2-2-82
Vol. 47 No. 22
Pages 4673-4978

federal register

Tuesday
February 2, 1982

Highlights

CONTINUED INSIDE

Highlights

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 Service, General Services Administration, Washington, D.C. 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, D.C. 20402.

The **Federal Register** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders and Federal agency documents having general applicability and legal effect, documents required to be published by Act of Congress and other Federal agency documents of public interest. Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless earlier filing is requested by the issuing agency.

The **Federal Register** will be furnished by mail to subscribers, free of postage, for $75.00 per year, or $45.00 for six months, payable in advance. The charge for individual copies is $1.00 for each issue, or $1.00 for each group of pages as actually bound. Remit check or money order, made payable to the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

There are no restrictions on the republication of material appearing in the **Federal Register.**

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

Contents

Federal Register

Vol. 47, No. 22

Tuesday, February 2, 1982

MEETINGS ANNOUNCED IN THIS ISSUE

HEARINGS

CFR PARTS AFFECTED IN THIS ISSUE

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

Federal Register
Vol. 47, No. 22
Tuesday, February 2, 1982

Presidential Documents

Title 3—
The President

Proclamation 4893 of January 28, 1982

Bicentennial Year of the American Bald Eagle and National Bald Eagle Day

By the President of the United States of America

A Proclamation

Whether silhouetted against the sky on a rocky pinnacle in Alaska or soaring majestically overhead in Florida, the bald eagle is admired as one of nature's most spectacular creatures.

To catch a glimpse of this majestic raptore is to understand why the Founding Fathers chose it to represent the strength and courage of our great Nation. Its grace and power in flight, its vigilance and loyalty in defending its family group, and, most of all, its courage make the eagle a proud and appropriate symbol for the United States. Its presence on the Great Seal of the United States—one talon extending the olive branch of peace, the other brandishing the arrows of defense—is a symbol of friendship and cooperation to our allies and a warning to our adversaries that we are not to be trod upon.

No one is certain what the original United States population of the bird was, although it may have approached 75,000–100,000. We do know, however, that its extinction has become a disheartening possibility in recent years.

We have sought to prevent that possibility by restricting the use of certain pesticides. Shooting and habitat destruction are also being brought under control as a result of protection and conservation programs conducted under the Bald Eagle Protection Act and the Endangered Species Act. Scientists believe we are now beginning to see a subtle but definite population increase through the cooperative efforts of Federal and State fish and wildlife agencies, conservation and industrial groups, scientists, and private citizens. These efforts are truly indicative of the spirit of cooperation and perseverance which is at the very heart of our national character.

On June 20, 1782, the bald eagle became our Nation's symbol and national bird. As we approach the bicentennial anniversary of that event, we have an excellent opportunity to pause and reflect upon the importance of the bald eagle, indeed of all our fish and wildlife resources, to a healthy America. On this occasion, let us renew our commitment and dedication to the conservation of our natural heritage as symbolized by the bald eagle.

NOW, THEREFORE, I, RONALD REAGAN, President of the United States of America, in accordance with a joint resolution of the Congress (S.J. Res. 121), do hereby proclaim June 20, 1982 as "National Bald Eagle Day" and designate the year 1982 as the "Bicentennial Year of the American Bald Eagle." I call upon the people of the United States to join in these observances with appropriate activities in their homes and communities.

IN WITNESS WHEREOF, I have hereunto set my hand this 28th day of January in the year of our Lord nineteen hundred and eighty-two, and of the Independence of the United States of America the two hundred and sixth.

Ronald Reagan

[FR Doc. 82-2767
Filed 1-29-82; 2:15 pm]
Billing code 3195-01-M

Rules and Regulations

Federal Register
Vol. 47, No. 22
Tuesday, February 2, 1982

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

Gypsy Moth Regulated Areas

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of final rules.

SUMMARY: This action affirms two final rules which amended the list of gypsy moth regulated areas (regulated areas are divided into high-risk areas and low-risk areas) under the Federal Gypsy Moth and Browntail Moth Quarantine and Regulations by (1) designating previously nonregulated areas in Maryland and New York as gypsy moth high-risk areas; (2) by redesignating areas in Connecticut, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, and Vermont from gypsy moth low-risk areas to gypsy moth high-risk areas; (3) by designating previously nonregulated areas in Illinois, Maryland, Michigan, and Ohio as gypsy moth low-risk areas; and (4) deleting areas in Maryland, Michigan, New York, and Ohio from the list of gypsy moth regulated areas. These actions are necessary in order to prevent the artificial spread interstate of gypsy moth and to eliminate the imposition of unnecessary restrictions on the interstate movement of certain articles.

EFFECTIVE DATE: February 2, 1982.

FOR FURTHER INFORMATION CONTACT: T. J. Lanier, Chief Staff Officer, Regulatory Support Staff, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Federal Building, 6505 Belcrest Road, Room 635, Hyattsville, MD 20782, (301) 436–8247.

SUPPLEMENTARY INFORMATION:

Executive Order 12291

The final rules have been determined to be not "major rules" under Executive Order 12291 and Secretary's Memorandum 1512–1. Based on information compiled by the Department, it has been determined that the rules will have, together, an annual effect on the economy of approximately $126,000; that the rules will not cause a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; and that these rules will not 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.

Alternatives were considered in connection with the final rules. Consideration was given, with regard to those areas where gypsy moth no longer occurs, whether to (1) delete restrictions on the interstate movement of regulated articles, or (2) to continue restrictions from these regulated areas on the interstate movement of regulated articles. Alternative (1) is adopted because it appears that otherwise there would be unnecessary restrictions on the movement of gypsy moth regulated articles where gypsy moth no longer occurs. With regard to those areas where gypsy moth has spread or is likely to spread, consideration was given whether to (1) impose restrictions on the interstate movement of regulated articles, or (2) to continue to allow the interstate movement of regulated articles without restrictions. Alternative (1) was adopted because it appears that otherwise there would be a significant threat of spread of gypsy moth throughout the United States. Under these circumstances, it appears that the final rules are cost effective. Also, it appears that the final rules maximize the net benefits to society at the lowest net cost.

Background

A document published in the **Federal Register** on April 9, 1981, (46 FR 21143–21144), amended 7 CFR 301.45–2a, by amending the list of gypsy moth regulated areas (regulated areas are divided into high-risk areas and low-risk areas) under the Federal Gypsy Moth and Browntail Moth Quarantine and Regulations. The list of the regulated areas was amended by (1) designating previously nonregulated areas in Maryland and New York as gypsy moth high-risk areas; (2) by redesignating areas in Connecticut, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, and Vermont from gypsy moth low-risk areas to gypsy moth high-risk areas; (3) by designating previously nonregulated areas in Illinois, Maryland, Michigan, and Ohio as gypsy moth low-risk areas; and (4) deleting areas in Maryland, Michigan, New York, and Ohio from the list of gypsy moth regulated areas.

A document published in the **Federal Register** on April 29, 1981 (46 FR 23914–23915) amended 7 CFR 301.45–2a by amending the list of gypsy moth regulated areas to add the town of Penfield in Monroe County, New York, and to add all of Orange County, New York, to the list of gypsy moth high-risk areas.

The amendments became effective on the dates of publication. The documents provided that the amendments were necessary as emergency measures in order to prevent the artificial spread interstate of gypsy moth and to delete unnecessary restrictions on the interstate movement of certain articles.

Comments were solicited for 60 days after publication of the amendments. Three written comments were received in response to the emergency final rule published in the **Federal Register** on April 9, 1981. Two of these comments were in favor of the emergency amendment, one of which was from a representative of the Ohio Department of Agriculture and the other from a representative of a public interest organization.

The third comment was received from a representative of the North Carolina Department of Agriculture objecting to Avery County, North Carolina, being regulated and listed as a low-risk area. The state contended that the criteria used to list low-risk areas for gypsy moth finds geographically removed from the generally infested area should not be the same as those finds not geographically removed from such areas. Also, by listing Avery County as a regulated area, it creates an impression that an infestation occurs there. No changes are made in this

amendment based on this comment since this amendment was not considering whether to change the criteria for determining whether an area is to be regulated or designated as a high-risk or low-risk area under the regulations. This amendment was concerned only with the question of whether the gypsy moth finds in Avery County meet the criteria of infestation for classifying the area as a low-risk area. A determination by the Department was made that it did. Consequently, Avery County was listed as a low-risk area by the Department in order to provide official notice of the likelihood that inspectors may conduct inspections in such areas and, based on the life stage findings, the movement of regulated articles may be regulated.

No comments were received in response to the emergency final rule published in the **Federal Register** on April 29, 1981.

It appears that the factual situations which were set forth in the documents of April 9, 1981, and April 29, 1981, still provide a basis for the amendment. Accordingly, it has been determined that the final rules should remain effective as published in the **Federal Register** on April 9, 1981, and April 29, 1981.

(Secs. 8 and 9, 37 Stat. 318, as amended; 7 U.S.C. 161, 162; 37 FR 28464, 28477, as amended; 38 FR 19141)

Done at Washington, D.C., this 28th day of January 1982.

Harvey L. Ford,

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

[FR Doc. 82-2715 Filed 2-1-82; 8:45 am]

BILLING CODE 3410-34-M

NUCLEAR REGULATORY COMMISSION

10 CFR Part 9

Privacy Act Regulations; Notice of Exemptions; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule; correction and clarification.

SUMMARY: The Nuclear Regulatory Commission is amending 10 CFR 9.95, Specific Exemptions, to identify more properly the pertinent Systems of Records and to correct the names of two of the 15 Systems of Records which contain exempt records.

EFFECTIVE DATE: February 2, 1982.

FOR FURTHER INFORMATION CONTACT: J. M. Felton, Director, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492-27211.

SUPPLEMENTARY INFORMATION: In order to update and clarify the information contained in 10 CFR 9.95, it is necessary to add the numerical designations for the NRC Systems of Records and to correct the names of two of the Systems of Records which contain exempt records. For purposes of convenience, the 15 exempted systems have been rearranged in numerical order.

Because these corrections and clarifications relate solely to minor procedural matters, good cause exists for omitting notice of proposed rulemaking and for making the amendments effective immediately upon publication without the customary 30-day notice.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552, 552a and 553 of Title 5 of the United States Code, as amended, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 9, are published as a document subject to codification.

PART 9—PUBLIC RECORDS

1. The citation of authority is revised to read as follows:

Authority: Sec. 161, Pub. L. 83-703, 68 Stat. 948 (42 U.S.C. 2201); sec. 201, Pub. L. 93-438, 88 Stat. 1242 (42 U.S.C. 5841).

Subpart A also issued under 5 U.S.C. 552; Subpart B also issued under 5 U.S.C. 552a; Subpart C also issued under 5 U.S.C. 552b.

2. Section 9.95 is revised to read as follows:

§ 9.95 Specific exemptions.

The following records, contained in the designated NRC Systems of Records (NRC-1, NRC-5, NRC-6, NRC-9, NRC-11, NRC-18, NRC-22, NRC-23, NRC-28, NRC-29, NRC-31, NRC-33, NRC-37, NRC-39, and NRC-40) are exempt from 5 U.S.C. a(c)(e); (d); (e)(i); (e)(4)(G), (H), (I), and (f) in accordance with 5 U.S.C. 552a(k). Each of these records is subject to the provisions of § 9.61 of this part:

(a) Appointment and Promotion Certification Records, NRC-1.

(b) Contracts Records Files, NRC-5.

(c) Development and Advancement for Regulatory Employees (DARE) Records, NRC-6.

(d) Equal Employment Opportunity Records Files, NRC-9.

(e) General Personnel Records (Official Personnel Folder and Related Records), NRC-11.

(f) Office of Inspector and Auditor Index File and Associated Records, NRC-18.

(g) Personnel Performance Appraisals, NRC-22.

(h) Personnel Research and Test Validation Records, NRC-23.

(i) Recruiting, Examining and Placement Records, NRC-28.

(j) Document Control System, NRC-29.

(k) Correspondence and Records Branch, Office of the Secretary, NRC-31.

(l) Special Inquiry File, NRC-33.

(m) Information Security Files and Associated Records, NRC-37.

(n) Personnel Security Files and Associated Records, NRC-39.

(o) Facility Security Support Files and Associated Records, NRC-40

Dated at Bethesda, Maryland, this 26th day of January 1982.

For the Nuclear Regulatory Commission.

William J. Dircks,

Executive Director for Operations.

[FR Doc. 82-2697 Filed 2-1-82; 8:45 am]

BILLING CODE 7590-01-M

SMALL BUSINESS ADMINISTRATION

13 CFR Part 101

[Revision 2, Amdt. 22]

Administration; Delegations of Authority To Conduct Program Activities in Field Office; Correction

AGENCY: Small Business Administration.

ACTION: Final rule; correction.

SUMMARY: This document corrects a final rule regarding changes to delegations of authority to conduct program activities in the field, which was published in the **Federal Register** on January 15, 1982 (47 FR 2305).

EFFECTIVE DATE: February 2, 1982.

FOR FURTHER INFORMATION CONTACT: Ronald Allen, Paperwork Management Branch, Small Business Administration, 1441 "L" Street, NW., Washington, D.C. 20416, (202) 653-8538.

SUPPLEMENTARY INFORMATION: In FR Doc. 82-980 appearing at page 2309 in the issue for Friday, January 15, 1982, Part IV, Section A, paragraph 1, line 6 now reading "8(a) matters accepted for litigation, exclusive * * *" should read "8(a) matters accepted for liquidation, exclusive * * *"

Part V, Section A, paragraph 2, line 5 now reading "Administrator for Management, and the * * *" should read "Administrator for Management Assistance, and the * * *"

Dated: January 26, 1982.

Ronald Allen,

Federal Register Liaison Officer.

[FR Doc. 82-2706 Filed 2-1-82; 8:45 am]

BILLING CODE 8025-01-M

DEPARTMENT OF COMMERCE

International Trade Administration

15 CFR Part 371

Shipper's Export Declaration Requirements for Shipments Under General License GLV

AGENCY: International Trade Administration, Commerce.

ACTION: Final rule; technical clarification.

SUMMARY: Section 371.5, "General License *GLV;* Shipments of Limited Value," is amended to clarify Shipper's Export Declaration (SED) requirements. A special provision is added to § 371.5 stating that the Export Control Commodity Number must be shown on the SED. This requirement is already stated in § 386.3(j)(2), and is therefore added to § 371.5 for clarity.

DATE: Effective February 2, 1982.

FOR FURTHER INFORMATION CONTACT: Mr. Archie Andrews, Director, Exporters' Service Staff, Office of Export Administration, Department of Commerce, Washington, D.C. 20230 (Telephone: (202) 377-4811).

SUPPLEMENTARY INFORMATION:

Rulemaking Requirements

Section 13(a) of the Export Administration Act of 1979 (Pub. L. 96-72, 50 U.S.C. app. 2401 *et seq.*) ("The Act") exempts regulations promulgated under the Act from the public participation in rulemaking procedures of the Administrative Procedure Act. Section 13(b) of the Act, which expresses the intent of Congress that to the extent practicable "regulations imposing controls on exports" be published in proposed form, is not applicable because these regulations do not impose new controls on exports. Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis.

In connection with various rulemaking requirements, the Office of Export Administration has determined that this rule does not impose an additional burden under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* This rule simply cross-references an existing requirement found in the regulations so that the regulations can be simplified and compliance with them can be easier. The Shipper's Export Declaration has received OMB clearance number 0607-0018. This rule is not subject to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 3501 *et seq.* This regulation is not a major rule within the meaning of section 1(b) of Executive Order 12291 (46 FR 13193, February 19, 1981).

PART 371—GENERAL LICENSES

Accordingly, § 371.5 of the Export Administration Regulations (15 CFR Parts 368-399) is amended by adding a new paragraph (e), reading as follows:

§ 371.5 General license GLV; shipments of limited value.

* * * * *

(e) *Special Provision.* In addition to the general license designation GLV, the Export Control Commodity Number, which in this case identifies a commodity that is eligible to be shipped under General License *GLV,* shall be shown in parentheses immediately below the Schedule B Number on the SED.

(Secs. 13, 15, and 21, Pub. L. 96-72, 93 Stat. 503, 50 U.S.C. app. 2401 *et seq.*; Executive Order No. 12214 (45 FR 29783, May 6, 1980); Department Organization Order 10-3 (45 FR 6141, January 25, 1980); International Trade Administration Organization and Function Orders 41-1 (45 FR 11862, February 22, 1980) and 41-4 (45 FR 65003, October 1, 1980))

Dated: January 8, 1982.

Vincent F. DeCain,

Acting Director, Office of Export Administration, International Trade Administration.

[FR Doc. 82-2665 Filed 2-1-82; 8:45 am]

BILLING CODE 3510-25-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 81

[Docket No. 76N-0366]

Provisional Listing of D&C Green No. 6; Postponement of Closing Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is postponing the closing date for the provisional listing of D&C Green No. 6 for use as a color additive in externally applied drugs and cosmetics. The new closing date will be March 31, 1982. This brief postponement will provide time for determining the applicability of the statutory standard for the listing of color additives to the results of scientific investigations of D&C Green No. 6.

EFFECTIVE DATE: Effective January 30, 1982, the new closing date for D&C Green No. 6 will be March 31, 1982.

FOR FURTHER INFORMATION CONTACT: Garnett R. Higginbotham, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: The current closing date of January 30, 1982, for the provisional listing of D&C Green No. 6 was established by a regulation published in the **Federal Register** of December 4, 1981 (46 FR 59235). This closing date for D&C Green No. 6 was established to provide time for completion of FDA's review and evaluation of the data concerning the external uses of D&C Green No. 6, for determining the applicability of the statutory standard for the listing of color additives to D&C Green No. 6, and for publication of a regulation in the **Federal Register** regarding the final decision on the petition for the permanent listing of this color additive. The regulation set forth below will postpone the January 30, 1982 closing date for the provisional listing of the color additive until March 31, 1982.

The review and evaluation of the data relevant to the use of D&C Green No. 6 in externally applied drugs and cosmetics and the decision about how to apply the statutory standard for the listing of color additives to such data have required more time than anticipated. FDA concludes that the brief extension of the closing date to March 31, 1982, is necessary. The agency has also concluded that no harm to the public health will result from this extension.

Because of the shortness of time until the March 31, 1982 closing date, FDA concludes that notice and public procedure on this regulation are impracticable, and that good cause exists for issuing this postponement as a final rule.

This regulation will permit the uninterrupted use of the color additive until further action is taken. In accordance with 5 U.S.C. 553 (b) and (d) (1) and (3), this postponement is issued as a final regulation and is being made effective on January 30, 1982.

PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

§ 81.1 [Amended]

Therefore, under the Transitional Provisions of the Color Additive Amendments of 1960 to the Federal Food, Drug, and Cosmetic Act (Title II, Pub. L. 86–618, sec. 203, 74 Stat. 404–407 (21 U.S.C. 376 note)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), Part 81 is amended in § 81.1 *Provisional lists of color additives,* by revising the closing date for "D&C Green No. 6" in paragraph (b) to read "March 31, 1982".

Effective date. This regulation is effective January 30, 1982.

(Sec. 203, 74 Stat. 404–407 (21 U.S.C. 376 note))

Dated: January 18, 1982.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 82–2727 Filed 1–29–82; 10:44 am]

BILLING CODE 4160–01–M

---

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs Not Subject to Certification; Cloprostenol Sodium

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) sponsored by Bayvet Division of Cutter Laboratories, Inc., providing for the use of cloprostenol sodium injectable in beef cattle and nonlactating dairy heifers to induce luteolysis.

EFFECTIVE DATE: February 2, 1982.

FOR FURTHER INFORMATION CONTACT: Richard Carnevale, Bureau of Veterinary Medicine (HFV–125), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1778.

SUPPLEMENTARY INFORMATION: Bayvet Division of Cutter Laboratories, Inc., P.O. Box 390, Shawnee Mission, KS 66201, is the sponsor of a new animal drug application, NADA 113–645, for Estrumate (cloprostenol sodium). The NADA provides for the intramuscular use of cloprostenol sodium in beef cattle and nonlactating dairy heifers to induce luteolysis (i.e., the functional and morphological regression of the corpus luteum). The drug is used for scheduling the estrous cycle to control breeding and for terminating unwanted pregnancies which result from mismatings. The NADA is approved and the regulations are amended to reflect the approval.

The Bureau of Veterinary Medicine has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement therefore will not be prepared. The Bureau's finding of no significant impact and the evidence supporting this finding, contained in an environmental impact analysis report (pursuant to 21 CFR 25.1(j)) may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (address above), from 9 a.m. to 4 p.m., Monday through Friday.

This action is governed by the provisions of 5 U.S.C. 556 and 557 and is therefore excluded from Executive Order 12291 by section 1(a)(1) of the Order.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Part 522 is amended by adding new § 522.460 to read as follows:

§ 522.460 Cloprostenol sodium.

(a) *Specifications.* Each milliliter of the aqueous solution contains 263 micrograms of cloprostenol sodium (equivalent to 250 micrograms of cloprostenol) in a sodium citrate, anhydrous citric acid and sodium chloride buffer containing 0.1 percent w/v chlorocresol B.P. as a bactericide.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use.* For intramuscular use in beef cattle and nonlactating dairy heifers to induce luteolysis to schedule the estrous cycle or to terminate pregnancies from mismatings.

(1) *Amount.* 2 milliliters (equivalent to 500 micrograms of cloprostenol).

(2) *Indications.* (i) For scheduling estrus and ovulation to control the time at which cycling cows or heifers can be bred.

(*a*) Single cloprostenol injection. Treat only animals with a mature corpus luteum. Estrus should occur in 2 to 5 days, and cattle should be inseminated at the usual time relative to the detection of estrus. If estrus is not observed, treated animals may be inseminated either once at 72 hours post injection or twice at 72 and 96 hours post injection.

(*b*) Double cloprostenol injection. Give cattle a second injection 11 days after the first injection. Estrus should occur 2 to 5 days after the second injection, and cattle should be inseminated at the usual time relative to the detection of estrus. If estrus is not observed, treated animals may be inseminated either once at about 72 hours post injection or twice at 72 and 96 hours following the second injection.

(ii) For terminating unwanted pregnancies from 1 week after mating until 5 months after conception.

(3) Do not administer to pregnant animals where the calf is not to be aborted.

(4) Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. Cloprostenol is readily absorbed through the skin and may cause abortion and/or bronchospasms. Accidental spillage on the skin should be washed off immediately with soap and water.

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

Effective date. This regulation is effective February 2, 1982.

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

Dated: January 26, 1982.

Gerald B. Guest,

Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 82–2422 Filed 2–1–82; 8:45 am]

BILLING CODE 4160–01–M

---

21 CFR Part 546

Tetracycline Antibiotic Drugs for Animal Use; Tetracycline Boluses

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) providing revised labeling for a tetracycline hydrochloride bolus used for control or treatment of bacterial enteritis (scours) and bacterial pneumonia in calves. The application was filed by American Cyanamid Co., in compliance with the National Academy of Sciences/National Research Council (NAS/NRC), Drug Efficacy Study Group evaluation of the product. The regulations are further amended to increase the preslaughter withdrawal period from 12 to 14 days.

EFFECTIVE DATE: February 2, 1982.

FOR FURTHER INFORMATION CONTACT: Richard A. Carnevale, Bureau of Veterinary Medicine (HFV–125), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1788.

SUPPLEMENTARY INFORMATION: American Cyanamid Co., P.O. Box 400, Princeton, NJ 08540, filed a supplemental NADA (65–270) providing for oral use in calves of a 500-milligram (mg) tetracycline hydrochloride (TC HCl) oblet (bolus) for control and treatment of bacterial enteritis (scours) caused by *E. coli* and bacterial pneumonia caused by *Pasteurella spp., Hemophilus spp.,* and *Klebsiella spp.* The NADA was originally approved April 29, 1954, for treating bacterial enteritis, bacterial pneumonia, hemorrhagic septicemia, metritis, and other uterine or vaginal infections in cattle, sheep, and swine.

American Cyanamid's oblet, along with several other sponsors' TC HCl formulations, was the subject of a NAS/NRC evaluation, which published in the **Federal Register** of July 8, 1970 (35 FR 10966). In that document, the NAS/NRC evaluated the subject drug products as probably effective for, in addition to certain other uses, oral treatment of infected wounds and gastrointestinal and respiratory diseases in calves, sheep, and goats. The NAS/NRC also evaluated American Cyanamid's oblet as probably effective for intrauterine treatment of metritis, cervicitis, and vaginitis in cattle, swine, and sheep. The NAS/NRC further stated that:

1. Most of the dosage directions provided for a less-than-effective dose, and the recommended minimum oral dose for large animals is 10 milligrams per pound of body weight daily in divided doses.

2. Each disease claim should be properly qualified as "appropriate for use in (name of disease) caused by pathogens sensitive to (name of drug)," and if the disease cannot be so qualified, the claim must be dropped.

3. Claims made "for prevention of" or "to prevent" should be replaced with "as an aid in the control of" or "to aid in the control."

4. The manufacturer of boluses, oblets, or tablets must provide evidence that they disintegrate in the gastrointestinal tract of the medicated species to produce the desired therapeutic effect.

5. Information is needed from manufacturers of boluses or oblets recommended for insertion in the uterus with respect to the degree of disintegration within the uterus, the presence of hazardous foreign body ingredients, and the chemical compatibility of the vehicle and active agent or agents, and the labeling should also provide information regarding proper sanitary techniques for intrauterine administration.

6. Additional documentation of effectiveness is needed to establish activity against Clostridia in animals.

FDA concurred with the NAS/NRC findings.

The NAS/NRC evaluation was concerned only with the drug's effectiveness and safety to the animal being treated and did not take into account the safety of food derived from treated animals. The evaluation was published to inform NADA holders of the findings of the NAS/NRC and FDA and to inform all interested persons that such articles may be marketed, provided they are the subject of approved NADA's and otherwise comply with the requirements of the Federal Food, Drug, and Cosmetic Act.

American Cyanamid submitted a supplemental NADA (65–270), which complied with the above-enumerated NAS/NRC recommendations as follows:

1. The label carries the 10 milligrams per pound of body weight in divided doses for calves for treatment and control of disease.

2. Disease entities have been qualified as to causative pathogens, and these are sensitive to tetracycline. Many disease claims and several animal species have been deleted from the indications for use.

3. The labeling has been revised to read "for the control of" instead of "for the prevention of."

4. Evidence has been provided which demonstrates that the tablet disintegrates in the gastrointestinal tract of the medicated species to produce the desired therapeutic effect.

5. All claims for uterine infection have been deleted from the labeling.

6. All claims for Clostridia infection have been deleted from the labeling.

American Cyanamid's labeling revisions and submission of data updating the manufacturing and controls portion of the NADA have substantiated upgrading the classification from probably effective to effective. Accordingly, the supplemental NADA is approved, and 21 CFR 546.180c is amended to reflect the approval. The product's dosage is increased, in compliance with NAS/NRC recommendations. American Cyanamid submitted new residue depletion data; based on these data the slaughter withdrawal period is increased from 12 to 14 days. Therefore, the subject regulation is further amended to reflect the new withdrawal period and also to reflect current format.

Because the dosage level is increased, this is a category II supplement under the Bureau of Veterinary Medicine's supplemental approval policy (42 FR 64367; December 3, 1977). However, the Bureau has determined that there will be no increased risk of human exposure because the residue studies submitted by the sponsor show that, with the extended withdrawal period, there is no increased risk of residues occurring. Consequently, this approval does not require reevaluation of the human safety data in the original approval.

NADA's that pertain to identical products and that are labeled for control and treatment of bacterial enteritis and bacterial pneumonia as set forth in the regulation do not require efficacy data as specified by 21 CFR 514.1(b)(8)(ii) or 514.111(a)(5)(vi). In lieu of such data, approval may require bioequivalency and safety data as suggested in the guideline for submitting NADA's for NAS/NRC-reviewed generic drugs. The guideline is available from the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

The Bureau of Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(i) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This action is governed by the provisions of 5 U.S.C. 566 and 557 and is therefore excluded from Executive Order 12291 by section 1(a)(1) of the Order.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of

safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (address above), from 9 a.m. to 4 p.m., Monday through Friday.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i) and (n), 82 Stat. 347, 350–351 (21 U.S.C. 360b(i) and (n)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Part 546 is amended by revising § 546.180c, to read as follows:

PART 546—TETRACYCLINE ANTIBIOTIC DRUGS FOR ANIMAL USE

§ 546.180c. Tetracycline boluses.

(a) *Requirements for certification.* The requirements for certification for tetracycline boluses are described under § 546.110d(a).

(b) *Tests and methods of assay.* The tests and methods of assay for tetracycline boluses are described under § 546.110d(b).

(c) *Conditions of marketing.*—(1) *Specifications.* Tetracycline boluses conform to the standards of identity, strength, quality, and purity prescribed by § 546.110d.

(2) *Sponsors.* See drug labeler codes in § 510.600(c) of this chapter for identity of sponsors as follows:

(i) No. 010042 for use of 500-milligram boluses as in paragraph (c)(6)(i) of this section.

(ii) No. 000009 for use of 500-milligram boluses as in paragraph (c)(6)(ii) of this section.

(3) *Special considerations.* The quantity of tetracycline in paragraph (c)(2) (i) and (ii) of this section refers to the activity of tetracycline hydrochloride.

(4) *Related tolerances.* See § 556.720 of this chapter.

(5) *NAS/NRC status.* The conditions of use specified in paragraph (c)(6)(i) of this section are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in § 514.111 of this chapter, but may require bioequivalency and safety information.

(6) *Conditions of use.* It is used as tetracycline hydrochloride in calves as follows:

(i) *Amount.* 10 milligrams per pound of body weight per day in divided doses.

(*a*) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *E. coli* and bacterial pneumonia caused by *Pasteurella spp., Hemophilus spp.,* and *Klebsiella spp.*

(*b*) *Limitations.* Administer orally for 3 to 5 days; do not slaughter animals for food within 14 days of treatment; use as sole source of tetracycline; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) *Amount.* 10 milligrams per pound of body weight per day divided into two daily doses.

(*a*) *Indications for use.* Treatment of bacterial pneumonia caused by organisms susceptible to tetracycline and bacterial enteritis caused by *E. coli* and salmonella organisms susceptible to tetracycline.

(*b*) *Limitations.* Administer orally for not more than 5 days; do not slaughter animals for food within 12 days of treatment; use as sole source of tetracycline; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Effective date. February 2, 1982.

(Sec. 512(i) and (n), 82 Stat. 347, 350–351 (21 U.S.C. 360b(i) and (n)).)

Dated: January 26, 1982.

Robert A. Baldwin,

Associate Director for Scientific Evaluation.

[FR Doc. 82-2488 Filed 2-1-82; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 5e

[T.D. 7802]

Travel Expenses of Members of Congress

AGENCY: Internal Revenue Service, Treasury.

ACTION: Correction to temporary regulations.

SUMMARY: This document contains corrections to the **Federal Register** publication for January 21, 1982, beginning at 47 FR 2986 of the temporary regulations which were the subject of Treasury Decision 7802, relating to deductions for Members of Congress for travel expenses in Washington, D.C.

EFFECTIVE DATE: The regulations are effective for taxable years beginning after December 31, 1980. This correction is to be effectice the same date.

FOR FURTHER INFORMATION CONTACT: Jason R. Felton of the Legislation and Regulations Division, Office of Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, D.C. 20224, Attention: CC:LR:T, 202–566–3318, not a toll-free call.

SUPPLEMENTARY INFORMATION:

Background

On January 21, 1981, temporary income tax regulations under section 113(b) of the Black Lung Benefits Revenue Act of 1981 were published in the **Federal Register** (47 FR 2986). These regulations amended the regulations under section 274 of the Internal Revenue Code of 1954 by adding regulations § 5e.274–8, Travel Expenses of Members of Congress.

Need for a Correction

As published, the temporary regulations which were the subject of Treasury Decision 7802 inaccurately identify the section in Title 5 of the United States Code that concerns the subsistence for Washington, D.C., that is payable to a Member of Congress. That section of the United States Code is to be utilized in determining the amount of travel expenses that may be deducted without substantiation. This error appears on page 2987 in the right-hand column in subdivisions (i) and (ii) of paragraph (c)(1). In both locations, the references to "5 U.S.C. 5707(c)" should read "5 U.S.C. 5702(c)".

Drafting Information

The principal author of this correction is Jason R. Felton of the Legislation and Regulations Division, Office of Chief Counsel, Internal Revenue Service.

Correction of Publication

PART 5e—TEMPORARY INCOME TAX REGULATIONS, TRAVEL EXPENSES OF MEMBERS OF CONGRESS

§ 5e.274–8 [Corrected]

Accordingly, the publication of the regulations which were the subject of FR Doc. 82–1267 is corrected in the last line of § 5e.274–8(c)(1)(i) and in the last line of § 5e.274–8(c)(1)(ii) at 47 FR 2987 by removing "5 U.S.C. 5707(c)" and inserting "5 U.S.C. 5702(c)" in lieu thereof

David E. Dickinson,

Director, Legislation and Regulations Division.

[FR Doc. 82-2716 Filed 2-1-82; 8:45 am]

BILLING CODE 4830-01-M

26 CFR Part 7

[T.D. 7805]

Temporary Income Tax Regulations; Use of Property That Has Been Valued Under Section 2032A to Satisfy a Pecuniary Bequest

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations.

SUMMARY: This document withdraws a portion of a notice of proposed rulemaking relating to the use of property that has been valued under section 2032A of the Internal Revenue Code of 1954 to satisfy a pecuniary bequest and adopts that portion of the same notice of proposed rulemaking relating to the removal from the Code of Federal Regulations of temporary carryover basis rules under Internal Revenue Code section 1023 for property acquired from a decedent. Although Code section 1023 has been repealed, its provisions and the temporary regulations being removed continue to apply in the case of a special election for property acquired from a decedent who died after December 31, 1976, and before November 7, 1978.

DATE: This document is effective February 2, 1982.

FOR FURTHER INFORMATION CONTACT: Stephen J. Small of the Legislation and Regulations Division, Office of Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, D.C. 20224, Attention: CC:LR:T, 202–566–3238, not a toll-free call.

SUPPLEMENTARY INFORMATION:

Background

On May 28, 1981, proposed amendments to the Income Tax Regulations (26 CFR Part 1) under section 1040 of the Internal Revenue Code of 1954 (Code) were published in the **Federal Register** (46 FR 28677). These amendments were proposed to conform the regulations to section 401(c)(2)(A) of the Crude Oil Windfall Profit Tax Act of 1980 (94 Stat. 300) which provided rules relating to the use of property that is valued under section 2032A to satisfy a pecuniary bequest.

The notice of proposed rulemaking also proposed to delete the temporary regulations found at §§ 7.1023(b)(3)–1 and 7.1023(h)–1 (26 CFR Part 7). These temporary regulations were deleted rather than revoked because they continue to be applicable for the estates of certain decedents whose executors or administrators elected carryover basis treatment for assets acquired or passing from decedents by filing Form 5970–A, Election of Carryover Basis.

Section 421(j)(2)(B) of the Economic Recovery Tax Act of 1981 (95 Stat. 312) amended retroactively section 1040 of the Code in such a substantive way by removing the restrictions relating to pecuniary bequests that the relevant portion of the notice of proposed rulemaking is no longer viable and must be withdrawn. The Internal Revenue Service anticipates issuing a new notice of proposed rulemaking under section 1040.

However, the deletion of the temporary carryover basis regulations remains appropriate, and that portion of the notice of proposed rulemaking is adopted by this Treasury decision.

The only comments received related to the portion of the notice that is being withdrawn. There was no request for a public hearing.

Drafting Information

The principal author of this regulation is Stephen J. Small of the Legislation and Regulations Division, Office of the Chief Counsel, 1111 Constitution Avenue, NW, Washington, D.C. However, personnel from other offices of the Internal Revenue Service and the Treasury Department participated in developing the regulation, both on matters of substance and style.

Adoption of Amendments to the Regulations

Accordingly, the amendments to the Income Tax Regulations (26 CFR Part 1) as proposed in paragraph 1 of the Notice of Proposed Rulemaking published on May 28, 1981 (46 FR 28677) are hereby withdrawn, and the amendments to the Temporary Income Tax Regulations under the Tax Reform Act of 1976 as proposed in paragraph 2 of that notice are hereby adopted.

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

Roscoe L. Egger, Jr.,

Commissioner of Internal Revenue

Approved: January 13, 1982.

John E. Chapoton,

Assistant Secretary of the Treasury.

PART 7—TEMPORARY INCOME TAX REGULATIONS UNDER THE TAX REFORM ACT OF 1976

Accordingly, §§ 7.1023(b(3)–1 and 7.1023(h)–1 are removed but not revoked.

§ 7.1023(b)(3)–1 Exclusion of certain personal and household effects from carryover basis treatment.

[Removed but not revoked.]

§ 7.1023(h)–1 Adjustment to basis of marketable bonds and securities acquired from a decedent dying after December 31, 1976, for appreciation occurring before January 1, 1977.

[Removed but not revoked.]

[FR Doc. 82–2243 Filed 2–1–82; 8:45 am]

BILLING CODE 4830–01–M

GENERAL SERVICES ADMINISTRATION

41 CFR Part 101–26

[FPMR Amendment E–249]

Procurement of Gasoline, Fuel Oil (Diesel and Burner), Kerosene, and Solvents

AGENCY: General Services Administration.

ACTION: Final rule.

SUMMARY: This amendment increases to 10,000 gallons the maximum annual amounts of gasoline, burner fuel oil, diesel oil, and kerosene that GSA and other agencies can procure without going through the Defense Logistics Agency's (DLA) Defense Fuel Supply Center by codifying FPMR Temporary Regulation E–71 and Supplement 1 thereto. This change will permit agencies to procure more bulk petroleum products from local sources through small purchase procedures, thereby making fuel more readily available where needed and allowing DLA to devote its time and effort to larger quantity and dollar volume procurements.

EFFECTIVE DATE: February 2, 1982.

FOR FURTHER INFORMATION CONTACT: Mr. Robert A. Renner, Director, Regulations Management Division (703–557–7970).

SUPPLEMENTARY INFORMATION: The General Services Administration has determined that this rule is not a major rule for the purposes of Executive Order 12291 of February 17, 1981, because it is not likely to result in an annual effect on the economy of $100 million or more; a major increase in costs to consumers or others; or significant adverse effects. The General Services Administration has based all administrative decisions underlying this rule on adequate information concerning the need for, and consequences of, this rule; has determined that the potential benefits to

society from this rule outweigh the potential costs and has maximized the net benefits; and has chosen the alternative approach involving the least net cost to society.

PART 101–26—PROCUREMENT SOURCES AND PROGRAMS

FPMR Temporary Regulation E–71 (45 FR 47149) and Supplement 1 (46 FR 31890) are canceled and deleted from the appendix at the end of Subchapter E, 41 CFR 101.

Section 101–26.602–3(a)(1) is revised to read as follows:

§ 101–26.602–3 Procurement of gasoline, fuel oil (diesel and burner), kerosene, and solvents.

(a) * * *

(1) Estimated annual requirements for any delivery point which total less than the following minimums shall not be submitted to the Defense Fuel Supply Center, unless the activity does not have authority or capability to procure locally.

Item	Minimum annual requirement (gallons)
Gasoline	10,000
Burner fuel oil	10,000
Diesel oil	10,000
Kerosene	10,000
Solvents	500

* * * * *

(Sec. 205(c), 63 Stat. 390; 40 U.S.C. 486(c))

Dated: January 18, 1982.

Ray Kline,

Acting Administrator of General Services.

[FR Doc. 82–2657 Filed 2–1–82; 8:45 am]

BILLING CODE 6820–24–M

FEDERAL EMERGENCY MANAGEMENT AGENCY

[Docket No. FEMA–5909]

44 CFR Part 70

Letter of Map Amendment for the City of Corpus Christi, Texas, under National Flood Insurance Program

AGENCY: Federal Emergency Management Agency.

ACTION: Final rule.

SUMMARY: The Federal Emergency Management Agency (FEMA) published a list of communities for which maps identifying Special Flood Hazard Areas have been published. This list included the City of Corpus Christi, Texas. It has been determined by the Associate Director, State and Local Programs and Support, after acquiring additional flood information and after further technical review of the Flood Insurance Rate Map for the City of Corpus Christi, that certain property is not within the Special Flood Hazard Area.

This map amendment, by establishing that the subject property is not within the Special Flood Hazard Area, removes the requirement to purchase flood insurance for that property as a condition of Federal or federally-related financial assistance for construction or acquisition purposes.

EFFECTIVE DATE: February 2, 1982.

FOR FURTHER INFORMATION CONTACT: Mr. Robert G. Chappell, P.E., Chief, Engineering Branch, Office of State and Local Programs and Support, Federal Emergency Management Agency, Washington, D.C. 20472, (202) 287–0270.

SUPPLEMENTARY INFORMATION: If a property owner was required to purchase flood insurance as a condition of Federal or federally-related financial assistance for construction or acquisition purposes, and the lender now agrees to waive the property owner from maintaining flood insurance coverage on the basis of this map amendment, the property owner may obtain a full refund of the premium paid for the current policy year, provided that no claim is pending or has been paid on the policy in question during the same policy year. The premium refund may be obtained through the insurance agent or broker who sold the policy, or from the National Flood Insurance Program (NFIP) at: P.O. Box 34294, Bethesda, Maryland 20034, Telephone: (800) 638–6620.

The map amendments listed below are in accordance with § 70.7(b):

Map No. H & I 485464B Panel 44, published on October 6, 1980, in 45 FR 66097, indicates that Lots 4 through 10, Block 1; Lots 1 through 7, Block 2; Lots 4 through 22, Block 4; and Lots 1 through 36, Block 5, Brandywine, Units 1B and 1C, Corpus Christi, Texas, as recorded in Volume 46, Page 134; and Volume 46 Pages 157 and 158 of Map Records, respectively, in the Office of the Clerk, Nueces County, Texas, are within the Special Flood Hazard Area.

Map No. H & I 485464B Panel 44 is hereby corrected to reflect that the above mentioned lots are not within the Special Flood Hazard Area identified on October 31, 1975. These lots are in Zone B.

Pursuant to provisions of 5 U.S.C. 605(b), the Associate Director, State and Local Programs and Support to whom authority has been delegated by the Director, Federal Emergency Management Agency, hereby certifies that this rule if promulgated will not have a significant economic impact on a substantial number of small entities. This rule provides routine legal notice of technical amendments made to designated special flood hazard areas on the basis of updated information and imposes no new requirements or regulations on participating communities.

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended; 42 U.S.C. 4001–4128; Executive Order 12127, 44 FR 19367; delegation of authority to Associate Director, State and Local Programs and Support)

Issued: December 31, 1981.

Lee M. Thomas,

Associate Director, State and Local Programs and Support.

[FR Doc. 82–2598 filed 2–1–82; 8:45 am]

BILLING CODE 6718–03–M

[Docket No. FEMA–6139]

44 CFR Part 70

Letter of Map Amendment for the City of Harker Heights, Texas, Under National Flood Insurance Program

AGENCY: Federal Emergency Management Agency.

ACTION: Final rule.

SUMMARY: The Federal Emergency Management Agency (FEMA) published a list of communities for which maps identifying Special Flood Hazard Areas have been published. This list included the City of Harker Heights, Texas. It has been determined by the Associate Director, State and Local Programs and Support, after acquiring additional flood information and after further technical review of the Flood Insurance Rate Map for the City of Harker Heights, that certain property is not within the Special Flood Hazard Area.

This map amendment, by establishing that the subject property is not within the Special Flood Hazard Area, removes the requirement to purchase flood insurance for that property as a condition of Federal or federally-related financial assistance for construction or acquisition purposes.

EFFECTIVE DATE: February 2, 1982.

FOR FURTHER INFORMATION CONTACT: Mr. Robert G. Chappell, P.E. Chief, Engineering Branch, Office of State and Local Programs and Support, Federal Emergency Management Agency, Washington, D.C. 20472, (202) 287–0270.

SUPPLEMENTARY INFORMATION: If a property owner was required to purchase flood insurance as a condition of Federal or federally-related financial assistance for construction or acquisition purposes, and the lender

now agrees to waive the property owner from maintaining flood insurance coverage on the basis of this map amendment, the property owner may obtain a full refund of the premium paid for the current policy year, provided that no claim is pending or has been paid on the policy in question during the same policy year. The premium refund may be obtained through the insurance agent or broker who sold the policy, or from the National Flood Insurance Program (NFIP) at: P.O. Box 34294, Bethesda, Maryland 20034, Telephone: (800) 638–6620.

The map amendments listed below are in accordance with § 70.7(b):

Map No. H & I 480029 Panel 0002B, published on September 25, 1981, in 46 FR 47226, indicates that Lots 2 through 11, Block 1; and Lots 3 through 10, Block 2, Preswick Hills, a 8.23 acre tract of land in the F. D. Cox Survey, Abstract Number 220, Harker Heights, Texas, as recorded in Plat Book 3, Page 2, in the Office of the Clerk, Bell County, Texas, are within the Special Flood Hazard Area.

Map No. H & I 480029 Panel 0002B is hereby corrected to reflect that the above mentioned lots are not within the Special Flood Hazard Area identified on August 3, 1981. These lots are in Zone C.

Pursuant to provisions of 5 U.S.C. 605(b), the Associate Director, State and Local Programs and Support to whom authority has been delegated by the Director, Federal Emergency Management Agency, hereby certifies that this rule if promulgated will not have a significant economic impact on a substantial number of small entities. This rule provides routine legal notice of technical amendments made to designated special flood hazard areas on the basis of updated information and imposes no new requirements or regulations on participating communities.

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended; 42 U.S.C. 4001–4128; Executive Order 12127, 44 FR 19367; delegation of authority to Associate Director, State and Local Programs and Support)

Issued: December 31, 1981.

Lee M. Thomas,

Associate Director, State and Local Programs and Support.

[FR Doc. 82–2599 Filed 2–1–82; 8:45 am]

BILLING CODE 6718–03–M

44 CFR Part 70

[Docket No, FEMA–5909]

Letter of Map Amendment for the City of Oklahoma City, Oklahoma, Under National Flood Insurance Program

AGENCY: Federal Emergency Management Agency.

ACTION: Final rule.

SUMMARY: The Federal Emergency Management Agency (FEMA) published a list of communities for which maps identifying Special Flood Hazard Areas have been published. This list included the City of Oklahoma City. It has been determined by the Associate Director, State and Local Programs and Support, after acquiring additional flood information and after further technical review of the Flood Insurance Rate Map for the City of Oklahoma City, that certain property is not within the Special Flood Hazard Area.

This map amendment, by establishing that the subject property is not within the Special Flood Hazard Area, removes the requirement to purchase flood insurance for that property as a condition of Federal or federally-related financial assistance for construction or acquisition purposes.

EFFECTIVE DATE: February 2, 1982.

FOR FURTHER INFORMATION CONTACT: Mr. Robert G. Chappell, P.E. Chief, Engineering Branch, Office of State and Local Programs and Support, Federal Emergency Management Agency, Washington, D.C. 20472, (202) 287–0270.

SUPPLEMENTARY INFORMATION: If a property owner was required to purchase flood insurance as a condition of Federal or federally-related financial assistance for construction or acquisition purposes, and the lender now agrees to waive the property owner from maintaining flood insurance coverage on the basis of this map amendment, the property owner may obtain a full refund of the premium paid for the current policy year, provided that no claim is pending or has been paid on the policy in question during the same policy year. The premium refund may be obtained through the insurance agent or broker who sold the policy, or from the National Flood Insurance Program (NFIP) at: P.O. Box 34294, Bethesda, Maryland 20034, Telephone: (800) 638–6620.

The map amendments listed below are in accordance with § 70.7(b):

Map No. H & I 405378A Panel 152, published on October 6, 1980, in 45 FR 66095, indicates that Lot 1, Block 8; Lots 1 through 38, and 45 through 69, Block 9; Lots 1 through 9, Block 10; Lots 2 through 16, Block 12; and Lots 1 and 15, Block 13, Green Valley Estates, Section III, and Lots 6, 7, 25, 26, 28, and 29, Block 2, Shroyer Green Valley Estates as recorded in Book 12, pages 169 and 170; and Book 10, pages 88 and 89, respectively, in the Office of the Clerk, Cleveland County, Oklahoma, are within the Special Flood Hazard Area.

