Kanasco Ex. 7, p. 15. Even assuming the truth of this assertion, the failure to have a specific procedure and record of this cleaning step is nevertheless a violation of CGMP. *See* 21 CFR 211.66(b)(3).

An overview of the foregoing observations and Kanasco's response thereto reveals the following: Employee training and supervision continue to be a problem that Kanasco has failed to address with a specific and successful plan. These deficiencies are evidenced not only by the absence of numerous key supervisory personnel, but also by the performance of line and supervisory personnel who, *inter alia:* performed and supervised a routine clean-up procedure that violated many of the basic tenets of aseptic technique; manufactured product while stagnant water remained on the floor of the clean room; made human and veterinary non-penicillin products using equipment and facilities that presented a very real possibility of cross-contamination; allowed new employees to neglect their responsibilities regarding environmental monitoring and the reviewing and signing of manufacturing records; and allowed equipment to be in disrepair and not calibrated. If there were no other findings during this inspection, FDA would, on these facts alone, be justified in concluding that this operation was seriously out of compliance with CGMP.

Insufficiently specific batch records, sign-off procedures, and instructions, and inadequate laboratory records and procedures continued to be a problem despite the fact that these items were explicitly addressed in the 1985 Consent Decree of Permanent Injunction (*See* FDA Ex. 39, pp. 2 and 3) and observed in the proceeding November 25 and 26, 1985 inspection.

The firm continued to offer a variety of excuses for the deficiencies (e.g., the laboratory procedures were in the process of being reviewed, new personnel did not understand that a particular procedure should be followed, FDA has not objected to the practice previously) and additional assurances that the problems would be or already had been corrected. In many cases the firm offered explanations for the deficiencies which served only to highlight its lack of appreciation for the very fundamentals of CGMP (e.g., the problems would have been overcome by another procedure later in the manufacturing process, particulate monitoring was done by visual examination).

It is also worth noting that FDA inspectors were able to observe so many violative conditions even though the firm was not making the product during the inspection. Kanasco ceased manufacturing operations within 5 minutes after FDA investigators entered the plant, and did not resume manufacturing during the remainder of the inspection. FDA Ex. 48, Pulham Declaration, para. 6.

It is Kanasco's responsibility to assure that it is in and remains in compliance with CGMP. Kanasco cannot except FDA to shoulder this responsibility or to serve as Kanasco's quality control unit. Kanasco's position that so long as FDA investigators do not object to a practice or problem, it must be acceptable is not only fundamentally unsound, but also is an underlying cause of the continuing, persistent compliance difficulties this company has experienced.

Finally, it should be pointed out that the above discussion by no means exhausts the list of unrebutted CGMP deficiencies that were observed in the Kanasco facility during the September 1986 inspection. The FDA investigators and microbiologist who visited Kanasco made many observations that were not disputed by the firm (e.g., laboratory employees failed to follow SOP's regarding the length of time that media should be cooked in the autoclave, Kanasco Ex. 7, p. 30; the laboratory failed to maintain a permanent written record of what materials were autoclaved in each cycle, *Id.*, p. 31; the raw material storage area was overcrowded and materials in the area

bore undated "released" and "quarantined" stickers on both sides of the same drum, *Id.*, p. 26; Kanasco personnel were unfamiliar with the temperature control and alarm functions of the conductivity meter used in its WFI system, *Id.*, p. 21; there were no records to document chemical and microbial monitoring of pre-filter and still feedwater or pre-holding tank distillate in the WFI system, *Id.*, the WFI system contained unacceptable threaded fittings and dead legs, and had pump failures with possible back siphonage of stagnant water from the dead legs, *Id.*, employees were allowed to enter the clean room area without monitoring to determine if they were shedding excessive microorganisms, *Id.*, p. 18; an endotoxin study of the heat tunnel failed in March of 1986 and had not been repeated as called for by the firm's own test report, *Id.*, p. 7 and 8.). *See also* Kanasco Ex. 5, *passim*, conceding the accuracy of many of the observations made during the September 1986 inspection, noting corrections that had been taken in some cases, and promising corrective action in others.

Based upon the findings of the foregoing September 1986 inspection and after reviewing Kanasco's written response to the List of Inspectional Observations, the government filed another motion to enforce the 1985 consent decree. *See* FDA Ex. 48. On October 17, 1986, the court entered a temporary order enjoining Kanasco from the further manufacture and shipment of injectable drugs. FDA Ex. 49. On October 26, 1986, Kanasco consented to an order which indefinitely continued the temporary order of injunction. FDA Ex. 50.

16. Events following the September 1986 Inspection: Kanasco's Current Status

The NOOH describes the subsequent events as follows:

On December 2, 1986, FDA representatives met with Kanasco representatives and explained why the firm's written response [to the September 1986 inspection] was unsatisfactory. At this meeting, FDA again advised Kanasco that inadequate training and supervision was a continuing problem at the firm.

On December 29, 1986 and January 27, 1987, Kanasco submitted validation data and other documents to FDA in an effort to show that the firm was in compliance with CGMP. On February 20, 1987, FDA officials met with Kanasco representatives to discuss the situation, and Kanasco advised FDA that it would be ready to resume manufacturing within 10 days to 2 weeks. On February 18 to 20, and 24 to 25, 1987, FDA visited the Kanasco facility to collect data pertaining to the firm's recent submissions and interview its supervisory personnel.

52 FR 7316. The NOOH also describes the results of FDA's review of Kanasco's data and the February 1987 inspection as follows:

Kanasco did not provide any data to show that personnel had received training by qualified individuals that would enable its employees to properly perform assigned functions. Nor was any plan proposed to ensure that Kanasco employees would receive sufficient training on a continuing basis to assure that employees would remain familiar with CGMP requirements or that the firm's employees would be periodically monitored to determine that training had been and would remain effective.

The firm was found to be using an unapproved ingredient in one of its products.

The firm had failed to cover or otherwise protect equipment used to aseptically process and fill sterile products from dust and debris caused by removing floor tiles, grinding concrete, and digging drainage lines through the earth.

Media fills which were conducted did not adequately mimic worst case or even normal production conditions. Media fill records contained unexplained discrepancies. For example, in one instance the firm's records indicated that media was being filled in containers prior to the time that the firm's records showed that a preliminary procedure had been completed. In another instance, dynamic environmental monitoring was performed after the media fill had been completed. In yet another instance, the media fill records showed that residual phenol (used to rinse equipment) exceeded Kanasco's limits without comment or explanation. The media fill records also did not document the performance of procedures with operator signatures. For example, there were no records to show that vials had been washed prior to going through the heat tunnel, the stoppers and seals had been washed prior to autoclaving, or that isopropyl alcohol used for sanitizing critical surfaces had been sterilized.

No data were submitted to validate the system used to deliver product ingredients from gel tanks to mixing tanks or the sterilization filter used in the delivery system. An insufficient number of media fills was conducted on one of two manufacturing tanks used by the firm.

The autoclave used to sterilize container closures and seals, equipment, uniforms, and other material was not adequately validated. For example, no data were presented to show that the load patterns which Kanasco used in its heat penetration studies represented maximum, minimum, or worst case load patterns; none of the load patterns included manufacturing equipment (which may be more difficult to sterlize); no data were submitted to show that the thermocouples used to measure temperatures in the autoclave (or sterilization depyrogenation heat tunnel) had been calibrated; and the reported results for all four of the heat distribution studies did not meet the performance criteria established by the reference work cited by the firm and generally recognized by the industry. The firm was unable to produce raw data to substantiate approximately one half of the autoclave cycles in its validation studies.

In several cases, raw data for heat tunnel endotoxin studies which FDA investigators collected at Kanasco were inconsistent with the firm's reports of those studies. In other cases, the firm was unable to produce raw data to substantiate its findings.

The firm had not installed primary barriers at the sites where sterile powders are placed into the sterile mixing tanks.

There was inadequate provision for ensuring that product containers which had passed through the depyrogenation-sterilization section of the heat tunnel would be maintained in an appropriately classified environment either in the cool down section of the heat tunnel or in the ante room through which they passed en route to the fillroom; the ante room also lacked a primary barrier.

Standard operating procedures for environmental monitoring set forth inappropriate action limits and sample collection frequencies. For example, non viable particulate counts were to be taken approximately once a month in critical manufacturing areas, whereas these samples should be taken on a daily basis; the firm's specification for non viable particulate matter in the area where sterile product is placed in vials in class 500, whereas it should be no more than class 100.

The firm failed to establish specifications for air pressure differentials between various rooms of the clean area.

The firm did not have appropriate specifications for air velocities of its high efficiency particulate air (HEPA) filters or for air change rates in clean areas.

The firm made no commitment to cease the manufacture of non penicillin products for human use in the same facility where penicillin products are made. Nor did the firm commit to cease distribution of non penicillin veterinary products without testing for the presence of penicillin.

Kanasco failed to provide evidence that there would be an adequate number of qualified personnel to supervise the manufacture of injectable products, even on the reduced, two-batch per week schedule proposed by the firm. For example, the firm's candidate for Director of Quality Assurance was the same person who had overall responsibility for the injectable facility during the October and November 1985 inspections and who (without FDA's knowledge or written consent as required by the 1985 consent decree) had been serving as Acting Director of Quality Assurance for 6 months prior to the September 1986 inspection, and while exercising that authority failed to prevent the CGMP deficiencies [observed by FDA during the October and November 1985 and September 1986 inspection].

When FDA investigators interviewed this person in February 1987, he stated that his primary experience before coming to Kanasco was in manufacturing, engineering, materials management and cost control, with only "some" exposure to quality control; he had with only "some" exposure to quality control; he had never performed quality

assurance work on a full time basis. Although, as noted above, he stated that he had been serving as Kanasco's Acting Quality Assurance Director for 10 months, he was not familiar with Kanasco's specifications for air quality in critical manufacturing areas. He also did not appreciate that excessive air velocity readings at the face of HEPA filters (used to protect critical manufacturing areas from potential airborne contaminants) could indicate that the filters were not performing this important function. The candidate stated that he would be responsible for reviewing and approving Kanasco's validation protocols and study results, and that he had reviewed and agreed with the analysis and interpretation of the validation data which Kanasco had recently submitted to FDA. However, he was unable to explain how the heat tunnel validation data (which comprised approximately one third of the firm's submission) would be used to determine whether product containers and closures were effectively being sterilized and depyrogenated during actual, day-to-day production. The candidate's understanding of Kanasco's autoclave validation data was also inadequate. For example, he did not recall how many or which organism had been used to challenge the autoclave. In addition, he stated that 10°C would be an acceptable temperature variability in the autoclave, a difference far in excess of any level recognized in the industry or even Kanasco's own criteria.

In several instances, Kanasco's data, which had been reviewed by the candidate for Director of Quality Assurance, provided further confirmation that this person either had not carefully reviewed the data and/or did not understand basic principles of validating an aseptic fill production process. For example, none of Kanasco's protocols for its autoclave, heat tunnels, or media fills sets forth production specifications that were to be validated (e.g., times, temperatures, pressures, load patterns, bottle size, and belt speeds); calculations made to evaluate the performance of the autoclave did not follow procedures generally recognized by the industry; in one heat penetration study, Kanasco improperly assumed what the coldest spot in the autoclave, and then incorrectly concluded that the coldest spot in the autoclave confirmed its initial assumption; although the amount of organisms recovered by Kanasco from spore strips used to validate autoclave effectiveness were significantly inconsistent with the spore strip manufacturer's certificate of analysis, no note of this fact was made.

Kanasco also failed to provide sufficient evidence that its candidate for Director of Quality Control had sufficient background, training or experience to perform his job properly. During the February 1987 discussions, the candidate told FDA investigators that he only intended to serve as quality control manager on an "acting" basis until a permanent replacement could be found. He stated that he had never served as quality control manager in any finished dosage form pharmaceutical plant and had virtually no hands-on experience in aspectic processing operations, environmental monitoring, or gowning techniques. Although he stated that he would be responsible for reviewing and approving all sterility tests, he had no practical experience in conducting the type of sterility test which Kanasco performs on its finished product. This person also was not familiar with Kanasco's procedures and/or specifications for monitoring air quality, air pressure differentials, and temperatures in critical manufacturing areas or the standards upon which those specifications were ultimately based.

This person stated that he too had reviewed and agreed with the approach and interpretation of the results of the autoclave validation data which Kanasco recently submitted to FDA. However, the individual indicated that he did not understand either the bioburden or overkill method of validation (both of which are standard in validation studies) and did not know which method had been used by Kanasco; nor did he know what level of sterility assurance Kanasco's studies had sought to demonstrate. Although the person stated that he would be responsible for releasing products based in part upon his review of autoclave sterilization records such as recording charts and biological indicator spore strips, he did not know how many spore strips should be in each loan pattern, how many load patterns were used by Kanasco, or which organism should be used to monitor the effectiveness of the autoclave. Although the candidate stated that he had reviewed and agreed with Kanasco's heat tunnel validation data and would be responsible for releasing products based in part on a review of temperature recording charts, he was not familiar with the general temperature configuration of the firm's heat tunnel and did not know how many temperature monitors of recording charts were used in normal production. Nor did he know what the acceptable temperature variance was for these recording charts at Kanasco. Finally, this person also failed to note or explain the above-described deficiencies in the validation data submitted by Kanasco. (Although FDA had previously told Kanasco pursuant to the 1985 consent decree that this person could serve as the firm's quality control manager, this advice was given before the September 1986 inspection, solely on the basis of a curriculum vitae and without benefit of an interview. In fact, he did not perform any quality control duties at the injectable facility during 1986.)

52 FR 7316 and 7317.

In its hearing request, Kanasco has again failed to offer specific facts which rebut the NOOH's characterization of its December 1986 and January 1987 submissions to FDA. Thus, with respect to the issue of inadequate training and supervision, Kanasco has not disputed that it failed to come forward with data showing that personnel had been trained to enable them to perform assigned functions, that its employees would receive such training on a continuing basis, or that employees would be periodically monitored to determine that training would be effective. To the contrary, in its January 1987 submission to FDA the firm stated, "Kanasco agrees that some of the practices observed by FDA on the evening of September 17 were unacceptable and will not be tolerated. These observations pointed out of Kanasco management the need for stricter enforcement of existing SOPs and adherence to generally accepted clean room practices. They also point out areas where management could make improvements". Kanasco Ex. 5, p. 4. However, the only remedy proposed by the firm was that "[s]trict enforcement of procedures and acceptable practices has been made a top priority of QA and Production management. * * * Kanasco management has committed itself to developing a more comprehensive and intensive employee training program to supplement its existing program. Outside help will be sought in areas where inhouse expertise may not be available." *Id.* No specifics or data were provided to FDA to particularize how Kanasco intended to implement this promise.

Even after the NOOH issued and after the Directors called for specific data and plans with respect to training, supervision, and monitoring of personnel (*See* 52 FR 7316), the *only* information which Kanasco supplied on this issue was Mr. Byers' single-sentence conclusion, "I have been personally involved in various training sessions in CGMP's and manufacturing processes along with other personnel, including Mr. John Wanner, and believe this program which is ongoing is adequate from a CGMP viewpoint." Kanasco Ex. 2, p. 6, May 15, 1987 Declaration of Theodore E. Byers (emphasis added).

Kanasco's offer of an unsubstantiated, nonspecific promise at this point is insufficient either to show compliance with CGMP or to necessitate an evidentiary hearing. Indeed, the firm still has not stated (even in conclusory fashion) that it employees have received the requisite training and are now ready to assume their assigned functions, much less offered any facts, data, or documentation to support such a conclusion. Nor has Kanasco offered even a conclusory assurance, much less a specific proposal supported by data, that a program is in place to monitor the performance of its employees.

In fact, another of Kanasco's CGMP experts, Dr. Arambulo, had a different impression of Kanasco's operation than Mr. Byers. Dr. Arambulo (whose entire discussion of all facets of Kanasco's CGMP status comprised two pages), stated:

As I have told FDA in the past, and most recently at our February 20, 1987 meeting, I

have had some concerns with the training and supervision of Kanasco personnel, but Kanasco has made substantial improvement in these areas, and any remaining problem(s) can be remedied, particularly if the plant is allowed to open initially on a reduced schedule. Therefore, lack of personnel training and supervisory coverage cannot provide a proper basic for FDA's proposed withdrawal of approval of Kanasco's NDAs and NADAs for Kanasco's sterile injectable drug products.

Kanasco Ex. 1, May 21, 1987 Declaration of Angel Arambulo, p. 4. Dr. Arambulo went on to state that based upon his three visits to the Kanasco plant (when it was not in production) and his review of records, many of which relate to personnel, "I have concluded that the stated deficiencies involving CGMPs by * * * Kanasco *are not out of line with similar deficiencies that I have observed in other elements of the pharmaceutical industry.* I am not aware of any instance in which such deficiencies have led to revocation of NDAs or NADAs". *Id.* (emphasis added.)

The foregoing testimony serves only to underscore Kanasco's lack of compliance with CGMP inasmuch as Dr. Arambulo supports FDA's evaluation of the historical lack of training and supervision at Kanasco and lack of compliance with CGMP. While Dr. Arambulo states that the problem "can be remedied," this is not at issue. The issue is whether Kanasco has offered specific facts to show that it was and is in compliance with CGMP. Neither Dr. Arambulo's testimony nor Mr. Byers' testimony makes this showing.

Kanasco's failure to adequately train, supervise, and evaluate the performance of its employees has been repeatedly brought to the firm's attention by the FDA. *See supra, passim.* All of the evidence in this proceeding shows that the firm has failed to correct the problem after it had been brought to its attention. *See* 21 CFR 211.25. On this ground alone, FDA is entitled to summary judgement.

There are more unrebutted facts stemming from the events following the September 1986 inspection which support summary judgment for FDA.

Kanasco's hearing request does not deny that the firm was using an unapproved ingredient (iron dextran) in one of its products. 21 CFR 211.22(c), 211.84(a), 211.84(b), and 211.100(a). This specific problem and ones similar to it have been brought to Kanasco's attention by means of a complaint for forfeiture filed with a district court, a Regulatory Letter, a Notice of Adverse Findings Letter, a letter from the Associate Commissioner of Regulatory Affairs, and similar correspondence. *See* e.g., FDA Exs. 5, 6, 11, 13, and 45.

Nor does the firm's hearing request deny that it failed to cover or otherwise protect equipment used to aseptically process and fill sterile products from dust and debris caused by removing floor tiles and digging in the earth. *See* FDA Ex. 55, containing, *inter alia,* photographs of equipment covered with dust; *See also* 21 CFR 211.67. Kanasco's failure to take adequate precautions to clean and maintain equipment was brought to its attention prior to 1984 *(See* FDA Ex. 7), during the February-March 1985 inspection (*See,* e.g., FDA Ex. 24, item 5), and during the September 1986 inspection (FDA Ex. 47, items III A 1–2, V A–C, and VII G).

Kanasco has not disputed any of the numerous, specific deficiencies which FDA found in its media fill records, including instances in which these records had "unexplained discrepancies" regarding the order in which various procedure were supposed to have been performed, the absence of operator signatures to reflect that various steps were actually performed, the failure to perform followup investigations when limits were exceeded. *Compare* 52 FR 7316, *with* 21 CFR 211.100(b), 211.194(a)(7) to (8), and 211.192. These deficiencies were brought to the firm's attention on many occasions (*See* FDA exhibits, *passim*) and were specificaly prohibited in the 1985 consent decree (*See* FDA Ex. 39, pp. 2 and 3).

Kanasco did not dispute that it failed to provide any data to validate the sterilization filter used in the delivery system. 52 FR 7316. Validation and supporting documentation are clearly called for by the CGMP regulations. 21 CFR 211.113(b), 211.194(a)(4) to (8). Kanasco has been advised of its failures to validate processes and document such validation on numerous occasions in the past. *See* e.g., FDA Exs. 7, 9, 13, 24, 38, 39 (1985 consent decree, pp. 4 and 6), 45, and 47 (item II A–H).

Kanasco did not offer any specific facts to deny that one of its critical pieces of equipment, the steam autoclave, had not been adequately validated in that: (a) no data were submitted to ensure that all representative load patterns, including those involving equipment, had been accounted for; (b) thermocouples used to measure the heat distribution in the validation studies had not been calibrated; (c) the results of all four of its heat distribution studies failed to meet generally recognized criteria that the firm itself referenced; and (d) the firm failed to provide raw data to document approximately one-half of the autoclave cycles which it attempted to study. *Compare* 52 FR 7316, *with* 21 CFR 211.113(b), 211.68, 211.192, and 211.194(a)(4) to (8). As noted, these and similar concerns had been brought to the firm's attention on many previous occasions.

In response to and in contrast with the specific concerns stated in the NOOH regarding the absence of data to validate identified systems and pieces of equipment and specific methodological failures, Kanasco's expert, Mr. Byers, offers the following, " * * * validation or revalidation occurred in every aspect of the sterile product manufacture including such things as validation of * * * sterilization procedures for equipment * * * I was personally involved in revising these procedures, establishing these procedures and observing their implementation. Kanasco Ex. 2, p. 3. Mr. Byers neither mentions the missing data nor addresses the identified systems and equipment discussed in the NOOH, nor does he address any of the methodological failures discussed in the NOOH regarding the manner in which the validation studies were conducted.

Kanasco's other expert, Dr. Arambulo, is even more circumspect on the validation issue. He states, "I have conducted an audit of the validation data, and *the data I reviewed* showed *those system's* [sic] to have been properly validated. Lack of validation cannot be a proper basis for withdrawing approval of Kanasco's NDA's and NADA's for sterile injectable products". Kanasco Ex. 1, pp. 3 and 4 (emphasis added). Dr. Arambulo does not explain what systems and records he is referring to, and what views, if any, he has on any of the specific deficiencies discussed in the NOOH.

Even assuming that Mr. Byers' reference to "sterilization procedures for equipment" relates to one load pattern of the autoclave (which is unlikely since no equipment load patterns were validated) and not to the cleaning of equipment surfaces with disinfectants, neither his nor Dr. Arambulo's general, unexplained, and unsubstantiated assurances are sufficient to raise a genuine and substantial issue of fact. 21 CFR 314.200(g); Rule 56(e), F. R. Civ. P.; *See also,* cases cited *supra* requiring expert conclusions to be supported by facts. Even if these general assurances were deemed adequate to raise a genuine and substantial issue with respect to the status of the autoclave, they do not do so with respect to the gel tank delivery system or the sterilization filter, both of which are critical in the processing of injectable products.

In its hearing request, Kanasco also has not denied that the endotoxin studies upon which it relies to validate its heat tunnel are missing raw data to document the findings claimed by the firm. *See* 21 CFR 211.194(a)(4) to (8). Neither Dr. Arambulo nor Mr. Byers have suggested how they were able to review these critical studies in the absence of raw data. Kanasco has not promised to supply the missing raw data or conduct new validation studies.

Kanasco has not denied that it still has not installed a primary barrier where sterile powders are placed into sterile mixing tanks. *See* 21 CFR 211.46(b). In its January 1987 response, 2 years after the problem was first brought to Kanasco's attention and the firm stated that the situation was "being evaluated", the firm claimed that the use of primary barriers over the mixing tanks "is under evaluation". *Compare* Kanasco Ex. 14, p. 3 (March 20, 1985 response to FD–483), *with* Kanasco Ex. 5, p. 4. Although Mr. Byers states that new hoods are being installed, he does not indicate how many or where the hoods are to be located. *See* Kanasco Ex. 2, p. 6.

Kanasco has not denied that product containers which have been sterilized and depyrogenated in the heat tunnel were not maintained in an appropriately classified (i.e., class 100) environment, either in the cool down section of the tunnel or upon exiting the tunnel en route to the filling room. Unless the sterility of these product containers is maintained after they have been so processed and before they are filled with previously sterilized product, the product may be placed in a nonsterile container. Nor has the firm presented any data to show that these areas will be maintained under class 100 conditions. *See* 21 CFR 211.46, 211.94(c), and 211.113(b).

The firm did not deny that its specification for non-viable particulates in the aseptic filling room was 500 whereas it should have been 100. *Id.* Dr. Arambulo's declaration does not address any environmental data, specifications, or concerns. *See* Kanasco Ex. 1. Mr. Byers merely states that "the environment in which the products are made is consistently within industry standards and practice and acceptable for the production of sterile products." Kanasco Ex. 2, p. 4. He does not address the issue of specifications at all. Nor does he specify the standards and practice "he finds acceptable."

Moreover, Mr. Byers' conclusion is based entirely on a review of Kanasco's records and does not address any of the numerous problems which FDA pointed out regarding the improper manner in which environmental data were collected, including the failure to properly test and control the media used to measure the environment. *See* FDA Ex. 47, pp. 5 to 7 and 11 to 13 discussing, *inter alia*, insufficient frequency of environmental testing, inadequate media control, overcooked media, failure to adequately monitor the temperature of the autoclave used to prepare the media, failure to monitor wall and floor surfaces, and failure to control air pressure between various manufacturing areas. Inasmuch as Kanasco's environmental data are based upon admittedly deficient procedures, the records can provide no reliable basis for accurately judging the condition of the environment. The firm's inadequate environmental specifications had been brought to its attention in October 1985 (*See* FDA Ex. 38) and September 1986 (FDA Ex. 47, item III A 1).

Kanasco has not disputed that it failed to establish any specifications for air pressure between various rooms in the clean area, or appropriate specifications for HEPA filters or air change rates in the clean room area. *See* 21 CFR 211.42(c)(10)(iii). These problems were brought to its attention in the February–March 1985 inspection (*See* FDA Ex. 24, item 2) and the September 1986 inspection (*See* FDA Ex. 47, items III B 2–3, C–2).

Finally, the firm still has not made any commitment to cease the manufacture of non-penicillin drugs for human use in the same facility where human penicillin products are made (21 CFR 211.42(d)), or to stop distributing veterinary non-penicillin products without testing for the presence of penicillin. *See* 21 CFR 211.176. These problems were raised in the September 1986 inspection and the absence of a commitment to cease these operations was specifically noted in the NOOH. 52 FR 7317.

With respect to the qualifications of its supervisory personnel, Kanasco did submit a declaration to rebut the statement in the NOOH that its proposed candidate for director of quality assurance was not qualified to supervise the manufacture of injectable products. *See* Kanasco Ex. 4. The declaration, submitted by the candidate, reviewed his education (a B.S. in Chemical Engineering, a Masters in Chemical Engineering, and an M.B.A. in Management) and background in the pharmaceutical industry prior to coming to Kanasco (including a production supervisor for parenteral and tablet manufacturing for a major pharmaceutical company and several management positions in manufacturing development and pharmaceutical engineering). The candidate stated that "my past educational and work experience demonstrate that I am qualified to be director of Kanasco's quality assurance [and the NOOH] fails to state how my experience is inadequate or what additional experience I need to be 'adequate' to perform my job." *Id.*, p. 3. Finally, the candidate stated that the NOOH's characterization of his interview was inaccurate or misleading for a number of reasons and that the interview itself had been conducted unfairly because he had not been warned that he would be subjected to a "surprise quiz" that could affect Kanasco's NDA's and NADA's. *Id.*, p. 6.

This declaration does not state specific facts that raise a genuine and substantial issue requiring an evidentiary hearing. For the purposes of this notice, the Commissioner accepts as true the candidate's recitation of his education and training. Even if the Commissioner also accepts as true his characterization of the FDA interview process and of the NOOH's review of the interview, the unrebutted evidence in this proceeding shows that, despite his education and background, the candidate has been unable—for a substantial period of time—to satisfactorily perform his duties or apply his experience under actual working conditions at Kanasco.

The candidate's declaration entirely overlooks the most significant and obvious evidence of his lack of qualification to serve as director of quality assurance: the substantial record of his past inadequate performance at Kanasco. The NOOH stated that while this candidate was serving as Kanasco's Executive Vice President and Director of Quality Assurance, he "failed to prevent the CGMP deficiencies" which were observed by FDA in October and November 1985 and September 1986 inspections. 52 FR 7317. These observations included CGMP deficiencies which cannot be squared with any claim that the director of quality assurance is qualified. For example, the uncontroverted record shows that this candidate either ordered or permitted injectable drugs to be produced for a period of at least three weeks in a room where stagnant water was on the floor. (This occurrence not only violates the most basic tenets of aseptic processing, but is inconsistent with even the average person's concept of minimal sanitation.)

The candidate also either allowed or ordered human drugs, that were required to be penicillin-free, to be produced in the same area, and with the same equipment used to make penicillin

products; he also either directed or allowed veterinary drugs that were required to be penicillin-free, to be made with the same equipment used to make penicillin products and to be distributed without testing for penicillin cross-contamination. (Both of these practices are clearly prohibited by the CGMP regulations, have been the subject of countless discussions in the scientific literature for decades, and present a potentially serious hazard to health. *See* FDA Ex. 48, Declaration of Kenneth Avis, p. 2 ("[t]hose procedures are in direct violation of CGMP, *See* 21 CFR 211.42(d) and 211.176, and could result in serious harm or even death to persons or animals who are sensitive to penicillin"); *Id.*, Declaration of Salvatore Turco, p. 4 ("a serious health hazard").)

The candidate also either allowed or permitted manufacturing-related activities to continue on the second shift without adequate supervision and by improperly trained employees. As a result, cleanups of the most critical processing area were conducted in the manner observed by FDA during the September 1986 inspection (*See* 52 FR 7315). The September 1986 inspection viewed as a whole (and taking into account only the FDA observations that are unrebutted) reflects a variety of CGMP deficiencies which span 21 CFR Part 211 from beginning to end. These deficiencies should have been obvious to any qualified person upon a tour of the plant and a review of the records and personnel.

Even after the September 1986 inspection, and as recently as February 1987, this candidate allowed an unapproved ingredient to be used in a product and permitted equipment used to aseptically process and fill sterile products to be exposed to dust and debris. 52 FR 7316. *See also*, 21 CFR 211.67(b)(5).

These practices are not only totally inconsistent with the letter and spirit of CGMP, but are also irreconcilable with a claim of fitness to serve in the role of director of quality assurance.

The CGMP regulations make it clear that mere education, training, and experience in CGMP are not alone sufficient to qualify a person for a particular job in a drug manufacturing facility. Rather, what is required is a combination of those elements which permit a person "to perform assigned functions in such a manner as *to provide assurance that the drug product has the safety, identity, strength, quality, and purity that it purports or* is presented to possess." 21 CFR 211.25(b) (emphasis added). *See also*, discussion of statutory and regulatory framework *supra*, which reflects a Congressional awareness and concern that CGMP requires "key technical and professional personnel" who are capable of providing the requisite assurance. As the undisputed facts of this proceeding readily demonstrate, the past performance of this candidate—despite his theoretical qualifications—renders such an assurance impossible.

Moreover, the candidate has not denied that he assumed his duties without FDA's consent and, therefore, in violation of the 1985 consent decree. This further underscores the candidate's lack of qualifications to serve as director of quality control. If the candidate cannot obey a court order of which he had actual notice (*See* FDA Ex. 39), he cannot be expected to faithfully adhere to the CGMP regulations in a manner that will assure that products will have the characteristics that they purport to have.

An FDA expert's remarks regarding Kanasco's previous director of quality assurance are equally applicable to this candidate. The expert stated:

> [A]s director of quality assurance and quality control for the Copanos firm, [this person] was ultimately responsible for assuring that CGMP are followed in all aspects of production, including recordkeeping. It is [this person's] role to be knowledgeable with respect to CGMP requirements and the principles on which those requirements are based. It is also [his] responsibility to act as the corporate conscience regarding the manner in which manufacturing operations are carried out. [He] either knew of the many CGMP deficiencies occurring at the firm and allowed them to continue for a substantial period of time, or was unaware of their existence. In either event, he failed to exercise sufficient oversight to prevent their occurrence and recurrence. He did not, in short, do his job. Under these circumstances, to allow a person to continue to serve in such a critical position with regard to the manufacture of parenteral drugs would be ill advised.

FDA Ex. 35, Declaration of Kenneth Avis, pp. 15 and 16.

Kanasco's candidate for the director of quality assurance also did not deny the NOOH's statement that *his* review of Kanasco's validation data showed either that he had not looked at the information carefully before submitting it to FDA (even though it was critical to the company's request to resume manufacturing operations) or that he did not understand basic principles of validating an aseptic fill production process. 52 FR 7317. The deficiencies in these data included incomplete protocols, improper calculations, unwarranted assumptions, and failure to note and comment upon glaring inconsistencies in the data. *Id.* In fact, although the candidate claimed that the interview was unfair because he could not consult references and "other appropriate staff members at Kanasco" (*id.*, p. 1), he has failed to address any of the deficiencies listed in the NOOH regarding the validation data despite the passage of 2 months and ample opportunity to consult whatever sources he deemed necessary.