Map No. H & I 405378A Panel 152 is hereby corrected to reflect that Lot 1, Block 8; Lots 1, 6, 45 through 48, 55 and 56, Block 9; Lots 1 through 9, Block 10; Lots 2, 3, 5, 8, and 15, Block 12; and Lots 1 and 15, Block 13, Green Valley Estates Section III are not within the special Flood Hazard Area identified on February 2, 1979. These lots are in Zone C.

Map No. H & I 405378A Panel 152 is also corrected to reflect that the existing structures located on Lots 2 through 5, 7 through 38, 49 through 54, and 57 through 69, Block 9; Lots 4, 6, 7, 9 through 14, and 16, Block 12, Green Valley Estates are not within the Special Flood Hazard Area identified on February 2, 1979. These structures are in Zone C.

Pursuant to provisions of 5 U.S.C. 605(b), the Associate Director, State and Local Programs and Support to whom authority has been delegated by the Director, Federal Emergency Management Agency, hereby certifies that this rule if promulgated will not have a significant economic impact on a substantial number of small entities. This rule provides routine legal notice of technical amendments made to designated special flood hazard areas on the basis of updated information and imposes no new requirements or regulations on participating communities.

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended; 42 U.S.C. 4001–4128; Executive Order 12127, 44 FR 19367; delegation of authority to Associate Director, State and Local Programs and Support)

Issued: December 31, 1981.

Lee M. Thomas,

Associate Director, State and Local Programs and Support.

[FR Doc. 82–2597 Filed 2–1–82; 8:45 am]

BILLING CODE 6718–03–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 87

[PR Docket No. 80-758; FCC 82-9]

Changes in Frequency Allotments for the Aeronautical Mobile (R) Services on a World-Wide Basis

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document implements changes in the frequency allotments to the Aeronautical Mobile (R) Service on a world-wide basis which were adopted at the ITU World Administrative Radio Conference on the Aeronautical Mobile (R) Service, Geneva, 1978 (ITU WARC, 1978). This document also implements several technical specifications adopted at the ITU WARC, 1978, concerning emissions, tolerances and mode of operation. The final allotment plan will become effective February 1, 1983, and frequencies to be used during the interim period are included in the rules. This will make new frequency allotments available for international en route communications and domestic flight tests.

EFFECTIVE DATE: March 8, 1982.

ADDRESS: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Nicholas G. Bagnato, Private Radio Bureau, (202) 632-7175.

SUPPLEMENTARY INFORMATION:

Adopted: January 13, 1982.

Released: January 29, 1982.

In the matter of an amendment of Part 87 of the rules to implement changes in frequency allotments for the Aeronautical Mobile (R) services on a world-wide basis which were adopted at the ITU World Administrative Radio Conference on the Aeronautical Mobile (R) Service, Geneva, 1978; PR Docket No. 80-758; *Report and Order* (Proceeding Terminated).

1. A Notice of Proposed Rule Making in the above-captioned matter, FCC 80-758, was released on January 13, 1981, and published in the **Federal Register**, 46 FR 9665; January 29, 1981.

2. By this action, we are amending the rules to establish a transition program affecting single sideband frequencies in the aeronautical enroute service in the band 2850–22000 kHz, which will be completed by February 1, 1983, and after that date only those frequencies listed in Appendix 27 Aer 2 will be used.

Background

3. The Final Acts of the World Administrative Radio Conference on the Aeronautical Mobile (R) Service, Geneva, 1978 (ITU WARC, 1978), came into force on September 1, 1979, and the Frequency Allotment Plan adopted at that conference will enter into force on February 1, 1983, in its entirety. This frequency allotment plan will make the use of single sideband mandatory in the band 2850–22000 kHz.

Summary of Commission Proposal

4. A new allotment plan was developed at the ITU WARC, 1978, by separating the frequencies at 3 kHz intervals throughout the 10 bands allocated to the Aeronautical Mobile (R) Service (AM(R)S) between 2850–22000 kHz.

5. A number of changes to the technical standards applicable to the use of frequencies in the bands between 2850–22000 kHz were proposed as follows:

a. Express tolerance of frequency stability in terms of parts per million rather than percentages;

b. Designate the authorized classes of emission for telegraphy in the AM(R)S after February 1, 1982;

c. Define the tolerance levels of emissions outside of the necessary bandwidth for aeronautical [1] and aircraft [2] stations in the AM(R)S for transmitters first installed before and after February 1, 1983; and

d. Amend the modulation requirements by adding a separate requirement for aeronautical stations and by specifying the degree of suppression for full carrier to a level of 0 to 6 dB below peak envelope power (from 3 to 6 dB below peak envelope power).

6. The aeronautical enroute service in the United States (except Alaska) is conducted on VHF. The frequencies contained in Regional and Domestic Air Route Area (RDARA) 11B (for the United States) are now assigned for flight test purposes and in support of offshore oil drilling operations. These requirements cannot be satisfied on VHF frequencies and we proposed replacement frequencies for continued use for these purposes.

7. ITU WARC 1978, allotted frequencies to new World-Wide Allotment Areas for long distance operational control (LDOC) between an aeronautical station and an aircraft station anywhere in the world. These frequencies are used by aircraft operators for exercising control over the efficiency and regularity of the flight as well as matters affecting the safety of the aircraft. The Commission proposed frequencies for this new LDOC requirement.

Comments

8. We have received comments from Aerospace and Flight Test Radio Coordinating Council (AFTRCC), Aeronautical Radio, Inc. (ARINC), Interdepartment Radio Advisory Committee of the National Telecommunications and Information Agency (IRAC) and Rockwell International Corporation (Rockwell). Each of the commenters supported the rulemaking. In addition, each of the commenters suggested relatively minor revisions and two of the commenters suggested that both the old and new frequencies should be listed in the rules for the convenience of the operators.

9. In addition to supporting the proposal, AFTRCC reiterated its requirement for HF frequencies for communications in support of flight test of aircraft and equipment. Flight testing may involve one of three modes: design testing of new and experimental products; production line testing to assure the continued safety of air and spacecraft in production; or crew training and testing. In testing for any of these purposes, the manufacturer must be able to assume safe and efficient operation of the equipment under a wide variety of weather and altitude conditions. To obtain such conditions during flight test, the manufacturer must frequently have the aircraft flown significant distances from the test or production facility or at low altitudes making VHF communications impossible. In addition to the continued requirement for the frequencies in the band 2850–17970 kHz, there is a new requirement for a frequency in the 22 MHz band for flight test as recommended in the ITU WARC, 1978.

10. ARINC generally agreed with the proposals contained in the notice, including the frequencies indicated for the concerned Major World Air Route Areas (MWARA's) and Regional and Domestic Air Route Areas (RDARA's). ARINC suggested that the text associated with § 87.285(c) be deleted since it pertains to VHF enroute operations and properly belongs in the section applicable to VHF enroute stations. ARINC stated that because of parallel rule makings, that the numbering of Part 87 sections has become confused. To avoid this

[1] An aeronautical station is a land station in the aeronautical mobile service.

[2] An aircraft station is a mobile station in the aeronautical mobile service on board an aircraft or an air or space vehicle.

confusion, ARINC in commenting on this docket aligned their comments with the format for the revision of Part 87 as shown in the Appendix in PR Docket No. 80–243.[3] ARINC suggested specific changes referring to the emission designator for selective calling (SELCAL) and some editorial corrections to clarify certain rule sections. ARINC also suggested that the format of the frequency tables be revised to show the frequencies now available, those to be replaced on February 18, 1982, and those to be replaced on February 1, 1983. ARINC submits that these tables should indicate the new frequencies available and also those replaced and the dates of the replacement until the entire plan is in force as a convenience to the operators.

11. IRAC suggested some editorial changes to clarify the phased transition program and to include both the old and new frequencies in the rules for the convenience of the operators. IRAC also suggested that footnote 2 to the emission table in § 87.67 be revised to show that after February 1, 1982, the emissions A3 and A3H are to be used only on 3023 and 5680 kHz for search and rescue operations. IRAC recommended that the emissions authorized for flight test operations be amended to include all of the emissions authorized for the aeronautical enroute service. The frequencies authorized for the West Indies are no longer required since the concerned airline has ceased operations. IRAC recommended that these frequencies be deleted and made available for assignment to other users.

12. Rockwell stated that the proposed rules appear to be satisfactory and reflect the results of the ITU WARC, 1978 for the AM(R)S. Rockwell suggested that the wording in the proposed § 87.71(b) does not make it entirely clear that specific aircraft transmitter models, type accepted before February 1, 1983, can still be used after that date. The ITU WARC 1978 provided that the old 4.0 kHz bandwidth applied to the calculation of unwanted emissions. The proposed rule could be interpreted to provide that the new 3.0 kHz bandwidth applies, which would defeat the grandfathering provision for pre-February 1, 1983, transmitters. Rockwell also suggested that a 22 MHz frequency be assigned for flight test operations for long-distance operational control of flight test aircraft and equipment testing.

[3] PR DOCKET NO. 80–243, FCC 81–295, Released July 24, 1981, (46 FR 38698, July 29, 1981)

Discussion

13. The comments received all substantially supported the proposed amendments to the rules. However, as we noted above, a number of questions were raised and recommendations made regarding the organization and wording of certain proposed rules. Each of these suggestions will be discussed in the following paragraphs. There was a concurrent rule making concerning the aeronautical enroute service in Docket No. 80–243, which was released on July 24, 1981. Action in Docket No. 80–243 will necessitate some reorganization of the rules proposed in Docket No. 80–758 to accommodate those changes.

14. AFTRCC and Rockwell suggested that a 22 MHz frequency be made available for flight test operations to assure that flight tests are representative of operational conditions of the aircraft. Such frequencies are now allotted to World-wide areas [4] for long distance operational control. We agree that a 22 MHz frequency is necessary for testing of aircraft installations in all of the representative frequency bands as well as control of the aircraft on long distance flight test operations. The ITU WARC, 1978 recommended and the ITU WARC, 1979 adopted an allocation at which five frequencies in the 22 MHz band were not allotted to any specific World-wide area. After coordination with IRAC, we are assigning one of these frequencies, 21931 kHz, for flight test operations.

15. ARINC and IRAC suggested that the old and new frequencies be listed to show the changes in frequencies during the transition period. We did not propose both frequencies since we believed that these rules would affect a limited number of operators and that it would preclude an editorial amendment at a later date to remove the obsolete frequencies. However, since the commenters believe that the listing of all of the frequencies during the transition period is desirable and a convenience to the operators, we will include the transition as well as the final frequencies in the rules.

16. The comments which can be considered editorial in nature, such as, adding the emission designator for SELCAL, deleting the reference to offset carrier operation for HF enroute frequencies, and adding the emissions A3 and A3H on the frequencies 3023 and 5680 kHz for search and rescue operations will be made. The enroute frequencies for the West Indies will be deleted and no further assignments to non-Government aeronautical enroute stations to serve this area will be made at this time.

17. Rockwell proposed that the rules show that prior to February 1, 1983, the basis for the tolerance levels of emissions outside of the necessary bandwidth be 4.0 kHz, and that after February 1, 1983, the basis be 3.0 kHz. We agree with this proposal and are adding the correct bandwidth where applicable. Rockwell also proposed that the rules state that aircraft transmitters type accepted prior to February 1, 1983, can be "first installed" after February 1, 1983. The ITU WARC, 1978 (MOD 27/66 Aer2) states that aircraft transmitter types and aeronautical station transmitter types "first installed" before February 1, 1983, shall use the applicable bandwidth of 4.0 kHz. A note was added (ADD 27/66A Aer2) that all transmitters first placed in operation after February 1, 1983, shall be based on the 3.0 kHz bandwidth. All aircraft transmitters "first installed" after February 1, 1983, and all aeronautical stations in use after February 1, 1983 shall have a tolerance level based on 3.0 kHz bandwidth. Therefore, we are unable to agree with the proposal, since this would permit installation of transmitters in aircraft stations contrary to the provisions of the ITU WARC, 1978.

Commission Action

18. For the reasons indicated above, we are amending Part 87 of the rules substantially as proposed taking into account a number of suggestions received in response to the NPRM. Thus, this action will incorporate in the rules technical specifications and the new frequency allotment plan contained in the Final Acts of the World Administrative Radio Conference on the Aeronautical Mobile (R) Service, Geneva, 1978.

19. Regarding questioins on matters covered in this document contact Nicholas G. Bagnato, (202) 632–7175.

20. Accordingly it is ordered, That under the authority contained in sections 4(i) and 303(b) and (r) of the Communications Act of 1934, as amended, the Commission's rules ARE AMENDED as set forth in the attached Appendix, effective March 8, 1982.

21. It is further ordered, That this proceeding is terminated.

(Secs. 4, 303, 307, 48 Stat., as amended, 1066, 1082, 1083; 47 U.S.C. 154, 303, 307)

[4] World-Wide Allotment Area is one in which frequencies are allotted to provide long-distance communication between an aeronautical station within the allotment area and aircraft operating anywhere in the world.

Federal Communications Commission.

William J. Tricarico,

Secretary.

Appendix

Part 87 of Chapter I of Title 47 of the Code of Federal Regulations is amended as follows:

PART 87—AVIATION SERVICES

1. Section 87.65(a) is amended to express the tolerance in parts per million in lieu of percentages.

§ 87.65 Frequency stability.

(a) Except as provided in paragraphs (c), (d), and (f) of this section, and § 87.81, the carrier frequency of each station in the Aviation Services shall be maintained within the applicable following tolerance of the assigned frequency in parts per million:

Frequency band (lower limit exclusive, upper limit inclusive) and categories of stations	Tolerances in parts 10^6
(1) Band—10 to 535 kHz:	
Land stations	100
Mobile stations	200
Radionavigation stations	100
(2) Band—1605 to 4000 kHz:	
Fixed stations:	
Power 200 w or less	100
Power above 200 w	50
Land stations:	
Power 200 w or less	100
Power above 200 w	50
Mobile stations	100
(3) Band—4 to 29.7 MHz:	
Fixed stations:	
Power 500 w or less	50
Power above 500 w	15
Land stations:	
Power 500 w or less	100
Power above 500 w	50
Mobile stations	100
(4) Band—29.7 to 100 MHz:	
Fixed stations except operational fixed:	
Power 200 w or less	50
Power above 200 w	30
Operational fixed stations:	
73–74.6 MHz	50
72.0–73.0 MHz and 75.4–76.0 MHz	5
Land stations:	
Power 15 w or less	50
Power above 15 w	20
Mobile stations:	
Power 5 w or less	100
Power above 5 w	50
Radionavigation stations	100
(5) Band—100 to 136 MHz:	
Land stations	[1] 20
Emergency locator transmitter test station	50
Mobile stations:	
Survival craft stations	50
Emergency locator stations	50
Aircraft and all other mobile stations	[2] 30
Radionavigation stations	50
(6) Band—136 to 470 MHz:	
Fixed stations:	
Power 50 w or less	50
Power above 50 w	20
Land stations	50
Mobile stations:	
Survival craft stations	50
Land mobile stations with power above 5 w	20
Aircraft and all other mobile stations	50
Radionavigation stations	50
(7) Band—470 to 960 MHz: All stations	100
(8) Band—960 to 1215 MHz:	
Land stations	20
Aircraft stations	100
(9) All stations on frequencies above 1215 MHz	100

[1] The tolerance shown is applicable to all types of transmitters first type accepted after January 1, 1974. Those types of transmitters meeting a tolerance of 50 parts in 10^6 which were type accepted before January 1, 1966, and those types of transmitters meeting a tolerance of 30 parts in 10^6 first type accepted during the period January 1, 1966, to January 1, 1974, may continue to operate. Stations using offset carrier techniques must comply with 20 parts in 10^6 tolerance.

[2] The tolerance shown in the Table is applicable to all types of transmitters first type accepted after January 1, 1974. Transmitters with 50 parts in 10^6 tolerance type accepted before January 1, 1974, may continue to be used until further notice.

* * * * *

2. The table and footnotes in § 87.67(b) are revised as follows:

§ 87.67 Types of emission.

* * * * *

(b) The emission normally available for assignment in the Aviation Services and the corresponding emission designators and authorized bandwidth are as follows:

Class of emission	Emission designator	Authorized bandwidth (kilohertz)		
		Below 50 MHz	Above 50 MHz	Frequency deviation
A1 [10]	0.1A1	0.25		
A2	2.1A2	2.74	50	
A2H [9] [11]	2.8A2H	3.0		
A3	6A3		[5]50	
A3A [2] [11]	2.8A3A [2]	3.0		
A3H [2] [11]	2.8A3H [2]	3.0		
A3J [2] [11]	2.8A3J [11]	3.0		
A7J [11]	2.8A7J [11]	3.0		
A9	13A9 [6]		[6]25	
A9	3.2A9 [7]		[7]25	
A9J [11]	2.8A9J [11]	3.0		
F1 [10]	1.7F1	1.7		
F1 [10]	2.4F1	2.5		
F3 [3]	36F3		40	15
F3 [4]	16F3		20	5
F9 [8]	([1])		([1])	
P	([1])	([1])		

[1] To be specified on authorization.

[2] Each aeronautical enroute station authorized to use A3A and/or A3J emission shall render service to those aircraft stations which are equipped for double sideband (DSB) operation as well as those equipped for single sideband (SSB). Aircraft equipped for SSB operation shall use full carrier except when it is known that the receiving station is capable of receiving reduced or suppressed carrier emission and shall use full carrier upon receipt of request of any station using the same frequency. A3A, A3H, and A3J emissions will be authorized only below 25000 kHz. After February 1, 1983, only the classes of emission A2H, A3J, A7J, and A9J will be authorized. Except that after February 1, 1982, the emissions A3 and A3H are to be used only on 3023 and 5680 kHz for Search and Rescue operations.

* * * * *

[8] The emission designator A2H shall be used by stations employing selective calling (SELCAL).

[10] A1 and F1 emissions are permitted provided they do not cause harmful interference to classes of emission A2H, A3J, A7J and A9J. These emissions shall be at or near the center of the channel.

[11] For single sideband emissions, except the class of emission A2H, the assigned frequency shall be at a value of 1400 Hz above the carrier frequency.

* * * * *

3. Section 87.71 is revised as follows:

§ 87.71 Emission limitations.

(a) When using transmissions other than single sideband (A3A, A3H, A3J), or frequency modulation (F9) in the frequency band 1435–1535 MHz, the mean power of the emission shall be attenuated below the mean output power of the transmitter as follows:

(1) On any frequency removed from the assigned frequency by more than 50 percent up to and including 100 percent of the authorized bandwidth: at least 25 dB;

(2) On any frequency removed from the assigned frequency by more than 100 percent up to and including 250 percent of the authorized bandwidth: at least 35 dB.

(3) On any frequency removed from the assigned frequency by more than 250 percent of the authorized bandwidth:

(i) Aircraft station transmitters: 40 dB;

(ii) Aeronautical station transmitters: $43+10 \log_{10}$ Pm (watts) dB.

(b) For aircraft station transmitter types and for aeronautical station transmitters first installed before February 1, 1983, and using single sideband classes of emission A2H, A3H, A3J, A7J or A9J, the mean power of any emission shall be less than the mean power (Pm) of the transmitter as follows:

(1) On any frequency removed from the assigned frequency by more than 50 percent up to and including 150 percent of the authorized bandwidth of 4.0 kHz: at least 25 dB.

(2) On any frequency removed from the assigned frequency by more than 150 percent up to and including 250 percent of the authorized bandwidth of 4.0 kHz: at least 35 dB.

(3) On any frequency removed from the assigned frequency by more than 250 percent of the authorized bandwidth of 4.0 kHz:

(i) Aircraft station transmitters: 40 dB;

(ii) Aeronautical station transmitters; $43+10 \log_{10}$ Pm (watts) dB.

(c) For aircraft station transmitters first installed after February 1, 1983, and for aeronautical station transmitter in use after February 1, 1983, and using single sideband classes of emission A2H, A3H, A3J, A7J or A9J, the peak envelope power (Pp) of any emission shall be less than the peak envelope power (Pp) of the transmitter as follows:

(1) On any frequency removed from the assigned frequency by more than 50 percent up to and including 150 percent of the authorized bandwidth of 3.0 kHz: at least 30 dB.

(2) On any frequency removed from the assigned frequency by more than 150 percent up to and including 250 percent of the authorized bandwidth of 3.0 kHz: at least 38 dB.

(3) On any frequency removed from the assigned frequency by more than 250 percent of the authorized bandwidth of 3.0 kHz:

(i) Aircraft transmitters: 43 dB.

(ii) Aeronautical station transmitters:

(A) For transmitter power up to and including 50 watts: $43+10 \log_{10}$ Pp (watts) dB: and.

(B) For transmitter power more than 50 watts: at least 60 dB.

(d) On any frequency removed from the assigned frequency by more than 250 percent of the authorized bandwidth except for telemetry in the 1435–1535 MHz band—aircraft station above 30 MHz and all ground stations: $43+10 \log_{10}$ Pm (watts) dB.

(e) [1] When using frequency modulated transmission (F9) for telemetry at flight test stations in the 1435–1535 MHz frequency band with an authorized bandwidth equal to or less than 1 MHz:

(1) On any frequency removed from the assigned frequency by more than 100 percent of the authorized bandwidth up to and including 100 percent of the authorized bandwidth plus 0.5 MHz: at least 60 dB or 25 dB below a milliwatt, whichever is greater, when measured in a 3 kHz bandwidth.

(2) On any frequencies removed from the assigned frequency by more than 100 percent of the authorized bandwidth plus 0.5 MHz: at least $55+10 \log_{10}$ Pm (mean power in watts) dB when measured in a 3 kHz bandwidth.

(f) [1] When using frequency modulated transmission (F9) for telemetry at flight test stations in the 1435–1535 MHz frequency band with a bandwidth greater than 1 MHZ:

(1) On any frequencies removed from the assigned frequency by more than 50 percent of the authorized bandwidth plus 0.5 MHz up to and including 50 percent of the authorized bandwidth plus 1.0 MHz: 60 dB or 25 dB below a milliwatt, whichever is greater, when measured in a 3 kHz bandwidth. (2) On any frequencies removed from the assigned frequency by more than 50 percent of the authorized bandwidth plus 1.0 MHz: at least $55+10 \log$ Pm (mean power in watts) dB measured in a 3 kHz bandwidth.

(g) When an emission outside of the authorized bandwidth results in harmful interference, the Commission may require appropriate technical changes in equipment to alleviate the interference.

4. In § 87.73, paragraphs (d) and (e) are revised as follows:

§ 87.73 Modulation requirements.

* * * * *

(d) In order to meet the requirements for type acceptance in the Aviation Services, a transmitter shall be capable of operation in the following modes.

Carrier mode	Level N(dB) of the carrier with respect to peak envelope power
Full carrier (for example A2H).	$0>N>-6$.
Suppressed carrier (for example A3J).	Aircraft stations $N<-26$; Aeronautical stations $N<-40$.

(e) For single sideband emissions, except for class A2H emission, the assigned frequency should be at a value 1400 Hz above the carrier (reference) frequency.

* * * * *

(5) In § 87.195, new paragraphs (h) and (i) are added as follows:

§ 87.195 Frequencies available.

* * * * *

(h) The carrier frequencies 2878 kHz, 3019 kHz, 3434 kHz, 4672 kHz, 5463 kHz and 5508 kHz are available for aircraft operating in support of offshore drilling operations in open water areas beyond the range of VHF.

(i) The frequencies available to aeronautical stations are listed in §§ 87.297, 87.301, 87.303 and 87.307.

§ 87.195 [Amended]

6. Section 87.195(b) is removed.

§ 87.201 [Amended]

7. Section 87.201(g) is removed.

8. In § 87.295, paragraphs (b) and (c) are revised as follows:

§ 87.295 Frequencies available for domestic HF service.

* * * * *

(b) The following frequencies are available for assignment to serve aircraft operating in support of offshore drilling operations in open water areas beyond the range of VHF propagation:

Frequencies available until 0001 G.m.t., Feb. 18, 1982 (carrier) kHz	Frequencies available from 0001 G.m.t., February 1982, until 0001 G.m.t., Feb. 1, 1983 (carrier) kHz	Frequencies available after 0001 G.m.t., Feb. 1, 1983 (carrier) kHz
2973	2973	2878
		3019
		3434
4654	4654	4672
		5463
		5508

(c) Alaska: The following frequencies are available for assignment to serve domestic air routes as in the indicated area of Alaska:

(1) Throughout Alaska: The following frequencies are shared with the Federal Aviation Administration and may be assigned where an applicant shows the need for a service not provided by the FAA.

Frequencies available until 0001 G.m.t., Feb. 18, 1982 (carrier) kHz	Frequencies available from 0001 G.m.t., Feb. 18, 1982, until 0001 G.m.t., Feb., 1, 1983 (carrier) kHz	Frequencies available after 0001 G.m.t. Feb. 1, 1983 (carrier) kHz
2861	2861	2866
5631	5631	5631

(2) Alaska Aleutian chain and feeders.

Frequencies available until 0001 G.m.t., Feb. 18, 1982 (carrier) kHz	Frequencies available from 0001 G.m.t., Feb. 18, 1982, until 0001 G.m.t. Feb. 1, 1983 (carrier) kHz	Frequencies available after 0001 G.m.t., Feb. 1, 1983 (carrier) kHz
2924	2924	2911
3446	3446	2956
		5496
6568	6568	6580
10057	10057	8855
11295	11295	10066
11319	11319	11363

(3) Central and Southeast Alaska and feeders.

Frequencies available until 0001 G.m.t., Feb. 18, 1982 (carrier) kHz	Frequencies available from 0001 G.m.t., Feb.18, 1982, until 0001 G.m.t., Feb. 1, 1983 (carrier) kHz	Frequencies available after 0001 G.m.t., Feb. 1, 1983 (carrier) kHz
2875	2875	2875
2924	2924	2911
3481	3481	3470
5547	5547	5484
6568	6568	6580
6617	6617	6604
		8876
10041	10041	11357

(4) The following frequencies are available to enroute stations in Alaska without regard to the restrictions contained in § 87.291 (c) or (d). These frequencies may also be used for communications between enroute stations concerning matters directly affecting aircraft with which they are engaged. Enroute stations located at an uncontrolled airport shall not transmit information concerning runway, wind or weather conditions during the operating hours of an aeronautical advisory station (unicom).

Frequencies available until 0001 G.m.t., Feb. 18, 1982 (carrier) kHz	Frequencies available from 0001 G.m.t., Feb. 18, 1982, until 0001 G.m.t., Feb. 1, 1983 (carrier) kHz	Frequencies available after 0001 G.m.t., Feb. 1, 1983 (carrier) kHz
3411	3411	3449
[1] 4383.8	[1] 4383.8	[1] 4383.8
4668	4668	5472
4693	4693	5490

[1] The frequency 4383.8 kHz, maximum power 150 watts PEP, may be used by any station authorized under this part to communicate with any other station authorized in the State of Alaska for emergency communications. No airborne operations will be permitted on this frequency.

9. Section 87.299 is amended by revising frequency lists in paragraphs (a) through (o) as follows:

[1] The requirements of paragraphs (e) and (f) of this section shall apply to transmitters type accepted after January 1, 1977, and to all transmitters first installed after January 1, 1983.

§ 87.299 Frequencies available for international HF service.

High frequencies available to enroute stations serving international flight operations on the Major World Air Route Areas (MWARA's) as defined in the international Radio Regulations and the International Civil Aviation Organization (ICAO) Assignment Plan are as follows:

(a) *Central East Pacific* (CEP):

Frequencies available until 0001 G.m.t., Feb. 18, 1982 (carrier) kHz	Frequencies available from 0001 G.m.t., Feb. 18, 1982, until 0001 G.m.t., Feb. 1, 1983 (carrier) kHz	Frequencies available after 0001 G.m.t., Feb. 1, 1983 (carrier) kHz
3001	3001	2869
3467	3467	3413
		4657
5554	5554	5547
		6673
5603	5603	5574
8875	8843	8843
13336	13336	10057
8931	11282	11282
13312	13300	13300
17909	17904	17904

(b) *Central West Pacific* (CWP):

Frequencies available until 0001 G.m.t., Feb. 18, 1982 (carrier) kHz	Frequencies available from 0001 G.m.t., Feb. 18, 1982, until 0001 G.m.t., Feb. 1, 1983 (carrier) kHz	Frequencies available after 0001 G.m.t., Feb. 1, 1983 (carrier) kHz
2896	2896	2998
		3455
4675	4675	4666
5505	5505	5652
		5661
		6532
6631	6631	6562
8854	8854	8903
		10081
11303	11303	11384
13296	13300	13300
17909	17904	17904

(c) *North Pacific* (NP):

Frequencies available until 0001 G.m.t., Feb. 18, 1982 (carrier) kHz	Frequencies available from 0001 G.m.t., Feb. 18, 1982, until 0001 G.m.t., Feb. 1, 1983 (carrier) kHz	Frequencies available after 0001 G.m.t., Feb. 1, 1983 (carrier) kHz
2910	2910	2932
5589	5589	5628
	6655	6655
		6661
8938	8938	10048
		11330
13264	13300	13300
17909	17904	17904

(d) *South Pacific* (SP):

Frequencies available until 0001 G.m.t., Feb. 18, 1982 (carrier) kHz	Frequencies available from 0001 G.m.t., Feb. 18, 1982, until 0001 G.m.t., Feb. 1, 1983 (carrier) kHz	Frequencies available after 0001 G.m.t., Feb. 1, 1983 (carrier) kHz
2945	2945	3467
	5559	5559
5638	5643	5643
8847	8847	8867
		10084
	11327	11327
13304	13300	13300
17909	17904	17904

(e) *North Atlantic* (NAT):

Frequencies available until 0001 G.m.t., Feb. 18, 1982 (carrier) kHz	Frequencies available from 0001 G.m.t., Feb. 18, 1982, until 0001 G.m.t., Feb., 1,, 1983, (carrier) kHz	Frequencies available after 0001 G.m.t., Feb. 1, 1983 (carrier) kHz
		2872
2987	2987	2899
2945	2962	2962
2868	2868	2971
2931	2931	3016
		3476
5624	5624	4675
5610	5610	5598
5673	5673	5616
5638	5638	5649
		6622
		6628
8945	8945	8825
		8831
8889	8889	8864
8854	8879	8879
8910	8891	8891
		8906
11303	11303	11279
		11309
		11336
13328	13291	13291
13288	13306	13306
17941	17946	17946

(f) *Europe* (EUR):

Frequencies available until 0001 G.m.t., Feb. 18, 1982 (carrier) kHz	Frequencies available from 0001 G.m.t., Feb. 18, 1982, until 0001 G.m.t., Feb. 1, 1983 (carrier) kHz	Frequencies available after 0001 G.m.t., Feb. 1, 1983 (carrier) kHz
2910	3479	3479
4689	4689	5661
6582	6582	6598
8875	10084	10084
		13288
17941	17941	17961

(g) *South America* (SAM):

Frequencies available until 0001 G.m.t., Feb. 18, 1982 (carrier) kHz	Frequencies available from 0001 G.m.t., Feb. 18, 1982, until 0001 G.m.t., Feb. 1, 1983 (carrier) kHz	Frequencies available after 0001 G.m.t., Feb. 1, 1983 (carrier) kHz
2889	2889	2944
2910	2910	3479
4696	4696	4669
5582	5582	5526
6666	6666	6649
8847	8847	8855
8826	8826	10024
11327	10096	10096
11343	11360	11360
13320	13297	13297
17925	17907	17907
17917		

(h) *South Atlantic* (SAT):

Frequencies available until 0001 G.m.t., Feb. 18, 1982 (carrier) kHz	Frequencies available from 0001 G.m.t., Feb. 18, 1982, until 0001 G.m.t., Feb. 1, 1983 (carrier) kHz	Frequencies available after 0001 G.m.t., Feb. 1, 1983 (carrier) kHz
2875	2875	2854
		2935
3432	3432	3452
6680	5565	5565
6610	6610	6535
8882	8882	8861
10049	10049	11291
13344	13357	13315
	13357	13357
17949	17955	17955

(i) *Southeast Asia* (SEA):

Frequencies available until 0001 G.m.t., Feb. 18, 1982 (carrier) kHz	Frequencies available from 0001 G.m.t., Feb. 18, 1982, until 0001 G.m.t., Feb. 1, 1983 (carrier) kHz	Frequencies available after 0001 G.m.t., Feb. 1, 1983 (carrier) kHz
2987	2987	3470
2868	2868	3485
5645	5645	5649
5624	5624	5655
5673	5673	6556
8840	8840	8942
8882	8882	10066
8868	11396	11396
	13309	13309
13288	13288	13318
17965	17907	17907

(j) *East Asia* (EA):

Frequencies available until 0001 G.m.t., Feb. 18, 1982 (carrier) kHz	Frequencies available from 0001 G.m.t., Feb. 18, 1982, until 0001 G.m.t., Feb. 1, 1983 (carrier) kHz	Frequencies available after 0001 G.m.t., Feb. 1, 1983 (carrier) kHz
2987	2987	3016
		3485
		3491
		5655
	5670	5670
5673	5673	6571
8931	8931	8897
		10042
	11396	11396
	13297	13297
	13303	13303
	13309	13309
17965	17907	17907

(k) *Middle East* (MID):

Frequencies available until 0001 G.m.t., Feb. 18, 1982 (carrier) kHz	Frequencies available from 0001 G.m.t., Feb. 18, 1982, until 0001 G.m.t., Feb. 1, 1983 (carrier) kHz	Frequencies available after 0001 G.m.t., Feb. 1, 1983 (carrier) kHz
		2944
3404	3404	2992
3446	3446	3467
		3473
		4669
5603	5603	5667
6624	6624	5658
		6625
		6631
8847	8847	8918
		8951
10009	10009	10018
		11375
13336	13336	13288
		13312
	17961	17961

(l) *Africa* (AFI):

Frequencies available until 0001 G.m.t., Feb. 18, 1982 (carrier) kHz	Frequencies available from 0001 G.m.t., Feb. 18, 1982, until 0001 G.m.t., Feb. 1, 1983 (carrier) kHz	Frequencies available after 0001 G.m.t., Feb. 1, 1983 (carrier) kHz
2868	2868	2851
3411	3411	2878
		3419
2917	2917	3425
2966	2966	3467
5484	5484	4657
5491	5491	
5498	5498	
5540	5540	
5519	5519	5493
		5652
6638	6638	
5505	5505	5658
5491	5491	6559
5498	5498	
6589	6589	
4682	4682	6574
5498	5498	
5659	5659	
6638	6638	6673
8826	8826	8894
	8903	8903
8924	8924	8894
8959	11300	11300
		11330
13304	13304	13273
13336	13336	13288
		13294
17925	17961	17961

(m) *Indian Ocean* (INO):

Frequencies available until 0001 G.m.t., Feb. 18, 1982 (carrier) kHz	Frequencies available from 0001 G.m.t., Feb. 18, 1982, until 0001 G.m.t., Feb. 1, 1983 (carrier) kHz	Frequencies available after 0001 G.m.t., Feb. 1, 1983 (carrier) kHz
3481	3481	3476
5505	5634	5634
8875	8875	8879
13336	13306	13306
17925	17961	17961

(n) *North Central Asia* (NCA):

Frequencies available until 0001 G.m.t., Feb. 18, 1982 (carrier) kHz	Frequencies available from 0001 G.m.t., Feb. 18, 1982, until 0001 G.m.t., Feb. 1, 1983 (carrier) kHz	Frequencies available after 0001 G.m.t., Feb. 1, 1983 (carrier) kHz
3425	3425	3004
		3019
3495	3495	
		4678
6533	6533	5646
6589	6589	5664
6603	6603	6592
8861	10096	10096
	13303	13303
		13315
		17958

(o) *Caribbean* (CAR):

Frequencies available until 0001 G.m.t., Feb. 18, 1982 (carrier) kHz	Frequencies available from 0001 G.m.t., Feb. 18, 1982, until 0001 G.m.t., Feb. 1, 1983 (carrier) kHz	Frequencies available after 0001 G.m.t., Feb. 1, 1983 (carrier) kHz
2952	2952	2887
2966	2966	3455
5568	5568	5520
5484	5550	5550
6540	6540	6577
6561	6561	6586
6568		
8840	8840	8846
8959	8959	8918
10017	11396	11396
11343	11387	11387
11320	13297	13297
17917		
17925	17907	17907

10. Section 87.301 is added to read as follows:

§ 87.301 Long distance operational control.

Long distance operational control communications provide for the exercise of authority over the initiation, continuation, diversion or termination of a flight affecting the safety of the aircraft and the regularity and efficiency of a flight. Assignments are to provide communications between an appropriate aeronautical station and an aircraft station anywhere in the world for exercising control over regularity of flight and safety of aircraft. World-wide frequencies are not to be assigned by administrations for MWARA, RDARA and VOLMET purposes.

Frequencies available until 0001 G.m.t., Feb. 18, 1982 (carrier) kHz	Frequencies available from 0001 G.m.t., Feb. 18, 1982, until 0001 G.m.t., Feb. 1, 1983 (carrier) kHz	Frequencies available after 0001 G.m.t., Feb. 1, 1983 (carrier) kHz
		3013
		3494
		5529
		5538
6526	6526	6637
		6640
		8933
		10033
10093	10093	10075
		11342
		11348
13356	13356	13330
	13348	13348
17941	17925	17925
21996	21996	21964

§ 87.309 [Removed]

11. Section 87.309 is removed.

12. Section 87.331 paragraph (c) is revised to read as follows:

§ 87.331 Frequencies available.

* * * * *

(c) The following frequencies are available for assignment to flight test stations for test of equipment, emergency and backup use only for communication with aircraft beyond the range of VHF propogation. Type A2H, A3J, A7J and A9J emissions shall be employed. A3H emission may be used until February 1, 1982.

Frequencies available until 0001 G.m.t., Feb. 18, 1982 (carrier) kHz	Frequencies available from 0001 G.m.t., Feb. 18, 1982, until 0001 G.m.t., Feb. 1, 1983 (carrier) kHz	Frequencies available after 0001 G.m.t., Feb. 1, 1983 (carrier) kHz
2868	2868	2851
2994	2994	3004
3474	3474	3443
4675	4675	
4682	4682	5451
5469	5469	5469
5596	5596	5571
6559	6559	6550
8917	8917	8822
10009	10009	10045
11287	11287	11288
11375	11375	11306
13356	13312	13312
17901		
17965	17965	17964
		21931

[FR Doc. 82-2487 Filed 2-1-82; 8:45 am]

BILLING CODE 6712-01-M

INTERSTATE COMMERCE COMMISSION

49 CFR Ch. X

[Ex Parte No. 311 (Sub-4)]

Modification of the Motor Carrier Fuel Surcharge Program

AGENCY: Interstate Commerce Commission.

ACTION: Notice of revised compliance schedule for final modifications.

SUMMARY: In a notice served October 8, 1981, the Commission replaced the revenue based fuel surcharge for motor vehicles and freight forwarders with a program which would reimburse owner-operators for fuel costs. That notice was published at 46 FR 50070, October 9, 1981, and corrected and clarified at 46 FR 54745 and 54746, November 4, 1981. On January 18, 1982, the United States Court of Appeals for the Eighth Circuit denied various motions for stay of that Commission decision pending review. The Commission may now implement the mileage-based fuel compensation plan. A new 60-day compliance period will begin on February 12, 1982.

EFFECTIVE DATE: February 12, 1982.

FOR FURTHER INFORMATION CONTACT:

Lee Alexander: (202) 275-7723
Alan Rothenberg: (202) 275-7597
Ted Kalick: (202) 275-6446
Richard Shullaw: (202) 275-7639

SUPPLEMENTARY INFORMATION: On November 5, 1981, the United States Court of Appeals for the Fifth Circuit, in No. 81-4437, *Central Forwarding, Inc., et*

al. v. *Interstate Commerce Commission,* stayed the Commission's decision in this proceeding pending further order of the Court. On January 18, 1982, the Court denied various motions for stay pending review. The Commission may now implement the mileage-based fuel compensation plan.

The Commission is issuing a revised compliance schedule. The 60-day transition period, during which carriers may fold in that portion of the surcharge necessary (1) to cover increased fuel costs since January 1979, and/or (2) to cover the new mileage payment to owner-operators, will begin on February 12, 1982. The fold-in shall be filed to become effective on not less than 30 days' notice. Any fuel surcharge remaining in effect after April 13, 1982 will be null and void.

The last weekly order establishing the revenue-based surcharge level will be issued during the week of February 8, 1982. The surcharge level will then be frozen for the 60-day transition period. During this period and until the fold-in is effected, each carrier shall continue to pay its owner-operators the maximum surcharge in effect on February 12, 1982.

No fold-in filings will be accepted prior to February 12, 1982.

Decided: January 25, 1982.

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

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-2641 Filed 2-1-82; 8:45 am]

BILLING CODE 7035-01-M

---

49 CFR Part 1033

[Sixth Revised Service No. 1495; Amdt. No. 1]

Burlington Northern Railroad Company and Fort Worth and Denver Railway Company Authorized To Use Tracks and/or Facilities of the Chicago, Rock Island and Pacific Railroad Company, Debtor (William M. Gibbons, Trustee)

AGENCY: Interstate Commerce Commission.

ACTION: Final rule; Amendment No. 1 to Sixth Revised Service Order No. 1495.

SUMMARY: Pursuant to Section 122 of the Rock Island Transition and Employee Assistance Act, Pub. L. 96-254, this order authorizes the Burlington Northern and Forth Worth and Denver to provide interim service over the Chicago, Rock Island and Pacific Railroad Company, Debtor (William M. Gibbons, Trustee), and to use such tracks and facilities as are necessary for operations. This order permits carriers to continue to provide service to shippers which would otherwise be deprived of essential rail transportation.

EFFECTIVE DATE: 11:59 p.m., January 31, 1982, and continuing in effect until 11:59 p.m., May 31, 1982, unless otherwise modified, amended or vacated by order of this Commission.

FOR FURTHER INFORMATION CONTACT: M. F. Clemens, Jr., (202) 275-7840 or 275-1559.

SUPPLEMENTARY INFORMATION:

Decided: January 27, 1982.

Upon further consideration of Sixth Revised Service Order No. 1495 (47 FR 776), and with respect to the duration of this amendment, the Commission has voted pursuant to its Notice of September 21, 1981, to continue to authorize interim operations during the bankruptcy process, and good cause appearing therefor:

§ 1033.1495 [Amended]

It is ordered, § 1033.1495 *Burlington Northern Railroad Company and Fort Worth and Denver Railway Company authorized to use tracks and/or facilities of the Chicago, Rock Island and Pacific Railroad Company, Debtor, (William M. Gibbons, Trustee),* Sixth Revised Service Order No. 1495 is amended by substituting the following paragraph (n) for paragraph (n) thereof:

* * * * *

(n) *Expiration date.* The provisions of this order shall expire at 11:59 p.m., May 31, 1982, unless otherwise modified, amended or vacated by order of this Commission.

Effective date. This amendment shall become effective at 11:59 p.m., January 31, 1982.

(49 U.S.C. 10304-10305 and Sec. 122, Pub. L. 96-254)

This amendment shall be served upon the Association of American Railroads, Transportation Division, as agent of the railroads subscribing to the car service and car hire agreement under the terms of that agreement and upon the American Short Line Railroad Association. Notice of this amendment shall be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing a copy with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board, members J. Warren McFarland, Bernard Gaillard, and John H. O'Brien.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-2644 Filed 2-1-82; 8:45 am]

BILLING CODE 7035-01-M

---

49 CFR Part 1033

[Service Order No. 1493; Amdt. No. 11]

Escanaba and Lake Superior Railroad Company Authorized To Use Tracks and/or Facilities of Chicago, Milwaukee, St. Paul and Pacific Railroad Company, Debtor, (Richard B. Ogilvie, Trustee)

AGENCY: Interstate Commerce Commission.

ACTION: Final rule; Amendment No. 11 to Service Order No. 1493.

SUMMARY: Amendment No. 11 extends the expiration date of Service Order No. 1493, which authorizes Escanaba and Lake Superior Railroad Company to use tracks and/or facilities of Chicago, Milwaukee, St. Paul and Pacific Railroad Company, Debtor, (Richard B. Ogilvie, Trustee) (MILW). The MILW Trustee has indicated that sufficient progress has been made in negotiations on compensation and that he concurs with this extension.

EFFECTIVE DATE: 11:59 p.m., January 30, 1982, and continuing in effect until 11:59 p.m., February 28, 1982, unless modified, amended or vacated by order of this Commission.

FOR FURTHER INFORMATION CONTACT: M. F. Clemens, Jr., (202) 275-7840 or 275-1559.

SUPPLEMENTARY INFORMATION:

Decided: January 27, 1982.

Upon further consideration of Service Order No. 1493 (46 FR 10742, 14896, 19822, 25311, 34593, 39148, 44190, 49127, 54562, 58491 and 47 FR 624), and good cause appearing therefor:

§ 1033.1493 [Amended]

It is ordered, § 1033.1493 *Escanaba and Lake Superior Railroad Company authorized to use tracks and/or facilities of the Chicago, Milwaukee, St. Paul and Pacific Railroad Company, Debtor, (Richard B. Ogilvie, Trustee),* Service Order No. 1493 is amended by substituting the following paragraph (n) for paragraph (n) thereof:

* * * * *

(n) *Expiration date.* The provisions of this order are extended to permit an additional (29) twenty-nine days for the Escanaba and Lake Superior Railroad

Company to complete compensation negotiations, and shall expire at 11:59 p.m., February 28, 1982, unless otherwise modified, amended or vacated by order of this Commission.

Effective date. This amendment shall become effective at 11:59 p.m., January 30, 1982.

(49 U.S.C. 10304–10305 and Sec. 122, Pub. L. 96–254)

This amendment shall be served upon the Association of American Railroads, Transportation Division, as agent of the railroads subscribing to the car service and car hire agreement under the terms of that agreement and upon the American Short Line Railroad Association. Notice of this amendment shall be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing a copy with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board, members J. Warren McFarland, Bernard Gaillard, and John H. O'Brien.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82–2643 Filed 2–1–82; 8:45 am]

BILLING CODE 7035–01–M

---

49 CFR Part 1033

[Thirty-first Revised Service Order No. 1473; Amdt. No. 1]

Various Railroads Authorized To Use Tracks and/or Facilities of the Chicago, Rock Island and Pacific Railroad Company, Debtor (William M. Gibbons, Trustee)

AGENCY: Interstate Commerce Commission.

ACTION: Final rule; Amendment No. 1 to Thirty-first Revised Service Order No. 1473.

SUMMARY: Pursuant to Section 122 of the Rock Island Transition and Employee Assistance Act, Pub. L. 96–254, this order authorizes various railroads to provide interim service over the Chicago, Rock Island and Pacific Railroad Company, Debtor (William M. Gibbons, Trustee), and to use such tracks and facilities as are necessary for operations. This order permits carriers to continue to provide service to shippers which would otherwise be deprived of essential rail transportation.

EFFECTIVE DATE: 11:59 p.m., January 31, 1982, and continuing in effect until 11:59 p.m., May 31, 1982, unless otherwise modified, amended or vacated by order of this Commission.

FOR FURTHER INFORMATION CONTACT: M. F. Clemens, Jr., (202) 275–7840 or 275–1559.

SUPPLEMENTARY INFORMATION:

Decided: January 27, 1982.

Upon further consideration of Thirty-first Revised Service Order No. 1473 (47 FR 2482), and with respect to the duration of this amendment, the Commission has voted pursuant to its Notice of September 21, 1981, to continue to authorize interim operations during the bankruptcy process, and good cause appearing therefor:

§ 1033.1473 [Amended]

It is ordered, § 1033.1473 *Various Railroads authorized to use tracks and/or facilities of the Chicago, Rock Island and Pacific Railroad Company, Debtor, (William M. Gibbons, Trustee),* Thirty-first Revised Service Order No. 1473 is amended by substituting the following paragraph (n) for paragraph (n) thereof:

* * * * *

(n) *Expiration date.* The provisions of this order shall expire at 11:59 p.m., May 31, 1982, unless otherwise modified, amended, or vacated by order of this Commission.

Effective date. This order shall become effective at 11:59 p.m., January 31, 1982.

(49 U.S.C. 10304–10305 and Sec. 122, Pub. L. 96–254)

This amendment shall be served upon the Association of American Railroads, Transportation Division, as agent of the railroads subscribing to the car service and car hire agreement under the terms to that agreement and upon the American Short Line Railroad Association. Notice of this amendment shall be given to the general public by depositing a copy in the office of the Secretary of the Commission at Washington, D.C., and by filing a copy with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board, members J. Warren McFarland, Bernard Gaillard and John H. O'Brien.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82–2642 Filed 2–1–82; 8:45 am]

BILLING CODE 7035–01–M

---

49 CFR Part 1100

[Ex Parte No. 55 (Sub-No. 54)]

Change to Rules Governing Qualifications and Requirements of ICC Non-Attorney Practitioners

AGENCY: Interstate Commerce Commission.