The only other evidence which Kanasco offered to rebut the NOOH's statement regarding this candidate's qualifications was the conclusory statement of Mr. Byers. He stated, "[s]ince I began consulting with Kanasco, the firm has employed personnel in key positions whom I believe to be qualified * * * [this candidate] was hired for various functions in Q.A. * * * [he has] to my observation, performed adequately." Kanasco Ex. 2, pp. 5 and 6. This conclusion lacks any supporting explanation or specific facts and does not address the candidate's total failure to address the numerous, significant violations of CGMP which occurred during the candidate's tenure. Indeed, Kanasco's other expert, Dr. Arambulo, stated on May 21, 1987, that "I have had some concerns with the training and supervision of Kanasco personnel, but * * * any remaining problem(s) can be remedied * * *" *See* Kanasco Ex. 1.

To summarize, the only evidence which Kanasco has presented to support the qualifications of this candidate is the candidate's recitation of his education and experience and a conclusory endorsement of one of Kanasco's two experts. The evidence regarding the candidate's background is at best predictive in nature and has little or no material probative value where, as here, the overwhelming and uncontroverted evidence points entirely in the other direction. To hold an evidentiary hearing under these circumstances would be a fruitless endeavor. *See* e.g., *Anderson* v. *Liberty Lobby, Inc.*,——— U.S.———, 106 S.Ct. 2505, 2512 (1986) (summary judgment is appropriate where evidence is so one-sided that movant must prevail as a matter of law); *See also*, 21 CFR 314.200(g); Rule 56(e), F.R. Civ. P.

The candidate that the firm proposed to serve as its director of quality control also submitted a declaration attesting to his qualifications to serve in this capacity. *See* Kanasco Ex. 3. This person described his educational background (including an honors degree in Chemistry and a Ph.D. in Chemical Microbiology) and his work experience (fellowships in bacteriology, immunology, and biochemistry at universities in Canada and England;

research work regarding the composition of bacterial cell walls; 9 years employment in the pharmaceutical industry in England where he helped develop the chemical and fermentation processes used to make antibiotics; and 5 years at Kanasco where he worked in the bulk production plant).

The proposed candidate for director of quality control admitted in his declaration that he had never served as a quality control manager in any finished dosage form pharmaceutical plant, had not personally conducted aseptic processing operations, had no hands-on experience with environmental monitoring, and had not personally conducted the type of sterility tests used by Kanasco. *Id.*, p. 3. He nevertheless contended that he was qualified to serve as the director of quality control because he understood the "mechanics and philosophy" and "general principles" of a sterile operation, and could consult "other Kanasco staff" and appropriate reference materials when the need arose. *Id.*, pp. 3 to 7. Although he too viewed the FDA interview of him during the February 1987 inspection as unfair and the NOOH's characterization of that interview as inaccurate, the candidate was able to identify only three items in the NOOH that he believed were inaccurate. The candidate stated that he was never asked questions regarding the level of sterility assurance used by Kanasco and the organisms that should be used to monitor the effectiveness of the autoclave. He also said that, contrary to what was stated in the NOOH, he was familiar with the general temperature configuration of the autoclave. *Id.* p. 6. (While this candidate suggests that the interview conducted in mid-February was unfair because he was "in the process of familiarizing" himself with the operation of the microbiology quality control laboratory and the sterile production area (*Id.*, p. 4), Kanasco representatives were, almost at the same moment the interview was being conducted, assuring FDA that Kanasco's manufacturing operations could resume within 10 days to 2 weeks. 52 FR 7316.)

This declaration also failed to cite specific facts which raise a genuine and substantial issue of fact requiring an evidentiary hearing. Assuming the truth of the candidate's education and work experience and even assuming further that the NOOH was inaccurate as claimed, the unrebutted evidence discussed below independently establishes that this person can not serve as Kanasco's director of quality control "in such a manner as to provide assurance that [any] drug product [made at Kanasco] has the safety, identity, strength, quality, and purity that it purports or is represented to process." 21 CFR 211.25(b).

The CGMP regulations, 21 CFR 211.22, list the following responsibilities of the quality control unit: (a) "approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling and drug products, * * *;" review production records to assure that no errors have occurred * * *;" (b) ensure the availability of "[a]adequate laboratory facilities for the testing and approval (or rejection)" of the foregoing; and (c) "* * * approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product."

The director of quality control is one of the most critical roles in an aseptic process facility. To perform it properly not only requires a substantial background and experience in manufacturing finished dosage form pharmaceuticals in general, but also a specific background in aseptic processes and procedures used to manufacture injectable products. The role also requires working knowledge of the CGMP regulations, applicable scientific references, current developments in the industry, as well as an intimate familiarity with the SOP's used by Kanasco and the interrelationship of those SOP's to each of the foregoing. *See* 21 CFR 211.22 and 211.25.

In view of this candidate's admissions that he (a) had never "served as a Quality Control Manager in a finished dosage form pharmaceutical plant," and (b) had no practical experience with manufacturing aseptically processed drugs (Kanasco Ex. 3, p. 3), there is an inadequate factual basis for claiming that he is qualified to serve as the sole and ultimate authority for releasing and approving sterile products at any pharmaceutical plant, much less an aseptic processing facility with the history of ongoing problems observed at this firm. Despite the candidate's repeated assurances that he is familiar with the "general principles" of a sterile operation, and that he can refer to "relevant SOP's, monographs, the CFR, PDA and other documents" when necessary (*Id.*, p. 7), he has no direct, practical experience either in manufacturing finished dosage form pharmaceuticals or in aseptic processing. Without a considerable measure of practical experience in aseptic processing, there can be no assurance that the candidate would know either when it may be necessary to consult the references or what references should be consulted.

Even less compelling that the candidate's assurance that he is familiar with "general principles" and can refer to appropriate materials, is the candidate's statement that, when necessary, he would consult his staff. *Id.*, p. 5. As director of quality control, his staff would be looking to him for advice. Moreover, the candidate did not identify any of the "staff" to whom he would, or could, turn to seek help in understanding the intricate interrelationship between the myriad pieces of equipment, processes, tests, and records used to make Kanasco's products. Whomever these person(s) may be, the unrebutted record in this proceeding shows that individually and collectively they have been consistently unable to prevent the numerous CGMP deficiencies which have occurred at Kanasco over the years.

By analogy, an engineer who has been educated in aerodynamics and worked in the industry for many years "developing" airplanes may be familiar with the general "principles," "philosophy," and "mechanics" of an airplane. He may know where to find the relevant texts and applicable regulations which relate to the operation of an airplane. These facts, however, do not establish that the person can oversee the construction of airplanes whose safety the public may rely upon with confidence. And, to carry the analogy a step further, the level of assurance is not increased if the engineer claims that, when necessary, he can turn to unidentified other persons each of whom has been employed by a company that has repeatedly been shown to be incapable of properly manufacturing airplanes. Indeed, in view of this candidate's acknowledgement that he "worked in close contact with the Quality Control and Production Departments and * * * was able to contribute effectively to the manufacturing operations" at Kanasco (*Id.*, p. 2), then he too must share the responsibility for the numerous CGMP deficiencies described in the NOOH.

The candidate's declaration provides the best evidence of his lack of qualification by what it omits. This individual, who claimed to be able to make all of the technical decisions necessary to ensure the quality of Kanasco's products, did not address any of the specific CGMP deficiencies stated in the NOOH or any of the specific criticisms which the NOOH identified concerning Kanasco's validation data. Instead, he merely stated that he is (or

will be) familiar with the "general principles" and "philosophy" of a sterile operation.

Nor did the candidate offer any data or facts to show that he even considered, much less devised, a plan to address the following questions raised by the FDA inspectional observations described in the NOOH: How many and which persons would be in the quality control unit that he proposes to head; what will their qualifications and duties be; what documents define the responsibilities and procedures for the quality control unit; and who will train these persons to perform their duties? *See* 21 CFR 211.22 and 211.25. The absence of this information in the candidate's declaration (and Kanasco's hearing request) serves only to highlight the inability of the candidate (and the firm) to appreciate what is expected and required of him (and it).

It should be emphasized that the Commissioner does not seek to denigrate the achievements of this candidate. Nor does the Commissioner seek to detract from his ability to participate, together with other qualified individuals, in carefully defined quality control roles, or even at some later date to serve as a quality control director. However, it is clear that the candidate has failed to present any specific facts to establish that he is presently able to serve as the director of quality control for a firm which seeks to distribute sterile pharmaceutical products to the public.

The foregoing review of the qualifications of Kanasco's candidates for directors of quality control and quality assurance provide an additional, independent basis for summary judgment. Kanasco has failed to present any specific facts which show that there will be an adequate number of qualified persons to supervise the manufacture of injectable drugs. 52 FR 7317. *See also*, 21 CFR 211.25. Instead, the firm has only offered to continue to operate the company using precisely the same persons who led it to this proceeding and the necessity of consent decrees of permanent injunction filed with the district court.

V. Miscellaneous Matters

Both in its memorandum of law and in two of its declarations, Kanasco has raised a variety of arguments to justify its hearing request. For the reasons set forth below, the Commissioner does not believe that any of these contentions raise genuine and substantial issues of fact which warrant an evidentiary hearing.

A. The Claimed "Bad Faith" Review of Validation Data

Kanasco argues that it has submitted approximately 1,000 pages of validation data that the agency failed to consider in "good faith." Kanasco Memo., p. 12. This contention is incorrect. The NOOH described numerous deficiencies with respect to the validation data submitted by Kanasco. *See* 52 FR 7316 and 7317. Kanasco has not offered a single specific fact to challenge the accuracy or significance of any of those deficiences. Instead, it merely alleges that the ciriticisms were made in bad faith. This allegation is not enough to justify a hearing. 21 CFR 314.200(g). Where, as here, the validation data are deficient in a number of respects (including the absence of supporting documentation to support some studies, absence of some studies in total, inconsistencies which raise questions about the authenticity and truthfulness of the records, improper calculations, and inadequate protocols), it is not incumbent on FDA to spend more time cataloging additional deficiencies. Kanasco has had an opportunity to challenge the criticisms, and it has failed to do so.

Nor is Kanasco's request for a hearing on the validation issue in any way enhanced by the conclusory declarations of its experts. As noted, Dr. Arambulo's entire views with respect to the validation question are, "I have conducted an audit of the validation data, and the data I reviewed showed those system's [sic] to have been properly validated". Kanasco Ex. 1, p. 3. Dr. Arambulo does not state what "data" or "systems" he is referring to nor does he address any of the concerns stated in the NOOH. Accordingly, his views do not warrant a hearing.

The same is true with respect to Mr. Byers' views on the validation issue. He states only that he was personally involved in establishing and implementing the "validation and revalidation [which] occurred in every aspect of the sterile product manufacture, including such things as validation of gowning procedures, validation of sterilization procedures for equipment, validation of a Sterile Water for Injection System, and validation of sterile and depyrogenation progress". Kanasco Ex. 2, pg. 3.

In view of Mr. Byers' failure to address any of the specific deficiencies listed in the NOOH, or to offer any specific facts to support his conclusory endorsement of Kanasco's validation data, no hearing is necessary. 21 CFR 314.200(g); Rule 56(e), F. R. Civ. P.; *See also, Evers* v. *General Motors Corp.*, 770 F.2d at 986; *Merit Motors, Inc.* v. *Chrysler Corp.*, 569 F.2d at 673 (expert's unsupported assumptions and refusal to acknowledge salient facts were not sufficient to "impose the fruitless expenses of litigation that would result from such a limitation on the powers of a court to grant summary judgment"); *United States* v. *Various Slot Machines on Guam*, 658 F.2d at 700–.1.

Mr. Byers also states that he personally participated in conducting the six media fills submitted to FDA in late 1986 as part of the firm's validation data, and that those [and other, previous] media fills showed that Kanasco's manufacturing environment and personnel practices were satisfactory. He goes on to state that "I know of no firm in the industry which has conducted so many media fills [or which] has any beter results from their media fills". Kanasco, Ex. 2, p. 4. Again, however, Mr. Byers has ignored the specific deficiencies which the Directors identified in the NOOH regarding the most recent media fills.

Moreover, even if FDA were to view Kanasco's conclusory allegations as specific facts, assume that the specific systems listed by Mr. Byers had been validated, and further assume that there were no deficiencies in the media fills (*But see* e.g., FDA Ex. 32, Avis Declaration; FDA Ex. 45, Avis Declaration, Turco Declaration, and June 24, 1986 letter to Kanasco counsel from the Associate Commissioner of Regulatory Affairs), there would still be no necessity for an evidentiary hearing. While validation is an extremely important aspect of CGMP, it is only one aspect. In fact, it is addressed only by a single sentence in one regulation, 21 CFR 211.113(b).

In view of Kanasco's failure to conform to CGMP in so many other respects, it is not material whether some or even all of its systems were validated. For example, it makes little difference if a company's systems and equipment are validated, if its employees are not trained and supervised to operate and maintain the equipment and systems properly, or cannot be relied upon the follow the manufacturing instructions upon which the validation data are based. Second, inasmuch as "a massive rebuilding and upgrading of the facilities has taken place" (Kanasco Ex. 2, p. 6) since October and November 1986 when media fills were conducted and the systems were validated, many or all of the systems will have to be revalidated. Thus, the quality of the previous validation data is a moot point insofar as the presence capacity of the facility is at issue. *See* e.g., Kanasco Ex. 5; FDA

Ex. 48, Pulham Declaration, para. 5; Avis Declaration, p. 3; and Turco Declaration, p. 2.

B. Promises of Future Compliance.

Kanasco also argues that the declarations of Dr. Arambulo and Mr. Byers show that the firm has taken appropriate efforts to correct CGMP deficiencies observed by FDA personnel during various inspections, and that FDA has failed to acknowledge these efforts.[8] Kanasco Memo., pp. 12 and 13. It is true that Kanasco has made some efforts to comply with CGMP. *See* e.g., Kanasco Ex. 2, p. 6. However, the FDC Act does not say that a manufacturer may continue to produce drugs so long as it is "making an effort" to comply with CGMP. Rather, the manufacturer's NDA's and NADAs may be withdrawn if its facilities, procedures, and personnel are inadequate and were not made adequate within a reasonable time after receipt of written notice specifying the matters complained of. 21 U.S.C. 335(e) and 360b(e)(2)(B). As shown above, the record in this proceeding is replete with evidence showing that Kanasco has repeatedly and continuously failed to respond to numerous CGMP deficiencies brought directly to its attention, e.g., complaints filed with the district court to enjoin the firm, seizures, recalls, and even the NOOH.

Despite all the warnings, many of the same problems found years ago persist today, not only uncorrected, but in some cases unacknowledged. In other instances, where a serious problem appeared to have abated, it reappeared as soon as FDA looked more closely (e.g., the use of unapproved ingredients in product, missing raw data, falsified manufacturing records). Whatever efforts may have been made, or were claimed to have been made, by Kanasco in some areas are overshadowed by the lack of effort and violations in other areas. Moreover, the record in this proceeding also shows many instances in which Kanasco promised to undertake a correction, and then failed to fulfill the promise. For example, Kanasco promised in writing to obey an agreement with FDA, and then began violating that agreement while it was still in its infancy. *See* 52 FR 7314; FDA Ex. 33, Hartman Declaration, Fourth Turner Declaration.

As the Supreme Court stated in *Allee* v. *Medrano*, 416 U.S. 802, 810–11 (1974), when faced with a similar contention, "[i]t is settled that an action for an injunction does not become moot merely because the conduct complained of has terminated, if there is a possibility of recurrence, * * *"); *United States* v. *A.W. Richberg*, 398 F.2d 523, 530 (5th Cir. 1968); *United States* v. *An Article of Drug * * * B Complex Cholinos Capsules*, 362 F.2d 923, 928 (3d Cir. 1956) (cessation of illegal activities "either before or after suit is begun" is no bar to issuance of an injunction).

It is also settled that one has no vested right to conduct a business regulated by the FDC Act in an unlawful manner. *United States* v. *Diapulse Corporation of America*, 457 F.2d 25, 29 (2d. Cir. 1972); *United States* v. *Ellis Research Laboratories, Inc.*, 300 F.2d 550, 554 (7th Cir.), *cert. denied*, 370 U.S. 918 (1962). Indeed, the FDC Act:

> does not provide that parties shall avoid doing such things if it is possible, it provides that it shall not be done at all. A party who cannot prepare proper * * * products under [proper] conditions must cease putting such products into interstate commerce.

United States v. *Lazere*, 56 F. Supp. 730, 733 (N.D. Iowa 1944).

One of Kanasco's experts, Dr. Arambulo, carefully refrained from stating, even at this late date, that Kanasco is in compliance with CGMP. In May 1987, 2 months after the NOOH was published, he stated that he has "had some concerns with the training and supervision of Kanasco personnel, and any remaining problem(s) *can be remedied*." Kanasco Ex. 1, p. 4 (emphasis added). Indeed, as noted, Dr. Arambulo also stated that his review of Kanasco's operation led him to conclude that the "deficiencies involving CGMPs by [Kanasco] are *not out of line with similar deficiencies that I have observed in other elements of the pharmaceutical industry*. *** The alleged violations of current good manufacturing practice regulations stated in the **Federal Register** are correctable." *Id.* p. 5 (emphasis added). Kanasco's other expert, Mr. Byers, could only state in the broadest possible language that some aspects of the firm were in compliance with CGMP. Mr. Byers could not say, however, that Kanasco's facilities and various pieces of equipment were now in compliance with CGMP because the facilities and equipment are still being built. Kanasco Ex. 2, p. 6. Rather, he was necessarily forced to predict that the rebuilt plant "will result" in an adequate facility. *Id.*, p. 7. This prediction is not enough to delay summary judgment. Given the history of this firm, such a prediction can only be viewed as yet another promise to comply with CGMP.

If the record in this case did not reveal that this firm had had such a longstanding history of failing to comply with CGMP or if FDA believed there was a realistic expectation that the rebuilding efforts, to which Kanasco has alluded, were all that was needed to rectify the situation, the agency would not have initiated this proceeding, or continued with it. This is not the case. From the outset and throughout the history of this firm, a fundamental problem has been an insufficient number of qualified personnel to operate the plant and supervise and train employees. These problems will not vanish with a new or rebuilt facility.

For example, Kanasco has stated it is spending substantial amounts of money to replace floor drains and rebuild its microbiology laboratory. Kanasco Memo., p. 14 and 15. FDA has never said that the drains or the laboratory needed to be rebuilt. What is needed is a person who recognizes that when a drain does become clogged—be it an old drain or a new drain—someone will recognize that production must be stopped while the problem is remedied. Similarly, the most modern and well-equipped laboratory in the industry will be of little help if the employees do not follow recognized test procedures, allow equipment to go out of calibration, perform improper calculations, or falsify records.

C. Alleged Failure to Cite Regulations or Rely on Expert Testimony.

Kanasco also claims that the NOOH did not establish the CGMP standards that the firm failed to meet because FDA did not cite its own CGMP regulations or rely on expert opinion to articulate the CGMP standards Kanasco has allegedly violated. Kanasco Memo., p. 15. These contentions are legally and factually without merit.

The failure of the NOOH to correlate the specific deficiencies with specific CGMP regulations has not in any way prejudiced Kanasco. First, Kanasco has not pointed to a single instance in which the firm was unable to correlate the listed deficiencies with particular regulations. Nor can it credibly do so. One of its experts, Mr. Byers, spent 28 years with the FDA during which time he served, *inter alia*, as the agency's Director and Associate Director for Compliance, Bureau of Drugs. Kanasco Ex. 2, p. 1. As Kanasco acknowledges, Mr. Byers "is intimately familiar with FDA's standards and expectations

[8] Kanasco also notes parenthetically that the observations of FDA investigators do not represent the agency's conclusions. Kanasco Memo., p. 12. Where, as here, the agency has adopted virtually all of the investigators' observations in various complaints filed with the district court and declarations filed with the court and in FDA's own administrative proceedings, this contention is irrelevant.

regarding good manufacturing practices." Kanasco Memo., p. 13. Moreover, not one of Kanasco's declarations has identified a specific FDA observation which is not consistent with CGMP. *See* Kanasco Exs. 1 to 4.

In making its "failure to cite a regulation" argument, Kanasco also ignores the fact that the numerous declarations and exhibits filed in this proceeding (and in the district court) do correlate the CGMP deficiencies with the CGMP regulations. *See* FDA Exs., *passim*. Many of these documents have been in Kanasco's possession for years. Kanasco has always been fully apprised of the exact issues in controversy, and has not been misled (or even claimed that it has been misled) by the absence of particular regulatory citations in the NOOH. In short, the company has had full and fair notice of the allegations and a fair opportunity to rebut. Neither due process nor common sense require more.

Kanasco's contention that NOOH is not supported by expert opinion is incorrect and avoids the evidence which the Directors have filed in support of this proceeding. All of the expert declarations quoted in this order were filed with the Dockets Management Branch at the initiation of this proceeding. The registered letter which transmitted the NOOH to Kanasco plainly stated, "[t]he documents in support of this notice have been placed on display with the Dockets Management Branch, Room 4-62, 5600 Fishers Lane, Rockville, MD and are available for public examination between 9:00 a.m. and 4:00 p.m. Monday through Friday." *See* March 9, 1987, Letter to J. D. Copanos, Inc. In addition, another letter advised counsel for the firm that "virtually all of the evidence which is cited in the NOOH (i.e., up to and including the evidence obtained during the September 1986 inspection discussed in the **Federal Register** (52 FR 7316)) has been brought to Copanos' attention during the course of lengthy litigation begun in the United States District Court for the District of Maryland in October of 1984 (Civil No. K-85-3356, D. Md.). Copanos has had ample opportunity to review this evidence and respond to it." *See* April 23, 1987 letter to Robert Dormer, Esq., *in* Docket No. 87N-0078. *See also*, the NOOH, which refers to the documents filed with the district court. 52 FR 7312. Moreover, on May 27, 1987, a representative of the law firm which represents Kanasco asked for and received a copy of approximately 300 pages taken from the FDA exhibits filed in this proceeding. *See* June 10, 1987, Memorandum to Docket No. 87N-0078 from Jenny Butler. Finally, Kanasco's legal memorandum refers to the index of FDA exhibits filed with the Dockets Management Branch which lists, *inter alia*, all of the declarations of the CGMP experts upon which FDA has relied in this order. *See* Kanasco Memo., p. 8 n.7 and 12.

Kanasco cannot make this evidence disappear simply by failing to acknowledge its existence.

D. Alleged Failure to Compare Kanasco with Other Manufacturers

Nor is Kanasco correct in arguing that "FDA has never stated that Kanasco's CGMP inspections were worse or better than similar manufacturing facilities." Kanasco Memo., p. 15. To the contrary, FDA has, on numerous occasions commented on the relative adequacy of Kanasco's CGMP. *See*, e.g., FDA Ex. 35, October 21, 1985 Declaration of Kenneth E. Avis, p. 17 ("[i]n my experience as a consultant to the FDA, I have seen few firms with CGMP problems as significant and longstanding as [Kanasco]"); *Id.*, October 21, 1985 Declaration of Salvatore I. Turco ("[i]n my experience as a consultant to the parenteral manufacturing industry and occasionally to the FDA, the type and extent of CGMP violations observed by FDA at this firm are unprecedented"); FDA Ex. 48, October 9, 1986 Declaration of David C. Pulham ("I have been employed by the FDA as an investigator for 12 years, during which time I have inspected approximately 30 manufacturers of sterile injectables drugs, 10 of which were veterinary drug manufacturers. In my opinion, the poor procedures and controls in place at this firm are among the most serious and extensive that I have ever observed.").

E. Alleged Failure to Distinguished Between Human Drugs and Animal Drugs

Equally without merit is Kanasco's argument that "FDA has failed to discuss whether there are differences in CGMP for human as opposed to animal drugs." Kanasco Memo., p. 15. Kanasco's suggestion that there are significant differences in CGMP for human as opposed to animal drugs is itself telling evidence of the firm's attitude toward CGMP. There is no difference. The CGMP regulations plainly state, "[t]he regulations in this part contain the minimum current good manufacturing practice for preparation of drug products for administration to humans or animals." 21 CFR 211.1 *See also*, FDA Ex. 35, October 21, 1985, Declaration of Kenneth E. Avis ("[t]he FDA has one set of regulations which spell out the minimum requirements for * * * CGMP and these regulations apply with equal force to both animal and human drugs").

F. Alleged Failure to Distinguish Between Kanasco's Oral and Injectable Manufacturing Operations

Kanasco's contention that FDA has not given any reason for the implicit determination that CGMP at Kanasco are adequate for oral dosage form drugs but not parenterals (Kanasco Memo., pp. 15 and 16) is not relevant. The agency has broad discretion to decide which proceedings to bring and which not to bring, and which regulatory measures it will apply in those matters it does bring. *Heckler* v. *Chaney*, 470 U.S. 821, 828 (1985). In this proceeding, there is abundant evidence to support the withdrawal of Kanasco's NDA's and NADA's.

Moreover, FDA has never stated that the CGMP at Kanasco's oral dosage form plant are faultless. To the contrary, FDA has pointed out CGMP problems to Kanasco on several occasions, and the agency has taken steps to effect compliance. *See e.g.*, FDA Ex. 36, September 5, 1985 Interim Order requiring, *inter alia*, that the oral dosage form plant be fully supervised by employees of Parke-Davis. In the event that these measures prove to be insufficient to correct the situation at the oral dosage form plant, FDA will proceed appropriately. However, as shown by this order, FDA has expended a great many resources trying to bring Kanasco's injectable plant into compliance with CGMP.

G. The "Moving Target" Claim

Kanasco next argues that FDA has applied inconsistent standards to it depending upon which investigator visited the Kanasco facility; as a result, the argument continues, the company has been forced to shoot at "a moving target". Kanasco Memo., p. 15. This argument was raised by Kanasco shortly after the February-March 1985 inspection, and the FDA's response was as follows:

> * * * it has been suggested that the agency's evaluation of the significance of [one investigator's] observations is inconsistent with conclusions reached in prior FDA inspections in which [one investigator] failed to make some of the same observations * * *. For several reasons, we decline to accept this suggestion. First, it implies that all previous inspections of your facility were comprehensive. As you know, this is not the case. Our inspections frequently are conducted for only a limited purpose and are narrow in scope, e.g., to collect samples, to follow up on complaints, or to collect information about a specific product. Therefore, the absence of an

observation during an inspection may simply reflect that the particular process was not examined. The absence of an observation may also reflect that an investigator did not focus on the same points within a process as [another investigator]. Indeed, the explanation for the absence of an observation may well be that the conditions in your plant deteriorated in the intervening [period] between inspections. Second, the absence of a particular observation on a FD-483 does not mean either that the item was not significant or that it was not observed and brought to management's attention. An example of this is [one investigator's] observations regarding the inadequate number and qualifications of personnel at your firm. These concerns were not listed in the FD-483 left with you on March 15, 1985, but were discussed with [Kanasco representatives] during the exit interview. Third, and finally, the fact that FDA did not observe a CGMP deviation does not relieve you of the responsibility to know what CGMP requrements are and to detect and promptly correct deviations from those requirements on your own initiative.

FDA Ex. 26, April 12, 1985 letter to John D. Copanos, p. 3.

Moreover, it is settled that the FDC Act "imposes not only a positive duty to seek out and remedy violations when they occur *but also, and primarily a duty to implement measures that will insure that violations will not occur.*" *United States* v. *Park*, 421 U.S. 658, 672 (1975) (emphasis added).

Finally, Kanasco cites only three examples to support its "moving target" argument (the WFI system, the frequency of monitoring the environment for non-viable particulate contaminants, and new methods for validating the autoclave and heat tunnel). Kanasco Memo., p. 15. Even assuming that these problems had not been raised previously by FDA investigators, there is abundant evidence in this proceeding that these and other "targets," which FDA placed in front of Kanasco, were ignored entirely or only shot at half-heartedly. These matters (e.g., the lack of employee training and supervision, inadequate records and recordkeeping practices, failure of employees to follow company SOP's, failure to investigate test failures promptly, and falsification of manufacturing records) provide ample justification to withdraw Kanasco's NDA's and NADA's.

Nor has Kanasco pointed to a single specific "new method" that it claims FDA raised with respect to validating the heat tunnel and autoclave. Among the deficiencies which FDA pointed out in these areas was the absence of data to show that measuring devices used to validate the autoclave had been calibrated. 52 FR 7316. This requirement is plainly stated in the regulations (*See* 21 CFR 211.68(a)), and even if it were not stated in the regulations, should be apparent to any competent scientist. Another deficiency pointed out in the NOOH was the absence of any raw data to substantiate approximately one-half of the autoclave cycles which Kanasco claimed were validated. 52 FR 7316. The requirement for documentary evidence to support scientific conclusions is also plainly set forth in the CGMP regulations (*See* 21 CFR 211.180 and 211.194) and represents a fundamental concept familiar to anyone involved in drug manufacturing.

H. Claimed Inability to Attract Qualified Personnel

Kanasco next argues that "FDA's determination to destroy Kanasco" is clearly shown by its publication of the NOOH which has made it difficult for Kanasco to attract qualified employees. Kanasco Memo., p. 17. Again, Kanasco cites no specific facts to support this argument. The unrebutted evidence in this proceeding demonstrates quite the opposite. During the course of the inspection which occurred in the summer and fall of 1984—before the Government had filed its first complaint for injunctive relief in the district court—the president of the firm acknowledged that he was unable to attract a sufficient number of qualified persons to work at Kanasco.

Mr. Copanos told FDA investigators that Copanos was understaffed and that the firm did not have enough employees to accompany the investigators and continue operating the plant. He also stated that because of the staff problems, FDA investigators could not get Copanos' production records promptly. On October 3, 1984, Mr. Copanos stated that he had difficulty hiring qualified employees."

FDA Ex. 18, October 18, 1984 Declaration of Thomas L. Hooker, p. 7.

A summary of the evidence relating to Kanasco's current status shows, *inter alia*, the following: (1) Kanasco has not stated any specific facts or offered any documented eivdence to show that its employees have been trained either in general CGMP or in aseptic processing techniques, that its employees would receive such training on a continuing basis, or that a program has been instituted whereby employees would be monitored on a continuing basis to ensure that the training they did receive was effective, 21 CFR 211.25; (2) Kanasco continues to use unapproved ingredients in its injectable products, 21 CFR 211.22(c), 211.84(a), and 211.100(a); (3) Kanasco does not protect equipment used to fill sterile products from contamination prior to use, 21 CFR 211.67(b)(4); (4) Kanasco's recordkeeping is deficient in many respects in that the firm still does not contemporaneously document manufacturing and testing steps at the time of performance, does not have its employees sign and countersign documents showing that significant steps are performed, and does not conduct followup investigations when internal specifications are exceeded, 21 CFR 211.100(b), 211.188(b)(11), 211.194(a)(7) and (8), and 211.192; (5) Kanasco has failed to provide any data to validate the system it uses to deliver product ingredients from gel tanks to mixing tanks, or the sterilization filter used in that delivery system, 21 CFR 113(b); (6) Kanasco has failed to provide data showing either that its steam autoclave has been validated with respect to all representative load patterns, or that the thermocouples used to measure the heat distribution in the autoclave validation studies had been calibrated, 21 CFR 211.113(b), 211.68(a); (7) Kanasco has not provided raw data to substantiate approximately one-half of the autoclave cycles it attempted to validate, 21 CFR 211.113(b) and 211.194(a) (4) to (8); (8) Kanasco has not conducted a followup investigation to determine why its autoclave heat distribution studies failed to meet its own specification, 21 CFR 211.192; (9) Kanasco has not provided documentation to substantiate the endotoxin studies upon which it relies to validate the heat tunnel, 21 CFR 211.194(a) (4) to (8); (10) Kanasco produces human drug products that are required to be penicillin-free in a facility and with equipment used to make penicillin products, and does not test for possible cross-contamination veterinary products which are required to be penicillin-free and which are produced in the same facility and with the same equipment as penicillin products, 21 CFR 211.42(d) and 211.176; (11) Kanasco has not offered any documentation to show that critical manufacturing areas are maintained under class 100 conditions or protected by primary barriers, 21 CFR 211.46(b); (12) kanasco has not shown that it has an adquate number of qualified personnel to operate and supervise its operations, 21 CFR 211.25; and (13) Kanasco claims it is now in the process of upgrading its facility and critical air-handling equipment, which will require it to undertake yet further efforts to revalidate many of its systems.

CGMP does not consist of recruiting experts to testify in vague and conclusory terms that a manufacturer's facility, personnel, and processes are in compliance with CGMP or no less deficient than other manufacturers whose drug applications have not been

withdrawn. *Cf. United States* v. *An Article of Drug * * * 4,680 Pails*, 725 F.2d. 976, 987 (5th Cir. 1984) ("[s]substantial evidence [of a drug product's effectiveness] does not consist of the expressed opinions of experts hired to testify on behalf of one party or the other. Instead, it consists of adequate and well-controlled studies * * *"; where data required by the applicable legal standard are not available, summary judgment found to be appropriate); *United States* v. *Articles of Drug * * * Promise Toothpaste*, 624 F.Supp. 776, 783 (N.D. Ill. 1985) ("the manufacturer cannot avoid summary judgment simply by recruiting experts to testify that a particular drug is generally recognized as effective * * *"; where affidavits not based upon well-controlled studies, summary judgment is appropriate). Nor does CGMP consist of promises of corrections, undocumented and partially documented validation studies, or assurances that admittedly false batch records were prepared by well-intentioned employees. *See* Kanasco Exs. 1 and 2.

Rather, CGMP consists of well-trained employees monitored by an adequate number of equally well-trained, qualified supervisors, all of whom are dedicated to following specific written instructions; properly maintained facilities and equipment; accurate, contemporaneously prepared, and complete records which reflect each step in the manufacture and testing of products; and substantiation by reliable and comprehensive documentation that each of the foregoing have occurred and will continue to occur without interruption. 21 CFR Part 211.

VI. Findings

On the basis of the foregoing review of all the evidence submitted and legal arguments offered, the Commissioner finds that the methods used in and the facilities and controls used for, the manufacture, processing, and packing of all sterile injectable drugs produced by Kanasco, including those listed below, are inadequate to assure their identity, strength, quality, and purity, and were not made adequate within a reasonable time after receipt of written notice specifying the inadequacies. 21 U.S.C. 355(e), 360b(e)(2)(B). The products covered by this order are all injectable drugs produced by Kanasco, including the following:

NDA 60-684; Streptomycin sulfate; J. D. Copanos, Inc., 6110 Robinwood Rd., Baltimore, MD 21225.

NDA 60-800; Penicillin G procaine; J. D. Copanos.

NDA 60-806; Penicillin G potassium; J. D. Copanos.

NDA 60-051; Penicillin G sodium; J. D. Copanos.

NDA 61-936; Ampicillin G sodium; J. D. Copanos.

NDA 80-555; Cyanocobalamin; J. D. Copanos.

NADA 12-571; Iron dextran; "Ferron-100;" J. D. Copanos.

NADA 12-627; Prednisolone; "Ramasone;" J. D. Copanos.

NADA 30-726; Iron dextran; J. D. Copanos.

NADA 47-646; Dexamethasone; "Dexasone;" J. D. Copanos.

NADA 49-554; Phenylbutazone; "Buta-Phen;" J. D. Copanos.

NADA 49-552; Oxytocin; J. D. Copanos.

NADA 65-105; Procaine penicillin G and dihydrostreptomycin sulfate; "Veticil;" J. D. Copanos.

NADA 65-120; Dihydrostreptomycin sulfate; J. D. Copanos.

NADA 65-136; Procaine penicillin G; J. D. Copanos.

NADA 65-144; Procaine penicillin G, dihydrostreptomycin sulfate, dexamethasone, and chlorpheniramine maleate; "Dexamycin;" J. D. Copanos.

NADA 65-277; Benzathene penicillin and procaine penicillin G; "Combipen;" J. D. Copanos.

NADA 65-365; Chloramphenicol; "Veticol;" J. D. Copanos.

NADA 93-578; Oxytetracycline; J. D. Copanos.

NADA 124-510; Dexamethasone; J. D. Copanos.

Kanasco has failed to demonstrate the existence of a genuine and substantial issue of fact requiring a hearing. In numerous instances, Kanasco has failed to come forward with any evidence to rebut the facts that demonstrate that its operations were not and are not in compliance with CGMP. In other instances, the company has proffered only denials and conclusory and unsupported allegations that its processes were and are in compliance with the law. Even if the Commissioner were to accept these conclusory allegations as having some weight, such evidence does not present a sufficient area of disagreement to require an evidentiary hearing. Rather, the evidence is "so one-sided that [FDA] must prevail as a matter of law." *Anderson* v. *Liberty Lobby, Inc.*, —— United States ——, 105 S.Ct. at 2512 (1986).

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 505(e), 52 Stat. 1052-1053 as amended (21 U.S.C. 355(e) and sec. 512(e), 82 Stat. 343 (21 U.S.C. 360b(e)), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Kanasco's motion for summary judgment and request for a hearing are denied, and approval of the above-listed NDA's and NADA's for sterile injectable products, and any other sterile injectable product made by Kanasco, and all amendments and supplements thereto, is hereby withdrawn. Distribution of these drug products in interstate commerce without an approved new drug or new animal drug application is illegal and subject to regulatory action. This order is effective September 8, 1987.

Dated: July 31, 1987.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 87-17828 Filed 8-5-87; 8:45 am]

BILLING CODE 4160-01-M

Health Resources and Services Administration

Subcommittee on Foreign Medical Graduates of the Council on Graduate Medical Education; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), announcement is made of the following National Advisory body scheduled to meet during the month of September 1987:

Name: Subcommittee on Foreign Medical Graduates of the Council on Graduate Medical Education

Time: September 1, 1987; 8:30 a.m.-6:30 p.m.

Place: Holiday Inn Crowne Plaza, 1750 Rockville Pike, Rockville, Maryland 20852

Purpose: The Subcommittee reviews and analyzes existing data and information on alien and U.S. foreign medical graduates in training and in practice regarding adequacy of existing data bases, effect of existing policies and procedures regarding distribution, service delivery and international relations.

The Subcommittee will draft a chapter for the first report of the Council. Recommendations will concern the appropriate Federal policies and efforts to be carried out voluntarily by hospitals, schools of medicine and osteopathy, licensing, certifying, and accrediting bodies with respect to issues relating to foreign medical graduates.

Agenda: Agenda items include Panel presentations on (1) international activities in the public and private sectors, (2) preliminary reports by contractors on studies on services to the indigent and FMG-dependent hospitals and health care quality control, and (3)

the recognition of foreign medical schools.

Anyone requiring information regarding the subject Subcommittee should contact Magdalena Miranda, Subcommittee Principal Staff Liaison, Division of Medicine, Bureau of Health Professions, Room 4C-13, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 30857 Telephone (301) 443-6785.

Agenda Items are subject to change as priorities dictate.

Date: August 3, 1987.

Jackie E. Baum,

Advisory Committee Management Officer, HRSA.

[FR Doc. 87-17829 Filed 8-5-87; 8:45 am]

BILLING CODE 4160-15-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AK-080-07-4213-23; F-85680]

Realty Action: Lease of Public Lands in Alaska for Airport Purposes; Alaska

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Realty Action.

SUMMARY: The State of Alaska, Department of Transportation and Public Facilities has requested an airport lease to improve and expand an existing landing strip located within an Air Navigation Site (ANS 164). The State needs the lease in order to obtain Federal funds from the Federal Aviation Administration for the purpose of expanding the airport.

ADDRESSES: Written comments on this Notice should be submitted to the District Manager, Bureau of Land Management, Steese/White Mountains District, 1541 Gaffney Road, Fairbanks, Alaska 99703.

FOR FURTHER INFORMATION CONTACT: Rod Everett, Realty Specialist, at the address given above or telephone (907) 356-5356.

SUPPLEMENTARY INFORMATION: The following described lands in Chicken, Alaska are being considered for lease to the State of Alaska for airport purposes under the Act of May 24, 1928, as amended (49 U.S.C., Appendix 211-213):

Copper River Meridian, Alaska

T. 26 N., R. 18 E.,
Sec. 6: within NE¼
T. 27 N., R. 18 E.,
Sec. 31: within S½

The area described contains 68.094 acres.

The lands being considered will be leased to the State for the purpose of improving and expanding an existing landing strip. Lease of the lands is consistent with the Bureau's planning for this area and would be in the public interest.

The above described lands have been, and remain, segregated from all appropriation under the public land laws, including the mining laws but not the mineral leasing laws, subject to valid existing rights. The subject lands have been segregated by Air Navigation Site withdrawal (ANS 164), and selections by the State of Alaska (F-79586 and F-79587).

For a period of 45 days from the date of this publication of this Notice in the **Federal Register**, interested parties may submit comments to the District Manager at the above address. Any adverse comments will be reviewed by the State Director, who may vacate, sustain, or modify the realty action and issue a final determination. In the absence of any objections, the final determination of the Department of the Interior will be made in accordance with this Notice.

Dated: July 30, 1987.

Donald E. Runberg,

Manager, Steese/White Mountains District.

[FR Doc. 87-17814 Filed 8-5-87; 8:45 am]

BILLING CODE 4310-84-M

[CA-940-07-5410-01-ZBJC; CA 20449]

Realty Action; Conveyance of Mineral Interest in California

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of realty action—conveyance of the reserved mineral interest.

SUMMARY: The private lands described in this notice will be examined for suitability for conveyance of the reserved mineral interest pursuant to section 209(b) of the Federal Land Policy and Management Act of October 21, 1976.

The mineral interest will be conveyed in whole or in part upon favorable mineral examination.

FOR FURTHER INFORMATION CONTACT: Lavonia Silva, California State Office, 2800 Cottage Way, Room E-2841, Federal Office Building, Sacramento, California 95825, (916) 978-4815.

The purpose is to allow consolidation of surface and subsurface ownership, for the lands described below, where there are no known mineral values or in those instances where the reservation of ownership of the mineral interest in the United States interferes with or precludes appropriate non-mineral development of the lands and such development would be a more beneficial use of the lands than its mineral development.

SAN BERNARDINO MERIDIAN

Serial No.	Legal description	Acres	County	Mineral reservation
CA 20449	T. 11 S., R. 4 E., Sec. 30, Lot 3, NW¼SE¼.	71.93	San Diego	100% All Minerals.

Upon publication of this Notice of Realty Action in the **Federal Register** as provided in 43 CFR 2720.1-1(b), the mineral interest owned by the United States in the private lands covered by the application shall be segregated to the extent that they will not be subject to appropriation under the public land laws, including the mining laws. The segregative effect of the application shall terminate either by publication of an opening order, in the **Federal Register** specifying the date and time of opening; upon issuance of a patent or other document of conveyance to such mineral interest; upon final rejection of the application or two years from the date of filing of the application, whichever occurs first.

Dated: July 30, 1987.

Nancy J. Alex,

Chief, Lands Section Branch of Adjudication and Records.

[FR Doc. 87-17865 Filed 8-5-87; 8:45 am]

BILLING CODE 4310-40-M

[ID-050-07-4212-13-I-22245]

Realty Action; Exchange of Public Land in Jerome and Gooding Counties for Private Land Within Camas County, ID

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Realty Action, Exchange of public land in Jerome and Gooding Counties for private land within Camas County, Idaho.

DATE: Comments should be submitted to the Shoshone District Office, Bureau of Land Management, P.O. Box 2B, Shoshone, Idaho, 83352 by September 14, 1987.

Summary: The purpose of the exchange is to acquire the non-Federal grazing land to improve the manageability of the public lands for livestock and wildlife habitat. The exchange is consistent with the Bureau's planning for the lands involved and has been discussed with all affected County Commissioners, Idaho Department of Fish & Game, and the Idaho Department of Water Resources. The public interest will be well served by making the exchange.

The following described public lands have been determined to be suitable for disposal by exchange under section 206 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1716.

T. 7S., R. 16E., Boise Meridian, Gooding County, Idaho,
Sec. 19: Lot 2, SE¼NW¼, SW¼NE¼.
T. 7S., R. 16E., Boise Meridian, Jerome County, Idaho,
Sec. 20: E½;
Sec. 29: W½NE¼, NW¼SW¼.
Containing 545.01 acres.

In exchange for these lands, the Federal Government will acquire non-Federal lands from James E. Campbell described below:

T. 1N., R. 16E., Boise Meridian, Camas County, Idaho,
Sec. 5: SW¼NE¼, W½NW¼, SE¼NW¼, N½SW¼, NW¼SE¼;
Sec. 6: NE¼, NE¼NW¼, NE¼SE¼.
T. 2N., R. 16E., Boise Meridian, Camas County, Idaho,
Sec. 34: Lots 1 & 2, NE¼NE¼, S½NE¼, N½SE¼;
Sec. 35: Lots 3 & 4, NW¼, N½SW¼.
Containing 1130.35 acres.

The value of the lands to be exchanged is approximately equal, and the acreage will be adjusted or money will be used to equalize the values upon completion of the final appraisal of the lands.

There will be a reservation for all minerals to the Federal government on the public lands with no mineral reservations on the offered private land.

The patent when issued will contain the following reservations and conditions to the United States:

1. A right-of-way for ditches or canals constructed by the authority of the United States, Act of August 30, 1890, 26 Stat. 391, 43 U.S.C. 945;

2. All valid existing rights and reservations of record on the date of patenting.

The publication of this notice in the **Federal Register** will segregate the public lands described above to the extent they will not be subject to appropriation under the public land laws, including the mining laws. As provided by the regulations of 43 CFR 2201.1(b), any subsequently tendered application, allowance of which is discretionary, shall not be accepted, shall not be considered as filed, and shall be returned to the applicant.

FOR FURTHER INFORMATION CONTACT: Detailed information concerning the exchange, including the environmental analysis and the record of public discussions, is available for review at the Shoshone District Office, 400 West F Street, Shoshone, Idaho, or by calling Mike Austin at (208) 886-2206.

SUPPLEMENTARY INFORMATION: For a period of 45 days from the date of this notice, interested parties may submit comments to the Shoshone District Manager regarding the proposed action. Any adverse comments will be evaluated by the District Manager, who may vacate or modify this realty action and issue a final determination. In the absence of any action by the District Manager, this realty action will become the final determination of the Department of Interior.

Dennis Schulze,
Acting District Manager.
Dated: July 29, 1987.

[FR Doc. 87-17838 Filed 8-5-87; 8:45 am]
BILLING CODE 4310-GG-M

[I-23542; ID-030-07-4212-12]

Realty Action; Exchange of Public Lands in Bingham and Bonneville Counties, ID

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of realty action; Exchange of Public Lands in Bingham and Bonneville Counties.

SUMMARY: The following described public lands have been determined to be suitable for disposal by exchange under section 206 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1716:

T. 1 N., R. 32 E., B.M.
Section 25;
T. 1 N., R. 33 E., B.M.
Sec. 2: SE¼SW¼, SW¼SE¼;
Sec. 6: S½;
Sec. 10;
Sec. 11: W½;
Sec. 12: S½;
Sec. 13: N½;
Sec. 21: SE¼;
Sec. 23: SW¼NE¼, NE¼SW¼, W½SE¼;
Sec. 28: SE¼NE¼, NE¼SE¼;
Sec. 31;
Sec. 35: SW¼NW¼, NW¼SW¼, E½SW¼, W½SE¼;
T. 2 N., R. 33 E., B.M.
Sec. 21: NW¼NW¼, S½NW¼, SW¼;
Sec. 23: E½;
Sec. 24;
Sec. 25: N½;
Sec. 28: NW¼NW¼;I26T. 1 N., R. 34 E., B.M.
Sec. 4: lot 4, W½NE¼NW¼, S½NW¼, SE¼, SW¼NW¼SE¼, S½SE¼;
Sec. 5: lots 1, 2, 3, and 4, S½N½;
Sec. 8: SW¼NE¼, E½SE¼;
Sec. 9: NE¼, E½NW¼, S½;
Sec. 10: S½NW¼NW¼, SW¼NW¼, W½SE¼NW¼, SW¼, SW¼NW¼SE¼, SW¼SE¼, S½SE¼SE¼;
Sec. 14: W½NW¼, W½SE¼NW¼, SW¼, SW¼NW¼SE¼;
Sec. 15;
Sec. 17: E½, SE¼NW¼, S½SW¼;
Sec. 19: NE¼, NE¼SW¼, N½SE¼;
Sec. 20: N½NE¼, W½, NE¼SE¼, S½SE¼;
Sec. 21: W½, W½E½;
Sec. 22: E½, NE¼NW¼, S½NW¼, N½SW¼, SE¼SW¼;
Sec. 23: W½NE¼, N½NW¼, W½SW¼, SW¼SE¼SE¼;
Sec. 26: W½NE¼NE¼, SW¼SW¼NE¼, NW¼NW¼, SW¼SW¼, N½SE¼SW¼, SW½NW¼SE¼, NW¼SW¼SE¼;
Sec. 27: N½NE¼, W½, S½SE¼;
Sec. 28: NE¼, NW¼NW¼, E½SE¼;
Sec. 29: NE¼NW¼;
Sec. 32: SW¼NE¼, SW¼,NW¼, SW¼, W½SE¼;
Sec. 33: N½NE¼, SW¼NE¼, E½NW¼, N½SW¼, SE¼;
Sec. 34: N½, N½SW¼, SW¼SW¼, N½SE¼, SE¼,SE¼;
Sec. 35: W½NW¼, W½SW¼, SW¼NE¼SW¼;
T. 2 N., R. 34 E., B.M.
Sec. 7: S½SE¼;
Sec. 18: lots 1 and 4, NE¼NW¼, SE¼SW¼, S½SE¼;
Sec. 19: NE¼;
Sec. 30: S½SE¼;
Sec. 33: W½NW¼NW¼, SW¼NW¼, N½SW¼, SW¼SW¼, W½SE¼SW¼;
Containing 13,952.48 acres.

In exchange for these lands, the Federal Government will acquire scattered sections of non-Federal lands in Butte, Custer, Blaine, Clark, and Bingham Counties from the State of Idaho, described as follows:

T. 3 N., R. 23 E., B.M.
Sec. 36;
T. 2 N., R. 24 E., B.M.
Sec. 16: lots 1, 3, and 4, W½NE¼, NW¼, N½SW¼, NW¼SE¼;
T. 4 N., R. 24 E., B.M.
Sec. 36;
T. 5 N., R. 24 E., B.M.
Sec. 16;
T. 6 N., R. 24 E., B.M.
Sec. 16;
T. 4 N., R. 25 E., B.M.
Sec. 16: W½, SW¼SE¼;
T. 5 N., R. 25 E., B.M.
Sec. 36;
T. 6 N., R. 25 E., B.M.
Sec. 16: E½NE¼, SW¼NE¼, SE¼NW¼, E½SW¼, SE¼;
T. 3 N., R. 26 E., B.M.
Sec. 36;
T. 1 N., R. 27 E., B.M.
Sec. 36;
T. 2 N., R. 27 E., B.M.
Sec. 16 and 36;
T. 3 N., R. 27 E., B.M.
Sec. 36;
T. 1 N., R. 28 E., B.M.
Secs. 16 and 36;
T. 1 N., R. 29 E., B.M.
Sec. 16;
T. 10 N., R. 29 E., B.M.
Sec. 36;
T. 9 N., R. 30 E., B.M.
Sec. 16;
T. 1 S., R. 27 E., B.M.
Sec. 36;
T. 2 S., R. 27 E., B.M.
Sec. 36;
T. 1 S., R. 28 E., B.M.
Sec. 16;
T. 1 S., R. 29 E., B.M.
Secs. 16 and 36;
T. 2 S., R. 31 E., B.M.
Sec. 16;
Containing 14,624.46 acres.

The purpose of the exchange is to dispose of scattered, difficult to manage public land parcels while acquiring State-owned lands which would compliment the Bureau's land management pattern. The exchange would also allow the Bureau to acquire certain State lands containing important wildlife and recreation values. The exchange is consistent with the Bureau's land use planning. The concept of land exchange has been generally discussed with Federal, State, and local governmental agencies, public land user groups, and individuals through participation in the Bureau's land use planning process. The exchange will include both surface and mineral estates.

The value of the lands to be exchanged is approximately equal, and the acreage will be adjusted to equalize the values upon completion of the final appraisal of the lands.

The terms and conditions applicable to the exchange are:

FEDERAL LANDS

1. The reservation to the United States of a right-of-way for ditches or canals constructed by the authority of the United States, Act of August 30, 1890 (43 USC 945).

2. Those rights for powerline purposes as granted to Utah Power & Light Company under serial number I-0881.

3. Those rights for powerline purposes as granted to Idaho Power Company under serial numbers I-3459 and I-6485.

STATE LANDS

1. Easement 4907—Road easement to the BLM.

2. Easement 568—Road easement to the State Highway Department.

3. Easement 2860—Powerline easement to Utah Power & Light Company.

4. Easement 4130—Road easement to the BLM.

5. Minerals Lease 0-1659—Oil & Gas lease to E.P. Operating Company.

6. Easement 5232—Road easement to the BLM.

7. Easement 4087—Powerline easement to Lost River Electric.

8. Easement 4391—Powerline easement to Lost River Electric.

The publication of this notice in the **Federal Register** will segregate the public lands described above to the extent that they will not be subject to appropriation under the public land laws, including the mining laws. As provided by the regulations of 43 CFR 2201.1(b), any subsequently tendered application, allowance of which is discretionary, shall not be accepted, shall not be considered as filed, and shall be returned to the applicant.

The non-Federal lands described above are subject to prior Federal reserved minerals. The prior Federal interests are hereby segregated to the extent that such interests will not be subject to appropriation under the mining laws until a notice pursuant to 43 CFR 2200.3(a) is issued.

Detailed information concerning the exchange, including the environmental analysis, is available for review at the Idaho Falls District Office, 940 Lincoln Road, Idaho Falls, Idaho 83401.

For a period of 45 days interested parties may submit comments to the Idaho Falls District Manager at the address listed above.

Date: July 31, 1987.

Lloyd H. Ferguson,

District Manager.

[FR Doc. 87-17909 Filed 8-5-87; 8:45 am]

BILLING CODE 4310-GG-M

[ID-040-07-4212-14; I-22491, I-23768, I-23339, I-23340]

Realty Action; Sale of Public Land in Lemhi County, ID; Correction

AGENCY: Bureau of Land Management, Interior.

REALTY ACTION: Sale of Public Land in Lemhi County, Idaho; Correction.

SUMMARY: Correction of Notices of Realty Action published in Vol. 52 No. 107, Thursday June 4, 1987, page 21126 (I-23339, I-23340) and Vol. 52 No. 122, Thursday, June 25, 1987, page 23896 (I-22491, I-23768). The notices are corrected by adding the following paragraph:

The segregation on these public lands will expire 270 days from the date of publication in the **Federal Register** or upon issuance of a patent, whichever comes first.

Dated: July 30, 1987.

Jerry W. Goodman,

District Manager.

[FR Doc. 87-17910 Filed 8-5-87; 8:45 am]

BILLING CODE 4310-GG-M

[CO-942-06-4520-12]

Filing of Plats of Survey; Colorado

July 28, 1987.

The plats of survey of the following described land, will be officially filed in the Colorado State Office, Bureau of Land Management, Lakewood, Colorado, effective 10:00 a.m., July 28, 1987.

The supplemental plat showing a subdivision of lot 8, section 30, T. 19 S., R. 73 W., Sixth Principal Meridian, Colorado was accepted July 13, 1987.

The supplemental plat prepared to correct the acreage of lot 22, in section 7 and correcting a platting error of the bearing of the N½ mile between sections 7 and 12, on the west boundary, T. 1 N., R. 100 W., Sixth Principal Meridian, Colorado, was accepted July 8, 1987.

The plat representing the dependent resurvey of portions of the First Guide Meridian East (west boundary), north boundary, and subdivisional lines, T. 45 N., R. 9 E., New Mexico Principal Meridian, Colorado, Group No. 819, was accepted July 16, 1987.

The plat representing the dependent resurvey of portions of the First Guide Meridian East (east boundary) and the south boundary, T. 46 N., R. 8 E., New Mexico Principal Meridian, Colorado, Group No. 819, was accepted July 16, 1987.

These surveys were executed to meet certain administrative needs of this Bureau.

The plat representing the dependent resurvey of the south boundary, portions of the east and west boundaries, subdivisional lines, and certain mineral surveys, and the metes-and-bounds survey of the Fairview Exchange in section 36, T. 51 N., R. 3½ W., New Mexico Principal Meridian, Colorado, Group No. 758, was accepted July 10, 1987.

The plat representing the dependent resurvey of the east boundary, a portion of the north boundary, and subdivisional lines and the subdivision of certain sections, T. 45 N., R. 4 W., New Mexico Principal Meridian, Colorado, Group No. 767, was accepted July 14, 1987.

These surveys were executed to meet certain administrative needs of the U.S. Forest Service.

The protraction diagram of the following described land, will be officially filed in the Colorado State Office, Bureau of Land Management, Lakewood, Colorado, effective 10:00 a.m., September 14, 1987.

Protraction Diagram No. 12A, prepared to delineate the remaining unsurveyed public lands in T. 10 S., R. 90 W., Sixth Principal Meridian, Colorado, was approved July 8, 1987.

This diagram was prepared to meet certain administrative needs of this Bureau.

All inquiries about this land should be sent to the Colorado State Office, Bureau of Land Management, 2850 Youngfield Street, Lakewood, Colorado 80215.

Jack A. Eaves,

Chief, Cadastral Surveyor for Colorado.

[FR Doc. 87-17866 Filed 8-5-87; 8:45 am]

BILLING CODE 4310-JB-M

[AK-932-07-4220-10; AA-9904]

Termination of Proposed Withdrawal and Reservation of Lands; Alaska

July 29, 1987.

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: This notice terminates the segregative effect of a proposed withdrawal and reservation of lands requested by the U.S. Coast Guard for use as aids to navigation at Gull Island Light, Cohen Island Light, Point Pogibshi Light, and Perl Rock Light, Alaska.

EFFECTIVE DATE: August 6, 1987.

FOR FURTHER INFORMATION CONTACT: Sandra C. Thomas, BLM Alaska State Office, 701 C Street, Box 13, Anchorage, Alaska 99513, 907-271-5477.

Notice of a proposed withdrawal and reservation of lands for the U.S. Coast Guard was published in the **Federal Register** on January 12, 1978, Vol. 43, No. 8, page no. 1841, FR Doc. 78-806. The purpose of the application, serial number AA-9904, was for aids to navigation. The lands described in the **Federal Register** publication referred to above are no longer under the jurisdiction of the Federal government, and the application has been denied. At 8:00 a.m., Alaska Daylight Time, on the date of this publication, such lands will be relieved of the segregative effect of the above-mentioned application.

Sue A. Wolf,

Chief, Branch of Land Resources.

[FR Doc. 87-17863 Filed 8-5-87; 8:45 am]

BILLING CODE 4310-JA-M

[AZ-040-07-4322-02]

Safford District Grazing Advisory Board Meeting; Arizona

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of meeting.

SUMMARY: The Bureau of Land Management (BLM), Safford District announces a forthcoming meeting of the Safford District Grazing Advisory Board.

DATE: Friday, September 11, 1987; 9:00 a.m.

ADDRESS: BLM Office, 425 E. 4th Street, Safford, Arizona 85546.

SUPPLEMENTARY INFORMATION: This meeting is held in accordance with Pub. L. 92-463. The agenda for the meeting will include:

1. Guidelines for time control grazing.
2. Policy on maintenance of Range Improvement Projects following a wildfire.
3. Report on Stewardship Conference.
4. Proposed Range Improvement projects for Fiscal Year 1988.
5. Allotment Management Plans to be implemented in Fiscal Year 1988.
6. BLM management update.
7. Business from the floor.

The meeting will be open to the public. Interested groups may make oral statements to the Board between 10:00 p.m. and 11:00 p.m. A written copy of the oral statement may be required to be provided at the conclusion of the presentation. Written statements may also be filed for the Board's consideration. Anyone wishing to make an oral statement must notify the District Manager, Bureau of Land Management, 425 E. 4th St., Safford, AZ 85546, by 4:15 p.m., Thursday, September 10, 1987.

Summary minutes of the Board meeting will be maintained in the District Office and will be available for public inspection and reproduction (during regular business hours) within thirty (30) days following the meeting.

Dated: July 29, 1987.

Ray A. Brady,

District Manager.

[FR Doc. 87-17836 Filed 8-5-87; 8:45 am]

BILLING CODE 4310-32-M

[OR-030-4322-02; GP7-257]

Vale District Grazing Advisory Board Meeting; Oregon

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given in accordance with Pub. L. 92-463 that a meeting of the Vale District Advisory Board will be held on September 17, 1987.

The meeting will begin at 9:00 a.m. in the conference room of the Bureau of Land Management at 100 Oregon Street, Vale, Oregon 97918.

The agenda for the meeting will include: (1) Report on Fiscal Year 1987 Projects, (2) Fiscal Year 1988 Project Plans, and, (3) Discussion and recommendations for the Whitehorse Allotment Management Plan.

The meeting is open to the public. Interested persons may make oral statements to the Board, or may file written statements for the Board's consideration. Anyone wishing to make oral statements must notify the District Manager, Bureau of Land Management, 100 Oregon Street, Vale, Oregon 97918, by September 16, 1987. Depending on the number of persons to make oral statements, a per person time limit may be established by the Dsitrict Manager.

Summary minutes of the Board meeting will be maintained in the District Office and be available during regular business hours for public inspection and reproduction within 30 days following the meeting.

FOR FURTHER INFORMATION CONTACT: Bill Calkins, District Manager, Vale District, Bureau of Land Management, P.O. Box 700, 100 Oregon Street, Vale, Oregon 97918, (Telephone 503/473-3144).

David Lodzinski,

Acting District Manager.

[FR Doc. 87-17837 Filed 8-5-87; 8:45 am]

BILLING CODE 4310-33-M

[UT-930-4322-02]

Combined District Advisory Board Meetings; Utah

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Notice is hereby given in accordance with Pub. L. 92-463 that a joint meeting of Utah District Grazing Boards will be held September 9, 10 and 11, 1987. The meeting will begin with a dinner in the Taggart Center on the campus of Utah State University (USU), Logan, Utah at 6:00 p.m. on September 9, 1987. The business meeting on September 10 will begin at 8:00 a.m. in the Eccles Conference Center, USU. The agenda for the business meeting will include:

1. Meeting challenges facing livestock industry.
2. Update on BLM rangeland policy.
3. Report for Range Extension Specialists.
4. Noxious Weed Control.

During the afternoon of September 10 and the morning of September 11 there will be a tour of the Resources Plant Research Lab and the Forage and Range Labs.

The meeting is open to the public. Interested persons must furnish their own transportation. Anyone wishing to participate or present a statement should notify the Public Affairs Office, Utah State Office, 324 South State Street, Suite 301, Salt Lake City, Utah 84111-2303, or telephone (801) 524-3146 by September 4, 1987.

FOR FURTHER INFORMATION CONTACT: Ken Boyer, Range Conservationist, BLM, Utah State Office, at the above address (801) 524-3121).

Dated: July 30, 1987.

Joseph Jewkes,

Acting State Director.

[FR Doc. 87-17908 Filed 8-5-87; 8:45 am]

BILLING CODE 4310-DQ-M

[WY 060-07-4121-02]

Casper District Advisory Council Meeting; Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Casper District Advisory Council meeting.

SUMMARY: The Casper District Advisory Council will meet Tuesday, September 22, 1987 in the conference room of the Casper District Office, 1701 East E Street, Casper, Wyoming. The meeting will begin at 9:00 a.m. MDT.

The meeting agenda will include an update on the known geologic structure (KGS) study, a discussion on the impacts of the cultural resource program on drill sites, updates on the Power River Basin resurvey and Operation Respect, a summary of the withdrawal review program, and comments from the public. Other topics may be considered as suggested by council members or the public.

Meetings are open to the public. Persons who desire to address the council are asked to contact Tim Monroe at (307) 261-5101 in advance of the meeting.

Dated: July 29, 1987.

James W. Monroe,

District Manager.

[FR Doc. 87-17906 Filed 8-5-87; 8:45 am]

BILLING CODE 4310-22-M

[WY-040-07-4133-15]

Rock Springs District Advisory Council Meeting; Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of meeting of the Rock Springs District Advisory Council.

DATE: The meeting and tour will be held September 3, 1987, at 8:45 a.m.

ADDRESS: Rock Springs District Office, Bureau of Land Management, U.S. Highway 191 North, Rock Springs, Wyoming.

FOR FURTHER INFORMATION CONTACT: Donald H. Sweep, District Manager, Rock Springs District, Bureau of Land Management, P.O. Box 1869, Rock Springs, Wyoming 82902-1869, (307) 382-5350.

SUPPLEMENTARY INFORMATION: The meeting and tour will begin at 8:45 a.m., Thursday, September 3, at the Kemmerer Resource Area Office Conference Room in Kemmerer. The tour will leave at 9 a.m. sharp and return about 5 p.m. The public is invited to attend; however, BLM will not provide transportation.

The agenda is: Oregon/Mormon Trail Management Briefing and Tour; Update on District Programs; Public Comment Period.

Gene C. Herrin,

Associate District Manager.

July 31, 1987.

[FR Doc. 87-17907 Filed 8-5-87; 8:45 am]

BILLING CODE 4310-22-M

[UT 080-07-4322-02]

Vernal District Grazing Advisory Board; Meeting

July 30, 1987.

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Vernal District Grazing Advisory Board meeting.

SUMMARY: Notice is hereby given in accordance with Pub. L. 92-463, that a meeting of the Vernal District Grazing Advisory Board will be held Wednesday, September 9, 1987, commencing at 8:00 a.m. The meeting will be held in the District Office conference room at 170 South 500 East, Vernal, Utah.

The agenda items will include (1) Range Improvements, (2) Predator and Pest Control, (3) Riparian Area Management Program, (4) Three Corners Rangeland Program Summary Update, (5) Items From The Public, If Any.

The meeting is open to the public. Interested persons wishing to participate or present a statement should notify the District Manager at the above mentioned address or phone him at (801) 789-1362 no later than September 8, 1987.

David E. Little,

District Manager.

[FR Doc. 87-17805 Filed 8-5-87; 8:45 am]

BILLING CODE 4310-DQ-M

Minerals Management Service

Development Operations Coordination Document; ARCO Oil and Gas Co.