ACTION: Final rule.

SUMMARY: The Commission has modified its procedures pertaining to candidates applying for permission to take the Interstate Commerce Commission Practitioners' Examination. The modifications codified certain practices, made changes in the examination schedule, and broadened qualification standards.

These procedures relaxed the standards for qualifying for admission as an ICC non-attorney practitioner. We did not adopt suggestions in the comments that would either make qualifications more difficult, or modify our examination procedures. The following amendments to the rules do adopt certain suggestions made in the comments received.

EFFECTIVE DATE: The rules became effective December 3, 1981, and apply to the next examination which will be held on June 1, 1982.

FOR FURTHER INFORMATION CONTACT: Ellen R. Watson, (202) 275–7424; Darlene Proctor, (202) 275–7233.

SUPPLEMENTARY INFORMATION: A period of 30 days from **Federal Register** publication was allowed for comments (46 FR 51253, October 19, 1981). Four comments were received. We have given careful consideration to all suggestions. This notice revises § 1100.9(e)(1) to clarify the certification of applicants by the Association of Interstate Commerce Commission Practitioners; and revises § 1100.9 (j) and (k) to clarify the treatment of applicants who fail to appear for the examination or who postpone taking the examination.

PART 1100—GENERAL RULES OF PRACTICE

1. In 49 CFR 1100.9(e)(1) and (j) and (k) are revised to read as follows:

§ 1100.9 Persons not attorneys-at-law—qualifications and requirements for practice before the Commission.

* * * * *

(e) *Additional Certification.* (1) When an application meets the required standards, a copy will be referred to the Association of Interstate Commerce Commission Practitioners for a report to the Commission as to the reputation and character of the applicant. Inquiry also will be made by the Commission of the sponsors as to their knowledge of the applicant's legal and technical qualifications as contemplated by the Commission's Rules of Practice. If the Commission is satisfied as to the applicant's qualifications, reputation and character, then applicant will be

considered eligible to take the examination.

* * * * *

(j) *Failure to appear for examination.* Applicants who have failed to appear for, or postponed taking an examination, a total of three times without showing good cause will have any subsequently filed application returned.

(k) *Failing or postponing the examination.* Applicants who have failed the examination may reapply by submitting a request in writing with an additional $50 fee. Applicants who have postponed taking the examination three times without showing good cause will have their applications returned.

2. In 49 CFR 1100.9 paragraphs (l) and (m) are redesignated as (n) and (o) and new paragraphs (l) and (m) are added to read as follows:

* * * * *

(l) The $50 filing fee is not refundable.

(m) Any application resubmitted to the Commission after being returned must be accompanied by a $50 filing fee.

* * * * *

This action does not affect significantly the quality of the human environment or the conservation of energy resources.

(49 U.S.C. 10308)

Dated: January 18, 1982.

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

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-2645 Filed 2-1-82; 8:45 am]

BILLING CODE 7035-01-M

Proposed Rules

Federal Register
Vol. 47, No. 22
Tuesday, February 2, 1982

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

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

Importation of Apples From Australia (Including Tasmania)

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: This document proposes to amend the fruits and vegetables regulations by deleting provisions requiring fumigation with methyl bromide of each shipment of apples imported into the United States from Australia (including Tasmania), and instead to require inspection of a biometrically designed statistical sample from each shipment and to require fumigation with methyl bromide for all shipments found upon such inspection to contain pests of the family Tortricidae (fruit-leaf roller complex). This appears to be warranted in order to delete unnecessary restrictions on the importation of apples from Australia (including Tasmania).

DATE: Written comments concerning the proposed rule must be received on or before March 4, 1982.

ADDRESS: Written comments concerning the proposed rule should be submitted to Thomas J. Lanier, Chief Staff Officer, Regulatory Support Staff, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Room 635 Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Written comments received may be inspected at Room 635 of the Federal Building between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Frank Cooper, Staff Officer, Regulatory Support Staff, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Room 635 Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301–436–8248.

SUPPLEMENTARY INFORMATION:

Comments

Written comments are solicited for 30 days after publication of this document in the **Federal Register**. (March 4, 1982) It is the general policy of the Department to provide a 60 day comment period for proposed rules unless a shorter period is warranted. However, in this instance, it appears that there is no longer a need for imposing certain restrictions on the importation of all apples from Australia and that prompt action should be taken to delete the unnecessary restrictions. Further, it appears that an effort should be made to complete this rulemaking proceeding by March, since the shipping season for apples imported from Australia begins in March. Therefore, a shorter comment period of 30 days appears to be warranted and adequate under the circumstances.

Background

The fruits and vegetables regulations (referred to below as the regulations) are contained in 7 CFR 319.56 through 319.56–8, and impose prohibitions and restrictions on the importation into the United States of certain fruits and vegetables.

Under the regulations, apples and pears from Australia (the term Australia includes Tasmania when used in the Background portion of this document) and New Zealand are allowed to be imported only in accordance with certain requirements, including requirements set forth in § 319.56–2k. The requirements set forth in § 319.56–2k were designed to prevent the introduction into the United States of insects of the family Tortricidae (fruit-leaf roller complex) which occur in Australia and New Zealand, and which could be spread to apple and pear orchards in the United States by the movement of apples and pears. These pests, which do not occur in the United States, are destructive pests of apples and pears.

Section 319.56–2k provides that apples imported from Australia are required to be fumigated with methyl bromide in accordance with specified procedures. This section also provides that inspection is required of a biometrically designed statistical sample from each shipment of apples or pears imported from New Zealand and each shipment of pears imported from Australia, and that such methyl bromide fumigation is required only for those shipments found to contain the pests.

Information submitted by officials of the Australian government indicated that the regulations should be amended to delete the provisions requiring mandatory fumigation with methyl bromide for each shipment of apples imported from Australia, and instead to require fumigation with methyl bromide in accordance with the criteria established for apples and pears from New Zealand and for pears from Australia.

The mandatory fumigation requirement for apples from Australia was imposed because of a high incidence of finds of such pests. For example, in the mid 1970's approximately 40% of these apples were found to contain the pests. Accordingly, since the pests were found in such a high percentage of shipments, all shipments were required to be fumigated.

However, because of the effect of control programs in Australia, it now appears that the population of such pests has been reduced to low levels and that such pests are rarely found in apples from Australia. This conclusion is based on information submitted by the government of Australia and a survey in Australia conducted by a representative of the Department. The survey included inspections of apples, growing sites, and packing houses.

Inspection of a biometrically designed statistical sample of each shipment of apples, coupled with such methyl bromide treatment for those shipments found to contain the pests, apppears to be adequate to prevent any significant risk of introducing such pests into the United States from apples imported from Australia. Therefore, it appears that it is no longer necessary to require mandatory fumigation of each shipment of apples from Australia.

Executive Order 12291 and Regulatory Flexibility Act

This proposed rule is issued in conformance with Executive Order 12291 and Secretary's Memorandum No. 1512–1, and has been determined to be not a "major rule." Based on information compiled by the Department, it has been

determined that this rule would not have a significant effect on the economy; would not cause a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; and would not cause significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Apples from Australia do not constitute a significant portion of the apples imported into the United states. Importations of apples from Australia for fiscal year 1981 totaled 810 metric tons, valued at $413,000. The total importations of apples for fiscal year 1981 totaled 80,000 metric tons, valued at $40 million. It is expected that the adoption of the proposed rule would not result in a large increase in the importation of apples from Australia. Further, it appears that the importation of apples from Australia is not the primary activity of any business in the United States.

There were fewer than 75 shipments of apples from Australia during fiscal year 1981. It appears that the adoption of the proposed rule would reduce the cost of each shipment by approximately $75 as a result of reducing the number of fumigations.

Alternatives were considered in connection with the proposal. Consideration was given concerning whether (1) to continue the system of mandatory fumigation with methyl bromide of each shipment of apples imported into the United States from Australia, or (2) to require inspection of a biometrically designed statistical sample from each shipment, and to require such fumigation for any shipments found upon inspection to contain pests of the family Tortricidae (fruit-leaf roller complex). Alternative (2) is proposed. As explained above, it appears that the less stringent provisions in alternative (2) would be adequate to allow apples to be imported from Australia without a significant risk of introducing insects of the family Tortricidae (fruit-leaf roller complex) into the United States. Further, it appears that there is no other feasible alternative that would maximize net benefits to society at a low net cost.

Dr. H. C. Mussman, Administrator of the Animal and Plant Health Inspection Service, has determined that, under the circumstances explained above, it is anticipated that the proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities.

Proposed Amendments

PART 319—FOREIGN QUARANTINE NOTICES

Under the circumstances referred to above, it is proposed to amend § 319.56–2k of the fruits and vegetables regulations (7 CFR 319.56–2k) as follows:

§ 319.56–2k [Amended]

1. By removing "each shipment of pears moved from" immediately before "Australia" in § 319.56–2k(a)(1).

2. By removing "for apples shipped from Australia (including Tasmania) and" in § 319.56–2k(a)(2).

(Secs. 5 and 9, 37 Stat. 316, 318 (7 U.S.C. 159, 162); 37 FR 28464, 28477, as amended; 38 FR 19141)

Done at Washington, D.C. this 28th day of January 1982.

Harvey L. Ford,

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

[FR Doc. 82–2714 Filed 2–1–82; 8:45 am]

BILLING CODE 3410–34–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[LR–4–82]

Travel Expenses of Members of Congress

AGENCY: Internal Revenue Service, Treasury.

ACTION: Correction to notice of proposed rulemaking.

SUMMARY: In the Rules and Regulations portion of this **Federal Register**, the Internal Revenue Service is issuing a correction relating to temporary income tax regulations (Treasury Decision 7802) that relate to deductions for Members of Congress for travel expenses in Washington, D.C., allowed without substantiation. The text of those temporary regulations also serves as the comment document for a notice of proposed rulemaking. This document reflects the fact that the text of Treasury Decision 7802 is corrected for purposes of the proposed rulemaking.

FOR FURTHER INFORMATION CONTACT: Jason R. Felton of the Legislation and Regulations Division, Office of Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, D.C. 20224, Attention: CC:LR:T, 202–566–3318, not a toll-free call.

SUPPLEMENTARY INFORMATION:

Background

On January 21, 1982, the **Federal Register** published Treasury Decision 7802 (47 FR 2986) which contained temporary regulations relating to travel expenses of Members of Congress. The text of the temporary regulations also served as the text of proposed regulations under 26 CFR Part 1 (§ 1.274) (47 FR 3006).

Need for Correction

The need for correction arises from a typographical error in the last line of § 5e.274–8(c)(1)(i) and in the last line of § 5e.274–8(c)(1)(ii).

Correction of Publication

For the text of the correction to the notice of proposed rulemaking (47 FR 3006), see FR Doc. 82–2716 published in the Rules and Regulations portion of this issue of the **Federal Register.**

David E. Dickinson,

Director, Legislation and Regulations Division.

[FR Doc. 82–2718 Filed 2–1–82; 8:45 am]

BILLING CODE 4830–01–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 906

Surface Coal Mining and Reclamation Operations on Federal Lands Under the Permanent Program; State-Federal Cooperative Agreements; Colorado

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

ACTION: Proposed rule.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) is proposing to adopt a cooperative agreement between the Department of the Interior and the State of Colorado for the regulation of surface coal mining operations on Federal lands in Colorado under the permanent regulatory program. Such a cooperative agreement is provided for in the Surface Mining Control and Reclamation Act of 1977. This notice of proposed rulemaking provides additional information on the proposed terms of the cooperative agreement and other issues.

DATES: The public comment period on this proposed rule will extend until April 5, 1982. The public hearing will be held at the location shown in **ADDRESSES,** below, on March 15, 1982, beginning at 9:30 a.m. Any person interested in making an oral or written presentation

at the hearing must contact OSM at the address and phone number listed under **FOR FURTHER INFORMATION CONTACT** by March 3, 1982.

ADDRESSES: Written comments must be mailed to:

Administrative Record R&I–09, Office of Surface Mining, Room 5315, South Interior Building, 1951 Constitution Avenue, NW., Washington, D.C. 20240.

Written comments may be hand carried to:

Office of Surface Mining, Room 241, South Interior Building, 1951 Constitution Avenue, NW., Washington, D.C. 20240; or

Office of Surface Mining, Room 5315, 1100 L Street, NW., Washington, D.C. 20005.

Copies of the proposed agreement and of the related information required under 30 CFR Part 745 are available for inspection Monday through Friday, 8:30 a.m. to 4 p.m., excluding holidays, at the following addresses:

State of Colorado, Department of Natural Resources, Mined Land Reclamation Division, 1313 Sherman Street, Denver, Colorado 80203;

Office of Surface Mining, Room 5315, 1100 L Street, NW., Washington, D.C. 20005.

The public hearing will be held at the Office of Surface Mining, U.S. Department of the Interior, Brooks Tower, 1020 15th Street, Denver, Colorado 80202. If no person has contacted OSM by March 3, 1982 to express an interest to participate in the hearing, the hearing will be cancelled. A notice announcing any cancellation will be published in the **Federal Register.**

FOR FURTHER INFORMATION CONTACT: Andrew F. DeVito, Office of Surface Mining, South Interior Building, 1951 Constitution Avenue, NW., Washington, D.C. 20240; Phone: (202) 343–5866.

SUPPLEMENTARY INFORMATION:

I. Procedural Matters

A. Public Hearing

Individual testimony at the public hearing will be limited to 15 minutes. The hearings will be transcribed by a court reporter. Filing of a written statement at the time of giving oral testimony will be helpful and would facilitate the job of the court reporter. Submission or written statements in advance of the hearing would greatly assist OSM officials who will attend the hearing by providing an opportunity to consider appropriate questions which could be asked for clarification or to request more specific information from the person testifying.

B. Public Meetings

Representatives of OSM will be available to meet during the comment period at the request of members of the public to receive their recommendations and comments concerning the proposed cooperative agreement. In order to schedule or attend such meetings, contact the individual listed under **FOR FURTHER INFORMATION CONTACT.** OSM representatives will be available for these meetings between 9 a.m. and 4 p.m. local time, Monday through Friday, excluding holidays. All such meetings will be open to the public. Notices of such meetings and where they will be held will be posted in advance in the Administrative Record Room, Room 5315, 1100 L Street, NW., Washington, D.C. 20005.

C. Contacts with State Representatives.

The Department has previously announced (45 FR 58378, September 3, 1980) its intention to follow the "Guidelines for Contacts with Employees and Officials During Consideration of State Permanent Regulatory Programs" published at 44 FR 54444 (September 19, 1979), during the process of developing cooperative agreements with the States. As written, the guidelines apply only to the State program review and decision process. However, the Department believes that the guidelines should also be applied in the development of State-Federal permanent program cooperative agreements because of the close interrelationship between each cooperative agreement and the approved State program. The need to reserve the ability of the Department and the State to work together through the stages of the cooperative agreement and the right of the public to be informed and to have the opportunity to comment meaningfully on issues raised are principles applicable to permanent program cooperative agreement rulemakings.

This decision requires that minor changes in the guidelines be made to clarify their applicability to cooperative agreement rulemakings.

Accordingly, revised guidelines for contacts with Departmental employess and officials during permanent program cooperative agreement rulemakings are given below. See the notice of September 19, 1979, 44 FR 54444, for a full discussion of the guidelines and supporting principles. The September 19, 1979, guidelines remain fully applicable to the State program review process.

1. Upon request the Department will meet with any member of the public through the end of the public comment period. Notices of scheduled meetings will be posted in a public place. The meetings will be open.

2. The Department will meet with State representatives or have telephone conversations with them, upon the initiative of either party, up to the point of the Secretary's decision to enter into a permanent program cooperative agreement with a State. These meetings will be open to the public unless the Department decides an executive session is appropriate. Advance notice of scheduled meetings will be posted in a public place. Notice of the executive sessions will be posted in a public place.

3. The Department will keep a summary record of all meetings and discussions, whether in person or by telephone, on a proposed cooperative agreement. This record will include a summary of the discussion and a list of all written information OSM receives. All such records along with all written communications relating to the cooperative agreement shall be made available to the public.

4. In those instances where the Department has conducted meetings or discussions with a State after the close of the public comment period, the Department will include summaries of the meetings in the record and, if necessary to assure an effective opportunity for public participation, provide an opportunity for the public to review the record of such meetings and discussions and to comment on them before a decision is made to enter into a permanent program cooperative agreement.

D. Public Comments

Written and oral comments should be as specific as possible. Although all comments are invited, those most likely to influence decisions on the cooperative agreement will be those which are supported by reasoning.

All written comments must be received by OSM by 5:00 p.m. e.s.t. on the date the comment period closes. Comments received after that hour will not be considered or included in the administrative record of this rulemaking. OSM cannot ensure that written comments received or delivered during the comment period to locations other than those specified above will be considered and included in the administrative record. Notices of meetings, summaries of all meetings and telephone conversations, along with all public comments received and a transcript of the public hearing, will also be made available for public review in the Office of Surface Mining at the address noted above.

In response to the Notice of Intent published on August 5, 1981, two letters were received from commenters concerning the terms of the cooperative agreement submitted by the State. Most of the matters commented on had already been revised during discussions held with representatives from Colorado. Those which remain will be dealt with in the preamble to the final rules after further discussion with the State.

II. Background

On August 5, 1981, the Office of Surface Mining (OSM) issued a Notice of Intent to publish a proposed cooperative agreement with the State of Colorado pursuant to Section 523(c) of the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act), 30 U.S.C. 1201 *et seq.*, and the implementing regulations at 30 CFR Part 745 (45 FR 39855). The purpose of this proposed rulemaking is to adopt a permanent program cooperative agreement between the Department of the Interior and the State of Colorado which will give Colorado primacy in the administration of its approved permanent regulatory program on Federal lands in that State. Section 523(c) of the Act allows for the State and the Secretary to enter into a permanent program cooperative agreement if the State has an approved State program for the regulation of surface coal mining operations on non-Federal and non-Indian lands.

Consistent with Congress' intent that implementation of the Act be accomplished in two phases, Section 523(c) of the Act provides for two kinds of State-Federal cooperative agreements: Initial program cooperative agreements and permanent program cooperative agreements. Initial program cooperative agreements are authorized by the second sentence of section 523(c), which provides that "States with cooperative agreements existing on the date of enactment of this Act, may elect to continue regulation on Federal lands within the State, prior to approval by the Secretary of their State program, or imposition of a Federal program, provided that such existing cooperative agreement is modified to fully comply with the initial regulatory procedures set forth in section 502 of this Act." 30 U.S.C. 1273(c). The State of Colorado had a cooperative agreement with the Department prior to August 3, 1977; however, it was not modified pursuant to section 523(c).

Permanent program cooperative agreements are authorized by the first sentence of section 523(c) which provides that "[a]ny State *with an approved State program* may elect to enter into a cooperative agreement with the Secretary to provide for State regulation of surface coal mining and reclamation operations on Federal lands within the State, provided the Secretary determines in writing that such State has the necessary personnel and funding to fully implement such a cooperative agreement in accordance with the provision of this Act." 30 U.S.C. 1273(c) (italics added). The procedures for States to elect to enter into permanent program cooperative agreements are found in 30 CFR 745.

On February 29, 1980, the Governor of the State of Colorado submitted the Colorado State program for approval pursuant to Section 503 of the Act and 30 CFR Part 731. The State program was conditionally approved by the Secretary and became effective upon publication in the **Federal Register** on December 15, 1980 (45 FR 82173).

By letter of March 11, 1981, the State of Colorado submitted a draft of a proposed permanent program cooperative agreement. On April 16, 1981, representatives from OSM and the State met to discuss the terms of that draft. On May 13, 1981, a formal request for the proposed permanent program cooperative agreement was received from the State. The May 13, 1981, proposal was published in the **Federal Register** on August 5, 1981 (46 FR 39855) with a request for comments from interested parties. On September 24, 1981, representatives from the State of Colorado met with OSM to discuss the May 13, 1981, terms submitted by the State.

In entering into a permanent program cooperative agreement with the State of Colorado, the Secretary will be implementing two other requirements of Section 523 of the Act. These statutory requirements are (1) consideration of the diverse and unique characteristics of Federal lands in Colorado, if any, and (2) incorporation of the requirements of the approved State program into the Federal lands program in Colorado. See 30 U.S.C. 1273(a).

III. The State of Colorado's Application

30 CFR 745.11(b) (1) through (8) of OSM's regulations require that certain information be submitted with a request for a permanent program cooperative agreement, if the information has not previously been submitted in the State program. The State of Colorado submitted a proposed permanent program cooperative agreement and the supporting information required by 30 CFR 745.11(b) on May 13, 1981. Most of the information relating to the budget, staffing, organization and duties of the State regulatory authority, the Colorado Mined Land Reclamation Division (MLRD), was described as appearing in Colorado's Proposed Permanent Coal Program Text. See 30 CFR 745.11(b) (1), (2), (3), (4), (5), and (6). In addition, a written certification from the Attorney General of the State of Colorado concluded that no State statutory, regulatory or other legal constraint exists which would limit the capability of the Department of Natural Resources, acting through the Mined Land Reclamation Division, to fully comply with Section 523(c) of the Act, as implemented by 30 CFR 745. See 30 CFR 745–11(b)(8).

IV. The Text of the Proposed Agreement

Since Colorado's submission of a proposed permanent program cooperative agreement on May 13, 1981, changes have been made based on meetings and discussions between representatives of Colorado and the Department of the Interior. The terms of the revised proposed agreement are summarized below. OSM emphasizes that the proposed permanent program cooperative agreement is subject to further change because of public comments and/or further discussion with the State of Colorado. In general, changes were made throughout the proposed cooperative agreement for clarity.

Article I: Introduction and Purpose. This article would set forth the legal authority for the cooperative agreement which is contained in Section 523 of the Act. The purposes of the agreement are also listed.

Article II: Effective Date. This article provides that the agreement would be effective following signing by the Secretary and the Governor, and upon publication as a final rule in the **Federal Register**. It would remain in effect until terminated as provided in Article XI.

Article III: Scope. Article III would provide that the laws, regulations, terms and conditions of Colorado's State program are applicable to Federal lands in Colorado except as otherwise stated in the agreement, the Act, 30 CFR 745.13, or other applicable laws. The effect of this provision would be to adopt the Colorado State program as substantive Federal law enforceable by the State and the United States. This provision also specifically implements Section 523(a) of the Act, which provides that "(w)here Federal lands in a State with an approved State program are involved, the Federal lands program shall, at a minimum, include the requirements of the approved State program." 30 U.S.C. 1273(a). Excluded

from the scope of the Agreement are the authorities and responsibilities reserved for the Secretary pursuant to the Act and 30 CFR 745.13.

Article IV: Requirements for Cooperative Agreement. This article would mutually bind the Governor and the Secretary to the provisions of the agreement and the conditions and requirements contained in Article IV. The responsible agency in the State of Colorado for purposes of administering this agreement would be the MLRD which has and must continue to have authority under State law to carry out this agreement. Comments are invited on whether MLRD has sufficient authority to carry out the terms of this agreement. See 30 CFR 745.11(f).

Article IV also would provide that the State may be reimbursed pursuant to Section 705(c) of the Act if the agreement has been implemented and if necessary funds have been appropriated to OMS by Congress. Section 705(c) of the Act provides that a State with a cooperative agreement may receive an increase in its annual grant for the development, administration and enforcement of a State program on Federal lands by an amount which the Secretary determines is approximately equal to the amount the Federal government would have expended to regulate surface coal mining and reclamation operations on the Federal lands within the State. See 30 U.S.C. 1295(c). The reference in section 705(c) to section 523(d) is obviously a typographical error. The correct reference is section 523(c). The regulations implementing section 705(c) appear at 30 CFR 735.16 through 735.26. If adequate funds have not been appropriated, OSM and MLRD will meet to decide on appropriate measures to insure that mining operations are regulated in accordance with the Program. Funds provided to the State are to be adjusted in accordance with Office of Management and Budget (OMB) Circular A–102 (Uniform Requirements For Assistance To State And Local Governments), Attachment E (Program Income). OSM recognizes the State's concern that the calculation of "program income" and any consequent adjustments required by the OMB Circular be made in an equitable manner.

The Article also deals with reports and records, personnel, the use of equipment and laboratories and permit application fees. The provisions are short and self-explanatory.

Article V: Definitions. This Article would specify which definitions will apply. Basically, it adopts the definitions presently in force in the Act, OSM's permanent regulatory program and the Colorado program. In the case of conflict, the State definition will apply except in the case of a term which defines the Secretary's continuing responsibilities under the Act and other laws.

It should be noted that the term "Federal lands" as defined in both the State and Federal statutes and regulations does not include "Indian lands." The term "permit application package," used throughout the cooperative agreement beginning in Article VI, is a new term. It includes the requirements of the Mineral Leasing Act of 1920 (MLA) implemented by the 30 CFR Part 211 regulations of the U.S. Geological Survey and the requirements of SMCRA for a surface coal mining permit implemented by 30 CFR Part 741. Comments are invited on use of the term "permit application package."

Article VI: Policies and Procedures: Review of a Permit Application to Conduct Surface Coal Mining and Reclamation Operations or Application for a Permit Revision. Under this Article, an operator on Federal lands would be required by MLRD and the Director of OSM to submit a permit application package in an appropriate number of copies to MLRD and OSM. The permit application package is to be in the form required by MLRD and contain any supplemental information, such as data pertaining to the life of the mine, which may be required by the Department of the Interior. At a minimum, the application package must include the necessary information for MLRD and the Department to make a determination of compliance with the State program, applicable terms and conditions of the Federal coal lease, and applicable requirements of other Federal laws and regulations. Comments are invited on whether more specificity is required under subsection 7(e) of this Article regarding the State program and other Federal laws and regulations which may be applicable.

Article VI also would describe the procedures for the cooperative review and analysis of permit applications on Federal lands. The proposed agreement identifies MLRD as primarily responsible for the analysis and review of the permit application on Federal lands in Colorado. OSM would assist the State in carrying out its responsibility for the analysis and review. However, this does not preclude an independent determination by the Department of the Interior with respect to those statutory requirements and decisions which the Secretary cannot delegate to the State. In assuming primary responsibility for review and analysis of the permit applications, MLRD would also be the primary point of contact for operators on behalf of both the State and the Department. All joint State-Federal determinations would be channeled to the operator through MLRD. However, this does not preclude the Secretary from contacting the operator independently of the State to carry out his statutory responsibilities. Copies of any correspondence with the applicant as well as any information OSM receives from an applicant will be provided to MLRD. OSM will coordinate with all appropriate Federal agencies to ensure timely funneling of analyses and conclusions to MLRD.

In addition, this Article refers to Appendix B. The exact procedures to be followed in processing the permit application package or application for a permit revision are listed in Appendix B, and in summary they are:

A. MLRD would be the primary point of contact and will coordinate communications with the applicant. MLRD and OSM would receive the permit application package or the application for a permit revision in an appropriate number. OSM would be required to transmit an appropriate number of copies to the Bureau of Land Management, Geological Survey, and other appropriate Federal agencies specified by the Secretary for their review.

MLRD would determine the completeness of the permit application package, coordinate the technical review of the permit application package, develop the decision document, and issue the permit or permit revision for surface coal mining operations. The Secretary would be required to review and approve the elements of the package relating to the MLA and other requirements of the permit application package such as cultural resources and post-mining land use which are required by Federal law and cannot be delegated to the State. Even though the permit is issued by the State, mining may not commence until the Secretary approves the mining plan pursuant to the requirements of the MLA and complies with the requirements of the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321, *et seq.* Because of the timing requirements of NEPA, it is possible that the permit will be issued before the mining plan is approved by the Secretary.

B. OSM, at the request of MLRD, would assist as possible in the review of the permit application package or application for a permit revision and provide technical assistance to the

MLRD. OSM also would coordinate with MLRD to incorporate NEPA requirements into the decision document. Responsibility for compliance with NEPA remains with OSM.

C. The Geological Survey would assist MLRD as arranged and would be the point of contract with the applicant on issues concerned exclusively with its regulations codified at 30 CFR Part 211.

D. The Bureau of Land Management would assist MLRD as arranged and would determine whether the pemit application or application for a permit revision provides for post-mining land use consistent with BLM's land use plan and whether it provides sufficient protection for resources not covered by the Federal coal lease.

E. Other agencies specified by the Secretary would review the permit application package or application for a permit revision in regard to their responsibilities under Federal law.

Coal Exploration. The original cooperative agreement proposed by the State and published in the **Federal Register** on August 5, 1981 (45 FR 39855), contained an Article dealing with the regulation of coal exploration on Federal lands. This Article (formerly Article VII) has been deleted to allow further consideration of the proper roles of OSM, GS, BLM, and the State.

Article VII: Inspections. This Article would specify that MLRD must conduct inspections on Federal lands and prepare and file inspection reports in accordance with its approved Program.

Administrative provisions of this Article include designation of MLRD as the principal point of contact with the operator and a provision for reasonable notice to the State prior to a Federal inspection.

The right of Federal and State agencies to conduct inspections for purposes outside the scope of the proposed cooperative agreement is not affected. In particular, this Article would preserve the Department's obligation and authority to conduct inspections pursuant to 30 CFR 743 and 842.

Article VIII: Enforcement. Proposed Article VIII sets forth the enforcement obligations and authorities of OSM and MLRD. MLRD would have primary enforcement authority on Federal lands in accordance with the requirements of the cooperative agreement and the approved State program.

This Article also would specify that the parties will consult prior to revoking or suspending a permit. The Secretary's obligation to enforce violations of Federal law other than the Act is preserved as is OSM's authority to take enforcement action to comply with Parts 843 and 845. In taking such action, OSM would apply the performance standards contained in the approved State program, but would use the Federal procedures and penalty system.

Article IX: Bonds. Under this Article, MLRD would require each operator to submit a single performance bond to meet Federal and State requirements. The bond would be payable to the State and the United States, if required by regulation. MLRD would be required to obtain the consent of the Department prior to releasing or forfeiting an operator's performance bond. In addition to a performance bond, an operator still would be required to furnish a lease bond and a lessee protection bond. Bonding requirements of the MLA and other Federal laws appear at 30 CFR Part 742 and 43 CFR Part 3474.

Article X: Designation of Lands as Unsuitable. This Article describes the roles of MLRD and OSM in the review and processing of petitions to designate lands as unsuitable for surface coal mining operations on adjacent Federal and non-Federal lands. The authority to designate Federal lands as unsuitable would be reserved to the Secretary or his designated representative. See 30 CFR 745.13. Petitions for designation must be filed in accordance with 30 CFR Part 769. This provision, taken from the Montana Cooperative Agreement, was substituted for the language originally proposed by Colorado. It was felt that the simplified language was more acceptable and was found to be working well in the Montana agreement.

Article XI: Termination of Cooperative Agreement. Article XI would provide for termination of the proposed permanent program cooperative agreement in accordance with 30 CFR 745.15.

Article XII: Reinstatement of Cooperative Agreement. Article XII would provide for reinstatement of the agreement under 30 CFR 745.16.

Article XIII: Amendment of Cooperative Agreement. Article XIII would provide that the proposed permanent program cooperative agreement may be amended by mutual agreement of the Governor and Secretary in accordance with 30 CFR 745.14.

Article XIV: Change in State or Federal Standards. This Article recognizes that the Secretary or the State may, from time to time, promulgate new or revised performance or reclamation requirements, or enforcement and administration procedures necessitating corresponding changes to the cooperative agreement. Such changes would be made in accordance with 30 CFR Part 732 in order to be consistent with State program regulations.

Article XV: Changes in Personnel and Organization. As required by 30 CFR 745.12, this Article would require the State and the Department to advise each other of changes in the organization, structure, functions, duties and funds of the offices, departments, divisions, and persons within their organizations which could affect administration or enforcement of the agreement.

Article XVI: Reservation of Rights. Article XVI recognizes that the Act, 30 CFR 745.13, and other authorities prohibit the Secretary from delegating certain authorities to the State. Article XVI would state that the cooperative agreement shall not be construed as waiving or preventing the assertion of any rights not expressly addressed in the agreement or available to the parties under the authorities cited in Appendix A.

Pursuant to 30 CFR 745.13 and the terms of this Article, the Secretary would reserve authority and responsibility for several MLA functions (*e.g.*, release of lease bonds). Under Section 523 of the Act and 30 CFR 745.13, the Secretary must retain authority to approve mining plans on Federal lands or major modifications thereto.

Section 745.13 of OSM's regulations lists other specific responsibilities reserved to the Secretary. Among these responsibilities is the designation of Federal lands as unsuitable for surface coal mining operations and the termination of such designations.

Other Reservations. The Department of the Interior also would reserve the authority and responsibility for several specific functions which are an integral part of the permit application review procedures discussed earlier. These items include, but are not limited to, the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321, *et seq.*; compliance with the consultation requirements of the Endangered Species Act of 1973, as amended, 16 U.S.C. 1531 *et seq.*; and Section 106 of the National Historic Preservation Act of 1966, 16 U.S.C. 470f.

Compliance with NEPA. The Department and its member offices and bureaus must comply with NEPA, its implementing regulations, and the Department's own guidelines. See 40 CFR 1500 *et seq.* (regulations of the Council on Environmental Quality) and 45 FR 27541 (April 23, 1980) (Department of the Interior Notice of Final Revised Procedures). See also 45 FR 10043 (February 14, 1980) (Notice of Proposed Revised Instructions for the Office of

Surface Mining). These authorities require the Department, prior to a decision on a permit application package on Federal lands, to prepare an environmental assessment or environmental impact statement. The current regulations at 30 CFR 745.13(b) do not allow the Secretary to delegate his NEPA duties to the States. However, the Secretary believes that this regulation does allow States to assist in preparation of NEPA documents (see 40 CFR 1506.2), with final action reserved to the Secretary.

The Department invites comment on whether the procedures for compliance with NEPA and its implementing regulations and guidelines are adequately addressed in the proposed cooperative agreement.

The Endangered Species Act (16 U.S.C. 1536). This Federal law requires that the Department take such steps as are necessary to insure that actions authorized, funded, or carried out by Federal departments and agencies do not jeopardize the continued existence of an endagered species, or result in the destruction or modification of a species' critical habitat. 16 U.S.C. 1536. See 50 CFR 402 (regulations on inter-agency cooperation under the Endangered Species Act). OSM's regulations at 30 CFR 745.13(m) provide that the Secretary's obligation to consult under Section 7(a) of the Endangered Species Act regarding actions on Federal lands may not be delegated to a State.

The National Historic Preservation Act (16 U.S.C. 470f). Compliance with Section 106 of the National Historic Preservation Act and its implementing regulations (36 CFR Part 800) is mandatory where the approval of mining on Federal lands may adversely affect sites, buildings, objects or districts which are listed on, or eligible for listing on, the National Register of Historic Places. Compliance is achieved through early consulation with and involvement of State Historic Preservation Officers and, in some cases, consultation with the Advisory Council on Historic Preservation.

OSM and the Department must also comply with Executive Order 11593, "Protection and Enhancement of the Cultural Environment" (May 13, 1971). Executive Order 11593 contains two principal requirements. First, with respect to properties not owned by the Federal government, agencies and departments must establish procedures for consultation with the Advisory Council on Federal plans and programs affecting such properties.

Second, the Order requires all Federal agencies and departments to inventory and nominate historic sites, buildings, districts and objects that are on Federal property and that may be eligible for inclusion on the National Register of Historic Places.

Pending completion of the inventory and nomination process, Federal agencies and departments must take measures ot ensure that eligible properties are not substantially altered, and no action affecting an eligible property can be taken without first providing the Advisory Council on Historic Preservation an opportunity to comment. The Archeological and Historic Preservation Act of 1974, 16 U.S.C. 469a–1, provides a means for private parties or the Federal government to actually recover archeological materials and data through, for example, surveys, excavation and removal to a museum. See Statement of Program Approach of the Heritage Conservation and Recreation Service at 44 FR 18117 (March 26, 1979).

These responsibilities would be reserved to the Secretary under the proposed cooperative agreement since they are not "expressly addressed" (Article XVI).

Floodplain Management and Wetland Protection. The Office of Surface Mining has published a general statement of policy which describes the existing procedural mechanisms for compliance with Executive Order 11988, Floodplain Management (May 24, 1977) and Executive Order 11990, Protection of Wetlands (May 24, 1977). See 45 FR 49872 (July 25, 1980). Secretarial approval of surface coal mining operations on Federal lands is discussed in that **Federal Register** notice at 45 FR 49872–73. As noted therein, the method and responsibility for compliance with these two Orders is to be a subject of the permanent program cooperative agreements under 30 CFR Part 745.

Since the proposed cooperative agreement with Colorado does not directly discuss compliance with these Orders, the obligation for compliance with them would remain with the Secretary and would not be delegated to Colorado.

Statement of Economic Effects and of Evironmental Impact. In a "Determination of Significance" document prepared on December 31, 1979, and approved by the Assistant Secretary, Energy and Minerals, on January 7, 1980, the Department determined that the "promulgation of proposed or final rules for entering into a cooperative agreeement with a State pursuant to 30 U.S.C. 1273 for State regulations of surface coal mining and reclamation operations on Federal lands was not a significant action and would not require a regulatory analysis." A copy of this determination was filed with the Department's Office of Policy Analysis and the Division of General Laws.

There are recordkeeping and reporting requirements in the proposed rules which are the same as and required by the permanent program regulations which required clearance from the Office of Management and Budget under 44 U.S.C. 3507 and were assigned the following clearance numbers:

Location of requirement	OMB clearance No.
Article IV.5.G (Required by 30 CFR Part 725)	1029–0012
Article VI.7 (Required by 30 CFR Part 741)	1029–0026
Article VI.10 (Required by 30 CFR Part 786)	1029–0041
Article VII.14 (Required by 30 CFR Part 840)	1029–0051
Article IX.23 (Required by 30 CFR Part 800)	1029–0043

The Department has reviewed this determination in light of recent changes in the regulatory process brought about by Executive Order 12291, February 17, 1981; the Regulatory Flexibility Act (Pub. L. 96–354); and the Paperwork Reduction Act of 1980 (Pub. L. 96–511). Having conducted this review, the Department has determined that this document is not a major rule and does not require a regulatory impact analysis under Executive Order 12291. The document will not have a significant economic effect on a substantial number of small entities and therefore does not require a regulatory flexibility analysis under the Regulatory Flexibility Act, 5 U.S.C. 605(b). This determination was made by the Director, OSM and approved by the Office of Assistant Secretary, Energy and Minerals. A copy is on file in the OSM Administrative Record Room, Room 5315.

The proposed rule was listed in the Department's October 30, 1981, Semiannual Agenda of rules scheduled for review and development.

Proceedings relating to adoption of a permanent program cooperative agreement are part of the Secretary's implementation of the Federal lands program pursuant to Section 523 of the Act. Such proceedings are, therefore, exempt under Section 702(d) of the Act from the requirements to prepare a detailed statement pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)).

Dated: January 11, 1982.

Daniel N. Miller, Jr.,

Assistant Secretary, Energy and Minerals.

Cooperative Agreement

The Governor of the State of Colorado, acting through the Mined

Land Reclamation Division (MLRD), and the Secretary of the Department of the Interior, acting through the Office of Surface Mining (OSM), enter into a Cooperative Agreement (Agreement) to read as follows.

Article I: Introduction and Purpose. 1. This Agreement is authorized by Section 523(c) of the Surface Mining Control and Reclamation Act (Act), 30 U.S.C. 1273(c), which allows a State with a permanent regulatory program (Program) approved by the Secretary under 30 U.S.C. 1253, to elect to enter into an Agreement for the regulation and control of surface coal mining operations on Federal lands.

This agreement provides for State regulation, consistent with the Act, the Federal lands program (30 CFR Part 745) and the Colorado program for surface coal mining and reclamation operations, on Federal lands.

2. The purpose of this Agreement is to (a) foster Federal-State cooperation in the regulation of surface coal mining; (b) eliminate intergovernmental overlap and duplication; and (c) provide uniform and effective application of the Program on all non-Indian lands in Colorado, in accordance with the Act and the Program.

Article II: Effective Date. 3. After being signed by the Secretary and the Governor, the Agreement shall be effective upon publication in the **Federal Register** as a final rule.

This Agreement shall remain in effect until terminated as provided in Article XI.

Article III: Scope. 4. Under this Agreement, the laws, regulations, terms, and conditions of the Program conditionally approved effective December 15, 1980, 30 CFR Part 906, or as hereinafter amended in accordance with 30 CFR 732.17, for the administration of the Act, are applicable to Federal lands within the State except as otherwise stated in this Agreement, the Act, 30 CFR 745.13, or other applicable laws.

Article IV: Requirements for Agreement. 5. The Governor and the Secretary affirm that they will comply with all of the provisions of this Agreement and will continue to meet all the conditions and requirements specified in this Article.

A. Responsible Administrative Agency: The MLRD shall be responsible for administering this Agreement on behalf of the Governor on Federal lands throughout the State. The Assistant Secretary—Energy and Minerals, or designee, shall administer this agreement on behalf of the Secretary in accordance with the regulations in 30 CFR Chapter VII.

B. Authority of State Agency: The MLRD has and shall continue to have the authority under State law to carry out this Agreement.

C. Funds: Upon application by the MLRD and subject to appropriations, the Department shall provide the State with the funds to defray the costs associated with carrying out responsibilities under this Agreement as provided in Section 705(c) of the Act and 30 CFR 735.16. If sufficient funds have not been appropriated to OSM, OSM and MLRD shall promptly meet to decide on appropriate measures that will insure that mining operations are regulated in accordance with the Program. If agreement cannot be reached, then either party may terminate the cooperative agreement.

Funds provided to the State shall be adjusted in accordance with OMB Circular A–102, Attachment E.

D. Reports and Records: The MLRD shall make annual reports to the Director containing information with respect to compliance with the terms of this Agreement, pursuant to 30 CFR 745.12(c). The MLRD and the Director shall exchange, upon request, except where prohibited by Federal law, information developed under this Agreement. The Director shall provide the MLRD with a copy of any final evaluation report prepared concerning State administration and enforcement of this Agreement.

E. Personnel: The MLRD shall have the necessary personnel to fully implement this Agreement in accordance with the provisions of the Act and the approved State program. If sufficient funds have not been appropriated, OSM and MLRD shall promptly meet to decide on appropriate measures that will insure that mining operations are regulated in accordance with the program.

F. Equipment and Laboratories: The MLRD shall have access to equipment, laboratories, and facilities with which all inspections, investigations, studies, tests, and analyses can be performed which are necessary to carry out the requirements of this Agreement.

G. Permit Application Fees: The amount of the fee accompanying an application for a permit shall be determined in accordance with section 34–33–110(l) CRS 1973, as amended. All permit fees shall be retained by the State and deposited with the State Treasurer in the General Fund. The Financial Status Report submitted pursuant to 30 CFR 725.23 shall include a report of the amount of fees collected during the prior State fiscal year.

Article V: Definitions. 6. Terms and phrases used in this Agreement which are defined in the Act, 30 CFR Parts 700, 701, and 740 and as defined in the Colorado Surface Coal Mining Reclamation Act and the rules and regulations promulgated pursuant to the Colorado act shall be given the meaning set forth in said definitions. Where there is a conflict between the above referenced State and Federal definitions, the definitions used in the approved State program will apply, except in the case of a term which defines the Secretary's continuing responsibilities under the Act and other laws.

Article VI: Policies and Procedures: Review of a Permit Application to Conduct Surface Coal Mining and Reclamation Operations or an Application for a Permit Revision. 7. The MLRD and the Director shall require an operator on Federal lands to submit a permit application package or an application for a permit revision in an appropriate number of copies to the MLRD and OSM. Any documentation or information prepared by the operator for the sole purpose of complying with the 3-year requirement of Section 7(c) of the Mineral Leasing Act (MLA) will be submitted directly to the Geological Survey. If such documentation is submitted as part of a permit application, a copy of the entire package will be forwarded to the Geological Survey by OSM.

The permit application package or application for a permit revision shall be in the format required by the MLRD and include any supplemental information required by the Department. The permit application package or application for a permit revision shall satisfy the requirements of 30 CFR 741.12(b) and 30 CFR 741.13, and include the information required by, or necessary for, the MLRD and the Department to make a determination of compliance with:

(a) Section 34–33–101, *et seq.*, CRS 1973, as amended;

(b) Regulations of the Colorado Mined Land Reclamation Board for Coal Mining;

(c) Applicable terms and conditions of the Federal coal lease;

(d) Applicable requirements of the Geological Survey's 30 CFR 211 regulations pertaining to the Mineral Leasing Act requirements; and

(e) Applicable requirements of the approved State program and other Federal laws including, but not limited to, those listed in Appendix A.

8. The MLRD shall assume the primary authority pursuant to Section 523(c) of the Act for the analysis, review and approval of the permit application or application for permit revision according to the standards of the

approved State program. The Director shall assist the MLRD in the analysis of the permit application or application for a permit revision and coordinate the other appropriate Federal agencies as specified by the Secretary according to the procedures set forth in Appendix B. The Department shall concurrently carry out its responsibilities which cannot be delegated to the State under the MLA, as amended, National Environmental Policy Act (NEPA), and other public laws (including, but not limited to, those in Appendix A) according to the procedures set forth in Appendix B so as to the maximum extent possible not duplicate the responsibilities of the State as set forth in this agreement and the State program. The Secretary may consider the information in the decision document described in Appendix B for the purpose of making the decisions required by the Act, MLA, NEPA and other public laws as described above.

9. As a matter of practice the Department will not independently initiate contacts with the applicant regarding permit application packages or applications for permit revisions. However, the Department reserves the right to act independently of the MLRD to carry out its statutory responsibilities under the Act, MLA, NEPA and other public laws provided, however, that the Department shall send copies of all relevant correspondence to the MLRD.

10. The MLRD shall maintain a file of all original correspondence with the applicant and any information received from the applicant which may have a bearing on decisions regarding the permit application or application for a revision.

11. OSM shall have access to files for mines on Federal lands. MLRD will provide OSM copies of information OSM deems necessary.

12. To the fullest extent allowed by State and Federal law, the Director and MLRD shall cooperate so that duplication will be eliminated in conducting the review and analysis of the permit application package or application for a permit revision.

Article VII: Inspections. 13. The MLRD shall conduct inspections on Federal lands and prepare and file inspection reports in accordance with its Program.

14. The MLRD shall, subsequent to conducting any inspection, and on a timely basis, file with the Director a copy of each inspection report. Such report shall adequately describe (1) the general conditions of the lands under the permit; (2) the manner in which the operations are being conducted; and (3) whether the operator is complying with applicable performance and reclamation requirements.

15. The MLRD will be the point of contact and primary inspection authority in dealing with the operator concerning operations and compliance with the requirements covered by this agreement, except as described hereinafter. Nothing in this Agreement shall prevent Federal inspections by authorized Federal or State agencies for purposes other than those covered by this Agreement. The Department may conduct any inspections necessary to comply with 30 CFR Parts 842 and 743, as Part 743 relates to obligations under laws other than the Act.

16. OSM shall ordinarily give the MLRD reasonable notice of its intent to conduct an inspection under 30 CFR 842.11 in order to provide State inspectors with an opportunity to join in the inspection. When the OSM is responding to a citizen complaint of an imminent danger to the public health and safety or significant, imminent environmental harm to land, air or water resources, pursuant to 30 CFR 842.11 (b)(1)(ii)(c), it will contact MLRD no less than 24 hours prior to the Federal inspection if practicable, to facilitate a joint Federal/State inspection. The Secretary reserves the right to conduct inspections without prior notice to MLRD to carry out his responsibilities under the Federal Act.

Article VIII: Enforcement. 17. MLRD shall be the primary enforcement authority under the Act concerning compliance with the requirements of this Agreement and the Program. Enforcement authority given to the Secretary under other laws and orders including, but not limited to, those listed in Appendix A is reserved to the Secretary.

18. During any joint inspection by OSM and MLRD, MLRD shall have primary responsibility for enforcement procedures including issuance of orders of cessation, notices of violation, and assessment of penalties. The MLRD shall consult OSM prior to issuance of any decision to suspend or revoke a permit.