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of the receipt of a proposed Development Operations Coordination Document (DOCD).

SUMMARY: Notice is hereby given that ARCO Oil and Gas Company has submitted a DOCD describing the activities it proposes to conduct on Lease OCS 0438, Block 175, Eugene Island Area, offshore Louisiana. Proposed plans for the above area provide for the development and production of hydrocarbons with support activities to be conducted from an onshore base located at Amelia, Louisiana.

DATE: The subject DOCD was deemed submitted on July 27, 1987.

ADDRESS: A copy of the subject DOCD is available for public review at the Public Information Office, Gulf of

Mexico OCS Region, Minerals Management Service, 1201 Elmwood Park Boulevard, Room 114, New Orleans, Louisiana (office Hours: 8 a.m. to 4:30 p.m., Monday through Friday).

FOR FURTHER INFORMATION CONTACT: Michael J. Tolbert; Minerals Management Service, Gulf of Mexico OCS Region, Field Operations, Plans, Platform and Pipeline Section, Exploration/Development Plans Unit; Telephone (504) 736-2867.

SUPPLEMENTARY INFORMATION: The purpose of this Notice is to inform the public, pursuant to section 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is considering approval of the DOCD and that it is available for public review.

Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in DOCDs 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 revised § 250.34 of Title 30 of the CFR.

Date: July 27, 1987.

J. Rogers Pearcy,

Regional Director, Gulf of Mexico OCS Region.

[FR Doc. 87-17867 Filed 8-5-87; 8:45 am]

BILLING CODE 4310-MR-M

Development Operations Coordination Document; Chevron, U.S.A.

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of the receipt of a proposed development operations coordination document (DOCD).

SUMMARY: Notice is hereby given that Chevron U.S.A. Inc., Unit Operator of the South Timbalier Block 135 Federal Unit Agreement No. 14-08-001-6669, has submitted a DOCD describing the activities it proposes to conduct on the South Timbalier Block 135 Federal unit. Proposed plans for the above area provide for the development and production of hydrocarbons with support activities to be conducted from an onshore base located at Leeville, Louisiana.

DATE: The subject DOCD was deemed submitted on July 23, 1987.

ADDRESS: A copy of the subject DOCD is available for public review at the Public Information Office, Gulf of Mexico OCS Region, Minerals Management Service, 1201 Elmwood Park Boulevard, Room 114, New Orleans, Louisiana (Office Hours: 8 a.m. to 4:30 p.m., Monday through Friday).

FOR FURTHER INFORMATION CONTACT: Mr. Steve Dessauer; Minerals Management Service, Gulf of Mexico OCS Region, Production and Development; Development and Unitization Section; Unitization Unit; Telephone (504) 736-2660.

SUPPLEMENTARY INFORMATION: The purpose of this Notice is to inform the public, pursuant to section 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is considering approval of the DOCD and that it is available for public review.

Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in DOCDs 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 revised § 250.34 of Title 30 of the CFR.

Dated: July 27, 1987.

J. Rogers Pearcy,

Regional Director, Gulf of Mexico OCS Region.

[FR Doc. 87-17869 Filed 8-5-87; 8:45 am]

BILLING CODE 4310-MR-M

Development Operations Coordination Document; Hughes-Denny Offshore Exploration, Inc.

AGENCY: Mineral Management Service, Interior.

ACTION: Notice of the receipt of a proposed Development Operations Coordination Document (DOCD).

SUMMARY: Notice is hereby given that Hughes-Denny Offshore Exploration, Inc. has submitted a DOCD describing the activities it proposes to conduct on Lease OCS-G 4761, Block 277, West Cameron Area, offshore Louisiana. Proposed plan for the above area provide for the development and production of hydrocarbons with support activities to be conducted from onshore bases located at Cameron, Houma, and Intracoastal City, Louisiana.

DATE: The subject DOCD was deemed submitted on July 27, 1987. Comments must be received within 15 days of the date of this Notice or 15 days after the Coastal Management Section receives a copy of the plan from the Minerals Management Service.

ADDRESSES: A copy of the subject DOCD is available for public review at the Public Information Office, Gulf of Mexico OCS Region, Minerals Management Service, 1201 Elmwood Park Boulevard, Room 114, New Orleans, Louisiana (Office Hours: 8 a.m. to 4:30 p.m., Monday through Friday). A copy of the DOCD and the accompanying Consistency Certification are also available for public review at the Coastal Management Section Office located on the 10th Floor of the State Lands and Natural Resources Building, 625 North 4th Street, Baton Rouge, Louisiana (Office Hours: 8 a.m. to 4:30 p.m.; Monday through Friday). The public may submit comments to the Coastal Management Section, Attention OCS Plans, Post Office Box 44487, Baton Rouge, Louisiana 70805.

FOR FURTHER INFORMATION CONTACT: Ms. Angie D. Gobert; Minerals Management Service, Gulf of Mexico OCS Region, Field Operations, Plans, Platform and Pipeline Section, Exploration/Development Plans Unit; Telephone (504) 736-2876.

SUPPLEMENTARY INFORMATION: The purpose of this Notice is to inform the public, pursuant to section 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is considering approval of the DOCD and that it is available for public review. Additionally, this Notice is to inform the public, pursuant to § 930.61 of Title 15 of the CFR, that the Coastal Management Section/Louisiana Department of Natural Resources is reviewing the DOCD for consistency with the Louisiana Coastal Resources Program.

Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in DOCD 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 revised Section 250.34 of Title 30 of the CFR.

Date: July 28, 1987.

J. Rogers Pearcy,

Regional Director, Gulf of Mexico OCS Region.

[FR Doc. 87-17868 Filed 8-5-87; 8:45 am]

BILLING CODE 4310-MR-M

Development Operations Coordination Document; Texaco U.S.A.

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of the receipt of a proposed Development Operations Coordination Document (DOCD).

SUMMARY: Notice is hereby given that Texaco U.S.A., Unit Operator of the South Marsh Island Block 236 Federal Unit Agreement No. 14-08-0001-20234, has submitted a DOCD describing the activities it proposes to conduct on the South Marsh Island Block 236 Federal unit. Proposed plans for the above area provide for the development and production of hydrocarbons with support activities to be conducted from onshore bases located at Louisa and Morgan City, Louisiana.

DATE: The subject DOCD was deemed submitted on July 24, 1987.

ADDRESS: A copy of the subject DOCD is available for public review at the Public Information Office, Gulf of Mexico OCS Region, Minerals Management Service, 1201 Elmwood Park Boulevard, Room 114, New Orleans, Louisiana (Office Hours: 8 a.m. to 4:30 p.m., Monday through Friday).

FOR FURTHER INFORMATION CONTACT: Mr. Roy Bongiovanni; Minerals Management Service; Gulf of Mexico OCS Region; Production and Development; Development and Unitization Section; Unitization Unit; Telephone (504) 736-2650.

SUPPLEMENTARY INFORMATION: The purpose of this Notice is to inform the public pursuant to section 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is considering approval of the DOCD and that it is available for public review.

Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in DOCDs 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 revised § 250.34 of Title 30 of the CFR.

Date: July 28, 1987.

J. Rogers Pearcy,

Regional Director, Gulf of Mexico OCS Region.

[FR Doc. 87-17864 Filed 8-5-87; 8:45 am]

BILLING CODE 4310-MR-M

Development Operations Coordination Document; Elf Aquitaine, Inc.

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of the receipt of a proposed Development Operations Coordination Document (DOCD).

SUMMARY: Notice is hereby given that Elf Aquitaine has submitted a DOCD describing the activities it proposes to conduct on Lease OCS-G 4864, Block 164, Eugene Island Area, offshore Louisiana. Proposed plans for the above area provide for the development and production of hydrocarbons with support activities to be conducted from an onshore base located at Intracoastal City, Louisiana.

DATE: The subject DOCD was deemed submitted on July 30, 1987. Comments must be received within 15 days of the date of this Notice or 15 days after the Coastal Management Section receives a copy of the plan from the Minerals Management Service.

ADDRESSES: A copy of the subject DOCD is available for public review at the Public Information Office, Gulf of Mexico OCS Region, Minerals Management Service, 1201 Elmwood Park Boulevard, Room 114, New Orleans, Louisiana (Office Hours: 8 a.m. to 4:30 p.m., Monday through Friday). A copy of the DOCD and the accompanying Consistency Certification are also available for public review at the Coastal Management Section Office located on the 10th Floor of the State Lands and Natural Resources Building, 625 North 4th Street, Baton Rouge, Louisiana (Office Hours: 8 a.m. to 4:30 p.m., Monday through Friday). The public may submit comments to the Coastal Management Section, Attention OCS Plans, Post Office Box 44487, Baton Rouge, Louisiana 70805.

FOR FURTHER INFORMATION CONTACT: Ms. Angie D. Gobert; Minerals Management Service, Gulf of Mexico OCS Region, Field Operations, Plans, Platform and Pipeline Section, Exploration/Development Plans Unit; Telephone (504) 736-2876.

SUPPLEMENTARY INFORMATION: The purpose of this Notice is to inform the public, pursuant to section 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is considering approval of the DOCD and that it is available for public review. Additionally, this Notice is to inform the public, pursuant to § 930.61 of Title 15 of the CFR, that the Coastal Management Section/Louisiana Department of Natural Resources is reviewing the DOCD for consistency with the Louisiana Coastal Resources Program.

Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in DOCDs 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 revised § 250.34 of Title 30 of the CFR.

Dated: July 31, 1987.

J. Rogers Pearcy,

Regional Director, Gulf of Mexico OCS Region.

[FR Doc. 87-17911 Filed 8-5-87; 8:45 am]

BILLING CODE 4310-MR-M

INTERSTATE COMMERCE COMMISSION

[No. MC-C-30038]

Petition for Declaratory Order; American Coach Lines, Inc.

AGENCY: Interstate Commerce Commission.

ACTION: Notice of filing of petition for declaratory order.

SUMMARY: American Coach Lines, Inc. (ACL), holds a certificate to conduct regular-route passenger operations that embrace incidental charter rights. The authority permits ACL to operate over routes extending generally between Washington, DC, on the one hand, and, on the other, Baltimore and Frederick, MD. ACL has filed a petition seeking a declaratory order as to whether it may conduct charter operations entirely within the Washington, DC, metropolitan area under this authority, or whether such operations are subject to the jurisdiction of the Washington Metropolitan Area Transit Commission. The Commission has instituted a proceeding and comments on this issue are invited.

DATES: Comments may be filed on or before September 8, 1987.

ADDRESSES: Send an original and 10 copies of comments referring to No. MC-C-30038 to:

Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

Send one copy of comments to each of petitioner's representatives:

Leonard A. Jaskiewicz, 1730 M Street, NW., Suite 501, Washington, DC 20036

Lawrence E. Lindeman, 805 King Street, Suite 400, Alexandria, VA 22314.

FOR FURTHER INFORMATION CONTACT: James L. Brown, (202) 275-7898

or

Andrew L. Lyon, (202) 275-7291.

SUPPLEMENTARY INFORMATION:

The Commission's decision contains additional information. To obtain a copy of the decision, write to the Office of the Secretary, Room 2215, Interstate Commerce Commission, Washington, DC 20423, or call (202) 275-7428.

Authority: 5 U.S.C. 554, 49 U.S.C. 10521(a), 10921, and 10932(c), and Pub. L. No. 86-794.

Decided: July 30, 1987.

By the Commission, Chairman Gradison, Vice Chairman Lamboley, Commissioners Sterrett, Andre, and Simmons.

Noreta R. McGee,

Secretary.

[FR Doc. 87-17877 Filed 8-5-87; 8:45 am]

BILLING CODE 7035-01-M

[No. 35940]

Investigation Into the Lawfulness of Interchange Arrangements Between the Bangor and Aroostook Railroad and CP Rail at Brownville Junction, ME

AGENCY: Interstate Commerce Commission.

ACTION: Notice of filing of petition by Canadian Pacific Limited (CP Rail) to lift cease and desist order.

SUMMARY: By petition filed May 27, 1987, CP Rail requests that the Commission lift a cease and desist order entered in *Interchange Arrangements Between BAR and CP*, 361 I.C.C. 615 (1979). The Bangor and Aroostook Railroad Company (BAR) submitted a letter in support. The Commission seeks comments from interested parties.

DATES: Comments are due on August 26, 1987. Replies are due on September 15, 1987.

ADDRESSES: Send comments referring to No. 35940 to:

(1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423

(2) Petitioner's representatives: Charles H. White, Jr., George M. Pond, Peper Martin, Jensen, Maichel, and Hetlage, 1700 Pennsylvania Ave., NW., Suite 400, Washington, DC 20006-4706.

FOR FURTHER INFORMATION CONTACT: Joseph H. Dettmar, (202) 275-7245.

SUPPLEMENTARY INFORMATION:

By decision in this proceeding at 356 I.C.C. 749 (1977), the Commission found that BAR and CP Rail had entered into an agreement in which BAR unjustifiably routed traffic originating or terminating on its lines via its interchange with petitioner at Brownville Junction, ME, rather than distributing it more evenly with an alternate interchange with the Maine Central Railroad Company (MEC) at Northern Maine Junction, ME. The Commission concluded that, between 1970 and 1974, BAR and petitioner unreasonably discriminated against MEC and its connecting carrier, the Boston and Maine Corporation (B&M), in distributing traffic not specifically routed by a shipper in violation of section 3(4) of the Interstate Commerce Act (now 49 U.S.C. 10701(c)). The Commission ordered BAR to pay damages to MEC and B&M, retained jurisdiction, and directed BAR and petitioner to refrain from further violations of section 3(4). In response to *Bangor & A.R. Co.* v. *I.C.C.*, 574 F.2d 1096 (1st Cir. 1978), the Commission, at 361 I.C.C. 615 (1979), modified its previous cease and desist order by setting more specific parameters of proscribed conduct.

Petitioner seeks removal of that order on grounds that it is contrary to the present Rail Transportation Policy of section 10101a, is anticompetitive, and conflicts with the freedom to contract conferred by section 10713(a). The Commission seeks comments from interested parties.

The petition is available for inspection in the Commission's Public Docket Room 1221. Additionally, a copy of the petition can be obtained from CP Rail's counsel, Charles H. White, Jr., at 1700 Pennsylvania Avenue, NW., Suite 400, Washington, DC 20006, or purchased by writing the Commission's Certification Unit, Room 1312, Interstate Commerce Commission, Washington, DC 20423.

Decided: July 30, 1987.

By the Commission, Chairman Gradison, Vice chairman Lamboley, Commissioners Sterrett, Andre, and Simmons.

Noreta R. McGee,

Secretary.

[FR Doc. 87-17876 Filed 8-5-87; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF JUSTICE

Consent Decree In Action To Enjoin Discharge of Water Pollutants; Apex Painting and Polishing Co., Inc.

In accordance with Departmental Policy, 28 CFR 50.7, 38 FR 19029, notice is hereby given that a consent decree in *United States* v. *Apex Plating and Polishing Co., Inc.*, Civil Action No. 86-0919 (JWB), was lodged with the United States District Court for the District of New Jersey on July 2, 1987. The consent decree establishes a compliance program for the New Jersey plant owned and operated by Apex to bring the plant into compliance with the Clean Water Act, 33 U.S.C. 1251 *et seq.*, and the applicable pretreatment regulations relating to the discharge of pollutants and requires payment of a civil penalty of $17,000.00.

The Department of Justice will receive for thirty (30) days from the date of publication of this notice, written comments relating to the consent decree. Comments should be addressed to the Assistant Attorney General, Land and Natural Resources Division, Department of Justice, Washington, DC 20530 and should refer to *United States* v. *Apex Plating and Polishing Co., Inc.*, D.J. Ref. No. 90-5-1-1-2532.

The consent decree may be examined at the office of the United States Attorney, District of New Jersey, U.S. Courthouse, 502 Federal Bldg., 970 Broad St., Newark, N.J. 07102; at the Region II office of the Environmental Protection Agency, 27 Federal Plaza, New York, New York 10278; and the Environmental Enforcement Section, Land and Natural Resources Division of the Department of Justice, Washington, DC 20530. In requesting a copy, please enclose a check in the amount of $1.50 (10 cents per page reproduction charge) payable to the Treasurer of the United States.

F. Henry Habicht II,

Assistant Attorney General, Land and Natural Resources Division.

[FR Doc. 87-17839 Filed 8-5-87; 8:45 am]

BILLING CODE 4410-01-M

Lodging of Consent Decree Pursuant to the Clean Water Act; Joliet, IL

In accordance with Department policy, 28 CFR 50.7, notice is hereby given that on July 28, 1987, a proposed consent decree in *United States* v. *City of Joliet*, Civil Action No. 86-C-2512, was lodged with the United States District Court for the Northern District of Illinois. The proposed consent decree resolves a judicial enforcement action brought by the United States against the City of Joliet for violations of the Clean Water Act.

The proposed consent decree requires the City of Joliet to implement and enforce the provisions of its pretreatment program. Joliet is required to (1) inspect all significant industrial users within six months of entry of the decree; (2) monitor its POTW influent, effluent and sludge on a monthly basis for priority pollutants; (3) take timely and appropriate enforcement action pursuant to its Enforcement Response Procedures to address violations of its pretreatment plan and its Sewer Use Ordinance; and (4) submit to U.S. EPA quarterly reports detailing all actions taken by Joliet pursuant to its pretreatment plan. The proposed decree also requires Joliet to pay a civil penalty of $30,000.

The proposed consent decree may be examined at the office of the United States Attorney, 219 South Dearborn Street, Chicago, Illinois and at the office of Regional Counsel, Environmental

Protection Agency, 230 South Dearborn Street, Chicago, Illinois.

Copies of the consent decree may be examined at the Environmental Enforcement Section, Land and Natural Resources Division of the Department of Justice, Room 1517, Ninth and Pennsylvania Avenue, NW., Washington, DC 20530. A copy of the proposed consent decree may be obtained in person or by mail from the Environmental Enforcement Section, Land and Natural Resources Division of the Department of Justice.

Roger J. Marzulla,

Acting Assistant Attorney General, Land and Natural Resources Division.

[FR Doc. 87-17840 Filed 8-5-87; 8:45 am]

BILLING CODE 4410-01-M

Lodging of Consent Decree Pursuant to Clean Water Act; Parker Metals

In accordance with departmental policy, 28 CFR 50.7, notice is hereby given that on July 6, 1987, a proposed consent decree in *United States* v. *Parker Metals*, Civil Action No. 85-3862-S, was lodged with the United States District Court for the District of Massachusetts. The proposed consent decree concerns violations of the general and categorical pretreatment requirements under section 307 and 308 of the Clean Water Act, 33 U.S.C. 1317 and 1318. The proposed consent decree requires the defendants to pay a civil penalty of $250,000; to comply with federal pretreatment standards as set forth in 40 CFR 403.12(b); to submit to the EPA and to the local POTW a Baseline Monitoring Report on cyandie, metals, and total toxic organisms; and to sample and analyze the process wastewater according to a proscribed schedule.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed consent decree. Comments should be addressed to the Assistant Attorney General of the Land and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to *United States* v. *Parker Metals*, D.J. Ref. 90-5-1-1-2450.

The proposed Consent Decree may be examined at the office of the United States Attorney, District of Massachusetts, 1107 John W. McCormack Federal Building, United States Post Office and Courthouse, Boston, Massachusetts 02109, and at the Region I Office of the Environmental Protection Agency, John F. Kennedy Federal Building, Room 2203, Boston, Massachusetts 02203. Copies of the Consent Decree may be examined at the Environmental Enforcement Section, Land and Natural Resources Division of the Department of Justice, Room 1517, Ninth Street and Pennsylvania Avenue, NW., Washington, DC 20530. A copy of the proposed consent decree may be obtained in person or by mail from the Environmental Enforcement Section, Land and Natural Resources Division of the Department of Justice. In requesting a copy, please enclose a check in the amount of $1.30 (10 cents per page reproduction cost) payable to the Treasurer of the United States.

Roger J. Marzulla,

Acting Assistant Attorney General, Land and Natural Resources Division.

[FR Doc. 87-17841 Filed 8-5-87; 8:45 am]

BILLING CODE 4410-01-M

Consent Decree in Action to Enjoin Discharge of Water Pollutants; Star Chromium Corp.

In accordance with Departmental Policy, 28 CFR 50.7, 38 FR 19029, notice is hereby given that a consent decree in *United States* v. *Star Chromium Corp.*, Civil Action No. 85-4479 was lodged with the United States District Court for the Eastern District of New York on July 29, 1987. The consent decree establishes a compliance program for the New York plant owned and operated by Star Chromium Corp. to bring the plant into compliance with the Clean Water Act, 33 U.S.C. 1251 et seq., and the applicable pretreatment regulations relating to the discharge of pollutants and requires payment of a civil penalty of $22,000.

The Department of Justice will receive for thirty (30) days from the date of publication of this notice, written comments relating to the consent decree. Comments should be addressed to the Assistant Attorney General, Land and Natural Resources Division, Department of Justice, Washington, DC 20530 and should refer to *United States* v. *Star Chromium Corp.*, D.J. Ref. No. 90-5-1-1-2466.

The consent decree may be examined at the office of the United States Attorney, Eastern District of New York, U.S. Courthouse, 225 Cadman Plaza East, Brooklyn, New York 11201; at the Region II office of the Environmental Protection Agency, 27 Federal Plaza, New York, New York 10278; and the Environmental Enforcement Section, Land and Natural Resources Division of the Department of Justice.

Roger J. Marzulla,

Acting Assistant Attorney General, Land and Natural Resources Division.

[FR Doc. 87-17842 Filed 8-5-87; 8:45 am]

BILLING CODE 4410-01-M

Bureau of Prisons

National Institute of Corrections; Annual Program Plan and Academy Training Schedule for Fiscal Year 1988

The National Institute of Corrections (NIC), U.S. Department of Justice, has released its "Annual Program Plan and Academy Training Schedule for Fiscal Year 1988." The document describes the Institute's program of training, technical assistance, information services, research/evaluation, and policy development projects planned for the next fiscal year. It also describes the Institute's schedule of training seminars to be conducted by the NIC National Academy of Corrections and contains application forms.

To obtain a copy of the document, contact the National Institute of Corrections, 320 First Street, NW., Washington, DC 20534. Telephone 202-724-8449; TDD for hearing impaired, 202-724-3156.

Raymond C. Brown,

Director.

[FR Doc. 87-17870 Filed 8-5-87; 8:45 am]

BILLING CODE 4410-05-M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (87-62)]

Agency Report Forms Under OMB Review

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of agency report forms under OMB review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to submit proposed information collection requests to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made the submission.

Copies of the proposed forms, the requests for clearance (S.F. 83's), supporting statements, instructions, transmittal letters and other documents submitted to OMB for review, may be obtained from the Agency Clearance Officer. Comments on the items listed should be submitted to OMB for review, may be obtained from the Agency Clearance Officer. Comments on the items listed should be submitted to the Agency Clearance Officer and the OMB Reviewer.

DATE: Comments must be received in writing by August 7, 1987. If you anticipate commenting on a form but

find that time to prepare will prevent you from submitting comments promptly, you should advise the OMB Reviewer and the Agency Clearance Officer of your intent as early as possible.

ADDRESS: Rayburn A. Metcalfe, NASA Agency Clearance Officer, Code NP, NASA Headquarters, Washington, DC 20546; Bruce McConnell, Office of Information and Regulatory Affairs, OMB, Room 3235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Shirley C. Peigare, NASA Reports Officer, (202) 453-1090.

Reports

Title: Application for Patent License.
OMB number: 2700-0039.
Type of request: Extension.
Frequency of report: As required.
Type of respondent: Businesses or other for-profit.
Annual responses: 25.
Annual burden hours: 150.
Abstract-need/uses: Pursuant to 35 U.S.C. 209, applicants for patent licenses must submit specific information in support of the application for license. The information is used to decide whether a request is approved or denied.

Rayburn A. Metcalfe,
Acting Director, General Management Division.

[FR Doc. 87-17856 Filed 8-5-87; 8:45 am]

BILLING CODE 7510-01-M

OFFICE OF PERSONNEL MANAGEMENT

Privacy Act of 1974; Systems of Records

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: This notice proposes the establishment of OPM/CENTRAL-4, Inspector General Case File Records, which is a new Office of Personnel Management (Office) system of records. This system covers case file records maintained on Office employees and other individuals (private sector or other agencies) relating to matters within the purview of the Office's Inspector General function.

DATE: Comments on the routine uses for the OPM/CENTRAL-4 system must be received on or before September 8, 1987.

ADDRESS: Send or deliver written comments to the Assistant Director for Workforce Information, Personnel Systems and Oversight Group, Office of Personnel Management, Room 5415, 1900 E Street, NW., Washington, DC 20415.

FOR FURTHER INFORMATION CONTACT: William H. Lynch, (202) 632-5433.

SUPPLEMENTARY INFORMATION: The Office's Inspector General has been maintaining case file records chronologically and by subject matter. However, because the case files will now be retrieved by name or other identifier associated with an individual, they will be considered to be a system of records within the meaning of the Privacy Act. This change in system maintenance is necessitated by use of automated storage media and the need to facilitate records management, including disposal of records according to established retention schedules.

Because these records will contain investigative material created by the Inspector General's staff and, perhaps, information obtained from other Office or agency investigative records, exemptions are being claimed from certain provisions of the Privacy Act regarding access to the files containing source data from systems for which an exemption is already claimed, the accounting of disclosures of the files, and amendment of records. The exemptions claimed for the system will be the subject of a separate **Federal Register** notice of changes to the Office's Privacy Act regulations (5 CFR Part 297).

The establishment of a new system is an action subject to the provisions of the Privacy Act (5 U.S.C. 552a(o)) requiring advance notice to Congress and the Office of Management and Budget. Because the conversion of the method of storage of these records will not occur until the system is established, no waiver of the 60-day advance notice period has been requested.

This notice becomes final, without any further **Federal Register** notice, on November 4, 1987, unless comments received necessitate otherwise.

Office of Personnel Management.

Constance Horner,
Director.

Accordingly, the Office proposes the following new system of records to be identified as OPM/CENTRAL-4, Inspector General Case File Records.

OPM/CENTRAL-4

SYSTEM NAME:

Inspector General Investigations Case Files.

SYSTEM LOCATION:

Office of the Inspector General, Office of Personnel Management, 1900 E Street, NW., Washington, DC 20415.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current and former Office employees, certain current and former employees of other Federal agencies, annuitants, and contractors with the Office.

CATEGORIES OF RECORDS IN THE SYSTEM:

Case files contain individual identifiers such as name, date of birth, social security number, employee number, civil service retirement case file number, and related personal information. Case files are created pertaining to matters including the following:

(1) Fraud against the Government; (2) Theft of Government property; (3) Misuse of Government property; (4) Improper personal conduct; (5) Irregularities in awarding contracts; (6) Improper personnel practices; (7) Call detailing case records; and (8) Initiatives arising from the President's Council on Integrity and Efficiency.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301.

PURPOSE:

Information in case files serves to document the outcome of investigations, reporting the results of investigations to other Office components or agencies for their use in evaluating their programs and imposition of any civil or administrative sanctions, and, if appropriate, reporting the results of the investigations to other agencies for any action deemed appropriate, and for retaining sufficient information to fulfill the reporting requirements of Pub. L. 95-452, Section 5.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

These records and information in these records may be used in disclosing information—

a. To designated officers and employees of agencies, offices, and other establishments in the executive, legislative, and judicial branches of the Federal Government having an interest in the individual for employment purposes, including a security clearance or access determination, and the need to evaluate qualifications, suitability, and loyalty to the United States Government.

b. To designated officers and employees of agencies, offices, and other establishments in the executive, legislative, and judicial branches of the Federal Government when such agency, office, or establishment conducts an investigation of the individual for

granting a security clearance, or for making a determination of qualifications, suitability, or loyalty to the United States Government, or access to classified information or restricted areas.

c. To any source from which information is requested in the course of an investigation, to the extent necessary to identify the individual, inform the source of the nature and purpose of the investigation, and to identify the type of information requested.

d. To the appropriate Federal, State, or local agency responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order when the Office becomes aware of an indication of a violation or potential violation of civil or criminal law or regulation.

e. To provide information to a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of that individual.

f. To another Federal agency, to a court or a party in litigation before a court or in an administrative proceeding being conducted by a Federal agency, either when the Government is a party to a judicial proceeding or to comply with the issuance of a subpoena.

g. To provide information to the Department of Justice, or in a proceeding before a court, adjudicative body, or other administrative body before which the agency is authorized to appear, when:

(1) The agency, or any component thereof is a party to litigation; or

(2) Any employee of the agency in his or her official capacity is a party to litigation; or

(3) Any employee of the agency in his or her individual capacity, where the Department of Justice or the agency has agreed to represent the employee, or

(4) The United States, where the agency determines that litigation is likely to affect the agency or any of its components, is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice or the agency is deemed by the agency to be relevant and necessary to the litigation, provided, however, that in each case it has been determined that the disclosure is compatible with the purpose for which the records were collected.

h. To the National Archives and Records Administration for records management inspections conducted under authority of 44 U.S.C. 2904 and 2906.

i. To the Office of Management and Budget at any stage in the legislative coordination and clearance process in connection with private relief legislation as set forth in OMB Circular No. A-19.

j. To respond to a request for discovery or for appearance of a witness, when relevant to the subject matter involved in a pending judicial or administrative proceeding.

k. To disclose information to officials of the Merit Systems Protection Board, including the Office of Special Counsel, when requested in connection with appeals, special studies of the civil service and other merit systems, review of Office rules and regulations, investigations of alleged or possible prohibited personnel practices, and such other functions; e.g., as promulgated in 5 U.S.C. 1205 and 1206, or as may be authorized by law.

l. To disclose information to the Equal Employment Opportunity Commission when requested in connection with investigations into alleged or possible discriminatory practices in the Federal sector, examination of Federal affirmative employment programs, or other functions vested in the Commission by the President's Reorganization Plan No. 1 of 1978.

m. To disclose information to the Federal Labor Relations Authority or its General Counsel when requested in connection with investigations of allegations of unfair labor practices or matters before the Federal Service Impasses Panel.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, SAFEGUARDING, AND RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained in file folders, on index cards, on microfilm, or disks.

RETRIEVABILITY:

Records are retrieved by the name, date of birth, social security number, employee number, case file number, or other unique identifying number, or by a combination of such identifiers.

SAFEGUARDS:

Records are maintained in file cabinets secured by combination locks, secured microfilm storage cabinets, and in computers with access limited to only certain employees through the use of individual identifiers and passwords.

RETENTION AND DISPOSAL:

Case files are retained while the person is under investigation and for 10 years after final disposition of the case or any litigation of the matter is completed.

SYSTEM MANAGER AND ADDRESS:

Inspector General, U. S. Office of Personnel Management, 1900 E Street, NW., Washington, DC 20415.

NOTIFICATION PROCEDURES:

Individuals wishing to learn whether this system contains information about them should contact the system manager. So that the record can be located and identified, the requester must furnish the following information:

a. Full name.

b. Date of birth and social security number.

c. Signature

d. Any additional information (e.g., type of investigation conducted, employee number or annuitant CSR number) that the requester believes might be helpful.

RECORD ACCESS PROCEDURE:

Specific records in this system have been exempted from Privacy Act provisions at 5 U.S.C. 552a (c)(3) and (d) regarding access to records. The section of this notice titled Systems Exempted from Certain Provisions of the Act, which follows, indicates the kinds of records exempted. Individuals wishing to request access to any records pertaining to them should contact the system manager. Requesters must furnish the following information for their records to be located and identified:

a. Full name.

b. Date of birth and social security number.

c. Signature.

d. Any additional information (e.g., type of investigation conducted, employee number or annuitant CSR number) that the requester believes may be helpful.

Individuals requesting access must also comply with the Office's Privacy Act regulations regarding verification of identity and access to records (5 CFR 297.201 and 297.203).

CONTESTING RECORD PROCEDURE:

Specific records in this system have been exempted from the Privacy Act provisions at 5 U.S.C. 552a(d) regarding amendment of records. The section of this notice titled Systems Exempted from Certain Provisions of the Act, which follows, indicates the kinds of records exempted. Individuals seeking to amend their records should contact the system manager. Requesters must furnish the following information for their records to be located and identified:

a. Full name.

b. Date of birth and social security number.

c. Signature.

d. Any additional information (e.g., type of investigation conducted, or employee number or annuitant CSR

number) that the requester believes may be helpful.

Individuals requesting amendment must also comply with the Office's Privacy Act regulations regarding verification of identity and amendment of records (5 CFR 297.201 and 297.208).

RECORD SOURCE CATEGORIES:

Information in this system is obtained from—

a. The individual who is the subject of the case file.

b. The individual's supervisor and co-workers.

c. Other Federal and non-Federal sources who have information relevant to the case.

d. Official records of the Office or another Federal agency.

e. Non-Government record sources.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

The Office has claimed exemptions from the access (including access to an accounting of disclosure) and amendment provisions of the Privacy Act (5 USC 552a (c)(3) and (d)) for several of its other systems of records under 5 U.S.C. 552a(k) (1), (2), (3), (4), (5), (6), and (7). During the course of developing a case file covered under this system, copies of the exempt records from these other systems may become part of the file. To the extent that this occurs, the Office has claimed the same exemptions for these copies as they have for the original documents.

Additionally, information within the scope of these exemptions may be developed by the Inspector General's staff during an investigation. These same exemptions are claimed for this developed information when the information is—

a. Classified material and pertains to the national defense and foreign policy (552a(k)(1)); or

b. Investigatory material compiled for law enforcement purposes (552a(k)(2)); or

c. Relates to providing protective services to the President or others (552a(k)(3)); or

d. Required by statute to be maintained and used solely as statistical records (552a(k)(4)); or

e. Investigatory material used in making suitability and qualification determinations and its release would reveal the identity of an individual who furnished information under an express or implied promise of confidentiality (552a(k)(5)); or

f. Testing or examining material the release of which would compromise the objectivity or fairness of the testing or examination process (552a(k)(6)); or

g. Evaluation material used to determine potential for promotion in the armed services, but only to the extent that release would reveal the identity of an individual who furnished information under an express or implied promise of confidentiality (552a(k)(7)).

[FR Doc. 87-17808 Filed 8-5-87; 8:45 am]

BILLING CODE 6325-01-M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Reports, Forms, and Recordkeeping Requirements: Submittals to OMB on July 31, 1987

AGENCY: Department of Transportation (DOT), Office of the Secretary.

ACTION: Notice.

SUMMARY: This notice lists those forms, reports, and recordkeeping requirements imposed upon the public which were transmitted by the Department of Transportation on July 31, 1987, to the Office of Management and Budget (OMB) for its approval in accordance with the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35).

FOR FURTHER INFORMATION CONTACT: John Chandler, Annette Wilson, or Cordelia Shepherd, Information Requirements Division, M-34, Office of the Secretary of Transportation, 400 Seventh Street, SW., Washington, DC 20590, telephone (202) 366-4735, or Gary Waxman or Sam Fairchild, Office of Management and Budget, New Executive Office Building, Room 3228, Washington, DC 20503, (202) 395-7340.

SUPPLEMENTARY INFORMATION:

Background

Section 3507 of Title 44 of the United States Code, as adopted by the Paperwork Reduction Act of 1980, requires that agencies prepare a notice for publication in the **Federal Register**, listing those information collection requests submitted to the Office of Management and Budget (OMB) for initial, approval, or for renewal under that Act. OMB reviews and approves agency submittals in accordance with criteria set forth in that Act. In carrying out its responsibilities, OMB also considers public comments on the proposed forms, reporting and recordkeeping requirements. OMB approval of an information collection requirement must be renewed at least once every three years.

Information Availability and Comments

Copies of the DOT information collection requests submitted to OMB may be obtained from the DOT officials listed in the "For Further Information Contact" paragraph set forth above. Comments on the requests should be forwarded, as quickly as possible, directly to the OMB officials listed in the "For Further Information Contact" paragraph set forth above. If you anticipate submitting substantive comments, but find that more than 10 days from the date of publication are needed to prepare them, please notify the OMB officials of your intent immediately.

Items Submitted for Review by OMB

The following information collection requests were submitted to OMB on July 31, 1987.

DOT No: 2958
OMB No: 2120-0018
Administration: Federal Aviation Administration
Title: Certification Procedures for Products and Parts, FAR 21
Need for Information: FAA needs this information to show compliance with applicable requirements and determine that products and parts have no unsafe features
Proposed Use of Information: To certify that products and parts have safe features
Frequency: On occasion
Burden Estimate: 44,176 hours
Respondents: Businesses
Form(s): FAA Forms 8110-12, 8130-1, 8130-6, 8130-9, 8130-12

DOT No: 2959
OMB No: 2115-0549
Administration: U.S. Coast Guard
Title: Carriage and Use of Liquefied or Nonliquefied Flammable Gas as Cooking Fuels on Vessels Carrying Passengers for Hire
Need for Information: This requirement is needed to ensure that operational safety is maintained on vessels mentioned above
Proposed Use of Information: This collection of information is used by any person operating the cooking appliance to ensure it is operated in a safe manner
Frequency: On occasion
Burden Estimate: 1,900 hours
Respondents: Owners/operators of passenger carrying vessels
Form(s): None

DOT No: 2960
OMB No: 2115-0094
Administration: U.S. Coast Guard

Title: Safety Approval of Cargo Containers
Need for Information: This information is needed to enforce safety requirements for intermodal containers. Also, the recordkeeping requirement ensures adequate documentation to verify the design type has been designed and tested in accordance with International Convention requirements, and to ensure that U.S. containers are permitted to move freely in international trade by other nations who are signatory to the Convention for Safe Containers
Proposed Use of Information: This information collection requirement is used to: (1) Receive information for plan review and approval; (2) receive information concerning continuous examination program; (3) ensure that no unauthorized changes are made when additional containers are manufactured to an approved design; (4) ensure that adequate documentation is available to verify the approval of an individual container or design type; (5) ensure that periodic examinations are carried out; (6) ensure that container handlers and authorities in other countries will allow free movement of U.S. containers in foreign trade
Frequency: On occasion
Burden Estimate: 29,269.5 Hours
Respondents: Container owners, operators, manufacturers and delegated approval authorities
Form(s): None.

DOT No: 2961
OMB No: 2115-0134
Administration: U.S. Coast Guard
Title: Carrying Persons in Addition to the Crew
Need for Information: This information collection requirement is necessary to allow some cargo vessels and other vessels engaged in certain fisheries to carry persons in addition to the normal crew without meeting the more stringent regulatory requirements. Therefore, this requirement reduces some of the regulatory burdens on some vessels.
Proposed Use of Information: Coast Guard will use this information to ensure that adequate safety is maintained on vessels when additional persons are allowed to be carried on board.
Frequency: On occasion
Burden Estimate: 200 hours
Respondents: Vessel owners/operators
Form(s): None

DOT No: 2962
OMB No: 2115-0106
Administration: U.S. Coast Guard
Title: Plan Approval and Records for Foreign Vessels Carrying Oil in Bulk
Need for Information: This information collection requirement is needed to regulate the design, construction, alteration, repair, maintenance, operation and equipping of foreign vessels entering U.S. waters which carry or are constructed or adapted to carry oil in bulk.
Proposed Use of Information: Coast Guard uses the information to ensure that: (1) Sufficient information is available to determine that a vessel is in compliance with standards prior to issuing the Certificate of Compliance; (2) sufficient information is available to vessel operating personnel to operate the vessels and the equipment required by the regulations safely and in compliance with standards; and (3) a means is available to appeal Coast Guard decisions and for obtaining waivers or exemptions permitted by the regulations.
Frequency: On occasion
Burden Estimate: 189 hours
Respondents: Owners and operators of foreign tank vessels
Form(s): None

DOT No: 2963
OMB No: 2115-0133
By: U.S. Coast Guard
Title: Passenger Vessel Reports
Need for Information: This is a recordkeeping requirement in which the Coast Guard issues a Control Verification Form which verifies that the vessel has been examined and that the applicable standards are met. This requirement is necessary for effective administration of our foreign vessel boarding programs. It is needed to ensure that specified foreign flag vessels meet the applicable federal and international requirements for safety and environmental protection.
Proposed Use of Information: The vessel master, agent or owner uses this requirement as evidence of Coast Guard examination and recent compliance with the requirements.
Frequency: On occasion
Burden Estimate: 5 hours
Respondents: Owners/operators of foreign flag passenger vessel
Form(s): CG-4504

DOT No: 2964
OMB No: 2115-0010
By: U.S. Coast Guard
Title: Recreational Boating Accident Report
Need for Information: Coast Guard needs this information collection requirement to: (1) Develop boat manufacturer standards; (2) gather information on the number of casualties which are alcohol related; and (3) determine the effectiveness and performance of personal flotation devices.
Proposed Use of Information: Coast Guard uses this information to identify possible manufacturer defects in boats or equipment, develop boat manufacturer standards, develop operator requirements, develop safe boating education programs and to publish statistics in accordance with 46 U.S.C. 6102.
Frequency: On occasion
Burden Estimate: 4232 hours
Respondents: Operators of recreational boats and local and state governments
Form(s): CG-3865, CG-3865A

DOT No: 2965
OMB No: 2105-0515
Administration: Office of the Secretary
Title: Commercial Space Transportation: Licensing Regulations
Need for Information: Mission and safety data is required for applications for a Federal Space Launch License
Proposed Use of Information: This information is needed so a decision can be made to grant a launch license or component thereof upon application by a launch firm or payload
Frequency: Upon application
Burden Estimate: 3,000 hours
Respondents: State and local government and businesses
Form(s): None

DOT No: 2966
OMB No: 2125-0074
Administration: Federal Highway Administration
Title: Endorsement for Motor Carrier Policies of Insurance
Need for Information: For the Federal Highway Administration and the Interstate Commerce Commission to determine a motor carrier's compliance with 49 CFR Part 387.
Proposed Use of Information: For a motor carrier to retain the endorsement and its surety bond at its principle place of business and to make the endorsement and surety bond available for public inspection.
Frequency: During period policy is in effect
Burden Estimate: 13,000 hours
Respondents: Affected Motor Carriers
Form(s): MCS-90 and MCS-82

Issued in Washington, DC on July 31, 1987.

Michael O'Hopp,

Acting Director of Information, Resource Management.

[FR Doc. 87-17824 Filed 8-5-87; 8:45 am]

BILLING CODE 4910-62-M

Federal Aviation Administration

[Summary Notice No. PE-87-18]

Exempt Petitions; Summary of Petitions Received and Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption (14 CFR Part 11), this notice contains a summary of certain petitions seeking relief from specified requirements of the Federal Aviation Regulations (14 CFR Ch. I), dispositions of certain petitions previously received, and corrections. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATE: Comments on petitions received must identify the petition docket number involved and must be received on or before: August 26, 1987.

ADDRESS: Send comments on any petition in triplicate to:

Federal Aviation Administration, Office of the Chief Counsel, Attn: Rules Docket (AGC-204), Petition Docket No. ———, 800 Independence Avenue, SW., Washington, DC 20591.

FOR FURTHER INFORMATION: The petition, any comments received, and a copy of any final disposition are filed in the assigned regulatory docket and are available for examination in the Rules Docket (AGC-204), Room 915G, FAA Headquarters Building (FOB 10A), 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267-3132.

This notice is published pursuant to paragraphs (c), (e), and (g) of § 11.27 of Part 11 of the Federal Aviation Regulations (14 CFR Part 11).

Issued in Washington, DC, on July 31, 1987.

Leonard R. Smith,

Manager, Program Management Staff.

PETITIONS FOR EXEMPTION

Docket No.	Petitioner	Regulations affected	Description of relief sought
25314	Hawaiian Air Tour Service	14 CFR 135.158	To allow petitioner to operate its DH-114-2X aircraft without an operable pitot heating indication system.
25208	Saab-Scandia-AB	14 CFR 145.71 and 145.73	To allow petitioner to perform maintenance and alteration work on Saab SF340 U.S.-registered aircraft that will fly predominately within the United States.
25291	Pumpkin Air	14 CFR 133.45(e)(1)	To allow petitioner emergency lifesaving Class D rotorcraft-load combination operation under certain conditions when one-engine inoperative hover capability cannot be met under the weight and altitude restrictions of the rotorcraft's type certificate.
23336	Simulator Training, Inc	14 CFR 61.63(d) (2) and (3), 61.157(d)(1), and 121.407(a).	To allow trainees of petitioner, who are applicants for an airline transport pilot certificate or are applying for a type rating to be added to their pilot certificate, to substitute the practical test requirements of § 61.157(a) for those of § 61.63(d) (2) and (3). In addition, to allow trainees of petitioner to complete that portion of the practical test for an airline transport pilot certificate for an additional type rating, as authorized by § 61.157(d), in a simulator. Granted, July 23, 1987.
23771	Cessna Aircraft Company	14 CFR 91.31 and 91.213	To allow operators of Cessna airplane models 550, S550, and 552 to operate their airplanes without a second-in-command pilot Granted, July 21, 1987.

[FR Doc. 87-17810 Filed 8-5-87; 8:45 am]
BILLING CODE 4910-13-M

Federal Highway Administration

Environmental Impact Statement, Wyoming County, PA

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an Environmental Impact Statement will be prepared for a proposed highway project in Wyoming County, Pennsylvania.

FOR FURTHER INFORMATION CONTACT: Philibert A. Ouellet, District Engineer, Federal Highway Administration, 228 Walnut Street, P.O. Box 1086, Harrisburg, Pennsylvania 17108, Telephone: (717) 782-4422, or Charles M. Mattei, P.E., District Engineer, Pennsylvania Department of Transportation, P.O. Box 111, Scranton, Pennsylvania 18501, Telephone: (717) 963-4010.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the Pennsylvania Department of Transportation, will prepare an Environmental Impact Statement (EIS) on a proposal to construct a transportation facility which would serve the traffic needs of Tunkhannock Borough and its surrounding area in Wyoming County, Pennsylvania. This proposed action has been designated as State Route 0006, Section E-10, Tunkhannock By-Pass. The easterly project limit is located on existing U.S. Route 6 approximately 0.9 miles east of the Tunkhannock Borough Line. From this point, the project area extends in a westerly direction for approximately 3.6 miles to its westerly limit which is a point on existing Route 6 approximately 1.0 mile west of the Borough of Tunkhannock.

Presently, the project area is congested due to a signalized intersection in the Central Business District of Tunkhannock Borough. This signalized intersection is located at the county's principal east-west (U.S. Route 6) and north-south (S.R. 0029-0309) roadway intersection. Present day traffic, which is funneled into the borough by the area's highway network and whose flow is dictated by the aforesaid signalized intersection, causes congestion with accompanying delays and safety hazards to both the motorists and pedestrians within the borough's central business district. The existing highway facility within the project limits will not provide future traffic with the required level of service established for a Distributor-Arterial Highway by current design standards.

The proposed project has been under consideration for many years and a variety of alignments have been studied. A Corridor Location Study for this project was completed in September, 1974. This study identified three corridors. These three build alternatives and a no-build alternative will be considered in this EIS.

Alternative A—construction of a new limited access roadway from existing U.S. Route 6 approximately 0.9 miles east of the Tunkhannock Borough line to

a point approximately 1 mile west of the Borough of Tunkhannock. This alternative will be located south of the existing alignment of U.S. Route 6.

Alternative B—upgrading the existing alignment of U.S. Route 6. This alternative includes widening of the existing roadway, resurfacing and signalizing.

Alternative C—construction of a new limited access roadway with the same project limits as Alternative A, but the roadway would be located north of existing U.S. Route 6.

Alternative D—the existing highway facilities would remain the same. This is the "Do Nothing" alternative.

The alternatives will be studied in detail in the area of preliminary engineering, air and noise quality, historical and archaeological resources, traffic/transportation/energy, water resources (including flood plains, water quality and hydrology, and wild and scenic rivers), socioeconomics and land use, farmlands, soils, terrestrial and aquatic ecology, wetlands, hazardous waste sites, section 4(f) resources, and cost analysis of effective alternatives.

Letters describing the proposed action and soliciting comments will be sent to appropriate Federal, State and local agencies, and to private organizations and citizens who express interest in the proposal. Scoping meetings are planned to be held with the agencies in summer 1987. Public meetings will be held in the area. Public notices of the time and place of these meetings and any required public hearings will be given. Public involvement and interagency coordination will be maintained throughout the development of the EIS.

To ensure that the full range of issues related to this proposed action are addressed and that all significant issues are identified, comments or questions concerning this action and the EIS should be directed to the FHWA or PennDOT at the address provided above.

"Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The provisions of Executive Order 12372, Intergovernmental Review of Federal Programs, regarding State and local review of Federal and Federally assisted programs and projects apply to this program."

Issued on: July 31, 1987.

Manuel A. Marks,

Division Administrator, Harrisburg, PA.

[FR Doc. 87-17871 Filed 8-5-87; 8:45 am]

BILLING CODE 4910-22-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Tax Forms Coordinating Committee Release of Tax Forms

The Internal Revenue Service is publishing advance proof copies of several major 1987 Federal tax forms. This release supplements the release of forms in May and June. Included are Forms 1120, 1120A, 1041, 1065, 1120S (and Schedules K-1), and Form 6251. Persons needing proof copies of any of these items may write to: IRS—CADC, 2402 East Empire, Bloomington, IL 61799.

Please note that these proofs are subject to change and OMB approval before being released for printing in early October.

The revised forms include changes required by the Tax Reform Act of 1986. Major changes are circled. Suggestions for improving these forms should be sent by September 4, 1987, to: Tax Forms Committee, ATTN: Early Release, Internal Revenue Service, Room 5577, 1111 Constitution Avenue NW., Washington, DC 20224.

Additional forms relating to nondeductible IRA contributions, passive activity loss limitations, and the home mortgage interest deduction will be released later this month. Also scheduled for release at that time are forms released earlier this year that were subsequently revised due to public comments, IRS forms testing efforts, or internal review.

Although IRS is not required to publish copies of the tax forms under section 1505 of the Federal Register Act or section 552 of the Administrative Procedures Act, we are doing so at this time due to wide public interest in changes to the forms caused by the Tax Reform Act of 1986 and to give the forms broad public exposure. We may be unable to give detailed replies to the comments we receive. However, each suggestion will be carefully considered before the final versions of the forms are issued.

Dated: July 31, 1987.

Approved:

Edmund I. Goldwag,

Director, Tax Forms and Publications Division.

BILLING CODE 4830-01-M

Form **1120**
Department of the Treasury
Internal Revenue Service

U.S. Corporation Income Tax Return

For calendar 1987 or tax year beginning _____, 1987, ending _____, 19 ____
▶ For Paperwork Reduction Act Notice, see page 1 of the instructions.

OMB No. 1545-0123
1987

Check if a—
A Consolidated return ☐
B Personal Holding Co. ☐
C Business Code No. (See the list in the instructions.)

Use IRS label. Otherwise please print or type.
Name
Number and street
City or town, state, and ZIP code

D Employer identification number
E Date incorporated
F Total assets (See Specific Instructions.) Dollars $ Cents

G Check applicable boxes: (1) ☐ Initial return (2) ☐ Final return (3) ☐ Change in address

Income	1a	Gross receipts or sales _____ b Less returns and allowances _____ Balance ▶		1c	
	2	Cost of goods sold and/or operations (Schedule A)		2	
	3	Gross profit (line 1c less line 2)		3	
	4	Dividends (Schedule C)		4	
	5	Interest		5	
	6	Gross rents		6	
	7	Gross royalties		7	
	8	Capital gain net income (attach separate Schedule D)		8	
	9	Net gain or (loss) from Form 4797, line 18, Part II (attach Form 4797)		9	
	10	Other income (see instructions—attach schedule)		10	
	11	TOTAL income—Add lines 3 through 10 and enter here ▶		11	
Deductions (See instructions for limitations on deductions)	12	Compensation of officers (Schedule E)		12	
	13a	Salaries and wages _____ b Less jobs credit _____ Balance ▶		13c	
	14	Repairs		14	
	15	Bad debts (see instructions)		15	
	16	Rents		16	
	17	Taxes		17	
	18	Interest		18	
	19	Contributions (**see instructions for 10% limitation**)		19	
	20	Depreciation (attach Form 4562)	20		
	21	Less depreciation claimed in Schedule A and elsewhere on return	21a	21b	
	22	Depletion		22	
	23	Advertising		23	
	24	Pension, profit-sharing, etc., plans		24	
	25	Employee benefit programs		25	
	26	Other deductions (attach schedule)		26	
	27	TOTAL deductions—Add lines 12 through 26 and enter here ▶		27	
	28	Taxable income before net operating loss deduction and special deductions (line 11 less line 27)		28	
	29	**Less: a** Net operating loss deduction (see instructions)	29a		
		b Special deductions (Schedule C)	29b	29c	
Tax and Payments	30	Taxable income (line 28 less line 29c)		30	
	31	**TOTAL TAX** (Schedule J)		31	
	32	**Payments: a** 1986 overpayment credited to 1987			
		b 1987 estimated tax payments			
		c Less 1987 refund applied for on Form 4466	( )		
		d Tax deposited with Form 7004			
		e Credit from regulated investment companies (attach Form 2439)			
		f Credit for Federal tax on gasoline and special fuels (attach Form 4136)		32	
	33	Enter any **PENALTY** for underpayment of estimated tax—check ▶ ☐ if Form 2220 is attached		33	
	34	**TAX DUE**—If the total of lines 31 and 33 is larger than line 32, enter AMOUNT OWED		34	
	35	**OVERPAYMENT**—If line 32 is larger than the total of lines 31 and 33, enter AMOUNT OVERPAID		35	
	36	Enter amount of line 35 you want: **Credited to 1988 estimated tax** ▶	**Refunded** ▶	36	

Please Sign Here

Under penalties of perjury, I declare that I have examined this return, including accompanying schedules and statements, and to the best of my knowledge and belief, it is true, correct, and complete. Declaration of preparer (other than taxpayer) is based on all information of which preparer has any knowledge.

▶ Signature of officer | Date | ▶ Title

Paid Preparer's Use Only

Preparer's signature ▶ | Date | Check if self-employed ☐ | Preparer's social security number

Firm's name (or yours, if self-employed) and address ▶ | E.I. No. ▶ | ZIP code ▶

Proof of August 5, 1987

Form 1120 (1987) Page 2

Schedule A Cost of Goods Sold and/or Operations (See instructions for line 2, page 1.)

1 Inventory at beginning of year	1	
2 Purchases	2	
3 Cost of labor	3	
4a Additional section 263A costs (see instructions)	4a	
b Other costs (attach schedule)	4b	
5 Total—Add lines 1 through 4b	5	
6 Inventory at end of year	6	
7 Cost of goods sold and/or operations—Line 5 less line 6. Enter here and on line 2, page 1	7	

8a Check all methods used for valuing closing inventory:

(i) ☐ Cost (ii) ☐ Lower of cost or market as described in Regulations section 1.471-4 (see instructions)

(iii) ☐ Writedown of "subnormal" goods as described in Regulations section 1.471-2(c) (see instructions)

(iv) ☐ Other (Specify method used and attach explanation.) ▶

b Check if the LIFO inventory method was adopted this tax year for any goods (if checked, attach Form 970) ☐

c If the LIFO inventory method was used for this tax year, enter percentage (or amounts) of closing inventory computed under LIFO | 8c |

d Do the rules of section 263A (with respect to property produced or acquired for resale) apply to the corporation? ☐ Yes ☐ No

e Was there any change in determining quantities, cost, or valuations between opening and closing inventory? ☐ Yes ☐ No
If "Yes," attach explanation.

Schedule C Dividends and Special Deductions (See Schedule C instructions.)

	(a) Dividends received	(b) %	(c) Special deductions multiply (a) X (b)
1 Domestic corporations subject to section 243(a) deduction (other than debt-financed stock)		see instructions	
2 Debt-financed stock of domestic and foreign corporations (section 246A)		see instructions	
3 Certain preferred stock of public utilities		see instructions	
4 Foreign corporations and certain FSCs subject to section 245 deduction		see instructions	
5 Wholly owned foreign subsidiaries and FSCs subject to 100% deduction (sections 245(b) and (c))		100	
6 Total—Add lines 1 through 5. See instructions for limitation			
7 Affiliated groups subject to the 100% deduction (section 243(a)(3))		100	
8 Other dividends from foreign corporations not included in lines 4 and 5			
9 Income from controlled foreign corporations under subpart F (attach Forms 5471)			
10 Foreign dividend gross-up (section 78)			
11 IC-DISC or former DISC dividends not included in lines 1 and/or 2 (section 246(d))			
12 Other dividends			
13 Deduction for dividends paid on certain preferred stock of public utilities (see instructions)			
14 Total dividends—Add lines 1 through 12. Enter here and on line 4, page 1 ▶			
15 Total deductions—Add lines 6, 7, and 13. Enter here and on line 29b, page 1 ▶			

Schedule E Compensation of Officers (See instructions for line 12, page 1.)

Complete Schedule E only if total receipts (line 1a, plus lines 4 through 10, of page 1, Form 1120) are $150,000 or more.

(a) Name of officer	(b) Social security number	(c) Percent of time devoted to business	Percent of corporation stock owned (d) Common	(e) Preferred	(f) Amount of compensation
		%	%	%	
		%	%	%	
		%	%	%	
		%	%	%	
		%	%	%	
		%	%	%	
		%	%	%	
Total compensation of officers—Enter here and on line 12, page 1					

Proof of August 5, 1987

Schedule J **Tax Computation** (See instructions.)

1 Check if you are a member of a controlled group (see sections 1561 and 1563) ▶ ☐

2 If line 1 is checked, see instructions. If your tax year includes June 30, 1987, complete both a and b below. Otherwise, complete only b.

a (i) $ ..... (ii) $ ..... (iii) $ ..... (iv) $ .....

b (i) $ ..... (ii) $ .....

3 Income tax (see instructions to figure the tax; enter this tax or alternative tax from Schedule D, whichever is less). Check if from Schedule D ▶ ☐ 3

4a Foreign tax credit (attach Form 1118) 4a

b Possessions tax credit (attach Form 5735) . . . . . b

c Orphan drug credit (attach Form 6765) c

d Credit for fuel produced from a nonconventional source (see instructions) . . . . . d

e General business credit. Enter here and check which forms are attached ☐ Form 3800 ☐ Form 3468 ☐ Form 5884 ☐ Form 6478 ☐ Form 6765 ☐ Form 8586 . . . . . e

5 Total—Add lines 4a through 4e 5

6 Line 3 less line 5 6

7 Personal holding company tax (attach Schedule PH (Form 1120)) 7

8 Tax from recomputing prior-year investment credit (attach Form 4255) 8

9a Alternative minimum tax (see instructions—attach Form 4626) 9a

b Environmental tax (see instructions—attach Form 4626) . . . . . b

10 Total tax—Add lines 6 through 9b. Enter here and on line 31, page 1 10

Additional Information (See instruction F.)

	Yes	No
H Did the corporation claim a deduction for expenses connected with:		
(1) An entertainment facility (boat, resort, ranch, etc.)?		
(2) Living accommodations (except employees on business)?		
(3) Employees attending conventions or meetings outside the North American area? (See section 274(h).)		
(4) Employees' families at conventions or meetings? If "Yes," were any of these conventions or meetings outside the North American area? (See section 274(h).)		
(5) Employee or family vacations not reported on Form W-2?		
I (1) Did the corporation at the end of the tax year own, directly or indirectly, 50% or more of the voting stock of a domestic corporation? (For rules of attribution, see section 267(c).) If "Yes," attach a schedule showing: (a) name, address, and identifying number; (b) percentage owned; (c) taxable income or (loss) before NOL and special deductions of such corporation for the tax year ending with or within your tax year; (d) highest amount owed by the corporation to such corporation during the year; and (e) highest amount owed to the corporation by such corporation during the year.		
(2) Did any individual, partnership, corporation, estate or trust at the end of the tax year own, directly or indirectly, 50% or more of the corporation's voting stock? (For rules of attribution, see section 267(c).) If "Yes," complete (a) through (e)		
(a) Attach a schedule showing name, address, and identifying number. Enter percentage owned ▶		
(b) Was the owner of such voting stock a person other than a U.S. person? (See instructions.) **Note:** *If "Yes," the corporation may have to file Form 5472.* If "Yes," enter owner's country ▶		
(c) Enter highest amount owed by the corporation to such owner during the year ▶		
(d) Enter highest amount owed to the corporation by such owner during the year ▶		
Note: *For purposes of I(1) and I(2), "highest amount owed" includes loans and accounts receivable/payable.*		

	Yes	No
J Refer to the list in the instructions and state the principal: Business activity ▶ ..... Product or service ▶		
K Was the corporation a U.S. shareholder of any controlled foreign corporation? (See sections 951 and 957.) If "Yes," attach Form 5471 for each such corporation.		
L At any time during the tax year, did the corporation have an interest in or a signature or other authority over a financial account in a foreign country (such as a bank account, securities account, or other financial account)? (See instruction F and filing requirements for form TD F 90-22.1.) If "Yes," enter name of foreign country ▶		
M Was the corporation the grantor of, or transferor to, a foreign trust which existed during the current tax year, whether or not the corporation has any beneficial interest in it? If "Yes," the corporation may have to file Forms 3520, 3520-A, or 926.		
N During this tax year, did the corporation pay dividends (other than stock dividends and distributions in exchange for stock) in excess of the corporation's current and accumulated earnings and profits? (See sections 301 and 316.) If "Yes," file Form 5452. If this is a consolidated return, answer here for parent corporation and on Form 851, Affiliations Schedule, for each subsidiary.		
O During this tax year did the corporation maintain any part of its accounting/tax records on a computerized system?		
P Check method of accounting: (1) ☐ Cash (2) ☐ Accrual (3) ☐ Other (specify) ▶		
Q Check this box if the corporation issued publicly offered debt instruments with original issue discount ☐ If so, the corporation may have to file Form 8281.		
R Enter the amount of tax-exempt interest received or accrued during the tax year ▶		
S If you are a member of a controlled group, enter the amount of taxable income for the entire group ▶		

Proof August 15, 1987

Form 1120 (1987) Page 4

Schedule L Balance Sheets

Assets	Beginning of tax year (a)	Beginning of tax year (b)	End of tax year (c)	End of tax year (d)
1 Cash				
2 Trade notes and accounts receivable				
a Less allowance for bad debts				
3 Inventories				
4 Federal and state government obligations				
5 Other current assets (attach schedule)				
6 Loans to stockholders				
7 Mortgage and real estate loans				
8 Other investments (attach schedule)				
9 Buildings and other depreciable assets				
a Less accumulated depreciation				
10 Depletable assets				
a Less accumulated depletion				
11 Land (net of any amortization)				
12 Intangible assets (amortizable only)				
a Less accumulated amortization				
13 Other assets (attach schedule)				
14 Total assets				
Liabilities and Stockholders' Equity				
15 Accounts payable				
16 Mortgages, notes, bonds payable in less than 1 year				
17 Other current liabilities (attach schedule)				
18 Loans from stockholders				
19 Mortgages, notes, bonds payable in 1 year or more				
20 Other liabilities (attach schedule)				
21 Capital stock: a preferred stock				
b common stock				
22 Paid-in or capital surplus				
23 Retained earnings—Appropriated (attach schedule)				
24 Retained earnings—Unappropriated				
25 Less cost of treasury stock		( )		( )
26 Total liabilities and stockholders' equity				

Schedule M-1 Reconciliation of Income per Books With Income per Return

Do not complete this schedule if the total assets on line 14, column (d), of Schedule L are less than $25,000.

1 Net income per books		7 Income recorded on books this year not included in this return (itemize)	
2 Federal income tax		a Tax-exempt interest $	
3 Excess of capital losses over capital gains			
4 Income subject to tax not recorded on books this year (itemize)		8 Deductions in this tax return not charged against book income this year (itemize)	
5 Expenses recorded on books this year not deducted in this return (itemize)		a Depreciation $	
a Depreciation $		b Contributions carryover $	
b Contributions carryover $			
		9 Total of lines 7 and 8	
6 Total of lines 1 through 5		10 Income (line 28, page 1)—line 6 less line 9	

Schedule M-2 Analysis of Unappropriated Retained Earnings per Books (line 24, Schedule L)

Do not complete this schedule if the total assets on line 14, column (d), of Schedule L are less than $25,000.

1 Balance at beginning of year		5 Distributions: a Cash	
2 Net income per books		b Stock	
3 Other increases (itemize)		c Property	
		6 Other decreases (itemize)	
		7 Total of lines 5 and 6	
4 Total of lines 1, 2, and 3		8 Balance at end of year (line 4 less line 7)	

Proof of August 5, 1987

Form **1120-A**

Department of the Treasury
Internal Revenue Service

U.S. Corporation Short-Form Income Tax Return

To see if you qualify to file Form 1120-A, see instructions.