19. During any inspection made solely by OSM or any joint inspection where the MLRD and OSM fail to agree regarding the propriety of any particular enforcement action, OSM may take any enforcement action necessary to comply with 30 CFR Parts 843 and 845. Such enforcement action shall be based on the performance standards included in the regulations of the approved Program, and shall be taken using the procedures and penalty system contained in 30 CFR Parts 843 and 845.

20. The MLRD and the Department shall promptly notify each other of all violations of applicable laws, regulations, orders, or approved mining permits subject to this Agreement and of all actions taken with respect to such violations.

21. Personnel of the State and representatives of the Department shall be mutually available to serve as witnesses in enforcement actions taken by either party.

22. This Agreement does not limit the Department's authority to enforce violations of Federal law which establish standards and requirements which are authorized by laws other than the Act.

Article IX: Bonds. 23. For all surface coal mining operations on Federal lands, the MLRD and the Secretary shall require each operator to submit a single performance bond payable to the State and to the United States, if required by regulation, to cover the operator's responsibilities under the Act and the Program. Such performance bond shall be conditioned upon compliance with all requirements of the Act, the Program and any other requirements imposed by the Department under the MLA, as amended. If the cooperative agreement is terminated, all bonds will revert to being payable only to the United States. Submission of a performance bond does not satisfy the requirements for a Federal lease bond required by 43 CFR Part 3474 or a lessee protection bond required in addition to a performance bond, in certain circumstances, by Section 715 of the Act.

24. Prior to releasing the operator from an obligation under a performance bond required by the Program, the MLRD shall obtain the concurrence of OSM. The MLRD shall also advise OSM of annual adjustments to the performance bond, pursuant to the Program. Departmental concurrence shall include coordination with other Federal agencies having authority over the lands involved.

25. The operator's performance bond shall be subject to forfeiture with the consent of OSM, in accordance with the procedures and requirements of the Program.

Article X. Designating Land Areas Unsuitable for All or Certain Types of Surface Coal Mining. 26. MLRD and the Director shall cooperate with each other in the review and processing of petitions to designate lands as unsuitable for surface coal mining operations. When either agency receives a petition that could impact adjacent Federal and non-Federal lands, respectively, the agency receiving the petition shall (1) notify the

other of receipt and of the anticipated schedule for reaching a decision; and (2) request and fully consider data, information and views of the other.

The authority to designate Federal lands as unsuitable for mining is reserved to the Secretary or his designated representative.

Article XI: Termination of Cooperative Agreement. 35. This Agreement may be terminated by the Governor or the Secretary under the provisions of 30 CFR 745.15.

Article XII: Reinstatement of Cooperative Agreement. 36. If this Agreement has been terminated in whole or in part it may be reinstated under the provisions of 30 CFR 745.16.

Article XIII: Amendment of Cooperative Agreement. 37. This Agreement may be amended by mutual agreement of the Governor and the Secretary in accordance with 30 CFR 745.14.

Article XIV: Changes in State or Federal Standards. 38. The Department or the State may from time to time promulgate new or revised performance or reclamation requirements or enforcement and administration procedures. Each party shall, if it determines it to be necessary to keep this Agreement in force, change or revise its regulations and request necessary legislative action. Such changes shall be made under the procedures of 30 CFR Part 732.

39. The MLRD and the Department shall provide each other with copies of any changes to their respective laws, rules, regulations and standards pertaining to the enforcement and administration of this Agreement.

Article XV: Changes in Personnel and Organization. 40. Each party to this Agreement shall notify the other, when necessary, of any changes in personnel, organization and funding or other changes that will affect the implementation of this Agreement to ensure coordination of responsibilities and facilitate cooperation.

Article XVI: Reservation of Rights. 41. In accordance with 30 CFR 745.13, this Agreement shall not be construed as waiving or preventing the assertion of any rights that have not been expressly addressed in this Agreement that the State or the Secretary may have under other laws or regulations, including but not limited to those listed in Appendix A.

Governor of Colorado

Date

Secretary of the Interior

Date

Appendix A

1. The Federal Land Policy and Management Act, 43 U.S.C. 1701 *et seq.*, and implementing regulations.

2. The Mineral Leasing Act of 1920, 30 U.S.C. 181 *et seq.*, and implementing regulations including 30 CFR Part 211.

3. The National Evironmental Policy Act of 1969, 42 U.S.C. 4321 *et seq.*,and implementing regulations including 40 CFR Part 1500.

4. The Endangered Species Act, 16 U.S.C. 1531 *et seq.*, and implementing regulations including 50 CFR Part 402.

5. The National Historic Preservation Act of 1966, 16 U.S.C. 470 *et seq.*, and implementing regulations, including 36 CFR Part 800.

6. The Clean Air Act, 42 U.S.C. 7401 *et seq.*, and implementing regulations.

7. The Federal Water Pollution Control Act, 33 U.S.C. 1251 *et seq.*, and implementing regulations.

8. The Resource Conservation and Recovery Act of 1976, 42 U.S.C. 6901 *et seq.*, and implementing regulations.

9. The Reservoir Salvage Act of 1960, amended by the Preservation of Historical and Archaeological Data Act of 1974, 16 U.S.C. 469 *et seq.*

10. Executive Order 11593 (May 13, 1971), Cultural Resource Inventories on Federal Lands.

11. Executive Order 11988 (May 24, 1977), for flood plain protection. Executive Order 11990 (May 24, 1977), for wetlands protections.

12. The Mineral Leasing Act for Acquired Lands, 30 U.S.C. 351 *et seq.*, and the implementing regulations.

13. The Stock Raising Homestead Act of 1916, 43 U.S.C. 291 *et seq.*

14. The Constitution of the United States.

15. The Constitution of the State and State Law.

Appendix B—Procedure for Cooperative Review of Permit Application Packages and Applications for Permit Revisions for Federal Mines in Colorado

I: Point of contact and coordination for the review of permit applications and applications for permit revisions.

A. The Colorado Mined Land Reclamation Division (MLRD) will:

1. Be the point of contact and coordinate communications with the applicant on issues concerned with the development, review and approval of the permit application or application for permit revisions.

2. Communicate with the applicant on issues of concern to the Office of Surface Mining (OSM), and shall immediately advise OSM of such issues and communications.

3. Provide OSM with a monthly report on the status of each permit application, or application for permit review.

B. OSM will:

1. Be responsible for coordinating the review of the permit application package with all Federal agencies which have responsibilities related to approval of the package.

2. Be responsible for ensuring that any information OSM receives which has a bearing on decisions regarding the permit application package or application for a permit revision is sent promptly to MLRD.

C. Geological Survey (GS) will:

1. Receive any documentation and information required by the 30 CFR Part 211 regulations.

2. Be the point of contact with the applicant on issues concerned exclusively with the 30 CFR Part 211 regulations.

3. Provide MLRD and OSM with copies of pertinent correspondence.

II: Receipt and distribution of permit applications package and applications for permit revisions.

A. MLRD will:

1. Receive the permit application package, application for a permit revision, or the review correspondence from the applicant. Copies of the permit application package or application for a permit revision submitted to MLRD are in addition to those submitted to OSM.

2. Identify an application manager responsible for coordinating the review and notify OSM.

3. Upon receipt of an application MLRD will meet with OSM to discuss the application and agree upon a work plan and schedule.

B. OSM will;

1. Distribute copies of the application package and the identity of the MLRD application manager to other Federal agencies as required.

C. OSM, GS and the Bureau of Land Management (BLM) will:

1. Each identify an application manager upon receipt of the application package. OSM will notify MLRD and all Federal agencies of the identity of the application managers.

III: Determination of Completeness.

A. MLRD will:

1. Determine the completeness of a permit application package or application for a permit revision in accordance with section 34–33–118(i) CRS 1973, as amended and as defined in rule 1.04(30) of the Rules and Regulations of the Colorado Mined Land Reclamation Board for Coal Mining promulgated pursuant to the Colorado Surface Coal Mining Reclamation Act.

2. Issue public notice of a complete application in accordance with the procedures of section 34–33–118(2) CRS 1973, as amended.

IV: Determination of Preliminary Findings of Substantive Adequacy.

A. MLRD will:

1. Consult with GS, BLM, OSM, and other appropriate Federal agencies to review the filed application for preliminary findings of substantive adequacy (henceforth "preliminary findings") and to assess the need for additional data requirements in their respective areas of responsibility.

2. Arrange meetings and field examinations with the interested parties as necessary to determine the preliminary findings.

3. Advise the applicant of the preliminary findings upon the advice and consent of BLM, GS, OSM and other Federal agencies specified by the Secretary.

4. Transmit the letter(s) informing the applicant of the preliminary findings with

copies to BLM, OSM, GS and other agencies specified by the Secretary.

5. Furnish the Director with copies of correspondence with the applicant and all information received from the applicant as requested.

B. OSM will:

1. At the request of MLRD, assist as possible in the review of the permit application or application for a permit revision. In any case where assistance has been agreed upon, furnish MLRD with preliminary findings within 45 calendar days of receipt of the request.

2. Work with other Federal agencies involved in the review to insure timely response and resolution of issues of particular concern regarding their statutory requirements.

3. Within 30 days from notification of completeness, OSM will initiate NEPA compliance procedures.

4. Participate, as arrange, in meeting and filed examinations.

C. BLM will:

1. Review the permit application package or application for permit revision for preliminary findings as to whether the applicant's proposed post-mining land use is consistent with BLM's land use plan, and as to the adequacy of measures to protect Federal resources not covered by the rights granted by the Federal coal lease.

2. Furnish OSM with preliminary findings and with any specific requirements for additional data, within 45 calendar days of BLM's receipt of the permit application package or application for a permit revision.

3. Participate, as arranged, in meetings and field examinations.

D. GS will:

1. Review the permit application package or application for a permit revision in regard to MLA requirements addressed in such application.

2. Furnish OSM with preliminary findings and with any specific requirements for additional data within 45 calendar days of GS's receipt of the permit application package or application for a permit revision.

3. Participate, as arranged, in meetings and field examinations.

E. Other appropriate Federal agencies specified by the Secretary will:

1. Review the permit application package or application for a permit revision for preliminary findings in regard to their responsibilites under law.

2. Furnish OSM with preliminary findings within 45 calendar days of receipt of the application with specific requirements for additional data.

3. Participate, as arranged, in meetings and field examinations.

V: Findings of Technical Adequacy and NEPA Compliance.

A. MLRD will:

1. Develop and coordinate the technical review of the permit application package or application for a permit revision. The review will include representatives of MLRD, GS, BLM, OSM and other appropriate Federal agencies specified by the Secretary.

2. Coordinate with OSM for the purpose of eliminating duplication, and provide to OSM a complete technical analysis pursuant to the approved State program that will serve as the technical base for any Environmental Analysis (EA) or an Environmental Impact Statement (EIS) which may be necessary to determine NEPA compliance for each permit application package.

3. Coordinate, for the purpose of eliminating duplication, with GS to conduct a technical analysis that will assist the GS in making findings as may be necessary to determine compliance with the MLA.

4. Coordinate, for the purpose of eliminating duplication, with BLM to conduct a technical analysis of issued regarding post-mining land use and the adequacy of measures to protect Federal resources not covered by the rights granted by the lease.

5. Coordinate, for the purposes of eliminating duplication, with other appropriate Federal agencies specified by the Secretary, to conduct a technical analysis of issues within their jurisdiction.

B. OSM will:

1. At the request of MLRD, assist as possible in the review of the application for technical adequacy in a timely manner as set forth by a schedule. Such schedule will be governed by the deadlines set forth in the Colorado Surface Coal Mining Reclamation Act and shall be developed by MLRD in cooperation with OSM.

2. Resolve conflicts and difficulties between other Federal agencies in a timely manner.

3. As soon as possible after receipt of the permit application package, determine the need for an EA or an EIS, pursuant to NEPA, with the assistance of BLM, GS, MLRD and other appropriate agencies, as arranged.

4. Publish notices of NEPA documents as required by Federal law and regulations.

5. Take the leadership role for the development of the EA and EIS including identification of areas where additional data is necessary.

6. Provide MLRD with the analysis and conclusions of the appropriate Federal agencies regarding those elements of the package which the Secretary cannot delegate to the State.

C. GS will:

1. Review the permit application package or application for a permit revision for compliance with 30 CFR 211 regulation.

2. Furnish MLRD through OSM findings on compliance in a timely manner as set forth by schedule. Such schedule will be governed by the statutory deadlines set forth in the Colorado Surface Coal Mining Reclamation Act and shall be developed by MLRD in cooperation with GS.

3. Participate, as arranged, in meetings and field examinations.

D. BLM will:

1. Determine whether the permit application or application for a permit revision provides for post-mining land use consistent with BLM's land use plan and determine the adequacy of measures to protect Federal resources under BLM's jurisdiction not covered by the rights granted by the Federal Coal Lease.

2. Furnish MLRD through OSM its determination on the technical adequacy in a timely manner as set forth by schedule. Such schedule will be governed by the statutory time limits set forth in the Colorado Surface Coal Mining Reclamation Act and shall be developed by MLRD in cooperation with BLM.

3. Participate, as arranged, in meetings and field examinations.

E. Other appropriate Federal agencies specified by the Secretary will:

1. Review the permit application package or application for a permit revision in regard to their responsibilities under law.

2. Furnish MLRD through OSM findings on compliance with other applicable Federal Laws and regulations in a timely manner as set forth by schedule. Such schedule will be governed by the statutory deadlines set forth in the Colorado Surface Coal Mining Reclamation Act and shall be developed in cooperation with MLRD.

3. Particiapte, as arranged, in meetings and field examinations.

VI: Preparation of the Decision Document and Transmittal

A. MLRD will:

1. Prepare the decision document for the permit application package or application for a permit revision, unless the work plan and schedule agreed upon provides otherwise. The decision document will be in a format approved by the Secretary. This decision document shall contain the following:

a. A brief but comprehensive discussion of the need for the proposal and alternatives to the proposal;

b. A preliminary draft analysis of the environmental impacts of the proposal and alternatives to the proposal prepared in conformance with NEPA, CEQ regulations and OSM's NEPA Compliance Handbook;

c. A finding of compliance with the Program as approved by the Secretary and the regulations promulgated thereunder, which will consist of an analysis of critical issues raised during the course of the review and the resolution of those issues;

d. All other specific written findings required under section 34–33–114 CRS 1973, as amended;

e. The determinations and recommendations of BLM;

f. The memorandum of recommendation from the GS to the Assistant Secretary, Energy and Minerals, with regard to MLA requirements;

g. The comments of other appropriate Federal agencies specified by the Secretary.

2. Transmit copies of drafts of the decision document to OSM for distribution to and comment from the appropriate Federal agencies.

3. Consider the comments of the OSM, GS, BLM and other appropriate Federal agencies and transmit the final decision document for the coal mining and reclamation operations approval to OSM.

B. OSM will:

1. Add to the decision document, an approved NEPA compliance finding.

2. Evaluate the draft decision document and promptly inform MLRD of suggested changes that should be made.

3. Provide all written comments from all appropriate Federal agencies on the decision document to MLRD.

C. BLM will:

1. Provide OSM with findings regarding post-mining land use and the adequacy of measures to protect Federal resources not covered by the rights granted by the Federal coal lease.

2. Evaluate the draft decision document and promptly inform OSM in writing of suggested changes, if any, that should be made pertinent to BLM's area of responsibility.

3. Provide written concurrence on the final decision document to OSM with regard to post-mining land use and the adequacy of measures to protect Federal resources not covered by rights granted by the Federal coal lease.

D. GS will:

1. Provide OSM with findings regarding its responsibilities under the MLA.

2. Evaluate the draft decision document and promptly inform OSM in writing of suggested changes, if any, that should be made pertinent to GS responsibilities.

3. Provide written concurrence on the final decision document to OSM with regard to GS's responsibilities.

E. Other agencies will:

1. Provide OSM with findings regarding their responsibilities under law.

2. Evaluate the draft decision document and promptly inform OSM in writing of suggested changes, if any, that should be made pertinent to their responsibilities.

3. Provide written concurrence on the final decision document to OSM with regard to their responsibilities.

VII: Decision and Permit Issuance.

A. The Secretary will:

1. Evaluate the analysis and conclusions as necessary to determine whether he concurs in the decision document in so far as it relates to his statutorily required decisions.

2. Inform the MLRD immediately of his decision. The reasons for not approving shall be specified and recommendations for remedy shall be specified.

B. MLRD will:

1. Issue the permit or revised permit for surface coal mining and reclamation operations after making a finding of compliance with the approved State program and this Agreement.

VIII: Resolution of Conflict.

A. Every effort will be made to resolve errors, omissions and conflicts on data and data analysis at the State and field level.

B. Areas of disagreement between the State and the Department shall be referred to the Governor and the Secretary for resolution.

[FR Doc. 82-2656 Filed 2-1-82; 8:45 am]

BILLING CODE 4310-05-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 35

[WH-FRL-2041-1]

Municipal Wastewater Treatment Works; Availability of Draft Paper

AGENCY: Environmental Protection Agency.

ACTION: Notice of availability.

SUMMARY: EPA has published a draft paper recommending revisions to the construction grants regulations, 40 CFR Part 35. The paper, developed as a continuation of the Agency's regulatory reform effort begun in July 1981, includes the proposed revision of the full regulation (published in the November 6, 1981 **Federal Register**, 46 FR 55220) and the amendments needed to implement the Municipal Wastewater Treatment Construction Grant Amendments of 1981.

DATE: Comments should be received on or before: February 28, 1982. This deadline is essential if the Agency is to have interim final regulations in place to authorize grant-making in the event of an appropriation for the 1982 Fiscal Year.

ADDRESS: Comments on the draft regulatory reform paper are encouraged. Comments and requests for the document should be sent to: Director, Office of Water Program Operations (WH-546), Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Jane Magee (202) 755-8253.

Joan M. Kovalic,

Acting Director, Office of Water Program Operations.

[FR Doc. 82-2799 Filed 2-1-82; 8:45 am]

BILLING CODE 6560-29-M

40 CFR Part 52

[A-3-FRL 2017-7]

State of Maryland; Proposed Revision of the Maryland State Implementation Plan

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The purpose of this notice is to propose approval of a revision to the Maryland State Implementation Plan (SIP) which was submitted on August 11, 1981. The public hearing on these changes, which include new iron and steel industry regulations, was held on July 15, 1981. The regulations were adopted by the State on August 11, 1981 and became effective on October 10, 1981. Besides the new regulations, this notice proposes to approve complementary changes to the definitions, the general emission regulations, and the technical memorandum relating to test procedures. In addition, the notice proposes to approve a new technical memorandum specifying the procedures for observing and evaluating visible emissions and a new Amended Plan for Compliance (PFC) for the Bethlehem Steel Corporation's Sparrows Point, Maryland plant. These amendments were submitted to satisfy a condition of approval of the Part D plan for attainment of the primary total suspended particulate standard. This notice solicits comments on EPA's proposed action.

DATE: Comments on this proposed SIP revision must be submitted on or before February 12, 1982.

ADDRESSES: Copies of the proposed SIP revision and the accompanying support documents are available for inspection during normal business hours at the following offices:

U.S. Environmental Protection Agency, Region III, Air Programs Branch, Curtis Building, Tenth Floor, Sixth & Walnut Streets, Philadelphia, Pennsylvania 19106; ATTN: Edward A. Vollberg

Maryland Department of Health and Mental Hygiene, Air Management Administration, 201 W. Preston Street, Baltimore, Maryland 21201; ATTN: George P. Ferreri

Public Information Reference Unit, Room 2922, EPA Library, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460

All comments should be directed to: Mr. Henry Sokolowski, Chief, MD-DE-DC Metro Section (3AH12), U.S. Environmental Protection Agency, Region III, Sixth & Walnut Streets, Philadelphia, PA 19106; ATTN: AH304MD.

FOR FURTHER INFORMATION CONTACT: Mr. Edward A. Vollberg (3AH12), U.S. Environmental Protection Agency, Region III, Sixth & Walnut Streets, Philadelphia, Pennsylvania 19106, telephone: 215/597-8990.

SUPPLEMENTARY INFORMATION:

Background

In 1972, the Bethlehem Steel Corporation challenged, under Section 307 of the Clean Air Act of 1970, EPA's approval of the Maryland State Implementation Plan (SIP) as it related to the steel industry operations. Subsequent to the company's challenge regarding the necessity and feasibility of the emission standards, the Fourth Circuit Court of Appeals remanded the plan to EPA for reconsideration. Based on this, the State of Maryland set out to revise the regulations to resolve the issues that led to the litigation. The State submitted the revised regulation on January 5, 1978. Since it was

impractical at that time for Bethlehem Steel's Sparrows Point facility to be in full compliance with the regulations by the effective date, a Plan for Compliance (PFC) was also submitted to EPA. EPA had significant problems with the enforceability of portions of the regulations and the PFC. While discussion of the problems and possible remedies were held with the State, Maryland prepared and submitted (on January 19, 1979) the Part D plan for attaining the primary National Ambient Air Quality Standard for Total Suspended Particulates (TSP). The State considered the regulations and the PFC submitted on January 5, 1978 to be a part of the control strategy for the Part D plan. EPA proposed the Part D plan revision on August 1, 1979 (44 FR 45194) noting that the enforceability issues remained with respect to the iron and steel regulations. The State of Maryland and EPA agreed that an amended PFC establishing enforceable provisions could be the remedy. As such, EPA proposed to approve the Part D plan (45 FR 53490, August 12, 1980) on the condition that Maryland submit an approvable PFC. Maryland, in considering this, requested until August 11, 1981 to renegotiate a PFC and to revise the iron and steel regulations. On August 11, 1981 the Governor of the State of Maryland submitted amended regulations as a revision to the Maryland State Implementation Plan. This revision, identified by Maryland as Revision 81–3, which includes State-initiated changes as well as new requlations (COMAR 10.18.10) and a new Amended Plan for Compliance (PFC) for the Bethlehem Steel Corporation Sparrows Point Plant, was adopted to satisfy a condition of approval of the Part D plan (46 FR 45341, Sept. 11, 1981). A public hearing on the PFC and the amended regulations was held on July 15, 1981 in Baltimore, Maryland. The regulations were adopted on August 11, 1981 and became effective State regulations on October 10, 1981. These amendments and the PFC have been developed and submitted in accordance with the requirements of Title 40, Code of Federal Regulations, Part 51.

Description of Revision

The revision as submitted to EPA includes:

1. New Iron and Steel Regulations (COMAR 10.18.10).
2. A new Technical Memorandum TM–AMA 81–04.
3. A new Method 13 test procedure (Amendment to TM–AMA 73–116).
4. State initiated regulation changes (COMAR 10.18.01 and COMAR 10.18.06).
5. A new Amended Plan for Compliance for the Bethlehem Steel Corporation's Sparrows Point, Maryland plant.

The regulations in COMAR 10.18.10 are an entirely new chapter replacing in total the previous provisions which regulated air pollutant emissions from the iron and steel industry. They apply to the Metropolitan Baltimore Air Quality Control Region (AQCR) which is designated as Area III by the State of Maryland.

These new regulations include a list of processes where Maryland's general no visible emission standard (COMAR 10.18.06) does not apply. This list, found in COMAR 10.18.10.04B(2), also specifies the particular pollution controls to be installed at these processes. COMAR 10.18.10.03C specifies alternative visible emissions standards applicable to most of these processes. However, where an alternate standard is not yet developed, the State of Maryland has supplied a schedule for its development. One significant change to the regulation applies to coke oven charging. It requires no more than 160 seconds of visible emissions during five consecutive charges. EPA proposes to approve this, because the State has demonstrated attainment of the primary standard for particulate in its Part D plan and RACT is not required since the source is located outside the primary nonattainment area. Another significant change concerns the requirement for self-monitoring of coke oven emissions which was deleted from the existing Plan for Compliance. It is now specified as Section D of COMAR 10.18.10.03.

All other sources, i.e., those not listed in COMAR 10.18.10.04B(2), are subject to the general "no visible emission" regulation (COMAR 10.18.06).

The new Technical Memorandum, AMA–TM 81–04, describes the exact procedures for observing and evaluating visible emissions from stationary sources. The methods specified in the Technical Memorandum are the only methods to be used to enforce the visible emission standards for the sources listed in COMAR 10.18.10.03B. There new methods differ in that they specify the position of the observer, background for the observation, procedure for opacity calculations, etc. Maryland intends to develop additional methods as needed in the future to be used for other specific stationary sources.

Part of the new regulation (COMAR 10.18.10) limits emissions from confined sources at an iron and steel production installation to 0.03 gr/scfd, except for coke quenching towers, which are limited to 800 ppm of total dissolved solids in the make-up water used in the towers. Compliance will be determined through the use of the new method 13 which has been added to TM–AMA 73–116. This method describes the procedure to be used to determine the total dissolved solids in the quench tower make-up water.

The major change in COMAR 10.18.01.01 is the addition of two new terms with definitions, "Confined emissions" and "Fugitive emissions." These terms are used to differentiate between stack emissions and non-stack emissions. COMAR 10.18.06 (General Emissions Standards) has been amended to reference the changes in the new COMAR 10.18.10.

Finally, the purpose of the new Amended Plan for Compliance is to describe Bethlehem Steel Corporation's program to achieve compliance with the new iron and steel regulations, COMAR 10.18.10, at its Sparrows Point facility. The PFC outlines the actions and schedule for installing the control equipment. This document supersedes the Amended Plan for Compliance of the Company aproved by the State of Maryland on December 30, 1980.

EPA Evaluation

EPA has reviewed the revision submitted by Maryland and finds it satisfies the condition of the approval of the Part D SIP. During the review of the revision, EPA identified four items which required clarification by the State of Maryland. The State responded to these items in a letter dated October 28, 1981. These issues are discussed below:

1. EPA requested that the State of Maryland clarify whether the intent underlying COMAR 10.18.10.03 is that the no visible emission standard applies to argon-oxygen decarbonization vessels.

Maryland responded that it is the intent of the State of Maryland that COMAR 10.18.10.03A(1), which requires no visible emissions other than water in an uncombined form, applies to the two buildings in Area III of the State which contain argon-oxygen decarbonization vessels.

2. EPA, in its review, questioned if the "reasonable control methods" required in COMAR 10.18.10.04B(2) (a), (b), (e), and (h) were in place and being employed and, if so, were the standards in COMAR 10.18.10.03B (1), (2), (4), and (5) effective and enforceable immediately.

The Bethlehem Steel Corporation Sparrows Point Plant is presently in compliance with COMAR 10.18.10.04B(2), (a), (b), (e), and (h). The "reasonable control methods" required

by these regulations are in place, and the visible emission requirements of COMAR 10.18.10.03B (1), (2), (4), and (5) were in effect as of October 10, 1981, the regulation's effective date.

3. EPA noted that the PFC delays enforceability of the mass emission standard for coke oven combustion stacks due to problems in the current test method. The agency requested that Maryland assure EPA in writing that alternate testing procedures developed for the particulate sampling method be submitted as a SIP revision no later than December 31, 1982.

Maryland pointed out that the PFC calls for an alternative test procedure for the particulate sampling method at the coke oven combustion stacks to be finalized by December 31, 1982. The State of Maryland anticipates no problem at the present time complying with this requirement and intends to submit the final test procedures to EPA as a SIP revision as soon as the procedure is finalized, which should be prior to December 31, 1982.

4. EPA's review revealed that the PFC allows the development of an alternate visible emission standard for the Basic Oxygen Furnaces (BOF) when reasonable controls are in place. It also indicates that the installation may occur in two stages. The agency has informed the State that an interim visible emission standard must be developed for the first stage.

Maryland stated that the PFC provides that the Department could require additional controls at the BOF Shop beyond those required in the Plan to be utilized by December 31, 1982. Should this occur, the State of Maryland commits to develop an interim visible emission standard for the BOF Shop and to submit it to EPA as a SIP revision no later than December 31, 1983.

Therefore, EPA proposes to approve the new iron and steel regulation (COMAR 10.18.10), the new Technical Memorandum TM–AMA 81–04, the new method 13 to be added to TM–AMA 732–116, the amended COMAR 10.18.01 and COMAR 10.18.06, and the Amended Plan for Compliance (considering the above necessary changes) for the Bethlehem Steel Corporation's Sparrows Point, Maryland plant.

Based upon the above evaluations, the Administrator is proposing to approve this revision to the Maryland State Implementation Plan as discussed in this notice.

The public is invited to submit comments on whether these amendments should be approved as a revision to the Maryland State Implementation Plan.

The Administrator's decision to approve or disapprove the proposed revision will be based upon the comments received and on a determination as to whether they meet the requirements of Part D of Title I and Section 110(a)(2) of the Clean Air Act.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Pursuant to the provisions of 5 U.S.C. 605(b), the Administrator has certified that SIP approvals under Sections 110 and 172 of the Clean Air Act will not have a significant economic impact on a substantial number of small entities. See 46 FR 8709 (January 27, 1981). This action, if promulgated, constitutes a SIP approval under Sections 110 and 172 within the terms of the January 27 certification. This action only approves State actions. It imposes no new requirements.

Dated: December 9, 1981.

Peter N. Bibko,

Regional Administrator.

[FR Doc. 82–2638 Filed 2–1–82; 8:45 am]

BILLING CODE 6560–38–M

---

40 CFR Parts 122, 260, 264, 265, and 266

[SWH–FRL–2040–8]

The Hazardous Waste Permit Program; Hazardous Waste Management System: General Standards Applicable to Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities; Standards for the Management of Specific Wastes and Specific Types of Facilities; Reopening of Comment Period on Proposed Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Reopening of comment period on proposed regulations.

SUMMARY: This notice reopens the comment period on a portion of EPA's November 17, 1980 proposed hazardous waste management and permitting regulations for wastewater treatment units (45 FR 76076). EPA is taking this action in order to allow the general public an opportunity to comment on issues raised by the National Solid Waste Management Association (NSWMA) in the course of settlement negotiations in *AMAX Inc.* v. *EPA* and to comment on a revision in the definition of "wastewater treatment unit."

DATE: EPA will accept comments on the issues discussed in this notice unitil March 4, 1982.

ADDRESSES: Comments should be addressed to Deneen M. Shrader, Docket Clerk, Office of Solid Waste (WH–562), U.S. Environmental Protection Agency, 401 M Street S.W., Washington, D.C. 20460, telephone (202) 755–9173. Comments should identify the regulatory docket as: "Section 3004—Wastewater Treatment Units."

The public docket for this rulemaking is located in Room 2711, U.S. Environmental Protection Agency, 401 M Street S.W., Washington, D.C. 20460 and is available for viewing from 8:00 a.m. to 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Howard M. Cohen, Hazardous and Industrial Waste Division, Office of Solid Waste (WH–565), U.S. Environmental Protection Agency, Washington, D.C. 20460, telephone (202) 755–4650.

SUPPLEMENTARY INFORMATION: On November 17, 1980 (45 FR 76076) EPA proposed special regulations applicable to owners and operators of "wastewater treatment units." The proposed regulations were intended to reduce the regulatory burden on a class of facilities which pose less of a risk to human health and the environment than other types of hazardous waste management facilities. EPA incorporated many but not all of the Part 265 operating requirements into these proposed standards and provided for a simplified permitting process by granting qualified facilities a permit-by-rule.

On November 17, 1980 EPA also temporarily suspended the applicability of the hazardous waste management and consolidated permit regulations to wastewater treatment units pending finalization of the proposed special standards. Pursuant to Section 7006 of the Resource Conservation and Recovery Act (RCRA) several persons petitioned the United States Court of Appeals for the District of Columbia for review of this action, *AMAX, Inc.* v. *EPA*, Nos. 81–1171 and 81–1172.

In the course of settlement neogitations in *AMAX*, NSWMA raised several issues related to the proposed regulations and offered to submit to the Agency a supplemental letter outlining their position. Other petitioners present at the negotiations asked for an opportunity to comment on the issues raised by NSWMA. In light of these events EPA has decided to reopen the public comment period to allow for a full airing of these issues and has summarized NSWMA's comments in the following paragraph.

NSWMA contends that the proposed Part 266 standards, as they apply to

owners and operators of wastewater treatment units, should include requirements for a general waste analysis (40 CFR 264.13), and for contingency plan and emergency procedures (40 CFR Part 264, Subpart D). They further identify the waste analysis, the development of a waste analysis plan, and the personnel training requirements as the most critical requirements that should be incorporated into the Part 266 Standards. NSWMA also expresses concern about possible ambiguities in the regulation of hazardous sludges generated in wastewater treatment units and contends that the sludges should be subject to the full RCRA Subtitle C regulations up to and including final disposal.

Copies of NSWMA's written statements are available for inspection in the RCRA public docket room.

Definition of Wastewater Treatment Unit

EPA has received a number of inquiries regarding the interpretation of "wastewater" as used in the definition of wastewater treatment unit. The Agency intends that only units legitimately engaged in treating a relatively dilute aqueous based waste be covered by the definition of wastewater treatment unit and is concerned that the definition not be interpreted so broadly as to include virtually any treatment operation that treats any liquid waste.

The Agency considered trying to define wastewater in terms of a percentage of water but encountered great difficulty in developing a workable and defensible definition. As an interim measure, the Agency in a July 31, 1980 letter to EPA regional offices advised that wastewater be interpreted to refer to "wastes which are substantially water with contaminants amounting to a few percent at most." EPA found this interpretation brought further inquiries.

EPA is now considering using the term "process waste water," in the definition of wastewater treatment unit to help clarify the meaning of wastewater. The term process wastewater, as defined in 40 CFR 122.3 and 401.11(q) means:

> any water which, during manufacturing or processing, comes into direct contact with or results from the production or use of any raw material, intermediate product, finished product, by-product, or waste product.

The Agency believes that the term process wastewater effectively limits the scope of the regulation and provides, based on the body of experience that has developed in applying the term, a greater degree of certainty in the meaning of wastewater treatment unit. For example, under this definition, process solutions such as solvents or acids which during manufacturing or processing come into direct contact with a product would not be considered a process wastewater, regardless of the percentage of water in the solvent or acid.

EPA invites comment on the use of the term "process wastewater" to help clarify the meaning of "wastewater treatment unit." The Agency also welcomes suggestions on how wastewater might otherwise be defined.

Dated: January 26, 1982.

Christopher J. Capper,

Acting Assistant Administrator.

[FR Doc. 82-2639 Filed 2-1-82; 8:45 am]

BILLING CODE 6560-38-M

GENERAL SERVICES ADMINISTRATION

41 CFR Part 101-41

Refunds From Carriers for Unused Transportation Services

AGENCY: General Services Administration.

ACTION: Proposed rule.

SUMMARY: The General Services Administration (GSA) proposes to amend the Federal Property Management Regulations to further revise and improve the procedures regarding refunds from carriers for exchanged tickets (traveler exchange of an original ticket for one of lesser value) and the redemption of unused tickets (tickets that have not been exchanged and on which no portion of travel has been performed). Compliance with these revised procedures by Government agencies and the carrier industry will expedite the recovery of outstanding refunds due the U.S. Government.

DATE: Comments must be received by March 4, 1982.

ADDRESS: Written comments should be sent to the General Services Administration (TACP), Washington, D.C. 20406.

FOR FURTHER INFORMATION CONTACT: John W. Sandfort, Chief, Reports and Procedures Branch, Office of Transportation Audits (202-275-0664).

SUPPLEMENTARY INFORMATION: The GSA has determined that this rule is not a major rule for the purposes of Executive Order 12291 of February 17, 1981, because it is not likely to result in an annual effect on the economy of $100 million or more; a major increase in costs to consumers or others; or significant adverse effects. The GSA has based all administrative decisions underlying this rule on adequate information concerning the need for, and consequences of, this rule; has determined that the potential benefits to society from this rule outweigh the potential costs and has maximized the net benefits; and has chosen the alternative approach involving the least net cost to society.

GSA proposes to amend Title 41, Part 101-41 of the Code of Federal Regulations (41 CFR Part 101-41) as follows:

PART 101-41—TRANSPORTATION DOCUMENTATION AND AUDIT

1. The table of contents for Part 101-41 (101-41.210—101-41.210-6) is amended by revising Subpart 101-41.210.

Subpart 101-41.2—Passenger Transportation Services Furnished for the Account of the United States

Authority: 31 U.S.C. 244 and 40 U.S.C. 486(c).

Subpart 101-41.2—Passenger Transportation Services Furnished for the Account of the United States

Section 101-41.210 is revised to read as follows:

§ 101-41.210 Unused transportation refund procedures.

Agencies shall not revise carrier bills or require carriers to rebill items except as provided in § 101-41.210-6, to recover from carriers the value of unused or unfurnished transportation.

Section 101–41.210–1 is revised to read as follows:

§ 101–41.210–1 Ticket exchanges.

Agencies shall not submit an SF 1170 to the carrier to receive a refund for the unused value of an exchanged ticket (traveler exchange of an original ticket for one of lesser value). Carriers are required to make refunds to the "bill charges to" office indicated on the ticket within 90 days from date of ticket exchange. If carriers cannot identify the issuing agency, refunds will be sent to GSA (TACA), Washington, D.C. 20406. The GTR number, ticket number, and the amount being refunded, must be included along with any information pertinent to the refund.

Section 101–41.210–1a is added to read as follows:

§ 101–41.210–1a Agency monitoring and processing of exchanged ticket refunds.

Agencies awaiting exchanged ticket carrier refunds shall:

(a) Obtain carrier refund applications from travelers for accounting purposes.

(b) Record and deposit refunds in conformity with agency fiscal procedures.

(c) Report refunds to GSA (TACP), Washington, D.C. 20406, on SF 1170 within 30-days of the receipt thereof.

(d) Forward carrier refund applications and any other pertinent information to GSA (TACP), if refund has not been received within 120 days from date of travel.

Section 101–41.210–2 is revised to read as follows:

§ 101–41.210–2 SF 1170, Redemption of unused tickets (tickets that have not been exchanged and on which all or some portion of travel remains unperformed).

Agencies shall make demand on the carriers through the use of SF 1170. A separate SF 1170 must be used for each GTR, though more than one ticket or adjustment transaction may be related to that GTR, and listed on the redemption form.

Section 101–41.210–3 is revised to read as follows:

§ 101–41.210–3 Agency processing of SF 1170.

Timely processing of SF 1170 is essential in order to facilitate prompt refunds from carriers. Agencies processing SF 1170 shall ensure that:

(a) All copies clearly show the required details;

(b) The original and the duplicate copy, together with pertinent unused tickets, are promptly forwarded to the carrier; and

(c) All other copies are retained by the agency for accounting control.

Section 101–41.210–3a is added to read as follows:

§ 101–41.210–3a Carrier processing of SF 1170.

Each carrier shall promptly refund moneys to adjust items listed on an SF 1170, whether or not the related GTR has been submitted or paid. The carrier shall indicate on the original SF 1170 the amount credited to each ticket and the total amount being refunded, and shall return the original with its refund to the agency. A refund that is inconsistent with the information on the SF 1170 shall be explained or computed on the SF 1170 or in an attached letter. A carrier declining to refund shall furnish an explanation on the original SF 1170. If a carrier is unable to determine which agency submitted the SF 1170, the payment and refund information shall be sent direct to the General Services Administration (TACA).

Section 101–41.210–4 is revised to read as follows:

§ 101–41.210–4 Agency processing of SF 1170 refunds.

Upon return of the original SF 1170 with the refund, the agency shall record and deposit the refund in conformity with its fiscal procedures and promptly forward the original SF 1170, together with any advice from the carrier regarding the basis of the refund, to the General Services Administration (TACA).

Section 101–41.210–5 is revised to read as follows:

§ 101–41.210–5 Report of carrier failure to make refund on SF 1170 demands.

If, within 120 days from the date of issuance of SF 1170, the carrier has failed to make refund for unused transportation or to furnish satisfactory explanation as to why no refund is due, the agency shall transmit the triplicate copy of the SF 1170 and all related correspondence to the General Services Administration (TACA), for appropriate action.

Section 101–41.210–5a is revised to read as follows:

§ 101–41.210–5a Carrier refund for unused tickets when SF 1170 has not been received.

If no SF 1170 is received, carriers shall refund to GSA (TACP) the value of unused tickets after they have expired. Carriers are required to make such refunds within 90 days from the expiration date. The GTR number, ticket number, and the amount being refunded, must be included along with any other information pertinent to the refund.

Section 101–41.210–5b is added to read as follows:

§ 101–41.210–5b Payment to carrier for subsequent use of ticket for transportation or second refund through the use of an SF 1170 after initial refund to GSA for unused expired ticket.

If, following the initial refund to GSA by the carrier of the value of an unused ticket which has expired, the ticket should subsequently be used for transportation or be refunded a second time through the use of an SF 1170, then either the value of the transportation or the amount of the second refund shall be paid to the carrier upon presentation of an SF 1113, Public Voucher for Transportation Charges. The SF 1113 shall be submitted for payment to GSA (TAD), Washington, D.C. 20406. The billing carrier shall note on the face of the SF 1113 the fact that it relates to a previously refunded expired ticket which was subsequently used for transportation or refunded a second time through the use of an SF 1170, as the case may be. The carrier shall submit with the SF 1113 copies of those documents pertinent to the previous refund and the current transportation charge when applicable.

Section 101–41.210–5c is added to read as follows:

§ 101–41.210–5c Agency recovery of carrier refunds sent direct to GSA.

To recover carrier refunds sent direct to GSA (TACA), agencies must forward either an SF 1080, Voucher for Transfer Between Appropriations and/or Funds, or SF 1081, Voucher and Schedule of Withdrawals and Credits, to the General Services Administration (TACA). Included on these forms must be the name of the carrier, carrier check number, date and amount of check, GTR number, and the appropriation number to be credited. Agency refund requests should be sent promptly to GSA (TACA). Refunds from carriers which are not identified and claimed by agencies within 180 days after receipt by GSA (TACA) will be returned to the U.S. Treasury as miscellaneous receipts.

(31 U.S.C. 244 and 40 U.S.C. 486(c))

Dated: January 8, 1981.

Allan W. Beres,

Commissioner, Transportation and Public Utilities Service.

[FR Doc. 82–2659 Filed 2–1–82; 8:45 am]

BILLING CODE 6820–AM–M

41 CFR Part 101-41

Payment of Transportation Claims

AGENCY: General Services Administration.

ACTION: Proposed rule.

SUMMARY: General Services Administration (GSA) proposes to amend the Federal Property Management Regulations to enable agencies to pay all supplemental bills (claims) quickly and to remove some restrictions currently in effect. Present regulations require agencies to pay certain claims that involve accessorial services and, with certain restrictions, claims that involve changes in rates, weights, classifications, nomenclature of commodities, and other categories. The proposed amendments will enable agencies to promptly pay all supplemental bills received from carriers, except for time-barred and doubtful claims. Compliance with these revisions will simplify and reduce the workload at the Federal agencies' finance offices.

DATE: Comments must be received by March 4, 1982.

ADDRESS: Comments should be sent to the General Services Administration (TACP), Washington, D.C. 20406.

FOR FURTHER INFORMATION CONTACT: John W. Sandfort, Chief, Reports and Procedures Branch, Office of Transportation Audits (202-275-0664).

SUPPLEMENTARY INFORMATION: The GSA has determined that this proposed rule is not a major rule for the purposes of Executive Order 12291 of February 17, 1981, because it is not likely to result in an annual effect on the economy of $100 million or more; a major increase in costs to consumers or others; or significant adverse effects. The GSA has based all administrative decisions underlying this proposed rule on adequate information concerning the need for, and consequences of, this rule; has determined that the potential benefits to society from this proposed rule outweigh the potential costs and has maximized the net benefits; and has chosen the alternative approach involving the least net cost to society.

PART 101-41—TRANSPORTATION DOCUMENTATION AND AUDIT

1. In § 101-41.604-1, the introductory text and paragraph (a) are revised, paragraph (b) is removed and paragraphs (c) and (d) are redesignated as paragraphs (b) and (c) as revised § 101-41.604-1 reads as set forth below.

§ 101-41.604-1. Transportation claims payable by agencies.

Unless GSA (TA) determines that a prepayment audit is necessary, each agency or department shall pay any properly documented claim for freight or passenger transportation charges that is not excepted by the provisions of § 101-41.604-2, provided the following guidelines are observed:

(a) The agency shall annotate each paid supplemental bill, other than a bill for air excess baggage charges, with the payment record on the related procuring Government bill of lading (GBL) or Government transportation request (GTR), including D.O. voucher number, bureau voucher number, date of payment, and D.O. symbol number.

(b) The agency shall make an administrative examination of each supplemental bill to ensure that it is not a duplicate billing of a previous payment and that it is properly supported, presented in the name of the carrier to which the original charges were paid, and in agreement with agency records concerning the amount previously paid.

(c) Claims paid in accordance with this § 101-41.604-1 shall be transmitted to GSA (TADS) separately from other paid transportation documents submitted for audit.

2. In § 101-41.604-2, paragraph (b)(3) and paragraph (c) are revised and paragraph (b)(4) is removed.

§ 101-41.604-2 Transportation claims not payable by agencies.

* * * * *

(b) * * *

(2) * * *

(3) Doubtful claims. A claim is doubtful when in the exercise of reasonable prudence either a person having final responsibility for deciding appropriate administrative action or the person who, in accordance with applicable statutes, will be held accountable if the claim were paid and then found to be incorrect, illegal, or improper, is unable to decide with reasonable certainty the validity and correctness of the claim.

(c) Claims will be handled by GSA under the provisions of § 101-41.605 of this subpart and shall be forwarded separately from other types of transportation documents to the General Services Administration (TACA), Washington, D.C. 20406. Agencies shall support each claim forwarded to GSA with:

* * * * *

(31 U.S.C. 244 and 40 U.S.C. 486(c))

Dated: January 7, 1982.

Allan W. Beres,

Commissioner,

[FR Doc. 82-2658 Filed 2-1-82: 8:45 am]

BILLING CODE 6820-AM-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 67

[Docket No. FEMA-6197]

National Flood Insurance Program; Proposed Flood Elevation Determinations; Washington

AGENCY: Federal Emergency Management Agency, FEMA.

ACTION: Proposed rule; revision.

SUMMARY: Technical information or comments are solicited on the proposed base (100-year) flood elevations listed below for selected locations in the City of Lynden, Washington.

Due to recent engineering analysis, this proposed rule revises the proposed determinations of base (100-year) flood elevations published in 46 FR 57705 on November 25, 1981 and in the *Lynden Tribune,* published on or about October 28, 1981, and November 4, 1981, and hence supersedes those previously published rules for the areas cited below.

DATES: The period for comment will be ninety (90) days following the second publication of this notice in a newspaper of local circulation in the above-named community.

ADDRESSES: Maps and other information showing the detailed outlines of the flood-prone areas and the proposed flood elevations are available for review at City Engineer's Office, 323 Front Street, Lynden, Washington.

Send comments to: The Honorable Egbert Maaf, 323 Front Street, Lynden, Washington 98264.

FOR FURTHER INFORMATION CONTACT: Mr. Robert G. Chappell, National Flood Insurance Program, (202) 287-0230, Federal Emergency Management Agency, Washington, D.C. 20472.

SUPPLEMENTARY INFORMATION: Proposed base (100-year) flood elevations are listed below for selected locations in the City of Lynden, Washington, 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 base (100-year) flood elevations are the basis for the flood plain 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 (NFIPP).

These modified elevations will also be used to calculate the appropriate flood insurance premium rates for new buildings and their contents and for the second layer of insurance on existing buildings and their contents.

Pursuant to the provisions of 5 U.S.C. 605(b), the Associate Director, 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 prescribe development. Thus, this action only forms the basis for future local actions. It imposes no new requirement; of itself it has no economic impact.

The proposed base (100-year) flood elevations are:

Source of flooding	Location	#Depth in feet above ground *elevation in feet (NGVD)
Nooksack River	Area approximately 150 feet south of intersection of East Front Street and Hawley Street.	*57

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended; 42 U.S.C. 4001–4128; Executive Order 12127, 44 FR 19367; and delegation of authority to the Associate Director).

Issued: January 19, 1982.

Lee M. Thomas,

Associate Director, State and Local Programs and Support.

[FR Doc. 82-2600 Filed 2-1-82; 8:45 am]

BILLING CODE 6718-03-M

---

44 CFR Part 67

[Docket No. FEMA-6197]

National Flood Insurance Program; Proposed Flood Elevation Determinations; New York; Correction

AGENCY: Federal Emergency Management Agency.

ACTION: Proposed rule; correction.

SUMMARY: This document corrects a Notice of Proposed Determinations of base (100-year) flood elevations previously published at 46 FR 57703 on November 25, 1981. This correction notice provides a more accurate representation of the Flood Insurance Study and Flood Insurance Rate Map for the Town of Marshall, Oneida County, New York.

EFFECTIVE DATE: February 2, 1982.

FOR FURTHER INFORMATION CONTACT: Mr. Robert G. Chappell, P.E., Federal Emergency Management Agency, National Flood Insurance Program, (202) 287–0230, Washington, D.C. 20472.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency gives notice of the correction to the Notice of Proposed Determinations of base (100-year) flood elevations for selected locations in the Town of Marshall, Oneida County, New York, previously published at 46 FR 57703 on November 25, 1981, 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).

Pursuant to the provisions of 5 U.S.C. 605(b), the Associate Director, 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 flood plain area. The elevation determinations, however, impose no restriction unless and until the local community voluntarily adopts flood plain 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 flood plain 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.

The Notice of Proposed Base Flood Elevation Determinations should be amended to read as follows:

Source of flooding and location	Elevation in feet national geodetic vertical datum
Oriskany Creek:	
Approximately 2,000' upstream of confluence of Watermans Brook	*775
Approximately 5,000' upstream of confluence of Watermans Brook	*799

National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended; 42 U.S.C. 4001–4128; Executive Order 12127, 44 FR 19367; and delegation of authority to the Associate Director)

Issued: January 21, 1982.

Lee M. Thomas,

Associate Director, State and Local Programs and Support.

[FR Doc. 82-2601 Filed 2-1-82; 8:45 am]

BILLING CODE 6718-03-M

---

44 CFR Part 67

[Docket No. FEMA-6218]

National Flood Insurance Program; Proposed Flood Elevation Determination; Massachusetts; Correction

AGENCY: Federal Emergency Management Agency.

ACTION: Proposed rule; correction.

SUMMARY: This document corrects a Notice of Proposed Determinations of base (100-year) flood elevations previously published at 46 FR 62102 on December 22, 1981. This correction notice provides a more accurate representation of the Flood Insurance Study and Flood Insurance Rate Map for the Town of Hanover, Plymouth County, Massachusetts.

EFFECTIVE DATE: February 2, 1982.

FOR FURTHER INFORMATION CONTACT: Mr. Robert G. Chappell, P.E., Federal Emergency Management Agency, National Flood Insurance Program, (202) 287–0230, Washington, D.C. 20472.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency gives notice of the correction to the Notice of Proposed Determinations of base (100-year) flood elevations for selected locations in the Town of Hanover, Plymouth County, Massachusetts, previously published at 46 FR 62102 on December 22, 1981, 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).

Pursuant to the provisions of 5 U.S.C. 605(b), the Associate Director, 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 flood plain area. The elevation determinations, however, impose no restriction unless and until the local community voluntarily adopts flood plain 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 flood plain 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.

Under the source of flooding, Indian Head River, the Base Flood elevation for the location "Cross Street (upstream side)" has been amended to read 39 feet in elevation (National Geodetic Vertical Datum).

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended; 42 U.S.C. 4001–4128; Executive Order 12127, 44 FR 19367; and delegation of authority to the Associate Director)

Issued: January 19, 1982.

Lee M. Thomas,

Associate Director, State and Local Programs and Support.

[FR Doc. 82–2602 Filed 2–1–82; 8:45 am]

BILLING CODE 6718–03–M

---

44 CFR Part 67

[Docket No. FEMA–6224]

National Flood Insurance Program; Proposed Flood Elevation Determinations; Correction; Kansas

AGENCY: Federal Emergency Management Agency.

ACTION: Proposed rule; correction.

SUMMARY: This document corrects a Notice of Proposed Determinations of base (100-year) flood elevations for selected locations in the Unincorporated Areas of Lyon County, Kansas, Previously published at 46 FR 63339 on December 31, 1981.

EFFECTIVE DATE: February 2, 1982.

FOR FURTHER INFORMATION CONTACT: Mr. Robert G. Chappell, National Flood Insurance Program, (202) 287–0230, Federal Emergency Management Agency, Washington, D.C. 20472.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency gives notice of the correction to the Notice of Proposed Determinations of base (100-year) flood elevations for selected locations in the Unincorporated Areas of Lyon County, Kansas previously published at 46 FR 63339 on December 31, 1981, in accordance with Section 110 of the Flood Disaster Protection Act of 1973 (Pub L. 93–234), 87 Stat. 980, which added 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)).

The Base Flood Elevation (BFE) Determination of 1116, located north of Dow Creek, was changed to 1117 to agree with the correct elevation shown on the profile. In addition, the BFE notice was corrected due to road name revisions which have been added to the maps as a result of additional information concerning the correct road labelling.

Pursuant to the provisions of 5 U.S.C. 605(b), the Associate Director, 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 of 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 flood plain area. The elevation determinations, however, impose no restriction unless and until the local community voluntary adopts flood plain 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 flood plain 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.

The listing appears correctly as follows:

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)
Kansas	(uninc.) Lyon County	Neosho River	Just upstream of U.S. Highway 50	*1,100
		Dow Creek	At mouth	*1,117
		Dry Creek	Just downstream of Old U.S. Highway 50 (about 25,300 feet above mouth).	*1,092
			Just upstream of Old U.S. Highway 50 (about 25,300 feet above mouth).	*1,095

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended; 42 U.S.C. 4001–4128; Executive Order 12127, 44 FR 19367; and delegation of authority to the Associate Director)

Issued: January 20, 1982.

Lee M. Thomas,

Associate Director, State and Local Programs and Support.

[FR Doc. 82–2603 Filed 2–1–82; 8:45 am]

BILLING CODE 6718–03–M

44 CFR Part 67

[Docket No. FEMA-6224]

National Flood Insurance Program; Proposed Flood Elevation Determinations; Correction; Missouri

AGENCY: Federal Emergency Management Agency.

ACTION: Proposed rule; correction.

SUMMARY: This document corrects a Notice of Proposed Determinations of base (100-year) flood elevations for selected locations in the Village of Silex, Lincoln County, Missouri, previously published at 46 FR 63340 on December 31, 1981.

EFFECTIVE DATE: February 2, 1982.

FOR FURTHER INFORMATION CONTACT: Mr. Robert G. Chappell, National Flood Insurance Program, (202) 287–0230, Federal Emergency Management Agency, Washington, D.C. 20472.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency gives notice of the correction to the Notice of Proposed Determinations of base (100-year) flood elevations for seclected locations in the Village of Silex, Lincoln County, Missouri previously published at 46 FR 63340 on December 31, 1981, in accordance with Section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93–234), 87 Stat. 980, which added 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)).

The Base Flood Elevation for the North Fork Cuivre River which reads 511 has been changed to 512 to agree with revisions made to the profile and FIRM. The previous elevation of 511 was not applicable to the community.

Pursuant to the provisions of 5 U.S.C. 605(b), the Associate Director, 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 flood plain area. The elevation determinations, however, impose no restriction unless and until the local community voluntarily adopts flood plain 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 flood plain 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.

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)
Missouri	(v) Silex, Lincoln County	North Fork Cuivre River	Just downstream of Church Street	*512

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended; 42 U.S.C. 4001–4128; Executive Order 12127, 44 FR 19367; and delegation of authority to the Associate Director.)

Issued: January 20, 1982.

Lee M. Thomas,

Associate Director, State and Local Programs and Support.

[FR Doc. 82-2804 Filed 2-1-82; 8:45 am]

BILLING CODE 6718-03-M

44 CFR Part 67

[Docket No. FEMA-6224]

National Flood Insurance Program; Proposed Flood Elevation Determinations; Correction; Iowa

AGENCY: Federal Emergency Management Agency.

ACTION: Proposed rule; correction.

SUMMARY: This document corrects a Notice of Proposed Determinations of base (100-year) flood elevations for selected locations in the Unincorporated Areas of Mills County, Iowa, previously published at 46 FR 63338 on December 31, 1981.

EFFECTIVE DATE: February 2, 1982.

FOR FURTHER INFORMATION CONTACT: Mr. Robert G. Chappell, National Flood Insurance Program, (202) 287–0230, Federal Emergency Management Agency, Washington, D.C. 20472.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency gives notice of the correction to the Notice of Proposed Determinations of base (100-year) flood elevations for selected locations in the Unincorporated Areas of Mills County, Iowa previously published at 46 FR 63338 on December 31, 1981, in accordance with Section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93–234), 87 Stat. 980, which added 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)).

The Base Flood Elevation Determination on the West Nishnabotna River, which reads about 5100 feet downstream of County Road H–12, has been changed from 1028 to 1029 to better agree with the flood profile.

Pursuant to the provisions of 5 U.S.C. 605(b), the Associate Director, 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 flood plain area. The elevation determinations, however, impose no restriction unless and until the local community voluntarily adopts flood plain 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 flood plain 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.

The listing appears correctly as follows:

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)
Iowa	(Uninc.) Mills County	West Nishnabotna River	About 5,100 feet downstream of County Road H-12	*1,029

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended; 42 U.S.C. 4001–4128; Executive Order 12127, 44 FR 19367; and delegation of authority to the Associate Director)

Issued: January 20, 1982.

Lee M. Thomas,

Associate Director, State and Local Programs and Support.

[FR Doc. 82-2605 Filed 2-1-82; 8:45 am]

BILLING CODE 6718-03-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Child Support Enforcement

45 CFR Part 302

Withholding of Unemployment Compensation for Support Purposes

AGENCY: Office of Child Support Enforcement (OCSE), HHS.

ACTION: Notice of decision to develop regulations.

SUMMARY: The Office of Child Support Enforcement is proposing to amend the Child Support Enforcement program regulations at 45 CFR Part 302 to implement the provisions of Section 2335 of Pub. L. 97–35, the Omnibus Budget Reconciliation Act, which requires withholding of unemployment compensation to collect unmet support obligations. Under the proposed amendment to Part 302, the child support enforcement (IV–D) agency will be required to determine on a periodic basis whether any individuals receiving compensation under the State's employment compensation law owe support obligations that are being enforced by the IV–D agency. The proposed regulations will further require the IV–D agency to enforce any obligations that are not being met by one of two methods. Under the proposed regulations, the IV–D agency must first attempt to enter into an agreement with the individual to have a specified amount withheld from unemployment compensation. If an agreement is signed, the IV–D agency must submit a copy of it to the State agency administering the unemployment compensation law. In the absence of an agreement with the individual, the IV–D agency may bring legal process in the nature of a garnishment to require a withholding of compensation. Finally, the proposed regulations will require IV–D agencies to reimburse the State agency administering the unemployment compensation law for its administrative costs related to child support enforcement activity.

DATE: OCSE anticipates that final regulations will become effective on October 1, 1982, the date on which Section 2335 of Pub. L. 97–35 becomes a requirement. The Department of Health and Human Services has classified these regulations as policy significant.

FOR FURTHER INFORMATION CONTACT: Eileen Brooks, Office of Child Support Enforcement, 6110 Executive Blvd., Room 1010, Rockville, Maryland 20852 (301) 443–5350.

Dated: December 30, 1981.

John A. Svahn,

Director, Office of Child Support Enforcement.

[FR Doc. 82-2640 Filed 2-1-82; 8:45 am]

BILLING CODE 4190-11-M

OFFICE OF MANAGEMENT AND BUDGET

Office of Federal Procurement Policy

48 CFR Part 49

Contract Termination Forms and Formats; Availability and Request for Comments

AGENCY: Office of Federal Procurement Policy, Office of Management and Budget.

ACTION: Notice of Availability and request for comment on draft Federal Acquisition Regulations.

SUMMARY: The Office of Federal Procurement Policy is making available for public and Government agency review and comment a segment of the draft Federal Acquisition Regulation (FAR).[1] Availability of additional segments for comment will be announced on later dates. The FAR is being developed to replace the current system of procurement regulations.

DATE: Comments must be received on or before March 19, 1982.

ADDRESS: Obtain copies of the draft regulation from and submit comments to William Maraist, Assistant Administrator for Regulations, Office of Federal Procurement Policy, 726 Jackson Place, NW., Room 9025, Washington, D.C. 20503. Federal agency requests must be directed to the FAR Agency Contact Point (see **Federal Register,** Vol. 46, No. 50, March 16, 1981, p. 16818 for list).

FOR FURTHER INFORMATION CONTACT: William Maraist, (202) 395–3300.

SUPPLEMENTARY INFORMATION: The fundamental purposes of the FAR are to reduce proliferation of regulations; to eliminate conflicts and redundancies; and to provide an acquisition regulation that is simple, clear and understandable. The intent is not to create new policy. However, because new policies may arise concurrently with the FAR project, the notice of availability of draft regulations will summarize the section or part available for review and describe any new policies therein.

The following parts of the draft Federal Acquisition Regulation are available upon request for public and Government agency review and comment.

[1] Filed as a part of the original document.

PART 49—TERMINATION OF CONTRACTS

This subpart contains suggested formats and prescribed standard forms related to the termination and settlement of contracts. The FPR formats and DAR forms have been consolidated in the FAR into six standard forms and various formats for termination notices, settlement agreements, delinquency notices, inventory schedules, etc. No policy change is intended in this coverage.

Dated: January 25, 1982.

LeRoy J. Haugh,

Associate Administrator for Regulatory Policies and Practices.

[FR Doc. 82-2879 Filed 2-1-82; 8:45 am]

BILLING CODE 3110-01-M

Notices

Federal Register
Vol. 47, No. 22
Tuesday, February 2, 1982

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

ADMINISTRATIVE OFFICE OF THE UNITED STATES COURTS

[Pay Order 82-2]

Rates of Pay for Certain Officers and Employees of the Judicial Branch

Pursuant to the authority which the laws of the United States of America vest in me as Director of the Administrative Office of United States Courts, I hereby ascertain, adjust, fix, or provide notice of pay rates for certain offices and positions in the Judicial Branch as follows:

1–1. Rates of Pay

1–101. Pay Rates Adjusted by Operation of Law

(a) The annual pay rates for offices having rates which the Executive Salary Cost-of-Living Adjustment Act (Pub. L. No. 94–82, § 205, 89 Stat. 419 (28 U.S.C. 461)) adjusts are set forth in Table 1.

(b) The annual pay rates for offices having rates linked to rates which the Executive Salary Cost-of-Living Adjustment Act adjusts are set forth in Table 2.

1–102. Pay Rates Fixed by Administrative Action

(a) The maximum annual pay rates for offices having maximum rates which the Executive Salary Cost-of-Living Adjustment Act adjusts are set forth in Table 3.

(b) The maximum annual pay rates for offices and positions having maximum rates linked to rates which the Executive Salary Cost-of-Living Adjustment Act adjusts are set forth in Table 4.

(c) The maximum pay rates for positions having maximum rate which may be adjusted pursuant to section 5307 of title 5, United States Code, are set forth in Table 5.

(d) The maximum annual pay rates for offices having maximum rates linked to rates which may be adjusted pursuant to section 5307 of title 5, United States Code, are set forth in Table 6.

(e) The maximum pay rates for positions having maximum rates linked to rates which are adjusted pursuant to section 5305 of title, 5, United States Code, are set forth in Table 7.

(f) The annual pay rates for positions having rates which the Judicial Conference of the United States fixes are set forth in Table 8.

(g) The annual pay rates for positions having rates fixed in accordance with the Judicial Salary Plan (established pursuant to 28 U.S.C. 604(a)(5)) are set forth in Table 9.

(h) The hourly pay rates for certain employees whose rates the Director of the Administrative Office of the United States Courts fixes in accordance with section 5349 of title 5, United States Code, are set forth in Table 10.

1–2. General Provisions

1–201. Incorporation of Tables

Each of the tables described above is incorporated herein.

1–202. Effective Date

(a) Adjustments of pay rates reflected in the attached tables were generally effective as of the beginning of the first applicable pay period commencing on or after October 1, 1981, except that those adjustments authorized by section 141(a) of Pub. L. 97–92 became effective on January 1, 1982. Implementing adjustments as a consequence of adjustments to maximum rates in the attached tables take effect in accordance with the determination of the administrative authority possessing pay-fixing responsibility.

(b) The adjustments of pay rates in Table 10 were effective as of October 19, 1981.

1–203. Determination of Adjustments

Certain adjustments in sections 1–101 and 1–102 depend upon the overall average percentage of the adjustment in the rates of pay under the General Schedule. According to the President's August 31, 1981 report to the Congress of the United States, this average was 4.8 percent. 17 Weekly Comp. of Pres. Doc. 917, 918 (Sept. 7, 1981).

1–204. "Formula Rates"

The difference between a rate of pay (or maximum rate) and a "formula rate," whenever a "formula rate" appears in the attached tables, is attributable to H.R.J. Res. 610, Pub. L. 96–369, § 101(c), 94 Stat. 1351, 1352 (Oct. 1, 1980); H.R.J. Res. 644, Pub. L. 96–536, § 101(c), 94 Stat. 3166, 3167 (Dec. 15, 1980); the Act of June 5, 1981, Pub. L. 97–12, § 401, 95 Stat. 14, 23; H.R.J. Res. 325, Pub. L. 97–51, § 101(c), 95 Stat. 958, 959 (Oct. 1, 1981); and H.R.J. Res. 370, Pub. L. 97–92, § 141(a), 95 Stat.—(Dec. 15, 1981).

1–205. Superseded Orders

This pay order supersedes Pay Order 82–1 of October 16, 1981.

Done at Washington, D.C., this 15th of January, 1982.

William E. Foley,

Director Administrative Office of the United States Courts.

[82–2–1]

TABLE 1.—ANNUAL PAY RATES FOR OFFICES HAVING RATES WHICH THE EXECUTIVE SALARY COST-OF-LIVING ADJUSTMENT ACT ADJUSTS

Office	Rate	Formula [1]	Basic authority	Adjustment authority
Chief Justice of the United States	$96,800		28 U.S.C. 5	28 U.S.C. 461.
Associate Justices of the Supreme Court of the United States	93,000		28 U.S.C. 5	Do.
Circuit Judges, United States Courts of Appeals	74,300		28 U.S.C. 44(d)	Do.
Judges, United States Court of Claims	74,300		28 U.S.C. 173	Do.
Judges, United States Court of Customs and Patent Appeals	74,300		28 U.S.C. 213	Do.
Judges, United States District Courts	70,300		28 U.S.C. 135	Do.
Judges, United States Court of International Trade	70,300		28 U.S.C. 252	Do.
Bankruptcy Judges (formerly Referees in Bankruptcy) (Full-time)	58,500	$61,200	Act of Nov. 6, 1978, Pub. L. No. 95–598, title IV, §§ 404(d), 411, 92 Stat. 2549, 2684, 2688.	Do.
Commissioners (Trial Judges), United States Court of Claims	57,500	62,700	28 U.S.C. 792(b)	Do.

[1] The "formula rates" in this column are furnished for convenience of reference only. They provide a basis for future cost-of-living adjustment calculations and the determination of legal pay rates in the absence of legislation to the contrary. Whenever this column is blank for a particular position, the "formula rate" is currently the same as the payable rate for that position.

[82–2–2]

TABLE 2.—ANNUAL PAY RATES FOR OFFICES HAVING RATES LINKED TO RATES WHICH THE EXECUTIVE SALARY COST-OF-LIVING ADJUSTMENT ACT ADJUSTS

Office	Rate	Formula [1]	Authority
District Judge, United States District Court for the District of the Canal Zone	$70,300		3 P.C.C. 5(b).
Judges, District Court of the Virgin Islands	70,300		48 U.S.C. 1614(a).
Judge, District Court of Guam	70,300		48 U.S.C. 1424b(a).
Judge, District Court for the Northern Mariana Islands	70,300		48 U.S.C. 1694(b)(1).
Director, Administrative Office of the United States Courts	70,300		28 U.S.C. 603.
Director, Federal Judicial Center	70,300		28 U.S.C. 626.
Deputy Director, Administrative Office of the United States Courts	57,500	$61,300	28 U.S.C. 603.

[1] See n. 1 on Table 1.

[82–2–3]

TABLE 3.—PAY FIXED BY ADMINISTRATIVE ACTION—MAXIMUM ANNUAL PAY RATES FOR OFFICES HAVING MAXIMUM RATES WHICH THE EXECUTIVE SALARY COST-OF-LIVING ADJUSTMENT ACT ADJUSTS

[Rate which the Judicial Conference of the United States Fixes[1]]

Office	Maximum rate	Formula[2]	Authority	Adjustment authority
Bankruptcy Judges (formerly Referees in Bankruptcy) (Part-time).	$30,600		Act of Nov. 6, 1978, Pub. L. No. 95–598, title IV, § 404(d), 411, 92 Stat. 2549, 2684, 2688.	28 U.S.C. 461.

[1] In accordance with the September 1974 resolution of the Judical Conference of the United States concerning cost-of-living adjustments for part-time bankruptcy judges and 5 U.S.C. 5307, the annual pay rate for each part-time bankrupty judge was adjusted as follows, effective October 1, 1981: Level 1, $30,600; level 2, $27,700; level 3, $25,200; level 4, $4,500.

[2] The "formula rates" in this column are furnished for convenience of reference only. They provide a basis for future cost-of-living adjustment calculations and the determination of maximum pay rates in the absence of legislation to the contrary. Whenever this column is blank for a particular postion, the "formula rate" is currently the same as the maxiumum payable rate for that position.

[82–2–4]

TABLE 4.—PAY FIXED BY ADMINISTRATIVE ACTION [1]—MAXIMUM ANNUAL PAY RATES FOR OFFICES AND POSITIONS HAVING MAXIMUM RATES LINKED TO RATES WHICH THE EXECUTIVE SALARY COST-OF-LIVING ADJUSTMENT ACT ADJUSTS

[Rate Which the Chief Justice of the United States Fixes]

	Maximum rate	Formula [2]	Authority
Office			
Administrative Assistant to the Chief Justice of the United States	$70,300		28 U.S.C. 677(a)
Rates Which the Judicial Conference of the United States Fixes			
United States Magistrates (Full-Time)	[3] $58,500	$61,200	28 U.S.C. 634(a) [4]
United States Magistrates (Part-Time)	[3] 26,750	30,600	28 U.S.C. 634(a) [4]
Circuit Executives	[5] 57,500	61,300	28 U.S.C. 332(f).
Rate Which the Judicial Council of the Circuit Fixes			
Federal Public Defender (for the Central District of California)	[6] $58,500	$64,600	18 U.S.C. 3006A(h)(2)(A); 5 U.S.C. 5315.
Rates Which the Director of the Federal Judicial Center Fixes			
Positions			
Professional Personnel, Federal Judicial Center	$57,500	$61,300	28 U.S.C. 625(b).

[1] The actual pay rates of officials included in this table are not subject to automatic adjustment. The authority possessing pay-fixing responsibility must act to administratively adjust actual pay rates. These adjustments, when made pursuant to 5 U.S.C. 5307, may be retroactive to January 1, 1982, or if applicable, to the beginning of the first pay period commencing on or after October 1, 1981.

[2] See n. 2 on Table 3.

[3] In accordance with the March, 1980 and March, 1981 resolutions of the Judicial Conference concerning cost-of-living adjustments for United States magistrates, the annual pay rates for magistrates as of January 1, 1982 are as follows:

Full-Time Magistrates, $58,500 (this rate shall not necessarily apply to full-time magistrates in special situations such as national parks).

Part-Time Magistrates: Level 15, $26,750; Level 14, $23,100; Level 13, $20,300; Level 12, $17,900; Level 11, $15,500; Level 10, $13,600; Level 9, $11,800; Level 8, $10,000; Level 7, $8,200; Level 6, $6,400; Level 5, $4,500; Level 4, $3,600; Level 3, $2,700; Level 2, $1,800; Level 1, $900.

[4] Section 232 of the Act of Nov. 6, 1978, Pub. L. No. 95–598, title II, 92 Stat. 2549, 2665, which amends 28 U.S.C. 634(a), will not become effective until April 1, 1984, in accordance with section 402(b) of the Act.

[5] The Judicial Conference at its March, 1977 session adopted a resolution administratively establishing the salary for level V of the Executive Schedule as the upper limit upon the pay of circuit executives and delegating the determination of actual compensation for each circuit executive position to the respective circuit judicial councils.

[6] The compensation of each federal public defender is fixed by the judicial council of the circuit at a rate not to exceed the compensation received by the United States attorney for the judicial district. The salary of the United States attorney for the Central District of California is established by 5 U.S.C. 5315 at level IV of the Executive Schedule. The salaries of the United States attorneys in al other judicial districts where federal public defender organizations have been established are fixed by the Attorney General pursuant to 28 U.S.C. 548 not to exceed the rate of pay for GS–18 of the General Schedule (see Table 6).

[82-2-5]

TABLE 5.—PAY FIXED BY ADMINISTRATIVE ACTION [1]—MAXIMUM PAY RATE FOR POSITION HAVING MAXIMUM RATE WHICH MAY BE ADJUSTED PURSUANT TO 5 U.S.C. 5307

[Rates Which the United States District Courts Fix]

Position	Maximum rate	Basic authority	Adjustment authority
Jury Commissioner	$76.08 per day	28 U.S.C. 1863(b)(1)	5 U.S.C. 5307.

[1] See n. 1 on Table 4.

[82-2-6]

TABLE 6.—PAY FIXED BY ADMINISTRATIVE ACTION [1]—MAXIMUM ANNUAL PAY RATES FOR OFFICES HAVING MAXIMUM RATES LINKED TO RATES WHICH MAY BE ADJUSTED PURSUANT TO 5 U.S.C. 5307

[Rates Which the Judicial Councils of the Circuits Fix]

Office	Maximum rate	Authority
Federal Public Defenders (except as provided in Table 4)	"* * * [C]ompensation received by the United States attorney for the district where representation is furnished. * * *".	18 U.S.C. 3006A(h)(2)(A); 28 U.S.C. 548.

[1] See n. 1 on Table 4.

[82-2-7]

TABLE 7.—PAY FIXED BY ADMINISTRATIVE ACTION—MAXIMUM PAY RATE FOR POSITION HAVING MAXIMUM RATE LINKED TO RATE WHICH IS ADJUSTED PURSUANT TO 5 U.S.C. 5305

Rates Which the Director of the Administrative Office of the United States Courts Fixes [1]

Position	Maximum rate	Authority
Land Commissioner	$221.12 per day	5 U.S.C. § 3109; 28 U.S.C. § 604(a)(5); H.R.J. Res. 370, Pub. L. No. 97-92, § 101(h), 95 Stat. ——(Dec. 15, 1981); H.R. 4169, title IV, "Fees of Jurors and Commissioners" 40 (July 16, 1981).

1. The Director has delegated authority to the United States district courts to fix the pay rates of officials included in this this table, subject to the limitations that (a) the hourly rate cannot exceed $40, and (b) notwithstanding the hourly rate, pay for any calendar day cannot exceed the maximum rate above. The district court must act to adjust actual pay rates.

[82-2-8]

TABLE 8.—PAY FIXED BY ADMINISTRATIVE ACTION—ANNUAL PAY RATES WHICH THE JUDICIAL CONFERENCE OF THE UNITED STATES FIXES [1]

Position	Rate	Authority
Court Reporters, United States District Courts		28 U.S.C. 753(e).
Level I	$33,133	
Level II	31,627	
Level III	30,121	

[1] In accordance with the March, 1971 resolution of the Judicial Conference concerning the General Plan of Qualification and Compensation for Court Reporters, the Director of the Administrative Office of the United States Courts makes the adjustments reflected in this table.

[82-2-9]

TABLE 9.—THE JUDICIAL SALARY PLAN [1]

[Annual Rates]

Grade	Steps									
	1	2	3	4	5	6	7	8	9	10
1	$8,342	$8,620	$8,898	$9,175	$9,453	$9,615	$9,890	$10,165	$10,178	$10,439
2	9,381	9,603	9,913	10,178	10,292	10,595	10,898	11,201	11,504	11,807
3	10,235	10,576	10,917	11,258	11,599	11,940	12,281	12,622	12,963	13,304
4	11,490	11,873	12,256	12,639	13,022	13,405	13,788	14,171	14,554	14,937
5	12,854	13,282	13,710	14,138	14,566	14,994	15,422	15,850	16,278	16,706
6	14,328	14,806	15,284	15,762	16,240	16,718	17,196	17,674	18,152	18,630
7	15,922	16,453	16,984	17,515	18,046	18,577	19,108	19,639	20,170	20,701
8	17,634	18,222	18,810	19,398	19,986	20,574	21,162	21,750	22,338	22,926
9	19,477	20,126	20,775	21,424	22,073	22,722	23,371	24,020	24,669	25,318
10	21,449	22,164	22,879	23,594	24,309	25,024	25,739	26,454	27,169	27,884
11	23,566	24,352	25,138	25,924	26,710	27,496	28,282	29,068	29,854	30,640
12	28,245	29,187	30,129	31,071	32,013	32,955	33,897	34,839	35,781	36,723
13	33,586	34,706	35,826	36,946	38,066	39,186	40,306	41,426	42,546	43,666
14	39,689	41,012	42,335	43,658	44,981	46,304	47,627	48,950	50,273	51,596
15	46,685	48,241	49,797	51,353	52,909	54,465	56,021	[2] 57,577	[2] 59,133	[2] 60,689
16	54,755	56,580	[2] 58,405	[2] 60,230	[2] 62,055	[2] 63,880	[2] 65,705	[2] 67,530	[2] 69,355	
17	[2] 64,142	[2] 66,280	[2] 68,418	[2] 70,556	[2] 72,694					
18	[2] 75,177									

[1] The Judicial Salary Plan has been administratively implemented by the Director of the Administrative Office of the United States Courts with the approval of the Judicial Conference of the United States pursuant to 28 U.S.C. 604(a)(5). It applies to various offices and positions in the courts of the United States for which the compensation is not otherwise fixed by law. The authority for its adjustment to reflect annual pay adjustments in the General Schedule is 5 U.S.C. 5307.

[2] These rates are "formula rates," which provide the basis for future cost-of-living adjustment calculations and the determination of legal pay rates in the absence of legislation to the contrary. Currently, the payable rate for each of these designated step levels is $57,500, the payable rate for level V of the Executive Schedule. See 5 U.S.C. 5308.

[82-2-10]

TABLE 10.—PAY FIXED BY ADMINISTRATIVE ACTION [1]

[Administrative Office Wage System]

	Hourly rates				
	Steps				
	1	2	3	4	5
Part A. Supervisors of Tradesmen and Craftsmen					
JT:					
1	$8.17	$8.50	$8.84	$9.19	$9.52
2	8.61	8.97	9.32	9.68	10.05
3	9.05	9.43	9.80	10.18	10.56
4	9.59	9.99	10.39	10.79	11.19
5	10.13	10.55	10.97	11.40	11.82
6	10.67	11.11	11.55	12.01	12.45
7	11.19	11.65	12.11	12.58	13.04
8	11.67	12.15	12.63	13.13	13.61
9	12.14	12.64	13.15	13.66	14.16
10	12.61	13.14	13.66	14.18	14.71
11	12.90	13.43	13.96	14.51	15.04
12	13.26	13.82	14.37	14.93	15.47
13	13.72	14.30	14.88	15.44	16.02
14	14.26	14.86	15.45	16.04	16.64
15	14.91	15.53	16.14	16.77	17.39
Part B. Leaders of Tradesmen and Craftsmen					
JL:					
1	5.73	5.97	6.21	6.45	6.68
2	6.21	6.47	6.73	6.99	7.25
3	6.70	6.99	7.27	7.54	7.82
4	7.30	7.60	7.91	8.21	8.52
5	7.89	8.21	8.54	8.87	9.20
6	8.48	8.84	9.20	9.55	9.90
7	9.07	9.45	9.83	10.20	10.58
8	9.64	10.03	10.43	10.84	11.24
9	10.14	10.56	10.98	11.41	11.83
10	10.67	11.11	11.55	12.01	12.45
11	11.20	11.67	12.14	12.60	13.07
12	11.72	12.21	12.71	13.19	13.68
13	12.25	12.76	13.27	13.78	14.29
14	12.78	13.32	13.85	14.38	14.92
15	13.33	13.88	14.44	14.99	15.55
Part C. Graded Tradesmen and Craftsmen (excluding lithographers and printers)					
JG:					
1	5.20	5.42	5.64	5.85	6.07
2	5.65	5.88	6.12	6.36	6.59
3	6.09	6.35	6.60	6.85	7.11
4	6.64	6.91	7.18	7.47	7.74
5	7.16	7.47	7.77	8.06	8.37
6	7.71	8.03	8.36	8.67	9.00
7	8.24	8.59	8.93	9.28	9.62
8	8.75	9.11	9.48	9.85	10.20
9	9.22	9.61	9.99	10.37	10.76
10	9.70	10.11	10.52	10.92	11.32
11	10.18	10.61	11.04	11.46	11.89
12	10.67	11.11	11.55	12.01	12.45
13	11.14	11.60	12.06	12.53	12.99
14	11.62	12.10	12.58	13.06	13.56
15	12.10	12.60	13.11	13.61	14.11

	Hourly rates		
	Steps		
	1	2	3
Part D. Graded Lithographers and Printers			
JP:			
1	5.83	6.14	6.44
2	6.13	6.45	6.78
3	6.44	6.78	7.11
4	6.73	7.09	7.45
5	7.04	7.40	7.77
6	7.34	7.73	8.12
7	7.65	8.04	8.44
8	7.94	8.36	8.78
9	8.25	8.68	9.11
10	8.55	9.00	9.45
11	8.85	9.31	9.77
12	9.15	9.64	10.12
13	9.46	9.95	10.45
14	9.76	10.28	10.79
15	10.06	10.59	11.12
16	10.36	10.90	11.45
17	10.66	11.23	11.80
18	10.97	11.54	12.12
19	11.26	11.86	12.46
20	11.58	12.18	12.79
21	11.87	12.50	13.13
22	12.17	12.81	13.45
23	12.48	13.14	13.80
24	12.78	13.45	14.12
25	13.07	13.77	14.46
26	13.39	14.09	14.79
27	13.68	14.41	15.13
28	13.99	14.72	15.45
29	14.29	15.04	15.80
30	14.59	15.36	16.12
31	14.89	15.67	16.46
32	15.20	16.00	16.79
33	15.49	16.31	17.13
34	15.80	16.63	17.45

[1] Hourly pay rates for certain employees having rates which the Director of the administrative office of the U.S. courts fixes pursuant to 5 U.S.C. 5349.

[FR Doc. 82-2471 Filed 2-1-82; 8:45 am]

BILLING CODE 2210-01-M

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

Tobacco Inspection; Growers' Referendum

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice of Referendum.

SUMMARY: This notice announces that a referendum will be conducted by mail during the period February 8–12, 1982, for producers of Maryland Broadleaf, Type 32, tobacco who sell their tobacco at auction in Maryland. The referendum is being conducted to determine if the designation of all Maryland tobacco auction markets should be terminated, thus eliminating the requirement for mandatory, federal inspection and grading for the 1981 and succeeding crop years.

DATES: The referendum will be held February 8–12, 1982.

FOR FURTHER INFORMATION CONTACT: J. T. Bunn, Acting Director, Tabacco Division, Agricultural Marketing Service, United States Department of Agriculture, Washington, D.C., 20250 (202) 447–7235.

SUPPLEMENTARY INFORMATION: Hughesville, LaPlata, Upper Marlboro, and Waldorf, Maryland, were designated on May 17, 1948, (13 FR 2579) as Maryland tobacco auction markets under the Tobacco Inspection Act of 1935. Under this Act these markets have been receiving free and mandatory grading services from USDA. As required by the Omnibus Budget Reconciliation Act of 1981, a user fee system was implemented October 1, 1981, for inspection and grading services performed by federal graders at designated tobacco auction markets throughout the tobacco producing states. These fees are collected from warehousemen at the rate of $.0045 per pound of tobacco sold at auction.

The Department has received requests from the Maryland Farm Bureau and various warehousemen in that State seeking to terminate the designation of the Maryland markets and eliminate the requirement for mandatory, federal inspection and grading of their crop. Maryland producers have declined the option of price supports in each referendum conducted since 1965. Based on this fact, they strongly contend that federal grading is unnecessary and wish to be exempted from the payment of fees imposed by the user fee legislation. Because the four markets involved in these requests represent an entire kind of tobacco, the Department determined that a referendum would be an appropriate means of deciding whether to discontinue mandatory grading on these markets. It is hereby determined that the referendum will be held by mail during the period February 8 through 12, 1982. The purpose of the referendum is to determine whether Maryland Broadleaf tobacco, Type 32, farmers are in favor of or opposed to (1) terminating the designation of the tobacco auction markets in Hughesville, LaPlata, Upper Marlboro, and Waldorf, Maryland; and (2) eliminating mandatory, federal grading of their crop for the 1981 and succeeding crop years. Accordingly, if a majority of the Maryland toabacco producers selling on the four designated Maryland auction markets who vote in the referendum favor termination of designations, the designation of each of these markets will be terminated. The referendum will be held in accordance with the provisions of Section 312(c) of the Agricultural Adjustment Act of 1938, as amended (7 U.S.C. 1312(c)) and the regulations set forth in 7 CFR Parts 29 and 717.

Dated: January 29, 1982.

C. W. McMillan,

Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 82-2854 Filed 2-1-82; 10:33 am]

BILLING CODE 3410-02-M

Forest Service

Sawtooth National Forest Grazing Advisory Board Committee; Meeting

The Sawtooth National Forest Grazing Advisory Board will meet at 1:00 p.m., March 16, 1982 at the Forest Supervisor's Office Conference Room, 1525 Addison Avenue East, Twin Falls, Idaho.

The purpose of the meeting will be to organize the Advisory Board, to discuss function of the board, to review use of Range Improvement funds for FY 1983, and to discuss allotment management plans to be developed in 1982 and 1983 for the Sawtooth National Forest.

Written statements may be filed with the Committee before or after the meeting.

The meeting will be open to the public. Their views and comments will be addressed at the end of the meeting. Written statements will be received prior to or within two weeks after the meeting.

Paul F. Barker,

Forest Supervisor.

January 25, 1982.

[FR Doc. 82-2660 Filed 2-1-82; 8:45 am]

BILLING CODE 3410-11-M

Science and Education

National Agricultural Research and Extension Users Advisory Board; Meeting

According to the Federal Advisory Committee Act of October 6, 1972, (Pub. L. 92-463, 86 Stat. 770-776) Science and Education announces the following meeting:

Name: National Agricultural Research and Extension Users Advisory Board.

Date: February 16-19, 1982.

Time: 8:00 a.m.-6:00 p.m., February 16-17; 8:30 a.m.-4:30 p.m., February 18; 8:30 a.m.-12:00 noon, February 19

Place: February 16—8:00 a.m.-12:00 noon, USDA, Rm. 104-A, Administration Building, Washington, D.C.; February 16—12:00 noon-February 19, Apollo Room, Capitol Holiday Inn, 550 C Street, SW., Washington, D.C. 20024.

Type of meeting: Open to the public. Persons may participate in the meeting as time and space permit.

Comments: The public may file written comments before or after the meeting with the contact person below.

Purpose: The Board will be reviewing and discussing agricultural research and extension program budgets and preparing its annual report to the President and Congress.

Contact person for agenda and more information: Barbara L. Fontana, Executive Secretary, National Agricultural Research and Extension Users Advisory Board; Room 351-A Administration Building, U.S. Department of Agriculture; Washington, D.C. 20250; telephone 202-447-3684.

Done at Washington, D.C., this 22th day of January 1982.

Gary R. Evans,

Associate Executive Director, National Agricultural Research and Extension Users Advisory Board.

[FR Doc. 82-2711 Filed 2-1-82; 8:45 am]

BILLING CODE 3410-03-M

CIVIL AERONAUTICS BOARD

[Docket 39975]

Trenton Hub Express Airline Fitness Investigation; Cancellation of Prehearing Conference

Pursuant to the request by Trenton Hub Express Airline, Inc., in a letter dated January 26, 1982, the prehearing conference in this case set for January 28, 1982 (47 FR 3153, January 22, 1982), is cancelled.

Dated at Washington, D.C., January 27, 1982.

William A. Kane, Jr.,

Administrative Law Judge.

[FR Doc. 82-2704 Filed 2-1-82; 8:45 am]

BILLING CODE 6320-01-M

[Docket 40147]

Stockton, Modesto and Merced, California; Carrier Selection Case; Oral Argument

Notice is hereby given, pursuant to the provisions of the Federal Aviation Act of 1958, as amended, that oral argument in this proceeding is assigned to be held before the Board on Wednesday, February 24, 1982, at 10:00 a.m. (local time), in Room 1027, Universal Building, 1825 Connecticut Avenue, NW., Washington, D.C.

Each party which wishes to participate in the oral argument shall so advise The Secretary, in writing, on or before Wednesday, February 10, 1982, together with the name of the person who will represent it at the argument.

Dated at Washington, D.C., January 28, 1982.

Phyllis T. Kaylor,

Secretary.

[FR Doc. 82-2705 Filed 2-1-82; 8:45 am]

BILLING CODE 6320-01-M

DEPARTMENT OF COMMERCE

International Trade Administration

Applications for Duty-Free Entry of Scientific Articles

The following are notices of the receipt of applications for duty-free entry of scientific articles pursuant to Section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89-651; 80 Stat. 897). Interested persons may present their views with respect to the question of whether an instrument or apparatus of equivalent scientific value for the purposes for which the article is intended to be used is being manufactured in the United States. Such comments must be filed in triplicate with the Director, Statutory Import Programs Staff, U.S. Department of Commerce, Washington, D.C. 20230, within 20 calendar days after the date on which this notice of application is published in the **Federal Register.**

Regulations (15 CFR 301.9) issued under the cited Act prescribe the requirements for comments.

A copy of each application is on file, and may be examined between 8:30 a.m. and 5.00 p.m., Monday through Friday, in Room 2097 of the Department of Commerce Building, 14th and Constitution Avenue, NW., Washington, D.C. 20230.

Docket No. 82-00057. Applicant: Medical College of Ohio Hospital, C. S. 10008, Toledo, Ohio 43699. Article: Radiation Therapy Special Simulator. Manufacturer: A.E.C.L., Canada. Intended use of article: The article is intended to be used in a variety of clinical and basic radiation therapy research projects to accurately define target volumes for irradiation. The initial projects in which the article will be used include:

1. Iodine 125, 5 fluororacil and Precision High Dose External Beam Radiation Therapy for Pancreatic Carcinoma.

2. Adjuvant "Sandwich" Radiation Therapy for Resectable Bladder Carcinoma.

3. Adjuvant "Sandwich" Radiation Therapy for Resectable Carcinoma of the Rectum.

4. Precision High Dose Radiation Therapy for Carcinoma of the Cervical Esophagus.

5. Intraoperative Pre-resection Radiation Therapy for Gastric Carcinoma.

6. Combined Radiation Therapy and Chemotherapy of Malignant Pleural Mesothelioma.

7. Detection of Occult Radiation Damage to Optic Pathways.

8. External and Interstitial Radiation Therapy for Intracranial Neoplasms.

The article will also be used for the education of medical students, residents in Radiation Therapy, residents in Surgical Oncology, residents in Medical Oncology and residents in other specialties, as well as for the education of student technologists and graduate physicians and physicists. Application received by Commissioner of Customs: November 20, 1981.

Docket No. 82–00058. Applicant: Niagara County Community College, 3111 Saunders Settlement Road, Sanborn, New York 14132. Article: Gear Pump Test Set. Manufacturer: Plint & Partners, United Kingdom. Intended use of article: The article is intended to be used for educational purposes in the course: MET 5431—Hydraulics and Pneumatics. The course content will include teaching basic principles of fluid mechanics with emphasis on the application of these concepts to hydraulic and pneumatic devices. Topics include fluid properties, hydraulic cylinders, fluid power, and pressure loss in pipes and fittings. Flow characteristics of valves, orifices, nozzles, venturis, and pumps are considered. Application received by Commissioner of Customs: November 20, 1981.

Docket No. 82–00060. Applicant: Monsanto Research Corporation, Mound Facility, Operated for the U.S. Department of Energy, Mound Road, Miamisburg, OH 45342. Article: X-Ray Photoelectron Spectrometer, X–SAM 800. Manufacturer: Kratos Scientific Instruments, United Kingdom. Intended use of article: The article is intended to be used in research on high energy material to elucidate the mechanism of ignition. Research which will be done initially on high energy materials will attempt to:

(1) Understand the role the oxide coating on fuels plays in ignition of pyrotechnic materials, and

(2) Understand the role the binder takes in igniting an explosive composite. This work will hopefully lead to safer high energy materials but without loss in performance, for use in society.

Application received by Commissioner of Customs: November 25, 1981.

Docket No. 82–00061. Applicant: University of California, Los Alamos National Laboratory, P.O. Box 990, Los Alamos, NM 87545. Article: Excimer Laser, EMG 101. Manufacturer: Lambda Physik, Gmbh and Co., West Germany. Intended use of article: The article is intended to be used in a research project centered on the selective multiphoton ionization of gas phase atoms. This method is being developed for the sensitive and specific detection of particular species in the presence of other detection atoms. Other experiments will involve the use of a dye laser system to produce high intensity visible light pulses in an effort to improve the isotopic selectivity of the multiphoton ionization process. Application received by Commissioner of Customs: November 25, 1981.

Docket No. 82–00064. Applicant: Purdue University, FREH Hall, West Lafayette, IN 47907. Article: Fiber Optic Doppler Anemometer with Laser. Manufacturer: SIRA Institute Ltd., United Kingdom. Intended use of article: The article is intended to be used in conducting the following types of experiments:

(1) Determine the particle size distribution of colloidal systems in their natural liquid state.

(2) Study the relationship between primary particle size and coagulate size of colloidal materials.

(3) Study the kinetics of aggregation and disaggregation of colloidal systems.

(4) Study particle-to-particle interactions in colloidal systems including systems containing several types of colloidal particles.

The overall objective of these studies is to obtain an understanding of colloidal systems in their natural, liquid state. Application received by Commissioner of Customs: December 14, 1981.

Docket No. 82–00065. Applicant: University of California, P.O. Box 5012, L 650, Lawrence Livermore National Laboratory, Livermore, CA 94550. Article: Faraday Rotator Glass Blanks, Type FR–5. Manufacturer: Hoya Corporation, Japan. Intended use of article: The article is intended to be used in the country's most advanced effort to demonstrate the feasibility of the generation of usable power in a controlled thermonuclear fusion reaction. Experiments will be conducted using the NOVA 10-arm laser system to obtain isentropic compression of deuterium-tritium targets to greater than 10,000 times liquid density, thereby producing for the first time in any research facility thermonuclear reaction of as many as 10^{14} neutrons per micro-explosion. Application received by Commissioner of Customs: December 14, 1981.

Docket No. 82–00066. Applicant: University of California, Los Alamos National Laboratory, P.O. Box 990, Los Alamos, NM 87545. Article: Excimer Laser, EMG–200. Manufacturer: Lambda Physics Gmbh & Co., West Germany. Intended use of article: The article is intended to be used as the master oscillator for an injection-locked unstable resonator KrF laser system. This system is the research test system for oscillator-pulse generation of the front end of a large KrF laser system being built for laser fusion research purposes. Application received by Commissioner of Customs: December 14, 1981.

Docket No. 82–00067. Applicant: University of California, Lawrence Livermore National Laboratory, P.O. Box 5012, Livermore, CA 94550. Article: Linear Actuator. Manufacturer: Klinger Scientific/Micro Controle, France. Intended use of article: The article is intended to be used in the country's most advanced effort to demonstrate the feasibility of the generation of usable power in a controlled thermonuclear fusion reaction. Experiments will be conducted using the NOVA 10-arm laser system to obtain isentropic compression of deuterium-tritium targets to greater than 10,000 times liquid density, thereby producing for the first time in any research facility thermonuclear reaction of as many as 10^{14} neutrons per microexplosion. Application received by Commissioner of Customs: December 14, 1981.

Docket No. 82–00068. Applicant: University of Pennsylvania, 3400 Walnut Street, Franklin Building, Philadelphia, PA 19104. Article: TMR 32/200 Magnet System. Manufacturer: Oxford Instruments, United Kingdom. Intended use of article: The article is intended to be used for studies for the creatine phosphate and inorganic phosphate content of human arm and leg together with that of animal models. The patient's arm or leg will be inserted into the sensitive volume of the instrument, and the radiofrequency pulses will be applied to excite the nuclei and to observe by a sensitive receiver the resonances. These will be plotted as a function of frequency and quantitatively evaluated for health and disease. The quantitative analyses of creatine phosphate and phosphate along the leg of the patient with peripheral vascular disease will be employed to determine whether vascular surgery is necessary or whether amputation is necessary. Application received by Commissioner of Customs: December 14, 1981.