For calendar 1987 or tax year beginning _____, 1987, ending _____, 19__

1235
OMB No 1545-0890
1987

See instructions for list of principal business

A Activity
B Product or service
C Code

Use IRS label. Otherwise, please type or machine print

Name
Number and street
City or town, state, and ZIP code

D Employer identification number (EIN)
E Date incorporated
F Total assets (See Specific Instructions.) Dollars $ Cents

G Check method of accounting: (1) ☐ Cash (2) ☐ Accrual (3) ☐ Other (specify) ▶

H Check applicable boxes: (1) ☐ Initial return (2) ☐ Change in address

Income	1a	Gross receipts or sales	b Less returns and allowances	Balance ▶	1c
	2	Cost of goods sold and/or operations (see instructions)			2
	3	Gross profit (line 1c less line 2)			3
	4	Domestic corporation dividends subject to the Section 243(a)(1) deduction			4
	5	Interest			5
	6	Gross rents			6
	7	Gross royalties			7
	8	Capital gain net income (attach separate Schedule D (Form 1120))			8
	9	Net gain or (loss) from Form 4797, line 18, Part II (attach Form 4797)			9
	10	Other income (see instructions)			10
	11	TOTAL income—Add lines 3 through 10			11
Deductions (See instructions for limitations on deductions)	12	Compensation of officers (see instructions)			12
	13a	Salaries and wages	b Less jobs credit	Balance ▶	13c
	14	Repairs			14
	15	Bad debts (see instructions)			15
	16	Rents			16
	17	Taxes			17
	18	Interest			18
	19	Contributions **(see instructions for 10% limitation)**			19
	20	Depreciation (attach Form 4562)	20		
	21	Less depreciation claimed elsewhere on return	21a		21b
	22	Other deductions (attach schedule)			22
	23	TOTAL deductions—Add lines 12 through 22			23
	24	Taxable income before net operating loss deduction and special deductions (line 11 less line 23)			24
	25	**Less:** a Net operating loss deduction (see instructions)	25a		
		b Special deductions (see instructions)	25b		25c
Tax and Payments	26	Taxable income (line 24 less line 25c)			26
	27	**TOTAL TAX** (from Part I, line 6 on page 2)			27
	28	**Payments:**			
		a 1986 overpayment allowed as a credit			
		b 1987 estimated tax payments			
		c Less 1987 refund applied for on Form 4466	( )		
		d Tax deposited with Form 7004			
		e Credit from regulated investment companies (attach Form 2439)			
		f Credit for Federal tax on gasoline and special fuels (attach Form 4136)			28
	29	Enter any **PENALTY** for underpayment of estimated tax—Check ▶ ☐ if Form 2220 is attached			29
	30	**TAX DUE**—If the total of lines 27 and 29 is larger than line 28, enter AMOUNT OWED			30
	31	**OVERPAYMENT**—If line 28 is larger than the total of lines 27 and 29, enter AMOUNT OVERPAID			31
	32	Enter amount of line 31 you want: **Credited to 1988 estimated tax** ▶		**Refunded** ▶	32

Please Sign Here

Under penalties of perjury, I declare that I have examined this return, including accompanying schedules and statements, and to the best of my knowledge and belief, it is true, correct, and complete. Declaration of preparer (other than taxpayer) is based on all information of which preparer has any knowledge.

▶ Signature of officer | Date | ▶ Title

Paid Preparer's Use Only

Preparer's signature ▶ | Date | Check if self-employed ▶ ☐ | Preparer's social security number

Firm's name (or yours if self-employed) and address ▶ | E.I. No. ▶ | ZIP code ▶

For Paperwork Reduction Act Notice, see page 1 of the instructions.

Form **1120-A** (1987)

Proof of August 5, 1987

Form 1120-A (1987) Page 2

Part I Tax Computation (See Instructions.) Enter EIN ▶

1 Income tax (See instructions to figure the tax. Enter lesser of this tax or alternative tax from Schedule D.) Check if from Schedule D ▶ ☐ 1
2 Credits. Check if from: ☐ Form 3800 ☐ Form 3468 ☐ Form 5884 ☐ Form 6478 ☐ Form 6765 ☐ Form 8586 2
3 Line 1 less line 2 3
4 Tax from recomputing prior-year investment credit (attach Form 4255) 4
5 Alternative minimum tax (see instructions—attach Form 4626) 5
6 Total tax—Add lines 3 through 5. Enter here and on line 27, page 1 6

Additional Information (See instruction F.)

I Was a deduction taken for expenses connected with:
(1) An entertainment facility (boat, resort, ranch, etc.)? Yes ☐ No ☐
(2) Employees' families at conventions or meetings? Yes ☐ No ☐

J Did any individual, partnership, estate, or trust at the end of the tax year own, directly or indirectly, 50% or more of the corporation's voting stock? (For rules of attribution, see section 267(c).) If "Yes," complete (1) and (2) Yes ☐ No ☐
(1) Attach a schedule showing name, address, and identifying number.
(2) Enter "highest amount owed," include loans and accounts receivable/payable:
(a) Enter highest amount owed by the corporation to such owner during the year ▶
(b) Enter highest amount owed to the corporation by such owner during the year ▶

K Enter the amount of tax-exempt interest received or accrued during the tax year ▶

L (1) If an amount for cost of goods sold and/or operations is entered on line 2, page 1, complete (a) through (c):
(a) Purchases ▶
(b) Additional sec. 263A costs (see instructions) ▶
(c) Other costs (attach schedule) ▶
(2) Do the rules of section 263A (with respect to property produced or acquired for resale) apply to the corporation? Yes ☐ No ☐

M At any time during the tax year, did you have an interest in or a signature or other authority over a financial account in a foreign country (such as a bank account, securities account, or other financial account)? (See instruction F for filing requirements for Form TD F 90-22.1.) Yes ☐ No ☐
If "Yes," write in the name of the foreign country ▶

N During this tax year, was any part of your accounting/tax records maintained on a computer/EDP system? Yes ☐ No ☐

O Enter amount of cash distributions and the book value of property (other than cash) distributions made in this tax year ▶

Part II Balance Sheets

		(a) Beginning of tax year	(b) End of tax year
Assets	1 Cash		
	2 Trade notes and accounts receivable		
	a Less: allowance for bad debts	( )	( )
	3 Inventories		
	4 Federal and state government obligations		
	5 Other current assets (attach schedule)		
	6 Loans to stockholders		
	7 Mortgage and real estate loans		
	8 Depreciable, depletable, and intangible assets		
	a Less: accumulated depreciation, depletion, and amortization	( )	( )
	9 Land (net of any amortization)		
	10 Other assets (attach schedule)		
	11 Total assets		
Liabilities and Stockholders' Equity	12 Accounts payable		
	13 Other current liabilities (attach schedule)		
	14 Loans from stockholders		
	15 Mortgages, notes, bonds payable		
	16 Other liabilities (attach schedule)		
	17 Capital stock (preferred and common stock)		
	18 Paid-in or capital surplus		
	19 Retained earnings		
	20 Less cost of treasury stock	( )	( )
	21 Total liabilities and stockholders' equity		

Part III Reconciliation of Income per Books With Income per Return (Must be completed by all filers)

1 Enter net income per books
2 Federal income tax
3 Income subject to tax not recorded on books this year (itemize)
4 Expenses recorded on books this year not deducted in this return (itemize)
5 Income recorded on books this year not included in this return (itemize)
6 Deductions in this tax return not charged against book income this year (itemize)
7 Income (line 24, page 1). Enter the sum of lines 1, 2, 3, and 4 less the sum of lines 5 and 6

1 1 1 1 1 1 2 2 2 3 3 3 3 3 3 3 4 4 4 4 4 5 5 5 5 5 6 6 6 6 6 7 8
1 1 1 1 1 2 2 2 2 2 3 3 3 3 3 3 3 4 4 5 6 6 7 7 7 7 7 7 8 9 10 11

Proof of August 5, 1987

Form **1041**
Department of the Treasury
Internal Revenue Service

U.S. Fiduciary Income Tax Return

For the calendar year 1987 or fiscal year

beginning , 1987, and ending , 19

OMB No 1545-0092

1987

Check applicable boxes:
- ☐ Decedent's estate
- ☐ Simple trust
- ☐ Complex trust
- ☐ Grantor type trust
- ☐ Bankruptcy estate
- ☐ Family estate trust
- ☐ Pooled income fund
- ☐ Initial return
- ☐ Amended return
- ☐ Final return

Name of estate or trust (grantor type trust, see instructions)

Name and title of fiduciary

Address of fiduciary (number and street)

City, state, and ZIP code

Employer identification number

Date entity created

Nonexempt charitable and split-interest trusts, check applicable boxes (see instructions):
- ☐ Described in section 4947(a)(1)
- ☐ Not a private foundation
- ☐ Described in section 4947(a)(2)

Check if this return is for a short taxable year (see instructions) ▶ ☐

Income

1	Dividends	1	
2	Interest income	2	
3	Income (or losses) from partnerships, other estates or other trusts (see instructions)	3	
4	Net rent and royalty income (or loss) (attach Schedule E (Form 1040))	4	
5	Net business and farm income (or loss) (attach Schedules C and F (Form 1040))	5	
6	Capital gain (or loss) (attach Schedule D (Form 1041))	6	
7	Ordinary gain (or loss) (attach Form 4797)	7	
8	Other income (state nature of income)	8	
9	**Total** income (add lines 1 through 8) ▶	9	

Deductions

10	Interest	10			
11	Fiduciary fees	11			
12	Charitable deduction (from Schedule A, line 6)	12			
13	Attorney, accountant, and return preparer fees	13			
14	Other deductions (including taxes) (attach schedule)	14			
15	**Total** (add lines 10 through 14) ▶			15	
16	Adjusted total income (or loss) (subtract line 15 from line 9)			16	
17	Income distribution deduction (from Schedule B, line 17) (see instructions) (attach Schedule K-1 (Form 1041))			17	
18	Estate tax deduction (attach computation)			18	
19	Exemption			19	
20	**Total** (add lines 17 through 19) ▶			20	
21	Taxable income of fiduciary (subtract line 20 from line 16) ▶			21	

Computation of Tax

Please attach check or money order here

22	**Tax:** ☐ **a** Tax rate schedule or ☐ Schedule D ; **b** Other tax ; Total ▶	22c	
23	**Credits:** **a** Foreign tax ; **b** Nonconventional fuel ; Total ▶	23c	
24	**Credits:** ☐ Form 3800 ☐ Form 3468 ☐ Form 5884 ☐ Form 6478 ☐ Form 6765 ☐ Form 8586	24	
25	**Total** (add lines 23c and 24) ▶	25	
26	**Balance** (subtract line 25 from line 22c)	26	
27	Recapture of investment credit (attach Form 4255)	27	
28	Alternative minimum tax (attach Form 8656)	28	
29	**Total** (add lines 26 through 28) ▶	29	
30	**Credits:** **a** Form 2439 ; **b** Form 4136 ; **c** Form 6249 ; Total ▶	30d	
31	**Payments** **a** 1987 estimated tax payments ▶		
	b Paid with extension of time to file (attach Form 2758) ▶ ; **c** Withheld ▶ ; Total ▶	31d	
32	**Total** (add lines 30d and 31d) ▶	32	
33	**Balance of tax due** (subtract line 32 from line 29) (see instructions)	33	
34	**Overpayment** (subtract line 29 from line 32)	34	
35	Amount of line 34 to be: **a** Credited to 1988 estimated taxes ▶		
	b Treated as paid by trust beneficiaries (Attach Form 1041-T) ▶ **Refunded** ▶	35c	
	Check ▶ ☐ if Form 2210 (2210F) is attached (see instructions) **Penalty: $**		

Please Sign Here

Under penalties of perjury, I declare that I have examined this return, including accompanying schedules and statements, and to the best of my knowledge and belief, it is true, correct, and complete. Declaration of preparer (other than fiduciary) is based on all information of which preparer has any knowledge.

▶ Signature of fiduciary or officer representing fiduciary ▶ Date

Paid Preparer's Use Only

Preparer's signature ▶ Date Check if self-employed ▶ ☐ **Preparer's social security no.**

Firm's name (or yours if self-employed) and address ▶ E.I. No ▶

ZIP code ▶

For Paperwork Reduction Act Notice, see page 1 of the instructions.

Form **1041** (1987)

Proof of August 5 1987

Do not complete Schedules A and B for a simple trust or a pooled income fund.

SCHEDULE A.—Charitable Deduction

(Write the name and address of each charitable organization to whom your contributions total $3,000 or more on an attached sheet.)

1 Amounts paid or permanently set aside for charitable purposes from current year's gross income	1		
2 Tax-exempt interest allocable to charitable distribution (see instructions)	2		
3 Balance (subtract line 2 from line 1)	3		
4 Enter the net short-term capital gain and the net long-term capital gain of the current tax year allocable to corpus paid or permanently set aside for charitable purposes	4		
5 Amounts paid or permanently set aside for charitable purposes from gross income of a prior year (see instructions)	5		
6 Total (add lines 3, 4, and 5). Enter here and on page 1, line 12	6		

SCHEDULE B.—Income Distribution Deduction

1 Adjusted total income (Enter amount from page 1, line 16.) (If net loss, enter zero.)		1	
2 Adjusted tax-exempt interest (see instructions)		2	
3 Net gain shown on Schedule D (Form 1041), line 17, column (a) (If net loss, enter zero.)		3	
4 Enter amount from Schedule A, line 4		4	
5 Long-term capital gain included on Schedule A, line 1		5	
6 Short-term capital gain included on Schedule A, line 1		6	
7 If the amount on page 1, line 6, is a capital loss, enter here as a positive figure		7	
8 If the amount on page 1, line 6, is a capital gain, enter here as a negative figure		8	
9 Distributable net income (combine lines 1 through 8)		9	
10 If a complex trust, amount of income for the tax year determined under the governing instrument (accounting income)	10		
11 Amount of income required to be distributed currently (see instructions)		11	
12 Other amounts paid, credited, or otherwise required to be distributed (see instructions)		12	
13 Total distributions (add lines 11 and 12). (If greater than line 10, see instructions.)		13	
14 Enter the total amount of tax-exempt income included on line 13		14	
15 Tentative income distribution deduction (subtract line 14 from line 13)		15	
16 Tentative income distribution deduction (subtract line 2 from line 9)		16	
17 Income distribution deduction (Enter the smaller of line 15 or line 16 here and on page 1, line 17.)		17	

Other Information

	Yes	No
1 If the fiduciary's name or address has changed, enter the old information ▶		
2 Did the estate or trust receive tax-exempt income? (If "Yes," enter the amount here ▶ ..... and attach a computation of the allocation of expenses.)		
3 Did the estate or trust have any passive activity income or loss? (If "Yes," enter the amount of any such income or loss on **Form 8582**, Passive Activity Loss Limitations, to figure the allowable loss.)		
4 Did the estate or trust receive all or any part of the earnings (salary, wages, and other compensation) of any individual by reason of a contract assignment or similar arrangement?		
5 At any time during the tax year, did the estate or trust have an interest in or a signature or other authority over a financial account in a foreign country (such as a bank account, securities account, or other financial account)? (See the instructions for question 5.) If "Yes," enter the name of the foreign country ▶		
6 Was the estate or trust the grantor of, or transferor to, a foreign trust which existed during the current tax year, whether or not the estate or trust has any beneficial interest in it? (If "Yes," you may have to file Form 3520, 3520-A, or 926.)		
7 Check this box if this entity has filed or is required to file **Form 8264**, Application for Registration of a Tax Shelter. ▶ ☐		
8 Check this box if this entity is a complex trust making the section 663(b) election ▶ ☐		
9 Check this box if a section 643(e)(3) election is made (attach Schedule D (Form 1041)) ▶ ☐		
10 Check this box if the decedent's estate has been open for more than 2 years (see instructions) ▶ ☐		

Proof of August 5, 1987

SCHEDULE K-1 (Form 1041)

Department of the Treasury
Internal Revenue Service

Beneficiary's Share of Income, Deductions, Credits, etc.—1987

for the calendar year 1987, or fiscal year

beginning ....., 1987, ending ....., 19 .....

Complete a separate Schedule K-1 for each beneficiary

OMB No. 1545-0092

1987

Name of estate or trust ▶

Beneficiary's identifying number ▶	Estate or trust's employer identification number ▶
Beneficiary's name, address, and ZIP code	Fiduciary's name, address, and ZIP code

A. 4-Year Proration.—Fiduciary: Check here ▶ ☐ if this Schedule K-1 is for a short taxable year required by section 1403 of the Tax Reform Act of 1986. **Beneficiary:** If this box is checked, you must prorate the column (b) amounts (except for line 9a) shown below over a four year period beginning with this tax year. (See the instructions on the other side of this schedule.)

(a) Allocable share item	(b) Amount	(c) Calendar year 1987 Form 1040 filers enter the amounts in column (b) on:
1 Dividends		Schedule B, Part II, line 4
2a Net short-term capital gain (or loss)		Schedule D, line 5, column (f) or (g)
b Net long-term capital gain (or loss)		Schedule D, line 12, column (f) or (g)
3 Interest		Schedule B, Part I, line 2
4a Other taxable income (itemize):		
(1) Income (or loss) from passive activities acquired before 10/23/86		Form 8582
(2) Income (or loss) from passive activities acquired after 10/22/86		Form 8582
(3) Other portfolio income (or loss)		Schedule E, Part III
b Depreciation (including cost recovery) and depletion:		
(1) Attributable to line 4a(1)		Form 8582
(2) Attributable to line 4a(2)		Form 8582
(3) Attributable to line 4a(3)		Schedule E, Part III
c Amortization deductions (itemize):		
(1) Attributable to line 4a(1)		Form 8582
(2) Attributable to line 4a(2)		Form 8582
(3) Attributable to line 4a(3)		Schedule E, Part III
5 Estate tax deduction (attach computation)		Schedule A, line 25
6 Excess deductions on termination (attach computation)		Schedule A, line 21
7 Distributable Net Alternative Minimum Taxable Income		Enter on applicable line of Form 6251
8 Foreign taxes (list on a separate sheet)		Form 1116 or Schedule A (Form 1040), line 7
9 Other (itemize):		
a Trust payments of estimated taxes credited to you		Include on Page 2, line 55, Form 1040
b Tax-exempt interest		Enter on Page 1, line 9
c		
d		(Enter on applicable line of appropriate tax form)
e		
f		
g		
h		

PROOF August 5, 1987

For Paperwork Reduction Act Notice, see page 1 of the instructions for Form 1041.

Schedule K-1 (Form 1041) 1987

Form **1065**

Department of the Treasury
Internal Revenue Service

U.S. Partnership Return of Income

▶ **For Paperwork Reduction Act Notice, see Form 1065 Instructions.**

For calendar year 1987, or fiscal year beginning _____, 1987, and ending _____, 19___

OMB No. 1545-0099

1987

A Principal business activity	Use IRS label. Otherwise, please print or type.	Name	D Employer identification number
B Principal product or service		Number and street (or P.O. Box number if mail is not delivered to street address)	E Date business started
C Business code number		City or town, state, and ZIP code	F Enter total assets at end of tax year $

G Check accounting method: (1) ☐ Cash (2) ☐ Accrual (3) ☐ Other

H Check applicable boxes: (1) ☐ Final return (2) ☐ Change in address (3) ☐ Amended return

	Yes	No
I Number of partners in this partnership ▶ _____		
J Is this partnership a limited partnership (see the Instructions)?		
K Is this partnership a partner in another partnership?		
L Are any partners in this partnership also partnerships?		
M Does the partnership meet **all** the requirements shown in the Instructions for **Question M**?		
N Was there a distribution of property or a transfer (for example, by sale or death) of a partnership interest during the tax year? If "Yes," see the Instructions concerning an election to adjust the basis of the partnership's assets under section 754		

	Yes	No
O At any time during the tax year, did the partnership have an interest in or a signature or other authority over a financial account in a foreign country (such as a bank account, securities account, or other financial account)? (See the Instructions for exceptions and filing requirements for Form TD F 90-22.1.) If "Yes," write the name of the foreign country. ▶ _____		
P Was the partnership the grantor of, or transferor to, a foreign trust which existed during the current tax year, whether or not the partnership or any partner has any beneficial interest in it? If "Yes," you may have to file Forms 3520, 3520-A, or 926		
Q Was this partnership in operation at the end of 1987?		
R Number of months in 1987 that this partnership was in operation ▶ _____		

S Check this box if the partnership has filed or is required to file Form 8264, Application for Registration of a Tax Shelter ☐

T Check this box if this is a partnership subject to the consolidated partnership audit procedures of TEFRA. (See page 6 of the Instructions.) ☐

Caution: *Include* **only** *trade or business income and expenses on lines 1a–21 below. See the instructions for more information.*

Income	1a	Gross receipts or sales $ _____ **1b** Minus returns and allowances $ _____ Balance ▶	1c	
	2	Cost of goods sold and/or operations (Schedule A, line 7)	2	
	3	Gross profit (subtract line 2 from line 1c)	3	
	4	Ordinary income (loss) from other partnerships and fiduciaries (attach schedule)	4	
	5	Net farm profit (loss) (attach Schedule F (Form 1040))	5	
	6	Net gain (loss) (Form 4797, line 18)	6	
	7	Other income (loss)	7	
	8	**TOTAL** income (loss) (combine lines 3 through 7)	8	
Deductions	9a	Salaries and wages (other than to partners) $ _____ **9b** Minus jobs credit $ _____ Balance ▶	9c	
	10	Guaranteed payments to partners	10	
	11	Rent	11	
	12	Deductible interest expense not claimed elsewhere on return (see Instructions)	12	
	13	Taxes	13	
	14	Bad debts	14	
	15	Repairs	15	
	16a	Depreciation from Form 4562 (attach Form 4562) $ _____ **16b** Minus depreciation claimed on Schedule A and elsewhere on return $ _____ Balance ▶	16c	
	17	Depletion (***Do not deduct oil and gas depletion.***)	17	
	18a	Retirement plans, etc.	18a	
	b	Employee benefit programs	18b	
	19	Other deductions (attach schedule)	19	
	20	**TOTAL** deductions (add amounts in column for lines 9c through 19)	20	
	21	Ordinary income (loss) from trade or business activity(ies) (subtract line 20 from line 8)	21	

Please Sign Here

Under penalties of perjury, I declare that I have examined this return, including accompanying schedules and statements, and to the best of my knowledge and belief, it is true, correct, and complete. Declaration of preparer (other than taxpayer) is based on all information of which preparer has any knowledge.

▶ Signature of general partner ▶ Date

Paid Preparer's Use Only

Preparer's signature ▶	Date	Check if self-employed ▶ ☐	Preparer's social security no.
Firm's name (or yours if self-employed) and address ▶		E.I. No. ▶	
		ZIP code ▶	

Proof of August 1987

Form 1065 (1987) Page 2

Schedule A Cost of Goods Sold and/or Operations

1	Inventory at beginning of year	1	
2	Purchases minus cost of items withdrawn for personal use	2	
3	Cost of labor	3	
4a	Additional section 263A costs (see instructions)	4a	
b	Other costs (attach schedule)	4b	
5	Total (add lines 1 through 4b)	5	
6	Inventory at end of year	6	
7	Cost of goods sold (subtract line 6 from line 5). Enter here and on page 1, line 2	7	

8a Check all methods used for valuing closing inventory:

(i) ☐ Cost

(ii) ☐ Lower of cost or market as described in regulations section 1.471-4

(iii) ☐ Writedown of "subnormal" goods as described in regulations section 1.471-2(c)

(iv) ☐ Other (specify method used and attach explanation) ▶

b Check if the LIFO inventory method was adopted this tax year for any goods (if checked, attach Form 970) ☐

c Do the rules of section 263A (with respect to property produced or acquired for resale) apply to the partnership? ☐ Yes ☐ No

d Was there any change in determining quantities, cost, or valuations between opening and closing inventory? ☐ Yes ☐ No
If "Yes," attach explanation.

Schedule H Income (Loss) From Rental Real Estate Activity(ies)

1 In the space provided below, show the kind and location of each rental property. Attach a schedule if more space is needed.

Property A

Property B

Property C

Rental Real Estate Income		Properties A	B	C	Totals (Add columns A, B, C, and amounts from any attached schedule)	
2 Gross Income					2	
Rental Real Estate Expenses						
3 Advertising	3					
4 Auto and travel	4					
5 Cleaning and maintenance	5					
6 Commissions	6					
7 Insurance	7					
8 Legal and other professional fees	8					
9 Interest expense	9					
10 Repairs	10					
11 Taxes	11					
12 Utilities	12					
13 Wages and salaries	13					
14 Depreciation from Form 4562	14					
15 Other (list)						
16 Total expenses. Add lines 3 through 15	16				16	
17 Net income (loss) from rental real estate activity(ies). Subtract line 16 from line 2. Enter total net income (loss) from all properties on Schedule K, line 2	17				17	

Proof of August 5, 1987

Form 1065 (1987) Page 3

Schedule K Partners' Shares of Income, Credits, Deductions, etc.

	(a) Distributive share items		(b) Total amount
Income (Loss)	1 Ordinary income (loss) from trade or business activity(ies) (page 1, line 21)	1	
	2 Net income (loss) from rental real estate activity(ies) (Schedule H, line 17)	2	
	3a Gross income from other rental activity(ies) 3a $		
	b Minus expenses (attach schedule) 3b $		
	c Balance net income (loss) from other rental activity(ies) ▶	3c	
	4 Portfolio income (loss):		
	a Interest income	4a	
	b Dividend income	4b	
	c Royalty income	4c	
	d Net short-term capital gain (loss) (Schedule D, line 4)	4d	
	e Net long-term capital gain (loss) (Schedule D, line 9)	4e	
	f Other portfolio income (loss) (attach schedule)	4f	
	5 Guaranteed payments	5	
	6 Net gain (loss) under section 1231 (other than due to casualty or theft)	6	
	7 Other (attach schedule)	7	
Deductions	8 Charitable contributions (attach list)	8	
	9 Expense deduction for recovery property (section 179)	9	
	10 Deductions related to portfolio income (do not include investment interest expense)	10	
	11 Other (attach schedule)	11	
Credits	12a Credit for income tax withheld	12a	
	b Low-income housing credit (attach Form 8586)	12b	
	c Qualified rehabilitation expenditures related to rental real estate activity(ies) (attach schedule)	12c	
	d Credit(s) related to rental real estate activity(ies) other than 12b and 12c (attach schedule)	12d	
	e Credit(s) related to rental activity(ies) other than 12b, 12c, and 12d (attach schedule)	12e	
	13 Other (attach schedule)	13	
Self-Employment	14a Net earnings (loss) from self-employment	14a	
	b Gross farming or fishing income	14b	
	c Gross nonfarm income	14c	
Tax Preference Items	15a Accelerated depreciation of real property placed in service before 1/1/87	15a	
	b Accelerated depreciation of leased personal property placed in service before 1/1/87	15b	
	c Depreciation adjustment on property placed in service after 12/31/86	15c	
	d Depletion (other than oil and gas)	15d	
	e (1) Gross income from oil, gas, and geothermal properties	15e(1)	
	(2) Deductions allocable to oil, gas, and geothermal properties	15e(2)	
	f Other (attach schedule)	15f	
Investment Interest	16a Interest expense on investment debts	16a	
	b (1) Investment income included on lines 4a through 4f, Schedule K	16b(1)	
	(2) Investment expenses included on line 10, Schedule K	16b(2)	
Foreign Taxes	17a Type of income	17a	
	b Foreign country or U.S. possession	17b	
	c Total gross income from sources outside the U.S. (attach schedule)	17c	
	d Total applicable deductions and losses (attach schedule)	17d	
	e Total foreign taxes (check one): ▶ ☐ Paid ☐ Accrued	17e	
	f Reduction in taxes available for credit (attach schedule)	17f	
	g Other (attach schedule)	17g	
Other	18 Attach schedule for other items and amounts not reported above. See Instructions		

Prior to August 5, 1987

Schedule L Balance Sheets

(See the Instructions for Question M Before Completing Schedules L and M.)

Assets	Beginning of tax year (a)	Beginning of tax year (b)	End of tax year (c)	End of tax year (d)
1 Cash				
2 Trade notes and accounts receivable				
a Minus allowance for bad debts				
3 Inventories				
4 Federal and state government obligations				
5 Other current assets (attach schedule)				
6 Mortgage and real estate loans				
7 Other investments (attach schedule)				
8 Buildings and other depreciable assets				
a Minus accumulated depreciation				
9 Depletable assets				
a Minus accumulated depletion				
10 Land (net of any amortization)				
11 Intangible assets (amortizable only)				
a Minus accumulated amortization				
12 Other assets (attach schedule)				
13 **TOTAL** assets				
Liabilities and Capital				
14 Accounts payable				
15 Mortgages, notes, bonds payable in less than 1 year				
16 Other current liabilities (attach schedule)				
17 All nonrecourse loans				
18 Mortgages, notes, bonds payable in 1 year or more				
19 Other liabilities (attach schedule)				
20 Partners' capital accounts				
21 **TOTAL** liabilities and capital				

Schedule M Reconciliation of Partners' Capital Accounts

(Show reconciliation of each partner's capital account on Schedule K-1 (Form 1065), Question I.)

(a) Capital account at beginning of year	(b) Capital contributed during year	(c) Income (loss) from lines 1, 2, 3c, and 4 of Sch. K	(d) Income not included in column (c), plus nontaxable income	(e) Losses not included in column (c), plus unallowable deductions	(f) Withdrawals and distributions	(g) Capital account at end of year

Designation of Tax Matters Partner

The following general partner is hereby designated as the tax matters partner (TMP) for the tax year for which this partnership return is filed:

Name of designated TMP ▶ Identifying number of TMP ▶

Address of designated TMP ▶

Proof of August 5, 1987

SCHEDULE K-1 (Form 1065)
Department of the Treasury
Internal Revenue Service

Partner's Share of Income, Credits, Deductions, etc.

For calendar year 1987 or fiscal year
beginning _____, 1987, and ending _____, 19___

OMB No. 1545-0099

1987

Partner's identifying number ▶

Partner's name, address, and ZIP code

Partnership's identifying number ▶

Partnership's name, address, and ZIP code

A(1) Is this partner a general partner? . . . ☐ Yes ☐ No
If "yes" to Question A(1):
(2) Did this partner materially participate in the trade or business activity(ies) of the partnership? (See page 11 of the Form 1065 Instructions. Leave blank if no trade or business activities.). . . . ☐ Yes ☐ No
(3) Did this partner actively participate in the rental real estate activity(ies) of the partnership? (See page 11 of the Form 1065 Instructions. Leave blank if no rental real estate activities.). . . . ☐ Yes ☐ No

B Partner's share of liabilities
Nonrecourse. . . . . $ _____
Other . . . . . $ _____

C What type of entity is this partner? ▶

D Enter partner's percentage of:

	(i) Before decrease or termination	(ii) End of year
Profit sharing	_____%	_____%
Loss sharing	_____%	_____%
Ownership of capital . . .	_____%	_____%

E IRS Center where partnership filed return ▶ _____

F Tax Shelter Registration Number ▶ _____

G(1) Did the partner's ownership interest in the partnership increase after Oct. 22, 1986? . . . . . ☐ Yes ☐ No
If yes, attach statement. (See page 12 of the Form 1065 Instructions.)
(2) Did the partnership start or acquire a new activity after Oct. 22, 1986? . . . . . ☐ Yes ☐ No
If yes, attach statement. (See page 12 of the Form 1065 Instructions.)

H Check here ▶ ☐ if this Schedule K-1 is for a short tax year required by section 706(b).

I Reconciliation of partner's capital account:

(a) Capital account at beginning of year	(b) Capital contributed during year	(c) Income (loss) from lines 1, 2, 3, and 4 below	(d) Income not included in column (c), plus nontaxable income	(e) Losses not included in column (c), plus unallowable deductions	(f) Withdrawals and distributions	(g) Capital account at end of year

Caution: *Refer to attached Partner's Instructions for Schedule K-1 (Form 1065) before entering information from this schedule on your tax return.*

		(a) Distributive share item	(b) Amount	(c) 1040 filers enter the amount in column (b) on:
Income (Loss)	1	Ordinary income (loss) from trade or business activity(ies)		(See Partner's Instructions for Schedule K-1 (Form 1065))
	2	Income or loss from rental real estate activity(ies)		
	3	Income or loss from other rental activity(ies)		
	4	Portfolio income (loss):		
	a	Interest		Sch. B, Part I, line 2
	b	Dividends		Sch. B, Part II, line 4
	c	Royalties		Sch. E, Part I, line 5
	d	Net short-term capital gain (loss)		Sch. D, line 5, col. (f) or (g)
	e	Net long-term capital gain (loss)		Sch. D, line 12, col. (f) or (g)
	f	Other portfolio income (loss) (attach schedule)		(Enter on applicable lines of your return)
	5	Guaranteed payments		(See Partner's Instructions for Schedule K-1 (Form 1065))
	6	Net gain (loss) under section 1231 (other than due to casualty or theft)		
	7	Other (attach schedule)		(Enter on applicable lines of your return)
Deductions	8	Charitable contributions		See Form 1040 Instructions
	9	Expense deduction for recovery property (section 179)		(See Partner's Instructions for Schedule K-1 (Form 1065))
	10	Deductions related to portfolio income		Sch. A, line 21
	11	Other (attach schedule)		(See Partner's Instructions for Schedule K-1 (Form 1065))
Credits	12a	Credit for income tax withheld		See Form 1040 Instructions
	b	Low-income housing credit		Form 8586, line 8
	c	Qualified rehabilitation expenditures related to rental real estate activity(ies) (attach schedule)		(See Partner's Instructions for Schedule K-1 (Form 1065))
	d	Credit(s) related to rental real estate activity(ies) other than 12b and 12c (attach schedule)		
	e	Credit(s) related to rental activity(ies) other than 12b, 12c, and 12d (attach schedule)		
	13	Other credits (attach schedule)		

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For Paperwork Reduction Act Notice, see Form 1065 Instructions.

Schedule K-1 (Form 1065) 1987

Schedule K-1 (Form 1065) (1987) Page 2

		(a) Distributive share item	(b) Amount	(c) 1040 filers enter the amount in column (b) on:
Self-employment	14a	Net earnings (loss) from self-employment		Sch. SE, Part I
	b	Gross farming or fishing income		(See Partner's Instructions for Schedule K-1 (Form 1065))
	c	Gross nonfarm income		
Tax Preference Items	15a	Accelerated depreciation of real property placed in service before 1/1/87		Form 6251, line 5a
	b	Accelerated depreciation of leased personal property placed in service before 1/1/87		Form 6251, line 5b
	c	Depreciation adjustment on property placed in service after 12/31/86		Form 6251, line 4g
	d	Depletion (other than oil and gas)		Form 6251, line 5h
	e	(1) Gross income from oil, gas, and geothermal properties		See Form 6251 Instructions
		(2) Deductions allocable to oil, gas, and geothermal properties		See Form 6251 Instructions
	f	Other (attach schedule)		(See Partner's Instructions for Schedule K-1 (Form 1065))
Investment Interest	16a	Interest expense on investment debts		Form 4952, line 1
	b	(1) Investment income included in Schedule K-1, lines 4a through 4f		(See Partner's Instructions for Schedule K-1 (Form 1065))
		(2) Investment expenses included in Schedule K-1, line 10		
Foreign Taxes	17a	Type of income		Form 1116, Check boxes
	b	Name of foreign country or U.S. possession		Form 1116, Part I
	c	Total gross income from sources outside the U.S. (attach schedule)		Form 1116, Part I
	d	Total applicable deductions and losses (attach schedule)		Form 1116, Part I
	e	Total foreign taxes (check one): ► ☐ Paid ☐ Accrued		Form 1116, Part II
	f	Reduction in taxes available for credit (attach schedule)		Form 1116, Part III
	g	Other (attach schedule)		See Form 1116 Instructions
Other	18	Other items and amounts not included in lines 1 through 17g and 19 that are required to be reported separately to you		(See Partner's Instructions for Schedule K-1 (Form 1065))

			A	B	C	
Property Subject to Recapture of Investment Credit	19	Properties:				
	a	Description of property (State whether recovery or nonrecovery property. If recovery property, state whether regular percentage method or section 48(q) election used.)				
	b	Date placed in service				Form 4255, top
	c	Cost or other basis				Form 4255, line 2
	d	Class of recovery property or original estimated useful life				Form 4255, line 3
	e	Date item ceased to be investment credit property				Form 4255, line 4
						Form 4255, line 8

Other Information Provided by Partnership:

Proof of August 5, 1987

Form **1120S**
Department of the Treasury
Internal Revenue Service

U.S. Income Tax Return for an S Corporation

For the calendar year 1987 or tax year beginning _____, 1987, ending _____, 19____

▶ For Paperwork Reduction Act Notice, see page 1 of the Instructions.

OMB No 1545-0130

1987

A Date of election as an S corporation

B Business code no. (see Specific Instructions)

Use IRS label. Otherwise, please print or type.

Name

Number and street (P.O. Box number if mail is not delivered to street address)

City or town, state, and ZIP code

C Employer identification number

D Date incorporated

E Total assets (see Specific Instructions) Dollars Cents $

F Check applicable boxes: (1) ☐ Initial return (2) ☐ Final return (3) ☐ Change in address (4) ☐ Amended return

G Check this box if this is an S corporation subject to the consolidated S corporation audit procedures of sections 6241 through 6245 (see instructions) . . . ▶ ☐

H Was this corporation in operation at the end of 1987? . . . Yes ☐ No ☐

I How many months in 1987 was this corporation in operation? ▶

Caution: Include **only** trade or business income and expenses on lines 1a through 20. See the instructions for more information.

Income	1a Gross receipts or sales _____ b Less returns and allowances _____ Balance ▶		1c	
	2 Cost of goods sold and/or operations (Schedule A, line 7)		2	
	3 Gross profit (subtract line 2 from line 1c)		3	
	4 Net gain (or loss) from Form 4797, line 18 (see instructions)		4	
	5 Other income (see instructions—attach schedule)		5	
	6 TOTAL income (loss)—Combine lines 3 through 5 and enter here ▶		6	
Deductions	7 Compensation of officers		7	
	8a Salaries and wages _____ b Less jobs credit _____ Balance ▶		8	
	9 Repairs		9	
	10 Bad debts (see instructions)		10	
	11 Rents		11	
	12 Taxes		12	
	13 Total deductible interest expense not claimed or reported elsewhere on return (see instructions)		13	
	14a Depreciation from Form 4562 (attach Form 4562) $ _____ 14b Minus depreciation claimed or reported on Schedule A and elsewhere on return $ _____ Balance ▶		14c	
	15 Depletion (**Do not deduct oil and gas depletion.** See instructions.)		15	
	16 Advertising		16	
	17 Pension, profit-sharing, etc. plans		17	
	18 Employee benefit programs		18	
	19 Other deductions (attach schedule)		19	
	20 TOTAL deductions—Add lines 7 through 19 and enter here ▶		20	
	21 Ordinary income (loss) from trade or business activity(ies)—Subtract line 20 from line 6		21	
Tax and Payments	22 Tax:			
	a Excess net passive income tax (attach schedule)	22a		
	b Tax from Schedule D (Form 1120S)	22b		
	c Add lines 22a and 22b		22c	
	23 Payments:			
	a Tax deposited with Form 7004	23a		
	b Credit for Federal tax on gasoline and special fuels (attach Form 4136)	23b		
	c Add lines 23a and 23b		23c	
	24 **TAX DUE** (subtract line 23c from line 22c). See instructions for Paying the Tax ▶		24	
	25 **OVERPAYMENT** (subtract line 22c from line 23c) ▶		25	

Please Sign Here

Under penalties of perjury, I declare that I have examined this return, including accompanying schedules and statements, and to the best of my knowledge and belief, it is true, correct, and complete. Declaration of preparer (other than taxpayer) is based on all information of which preparer has any knowledge.

▶ Signature of officer | Date ▶ Title

Paid Preparer's Use Only

Preparer's signature ▶ | Date | Check if self-employed ▶ ☐ | Preparer's social security number

Firm's name (or yours if self-employed) and address ▶ | E.I. No. ▶ | ZIP code ▶

Form **1120S** (1987)

Proof of August 5, 1987

Form 1120S (1987) Page 2

Schedule A Cost of Goods Sold and/or Operations (See instructions for Schedule A.)

1	Inventory at beginning of year	1	
2	Purchases	2	
3	Cost of labor	3	
4a	Additional section 263A costs (attach schedule)	4a	
b	Other costs (attach schedule)	4b	
5	Total—Add lines 1 through 4b	5	
6	Inventory at end of year	6	
7	Cost of goods sold and/or operations—Subtract line 6 from line 5. Enter here and on line 2, page 1	7	

8a Check all methods used for valuing closing inventory:

(i) ☐ Cost

(ii) ☐ Lower of cost or market as described in Regulations section 1.471-4 (see instructions)

(iii) ☐ Writedown of "subnormal" goods as described in Regulations section 1.471-2(c) (see instructions)

(iv) ☐ Other (Specify method used and attach explanation) ▶

b Check this box if the LIFO inventory method was adopted this tax year for any goods (if checked, attach Form 970) ☐

c If the LIFO inventory method was used for this tax year, enter percentage (or amounts) of closing inventory computed under LIFO | 8c |

d Do the rules of section 263A (with respect to property produced or acquired for resale) apply to the corporation? ☐ Yes ☐ No

e Was there any change in determining quantities, cost, or valuations between opening and closing inventory? ☐ Yes ☐ No
If "Yes," attach explanation.

Additional Information Required

	Yes	No
J Did you at the end of the tax year own, directly or indirectly, 50% or more of the voting stock of a domestic corporation? (For rules of attribution, see section 267(c).)		
If "Yes," attach a schedule showing:		
(1) Name, address, and employer identification number;		
(2) Percentage owned;		
(3) Highest amount owed by you to such corporation during the year; and		
(4) Highest amount owed to you by such corporation during the year.		
(Note: *For purposes of J(3) and J(4), "highest amount owed" includes loans and accounts receivable/payable.*)		
K Refer to the listing of business activity codes at the end of the instructions for Form 1120S and state your principal:		
Business activity ▶ Product or service ▶		
L Were you a member of a controlled group subject to the provisions of section 1561?		
M Did you claim a deduction for expenses connected with:		
(1) Entertainment facilities (boat, resort, ranch, etc.)?		
(2) Living accommodations (except for employees on business)?		
(3) Employees attending conventions or meetings outside the North American area? (See section 274(h).)		
(4) Employees' families at conventions or meetings?		
If "Yes," were any of these conventions or meetings outside the North American area? (See section 274(h).)		
(5) Employee or family vacations not reported on Form W-2?		
N At any time during the tax year, did you have an interest in or a signature or other authority over a financial account in a foreign country (such as a bank account, securities account, or other financial account)? (See instructions for exceptions and filing requirements for form TD F 90-22.1.)		
If "Yes," enter the name of the foreign country ▶		
O Were you the grantor of, or transferor to, a foreign trust which existed during the current tax year, whether or not you have any beneficial interest in it? If "Yes," you may have to file Forms 3520, 3520-A, or 926		
P During this tax year did you maintain any part of your accounting/tax records on a computerized system?		
Q Check method of accounting: (1) ☐ Cash (2) ☐ Accrual (3) ☐ Other (specify) ▶		
R Check this box if the S corporation has filed or is required to file **Form 8264,** Application for Registration of a Tax Shelter ▶ ☐		
S Check this box if the corporation issued publicly offered debt instruments with original issue discount ▶ ☐ If so, the corporation may have to file **Form 8281,** Information Return for Publicly Offered Original Issue Discount Instruments.		

Designation of Tax Matters Person

The following shareholder is hereby designated as the tax matters person (TMP) for the tax year for which this tax return is filed:

Name of designated TMP ▶ Identifying number of TMP ▶

Address of designated TMP ▶

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Form 1120S (1987) Page 3

Schedule K Shareholders' Shares of Income, Credits, Deductions, etc. (See Instructions.)

(a) Distributive share items			(b) Total amount
Income (Losses) and Deductions			
1 Ordinary income (loss) from trade or business activity(ies) (page 1, line 21)		1	
2a Gross income from rental real estate activity(ies)	2a		
b Minus expenses (attach schedule)	2b		
c Balance net income (loss) from rental real estate activity(ies)		2c	
3a Gross income from other rental activity(ies)	3a		
b Minus expenses (attach schedule)	3b		
c Balance net income (loss) from other rental activity(ies)		3c	
4 Portfolio income (loss):			
a Interest income		4a	
b Dividend income		4b	
c Royalty income		4c	
d Short-term capital gain (loss) (Schedule D (Form 1120S))		4d	
e Long-term capital gain (loss) (Schedule D (Form 1120S))		4e	
f Other portfolio income (loss) (attach schedule)		4f	
5 Net gain (loss) under section 1231 (other than due to casualty or theft)		5	
6 Other income (loss) (attach schedule)		6	
7 Charitable contributions (attach schedule)		7	
8 Section 179 expense deduction (attach schedule)		8	
9 Expenses related to portfolio income (loss) (attach schedule) (see instructions)		9	
10 Other deductions (attach schedule)		10	
Credits			
11a Jobs credit (attach Form 5884)		11a	
b Low-income housing credit (attach Form 8586)		11b	
c Qualified rehabilitation expenditures related to rental real estate activity (attach schedule)			
d Other credits related to rental real estate activity other than on line 11b and 11c (attach schedule)		11d	
e Credit(s) related to rental activity other than on lines 11b, 11c, and 11d (attach schedule)		11e	
12 Other credits (attach schedule)		12	
Tax Preference and Adjustment Items			
13a Accelerated depreciation of real property placed in service before 1987		13a	
b Accelerated depreciation of leased personal property placed in service before 1987		13b	
c Depreciation adjustment on property placed in service after 1986		13c	
d Depletion (other than oil and gas)		13d	
e (1) Gross income from oil, gas, or geothermal properties		13e(1)	
(2) Gross deductions allocable to oil, gas, or geothermal properties		13e(2)	
f Other items (attach schedule)		13f	
Investment Interest			
14a Interest expense on investment debts paid or accrued in 1987		14a	
b (1) Investment income included on lines 4a through 4f, Schedule K		14b(1)	
(2) Investment expenses included on line 9, Schedule K		14b(2)	
Foreign Taxes			
15a Type of income			
b Name of foreign country or U.S. possession			
c Total gross income from sources outside the U.S. (attach schedule)		15c	
d Total applicable deductions and losses (attach schedule)		15d	
e Total foreign taxes (check one): ▶ ☐ Paid ☐ Accrued		15e	
f Reduction in taxes available for credit (attach schedule)		15f	
g Other (attach schedule)		15g	
Other Items			
16 Total property distributions (including cash) other than dividend distributions reported on line 18, Schedule K		16	
17 Other items and amounts not included in lines 1 through 16, Schedule K, that are required to be reported separately to shareholders (attach schedule).			
18 Total dividend distributions paid from accumulated earnings and profits contained in other retained earnings (line 26 of Schedule L)		18	

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Form 1120S (1987) Page 4

Schedule L Balance Sheets

Assets	Beginning of tax year (a)	Beginning of tax year (b)	End of tax year (c)	End of tax year (d)
1 Cash				
2 Trade notes and accounts receivable				
a Less allowance for bad debts				
3 Inventories				
4 Federal and state government obligations				
5 Other current assets (attach schedule)				
6 Loans to shareholders				
7 Mortgage and real estate loans				
8 Other investments (attach schedule)				
9 Buildings and other depreciable assets				
a Less accumulated depreciation				
10 Depletable assets				
a Less accumulated depletion				
11 Land (net of any amortization)				
12 Intangible assets (amortizable only)				
a Less accumulated amortization				
13 Other assets (attach schedule)				
14 Total assets				
Liabilities and Shareholders' Equity				
15 Accounts payable				
16 Mortgages, notes, bonds payable in less than 1 year				
17 Other current liabilities (attach schedule)				
18 Loans from shareholders				
19 Mortgages, notes, bonds payable in 1 year or more				
20 Other liabilities (attach schedule)				
21 Capital stock				
22 Paid-in or capital surplus				
23 Accumulated adjustments account				
24 Other adjustments account				
25 Shareholders' undistributed taxable income previously taxed				
26 Other retained earnings (see instructions)				
Check this box if the corporation has subchapter C earnings and profits at the close of the tax year ▶ ☐ (see instructions)				
27 Total retained earnings per books—Combine amounts on lines 23 through 26, columns (a) and (c) (see instructions)				
28 Less cost of treasury stock		( )		( )
29 Total liabilities and shareholders' equity				

Schedule M Analysis of Accumulated Adjustments Account, Other Adjustments Account, and Shareholders' Undistributed Taxable Income Previously Taxed (If Schedule L, column (c), amounts for lines 23, 24, or 25 are not the same as corresponding amounts on line 9 of Schedule M, attach a schedule explaining any differences. See instructions.)

	Accumulated adjustments account	Other adjustments account	Shareholders' undistributed taxable income previously taxed
1 Balance at beginning of year			
2 Ordinary income from page 1, line 21			
3 Other additions			
4 Total of lines 1, 2, and 3			
5 Distributions other than dividend distributions			
6 Loss from page 1, line 21			
7 Other reductions			
8 Add lines 5, 6, and 7			
9 Balance at end of tax year—Subtract line 8 from line 4			

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SCHEDULE K-1 (Form 1120S)

Department of the Treasury
Internal Revenue Service

Shareholder's Share of Income, Credits, Deductions, etc.

For calendar year 1987 or tax year
beginning ..... 1987, and ending ..... 19 ....

▶ **For Paperwork Reduction Act Notice, see page 1 of Instructions for Form 1120S.**

OMB No 1545-0130

1987

Shareholder's identifying number ▶	**Corporation's identifying number ▶**
Shareholder's name, address, and ZIP code	Corporation's name, address, and ZIP code

A (1) Shareholder's percentage of stock ownership for tax year ▶ ____ % and (2) Number of shares owned by shareholder at tax year end ▶ (see instructions for Schedule K-1)

B Internal Revenue Service Center where corporation filed its return ▶

C Tax shelter registration number (see Instructions for Schedule K-1) ▶

D Did the shareholder materially participate in the trade or business activity(ies) of the corporation? (See page 8 of the Form 1120S Instructions. Leave the check boxes blank if there are no trade or business activities.) ☐ Yes ☐ No

E Did the shareholder actively participate in the rental real estate activity(ies) of the corporation? (See page 8 of the Form 1120S Instructions. Leave the check boxes blank if there are no rental real estate activities.) ☐ Yes ☐ No

F If (1) question D is checked "No" or income or loss is reported on line 2 or 3 and (2) the shareholder had acquisition(s) of corporate stock after 10/22/86, check here ▶ ☐ and enter the shareholder's weighted percentage increase in stock ownership for 1987 (see instructions for Schedule K-1) ▶ %

G If question D is checked "No" and any activity referred to in question D was started or acquired by the corporation after 10/22/86, check here ▶ ☐ and enter the date of start-up or acquisition in the date space on line 1. Also, if an activity for which income or loss is reported on line 2 or 3 was started after 10/22/86, check the box and enter the start-up date in the date space on line 2 or 3.

H If short tax year shown above was a result of a change in tax year required by section 378, check ▶ ☐

Caution: *Refer to attached Instructions for Schedule K-1 before entering information from Schedule K-1 on your tax return.*

		(a) Distributive share items	(b) Amount	(c) Form 1040 filers enter the amount in column (b) on
Income (Losses) and Deductions	1	Ordinary income (loss) from trade or business activity(ies). Date:		See Shareholder's Instructions for Schedule K-1 (Form 1120S).
	2	Income or loss from rental real estate activity(ies). Date:		
	3	Income or loss from rental activity(ies) other than line 2 above. Date:		
	4	Portfolio income (loss):		
	a	Interest		Sch. B, Part I, line 2
	b	Dividends		Sch. B, Part II, line 4
	c	Royalties		Sch. E, Part I
	d	Net short-term capital gain (loss)		Sch. D, line 5, col. (f) or (g)
	e	Net long-term capital gain (loss)		Sch. D, line 12, col. (f) or (g)
	f	Other portfolio income (loss)		(Enter on applicable line of your return.)
	5	Net gain (loss) under section 1231 (other than due to casualty or theft)		Form 4797, line 1
	6	Other income (loss) (attach schedule)		(Enter on applicable line of your return.)
	7	Charitable contributions		See Form 1040 Instructions.
	8	Section 179 expense deduction (attach schedule)		See Shareholder's Instructions for Schedule K-1 (Form 1120S).
	9	Deductions related to portfolio income (attach schedule)		
	10	Other deductions (attach schedule)		
Credits	11a	Jobs credit		Form 5884
	b	Low-income housing credit		Form 8586
	c	Qualified rehabilitation expenditures related to rental real estate activity(ies) (attach schedule)		See Shareholder's Instructions for Schedule K-1 (Form 1120S).
	d	Credits related to rental real estate activity(ies) other than on line 11b and 11c (attach schedule)		
	e	Credits(s) related to rental activity(ies) other than on line 11b, c, and d (attach schedule)		
	12	Other credits (attach schedule)		
Tax Preference and Adjustment Items	13a	Accelerated depreciation of real property placed in service before 1987		Form 6251, line 5a
	b	Accelerated depreciation of leased personal property placed in service before 1987		Form 6251, line 5b
	c	Depreciation adjustment on property placed in service after 1986		Form 6251, line 4g
	d	Depletion (other than oil and gas)		Form 6251, line 5h
	e	(1) Gross income from oil, gas, or geothermal properties		See Form 6251 Instructions.
		(2) Gross deductions allocable to oil, gas, or geothermal properties		
	f	Other items (attach schedule)		See Shareholder's Instructions for Schedule K-1 (Form 1120S).

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Schedule K-1 (Form 1120S) (1987) Page 2

	(a) Distributive share items	(b) Amount	(c) Form 1040 filers enter the amount in column (b) on:
Investment Interest	14a Interest expense on investments debts paid or accrued in 1987		Form 4952, line 1
	b (1) Investment income included in Schedule K-1, lines 4a through 4f		See Shareholder's Instructions for Schedule K-1 (Form 1120S).
	(2) Investment expenses included in Schedule K-1, line 9		
Foreign Taxes	15a Type of income ▶		Form 1116, Check boxes
	b Name of foreign country or U.S. possession ▶		Form 1116, Part I
	c Total gross income from sources outside the U.S. (attach schedule)		Form 1116, Part I
	d Total applicable deductions and losses (attach schedule)		Form 1116, Part I
	e Total foreign taxes (check one): ▶ ☐ Paid ☐ Accrued		Form 1116, Part II
	f Reduction in taxes available for credit (attach schedule)		Form 1116, Part III
	g Other (attach schedule)		See Form 1116 Instructions.
Other Items	16 Property distributions (including cash) other than dividend distributions reported to you on Form 1099-DIV		See Shareholder's Instructions for Schedule K-1 (Form 1120S).
	17 Amount of loan repayments for "Loans from Shareholders"		

Property Subject to Recapture of Investment Credit	18 Properties:	A	B	C	
	a Description of property (State whether recovery or non-recovery property. If recovery property, state whether regular percentage method or section 48(q) election used.)				
	b Date placed in service				Form 4255, top Form 4255, line 2
	c Cost or other basis				Form 4255, line 3
	d Class of recovery property or original estimated useful life				Form 4255, line 4
	e Date item ceased to be investment credit property				Form 4255, line 8

Supplemental Schedules

19 Supplemental information for lines 6, 8, 9, 10, 11c, 11d, 11e, 12, 13f, 15c, 15d, 15f, 15g, or other items and amounts not included in lines 1 through 18 that are required to be reported separately to each shareholder (attach additional schedules if more space is needed):

Proof of August 5, 1987

Form **6251**

Department of the Treasury
Internal Revenue Service

Alternative Minimum Tax—Individuals

▶ Attach to Form 1040 or Form 1040NR. Estates and trusts, use Form 8656.

OMB No 1545-0227

1987

Attachment Sequence No. 32

Name(s) as shown on Form 1040

Your social security number

1	Taxable income from Form 1040, line 36		1	
2	Net operating loss deduction		2	
3	Add lines 1 and 2		3	
4	Adjustments:			
a	Standard deduction from Form 1040, line 33b	4a		
b	Medical and dental expense (see instructions)	4b		
c	Miscellaneous itemized deductions from Schedule A, line 24	4c		
d	Taxes from Schedule A, line 8	4d		
e	Interest from Schedule A, line 12b	4e		
f	Other interest adjustments (see instructions)	4f		
g	Depreciation of property placed in service after 1986	4g		
h	Circulation and research and experimental expenditures paid or incurred after 1986	4h		
i	Mining exploration and development costs paid or incurred after 1986	4i		
j	Long-term contracts entered into after 2/28/86	4j		
k	Pollution control facilities placed in service after 1986	4k		
l	Installment sales of certain property	4l		
m	Basis adjustment (see instructions)	4m		
n	Certain loss limitations (see instructions)	4n		
o	Tax shelter farm loss	4o		
p	Passive activity loss	4p		
q	Beneficiaries of estates and trusts (see instructions)	4q		
r	Other (see instructions)	4r		
s	Total adjustments (combine lines 4a through 4r)		4s	
5	Tax preference items:			
a	Accelerated depreciation of real property placed in service before 1987	5a		
b	Accelerated depreciation of leased personal property placed in service before 1987	5b		
c	Amortization of certified pollution control facilities placed in service before 1987	5c		
d	Appreciated property charitable deduction	5d		
e	Incentive stock options	5e		
f	Tax-exempt interest from private activity bonds issued after August 7, 1986	5f		
g	Intangible drilling costs	5g		
h	Depletion	5h		
i	Reserves for losses on bad debts of financial institutions	5i		
j	Total tax preference items (add lines 5a through 5i)		5j	
6	Combine lines 3, 4s, and 5j		6	
7	Alternative tax net operating loss deduction (Do not enter more than 90% of line 6)		7	
8	Alternative minimum taxable income (subtract line 7 from line 6)		8	
9	Enter: $40,000 ($20,000 if married filing separately; $30,000 if single or head of household)		9	
10	Enter: $150,000 ($75,000 if married filing separately; $112,500 if single or head of household)		10	
11	Subtract line 10 from line 8. If result is zero or less, enter zero		11	
12	Multiply line 11 by 25% (.25)		12	
13	Subtract line 12 from line 9. If result is zero or less, enter zero		13	
14	Subtract line 13 from line 8		14	
15	Multiply line 14 by 21% (.21)		15	
16	Alternative minimum tax foreign tax credit		16	
17	Tentative minimum tax (subtract line 16 from line 15)		17	
18	Regular tax before credits (Form 1040, line 37) minus foreign tax credit (Form 1040, line 44)		18	
19	Alternative minimum tax (subtract line 18 from line 17). Enter on Form 1040, line 49		19	

For Paperwork Reduction Act Notice, see separate instructions.

Form **6251** (1987)

Proof of August 5, 1987

1987

Department of the Treasury
Internal Revenue Service

Instructions for Form 6251

Alternative Minimum Tax—Individuals

(Section references are to the Internal Revenue Code.)

General Instructions

Paperwork Reduction Act Notice.—We ask for this information to carry out the Internal Revenue laws of the United States. We need it to ensure that taxpayers are complying with these laws and to allow us to figure and collect the right amount of tax. You are required to give us this information.

Changes You Should Note.—The Tax Reform Act of 1986 changed the method for figuring the alternative minimum tax. Some items which previously were tax preference items are now adjustments to taxable income to arrive at alternative minimum taxable income. In addition, certain tax preference items and adjustments have changed.

This form is now used only by individuals to figure their alternative minimum tax. Estates and trusts should use Form 8656 to figure their alternative minimum tax.

Who Must File.—File this form if: (a) You are liable for the alternative minimum tax or your credits are limited by the tentative minimum tax; or (b) Line 6 is more than line 9, and you have one or more adjustments on lines 4(f) through (q), or tax preference items on line 5.

For more information, see **Publication 909,** Alternative Minimum Tax for Individuals.

Partners, Shareholders, etc.—If you are a partner or shareholder of an S corporation, take into account separately your distributive share of items of income and deductions that enter into the computation of your alternative minimum tax adjustments and tax preference items.

Short period return.—If this is a short period return, use the formula in section 443(d) to determine your alternative minimum taxable income and alternative minimum tax.

Nonresident alien individuals.—If you disposed of U.S. real property interests at a gain, see Form 1040NR instructions for a special rule in figuring Form 6251, line 15.

Carryback and carryover of unused credits.—It may be necessary to figure the carryback or carryover of certain unused credits. See the appropriate credit forms and Code sections for more information.

Earned income credit.—If you have an earned income credit, you must reduce that credit by any alternative minimum tax.

Line-by-Line Instructions

Line 4(a).—If you have an amount on Form 1040, line 33(b), enter that amount. If you itemize deductions, enter zero.

Line 4(b).—If you have an entry on Schedule A, line 4, multiply Form 1040, line 31 by 2½% (.025) and enter the result on line 4(b). If the result is more than the amount on Schedule A, line 4, enter the amount from Schedule A, line 4 on line 4(b).

Line 4(d).—Enter your state and local income taxes, real estate taxes, and personal property taxes from Schedule A, lines 5, 6, and 7.

Line 4(f)—Other interest adjustment.—If your mortgage interest deduction includes interest from refinancing your mortgage for an amount above your mortgage balance before refinance, enter on line 4(f) the interest attributable to the excess of your mortgage balance after refinance over your mortgage balance before refinance. However, if the increased mortgage amount was used for property improvements, do not enter the interest attributable to those improvements.

If you have investment interest, refigure Form 4952 (Investment Interest Expense Deduction) through line 7 for purposes of the alternative minimum tax, and include interest on any private activity bond issued after August 7, 1986, as investment interest and investment income. On this Form 4952, do not complete lines 8 through 13, but enter line 7 on line 14. Subtract your recomputed line 15 from 15 of the Form 4952 you used for the regular tax. Include that result on Form 6251, line 4(f). See the instructions below for line 5(f) for definition of private activity bond.

Line 4(g)—Depreciation of property placed in service after 1986, or after 7/31/86 if election was made.—Refigure your depreciation as follows: For property other than real property and property on which the straight line method was used, use the 150 percent declining balance method, switching to straight line for the 1st tax year when that method gives a better result. Use the same class lives and conventions as you used on Form 4562. For residential rental and nonresidential real property, use the straight line method over 40 years. Use the same conventions as you used on Form 4562. Determine your depreciation adjustment by subtracting your recomputed depreciation from the depreciation you took on Form 4562. Enter the difference on line 4(g).

Line 4(h)—Circulation and research and experimental expenditures paid or incurred after 1986.—Refigure your circulation expenditures by amortizing them over three years beginning with the year the expenditures were made. Refigure your research and experimental expenditures by amortizing them over ten years beginning with the year the expenditures were made. Figure your adjustment by subtracting these refigured amounts from the deductions you took under sections 173 and 174(a). Enter the difference on line 4(h). If you had a loss with respect to those expenditures, see section 56(b)(2)(B).

Line 4(i)—Mining exploration and development costs paid or incurred after 1986.—With respect to each mine or other natural deposit (other than an oil, gas, or geothermal well), refigure your expenses by amortizing them over ten years beginning with the year in which the expenses were made. Figure your adjustment by subtracting the refigured amount from the deduction you took under sections 616(a) or 617(a). If you had a loss with respect to those expenditures, see section 56(a)(2)(B).

Line 4(j).—If you entered into a long-term contract after 2/28/86, determine your taxable income from such contract under the percentage of completion method of accounting as modified by section 460(b). Determine the difference between the result using the percentage of completion method and the result you got on the contract when figuring your regular tax, and enter the difference on this line. If the refigured taxable income is less than the result when determining your regular tax, enter the difference as a negative amount.

Line 4(k).—For any certified pollution control facility placed in service after 1986, figure your entry for this line in the same manner you figured line 4(g).

Line 4(l)—Installment sales of certain property.—In the case of any disposition after 3/1/86 of property which is inventory or stock in trade, or other disposition if an obligation arising from such disposition would be an applicable installment obligation under section 453C, determine the income from such disposition without using the installment method. Your adjustment will be the difference between this result and the result you obtained when figuring your regular tax. If this result is less than the result you obtained when figuring your regular tax, enter the difference as a negative amount. If you made an election under section 453C(e)(4), enter zero on this line.

Line 4(m)—Basis adjustment.—If you disposed of property during the year, refigure your gain or loss from such sale taking into consideration your alternative minimum tax adjustments on lines 4(g), (h), (i), and (k). Enter the difference between the gain or loss reported on your tax return for purposes of the regular tax and your recomputed gain or loss. If the recomputed gain is less, or the loss is more, enter the difference as a negative amount.

Line 4(n)—Certain loss limitations.—Refigure your allowable losses from at-risk activities and basis limitations applicable to partnerships and S corporations, taking into account your alternative minimum tax adjustments and tax preference items. See

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sections 59(h), 465, 704(d), and 1366(d). Enter the difference between the loss reported on your tax return for purposes of the regular tax and your recomputed loss. If the recomputed loss is more than the loss reported for purposes of the regular tax, enter as a negative amount.

Line 4(o).—Figure the amount of any disallowed loss from a tax shelter farm activity as defined in section 464(c) and any other farm activity which is a passive activity under section 469(d). Enter on this line the difference between the amount of such disallowed losses and the amount of losses from these activities which are disallowed for regular tax purposes, such as under the passive activity loss rules. In figuring the amount of the loss, take into consideration your alternative minimum tax adjustments and tax preference items. Any loss entered on this line shall be treated as a deduction allocable to such activity in the first succeeding year.

Line 4(p)—Passive activity loss.—Refigure your passive activity loss taking into consideration your alternative minimum tax adjustments from passive activities and adding back your tax preference items from passive activities. Refigure this loss on Form 8582, but do not complete line 23 of the form, relating to the phase in of the disallowance. Enter on line 4(p) the difference between your recomputed loss and the loss obtained when figuring your regular tax. For purposes of this line, do not take into consideration any losses from tax shelter farm activities.

Line 4(q)—Beneficiaries of estates and trusts, if the Schedule K-1 you received from the estate or trust has an entry on line 7, enter the difference between the distribution you included in income for purposes of the regular tax and the amount included on Schedule K-1(Form 1041), line 7.

Line 4(r)—Other.—At the time Form 6251 and these instructions were developed, Congress was c onsidering legislation that would not allow the deduction for personal exemptions in figuring alternative minimum taxable income.

Line 5(a)—Accelerated depreciation of real property placed in service before 1987.—Enter on this line (never less than zero) the difference between the depreciation you got for this property in determining the regular tax and depreciation as refigured using the straight line method. Figure this amount separately for each property. For 15, 18, or 19-year real property, or low income housing, use the straight line method over 15, 18, or 19 years, using the half-year convention and no salvage value.

Line 5(b)—Accelerated depreciation of leased personal property placed in service before 1987.—For leased personal property, other than recovery property, enter the difference (never less than zero) between the depreciation you got for this property in determining the regular tax and depreciation as refigured using the straight line method. Figure this amount separately for each property.