Docket No. 82–00069. Applicant: NIEHS, P.O. Box 12233, Research Triangle Park, NC 27709. Article: Fast Atom Bombardment Upgrade. Manufacturer: VG Analytical, Ltd., United Kingdom. Intended use of article: The article is an accessory which will be used to study the mass spectrometry of

polypeptides, metabolites of environmental chemicals and their conjugates, and degradation products of chemically modified DNA. This information will in turn be used for chemical analysis. The article will be used in support of a wide variety of biological and biochemical studies, each of which has a specific protocol. Application received by Commissioner of Customs: December 14, 1981.

Docket No. 82–00070. Applicant: University of North Carolina, North Carolina Memorial Hospital, Chapel Hill, NC 27514. Article: Electron Microscope, Model EM 109. Manufacturer: Carl Zeiss, West German. Intended use of article: The article is intended to be used for studies of tissues removed from hospitalized or non-hospitalized patients at the time of operation or during clinic visits respectively. The materials are to be evaluated to achieve a diagnosis such that proper therapy may be instituted. The article will also be used for training and education of resident physicians in the use of electron microscopy as a diagnostic tool. Application received by Commissioner of Customs: December 23, 1981.

Docket No. 82–00071. Applicant: Harvard University, Department of Geological Sciences, 20 Oxford Street, Hoffman Laboratory, Cambridge, MA 02138. Article: Isomass 54R Thermal Ionization Mass Spectrometer. Manufacturer: VG Isotopes Limited, United Kingdom. Intended use of article: The article is intended to be used for studies of terrestrial, lunar and meteoritic materials to get a better understanding of the early history of the solar system and the evolution of the earth and the moon through time. In addition, the article will be used to educate graduate students in the use of high precision thermal ionization mass spectrometry to solve geochemical problems. Application received by Commissioner of Customs: December 23, 1981.

Docket No. 82–00072. Applicant: University of California, Lawrence Livermore National Laboratory, P.O. Box 5012, Livermore, CA 94550. Article: Beam Dump Prototype Filter Glass. Manufacturer: Hoya, Japan. Intended use of article: The article is intended to be used in the country's most advanced effort to demonstrate the feasibility of the generation of usable power in a controlled thermonuclear fusion reaction. Experiments will be conducted using the NOVA 10-arm laser system to obtain isentropic compression of deuterium-tritium targets to greater than 10,000 times liquid density, thereby producing for the first time in any research facility thermonuclear reaction of as many as 10^{14} neutrons per microexplosion. Application received by Commissioner of Customs: December 23, 1981.

Docket No. 82–00073. Applicant: University of Arizona, Department of Pathology, Arizona Health Science Center, Campbell Avenue, Tucson, Arizona 85724. Article: Electron Microscope, Model JEM–100CX with Accessories. Manufacturer: JEOL Ltd., Japan. Intended use of article: The article is intended to be used to study pathologic specimens, primarily those related to the pathogenesis of renal, neurologic, and oncologic diseases. The experiments to be conducted will range from studying the basement membrane changes in diabetic animals to the kinetics of glomerular cell proliferation using tissue cultured cells. Additionally, the article will be used to analyze the ultra-structural localization of various antigens using ultrastructural immunocytochemistry. The article will also be used to provide teaching materials in a course in Basic Medical Pathology and in the training of residents and post-graduate fellows in diagnostic pathology. Application received by Commissioner of Customs: December 23, 1981.

Docket No. 82–00074. Applicant: Bridgeport Hospital, 267 Grant Street, Bridgeport, CT 06602. Article: Electron Microscope, Model EM 109 and Accessories. Manufacturer: Carl Zeiss, West Germany. Intended use of article: The article is intended to be used to examine tissues or fluids obtained at surgery or autopsy for investigation of the relationship between congenital CMV infection and hearing loss in humans and animal models and the relationship of the findings to other neonatal diseases and viral infections. The article will also be used for teaching purposes at the hospital. Application received by Commissioner of Customs: December 23, 1981.

Docket No. 82–00075. Applicant: Syracuse University, Department of Chemistry, Bowne Hall, Syracuse, NY 13210. Article: Superconducting Fourier NMR Spectrometer, Model WM–360 WB and Components. Manufacturer: Spectrospin A.G., Switzerland. Intended use of article: The article is intended to be used for NMR studies of the following:

(1) Synthesized and natural-source biological macromolecules such as proteins, carbohydrates and nucleic acids with emphasis placed on studies of deoxyribonucleic acid (DNA),

(2) Low molecular weight natural products such as alkaloids, co-enzymes, etc.,

(3) A broad range of ^{13}C, ^{15}N, ^{1}H, and other nuclei NMR studies, and

(4) Synthetic high polymers, small-sized organic synthetic intermediates and final products as well as inorganic and organometallic molecules.

Application received by Commissioner of Customs: December 23, 1981.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Frank W. Creel,

Acting Director, Statutory Import Programs Staff.

[FR Doc. 82–2661 Filed 2–1–82; 8:45 am]

BILLING CODE 3510–25–M

National Oceanic and Atmospheric Administration

Issuance of Permit To Import Endangered Marine Mammals

On December 22, 1981, Notice was published in the **Federal Register** (46 FR 62130), that an application had been filed with the National Marine Fisheries Service by Dr. Darlene R. Ketten, School of Hygiene and Public Health, Johns Hopkins University, Baltimore, Maryland, for a Scientific Research and Scientific Purposes Permit to import an unspecified number of specimens from various cetacean species for scientific research.

Notice is hereby given that on January 27, 1982, the National Marine Fisheries Service issued a Scientific Research and Scientific Purposes Permit as authorized by the provisions of the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361–1407), and the Endangered Species Act of 1973 (16 U.S.C. 1531–1543), to Dr. Darlene R. Ketten subject to certain conditions set forth therein.

Issuance of this Permit as required by the Endangered Species act of 1973 is based on a finding that such permit: (1) Was applied for in good faith; (2) will not operate to the disadvantage of the endangered species which are the subject of this Permit; and (3) will be consistent with the purposes and policies set forth in Section 2 of the Endangered Species Act of 1973. This Permit was also issued in accordance with, and is subject to Parts 220–222 of Title 50 CFR, the National Marine Fisheries Service regulations governing endangered species permits.

The Permit is available for review in the following offices:

Assistant Administrator for Fisheries, 3300 Whitehaven Street, NW., Washington, D.C.; and
Regional Director, Northwest Region, National Marine Fisheries Service, 14 Elm Street, Federal Building, Gloucester, Massachusetts 01930.

Dated: January 27, 1982.

Richard B. Roe,

Acting Director, Office of Marine Mammals and Endangered Species, National Marine Fisheries Service.

[FR Doc. 82-2707 Filed 2-1-82; 8:45 am]

BILLING CODE 3510-22-M

Issuance of Permit To Take Marine Mammals

On December 16, 1981, notice was published in the **Federal Register** (46 FR 241), that an application had been filed with the National Marine Fisheries Service by Southwest Fisheries Center, National Marine Fisheries Service, for a permit to capture, maintain, tag, mark, and release six weaned Hawaiian monk seal pups (*Monachus schauinslandi*), to capture, measure, weigh, tag, mark, and release ten weaned Hawaiian monk seal pups, and to bleach mark twenty-five sleeping juvenile and sub-adult Hawaiian monk seals.

Notice is hereby given that on January 27, 1982, and as authorized by the provisions of the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361–1407), and the Endangered Species Act of 1973 (16 U.S.C. 1531–1543), the National Marine Fisheries Service issued a permit to the Southwest Fisheries Center, for the above taking subject to certain conditions set forth therein.

As required by the Endangered Species Act of 1973, issuance of this permit is based on a finding that such permit: (1) Was applied for in good faith; (2) will not operate to the disadvantage of the endangered species which are the subject of the permit; and (3) will be consistent with the purposes and policies set forth in Section 2 of the Endangered Species Act of 1973. This Permit was also issued in accordance with, and is subject to, Parts 220 and 222 of Title 50 CFR, the National Marine Fisheries Service regulations governing endangered species permits (39 FR 41367, November 27, 1974).

The Permit is available for review in the following offices:

Assistant Administrator for Fisheries, National Marine Fisheries Service, 3300 Whitehaven Street, NW., Washington, D.C.; and
Regional Director, National Marine Fisheries Service, Southwest Region, 300 South Ferry Street, Terminal Island, California 90731.

Dated: January 27, 1982.

Richard B. Roe,

Acting Director, Office of Marine Mammals and Endangered Species, National Marine Fisheries Service.

[FR Doc. 82-2708 Filed 2-1-82; 8:45 am]

BILLING CODE 3510-22-M

Denial of Permit To Take Marine Mammals

On September 18, 1981, Notice was published in the **Federal Register** (46 FR 46375), that an application had been filed with the National Marine Fisheries Service by Louis Scarpuzzi Enterprises, Inc. for a permit to take four (4) Atlantic bottlenose dolphins (*Tursiops truncatus*) for public display.

Notice is hereby given that pursuant to the provisions of the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361–1407), after having considered all pertinent information and facts, the National Marine Fisheries Service has determined that the permit request submitted by Louis Scarpuzzi Enterprises should be denied. The Applicant was notified on January 28, 1982.

Documentation relating to this application is available for review in the following offices:

Assistant Administrator for Fisheries, National Marine Fisheries Service, 3300 Whitehaven Street, NW., Washington, D.C.; and
Regional Director, National Marine Fisheries Service, Southeast Region, 9450 Koger Boulevard, St. Petersburg, Florida 33702.

Dated: January 28, 1982.

William H. Stevenson,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 82-2709 Filed 2-1-82; 8:45 am]

BILLING CODE 3510-22-M

DEPARTMENT OF ENERGY

Economic Regulatory Administration

Mountain Fuel Supply Company; Action Taken on Consent Order

AGENCY: Economic Regulatory Administration, DOE.

ACTION: Notice of action taken on consent order.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) announces notice of a final Consent Order.

EFFECTIVE DATE: December 1, 1981.

FOR FURTHER INFORMATION CONTACT: David H. Jackson, Director, Kansas City Office, Economic Regulatory Administration, United States Department of Energy, 324 East 11th Street, Kansas City, Missouri 64106–2466. Telephone (816) 374–2092.

SUPPLEMENTARY INFORMATION: On October 19, 1981, Vol. 46, No. 201 **Federal Register** 51274, 1981, the Office of Enforcement of the ERA published notification in the **Federal Register** that it had executed a proposed Consent Order with Mountain Fuel on September 11, 1981, which would not become effective sooner than thirty days after publication. Pursuant to 10 CFR 205.199J(c), interested persons were invited to submit comments concerning the terms, conditions or procedural aspects of the proposed Consent Order.

Although interested persons were invited to submit comments regarding the proposed Consent Order, no comments were received. The proposed Consent Order, therefore, was finalized and made effective on December 1, 1981.

Issued in Kansas City, on the 14th day of January, 1982.

David H. Jackson,

Director, Kansas City Office, Economic Regulatory Administration.

[FR Doc. 82-2561 Filed 2-1-82; 8:45 am]

BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Project No. 5702-000]

Barnet Hydro Co.; Application for License (5 MW or Less)

January 29, 1982.

Take notice that Barnet Hydro Company (Applicant) filed on November 30, 1981, an application for license (pursuant to the Federal Power Act, 16 U.S.C. 791(a)–825(r)) for construction and operation of a water power project to be known as Barnet Project No. 5702. The project would be located on the Stevens River in Barnet Village, Caledonia County, Vermont. Correspondence with the Applicant should be directed to: L. MacRae Road, Box 142, Warren, Vermont 05674.

Project Description—The proposed project would consist of (1): A new 1 to 5-foot high, 60-foot long concrete gravity spillway/diversion dam; (2) a pond with no storage capacity at elevation 537.0 feet m.s.l.; (3) a new forebay at the west dam abutment; (4) a 42-inch diameter, 450-foot long, buried steel penstock; (5) a new powerhouse containing two new turbine-generators with a total rates

capacity of 530 kW; (6) a transmission line; and (7) appurtenant facilities. The proposed run-of-the-river project would generate up to 2,342,000 kWh annually. Energy produced at the project would be sold to the local utility. Project property is owned by Harold Dunbar, Kenneth Bowles, Harold Kimball, Denzil Whitehill, William Encrowe and Robert Farmon all of Barnet, Vermont and Green Mountain Power Corporation. This license application was filed as a competing application to preliminary permit applications under 18 CFR 4.33 (1980), for the Barnet Project No. 5327 filed on September 4, 1981, by L. MacRae Road and Barnet Project No. 5607 filed on November 4, 1981, by Vermont Power Consortium.

Agency Comments—Federal, State, and local agencies that receive this notice through direct mailing from the Commission are requested to provide comments pursuant to the Federal Power Act, the Fish and Wildlife Coordination Act, the Endangered Species Act, the National Historic Preservation Act, the Historical and Archeological Preservation Act, the National Environmental Policy Act, Pub. L. No. 88–29, and other applicable statutes. No other formal requests for comments will be made.

Comments should be confined to substantive issues relevant to the issuance of a license. A copy of the application may be obtained directly from the Applicant. If an agency does not file comments within the time set below, it will be presumed to have no comments.

Competing Applications—Anyone desiring to file a competing application must submit to the Commission, on or before April 12, 1982, either the competing application itself (See 18 CFR 4.33 (a) and (d)) or a notice of intent (See 18 CFR 4.33 (b) and (c)) to file a competing application. Submission of a timely notice of intent allows an interested person to file an acceptable competing application no later than the time specified in § 4.33(c) or § 4.101 et seq. (1981).

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the rules of practice and procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before April 12, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS," "NOTICE OF INTENT TO FILE COMPETING APPLICATION," "COMPETING APPLICATION," "PROTEST," or "PETITION TO INTERVENE," as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82–2582 Filed 2–1–82; 8:45 am]

BILLING CODE 6717–01–M

[Project No. 5805–000]

City of Bandon, Oregon and Pacific Power & Light Co.; Application for Preliminary Permit

January 28, 1982.

Take notice that the City of Bandon, Oregon and Pacific Power & Light Company (Applicant) filed on December 21, 1981, an application for preliminary permit (pursuant to the Federal Power Act, 16 U.S.C. 791(a)–825(r)) for Project No. 5805 to be known as the Eden Ridge Project located on the South Fork Coquille River in Coos County, near Powers, Oregon. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to Leighton and Sherline, 1701 K Street, NW., Washington, D.C. 20006 with a copy to Mr. Ben M. McMaken, City Manager, P.O. Box 67, Bandon, Oregon 97411. The project would be located within the boundaries of Siskiyou National Forest.

Project Description—The proposed project would consist of: (1) A 210-foot high, 740-foot long dam (designated Eden Ridge Dam) creating; (2) a reservoir with a storage capacity of 115,000 acre-feet and a surface area of 1,680 acres; (3) a 125-foot high, 560-foot long dam (designated Lockhart Dam) located 2.5 miles downstream of Eden Ridge Dam creating; (4) a reservoir with a storage capacity of 7,500 acre-feet and a surface area of 205 acres; (5) a 12,000-foot long, 10.5-foot diameter horseshoe tunnel; (6) a 3,140-foot long steel penstock; (7) a powerhouse to contain one Pelton-type, turbine-generating unit with a rated capacity of 90 MW (maximum static head of 1,800 feet); (8) 25 miles of transmission line to connect to an existing Pacific Power & Light Company transmission system; and (9) access roads.

Proposed Scope of Studies Under Permit.—A preliminary permit, if issued, does not authorize construction. The Applicant seeks a 30-month permit to study the feasibility of the project. No new road would be required to conduct the studies. Applicant states that drill holes, auger holes, test pits, and trenches would be plugged and filled to restore original surface contour and revegetated if required.

Competing Applications—Anyone desiring to file a competing application for preliminary permit must submit to the Commission, on or before April 9, 1982, the competing application itself, or a notice of intent to file such an application (see: 18 CFR 4.30 et. seq. (1981); and Docket No. RM81–15, issued October 29, 1981, 46 FR 55245, November 9, 1981.)

The Commission will accept applications for license or exemption from licensing, or a notice of intent to submit such an application in response to this notice. A notice of intent to file an application for license or exemption must be submitted to the Commission on or before April 9, 1982, and should specify the type of application forthcoming. Any application for license or exemption from licensing must be filed in accordance with the Commission's regulations (see: 18 CFR 4.30 et. seq. or 4.101 et. seq. (1981), as appropriate).

Submission of a timely notice of intent to file an application for preliminary permit, allows an interested person to file an acceptable competing application for preliminary permit no later than June 9, 1982.

Agency Comments—Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the rules of practice and procedure, 18 CFR 1.8 or 1.10 (1980). In

determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before April 9, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS," "NOTICE OF INTENT TO FILE COMPETING APPLICATION," "COMPETING APPLICATION," "PROTESTS," or "PETITION TO INTERVENE," as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-2583 Filed 2-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5593-000]

City of Vallejo, California; Application for Exemption of Small Conduit Hydroelectric Facility

January 29, 1982.

Take notice that on October 30, 1981, the City of Vallejo, California (Applicant) filed an application under Section 30 of the Federal Power Act (Act) (16 U.S.C. 823(a)), for exemption of a proposed hydroelectric project from requirements of Part I of the Act. The proposed Fleming Hill Project (FERC Project No. 5593) would be located on the Fleming Hill water supply pipeline in Solano County, California. Correspondence with the Applicant should be directed to: Mr. Glenn A. Harris, Director of Public Works, City of Vallejo, 555 Santa Clara Street, Vallejo, California 94590.

Purpose of Project—The energy generated by the project would be utilized by the City of Vallejo.

Project Description—The proposed project would consist of an induction type generating unit, rated at 285 kW, to be installed in line with the 27-inch diameter Fleming Hill water supply pipeline, owned by the City of Vallejo. The average annual energy generation is estimated to be 1.85 million kWh.

Agency Comments—The U.S. Fish and Wildlife Service and the California Department of Fish and Game are requested, pursuant to Section 30 of the Federal Power Act, to submit within 45 days from the date of issuance of this notice appropriate terms and conditions to protect any fish and wildlife resources or otherwise carry out the provisions of the Fish and Wildlife Coordination Act. If no comments are filed within this time period, an agency will be presumed to have determined that no terms or conditions to the exemption are necessary. Other Federal, State, and local agencies that receive this notice through direct mailing from the Commission are requested to provide any comments they may have in accordance with their duties and responsibilities. Comments are due within 45 days from the date of issuance of this notice. No other formal requests for comments will be made. Comments should be confined to substantive issues relevant to the granting of an exemption. One copy of an agency's comments must also be sent to the Applicant's representatives.

Comments, Protests, or Petitions To Intervene—Anyone desiring to be heard or to make any protests about this application should file a petition to intervene or a protest with the Commission, in accordance with the requirements of its rules of practice and procedure, 18 CFR 1.8 or 1.10 (1980). Comments not in the nature of a protest may also be submitted by conforming to the procedures specified in § 1.10 for protests. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but a person who merely files a protest or comments does not become a party to the proceeding. To become a party, or to participate in any hearing, a person must file a petition to intervene in accordance with the Commission's rules. Any comments, protests, or petitions to intervene must be receive on or before March 17, 1982. The Commission's address is: 825 North Capitol Street, NE., Washington, D.C. 20426. The application is on file with the Commission and is available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-2584 Filed 2-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP82-135-000]

Consolidated Gas Supply Corp.; Application

January 28, 1982.

Take notice that on December 23, 1981, Consolidated Gas Supply Corporation (Applicant), 445 West Main Street, Clarksburg, West Virginia 26301, filed in Docket No. CP82-135-000 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the construction and operation of certain transmission, compression and related and appurtenant facilities in the State of New York, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant proposes to construct and operate the following facilities:

Project 1. Approximately 7.7 miles of 20-inch Line No. 554 looping existing Line Nos. 14 and 24 and extending in a northerly direction from Perry Center Gate to Craigs Connection all in Wyoming and Livingston Counties, New York.

Project 2. One 5,800 horsepower turbine-driven centrifugal compressor unit at the existing Borger compressor station located in Tompkins County, New York, replacing three 660 horsepower reciprocating compressor units.

It is stated that the Borger compressor station compresses gas for transmission in Applicant's existing Line Nos. 1 and 31 to markets in the Syracuse, New York, area and in Line Nos. 30 and 550 for delivery to customers in the Utica, Schenectady, Albany and Troy, New York, market areas.

It is stated that the estimated cost of the proposed facilities is $11,282,000 which would be financed from funds on hand or funds to be obtained from Applicant's parent corporation, Consolidated Natural Gas Company.

Applicant submits that the facilities proposed in the instant application are needed to meet normal growth in the peak flow requirements in Applicant's markets in the State of New York during the 1982-1983 winter and thereafter.

Any person desiring to be heard or to make any protest with reference to said application should on or before February 17, 1982, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10) and the

Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's rules.

Take further notice that, pursuant to the authority contained in and subject to 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 application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-2585 Filed 2-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5293-001]

Hydro Resource Co.; Application for Preliminary Permit

January 29, 1982.

Take notice that Hydro Resource Company (Applicant) has amended the application filed on August 28, 1981, for preliminary permit (pursuant to the Federal Power Act, 16 U.S.C. 791(a)-825(r)) for Project No. 5293 to be known as the Smith Creek Project located on Smith and Johnson Creeks, within Gifford Pinchot National Forest in Lewis County, Washington. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: Mr. Jerry L. Johnson, Post Office Box 485, Lyden, Washington 98264.

Project Description. The proposed project, as amended, would consist of: A (1) a concrete gravity diversion dam 6 feet high, crest elevation 2,640 feet, on Smith Creek; (2) 13,500 feet of pipeline and penstock; (3) a powerhous containing a turbine generator with 5.9 MW capacity; B (1) a concrete gravity diversion dam 8 feet high, crest elevation 1,760 feet, on Johnson Creek; (2) 20,000 feet of pipeline and penstock; (3) a powerhouse containing a turbine generator with 8.5 MW capacity; and 3,500 feet of transmission line connecting the powerhouses to a common switchyard and that to existing powerlines. A total annual energy output of 96 GWh is estimated, the potential market for which includes the Lewis County Public Utility District and Bonneville Power Administration.

Proposed Scope of Studies Under Permit. A preliminary permit, if issued, does not authorize construction. The applicant seeks issuance of a preliminary permit for a term of 24 months, during which engineering, economic and environmental studies will be conducted to ascertain project feasibility and to support application for a license to construct and operate the project. The estimated cost of permit activities is $230,000.

Competing Applications. This application was originally filed by Hydro Resource Company for Project No. 5293 on August 28, 1981. Capital Development Company's application for Project No. 5324 was filed on September 4, 1981, as a competing application. Public notice of the filing of the initial application, which has already been given, established the due date for filing competing applications or notices of intent. In accordance with the Commission's regulations, no competing application for preliminary permit, or notices of intent to file an applicating for preliminary permit, or license will be accepted for filing in response to this notice. Any application for licence or exemption from licensing, or notice of intent to file an exemption application, must be filed in accordance with the Commission's regulations (see 18 CFR 4.30 et. seq. or 4.101 et. seq. (1981), as appropriate).

Agency Comments. Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions to Intervene. Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the rules of practice and procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before March 17, 1982.

Filing and Service of Responsive Documents. Any filings must bear in all capital letters the title "COMMENTS," "PROTEST," or "PETITION TO INTERVENE," as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Room 208 RB at the above address. A copy of any petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-2586 Filed 2-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. CP63-174, CP76-517 and CP78-175]

Natural Gas Pipeline Company of America; Petition to Amend

January 28, 1982.

Take notice that on December 14, 1981, Natural Gas Pipeline Company of America (Petitioner), 122 South Michigan Avenue, Chicago, Illinois 60603, filed in Docket Nos. CP63-174, CP76-517 and CP78-175 a petition to amend the orders issued pursuant to Section 7(c) of the Natural Gas Act on March 15, 1965, in Docket No. CP63-174,[1] September 19, 1977,[1] in Docket No. CP76-517, and May 22, 1978, in Docket No. CP78-175, so as to delete certain reporting conditions contained in such orders, all as more fully set forth in the petition to amend which is on file with the Commission and open to public inspection.

It is submitted that by order issued March 15, 1965, in Docket No. CP63-174 Petitioner was authorized to construct and operate additional transmission facilities and to sell additional volumes of gas to its customers on the condition that Petitioner file with the Commission

[1] This proceeding was commenced before the FPC. By joint regulation of October 1, 1977 (10 CFR 1000.1), it was transferred to the Commission.

annual reports of the monthly volumes of gas resold by its distribution customers for end use as boiler fuel in the generation of electricity. Petitioner states that it filed such reports with the Commission for the year 1965 through 1980.

It is submitted that on September 19, 1977, in Docket No. CP76–517 Petitioner was authorized to construct and operate transmission and storage facilities to provide additional storage service to its customers under a new leased storage Rate Schedule LS–2 on the condition that Petitioner file with the Commission annual reports of increases in its LS–2 customers' Priority 1 loads. Petitioner states that it filed such reports with the Commission for the years 1977 through 1980.

It is submitted that by order issued May 22, 1978, in Docket No. CP78–175 Petitioner was authorized to construct and operate storage facilities to enable Petitioner to increase storage service to its customers under a new leased storage Rate Schedule LS–3 on the condition that Petitioner file with the Commission annual reports of increases in the high priority loads of the years 1979 and 1980.

Petitioner asserts that developments since 1973 have eliminated the need for the information which Petitioner is required to supply in the three annual reports described above. Petitioner contends that all three reports were designed to address the gas supply shortage which existed several years ago but which does not exist today. Petitioner states that the Powerplant and Industrial Fuel Use Act of 1978 imposes limitations on certain gas use, including boiler fuel gas use; while the Natural Gas Policy Act of 1978 provides for incremental pricing of natural gas and eventual deregulation of wellhead prices. The effect of these two statuses, Petitioner argues, is to reduce the availability and attractiveness of natural gas for industrial uses including the generation of electricity and must, therefore, alleviate any concern about the competitive position of coal as against natural gas in boiler fuel markets.

Petitioner also contends that the Commission's concern that new high priority loads could necessitate curtailment or aggravate existing curtailment situations is not currently valid. Petitioner avers that increases in gas supply have rendered curtailment of service to end users unnecessary, that the Federal government has actively discouraged use of natural gas for low priority purposes with the express intention of making more gas available for high priority purposes, and further, that Petitioner has experienced a significant reduction in the demand for gas because of continuing conservation by end users.

Petitioner finally asserts that the annual load growth and end-use reporting requirements constitute an undue burden upon Petitioner and its customers and, therefore such conditions should be deleted from the orders described above.

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before February 17, 1982, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10) and the regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's rules.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82–2587 Filed 2–1–82; 8:45 am]

BILLING CODE 6717–01–M

[Project No. 5511–000]

New York State Energy Research and Development Authority; Application for Preliminary Permit

January 28, 1982.

Take notice that New York State Energy Research and Development Authority (Applicant) filed on October 16, 1981, an application for preliminary permit (pursuant to the Federal Power Act, 16 U.S.C. 791(a)–825(r)) for Project No. 5511 to be known as the Champlain Barge Canal/Lock C–4 Project located on the Hudson River and New York State Champlain Canal in Saratoga and Rensselaer Counties, New York. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: C. Todd Miles, Assistant Counsel, New York State Energy Research and Development Authority, Two Rockefeller Plaza, Albany, New York 12223.

Project Description—The proposed project would consist of: (1) The existing Niagara Mohawk Power Corporation (NMPC) Lock 4 Dam, a concrete gravity structure 10 feet high and 1,400 feet long; (2) an existing lock and connecting dam owned and operated by the New York State Department of Transportation, 6 feet high and 300 feet long, connecting two islands south of the Lock 4 Dam; (3) the existing reservoir having a surface area of 1,300 acres and a mean surface elevation of 82.3 feet (USGS datum); (4) a new intake structure; (5) a new powerhouse with a generating capacity of approximately 9,970 kW located either at the west side of the dam near the ruin of the previous NMPC powerhouse, or adjacent to the lock and canal; (6) a new tailrace; (7) a new switchyard; (8) new transmission lines; and (9) appurtenant facilities. The Applicant estimates that the annual average energy output would be 24,600,000 kWh. Project energy would be sold to local public utilities.

Proposed Scope of Studies Under Permit—A preliminary permit, if issued, does not authorize construction. Applicant seeks issuance of a preliminary permit for a period of 18 months, during which time it would investigate the feasibility of project construction, operation, and design alternatives. Depending upon the outcome of the investigation. The Applicant would decide whether to proceed with an application for FERC license. Applicant estimates the cost of the studies under the permit would be $95,000.

Competing Applications—This application was filed as a competing application to the Hudson/Champlain Canal Lock 4 Project's application for Project No. 4684 filed on May 18, 1981, by Long Lake Energy Corp. Public notice of the filing of the initial application, which has already been given, established the due date for filing competing applications or notices of intent. In accordance with the Commission's regulations, no competing application for preliminary permit, or notice of intent to file an application for preliminary permit or license will be accepted for filing in response to this notice. Any application for license or exemption from licensing, or notice of intent to file an exemption application, must be filed in accordance with the Commission's regulations (see 18 CFR 4.30 et. seq. or 4.101 et. seq. (1981), as appropriate).

Agency Comments—Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordacne with the requirements of the rules of practice and procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before March 16, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS," "PROTESTS," or "PETITION TO INTERVENE," as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Room 208 RB at the above address. A copy of any petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-2588 Filed 2-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5778-000]

Public Utility District No. 1 of Snohomish County, Washington; Application for Preliminary Permit

January 28, 1982.

Take notice that Public Utility District No. 1 of Snohomish County, Washington (Applicant) filed on December 16, 1981, an application for preliminary permit (pursuant to the Federal Power Act, 16 U.S.C. 791(a)–825(r)) for Project No. 5778 to be known as the Lake Calligan Project located on Calligan Lake, near North Bend in King County, Washington. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: William G. Hulbert, Jr., Manager, Public Utility District No. 1 of Snohomish County, P.O. Box 1107, Everett, Washington 98206.

Project Description—The proposed project would consist of: (1) The existing 295-acre Calligan Lake, which will be increased to 329 acres; (2) a 20-foot high concrete diversion weir; (3) a 9,000-foot long, 42-inch diameter steel penstock; (4) a powerhouse containing a generating unit rated at 7.7 MW; and (5) a transmission line. The average annual energy generation is estimated to be 34.5 million kWh.

Proposed Scope of Studies Under Permit—A preliminary permit, if issued, does not authorize construction. Applicant seeks issuance of a preliminary permit for a period of 36 months, during which time it would conduct environmental, economic, engineering, and feasibility studies, and prepare an FERC license application. No new roads would be required to conduct the studies. Applicant proposes to conduct subsurface investigations at the dam and powerhouse sites. All disturbed areas will be restored. The cost of the work to be performed under the preliminary permit is $250,000.

Competing Applications—This application was filed as a competing application to Puget Sound Power and Light Company's application for Project No. 5064 filed on July 7, 1981. Public notice of the filing of the initial application, which has already been given, established the due date for filing competing applications or notices of intent. In accordance with the Commission's regulations, no competing application for preliminary permit, or notices of intent to file an application for preliminary permit or license will be accepted for filing in response to this notice. Any application for license or exemption from licensing, or notice of intent to file an exemption application, must be filed in accordance with the Commission's regulations (see: 18 CFR 4.30 et. seq. or 4.101 et seq. (1981), as appropriate).

Agency Comments—Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant). If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the rules of practice and procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before March 16, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS," "PROTEST," or "PETITION TO INTERVENE," as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Room 208 RB at the above address. A copy of any petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-2589 Filed 2-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5777-000]

Public Utility District No. 1 of Snohomish County, Washington; Application for Preliminary Permit

January 28, 1982.

Take notice that Public Utility District No. 1 of Snohomish County, Washington (Applicant) filed on December 16, 1981, an application for preliminary permit (pursuant to the Federal Power Act, 16 U.S.C. 791(a)–825(r)) for Project No. 5777 to be known as the Lake Hancock Project located on Hancock Lake, near North Bend in King County, Washington. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: William G. Hulbert, Jr., Manager, Public Utility District No. 1 of Snohomish County, P.O. Box 1107, Everett, Washington 98206.

Project Description—The proposed project would consist of: (1) The existing 225-acre Hancock Lake; (2) a 20-foot high concrete diversion weir; (3) a 7,000-foot long, 42-inch diameter steel penstock; (4) a powerhouse containing a generating unit rated at 6.6 MW; and (5) a transmission line. The average annual energy generation is estimated to be 29.5 million kWh.

Proposed Scope of Studies Under Permit—A preliminary permit, if issued, does not authorize construction. Applicant seeks issuance of a preliminary permit for a period of 36

months, during which time it would conduct environmental, economic, engineering, and feasibility studies, and prepare an FERC license application. No new roads would be required to conduct the studies. Applicant proposes to conduct subsurface investigations at the dam and powerhouse sites. All disturbed areas will be restored. The cost of the work to be performed under the preliminary permit is $250,000.

Competing Applications—This application was filed as a competing application to Puget Sound Power and Light Company's application for Project No. 5065 filed on July 7, 1981. Public notice of the filing of the initial application, which has already been given, established the due date for filing competing applications or notices of intent. In accordance with the Commission's regulations, no competing application for preliminary permit, or notices of intent to file an application for preliminary permit or license will be accepted for filing in response to this notice. Any application for license or exemption from licensing, or notice of intent to file an exemption application, must be filed in accordance with the Commission's regulations (see: 18 CFR 4.30 et seq. or 4.101 et seq. (1981), as appropriate).

Agency Comments—Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the rules of practice and procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before March 16, 1982.

Filing and Service of Responsive Documents—Any filing must bear in all capital letters the title "COMMENTS," "PROTEST," or "PETITION TO INTERVENE," as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Room 208 RB at the above address. A copy of any petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-2590 Filed 2-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5758-000]

Public Utility District No. 1 of Snohomish County, Washington; Application for Preliminary Permit

January 29, 1982.

Take notice that Public Utility District No. 1 of Snohomish County, Washington (Applicant) filed on December 14, 1981, an application for preliminary permit (pursuant to the Federal Power Act, 16 U.S.C. 791(a)–825(r)) for Project No. 5758 to be known as the Trout Creek Project located on Trout Creek, near Index, in Snohomish County, Washington. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: William G. Hulbert, Jr., Manager, Public Utility District No. 1 of Snohomish County, P.O. Box 1107, Everett, Washington 98206.

Project Description—The proposed project would consist of: (1) A 7-foot high diversion and intake structure; (2) a 5,020-foot long pipeline; (3) a headworks; (4) a 1,500-foot long, 6-foot diameter steel penstock; (5) a powerhouse containing one generating unit rated at 7.7 MW; and (6) a 5-mile long transmission line. The average annual energy generation is estimated to be 28.4 million kWh.

Proposed Scope of Studies Under Permit. A preliminary permit, if issued, does not authorize construction. Applicant seeks issuance of a preliminary permit for a period of 36 months, during which time it would conduct environmental, economic, engineering, and feasibility studies, and prepare an FERC license application. No new roads would be required to conduct the studies. Applicant proposes to conduct test borings at the diversion and powerhouse locations. The estimated cost of the studies is $200,000.

Competing Applications—This application was filed as a competing application to Western Power Inc.'s application for Project No. 5342 filed on September 8, 1981. Public notice of the filing of the initial application, which has already been given, established the due date for filing competing applications or notices of intent. In accordance with the Commission's regulations, no competing application for preliminary permit, or notices of intent to file an application for preliminary permit or license will be accepted for filing in response to this notice. Any application for license or exemption from licensing, or notice of intent to file an exemption application, must be filed in accordance with the Commission's regulations (see 18 CFR 4.30 et seq. or 4.101 et seq. (1981), as appropriate).

Agency Comments. Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions To Intervene. Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the rules of practice and procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before March 17, 1982.

Filing and Service of Responsive Documents. Any filings must bear in all capital letters the title "COMMENTS," "PROTEST," or "PETITION TO INTERVENE," as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Room 208 RB at the above address. A copy of any petition to intervene must also be served upon each representative of the

Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-2591 Filed 2-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 3472-001]

Southwire Co.; Application for License (5 MW or Less)

January 29, 1982.

Take notice that Southwire Company (Applicant) filed on October 5, 1981, an application for license (pursuant to the Federal Power Act, 16 U.S.C. 791(a)–825(r)) for construction and operation of a water power project to be known as the Wyre-Wynd Project No. 3472. The project would be located on the Quinebaug River in Jewett City, New London and Windham Counties, Connecticut. Correspondence with the Applicant should be directed to: Mr. Fred Stackpole, Wyre-Wynd Inc., Anthony Street, P.O. Box 275, Jewett City, Connecticut 06351.

Project Description—The proposed project would consist of: (1) An existing 19-foot high, 473-foot long rubble masonry and concrete dam with 2-foot high flashboards; (2) an existing 20.75-foot high inlet gate section with 5 sluice gates; (3) a 333-acre reservoir with a usable storage capacity of 167 acre-feet at elevation 97.3 feet m.s.l; (4) an existing 250-foot long, 50-foot wide forebay-inlet canal with 5 flood gates and an 110-foot long overflow weir which discharges below the dam; (5) an existing outlet gate at the west end of the forebay-canal with three 10-foot diameter penstocks; (6) an existing tailrace canal; and (7) appurtenant facilities. The Applicant proposes to remove the three outlet gates and penstocks, increase the height of the overflow weir by 1-foot and construct a powerhouse containing a turbine-generator unit with a rated capacity of 2.5 MW in the west end of the canal forebay. The proposed project would generate up to 11,000,000 kWh annually. The project is owned by the Applicant.

Purpose of Project—Energy produced at the project would be utilized by the Applicant's adjacent mill or sold to the local utility.

Agency Comments—Federal, State, and local agencies that receive this notice through direct mailing from the Commission are requested to provide comments pursuant to the Federal Power Act, the Fish and Wildlife Coordination Act, the Endangered Species Act, the National Historic Preservation Act, the Historical and Archeological Preservation Act, the National Environmental Policy Act, Pub. L. No. 88–29, and other applicable statutes. No other formal requests for comments will be made.

Comments should be confined to substantive issues relevant to the issuance of a license. A copy of the application may be obtained directly from the Applicant. If an agency does not file comments within the time set below, it will be presumed to have no comments.

Competing Applications— Anyone desiring to file a competing application must submit to the Commission, on or before April 12, 1982, either the competing application itself (See 18 CFR 4.33(a) and (d)) or a notice of intent (See 18 CFR 4.33(b) and (c)) to file a competing application. Submission of a timely notice of intent allows an interested person to file an acceptable competing application no later than the time specified in § 4.33(c) of § 4.101 et. seq. (1981).

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the rules of practice and procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before April 12, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS," "NOTICE OF INTENT TO FILE COMPETING APPLICATION," "COMPETING APPLICATION," "PROTEST," or "PETITION TO INTERVENE," as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-2592 Filed 2-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP82-76-000]

Texas Eastern Transmission Corp.; Further Notice of Application

January 28, 1982.

Take further notice that on November 13, 1981, Texas Eastern Transmission Corporation (Applicant), P.O. Box 2521, Houston, Texas 77001, filed in Docket No. CP82-76-000 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the construction and operation of certain tap facilities necessary for Applicant to take into its system synthetic gas to be purchased from Conoco, Inc. (Conoco), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant further states that Article VIII of the purchase contract specifies the basis for the price to be paid by Applicant for volumes of synthetic gas to be purchased from Conoco. Paragraph 1 of the subject article provides that the initial price to be paid by Buyer to Seller for each Mcf of gas having a total heating value of 1,000 Btu per cubic foot shall be $6.987 effective March 1, 1981, and increasing on April 1, 1981, and the first of each month thereafter, by an amount equal to the applicable monthly adjustment prescribed by the Commission pursuant to Section 102 of Title I of the Natural Gas Policy Act of 1978. It is explained that $6.987 is the arithmetic average of the highest price being paid for natural gas in the field on non-affiliated entities by each of two different interstate pipeline purchasers other than Buyer in the Texas Gulf Coast-South Louisiana areas south of the 31st parallel of latitude according to the February 1981 issue of Foster Bulletin on Deregulated Gas.

Applicant further asserts that paragraph 2 of the subject article provides that upon initial delivery of gas Seller shall have the right to accept the price set out in Paragraph 1 or make a written request for redetermination of the price based upon the higher of the following:

(1) An arithmetic average of the highest price being paid for natural gas in the field to non-affiliated entities at the time of Seller's request for

redetermination by each of two different interstate pipeline purchasers other than Buyer in the Texas Gulf Coast-South Louisiana areas south of the 31st parallel of latitude pursuant to interstate contracts for a term of five years or longer and for volumes of pipeline quality gas of at least five million cubic feet per day.

(2) An amount equal to the higher of the price being paid by Border Gas Inc. to Petroleos Mexicanos pursuant to the contract dated October 19, 1979, as such contract may be amended or replaced from time to time for gas imported from Mexico at the time of Seller's request for redetermination, or the governmentally approved price being paid for Canadian gas at the Canadian-United States Border.

Any person desiring to be heard or to make any protest with reference to said application should on or before February 17, 1982, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10) and the regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's rules. Persons having heretofore filed need no do so again.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-2593 Filed 2-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP82-139-000]

Transwestern Pipeline Co.; Application

January 28, 1982.

Take notice that on December 29, 1981, Transwestern Pipeline Company (Applicant), P.O. Box 2521, Houston, Texas 77001, filed in Docket No. CP82-139-000 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the construction and operation of facilities and recovery of cost of transportation, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant proposes to construct and operate the following facilities:

(1) 58.9 miles of 20-inch pipeline and related facilities originating at a point on Applicant's 24-inch Panhandle Lateral in Hemphill County, Texas, and extending into Roger Mills County, Oklahoma;

(2) 21.1 miles of 12-inch pipeline and related facilities orginating near the terminus of the proposed 20-inch main line and extending to a delivery point in Roger Mills County, Oklahoma.

It is stated that the total costs for the proposed facilities are estimated to be $38,095,000 which would be financed initially by Applicant with funds on hand, borrowings under Applicant's revolving credit arrangements or short-term financing. Permanent financing would be undertaken as part of Applicant's overall long-term financing program at later dates.

Applicant states that the proposed facilities would permit Applicant to attach significant quantities of natural gas reserves presently being developed in several areas in western Oklahoma.

It is asserted that Applicant has previously entered into a transportation agreement with Delhi Pipeline Company (Delhi) which has provided Applicant access to developing gas supplies remote from its existing system. Applicant explains that such agreement is subject to interruption by Delhi, but nonetheless, at that time obviated the need for Applicant to construct extensive facilities to connect needed firm gas supplies. Applicant submits that it is in the public interest to permit it to track the transportation cost associated with this arrangement.

Any person desiring to be heard or to make any protest with reference to said application should on or before February 17, 1982, filed with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10) and the regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to 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 application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-2594 Filed 2-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5363-000]

Warrensburg Pulp and Paper Corp., Application for Exemption for Small Hydroelectric Power Project Under 5 MW Capacity

January 29, 1982.

Take notice that on September 15, 1981, Warrensburg Board and Paper Corporation (Applicant) filed an application under Section 408 of the Energy Security Act of 1980 (Act) (16 U.S.C. 2705 and 2708 *as amended*), for exemption of a proposed hydroelectric project from licensing under Part I of the Federal Power Act. The proposed small hydroelectric project (Project No. 5363) would be located on Schroon River, in Warrensburg County, New York. Correspondence with the Applicant should be directed to: Alex Landy, Warrensburg Board and Paper Corporation, 510 West 27th Street, New York, New York.

Project Description—The proposed project would consist of: (1) An existing concrete gravity dam 24 feet high and 188 feet long with a concrete wing wall extending about 100 feet from the spillway to an anchorage on the north abutment; (2) an existing concrete forebay structure; (3) an existing forebay reservoir with a negligible storage capacity; (4) a proposed reservoir having a storage capacity of approximately 500 acre-feet and a normal maximum surface elevation of 645 M.S.L.; (5) a proposed powerhouse with an anticipated generating capacity of 2,600 kW; (6) a proposed tailrace channel; (7) a proposed switch yard; (8) a proposed transmission line; (9) a new powerhouse access road; and (10) appurtenant facilities. The applicant estimates that the average energy production would be

10,300,000 kWh. The energy would be sold to public utilities.

Purpose of Project—An exemption, if issued, gives the Exemptee priority of control, development, and operation of the project under the terms of the exemption from licensing, and protects the Exemptee from permit or license applicants that would seek to take or develop the project.

Agency Comments—The U.S. Fish and Wildlife Service, The National Marine Fisheries Service, and the New York State Department of Environmental Conservation are requested, for the purposes set forth in Section 408 of the Act, to submit within 60 days from the date of issuance of this notice appropriate terms and conditions to protect any fish and wildlife resources or to otherwise carry out the provisions of the Fish and Wildlife Coordination Act. General comments concerning the project and its resources are requested; however, specific terms and conditions to be included as a condition of exemption must be clearly identified in the agency letter. If an agency does not file terms and conditions within this time period, that agency will be presumed to have none. Other Federal, State, and local agencies are requested to provide any comments they may have in accordance with their duties and responsibilities. No other formal requests for comments will be made. Comments should be confined to substantive issues relevant to the granting of an exemption. If an agency does not file comments within 60 days from the date of issuance of this notice, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Competing Application—Any qualified license applicant desiring to file a competing application must submit to the Commission, on or before March 10, 1982, either the competing license application that proposes to develop at least 7.5 megawatts in that project, or notice of intent to file such a license application. Submission of a timely notice of intent allows an interested person to file the competing license application no later than 120 days from the date that comments, protests, etc. are due. Applications for preliminary permit will not be accepted.

A notice of intent must conform with the requirements of 18 CFR 4.33 (b) and (c) (1980). A competing license application must conform with the requirements of 18 CFR 4.33 (a) and (d) (1980).

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of its rules of practice and procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before March 10, 1982.

Filing and Service of Responsive Documents—Any filing must bear in all capital letters the title "COMMENTS," "NOTICE OF INTENT TO FILE COMPETING APPLICATION," "COMPETING APPLICATION," "PROTEST," or "PETITION TO INTERVENE," as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB, 825 North Capitol Street, N.E., Washington, D.C. 20426. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-2595 Filed 2-1-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5449-000]

Western Power, Inc.; Application for Preliminary Permit

January 28, 1982.

Take notice that Western Power, Incorporated (Applicant) filed on October 5, 1981, an application for preliminary permit (pursuant to the Federal Power Act, 16 U.S.C. 791(a)-825(r)) for Project No. 5449 to be known as the Prairie Mountain Power Project located on Davis Creek partially within the Gifford Pinchot National Forest, in Lewis County, Washington. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: Mr. Thomas R. Childs, Western Power, Incorporated, 2136 James Street, Bellingham, Washington 98225.

Project Description—The proposed project would consist of: (1) A concrete diversion structure 5 feet high; (2) a pipeline 7,800 feet long, surge tank and penstock 2,600 feet long; (3) a powerhouse containing a turbine generator with 7.2 MW capacity and 35.32 GWh annual energy production; (4) transmission line; and (5) appurtenant facilities. Generated power will be sold to the Lewis County Public Utility District.

Proposed Scope of Studies Under Permit—A preliminary permit if issued, does not authorize construction. The Applicant seeks issuance of a preliminary permit for a term of 24 months, during which time engineering, economic and environmental studies will be conducted to ascertain project feasibility and to support application for a license to construct and operate the project. The estimated cost of the activities is $225,000.

Competing Applications—Anyone desiring to file a competing application for preliminary permit must submit to the Commission, on or before April 9, 1982, the competing application itself, or a notice of intent to file such an application (see: 18 CFR 4.30 et. seq. (1981)).

The Commission will accept applications for license or exemption from licensing, or a notice of intent to submit such an application in response to this notice. A notice of intent to file an application for license or exemption must be submitted to the Commission on or before April 9, 1982, and should specify the type of application forthcoming. Any application for license or exemption from licensing must be filed in accordance with the Commission's regulations (see: 18 CFR 4.30 et. seq. or $.101 et. seq. (1981), as appropriate).

Submission of a timely notice of intent to file an application for preliminary permit, allows an interested person to file an acceptable competing application for preliminary permit no later than June 7, 1982.

Agency Comments—Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the rules of practice and procedure, 18 CFR 1.8 or 1.10 (1980). In determining the appropriate action to

take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before April 9, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS," "NOTICE OF INTENT TO FILE COMPETING APPLICATIONS," "COMPETING APPLICATION," "PROTEST," or "PETITION TO INTERVENE," as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-2596 Filed 2-1-82; 8:45 am]

BILLING CODE 6717-01-M

Office of Hearings and Appeals

Issuance of Decisions and Orders; Week of November 30 Through December 4, 1981

During the week of November 30 through December 4, 1981, the decisions and orders summarized below were issued with respect to appeals and applications for exception or other relief filed with the Office of Hearings and Appeals of the Department of Energy. The following summary also contains a list of submissions that were dismissed by the Office of Hearings and Appeals.

Appeals

Bracewell & Patterson, 12/2/81, HFA-0010

Bracewell & Patterson filed an appeal from a partial denial by the Deputy General Counsel for Regulation of a Request for Information which the firm had submitted under the Freedom of Information Act (the FOIA). In considering the Appeal, the DOE found that a portion of one document which was initially withheld under Exemption 5 should be released to the public. The remainder of the documents were drafts of a final agency rule. The DOE found that the drafts should be withheld in their entirety because all portions of a draft are predecisional, deliberative documents which are recommendatory in nature. The DOE also found that the search for responsive documents was adequate.

The Standard Oil Company, 12/1/81, HFA-0006

The Standard Oil Company (Sohio) filed an Appeal from a denial by the Office of Special Counsel of a Request for Information which the firm had submitted under the Freedom of Information Act (the FOIA). In considering the Appeal, the DOE found that two documents which were initially withheld under Exemptions 5 and 7(A) contained segregable portions which should be released to the public. An important issue that was considered in the Decision and Order was whether to order the segregation of the factual information in the documents withheld under Exemption 5 where Exemption 7(A) was also found to apply.

Remedial Order

Lobo Oil Corporation, 11/30/81, BRO-1414

Lobo Oil Corporation filed a Statement of Objections to a Proposed Remedial Order (PRO) which the DOE Southwest Enforcement District issued to it on February 6, 1981. In the PRO, the Southwest Enforcement District concluded that Lobo had sold crude oil from three of its properties at prices which exceeded the ceiling price levels permitted by DOE regulations. After considering Lobo's objections, the OHA affirmed the findings in the PRO. The important issues considered in the Decision include: (i) whether the enformation action against Lobo was barred by the Texas state statute of limitations; (ii) whether crude oil produced from a well that was recompleted into a new reservoir constituted crude oil produced from a new property prior to the amendment of the property definition on September 1, 1976; (iii) whether a firm may count disposal wells when determining average daily production per well for purposes of the stripper well property exemption.

Lobo also objected to the interest provisions of the PRO. In considering Lobo's objection, the OHA determined that Lobo had not been informed of a recent change in DOE interest rate policy until it received the PRO. Accordingly, the interest provisions of the PRO were modified so that the interest rates for periods prior to the date of issuance of the PRO were based on the previous DOE policy. The modified Proposed Remedial Order was issued as a final order.

Motion for Modification and/or Recission

Plateau, Inc., 12/2/81 BYR-0160

Plateau, Inc. filed a Motion for Reconsideration of a Supplemental Order issued to the firm on September 1, 1981, *Plateau, Inc.,* 8 DOE ¶ 82,623 (1981), in which the DOE found that Plateau had received excessive entitlements exception relief for its 1980 fiscal year. In its Motion for Reconsideration, Plateau contended that the Supplemental Order violated certain procedural requirements. Plateau also claimed that, because of an apparent typographical error in the Supplemental Order, the amount of the firm's refund obligation had been overstated by $3,000. In considering the Motion for Reconsideration, the DOE determined that the Supplemental Order did not violate any procedural requirements. However, the DOE found that Plateau was correct in noting that the Supplemental Order had overstated the firm's refund obligation. Thus, the DOE reduced the amount of the refund obligation by $3,000.

Requests for Exception

Petroleum Products Corporation; Exxon Company, U.S.A., 12/1/81, DEE-2888; BEX-0039; BEA-0319

Petroleum Products Corporation (PPC) filed an Application for Exception from the provisions of 10 CFR Part 211 in which the firm sought the assignment of new, lower-priced suppliers of motor gasoline to replace the higher-priced base period suppliers of the firm. In considering the request, the DOE found that PPC was threatened with serious financial injury as a result of its uncompetitively high acquisition cost for motor gasoline. Accordingly, on February 15, 1980, the DOE issued proposed and interim determinations which ordered the Economic Regulatory Administration (ERA) to select moderately-priced suppliers for PPC with respect to the months of January and February 1980. Pursuant to these determinations, the ERA issued assignment orders to Exxon Company, U.S.A. (Exxon) and the Atlantic Richfield Company.

In the final determination in this proceeding, the DOE considered Exxon's Appeal of the ERA's Assignment Order; Statements of Objections to the proposed determination filed by PPC, Exxon, and two of PPC's base period suppliers of motor gasoline; and Exxon's Motion for Modification of the February 15, 1980 Interim Decision and Order. In considering Exxon's Appeal, the DOE rejected the firm's arguments that the ERA's administrative procedures were deficient and that PPC had forefeited its right to purchase product from Exxon because of its delays in implementing the provisions of the Assignment Order. Exxon's Appeal was accordingly denied. The DOE also considered Exxon's Statement of Objections and found no basis in that submission for altering the findings of proposed exception decision. Finally, the DOE determined that the remaining submissions described above were moot and should be dismissed. The DOE therefore affirmed its preliminary findings on the PPC exception request and issued the Proposed Decision and Order in final form.

Raymond Oil Co., 12/4/81 BEE-1192

Raymond Oil Company filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart D. The exception request, if granted, would permit Raymond to retroactively certify the crude oil produced from the firm's one-well property during calendar years 1978 and 1979 as stripper well crude oil. In its exception request, Raymond claimed that it did not receive market prices for its crude oil during 1978 and 1979 because the employee responsible for conducting the firm's business affairs apparently failed to

certify Raymond's property as a stripper well lease because she suffered from diminished mental capacity. Raymond claimed that it would be inequitable to penalize it for the inaction of its employee. After a thorough evaluation of Raymond's position, the DOE concluded that there was little merit to Raymond's arguements and that the Proposed Decision and Order which denied the firm's exception request should be issued in final form. The DOE noted that Raymond has failed to demonstrate that the application of the certification time limit to its operation resulted in a gross inequity since all producers of crude oil were subject to the same regulatory requirement. In addition, the DOE rejected Raymond's contention that it should not be held responsible for the inactions of its employee. In this regard, the DOE noted that the hiring and supervision of the accountant was entirely Raymond's responsibility. The DOE noted further that the accountant was an equity owner of the property involved and could reasonably be expected to protect her interests in a prudent and timely fashion. Accordingly, the Raymond request for exception was denied.

Motions for Discovery

Imperial Refineries Corporation, 12/3/81, BRD–0093, BRH–0093

On December 20, 1979, Imperial Refineries Corporation filed Motions for Discovery and for Evidentiary Hearing pursuant to 10 CFR §§ 205.198 and 205.199. The motions relate to Imperial's objections to a Proposed Remedial Order that was issued to the firm on September 27, 1979. In considering Imperial's motions, the DOE first determined that the Motion for Discovery should be dismissed as moot. In addition, the DOE determined that the Motion for Evidentiary Hearing should be denied because the firm had failed to demonstrate that disputes concerning its accounting methods cannot be resolved through the submission of well-organized written statements and affidavits followed by oral argument.

Coy Shockley, d.b.a. Shockley's Exxon Service and Towing, 12/3/81, BRD–1252, BRH–1252

Coy Shockley d.b.a. Shockley's Exxon Service and Towing filed motions for evidentiary hearing and discovery in connection with their Statement of Objections to a Proposed Remedial Order issued to the firm on November 8, 1979. In considering the evidentiary hearing request, the OHA found that Shockley's had failed to meet its burden of establishing that a genuine dispute existed as to relevant and material issues of fact with respect to any of the proffered issues. Shockley's Motion for Evidentiary Hearing was therefore denied. With respect to Shockley's Motion for Discovery, the OHA found that the firm had not met its burden of establishing that the requested discovery was necessary in order to obtain relevant and material evidence. Accordingly, Shockley's Motion for Discovery was denied.

Interlocutory Orders

Office of Special Counsel, 12/1/81, HRZ–0002

The Office of Special Counsel sought an order deeming as admitted by Texaco Inc. certain allegations contained in a Proposed Remedial Order issued to the firm which Texaco failed to controvert in its Statement of Factual Objections. The Office of Hearings and Appeals entered an order deeming admitted the majority of the allegations specified in the OSC's motion.

Office of Special Counsel, 12/3/81, HRZ–0004

The Office of Special Counsel filed a motion to strike from the record a submission filed by Texaco Inc. in connection with a compliance proceeding pending before the Office of Hearings and Appeals. The OHA found that Texaco's filing of substantive amendments to its Statement of Factual Objections without obtaining prior leave of OHA violated the terms of prior OHA orders and granted the OSC motion on that basis. *See Office of Special Counsel,* 9 DOE ¶ No. HRZ–0003 (November 9, 1981).

Supplemental Orders

Vic and Lou's Union, 12/2/81 HRX–0003

On October 22, 1981, Vic Mareta d/b/a Vic and Lou's Union filed a notice of intent to appeal to the Federal Energy Regulatory Commission (FERC) a Decision and Order that the Department of Energy had issued to the firm on September 22, 1981. *Vic & Lou's Union,* 8 DOE ¶ 82,633 (1981). The Decision modified certain provisions of a Remedial Order that the DOE had previously issued to the firm. In considering the firm's submission, the DOE determined that the firm had waived all rights of appeal with regard to those portions of the Remedial Order not modified by the subsequent order of September 22, 1981. The DOE also determined that, because those provisions of an order that modify a previously issued Remedial Order themselves constitute a "Remedial Order" within the meaning of 42 U.S.C. 7193(b) and 10 CFR 205.199C, those new matters involved in the September 22, 1981 Decision are appealable to the FERC.

Dismissals

The following submissions were dismissed without prejudice:

Name and Case No.
Diversified Chemicals and Propellants Co., DRO–0160
Glaser Gas, Inc., BRO–1316, BRD–1316

Copies of the full text of these decisions and orders are available in the Public Docket Room of the Office of Hearings and Appeals, Room B–120, 2000 M Street, NW., Washington, D.C. 20461, Monday through Friday, between the hours of 1:00 p.m. and 5:00 p.m., except federal holidays. They are also available in *Energy Management; Federal Energy Guidelines,* a commercially published loose leaf reporter system.

George B. Breznay,

Director, Office of Hearings and Appeals.

January 26, 1982.

[FR Doc. 82–2562 Filed 2–1–82; 8:45 am]

BILLING CODE 6450–01–M

Issuance of Decisions and Orders; Week of December 7 Through December 11, 1981

During the week of December 7 through December 11, 1981, the decisions and orders summarized below were issued with respect to appeals and applications for exception or other relief filed with the Office of Hearings and Appeals of the Department of Energy. The following summary also contains a list of submissions that were dismissed by the Office of Hearings and Appeals.

Appeals

Babcock Contractors, Inc., 12/11/81, HFA–0013

Babcock Contractors, Inc. filed an Appeal from a partial denial by the Director of Contract Operations, Division A, of the Office of Procurement Operations of the Department of Energy of a request for information which the firm had submitted under the Freedom of Information Act. In considering the Appeal, the DOE upheld in part the Director's decision to withhold certain paragraphs contained in a memorandum to file pursuant to Exemption 5. The DOE found, however, that two of the paragraphs withheld in the initial determination should be released in the public interest. Therefore, these paragraphs were released together with the Decision and Order in two appendices.

Sunbelt Energy Systems, Inc., 12/7/81, HFA–0008

Sunbelt Energy Systems, Inc. filed an Appeal from a denial by the Bonneville Power Administration of a Request for Information which the firm had submitted under the Freedom of Information Act (the FOIA). In considering the Appeal, the DOE found that certain of the documents which were initially withheld under Exemption 4 should be released to the public. An important issue that was considered in the Decision and Order was the adequacy of the index which had been prepared by the denying offical.

Conoco, Inc., 12/10/81, HFA–0014

On November 12, 1981, Conoco, Inc. filed and Appeal from a partial denial by the Acting Director of the DOE Office of Special Counsel for Compliance (Acting Director) of a Request for Information which the firm had submitted under the Freedom of Information Act (FOIA). In considering the Appeal, the DOE found that the Acting Director's determination with respect to certain documents which he withheld under Exemption 4 was inadequate. Accordingly, the DOE remanded those documents to the Acting Director for a more suitable determination. The DOE further found that the Acting Director had correctly withheld certain other documents under Exemption 5. Finally, the Doe concluded that there is a distinct possibility that

the Office of Special Counsel possesses additional documents which are responsive to Conoco's request. Accordingly, the DOE ordered the Acting Director to conduct a further search of the appropriate offices for any such additional documents.

Chuck Hansen, 12/8/81, HFA-0001

Chuck Hansen filed an Appeal from a denial by the Director of the Office of Classification of a request for information which Mr. Hansen had submitted under the Freedom of Information Act (FOIA). In considering the Appeal, the DOE found that the Director of the Office of Classification had properly withheld pursuant to Exemption 3 of the FOIA portions of the document entitled "Weapon Development During June, 1958 (UCRL-5280)." In finding that the document was properly classified as Restricted Data under the Atomic Energy Act, the DOE determined that (i) neither Executive Order No. 12065 nor the Atomic Energy Act prohibit a document which has been mistakenly marked as declassified as a result of a clerical error from retaining its Restricted Data status; (ii) limited public access to the document did not move it into the public domain; and (iii) public awareness of general thermonuclear weapons concepts does not require the release of detailed technical weapons reports. Accordingly, the DOE concluded that the Hansen Appeal should be denied.

Remedial Orders

Bob Heinz, d.b.a Granada Chevron, 12/8/81, BRO-1447

Bob Heinz d.b.a. Granada Chevron objected to a Proposed Remedial Order which the Western District Office of Enforcement of the Economic Regulatory Administration issued to the firm on May 29, 1981. In the Proposed Remedial Order, the ERA found that during the period August 1, 1979 through January 6, 1981, Heinz violated the provisions of 10 CFR 212.93(a)(2) by charging prices for retail gasoline which exceeded the maximum lawful selling price for that product. In considering Heinz's objections, the DOE rejected Heinz's contention that its overcharges should be excused since the firms average yearly margin was less than the MLSP. The DOE therefore concluded that the Proposed Remedial Order should be issued as a final Order subject to the modification that Heinz compute interest on its overcharges at the rate of 6 percent per year for periods prior to February 1, 1980 and at 1 percent per month for periods after February 1, 1980 rather than at the prime rate as contemplated in the PRO.

Williams & Sons Enterprises, Inc., d.b.a. Campbell Point Boat Dock, 12/8/81, BRO-1383

Williams & Sons Enterprises, Inc. d.b.a. Campbell Point Boat Dock filed a Statement of Objections to a Proposed Remedial Order (PRO) issues to the firm by the Central Enforcement District of the Economic Regulatory Administration. In considering Williams' submission, the DOE determined that the firm's objections should be denied. Accordingly, the PRO was issued in final form, subject to a modification of the interest rate and payback provisions.

W. V. Ullner, d.b.a. Everett Street Exxon, 12/9/81, BRO-1465

W. V. Ullner objected to a Proposed Remedial Order which the Western District of Enforcement of the DOE issues to the firm on March 31, 1981. In the Proposed Remedial Order, the Office of Enforcement found that the firm had charged more than the maximum lawful selling price for one or more grades of gasolne in violation of 10 CFR 212.93. Because the firm failed to file a Statement of Objections as required by 10 CFR 205.196, the DOE dismissed the Notice of Objection and issued the Proposed Remedial Order as a Remedial Order of the Department of Energy.

In the following case involving Proposed Remedial Order, no Statement of Objections was filed. The DOE therefore issued the order in final form.

Company Name and Case No.

Steven Frank, d.b.a., BRW-0085
Steven Frank Arco

Request for Modification and/or Rescission

Caribou Four Corners, Inc., 12/8/81, BER-0156, BES-0169

Caribou Four Corners, Inc. filed a Motion for Reconsideration and an Application for Stay of a Decision and Order that the DOE issued on June 25, 1981, *Caribou Four Corners, Inc.*, 8 DOE ¶ 81,062 (1981). In its Motion for Reconsideration Caribou requested that its refined product resale revenues be included in calculating the firm's profit margin for the purpose of determining entitlements exception relief for fiscal year 1981. During this proceeding, the DOE required Caribou to have its resale record examined and certified by an independent CPA firm. After receiving the CPA certification, the DOE granted Caribou's request and recalculated the *Delta* relief for the firm by including its resale revenues. As a result of this recalculation, Caribou has been awarded an additional entitlement exception relief of $445,672 for its 1980 fiscal year.

Request for Exception

Union Oil Co. of California, Conoco, Inc ., 12/9/81, DEE-5748, BEH-0023

Union Oil Company of California (Union) requested exception relief that would remedy the firm's crude oil cost disparity *vis-a-vis* other major oil companies. In considering the request, the DOE found that during the third quarter of 1979, Union had been disproportionately dependent upon the foreign spot market for its crude oil supplies. As a result, Union's prices for refined petroleum products were significantly higher than its competitors, thus causing hardship to Union's marketers. In order to remedy the burden on the Union marketing system, the DOE directed the fourteen largest domestic refiners to supply Union with 75,046 barrels of crude oil per day (BPD) for December 1979, 70,881 BPD for January 1980, and 58,560 BPD for February 1980.

Interlocutory Order

Office of Special Counsel for Compliance, 12/9/81, BRZ-0108

The Office of Special Counsel for Compliance (OSC) sought an Order adopting certain factual findings made in a Proposed Remedial Order (PRO) issued to the Atlantic Richfield Company (Arco). Arco sought an Order adopting certain factual findings which it made in its Statement of Factual Objections (SFO) to the PRO. The DOE entered an order finding Arco to have admitted specified factual findings in the PRO that it failed to controvert in its SFO. The DOE additionally entered an order establishing as factual findings matters OSC admitted in responding to a request for admissions by Arco.

Dismissals

The following submissions were dismissed without prejudice:

Name and Case No.

Bayside Fuel Oil Corp., DRO-0361
Bayside Fuel Oil Depot Corp., DRO-0362, BRH-0013, BRD-0013
Dalco Petroleum, Inc., BRO-1427
Lawrence G. Spielvogel, Inc., BEG-0059
Riley, Flauris, HEE-0005

Copies of the full text of these decisions and orders are available in the Public Docket Room of the Office of Hearings and Appeals, Room B-120, 2000 M Street, NW., Washington, D.C. 20461, Monday through Friday, between the hours of 1:00 p.m. and 5:00 p.m., except federal holidays. They are also available in *Energy Management: Federal Energy Guidelines*, a commercially published losse leaf reporter system.

George B. Breznay,

Director, Office of Hearings and Appeals.

January 26, 1982.

[FR Doc. 82-2563 Filed 2-1-82; 8:45 am]
BILLING CODE 6450-01-M

Issuance of Proposed Decision and Order; Period of December 28, 1981, Through January 15, 1982

During the period of December 28, 1981, through January 15, 1982, the proposed decision and order summarized below was issued by the Office of Hearings and Appeals of the Department of Energy with regard to an application for exception.

Under the procedural regulations that apply to exception proceedings (10 CFR Part 205, Subpart D), any person who will be aggrieved by the issuance of a proposed decision and order in final form may file a written notice of objection within ten days of service. For purposes of the procedural regulations, the date of service of notice is deemed

to be the date of publication of this Notice or the date an aggrieved person receives actual notice, whichever occurs first.

The procedural regulations provide that an aggrieved party who fails to file a Notice of Objection within the time period specified in the regulations will be deemed to consent to the issuance of the proposed decision and order in final form. An aggrieved party who wishes to contest a determination made in a proposed decision and order must also file a detailed statement of objections within 30 days of the date of service of the proposed decision and order. In the statement of objections, the aggrieved party must specify each issue of fact or law that it intends to contest in any further proceeding involving the exception matter.

Copies of the full text of these proposed decisions and orders are available in the Public Docket Room of the Office of Hearings and Appeals, Room B–120, 2000 M Street, NW., Washington, D.C. 20461, Monday through Friday, between the hours of 1:00 p.m. and 5:00 p.m., except federal holidays.

George B. Breznay,

Director, Office of Hearings and Appeals.

January 26, 1982.

Colebrook School District, Colebrook, New Hampshire, BEE–1689, Conservation Grant

Colebrook School District filed an Application for Exception from the provisions of 10 CFR Part 455. The exception request, if granted, would permit Colebrook School District to receive DOE funding for Energy Conservation Measures it implemented at Colebrook Academy during 1980. On January 15, 1982, the Department of Energy issued a Proposed Decision and Order which determined that the exception request be denied.

[FR Doc. 82–2655 Filed 2–1–82; 8:45 am]

BILLING CODE 6450–01–M

ENVIRONMENTAL PROTECTION AGENCY

[OPTS–51376A; TSH–FRL–2040–1]

Certain Chemicals; Premanufacture Notices; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice corrects the PMN specific gravity on a premanufacture notice (PMN) published in the **Federal Register** of January 8, 1982 (47 FR 1021).

FOR FURTHER INFORMATION CONTACT: David Dull, Acting Chief, Notice Review Branch, Chemical Control Division (TS–794), Office of Toxic Substances, Environmental Protection Agency, Rm. E–216, 401 M St., SW., Washington, DC 20460, (202–382–3729).

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 8, 1982 (47 FR 1021), EPA issued a notice of receipt of PMN 81–662.

In the FR Doc. 82–488 appearing at page 1021 under "PMN 81–662", third column, Physical/Chemical Properties, "Specific gravity–1–10" is corrected to read "Specific gravity–1.10."

Dated: January 25, 1982.

Woodson W. Bercaw,

Acting Director, Management Support Division.

[FR Doc. 82–2648 Filed 2–1–82; 8:45 am]

BILLING CODE 6560–31–M

[OPTS–51388; TSH–FRL–2040–2]

Certain Chemicals; Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before manufacture or import commences. Statutory requirements for section 5(a)(1) premanufacture notices are discussed in EPA statements of interim policy published in the **Federal Register** of May 15, 1979 (44 FR 28558) and November 7, 1980 (45 FR 74378). This notice announces receipt of two PMNs and provides a summary of each.

DATES: Written comments by: PMN 82–41 and 82–42, March 23, 1982.

ADDRESS: Written comments, identified by the document control number "[OPTS–51388]" and the specific PMN number should be sent to: Document Control Officer (TS–793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E–409, 401 M St., SW., Washington, DC 20460 (202–382–3532).

FOR FURTHER INFORMATION CONTACT: David Dull, Acting Chief, Notice Review Branch, Chemical Control Division (TS–794), Office of Toxic Substances, Environmental Protection Agency, Rm. E–216, 401 M St., SW., Washington, DC 20460 (202–382–3729).

SUPPLEMENTARY INFORMATION: The following are summaries of information provided by the manufacturer on the PMNs received by EPA:

PMN 82–41

Close of Review Period. April 22, 1982.

Manufacturer's Identity. American Color and Chemical Corporation, Mt. Vernon Street, Lock Haven, PA 17745.

Specific Chemical Identity. Claimed confidential business information. Generic name provided: Naphthalenedisulfonic acid, disazo acid dye, lithium salt.

Use. The manufacturer states that the PMN substance will be used in an industrial paper.

PRODUCTION ESTIMATES

	Kilograms per year	
	Minimum	Maximum
1st year	5,000	8,000
2d year	8,000	11,000
3d year	10,000	16,000

Physical/Chemical Properties

Appearance—Dark navy blue solution.

pH—9.0–10.0.

Toxicity Data. No data were submitted.

Exposure. The manufacturer states that during manufacture and use 2 workers may experience cleaning clarification press and handling liquid exposure 2 hrs/yr during transfer and handling.

Environmental Release/Disposal. The manufacturer states that less than 10 kg/yr will be released to air, land, and water. Disposal is to a publicly owned treatment works (POTW).

PMN 82–42

Close of Review Period. April 22, 1982.

Manufacturer's Identity. Claimed confidential business information. Organization information provided:

Manufacturing site—Middle Atlantic region.

Standard Industrial Classification Code—285;e.

Specific Chemical Identity. Claimed confidential business information. Generic name provided: Alkyd polymer from fatty acids, substituted alkane triols, carbomonocyclic acids and an anhydride.

Use. Claimed confidential business information. Generic use information provided: The manufacturer states that the PMN substance will be used in an open use.

PRODUCTION ESTIMATES

	Kilograms per year	
	Minimum	Maximum
1st year	7,000	45,000
2d year	13,200	90,000

PRODUCTION ESTIMATES—Continued

	Kilograms per year	
	Minimum	Maximum
3d year	33,000	225,000

Physical/Chemical Properties

Flash point—138° F.
Viscosity—W.
Color—8.
Percent solid @ 105° C—32.0.

Toxicity Data. No data were submitted.

Exposure. The manufacturer states that during manufacture, processing, and use a total of 115 workers may experience dermal and occular exposure up to 6 hrs/day, up to 250 days/yr during extraction, sampling, filling, and clean-up.

Environmental Release/Disposal. The manufacturer states that less than 10 kg/yr will be released to air and water with 10–1,000 kg/yr released to land. Disposal is by an approved landfill, distillation, and incineration.

Dated: January 25, 1982.

Woodson W. Bercaw,

Acting Director, Management Support Division.

[FR Doc. 82-2647 Filed 2-1-82; 8:45 am]

BILLING CODE 6560-31-M

[OPTS-51389; TSH-FRL-2040-3]

Certain Chemicals; Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before manufacture or import commences. Statutory requirements for section 5(a)(1) premanufacture notices are discussed in EPA statements of interim policy published in the **Federal Register** of May 15, 1979 (44 FR 28558) and November 7, 1980 (45 FR 74378). This notice announces receipt of two PMNs and provides a summary of each.

DATES: Written comments by: PMN 82-44 and 82-45, March 26, 1982.

ADDRESS: Written comments, identified by the document control number "[OPTS-51389]" and the specific PMN number should be sent to: Document Control Officer (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-409, 401 M St., SW., Washington, DC 20460, (202-382-3532).

FOR FURTHER INFORMATION CONTACT: David Dull, Acting Chief, Notice Review Branch, Chemical Control Division (TS-794), Office of Toxic Substances, Environmental Protection Agency, Rm. E-216, 401 M St., SW., Washington, DC 20460, (202-382-3729).

SUPPLEMENTARY INFORMATION: The following are summaries of information provided by the manufacturer on the PMNs received by EPA:

PMN 82-44

Close of Review Period. April 25, 1982.

Manufacturer's Identity. Claimed confidential business information. Organization information provided:

Annual sales—Over $500,000,000.
Manufacturing site—Northeast region.

Specific Chemical Identity. Claimed confidential business information. Generic name provided: Chloroheteropolycyclic, hydrochloride salt.

Use. The manufacturer states that the PMN substance will be used as a site limited and industrial intermediate.

PRODUCTION ESTIMATES

	Kilograms per year	
	Minimum	Maximum
1st year	1,000	10,000
2d year	1,000	10,000
3d year	1,000	10,000

Physical/Chemical Properties

Appearance—Cream colored solid.
Melting—> 300° C.
Solubility: water at 20° C—Very soluble.
Percent volatiles by volume—Nil.
Evaporation rate (Butyl Acetate=1) Nil.

Toxicity Data

Skin irritation—Not a skin irritant.
Eye irritation—Moderate eye irritant.
Skin absorption—Not toxic by this route.
Ingestion—Moderately acutely toxic.

Exposure. The manufacturer states that during manufacture processing a total of 72 workers may experience dermal and inhalation exposure up to 24 hrs/day, up to 322 days/yr.

Environmental Release/Disposal. The manufacturer states that less than 10 kg/yr will be released to air with 10–100 kg/yr released to land and water. Disposal is to a publicly owned treatment works (POTW) or approved landfill, or by treatment or recovery.

PMN 82-45

Close of Review Period. April 25, 1982.

Manufacturer's Identify. Claimed confidential business information. Organization information provided:

Annual sales—Over $500,000,000.
Manufacturing site—Northeast region.

Specific Chemical Identity. Claimed confidential business information. Generic name provided: Substituted pyridinium bromide.

Use. Claimed confidential business information. Generic use information provided: The manufacturer states that the PMN substance will be incorporated into a consumer article.

PRODUCTION ESTIMATES

	Kilograms per year	
	Minimum	Maximum
1st year	100	1,000
2d year	1,000	5,000
3d year	1,000	5,000

Physical/Chemical Properties

Appearance—White powder odorless.
Melting point—> 100° C.
Solubility: water at 20° C 10 g/l.
Percent volatiles by volume Nil.
Vapor pressure mm Hg Nil.
Evaporation rate (Butyl Acetate=1) Nil.

Toxicity Data

Skin irritation—Not likely to be a skin irritant.
Eye irritation—Mild irritant.
Skin absorption—May be absorbed in toxic amounts.
Ingestion—Moderately acutely toxic.

Exposure. The manufacturer states that during manufacture, processing and disposal a total of 328 workers may experience dermal and inhalation exposure up to 24 hrs/day, up to 355 days/yr.

Environmental Release/Disposal. The manufacturer states that less than 10 kg/yr will be released to air with 10–100 kg/yr released to land and 10–1,000 kg/yr to water. Disposal is to a POTW or approved landfill, or treatment or recovery.

Dated January 26, 1982.

Woodson W. Bercaw,

Acting Director, Management Support Division.

[FR Doc. 82-2646 Filed 2-1-82; 8:45 am]

BILLING CODE 6560-31-M

[W-3-FRL-2040-6]

Groundwater System of a Limestone Aquifer of the Piedmont Region in York County, Pennsylvania: Request for EPA Determination Regarding Aquifer System; Comment Period

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The Environmental Protection Agency announces the receipt of a petition requesting the designation of the groundwater system of a limestone aquifer of the Piedmont Region as a sole or principal source of drinking water and opens a public comment period to request information about the basins.

DATES: Comments will be accepted until April 30, 1982. The Agency's proposal to grant or deny the petition and the notice of a public hearing will be announced concurrently in the **Federal Register** and in newspapers of general circulation in the affected area. At least 30 days notice will be given before that hearing will be held.

ADDRESS: Written comments should be sent to: Environmental Protection Agency, Region III, Water Management Division, Attn: Groundwater Protection Section (3WM42), 6th & Walnut Streets, Philadelphia, PA 19106.

FOR FURTHER INFORMATION CONTACT: Benjamin Lacy, Chief, Groundwater Protection Section, at the above address, or telephone (215) 597–9000. Copies of the petition are available upon request.

SUPPLEMENTARY INFORMATION: Section 1424(e) of the Safe Drinking Water Act (Pub. L. 93–523) authorizes the Administrator of the Environmental Protection Agency (EPA) to determine that an area has an aquifer which is the sole or principal drinking water source for the area. Opposing Unnecessary Chemical Hazards, (O.U.C.H.), Inc., has requested the Administrator to determine that the limestone aquifer of the Piedmont Region is the sole or principal drinking water source for the area in and around Seven Valleys, Pennsylvania. The petitioned area is that area directly overlying the Conestoga Limestone aquifer in the vicinity of Sinsheim, Jefferson, and Seven Valleys. There are portions of two major streams which comprise the stream flow source zones for the aquifer; the East Branch of West Branch Codorus Creek and South Branch Codorus Creek. Information is solicited about the petitioned area's hydrogeologic system, including the surface boundary of its recharge area and about the number and kinds of small entities (business, governmental jurisdictions, and organizations) receiving Federal financial assistance in the area. This will assist EPA in evaluating the aquifer system and the potential impact of a designation on small entities pursuant to Regulatory Flexibility Act requirements. Based on EPA experience with other sole source designations, some Federal financially assisted projects that potentially may be affected include highway construction, subdivision construction, and waste disposal sites. EPA will decide whether to make the requested determination following its review of relevant data and after providing an opportunity for full public participation on its proposed decision.

Dated: January 18, 1982.

Peter N. Bibko,

Regional Administrator.

[FR Doc. 82–2650 Filed 2–1–82; 8:45 am]

BILLING CODE 6560–38–M

FEDERAL COMMUNICATIONS COMMISSION

[Report No. 16770; PR Docket No. 82–10]

Commission Launches Inquiry into Private Land Mobile Radio's Future Requirements; Action in Docket Case

January 15, 1982.

In an effort to accommodate the needs of private land mobile radio users, the Commission has launched an inquiry to determine the best overall strategy for meeting the future communication requirements of those users.

The Commission said an inquiry was necessary at this time because of the tremendous growth of private land mobile radio which, if it continues at the projected rate, could result in a serious frequency congestion problem.

Land mobile radio describes both voice and non-voice communication between a fixed place and a moving vehicle or person, or between two or more moving vehicles or persons. It is currently divided into two major service areas for regulatory purposes: the Domestic Public Land Mobile Radio Services and the Private Land Mobile Radio Services.

Although there is some overlap between these two services, the FCC said its inquiry will mainly be concerned with the Private Land Mobile Radio Services whose users include police, doctors, utility crews, taxis and many others.

The inquiry has been broken into two major areas, the first to deal with anticipated private land mobile requirements and the second with possible sources of spectrum to meet those requirements.

The Commission is seeking comments on several issues within these two areas. Some of the questions being asked by the FCC include the following:

—What factors are likely to affect the rate of growth of land mobile communications in the next 10–20 years?

—What is the most appropriate unit for measuring spectrum use in the private land mobile services?

—What new land mobile communications applications do you anticipate in the next 10–20 years?

—How would you rank the following approaches to providing additional spectrum for private land mobile?

(a) Possible new exclusive or shared allocations.

(b) Increased sharing between land mobile and other services.

(c) Use of new, more efficient narrowband or wideband technologies and systems such as trunking, cellular, etc.

In addition to satisfying the future needs of private land mobile radio users, the Commission hopes the inquiry will help in providing closer cooperation between the agency and the land mobile user community resulting in a positive, stable and flexible regulatory environment.

Parties interested in filing comments in the proceeding may do so by June 9, 1982. Reply comments will be due by July 7, 1982.

Action by the Commission January 13, 1982, by Notice of Inquiry (FCC No. 82–8). Commissioners Fowler (Chairman), Quello, Washburn, Fogarty, Jones, Dawson and Rivera.

For further information contract Joseph Levin or Arthur Radice at (202) 254–3301.

Note.—Due to the ongoing effort to minimize publishing costs, the Notice of Inquiry will not be printed herein. Please direct inquiries regarding copies to the Office of Public Affairs, Room 202, 1919 M Street, NW., Washington, D.C. 20554.

[FR Doc. 82–2481 Filed 2–1–82; 8:45 am]

BILLING CODE 6712–01–M

FEDERAL MARITIME COMMISSION

Agreements Filed

The Federal Maritime Commission hereby gives notice that the following agreements have been filed with the Commission for approval pursuant to section 15 of the Shipping Act, 1916, as amended (39 Stat. 733, 75 Stat. 763, 46 U.S.C. 814).

Interested parties may inspect and obtain a copy of each of the agreements

and the justifications offered therefor at the Washington Office of the Federal Maritime Commission, 1100 L Street NW., Room 10327; or may inspect the agreements at the Field Offices located at New York, N.Y.; New Orleans, Louisiana; San Francisco, California; Chicago, Illinois; and San Juan, Puerto Rico. Interested parties may submit comments on each agreement, including requests for hearing, to the Secretary, Federal Maritime Commission, Washington, D.C. 20573, on or before February 22, 1982. Comments should include facts and arguments concerning the approval, modification, or disapproval of the proposed agreement. Comments shall discuss with particularity allegations that the agreement is unjustly discriminatory or unfair as between carriers, shippers, exporters, importers, or ports, or between exporters from the United States and their foreign competitors, or operates to the detriment of the commerce of the United States, or is contrary to the public interest, or is in violation of the Act.

A copy of any comments should also be forwarded to the party filing the agreements and the statement should indicate that this has been done.

Agreement No. T–4016.

Filing party: Richard L. Landes, Deputy, Harbor Branch Office, Offices of the City Attorney of Long Beach, Harbor Administration Building, P.O. Box 570, Long Beach, California 90801.

Summary: Agreement No. T–4016 between the City of Long Beach (City) and Pacific Maritime Services, Inc. (PMS) provides for the 20-year non-exclusive Preferential assignment to PMS of 39 acres, Parcel I and 23.5 acres Parcel II at Berths 245–247, Pier J, Long Beach, California for operation as a contract marine terminal warehouse and rail and truck facility. As compensation PMS shall pay City revenues collected from those charges assessed pursuant to Port of Long Beach Tariff. PMS shall pay City as rental for the use of Parcel I $104,319 per month and for the use of Parcel II $86,218 per month. If the total area of Parcel II is not ready for occupancy at the time PMS accepts occupancy, the monthly rental for Parcel II will be reduced by $3,200 per month. PMS agrees to file its schedule of terminal rates and charges with the City, or in lieu thereof, may elect to use and be bound by the Port of Long Beach Tariff. If PMS publishes its own tariff, all charges assessed must conform as nearly as possible with like charges published in the Long Beach Tariff and no change may be made without City's prior written approval. Upon completion of improvements by the City to Parcel II, PMS shall pay to City an additional compensation of a sum equal to 1/12th of the product obtained by multiplying the total cost of the improvements by 15.10 percent. This agreement terminates Agreement No. T–2894, between the parties, approved by the Commission on March 27, 1974.

Agreement No. 10434.

Filing party: Leroy F. Fuller, Bogle & Gates, Suite 725, 1575 I Street NW., Washington, D.C. 20005.

Summary: Agreement No. 10434, between Georgia-Pacific Corporation (G–P) and Clipper Maritime Limited (Clipper), provides for the establishment of a joint venture for the purpose of conducting an ocean common carrier service between U.S. Atlantic and Gulf Coast ports and ports in Ireland, the United Kingdom, Continental Europe and on the Mediterranean Sea. The joint venture will operate under the name of Atlantic Cross Shipping. G–P will contribute $100,000 and two vessels and Clipper will contribute not less than $100,000 and the time and skill of its employees and agents for the booking, management and operational functions of the joint venture. Clipper will be responsible for the management and operation of the joint venture, subject to the policies established and agreed upon between the parties. Peraco Chartering Corporation will receive a charter brokerage commission for any time-charter tonnage used by the joint venture. At the end of each calendar year, net profits will be divided equally between G–P and Clipper with Clipper to bear any net loss sustained by the joint venture.

By Order of the Federal Maritime Commission.

Dated: January 27, 1982.

Francis C. Hurney,

Secretary.

[FR Doc. 82–2654 Filed 2–1–82; 8:45 am]

BILLING CODE 6730–01–M

Independent Ocean Freight Forwarder License; Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission applications for licenses as independent ocean freight fowarders pursuant to section 44(a) of the Shipping Act, 1916 (75 Stat. 522 and 46 U.S.C. 841(c)).

Persons knowing of any reason why any of the following applicants should not receive a license are requested to communicate with the Director, Bureau of Certification and Licensing, Federal Maritime Commission, Washington, D.C. 20573.

Atlantic Freight Fowarders, Inc., 7262 N.W. 66th Street, Miami, FL 33166, Officers: Alicia M. Gonzalez, President/Treasurer, Esther C. Gonzalez, Secretary/Vice President.

Richard R. Lyle, 334 Carroll Park East, Long Beach, CA 90814.

Worthmore Forwarding, Inc., 138–01 Springfield Blvd., Suite 2–1, Springfield Gardens, NY 11413, Officer: Richard V. Lata, President.

Southland International Forwarding, Inc., P.O. Box 3187, 507 Shipyard Blvd., Couch Office Bldg., Rooms 5 & 6, Wilmington, NC 28406, Officers: Paul Kirby Thomas, President/Secretary, Sue Nance Thomas, Treasurer.

Metropolitan Fowarders, Inc., 10004 N.W. 80th Avenue, Hialeah Gardens, FL 33016, Officer: Edwin Torres, President.

By the Federal Maritime Commission.

Dated: January 28, 1982.

Francis C. Hurney,

Secretary.

[FR Doc. 82–2695 Filed 2–1–82; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

United Ban Holding Corp.; Formation of Bank Holding Company

United Ban Holding Corp., Norman, Oklahoma, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 80 per cent or more of the voting shares of United Bank of Norman, Norman, Oklahoma. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than February 24, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, January 26, 1982.

Theodore E. Downing, Jr.,

Assistant Secretary of the Board.

[FR Doc. 82–2579 Filed 2–1–82; 8:45 am]

BILLING CODE 6210–01–M

United Banks of Colorado, Inc.; Acquisition of Bank

United Banks of Colorado, Inc., Denver, Colorado, has applied for the Board's approval under section 3(a)(5) of the Bank Holding Company Act (12 U.S.C. 1842(a)(5)) to merge with Lorin Investment Company, Brighton, Colorado. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

United Banks of Colorado, Inc., Denver, Colorado, is also engaged in the following nonbank activities: Operating a mortgage company, data processing services, acting as agent for credit related insurance, and reinsuring credit life policies. In addition to the factors considered under section 3 of the Act (banking factors), the Board will consider the proposal in the light of the company's nonbanking activities and the provisions and prohibitions in section 4 of the Act (12 U.S.C. 1843).

The application may be inspected at the offices of the Board of Governors or the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than February 24, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, January 26, 1982.

Theodore E. Downing, Jr.,

Assistant Secretary of the Board.

[FR Doc. 82-2580 Filed 2-1-82; 8:45 am]

BILLING CODE 6210-01-M

Washington Community Bancshares, Inc.; Formation of Bank Holding Company

Washington Community Bancshares, Inc., Tacoma, Washington, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 100 per cent of the voting shares of Western Community Bank, N.A., the successor by merger to Western Community Bank, Tacoma, Washington. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of San Francisco. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than February 25, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, January 26, 1982.

Theodore E. Downing, Jr.,

Assistant Secretary of the Board.

[FR Doc. 82-2581 Filed 2-1-82; 8:45 am]

BILLING CODE 6210-01-M

Chicago Heights Bancorp, Inc.; Formation of Bank Holding Company

Chicago Heights Bancorp, Inc., Crestwood, Illinois, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 80 per cent or more of the voting shares of The Chicago Heights National Bank, Chicago Heights, Illinois. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Chicago. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than February 25, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, January 26, 1982.

Theodore E. Downing, Jr.,

Assistant Secretary of the Board.

[FR Doc. 82-2565 Filed 2-1-82; 8:45 am]

BILLING CODE 6210-01-M

Continental Bancorp, Inc.; Formation of Bank Holding Company

Continental Bancorp, Inc., Philadelphia, Pennsylvania, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 100 per cent of the voting shares of Continental Bank, Norristown, Pennsylvania. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Philadelphia. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than February 20, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, January 26, 1982.

Theodore E. Downing, Jr.,

Assistant Secretary of the Board.

[FR Doc. 82-2566 Filed 2-1-82; 8:45 am]

BILLING CODE 6210-01-M

Continental Illinois Corp.; Acquisition of Bank

Continental Illinois Corporation, Chicago, Illinois, has applied for the Board's approval under section 3(a)(3) of the Bank Holding Company Act (12 U.S.C. 1842(a)(3)) to acquiring 100 per cent of the voting shares, less directors' qualifying shares, of Buffalo Grove National Bank, Buffalo, Grove, Illinois. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Chicago. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, to be received not later than February 25, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, January 26, 1982.

Theodore E. Downing, Jr.,

Assistant Secretary of the Board.

[FR Doc. 82-2567 Filed 2-1-82; 8:45 am]

BILLING CODE 6210-01-M

Crookston Financial Services, Inc.; Formation of Bank Holding Company

Crookston Financial Services, Inc., Crookston, Minnesota, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 80 per cent or more of the voting shares of Crookston National Bank, Crookston, Minnesota. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Minneapolis. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than February 19, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, January 26, 1982.

Theodore E. Downing, Jr.,

Assistant Secretary of the Board.

[FR Doc. 82-2566 Filed 2-1-82; 8:45 am]

BILLING CODE 6210-01-MM

England Bancorp; Formation of Bank Holding Company

England Bancorp, Axtell, Nebraska, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 100 percent of the voting shares of Farmers and Merchants Bank, Axtell, Nebraska. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than February 24, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, January 26, 1982.

Theodore E. Downing, Jr.,

Assistant Secretary of the Board.

[FR Doc. 82-2569 Filed 2-1-82; 8:45 am]

BILLING CODE 6210-01-M

Fifth Third Bancorp; Acquisition of Bank

Fifth Third Bancorp, Cincinnati, Ohio, has applied for the Board's approval under section 3(a)(3) of the Bank Holding Company Act (12 U.S.C. 1842(a)(3)) to acquire 100 percent of the voting shares of The Farmers and Merchants Banks, Fairborn, Ohio. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Cleveland. Any person wishing to comment on the application should submit views in writing to the Reserve Bank to be received not later than February 25, 1982. Any comment on an application that request a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, January 26, 1982.

Theodore E. Downing, Jr.,

Assistant Secretary of the Board.

[FR Doc. 82-2570 Filed 2-1-82; 8:45 am]

BILLING CODE 6210-01-M

First Prague Bancorporation, Inc.; Formation of Bank Holding Company

First Prague Bancorporation, Inc., Prague, Oklahoma, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 80 per cent or more of the voting shares of First National Bank of Praque, Praque, Oklahoma. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than February 25, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, January 26, 1982.

Theodore E. Downing, Jr.,

Assistant Secretary of the Board.

[FR Doc. 82-2571 Filed 2-1-82; 8:45 am]

BILLING CODE 6210-01-M

First Rockford Bancorp, Inc.; Formation of Bank Holding Company

First Rockford Bancorp, Inc., Rockford, Illinois, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 100 percent of the voting shares of the successor by merger to First National Bank and Trust Company of Rockford, Rockford, Illinois; North Towne National Bank of Rockford, Rockford, Illinois; First Bank of Roscoe, Roscoe, Illinois; and First Bank of Loves Park, Loves Park, Illinois. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Chicago. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than February 24, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, January 26, 1982.

Theodore E. Downing, Jr.,

Assistant Secretary of the Board.

[FR Doc. 82-2572 Filed 2-1-82; 8:45 am]

BILLING CODE 6210-01-M

First Stratford Bancorporation, Inc.; Formation of Bank Holding Company

First Stratford Bancorporation, Inc., Stratford, Oklahoma, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 80 percent or more of the voting shares of First American Bank, Stratford, Oklahoma. The factors that are considered in acting on the application

are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than February 25, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, January 26, 1982.

Theodore E. Downing, Jr.,

Assistant Secretary of the Board.

[FR Doc. 82-2573 Filed 2-1-82; 8:45 am]

BILLING CODE 6210-01-M

Liberty Holding Co.; Formation of Bank Holding Company

Liberty Holding Company, Cantonment, Florida, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 80 per cent or more of the voting shares of Liberty Bank of Cantonment, Cantonment, Florida. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Atlanta. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than February 12, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, January 26, 1982.

Theodore E. Downing, Jr.,

Assistant Secretary of the Board.

[FR Doc. 82-2574 Filed 2-1-82; 8:45 am]

BILLING CODE 6210-01-M

Lubbock Bancorporation, Inc.; Formation of Bank Holding Company

Lubbock Bancorporation, Inc., Lubbock, Texas, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 90 percent of the voting shares of the West, Lubbock, Texas. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Dallas. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than February 25, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, January 26, 1982.

Theodore E. Downing, Jr.,

Assistant Secretary of the Board.

[FR Doc. 82-2575 Filed 2-1-82; 8:45 am]

BILLING CODE 6210-01-M

Mercantile Texas Corp.; Acquisition of Bank

Mercantile Texas Corporation, Dallas, Texas, has applied for the Board's approval under section 3(a)(3) of the Bank Holding Company Act (12 U.S.C. 1842(a)(3)) to acquire 100 per cent of the voting shares, less directors' qualifying shares, of Southwest Bank, Mesquite, Texas. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Dallas. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, to be received not later than February 25, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, January 26, 1982.

Theodore E. Downing, Jr.,

Assistant Secretary of the Board.

[FR Doc. 82-2576 Filed 2-1-82; 8:45 am]

BILLING CODE 6210-01-M

Southwest Financial Corp.; Formation of Bank Holding Company

Southwest Financial Corporation, Evergreen Park, Illinois, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 100 per cent of the voting shares, less directors' qualifying shares, of the successor by merger to Evergreen Plaza Bank, Evergreen Park, Illinois. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Chicago. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than February 17, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, January 26, 1982.