For leased recovery property, other than 15, 18, or 19-year real property, or low income housing, enter the amount by which your depreciation deduction determined for your regular tax is more than the deduction allowable using the straight line method with a half-year convention, no salvage value, and the following recovery period:

3-year property	5 years
5-year property	8 years
10-year property	15 years
15-year public utility property	22 years

Note: *If the recovery period actually used is longer than the recovery period in 5(a) or 5(b), do not complete those lines with respect to that recovery property.*

Line 5(c)—Amortization of certified pollution control facilities placed in service before 1987.—Enter the amount by which the amortization allowable under section 169 is more than the depreciation deduction otherwise allowable.

Line 5(d)—Appreciated property charitable deduction.—Enter the amount by which your contribution deduction for capital gain and section 1231 property would be reduced if such property was taken into account at its cost or other basis, rather than fair market value.

Line 5(e)—Incentive stock options.—If you received stock by the exercise of an incentive stock option, enter the amount by which the fair market value of the shares at the time of exercise was more than the option price. The basis of the stock is increased by the amount of this tax preference item for purposes of the alternative minimum tax, in determining gain or loss on any disposition of the stock. Adjust the tax preference item by the difference between your taxable gain or loss with this basis adjustment, and the gain or loss reported on your tax return in figuring your regular tax. See sections 57(a)(3) and 422A.

Line 5(f)—Tax-exempt interest.—Enter your interest on private activity bonds issued after August 7, 1986, reduced by any deduction attributable to it. Private activity bonds are bonds where more than 10% of the proceeds are to be used for any private business use and the private security or payment test of section 141(b)(2) is met. A bond is also considered a private activity bond if it meets the private loan financing test of section 141(c).

Line 5(g)—Intangible drilling costs.—Enter the amount by which your excess intangible drilling costs are more than 65 percent of your net income from oil, gas, and geothermal properties.

Figure excess intangible drilling costs as follows: From the allowable intangible drilling and development costs (except costs in drilling a nonproductive well), subtract the amount that would have been allowable if you had capitalized these costs and either amortized them over the 120 months that started when production began, or treated them according to any election you made under section 57(b)(2).

Your net income from oil, gas, and geothermal properties is your gross income from them, minus the deductions allocable to them, except for excess intangible drilling costs and nonproductive well costs.

Figure the line 5(g) amount separately for oil and gas properties which are not geothermal deposits and for oil and gas properties which are geothermal deposits.

Line 5(h)—Depletion.—In the case of mines, wells, and other natural deposits, enter the amount by which your deduction for depletion is more than your adjusted basis of the property at the end of your tax year. Figure the adjusted basis without regard to the depletion deduction and figure the excess separately for each property.

Line 5(i)—Reserves for losses on bad debts of financial institutions.—In the case of a financial institution, enter your share of the excess of the deduction allowable for a reasonable addition to a reserve for bad debts over the amount that would have been allowable had the institution maintained its bad debt reserve for all tax years based on actual experience.

Line 7—Alternative tax net operating loss deduction.—Your alternative tax net operating loss deduction is your net operating loss deduction refigured as follows: For any loss year after 1982, reduce the loss by your tax preference items and by your itemized deductions which were not allowed in figuring alternative minimum tax to the extent those items were included in your net operating loss for that year. Use your alternative minimum taxable income instead of taxable income when figuring the amount of your loss to carry over from one year to the next.

Line 16—Alternative minimum tax foreign tax credit.—Your alternative minimum tax foreign tax credit is your foreign tax credit refigured as follows:

(1) Use and attach a separate Form 1116 for each type of income specified at the top of Form 1116. Print across the top of each Form 1116 used "Alt Min Tax."

(2) Fill in a new Part I using that portion of your taxable income, adjustments and tax preference items from Form 6251, attributable to sources outside the United States.

(3) Fill in a new Part III using your alternative minimum taxable income (Form 6251, line 8) instead of taxable income on line 9. On line 11 enter Form 6251, line 15 less 10% of the amount that would be on that line if Form 6251 was refigured using zero on line 7.

(4) Fill in a new Part IV, but do not enter on Form 6251, line 16 more than Form 6251, line 15 less 10% of the amount that would be on that line if Form 6251 was refigured using zero on line 7.

[FR Doc. 87-17759 Filed 8-5-87; 8:45 am]

BILLING CODE 4830-01-C

Proof 8/5/87

UNITED STATES INFORMATION AGENCY

Reporting and Information Collection Requirements Under OMB Review

AGENCY: United States Information Agency.

ACTION: Notice of reporting requirements submitted for OMB review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C., Chapter 35), agencies are required to submit proposed or established reporting and record-keeping requirements to OMB for review and approval, and to publish a notice in the Federal Register notifying the public that the Agency has made such a submission. USIA is requesting a generic clearance of its information-collecting activities among grantees and alumni/ae of USIA-funded educational and cultural exchange activities regarding program effectiveness.

DATE: Comments must be received by August 31, 1987.

Copies: Copies of the Request for Clearance (SP-83), supporting statement, transmittal letter, and other documents submittee to OMB for approval may be obtained from the USIA Clearance Officer. Comments on the items listed should be submitted to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for USIA, and also to the USIA Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Agency Clearance Officer, Retta Graham-Hall, United States Information Agency, M/ASP, 301 Fourth Street, SW., Washington, D.C. 20547, telephone (202) 485-7501; and OMB review: Francine Picoult, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Bldg., Washington, DC 20503, telephone (202) 395-7340.

SUPPLEMENTARY INFORMATION: Title: USIA-Supported Educational and Cultural Exchange Activities.

Abstract: In the interest of sound program management, USIA undertakes the collection of information about program effectiveness necessary to the management and evaluation of USIA-funded educational and cultural exchange programs. USIA seeks clearance from OMB for these information-collection activities among grantees and alumni/ae of these programs.

Proposed Frequency of Responses: Maximum annual estimates of total burden for all information collections are as follows:

No. of Respondents—1,700
Recordkeeping Hours—332
Response Hours—1,275
Total annual burden—1,607

Dated: July 30, 1987.

Charles N. Canestro,

Federal Register Liaison.

[FR Doc. 87-17843 Filed 8-5-87; 8:45 am]

BILLING CODE 8230-01-M

Culturally Significant Objects Imported for Exhibition; Determination

Notice is hereby given of the following determination: Pursuant to the authority vested in me by the act of October 19, 1965 (79 Stat. 985, 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978 (43 FR 13358, March 29, 1978), and Delegation Order No. 85-5 of June 27, 1985 (50 FR 27393, July 2, 1985), I hereby determine that the objects to be included in the exhibit, "Carthage: A Mosaic of Ancient Tunisia" (see list [1]) imported from abroad for the temporary exhibition without profit within the United States are of cultural significance. These objects are importerd pursuant to loan agreements with the foreign lenders. I also determine that the temporary exhibition or display of the listed exhibit objects at the American Museum of Natual History, New York, New York, beginning on or about December 1, 1987, to on or about May 15, 1988, at the New Orleans Museum of Art, New Orleans, Louisiana, beginning on or about November 15, 1988, to on or about February 15, 1989, and at the Los Angeles County Museum of Natural History, Los Angeles, California, beginning on or about September 15, 1989, to on or about December 30, 1989, with at least two other intermediate exhibitions, is in the national interest.

Public notice of this determination is ordered to be published in the **Federal Register.**

Dated: August 4, 1987.

C. Normand Poirier,

Acting General Counsel.

[FR Doc. 87-18057 Filed 8-5-87; 11:20 am]

BILLING CODE 8230-01-M

[1] A copy of this list may be obtained by contacting Mr. R. Wallace Stuart of the Office of the General Counsel of USIA. The telephone number is 202-485-7976, and the address is Room 700, U.S. Information Agency, 301 4th Street, SW., Washington, DC 20547.

VETERANS ADMINISTRATION

Agency Form Under OMB Review

AGENCY: Veterans Administration.

ACTION: Notice.

The Veterans Administration has submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). This document contains an extension and lists the following information: (1) The department or staff office issuing the form, (2) the title of the form, (3) the agency form number, if applicable, (4) a description of the need and its use, (5) how often the form must be filled out, (6) who will be required or asked to report, (7) an estimate of the number of responses, (8) an estimate of the total number of hours needed to fill out the form, and (9) an indication of whether section 3504(h) of Pub. L. 96-511 applies.

ADDRESSES: Copies of the forms and supporting documents may be obtained from Patti Viers, Agency Clearance Officer (732), Veterans Administration, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 233-2146. Comments and questions about the items on the list should be directed to the VA's OMB Desk Officer, Elaina Norden, Office of Management and Budget, 726 Jackson Place, NW., Washington, DC 20503, (202) 395-7316.

DATES: Comments on the information collection should be directed to the OMB Desk Officer within 60 days of this notice.

Dated: July 30, 1987.

By direction of the Administrator.

David A. Cox,

Associate Deputy Administrator for Management.

Extension

1. Office of Facilities
2. Daily Report of Workers and Material Daily Log—Formal Contract
3. VA Form 08-6131
4. This information is needed to determine the contractor's compliance with the terms and conditions of the construction contract.
5. Every workday
6. Busineses or other for-profit and Small businesses or organizations
7. 78,000 responses
8. 13,000 hours
9. Not applicable

[FR Doc. 87-17859 Filed 8-5-87; 8:45 am]

BILLING CODE 8320-01-M

Agency Form Under OMB Review

AGENCY: Veterans Administration.

ACTION: Notice.

The Veterans Administration has submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). This document contains an extension and lists the following information: (1) The department or staff office issuing the form, (2) the title of the form, (3) the agency form number, if applicable, (4) a description of the need and its use, (5) how often the form must be filled out, (6) who will be required or asked to report, (7) an estimate of the number of responses, (8) an estimate of the total number of hours needed to fill out the form, and (9) an indication of whether section 3504(h) of Pub. L. 96-511 applies.

ADDRESES: Copies of the forms and supporting documents may be obtained from Patti Viers, Agency Clearance Officer (732), Veterans Administration, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 233-2146. Comments and questions about the items on the list should be directed to the VA's OMB Desk Officer, Elaina Norden, Office of Management and Budget, 726 Jackson Place, NW., Washington, DC 20503, (202) 395-7316.

DATES: Comments on the information collection should be directed to the OMB Desk Officer within 60 days of this notice.

Dated: July 30, 1987.

By direction of the Administrator.

David A. Cox,

Associate Deputy Administrator for Management.

Extension

1. Office of Budget and Finance (Controller)
2. Financial Status Report
3. VA Form 4-5655
4. This information is used to determine eligibility of a person requesting a repayment plan, waiver of a debt, or making a compromise offer.
5. On occasion
6. Individuals or households
7. 250,000 responses
8. 250,000 hours
9. Not applicable

[FR Doc. 87-17860 Filed 8-5-87; 8:45 am]

BILLING CODE 8320-01-M

Sunshine Act Meetings

Federal Register
Vol. 52, No.151
Thursday, August 6, 1987

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).

FEDERAL ELECTION COMMISSION

"FEDERAL REGISTER" NO.: 87-17408.

PREVIOUSLY ANNOUNCED DATE AND TIME: Thursday, August 6, 1987, 10:00 a.m.

THE FOLLOWING ITEM HAS BEEN ADDED TO THE AGENDA:

Draft Advisory Opinion 1987-15—James F. Schoener on behalf of Kemp for President Committee.

DATE AND TIME: Tuesday, August 11, 1987, 10:00 a.m.

PLACE: 999 E Street, NW., Washington, DC

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. 437g.
Audits conducted pursuant to 2 U.S.C. 437g, 438(b), and Title 26, U.S.C.
Matters concerning participation in civil actions or proceedings or arbitration.
Internal personnel rules and procedures or matters affecting a particular employee.

DATE AND TIME: Thursday, August 13, 1987, 10:00 a.m.

PLACE: 999 E Street, NW., Washington, DC (Ninth Floor).

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED:

Setting of Dates for Future Meetings.
Correction and Approval of Minutes.
Eligibility Report for Candidates to Receive Presidential Primary Matching Funds.
Proposed Revisions to the Delegate Selection Regulations (11 CFR 110.14).
Draft Advisory Opinion 1987-23—Rand Hoch on behalf of Electro Political Action Committee 323.
Routine Administrative Matters.

PERSON TO CONTACT FOR INFORMATION: Mr. Fred Eiland, Information Officer, Telephone: 202-376-3155.

Marjorie W. Emmons,
Secretary of the Commission.

[FR Doc. 87-17987 Filed 8-4-87; 2:35 p.m.]

BILLING CODE 6715-01-M

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

TIME AND DATE: 10:00 a.m., Wednesday, August 12, 1987.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

1. Any items carried forward from a previously anounced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

James McAfee,
Associate Secretary of the Board.

Date: August 4, 1987.

[FR Doc. 87-18018 Filed 8-4-87; 3:53 p.m.]

BILLING CODE 6210-01-M

Corrections

Federal Register
Vol. 52, No. 151
Thursday, August 6, 1987

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents and volumes of the Code of Federal Regulations. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF COMMERCE

International Trade Administration

15 CFR Part 377

[Docket No. 70747-7147]

Short Supply Controls and Monitoring

Correction

In rule document 87-16924 beginning on page 28136 in the issue of Tuesday, July 28, 1987, make the following corrections:

1. On page 28136, in the third column, in amendatory instruction 2(e), in the 5th line, "l" should read "m".

2. On page 28137, in the first column, amendatory instruction 10 was incorrectly designated as amendatory instruction 11.

BILLING CODE 1505-01-D

DEPARTMENT OF COMMERCE

Minority Business Development Agency

Financial Assistance Application Announcements; North Carolina

Correction

In notice document 87-17014 beginning on page 28181 in the issue of Tuesday, July 28, 1987, make the following correction:

On page 28181, in the **SUMMARY**, the last sentence should have been two sentences and should have read: "The cost of performance for the first 12 months is estimated at $165,000 for the budget period January 1, 1988 to December 31, 1988. The IBDC will operate in the Cherokee/Ashville, North Carolina Metropolitan Statistical Area (MSA)."

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 410

[Docket Nos. 85N-0322 and BERC-324-F]

Cardiac Pacemaker Registry

Correction

In rule document 87-16592 beginning on page 27756 in the issue of Thursday, July 23, 1987, make the following correction:

PART 410--[CORRECTED]

On page 27765, in the first column, in the **Authority**, in the third line, "13951" should read "1395l".

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 87-NM-77-AD]

Airworthiness Directives; Boeing Model 737 Series Airplanes

Correction

In proposed rule document 87-15122 beginning on page 25024 in the issue of Thursday, July 2, 1987, make the following correction:

On page 25024, in the second column, in the **DATE** paragraph, in the second line, "August 2, 1987" should read "August 22, 1987".

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 87-AGL-5]

Proposed Alteration of VOR Federal Airways; Illinois

Correction

In proposed rule document 87-15853 beginning on page 26350 in the issue of Tuesday, July 14, l987, make the following correction:

On page 26351, in the first column, under **V-340 [Revised]**, in the first line, insert "M" after "063°".

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 87-AWA-10]

Proposed Alteration of VOR Federal Airways; Expanded East Coast Plan, Phase II

Correction

In proposed rule document 87-15854 beginning on page 26351 in the issue of Tuesday, July 14, 1987, make the following corrections:

1. On page 26352, in the first column, under **V-36[Amended]**, in the seventh line, insert "T" after "310°".

2. On the same page, in the same column, under **V-44[Amended]**, in the 12th line, "211°" should read "221°", and in the 13th line, "BRIDGEPORT" should read "Bridgeport".

BILLING CODE 1505-01-D

DEPARTMENT OF THE TREASURY

Customs Service

Application for Recordation of Trade Name: "Two's Company"

Correction

In notice document 87-17532 appearing on page 28774 in the issue of Monday, August 3, 1987, make the following correction:

In the third column, in the second line"October 3" should read "October 2".

BILLING CODE 1505-01-D

federal register

Thursday
August 6, 1987

Part II

Department of Education

34 CFR Part 650

Jacob K. Javits Fellows Program; Final Regulations

DEPARTMENT OF EDUCATION

34 CFR Part 650

Jacob K. Javits Fellows Program

AGENCY: Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary amends the regulations governing the Jacob K. Javits Fellows Program, formerly called the National Graduate Fellows Program. These regulations are needed to implement Title IX, Part C of the Higher Education Act, as amended by the Higher Education Amendments of 1986.

EFFECTIVE DATE: These regulations take effect either 45 days after publication in the **Federal Register** or later if the Congress takes certain adjournments. If you want to know the effective date of these regulations, call or write the Department of Education contact person.

FOR FURTHER INFORMATION CONTACT: Allen P. Cissell, Jacob K. Javits Fellows Program, Office of Higher Education Programs, Office of Postsecondary Education, U.S. Department of Education, 400 Maryland Avenue, SW., Room 3022, ROB-3, Washington, DC 20202. Telephone: (202) 732-4415.

SUPPLEMENTARY INFORMATION: The Jacob K. Javits Fellows Program provides fellowships to students for study at the doctoral level in selected fields of the humanities, arts and social sciences. Many of the responsibilities under this program regarding procedures and criteria for selection of fellows and general policies for the program are vested in the Fellowship Board. Members of the Fellowship Board are appointed by the Secretary of Education. These regulations do not establish rules on matters for which the Fellowship Board has responsibility.

Several changes were made in the program by the Higher Education Amendments of 1986. These were:

- The 1986 legislation has changed the name of the National Graduate Fellows Program to the Jacob K. Javits Fellows Program.
- The 1986 legislation requires the secretary to pay $6,000 to each institution for each individual awarded a fellowship and enrolled at such institution.
- The Secretary has determined that the financial need on which the stipend levels are based will be calculated under the provisions of Part F, Title IV of the Higher Education Act, with exceptions as noted for fellows selected in 1986.
- The 1986 legislation requires that stipends shall provide a level of support comparable to that provided by federally funded graduate fellowships in the science and engineering fields. The Secretary has determined that the stipends as calculated under § 650.42 of these regulations are comparable to those provided by federally-funded graduate fellowships in science and engineering.
- On April 15, 1987, the Secretary published a notice of proposed rulemaking (NPRM) for the Jacob K. Javits Fellows Program in the **Federal Register** (52 FR 12360). The provisions of these final regulations are the same as those of the NPRM except for technical changes. Interested parties were provided 30 days to submit their comments to the Secretary. A summary of the two comments received and the Secretary's responses to these comments follow:

Summary of Comments and Responses

Section 650.42 How are stipends to be administered?

Comment: Both commenters pointed out that the definition of "independent student" in § 650.42(c), applicable to fellowships initially awarded in fiscal year 1986, is based on the definition of "independent student" in the Higher Education Act of 1965 (HEA) prior to the Higher Education Amendments of 1986 (Pub. L. 99-498). Both commenters suggested that the definition of "independent student" be changed to conform with the definition of "independent student" in section 480(d) of the HEA as amended.

Discussion: Under section 933(a) of the HEA, as amended, stipends for Jacob K. Javits Fellows are to be calculated in accordance with measurements of need approved by the Secretary. The Secretary has chosen to use the need analysis system authorized by Part F of Title IV of the HEA, as amended. However, the Secretary has chosen to use the definition of "independent student" for those fellowships awarded in fiscal year 1986 that was in effect at the time of award for the duration of the fellowships. The definition of "independent student" previously in effect is retained for the fellowships awarded in fiscal year 1986. The new definition of "independent student" in the HEA, as amended, will apply for fellowships initially awarded in 1987 and subsequent fiscal years.

Changes: None.

Executive Order 12291

The regulations have been reviewed under Executive Order 12291. They are not classified as major because they do not meet the criteria for major regulations established in the order.

Paperwork Reduction Act of 1980

These regulations have been examined under the Paperwork Reduction Act of 1980 and have been found to contain no information collection requirements.

Assessment of Educational Impact

In the notice of proposed rulemaking, the Secretary requested comments on whether the proposed regulations would require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

Based on the response to the proposed rules and on its own review, the Department has determined that the regulations in this document do not require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

List of Subjects in 34 CFR Part 650

Colleges and universities, Education, Fellowships, Grant program-education, Reporting and recordkeeping.

(Catalog of Federal Domestic Assistance Number 84.173—Jacob K. Javits Fellows Program)

Dated: July 21, 1987.

William J. Bennett,

Secretary of Education.

The Secretary amends Part 650 of Title 34 of the Code of Federal Regulations as follows:

PART 650—JACOB K. JAVITS FELLOWS PROGRAM

1. The authority citation for Part 650 is revised to read as follows:

Authority: 20 U.S.C. 1134h–1134k, unless otherwise noted.

2. All references to "National Graduate Fellows Program" throughout Part 650 are revised to read "Jacob K. Javits Fellows Program".

3. In § 650.1, the current text is designated as paragraph (a) and a new paragraph (b) is added to read as follows:

§ 650.1 What is the Jacob K. Javits Fellows Program?

* * * * *

(b) Students awarded fellowships under this program are called Jacob K. Javits Fellows.

(Authority: 20 U.S.C. 1134)

4. Section 650.2 is amended by revising paragraph (b)(4) to read as follows:

§ 650.2 Who is eligible to apply for a fellowship under this program?

* * * * *

(b) * * *

(4) Is a permanent resident of the Trust Territory of the Pacific Islands; and

* * * * *

5. In § 650.4, the definition of "Fellowship Board" is amended by revising the word "President" to read "Secretary", the references to "1956" in the definition of "Act" is revised to read "1965", and the definition of "Fellow" is revised to read as follows:

§ 650.4 What definitions apply to the Jacob K. Javits Fellows Program?

* * * * *

"Fellow" means a recipient of a Jacob K. Javits fellowship under this part.

* * * * *

6. Section 650.5 is amended by revising paragraph (b) to read as follows:

§ 650.5 What does a fellowship award include?

* * * * *

(b) An annual allowance paid to the institution in which the fellow is enrolled of $6000.

* * * * *

§ 650.33 [Amended]

7. In § 650.33, paragraphs (a)(3) and (b) are removed; the designation "(a)" is removed from the introductory text; paragraph (a)(1) is amended by adding "and" at the end of the paragraph; paragraph (a)(2) is amended by removing "; and" and adding a period in its place, and paragraphs (a)(1) and (a)(2) are redesignated as paragraphs (a) and (b) respectively.

8. Section 650.42 is revised to read as follows:

§ 650.42 How are stipends to be administered?

(a) Except as provided in paragraph (c) of this section, an institution shall calculate the amount of a fellow's financial need annually in the same manner as that in which the institution calculates its students' financial need under Part F of Title IV of the Act. For this purpose the institution shall not treat—

(1) Any instructional costs covered by the institutional allowance under § 650.41, as costs of attendance; or

(2) Income derived from a fellow's teaching and research assistantship, that is a required part of the fellow's academic program, as income.

(b) The institution shall pay the fellow a stipend in the amount of the fellow's financial need or $10,000, whichever is less.

(c) For a fellowship initially awarded in fiscal year 1986, the institution shall, in fiscal year 1987 and in each subsequent fiscal year for the duration of the fellowship, calculate the amount of a fellow's financial need under the procedure in paragraph (a) of this section, except that—

(1) Subject to the provisions of paragraphs (c) (2) and (3) of this section, a fellow qualifies as an independent student for an award year if the fellow—

(i) Does not, during any of the relevant years described in paragraph (c)(2) of this section, live for more than six weeks in the home of his or her parent(s) for whom income must be reported;

(ii) Is not, for any of the relevant years described in paragraph (c)(2) of this section, claimed as a dependent for Federal income tax purposes by those parent(s); and

(iii) Does not, during any of the relevant years described in paragraph (c)(2) of this section, receive financial assistance of more than $750 from those parent(s).

(2) Except as provided in paragraph (c)(3) of this section, to qualify as an independent student for any award year—

(i) An unmarried fellow must satisfy the criteria in paragraph (c)(1) of this section for the first calendar year of an award year and the preceding calendar year; and

(ii) A married fellow must satisfy the criteria in paragraph (c)(1) of this section for the first calendar year of the award year.

(3) The Secretary considers any fellow to be an independent student if, before the end of the award year—

(i) The fellow's parents die; or

(ii) The fellow is declared a ward of the court.

(4) As used in this paragraph—

(i) "Award year" means the period of time from July 1 through June 30 of the following year.

(ii) "Parent" means a fellow's natural or adoptive mother or father. A parent also includes a fellow's legal guardian who has been appointed by a court and who is specifically required by the court to use his or her own resources to support the fellow.

(iii) "Parent(s) for whom income must be reported" means a parent for whom income must be reported under the Pell Grant Program regulations, 34 CFR 690.33, as in effect on July 1, 1986. For this purpose, the references in § 690.33 to the date of the fellow's application are considered references to the date the fellow applies for a determination of need under Part F of Title IV of the Act.

(d) If a fellow is enrolled for less than a full academic year, the institution shall pay the fellow a pro rata share of the stipend.

(Authority: 20 U.S.C. 1134j)

[FR Doc. 87-17874 Filed 8-5-87; 8:45 am]

BILLING CODE 4000-01-M

federal register

Thursday
August 6, 1987

Part III

Department of Housing and Urban Development

Office of the Assistant Secretary for Public and Indian Housing

24 CFR Parts 905 and 990
Technical Changes to Performance Funding System; Final Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Public and Indian Housing

24 CFR Parts 905 and 990

[Docket No. R-87-1343; FR-2355]

Technical Changes to Performance Funding System

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Final rule.

SUMMARY: This rule will permit public housing agencies (PHAs) that receive under $25,000 per year in Federal financial assistance to obtain operating subsidy to cover the cost of an annual independent audit, as do the PHAs that receive at least $25,000 per year in Federal financial assistance, even though such an audit is no longer required by HUD regulations for these PHAs. The rule will also remove an obsolete requirement that rentals payable to a PHA must equal at least one-fifth of the incomes of all the families.

EFFECTIVE DATE: October 12, 1987.

FOR FURTHER INFORMATION CONTACT: John Comerford, Financial Management Division, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 426-1872. (This is not a toll-free telephone number.)

SUPPLEMENTARY INFORMATION: The change to permit audit costs to be covered by operating subsidy for PHAs receiving less than $25,000 in any PHA fiscal year is needed because the current rule (§ 990.108(a)) permits coverage for "the cost of the required IPA audit". Since amendment of 24 CFR Part 44 to implement the Single Audit Act of 1984 (effective November 1, 1985), IPA audits have not been "required" for PHAs receiving less than $25,000 annually in Federal financial assistance, which is defined in Part 44 to include grants (such as operating subsidy, annual contributions for debt service, and modernization funds), loans, loan guarantees, property, cooperative agreements, interest subsidies, insurance or direct appropriations. Before that change, PHAs receiving less than $25,000 annually had been required to obtain an IPA audit and were therefore eligible for operating subsidy specifically to cover the costs of a biennial IPA audit. Since the change to implement the Single Audit Act of 1984 changed the effect of § 990.108 only incidentally—and unintentionally—to eliminate eligibility for subsidy to cover IPA audit costs for these PHAs, this amendment is being made to restore eligibility for such PHA's audit costs. A related change included in this rulemaking is to replace the term "IPA audit" with "independent audit", the meaning given to "IPA audit" in 24 CFR Part 44. This term is used in §§ 905.311, 990.104 and 990.108.

Other technical changes are to add a cross-reference in § 990.109(e)(1), dealing with estimated investment income, to the year end adjustment of estimated investment income found in § 990.110 and to remove § 990.114 in its entirety as obsolete since the implementation in 1985 of statutorily-fixed rents for tenants based on their income.

Justification for Final Rule

It is the policy of this Department to publish for comment, rules relating to public property, loans, grants, benefits, or contracts, despite the exemption for these rules contained in 5 U.S.C. 553 from the requirement to solicit public comment. However, under 24 CFR Part 10, in a particular case, the Department may omit solicitation of public comment before publishing a final rule if comment is not required by statute and solicitation and consideration of public comment are "impracticable, unnecessary or contrary to the public interest."

In this case, the changes being made are technical in nature. The change with respect to "required" audits has substantive impact, but it is beneficial to program participants, restoring eligibility for subsidy to cover audits as a separate item of funding for certain PHAs who were eligible for funding of audits before November 1, 1985. Therefore, the Department has concluded that solicitation of comment is not required by statute and is unnecessary, and that the delay in effectiveness that would be caused by solicitation of comment would be contrary to the public interest.

Findings and Certifications

Environmental Review

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations at 24 CFR Part 50 that implement section 102(2)(C) of the National Environmental Policy Act of 1969, 42 U.S.C. 4332. The Finding of No Significant Impact is available for public inspection and copying during regular business hours in the Office of the Rules Docket Clerk, Room 10276, 451 Seventh Street, SW., Washington, DC 20410.

Regulatory Impact

This rule does not constitute a "major rule" as that term is defined in section 1(b) of the Executive Order on Federal Regulation issued by the President on February 17, 1981 (E.O. 12291). Analysis of the rule indicates that it does not: (1) Have an annual effect on the economy of $100 million or more; (2) cause a major increase in prices for consumers, individual industries, Federal, State or local government agencies or geographic regions; or (3) have a significant adverse effect 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.

Impact on Small Entities

Under 5 U.S.C. 605(b) (the Regulatory Flexibility Act), the undersigned hereby certifies that this rule does not have a significant economic impact on a substantial number of small entities, because it consists of technical refinements to existing rules concerning eligibility for public housing operating subsidy.

Regulatory Agenda

This rule was not listed in the Department's Semiannual Regulatory Agenda published on April 27, 1987 (52 FR 14362), under Executive Order 12291 and the Regulatory Flexibility Act.

Paperwork Reduction Act

This rule contains no information collection requirements, as described in the Paperwork Reduction Act of 1980 (44 U.S.C. 3501-3520).

Catalog

The Catalog of Federal Domestic Assistance Program Number is 14.850, Lower Income Housing Assistance Program (Public Housing).

List of Subjects

24 CFR Part 905

Grant programs: Indians, Low and moderate income housing, Public housing, Homeownership.

24 CFR Part 990

Low and moderate income housing, Public housing.

Accordingly, HUD amends 24 CFR Parts 905 and 990 as follows:

PART 905—INDIAN HOUSING

1. The authority citation for Part 905 continues to read as follows:

Authority: Secs. 3, 4, 5, 6, 9, 11, 12 and 16, U.S. Housing Act of 1937 (42 U.S.C. 1437a, 1437b, 1437c, 1437d, 1437g, 1437i, 1437j, 1437n); sec. 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

§ 905.311 [Amended]

2. Section 905.311(b) is amended by removing the words "costs of Independent Public Accountant audits" and replacing them with the words "cost of an independent audit".

PART 990—ANNUAL CONTRIBUTIONS FOR OPERATING SUBSIDY

3. The authority citation for Part 990 continues to read as follows:

Authority: Sec. 9, U.S. Housing Act of 1937 (42 U.S.C. 1437g); sec. 7(d), Department of HUD Act (42 U.S.C. 3535(d)).

§ 990.104 [Amended]

4. Section 990.104(a) is amended by removing the words "costs of Independent Public Accountant (IPA) audits" and replacing them with the words "cost of an independent audit", and by removing the words "the IPA" and replacing them with the words "an independent"

§ 990.105 [Amended]

5. Section 990.105(a)(2) is amended by removing the words "IPA audits" and replacing them with the words "an independent audit".

6. Section 990.108 is amended by revising paragraph (a) to read as follows:

§ 990.108 Other costs.

(a) *Cost of independent audits.* (1) Eligibility to receive operating subsidy for independent audits is considered separately from the PFS. However, the PHA shall not request, nor will HUD approve, an operating subsidy for the cost of an independent audit if the audit has been funded by subsidy in a prior year or the subsidy would create residual receipts after provision for the operating reserve. The PHA's estimate of cost of the independent audit is subject to adjustment by HUD. If the PHA requires assistance in determining the amount of cost to be estimated, the HUD Field Office should be contacted.

(2) A PHA that is required by the Single Audit Act (see 24 CFR Part 44) to conduct a regular independent audit may receive operating subsidy to cover the cost of the audit. The amount shall be prorated between the PHA's Development Cost Budget and its annual Operating Budget, as appropriate. The estimated cost of an independent audit, applicable to the operations of PHA-owned rental housing, is not included in the Allowable Expense Level, but it is allowed in full in computing the amount of operating subsidy under § 990.104, above.

(3) A PHA that is exempt from the audit requirements under the Single Audit Act (24 CFR Part 44) may receive operating subsidy to offset the cost of an independent audit chargeable to operations (after the End of the Initial Operating Period) if the PHA chooses to have an audit.

* * * * *

§ 990.109 [Amended]

7. Section 990.109 is amended by adding, at the end of paragraph (e)(1), the following sentence: See § 990.110(b).

§ 990.114 [Removed]

8. Section 990.114 is removed.

Dated: July 30, 1987.

James E. Baugh,

General Deputy Assistant Secretary for Public and Indian Housing.

[FR Doc. 87-17888 Filed 8-5-87; 8:45 am]

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S.J. Res. 151/Pub. L. 100-82

To designate August 1, 1987, as "Helsinki Human Rights Day." (Aug, 4, 1987; 101 Stat. 545; 4 pages) Price: $1.00