Theodore E. Downing, Jr.,

Assistant Secretary of the Board.

[FR Doc. 82-2577 Filed 2-1-82; 8:45 am]

BILLING CODE 6210-01-M

Traxshares, Inc.; Formation of Bank Holding Company

Traxshares, Inc., LeCenter, Minnesota, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 80.5 percent or more of the voting shares of First National Bank of LeCenter, LeCenter, Minnesota. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Minneapolis. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than February 25, 1982. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and

summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, January 26, 1982.

Theodore E. Downing, Jr.,

Assistant Secretary of the Board.

[FR Doc. 82-2578 Filed 2-1-82; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Alcohol, Drug Abuse, and Mental Health Administration

Advisory Bodies; Meetings

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. Appendix I), announcement is made of the following national advisory bodies scheduled to assemble during the month of February 1982.

Life Course Review Committee

February 19–20; 9 a.m.

The Shoreham Hotel, Room E630, 2500 Calvert Street, NW., Washington, D.C. 20008
Open—February 19, 9–9:30 a.m.
Closed—Otherwise
Contact: Ms. Dee Herman, Room 9C–18, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443–1367

Purpose

The Committee is charged with the initial review of applications for assistance from the National Institute of Mental Health for support of research activities in the fields of child, family, and aging, and makes recommendations to the National Advisory Mental Health Council for final review.

Agenda

From 9–9:30 a.m., February 19, 1982, the meeting will be open for discussion of administrative announcements and program developments. Otherwise, the Committee will be performing intitial review of applications for assistance and will not be open to the public in accordance with the determination by the Administrator, Alcohol, Drug Abuse, and Mental Health Administration, pursuant to the provisions of 5 U.S.C. 552b(c)(6), and section 10(d) of Pub. L. 92–463 (5 U.S.C. Appendix I).

Psychiatry Education Review Committee

February 22–24; 9 a.m.

Conference Room H, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857
Open—February 22, 9–10 a.m.
Closed—Otherwise
Contact: Irma Fisher, Room 9C02, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443–4728

Purpose

The Committee is charged with the initial review of applications for assistance from the National Institute of Mental Health for support of activities in the fields of psychiatry education and manpower development, and makes recommendations to the National Advisory Mental Health Council for final review.

Agenda

From 9–10 a.m., February 22, the meeting will be open for discussion of administrative announcements and program developments. Otherwise, the Committee will be performing intital review of applications for assistance and will not be open to the public in accordance with the determination by the Administrator, Alcohol, Drug Abuse, and Mental Health Administration, pursuant to the provisions of 5 U.S.C. 552b(c)(6), and section 10(d) of Pub. L. 92–463 (5 U.S.C. Appendix I).

Psychology Education Review Committee

February 24–26; 9 a.m.

Conference Room 3A77, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857
Open—February 24, 9–10 a.m.
Closed—Otherwise
Contact: Irma Fisher, Room 9C02, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443–4728

Purpose

The Committee is charged with the initial review of applications for assistance from the National Institute of Mental Health for support of activities in the fields of psychology education and makes recommendations to the National Advisory Mental Health Council for final review.

Agenda

From 9–10 a.m., February 24, the meeting will be open for discussion of administrative announcements and program developments. Otherwise, the Committee will be performing initial review of applications for assistance and will not be open to the public in accordance with the determination by the Administrator, Alcohol, Drug Abuse, and Mental Health Administration, pursuant to the provisions of 5 U.S.C. 552b(c)(6), and section 10(d) of Pub. L. 92–463 (5 U.S.C. Appendix I).

Drug Abuse Clinical and Behavioral Research Subcommittee, Drug Abuse Clinical, Behavioral, and Psycholosocial Research Review Committee

February 22–25; 9 a.m.

Linden Hill Hotel, Longwood Room, 5400 Pooks Hill Road, Bethesda, Maryland 20014
Open—February 22, 9–9:30 a.m.
Closed—Otherwise
Contact: Mr. Daniel L. Mintz, Executive Secretary, DACB, Room 10–42, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443–2620

Purpose

The Committee is charged with the initial review of applications for assistance from the National Institute on Drug Abuse for support of research and research training activities and makes recommendations to the National Advisory Council on Drug Abuse for final review.

Agenda

From 9:00–9:30 a.m., February 22, the meeting will be open for discussion of administrative announcements and program developments. Otherwise, the Committee will be performing initial review of applications for assistance and will not be open to the public in accordance with the determination by the Administrator, Alcohol, Drug Abuse and Mental Health Administration, pursuant to the provisions of 5 U.S.C. 552b(c)(6), and section 10(d) of Pub. L. 92–463 (5 U.S.C. Appendix I).

Psychosocial Research Subcommittee, Drug Abuse Clinical; Behavioral, and Psychosocial Research Review Committee

February 22–25; 9:00 a.m.

Conference Room G, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857
Open—February 22, 9:00–9:30 a.m.
Closed—Otherwise
Contact: Mr. Ron Gold, Executive Secretary, DACA, Room 10–42, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 446–2620

Purpose

The Committee is charged with the initial review of applications for assistance from the National Institute on Drug Abuse for support of research and research training activities and makes recommendations to the National Advisory Council on Drug Abuse for final review.

Agenda

From 9:00–9:30 a.m., February 22, the meeting will be open for discussion of administrative announcements and program developments. Otherwise, the Committee will be performing initial review of applications for assistance and will not be open to the public in accordance with the determination by the Administrator, Alcohol, Drug Abuse, and Mental Health Administration, pursuant to the provisions of 5 U.S.C. 552b(c)(6), and section 10(d) of Pub. L. 92–463 (5 U.S.C. Appendix I).

Drug Abuse Biomedical Research Review Committee

February 22–26; 9:00 a.m.

Linden Hill Hotel, Sea Pines Room, 5400 Pooks Hill Road, Bethesda, Maryland 20014
Open—February 22, 9:00–9:30 a.m.
Closed—Otherwise
Contact: Dr. Alan A. Schreier, Executive Secretary, DABR, Room 10–42, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443–2620

Purpose

The Committee is charged with the initial review of applications for assistance from the National Institute on Drug Abuse for support

of research and research training activities and makes recommendations to the National Advisory Council on Drug Abuse for final review.

Agenda

From 9:00–9:30 a.m., February 22, the meeting will be open for discussion of administrative announcements and program developments. Otherwise, the Committee will be performing initial review of applications for assistance and will not be open to the public in accordance with the determination by the Administrator, Alcohol, Drug Abuse, and Mental Health Administration, pursuant to the provisions of 5 U.S.C. 552b(c)(6), and section 10(d) of Pub. L. 92–463 (5 U.S.C. Appendix I).

Psychiatric Nursing Education Review Committee

February 25; 8:30 a.m.

Conference Room H, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857
Open—February 25, 8:30–9:30 a.m.
Closed—Otherwise
Contact: Irma Fisher, Room 9C02, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443–4728

Purpose

The Committee is charged with the initial review of applications for assistance from the National Institute of Mental Health for support of activities in the field of psychiatric-mental health nursing personnel development, and makes recommendations to the National Advisory Mental Health Council for final review.

Agenda

From 8:30–9:30 a.m., February 25, the meeting will be open for discussion of administrative announcements and program developments. Otherwise, the Committee will be performing initial review of applications for assistance and will not be open to the public in accordance with the determination by the Administrator, Alcohol, Drug Abuse, and Mental Health Administration, pursuant to the provisions of 5 U.S.C. 552b(c)(6), and section 10(d) of Pub. L. 92–463 (5 U.S.C. Appendix I).

Mental Health Services Manpower Development Review Committee

February 25–26; 9:00 a.m.

Conference Room K, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857
Open—February 25, 9:00–10:00 a.m.
Closed—Otherwise
Contact: Irma Fisher, Room 9C02, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443–4728

Purpose

The Committee is charged with the initial review of applications for assistance from the National Institute of Mental Health for support of grants relating to the development of manpower to meet priority mental health service delivery needs and makes recommendations to the National Advisory Mental Health Council for final review.

Agenda

From 9–10 a.m., February 25, the meeting will be open for discussion of administrative announcements and program developments. Otherwise, the Committee will be performing initial review of applications for assistance and will not be open to the public in accordance with the determination by the Administrator, Alcohol, Drug Abuse, and Mental Health Administration, pursuant to the provisions of 5 U.S.C. 552b(c)(6), and section 10(d) of Pub. L. 92–463 (5 U.S.C. Appendix I).

Substantive information may be obtained from the contact persons listed above. Summaries of the meetings and rosters of Committee members may be obtained as follows: NIDA: Ms. Susan Lachter, Director, Office of Communications and Public Affairs, Room 10A–56, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443–1124. NIMH: Ms. Helen W. Garrett, Committee Management Officer, National Institute of Mental Health, Room 9–95, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. (301) 443–4333.

Dated: January 27, 1982.

Elizabeth A. Connolly,

Committee Management Officer, Alcohol, Drug Abuse, and Mental Health Administration.

[FR Doc. 82–2557 Filed 2–1–82; 8:45 am]

BILLING CODE 4160–20–M

Food and Drug Administration

[Docket No. 81F–0408]

Ciba-Geigy Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ciba-Geigy Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of hexamethylene bis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate) as an antioxidant in lubricants which have incidental contact with food.

FOR FURTHER INFORMATION CONTACT: Anthony P. Brunetti, Bureau of Foods (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, D.C., 202–472–5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 2B3595) has been filed by Ciba-Geigy Corp., Plastics and Additives Division, Ardsley, NY 10502, proposing that § 178.3570 *Lubricants with incidental food contact* (21 CFR 178.3570) be amended to provide for the safe use of hexamethylene bis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate) as an antioxidant in lubricants that have incidental food contact.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significanf impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c) (proposed December 11, 1979; 44 FR 71742).

Dated: January 25, 1982.

Sanford A. Miller,

Director, Bureau of Foods.

[FR Doc. 82–2424 Filed 2–1–82; 8:45 am]

BILLING CODE 4160–01–M

Health Resources Administration

Advisory Committee; 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 March, 1982:

Name: National Council on Health Planning and Development
Date and Time: March 18–19, 1982: 8:30 a.m.
Place: Auditorium, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, D.C. 20201
Open for entire meeting

Purpose: The National Council on Health Planning and Development is responsible for advising and making recommendations with respect to (1) the development of national guidelines under section 1501 of Pub. L. 93–641, (2) the implementation and administration of Title XV and XVI of Pub. L. 93–641, and (3) an evaluation of the implications of new medical technology for the organization, delivery and equitable distribution of health care services. In addition, the Council advises and assists the Secretary in the preparation of general regulations to carry out the purposes of section 1122 of the Social Security Act and on policy matters arising out of the implementation of it, including the coordination of activities under that section with those under other parts of the Social Security Act or under other Federal or federally assisted health programs. The Councils considers and advises the Secretary on proposals submitted by the Secretary under the provisions of section 1122(d)(2) that health care facilities or health maintenance organizations be reimbursed for expenses related to capital expenditures notwithstanding that under section 1122(d)(1) there would otherwise be exclusion of reimbursement for such expenses.

Agenda: The Role of Planning in a Pro-competitive Health System; Appreciation of services provided by Council staff; CT Scanning Standards/Regulations Update; and status reports by Health Resources Administration officials.

Note.—Plans do not currently exist for Councils Subcommittees to meet during these two days.

Anyone requiring information regarding the subject Council should write to or contact Mr. Paul Schwab, Executive Secretary, National Council on Health Planning and Development, Health Resources Administration, Room 10–27, Center Building, 3700 East-West Highway, Hyattsville, Maryland, 20782. Telephone (301) 436–7170.

Agenda items are subject to change as priorities dictate.

Dated: January 25, 1982.

Jackie E. Nylen,

Advisory Committee Management Officer, HRA.

[FR Doc. 82–2682 Filed 2–1–82; 8:45 am]

BILLING CODE 4160–15–M

Public Health Service

Health Maintenance Organizations

AGENCY: Public Health Service, HHS.

ACTION: Notice, continued regulation of health maintenance organizations: Reestablishment of compliance.

SUMMARY: On December 24, 1981, the Office of Health Maintenance Organizations (OHMO) notified HealthCare of Louisville, Inc. (HCL), 4545 Bishop Lane, Louisville, Kentucky 40210, a federally qualified health maintenance organization (HMO), that HCL had successfully reestablished compliance with its assurance to the Secretary that it would maintain a fiscally sound operation. This determination took effect on January 1, 1982.

FOR FURTHER INFORMATION CONTACT: Frank H. Seubold, Ph.D., Director, Office of Health Maintenance Organizations, Park Building—3rd Floor, 12420 Parklawn Drive, Rockville, Maryland 20857, 301/443–4106.

SUPPLEMENTARY INFORMATION: Under section 1312(b)(1) of the Public Health Service Act (42 U.S.C. 300e–11(b)(1)), if the Secretary makes a determination under section 1312(a) that a qualified HMO is not organized or operated in the manner prescribed by section 1301(c), then the HMO shall be (1) notified in writing of the determination, and (2) directed to initiate corrective action to bring it into compliance with the assurances it provided to the Secretary under section 1310(d)(1). Section 1312(b)(1) also provides that the Secretary shall publish in the **Federal Register** notices of determinations made under that section.

On May 12, 1978, HCL was officially notified that it was not in compliance with the assurance it had given the Secretary that it would maintain a fiscally sound operation as required by section 1301(c)(1)(A) of the Act. This determination, a notice of which was published at 45 FR 2109 on January 10, 1980, did not affect HCL's status as a federally qualified HMO. Subsequently, HCL implemented successfully corrective action to bring it into compliance with its assurances. On December 24, 1981, HCL was notified by OHMO that it had reestablished compliance with its assurance to the Secretary that it would maintain a fiscally sound operation. This determination took effect on January 1, 1982.

Dated: January 25, 1982.

Frank H. Seubold,

Director, Office of Health Maintenance Organizations.

[FR Doc. 82–2558 Filed 2–1–82; 8:45 am]

BILLING CODE 4160–17–M

Title XVI, Public Health Service Act, Health Resources Development; Delegation of Authority

Notice is hereby given that in furtherance of the delegation of November 20, 1980, by the Secretary of Health and Human Services to the Assistant Secretary for Health (46 FR 1032), which was amended on December 8, 1980 (45 FR 82721), the Assistant Secretary for Health has delegated to the Administrator, Health Resources Administration, all the authority delegated to the Assistant Secretary for Health under Title XVI of the Public Health Service Act (42 U.S.C. 3000 *et seq.)*, as amended, pertaining to health resources development. The authority delegated to the Administrator, Health Resources Administration, may be redelegated, except that the authority under Section 1602(f) concerning loan default prevention and protection of the interests of the United States in the event of default may be redelegated only after regulations establishing the terms of and conditions for making expenditures under 1602(f) are in effect.

The April 20, 1979 delegation (44 FR 25929–25930), from the Assistant Secretary for Health to the Administrator, Health Resources Administration, as it pertains to authorities under Title XVI of the Public Health Service Act, and the June 11, 1980 delegation (45 FR 45963–45964), from the Assistant Secretary for Health to the Administrator, Health Resources Administration, as it pertains to the authority under Section 1602(f) of the Public Health Service Act, have been superseded. Provision has been made for previous delegations and redelegations of authority under Title XVI of the Public Health Service Act to officials within the Health Resources Administration to continue in effect for no more than 60 days from the effective date of the delegation to the Administrator, Health Resources Administration, provided they are consistent with the delegation to the Administrator, Health Resources Administration.

The delegation to the Administrator, Health Resources Administration, became effective on January 19, 1982.

Dated: January 19, 1982.

Edward N. Brandt, Jr.,

Assistant Secretary for Health.

[FR Doc. 82–2703 Filed 2–1–82; 8:45 am]

BILLING CODE 4160–15–M

Public Health Service

Food and Drug Administration; Statement of Organization, Functions, and Delegations of Authority

Correction

In FR Doc. 82–1837, appearing on page 3608, in the issue of Tuesday, January 26, 1982, make the following change:

In the third column, the Table should appear as set forth below:

State and city	Type of office	Address and zip code
New York:		
Brooklyn	Field/District Office Import District Office.	850 Third Ave. 11232
Buffalo	New York Laboratory Div. District Office.	599 Delaware Ave. 14202

BILLING CODE 1505–01–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[Serial Number: A 15962]

Arizona; Realty Action—Noncompetitive Sale—Public land in Maricopa County, Ariz.

The following described lands have been determined to be suitable for disposal by noncompetitive public sale under Section 203 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1716:

Township 7 North, Range 2 East, G & SRM

Section 27, Lot 48.

Containing .758 Acres.

Purpose of the sale is to legalize an encroachment on public land dating back more than 13 years. Purchaser will be Gustavious W. and Norma Jean Comeaux.

The lands involved are an integral part of a long-established permanent building which is situated on the subject land and the adjacent privately owned Lot 18.

Provisions in 43 CFR 2711.3–2(2)(b) provide for noncompetitive sale when, in the opinion of the authorized officer, the public interest would best be served by a direct sale.

There is need to recognize that the Comeaux's existing business would be threatened if the tract were purchased by another party.

Management of the parcel by the Bureau is considered to be uneconomical and difficult. Disposal of the subject land is consistent with the Bureau's land-use planning. No other agency or group has expressed interest in acquisition of the parcel.

An appraisal has been completed and a fair-market value of $7,500.00 will be charged for the lands.

There will be reserved to the United States right-of-way for ditches and canals pursuant to the Act of August 30, 1980, 26 Stat. 391, 43 U.S.C. 945. Mineral estate will be reserved to the United States per 43 CFR 2711.5–1.

Detailed information concerning this public sale, including the environmental assessment and the record of public input is available for review at the Phoenix District Office, Bureau of Land Management, 2929 West Clarendon Avenue, Phoenix, Arizona.

For a period of 45 days, interested parties may submit comments to the Phoenix District Manager, 2929 West Clarendon Avenue, Phoenix, Arizona 85017. Any adverse comments will be evaluated by the Secretary of the Interior, who may vacate or modify this realty action and issue a final determination. In the absence of any action by the Secretary, this realty action will become the final determination of the Department of the Interior and the required payment plus the cost of publishing this notice will be requested of Gustavious and Jean Comeaux. Such payment in full is in accordance with 43 CFR 1822.1–2.

Dated: January 21, 1982.

William K. Barker,

District Manager.

[FR Doc. 82–2664 Filed 2–1–82; 8:45 am]

BILLING CODE 4310–84–M

[Serial No. A 17000–I (Partial)]

Arizona; Classification of Public Lands for State Indemnity Selection

1. The Arizona State Land Department has filed a petition for classification and application to acquire the lands described in paragraph 5 below, under the provisions of the Act of June 20, 1910 (36 Stat. 557), as amended, in lieu of certain school lands that were encumbered by other rights or reservations before the State's title could attach. This application has been assigned the serial number A 17000–I.

2. The Bureau of Land Management will examine these lands for evidence of prior valid rights or other statutory constraints that would bar transfer. Those lands found suitable for transfer will be held to be classified 60 days from date of publication of this notice in the **Federal Register**. Classification is pursuant to Title 43 Code of Federal Regulations, Subpart 2400 and Section 7 of the Act of June 28, 1934.

3. Information concerning these lands and the proposed transfer to the State of Arizona may be obtained from the District Manager, Yuma District Office, Bureau of Land Management, P.O. Box 5680, Yuma, Arizona 85364 (602–726–6300) or the District Manager, Phoenix District Office, Bureau of Land Management, 2929 West Clarendon Avenue, Phoenix Arizona 85017 (602–241–2854).

4. For a period of 60 days from the date of publication of this notice in the **Federal Register** (until April 5, 1982), all persons who wish to submit comments on the above classification may present their views in writing for consideration to the Phoenix District Manager, Bureau of Land Management, 2929 West Clarendon Avenue, Phoenix, Arizona 85017. As provided by Title 43 Code of Federal Regulations, Subpart 2462.1, a public hearing will be scheduled by the District Managers if they determine that sufficient public interests exists to warrant the time and expense of a hearing.

5. The lands included in this classification are located in Yuma and Mohave Counties, Arizona and are described as follows: (footnotes correspond to numbered authorized users or applicants listed in Paragraph 6).

Application A 17000–I (Partial)

Gila and Salt River Meridian, Arizona

T. 1 N., R. 23 W.,
Sec. 1, Lots 1, 2, 3, 4, S½, S½; [1 4]
Sec. 12, N½; [1 3 4]
Sec. 14, N½; [2 4]
Sec. 27, NW¼NW¼.[2 4]
Total—Approximately 1,320.80 acres.

T. 2 N., R. 22 W.,
Sec. 3, Lots 1, 2, S½NE¼; [1 2 3]
Sec. 16, W½; [2 3]
Sec. 17, SE¼; [2 4]
Sec. 30, E½; [2 4]
Sec. 31, Lots 1 thru 16 incl., E½.[2 4]
Total—Approximately 1,909.91 acres.

T. 2 N., R. 23 W.,
Sec. 36, E½.[1 2]
Total—Approximately 320.00 acres.

T. 3 N., R. 21 W.,
Sec. 19, Lots 1, 2, 3, 4, SW¼NE¼, SE¼NW¼, E½SW¼, W½SE¼, SE¼SE¼.[1 2]
Total—Approximately 423.44 acres.

T. 3 N., R. 22 W.,
Sec. 15, SE¼; [1 2 3]
Sec. 23, N½N½, N½S½N½; [3 4]
Sec. 24, NE¼, E½NW¼, SW¼NW¼, N½S½, E½SE¼SE¼.[1 3 4]
Total—Approximately 860.00 acres.

T. 8 N., R. 18 W.,
Sec. 32, N½, NE¼SW¼, N½SE¼, SE¼SE¼; [1 2 3]
Sec. 36, NW¼.[1 2 3]
Total—Approximately 640.00 acres.

T. 9 N., R. 19 W.,
Sec. 2, Lots 1–6 incl., S½NE¼, SE¼NW¼, SE¼SW¼, E½SW¼SE¼, E½SE¼.[1 2 3]
Total—Approximately 503.67 acres.

T. 10 N., R. 19 W.,
Sec. 1, Lot 3; [1 2 3 6]
Sec. 23, All except Mineral Survey 4406–A; [1 2 3 6]
Sec. 24, W½W½; [6]
Sec. 25, SW¼NE¼NW¼, W½NW¼, W½SE¼NW¼, SE¼SE¼NW¼, SW¼, SW¼SE¼, S½SE¼; [2 4 6]
Sec. 26, All; [2 3 4 5 6]
Sec. 35, N½NE¼, NE¼NW¼; [3 6]
Sec. 36; NW¼NW¼.[6]
Total—Approximately 1,944.33 acres.

T. 19 N., R. 21 W.,
Sec. 7, Lot 4, SE¼SW¼; [4]
Sec. 17, All; [4]
Sec. 18, Lots 1, 2, 3, 4, E½2W½, E½; [1 2 4 5]
Sec. 19, Lots 1, 2, 3, 4, E½W½, E½; [2 4]
Sec. 20, All; [4 5]
Sec. 21, All; [4]
Sec. 28, N½N½; [4 5]
Sec. 29, N½N½; [4]
Sec. 30, Lot 1, N½NE¼, NE¼NW¼.[2 3 4 6]
Total—Approximately 3,759.49 acres.

T. 19 N., R. 22 W.,
Sec. 12, S½S½; [1 2 3 4]
Sec. 24, N½, E½SW¼, E½NW¼SW¼, NW¼NW¼SW¼, SE¼.[1 2 3 4]
Total—Approximately 750.00 acres.

T. 21 N., R. 21 W.
Sec. 26, All; [3 4]
Sec. 28, All; [1 3]
Sec. 34, All.[2 3]
Total—Approximately 1920.00 acres.

T. 15, R. 23 W.,
Sec. 5, SW¼NW¼, W½SW¼; [2 3]
Sec. 20, W½W½W½.[1 2 3]
Total—Approximately 200.00 acres.

The total acreage described above on Application A 17000–I is approximately 14,551.64 acres.

6. The following listed corporations and individuals are holders of or applicants for leases, permits, withdrawals, and/or rights-of-way on the public lands described in Paragraph 5 above:

T. 1 N., R. 23 W.,

Grazing Lessees

1. Anita W. Williams and Juanita W. Loomis, c/o Juanita W. Loomis, 2150 Ave. A, Apt 54, Yuma, AZ 85364.
2. Lewis C. Biship, P.O. Box 111, Ehrenberg, AZ 85334.

Range Improvement

3. Juanita A. Loomis; Fence; No. 0604.

Oil and Gas Lease Application

4. Robert P. Kunkel, 757 Northcliffe Drive, Salt Lake City, Utah 94103, A 17129, A 17131.

T. 2 N., R. 22 W.,

Rights-of-Way

1. Southern California Edison Company, P.O. Box 410, Long Beach CA 90801, A 9878.

Grazing Lessee

2. Anita W. Williams and Juanita W. Loomis, c/o Juanita W. Loomis, 2150 Avenue A., Apt 54, Yuma, AZ 85364.

Oil and Gas Leases

3. Joe Lyon, Jr., 600 E. Capitol Street, Salt Lake City, UT 84103, A 17139.
4. Grant Gaeth, 621 17th Street, Suite 811, Denver, CO 80203, A 17125, A 17126.

T. 2 N., R. 23 W.,

Grazing Lessee

1. Anita W. Williams and Juanita W. Loomis, c/o Juanita W. Loomis, 2150 Avenue A., Apt 54, Yuma, AZ 85364.

Oil and Gas Lease

2. Robert P. Kunkel, 757 Northcliffe Drive, Salt Lake City, UT 84103, A 17129.

T. 3 N., R. 21 W.,

Grazing Lessee

1. Anita W. Williams and Juanita W. Loomis, c/o Juanita W. Loomis, 2150 Avenue A, Apt 54, Yuma, AZ 85364.

Oil and Gas Lease Application

2. Joe Lyon, Jr., 600 E. Capitol Street, Salt Lake City, UT 84103, A 17107.

T. 3 N., R. 22 W.,

Rights-of-Way

1. Arizona Department of Transportation, 205 S. 17th Avenue, Phoenix, AZ 85007, AR 030099.
2. El Paso Natural Gas Company, Box 1492, El Paso, TX 79978, PHX 083225, AR 03819, A 2136, A 4476.

Grazing Lessee

3. Anita W. Williams and Juanita W. Loomis, c/o Juanita W. Loomis, 2150 Avenue A., Apt 54, Yuma, AZ 85364.

Oil and Gas Lease Application

4. Joe Lyon, Jr., 600 E. Capitol Street, Salt Lake City, UT 84103, A 17174.

T. 8 N., R. 18 W.,

Right-of-Way

1. Atchison-Topeka and Santa Fe R.R., Santa Fe Railway Company, 80 E. Jackson Blvd., Room 235, Chicago, IL 60604.

Grazing Lessee

2. Keith W. Pierson, Rt. 1, Box 178, Blythe, CA 92225.

Oil and Gas Lease

3. Marshall R. Young Oil Co., 750 W. Fifth Street, Fort Worth, TX 76102, A 15335, A 15336.

T. 9 N., R. 19 W.,

Right-of-Way

1. U.S. Bureau of Reclamation, Parker Dam Project, P.O. Box 392, Phoenix, AZ 85073, A 7316, PHX 086406.

Grazing Lessee

2. Robert H. and James E. Jones, P.O. Box 924, Parker, AZ 85344.

Cooperative Agreement

3. Robert H. Jones; Fence, No. 4352.

T. 10 N., R. 19 W.,

Rights-of-Way

1. U.S. Bureau of Reclamation, Parker Dam Project, P.O. Box 392, Phoenix, AZ 85073, PHX 080583, PHX 085708.
2. Continental Telephone Co. of California 16071 Marjorie Drive, Victorville, CA 92392, AR 033005, A 11568.
3. U.S. Department of Interior, Colorado River Agency, Power Section, Rt 1, Box 9–C, Parker, AZ 85344, AR 02975, A 14738.
4. Arizona Department of Transportation, 205 S. 17th Avenue, Phoenix, AZ 85007, A 13975.
5. U.S. Geological Survey, Office of Earthquake Studies, 345 Middlefield Road, Menlo Park, CA 94025, A 9894.

Grazing Lessee

6. Robert H. and James E. Jones, P.O. Box 924, Parker, AZ 85344.

T. 19 N., R. 21 W.,

Rights-of-Way

1. Mohave County Board of Supervisors, P.O. Box 390, Kingman, AZ 86402, A12433.
2. Mohave Electric Co-op, Inc., P.O. Box 711, Kingman, AZ 86401, A 1876.
3. Transwestern Pipeline Co., P.O. Box 1612, Shreveport, LA 71102, A 4545.

Grazing Lessee

4. Albert Bojorquez, P.O. Box 277, Bullhead City, AZ 86430.

Oil and Gas Leases

5. Patrick Petroleum Corporation of Michigan, 950 17th Street, Suite 1655, Denver, CO 80202, A 15592.
6. NCC Energy, Inc., 1300 N. 17th Street, Suite 1300, Rosslyn, VA 22209, A 16981.

T. 19 N., R. 22 W.,

Rights-of-Way

1. Transwestern Pipeline Company, P.O. Box 1612, Shreveport, LA 71102, A 4545.
2. Mohave County Board of Supervisors, P.O. Box 390, Kingman, AZ 86402, A 15807.

Grazing Lessee

3. Albert Bojorquez, P.O. Box 277, Bullhead City, AZ 86430.

Oil and Gas Lease

4. Patrick Petroleum Corporation of Michigan, 950 17th Street, Suite 1655, Denver, CO 80202, A 15593.

T. 21 N., R. 21 W.,

Rights-of-Way

1. Citizens Utilities Company, Hualapai Branch, Box 8128, Kingman, AZ 86401, A 9222.
2. Black Mesa Pipeline, Inc., 610 S. Main Street, Los Angeles, CA 90014, A 438.

Grazing Lessee

3. Florence Landon, P.O. Box 142, Glendora, CA 91740.

Oil and Gas Lease

4. Corbin J. Robertson, 601 Jefferson Street, Cullen Center, Houston, TX 77002.

T. 1 S. R. 23 W.,

Right-of-Way

1. Francisco Grande Development Company, c/o Franklin Gibson, 525 W. Southern, Mesa, AZ 85702, A 11888.

Grazing Lessee

2. Lewis C. Bishop, P.O. Box 111, Ehrenberg, AZ 85334.

Oil and Gas Lease

3. Robert P. Kunkel, 757 Northcliffe Drive, Salt Lake City, UT 84103, A 17133, A 17134.

7. Rights-of-way granted by BLM will transfer with the land. Oil and gas leases will remain in effect under the terms and conditions of the lease. State Law and Land Department procedures (R 12–5–154 D Administrative Rules and Regulations, Arizona State Land Department) provide for the offering to holders of BLM grazing permits the first right to lease lands that are transferred to the State. this constitutes official notice to grazing lessees that their Bureau of Land Management leases will be terminated in part upon transfer of the land to the State of Arizona.

Dated: January 6, 1982.

Raymond G. Evans,

Acting District Manager.

Dated: January 15, 1982.

Gary A. McVicker,

Assistant District Manager.

[FR Doc. 82–2559 Filed 2–1–82; 8:45 am]

BILLING CODE 4310–84–M

[Serial Nos. A 17000–J (Partial), A 17000–K (Partial), A 17000–U (Partial), A 17000–W (Partial)]

Arizona; Classification of Public Lands for State Indemnity Selection

1. The Arizona State Land Department has filed a letter of intent to

acquire and a petition for classification and application to acquire the lands described in paragraph 5 below, under the provisions of the Act of June 10, 1910 (36 Stat. 557), as amended, in lieu of certain school lands that were encumbered by other rights or reservations before the State's title could attach. These applications have been assigned the serial numbers A 17000–J, A 17000–K, A 17000–U, and A 17000–W. This notice applies to portions of the total applications.

2. The Bureau of Land Management will examine these lands for evidence of prior valid rights or other statutory constraints that would bar transfer. Those lands found suitable for transfer will be held to be classified on or before April 5, 1982. Classification is pursuant to Title 43 Code of Federal Regulations, Subpart 2400 and Section 7 of the Act of June 28, 1934.

3. Information concerning these lands and the proposed transfer to the State of Arizona may be obtained from the District Manager, Yuma District Office, Bureau of Land Management, P.O. Box 5680, Yuma, Arizona 85364 (602–726–6300) or the District Manager, Phoenix District Office, Bureau of Land Management, 2929 West Clarendon Avenue, Phoenix, Arizona 85017 (602–241–2854).

4. On or before April 5, 1982 all persons who wish to submit comments on the above classification may present their views in writing for consideration to the Phoenix District Manager, Bureau of Land Management, 2929 West Clarendon Avenue, Phoenix, Arizona 85017. As provided by Title 43 Code of Federal Regulations, Subpart 2462.1, a public hearing will be scheduled by the District Managers if they determine that sufficient public interest exists to warrant the time and expense of a hearing.

5. The lands included in this classification are located in Yuma and Mohave Counties, Arizona and are described as follows: (footnotes correspond to numbered authorized users or applicants listed in Paragraph 6).

Application A 17000–J (Partial); Application A 17000–K (Partial); Application A–17000–U (Partial); Application A 17000–W (Partial).

Gila and Salt River Meridian, Arizona

T. 1 N., R. 23 W.,
Sec. 11, E½, E½W½, E½NW¼SE¼, SW¼SE¼; [1, 2, 3, 5, 6]
Sec. 15, E½SE¼, E½SW¼SE¼; [1, 2, 4, 6]
Sec. 22, NE¼NW¼, S½NW¼, SW¼; [1, 2, 4, 6]
Sec. 28, E½NE¼, SE¼SW¼, NE¼SE¼; [1, 2, 4, 6]
Sec. 33, SW¼SW¼. [1, 2, 4, 6]
Total: Approximately 1,120.00 acres.

T. 2 N., R. 22 W.,
Sec. 3, S½NW¼; [1, 2, 3, 4]
Sec. 4, SE¼SW¼, NE¼SE¼, S½SE¼; [1, 2, 3, 4, 5]
Sec. 8, SE¼NE¼, E½E½SW¼, SE¼; [1, 2, 4, 5]
Sec. 9, W½; [1, 2, 4, 5]
Sec. 17, NE¼NE¼, S½NE¼, NE¼SW¼, S½SW¼; [1, 2, 4, 5]
Sec. 18, SE¼SE¼SE¼; [1, 2, 4, 5]
Sec. 19, Lots 9, 10, 11, 13, 14, 15, 16, NE¼NE¼, S½NE¼, SE¼; [1, 2, 4, 5]
Sec. 30, Lots 1, 2, 6–10 incl., 12–20 incl.; [1, 2, 4]
Total: Approximately 2,309.81 acres.

T. 3 N., R. 21 W.;
Sec. 4, NW¼SW¼, N½SW¼SW¼, SW¼SW¼SW¼, W½SE¼SW¼SW¼, N½NE¼SE¼SW¼SW¼, N½SE¼SW¼, N½NW¼SW¼SE¼SW¼, E½SW¼SE¼SW¼, SE¼SE¼SW¼; [1, 2, 3, 4, 5, 8, 9]
Sec. 5, SW¼NW¼, S½; [1, 2, 3, 4, 5, 8, 9]
Sec. 6, Lots 6, 7, SE¼NE¼, E½SW¼, SE¼; [1, 2, 3, 4, 5, 8, 9]
Sec. 7, Lots 1, 2, E½NW¼, NE¼; [1, 3, 4, 5, 8, 9]
Sec. 8, N½N½, N½S½N½, SE¼SW¼; [1, 3, 4, 6, 8, 9]
Sec. 9, N½NE¼, E½NE¼NW¼, NE¼NW¼NE¼NW¼, S½NW¼NW¼ NE¼NW¼, S½NW¼NE¼NW¼, SW¼NE¼NW¼, SE¼NW¼NW¼, NW¼NE¼NW¼NW¼, S½NE¼NW¼ NW¼, S½NE¼NE¼NW¼NW¼, W½NW¼NW¼; [1, 3, 6, 7, 8, 9]
Total: Approximately 1,612.65 acres.

T. 3 N., R. 22 W.
Sec. 1, Lots 1, 2, 3, 4, S½N½, S½ (All); [1, 3, 4, 5, 6, 8, 9]
Sec. 12, N½; [1, 8, 9]
Sec. 14, S½NW¼, SW¼; [1, 5, 6, 8, 9]
Sec. 15, Lot 4, E½NE¼, SE¼; [1, 2, 4, 5, 6, 8, 9]
Sec. 22, Lots 1, 5, 6, 9, NE¼, NE¼NW¼, E½SE¼, NW¼SE¼; [1, 2, 8, 9]
Sec. 27, Lots 1, 4, 5, 8, E½E½; [1, 2, 8, 9]
Total: Approximately 2,089.54 acres.

T. 9 N., R. 19 W.
Sec. 1, Lots 1, 2, 3, 4, S½N½, N½S½; [1, 10, 11, 12]
Sec. 3, Lot 7; [10, 13]
Sec. 12, NE¼; [1, 2, 10]
Sec. 14, Lots 5, 6, 7, 8; [4, 5, 6, 7, 8, 9, 10, 13, 14]
Sec. 22, Lot 5; [10, 14]
Sec. 23, Lots 1, 2, 3, 4, E½, E½NW¼, E½SW¼, SW¼SW¼; [10, 14, 15, 16]
Sec. 26, All; [10]
Sec. 27, Lots 5–8, E½SE¼; [10, 14]
Sec. 34, Lots 5–8, NE¼NE¼, S½NE¼, SE¼; [10, 14]
Sec. 35, All; [10]
Total: Approximately 3,206.23 acres.

T. 10 N., R. 18 W.
Sec. 5, Lot 4, SW¼NW¼, SW¼; [1, 7]
Sec. 6, Lots 1, 6, 7; Lots 8, 9, East of Hwy 95, SE¼NE¼, SE¼; [1, 2, 3, 4, 5, 6, 7]
Sec. 7, Lots 1, 2, 3, 4, NE¼, N½SE¼, SW¼SE¼; [1, 7]
Sec. 18, Lot 1, NW¼NE¼; [1, 7]
Total: Approximately 1,211.82 acres.

T. 10 N., R. 19 W.
Sec. 13, NE¼, E½NW¼, SW¼NW¼, W½SW¼; [4, 6]
Sec. 14, Lots 4, 5, 6, NE¼NE¼, SW¼NE¼, NE¼SW¼, SW¼SW¼ all east of Hwy 95; SE¼NE¼, SE¼SW¼, SE¼; [1, 2, 3, 4, 5, 6, 8, 9]
Sec. 22, Lot 5, NE¼NE¼ all east of Hwy 95; SE¼NE¼, NE¼SE¼; [1, 2, 3, 4, 6]
Sec. 34, Lot 7, E½SE¼; [6, 7]
Sec. 35, SW¼; [3, 6]
Sec. 36, SW¼SW¼; [6]
Total: Approximately 1,205.84 acres.

T. 11 N., R. 18 W.
Sec. 13, SW¼SW¼; [1, 2, 3, 4, 5, 6]
Total: Approximately 40.00 acres.

T. 13 N., R. 19 W.
Sec. 20, N½SW¼; [1]
Total: Approximately 80.00 acres.

T. 14 N., R. 20 W.
Sec. 4, Lot 4, SW¼NW¼, SW¼, SW¼SE¼; [3, 4, 5, 9, 10]
Sec. 5, Lots 1, 2, 3, 4, S½N½, S½; [5, 6, 9]
Sec. 8, All; [5, 6, 7, 9, 10]
Sec. 9, All; [3, 4, 5, 9]
Sec. 27, NE¼; [4, 8, 9]
Sec. 28, NE¼; [1, 2, 9]
Total: Approximately 2,517.21 acres.

T. 15 N., R. 20 W.
Sec. 32, All; [1, 2, 3, 4, 5, 6, 7]
Sec. 33, NW¼, W½SW¼; [1, 2, 3, 4, 5, 6, 7]
Total: Approximately 880.00 acres.

T. 20 N., R. 22 W.
Sec. 20: Lots 5, 6, W½SE¼, SW¼; [1, 2, 3, 4, 5, 6, 7]
Total: Approximately 268.72 acres.

T. 1 S., R. 23 W.
Sec. 6, NE¼SE¼, E½SE¼SE¼; [1, 4, 5, 6]
Sec. 7, E½E½; [1, 2, 6]
Sec. 18, NE¼NE¼, E½SE¼; [1, 2, 6]
Sec. 19, E½NE¼, NE¼SE¼; [1, 3, 6]
Sec. 29, W½NW¼, NW¼SW¼; [1, 2, 7]
Total: Approximately 590.00 acres.

T. 9 S., R. 25 W.
Sec. 24: Lots 1, 3, 4, 5; [1, 2, 3, 4, 7, 8]
Sec. 35: Lots 8, 9, 12, 13, E½SE¼; [1, 2, 3, 4, 5, 6, 8]
Total: Approximately 213.22 acres.

T. 10 S., R. 15 W.
Sec. 2: Lots 12, 15, 16, 17, 19; [1, 2, 3, 4, 5, 6]
Total: Approximately 89.25 acres.

The total acreage described above is approximately 17,424.23 acres.

6. The following listed corporations and individuals are holders of or applicants for leases, permits, withdrawals, and/or rights-of-way on the public lands described in paragraph 5 above:

Gila and Salt River Meridian

All withdrawals hereafter listed are under the management of the Bureau of Reclamation, Lower Colorado Regional Office, P.O. Box 427, Boulder City, Nevada 89005.

T. 1 N., R. 23 W.

Withdrawals

1. SO 1–31–1903: Temporary withdrawal Colorado River Survey.
2. SO 2–19–1929: Colorado River Storage Project.

Grazing Lessees

3. Anita W. Williams and Juanita W. Loomis, c/o Juanita W. Loomis, 2150 Avenue A, Apt 54, Yuma, AZ 85364.
4. Lewis C. Biship, P.O. Box 111, Ehrenberg, AZ 85334.

Range Improvement

Juanita A. Loomis; Fence; No. 0604

Oil and Gas Lease and Application

Robert P. Kunkel, 757 Northcliffe Drive, Salt lake City, Utah 84103, A–17129, A–17131, T. 2 N., R. 22 W.

Withdrawals

1. SO 1–31–1903: Temporary withdrawal, Colorado River Survey.
2. SO 2–19–1929: Colorado River Storage Project.

Right-of-Way

3. Southern California Edison Co., P.O. Box 410, Long Beach, CA 90801, A 9878.

Grazing Lessee

4. Anita W. Williams and Juanita W. Loomis, c/o Juanita W. Loomis, 2150 Avenue A, Apt 54, Yuma, AZ 85364.

Oil and Gas Lease Application

5. Joe Lyon, Jr., 600 E. Capitol Street, Salt Lake City, Utah 84103.
T. 3 N., R. 21 W.

Withdrawals

1. SO 1–31–1903: Temporary withdrawal, Colorado River Survey.

Rights-of-Way

2. American Telephone and Telegraph Co., 74 New Montgomery Street, San Francisco, CA 94119, PHX 083392.
3. Arizona Department of Transportation, 205 So. 17th Avenue, Phoenix, AZ 85007, PHX 079556, PHX 083769, PHX 083770, AR 0330099, A 4343.
4. Arizona Public Service Company, P.O. Box 21666, Phoenix, AZ 85036, A 6223, A 9278, A 9576.
5. Southwestern Telephone Company, P.O. Box 238, Salome, AZ 85348, A 8879, A 9594.
6. El Paso Natural Gas Co., P.O. Box 1492, El Paso, TX 79978, PHX 083225, AR 03819, A 2136, A 3952, A 4476.
7. Mrs. Juanita Loomis, 2150 Avenue A, Apt 54, Yuma, AZ 85364, AR 0351.

Grazing Lessee

8. Anita W. Williams and Juanita W. Loomis, c/o Juanita W. Loomis, 2150 Avenue A, Apt 54, Yuma, AZ 85364.

Oil and Gas Lease Application

9. Joe Lyon, Jr., 600 E. Capitol Street, Salt Lake City, Utah 84103, A 17107.
T. 3 N., R. 22 W.

Withdrawals

1. SO 1–31–1903: Temporary Withdrawal, Colorado River Survey.
2. SO 1–19–1929: Colorado River Storage Project.

Rights-of-Way

3. Arizona Public Service Company, Box 21666, Phoenix, AZ 85036, A 6223.
4. American Telephone and Telegraph Company, 74 New Montgomery Street, San Francisco, CA 94119, PHX 083392.
5. Arizona Department of Transportation, 205 S. 17 Avenue, Phoenix, AZ 85007, PHX 083773, AR 030099.
6. El Paso Natural Gas Company, Box 1492, El Paso, TX 79978, PHX 083225, AR 033819, A 2136, A 4476.
7. Yuma County Highway Department, 2703 S. Avenue B, Yuma, AZ 85364, R. S. 2477 (Cibola Road).

Grazing Lessee

8. Anita W. Williams and Juanita W. Loomis, c/o Juanita W. Loomis, 2150 Avenue A, Apt 54, Yuma, AZ 85364.

Oil and Gas Lease Application

9. Joe Lyon, Jr., 600 E. Capitol Street, Salt Lake City, UT 84103, A 17174.
T. 9 N., R. 19 W.

Rights-of-Way

1. Bureau of Reclamation, Parker Dam Project, P.O. Box 392, Phoenix, AZ 85073, A 3756, A 7316.
2. Arizona Public Service Company, P.O. Box 21666, Phoenix, AZ 85037, AR 031091.
3. Bureau of Reclamation, Arizona Project Office, 201 N. Central Avenue, Phoenix, AZ 85073, PHX 086406.
4. Parker Amateur Radio Assoc. Inc., Box AF, Parker, AZ 85344, A 7037.
5. Cactus Radio Club, Box 18077, Irvine, CA 92713, A 7037–A.
6. Parker Community Hospital, Box 1149, Parker, AZ 85344, A 7037–B.
7. San Bernardino County, Forestry and Fire Department, 3800 Sierra Way, San Bernardino, CA 92405, A 7037–C.
8. Gilbert Leivas, P.O. Box 774, Parker, AZ 85344, A 7037–D.
9. Continental Telephone Company of CA, 16071 Mojave Drive, Victorville, CA 92392, A 7227.

Grazing Lessee

10. Rober H. and James E. Jones, P.O. Box 924, Parker, AZ 85344.

Cooperative Agreements and Range Improvements

11. Robert H. Jones: Corrals; No. 4530.
12 Robert H. Jones: Windmill and well; No. 4537.
13 Robert H. Jones: Fence; No. 4352
14. Robert H. Jones: Fence; No. 0424.
15. Robert H. Jones: Corral; No. 4531.
16. Robert H. Jones: Well; No. 4538.
T. 10 N., R. 18 W.

Withdrawals

1. SO 10/16/1931; Colorado River Storage Project.

Rights-of-Way

2. U.S. Bureau of Reclamation, Parker Dam Project, P.O. Box 392, Phoenix, AZ 85073, PHX 080583, PHX 085708.
3. Bureau of Indian Affairs, Colorado River Agency, Route 1, Box 9–C, Parker, AZ 85344, AR 02975, A 6929.
4. Continental Telephone Company of California, 16071 Marjorie Drive, Victorville, CA 92392, AR 033005.
5. Arizona Department of Transportation, 205 S. 17th Avenue, Phoenix, AZ 85007, AR 022113.
6. Lagrand D. Hunt, Route 2, Box 665, Parker, AZ 85344, A 16127.

Grazing Lessee

7. Robert H. and James E. Jones, P.O. Box 924, Parker, AZ 85344.
T. 10 N., R. 19 W.

Concession Contracts

8. Fox's Pierpoint Landing, c/o Jerry L. Davis, P.O. Box 646, Parker, AZ 85344, Y 0037.
9. Red Rock Camp Grounds, c/o LaGrand D. Hunt, Route 2, Box 665, Parker, AZ 85344, A 12740.
T. 10 N., R. 19 W.

Withdrawals

1. SO 3/14/1929: Colorado River Storage Project. SO 1/31/1903: Temporary Withdrawal Colorado River Project. SO 9/8/1903: Temporary Withdrawal Colorado River Project.

Rights-of-Way

2. Continental Telephone Company of California, 16071 Marjorie Drive, Victorville, CA 92392, AR 03305, A 7632, A 11568.
3. U.S. Bureau of Reclamation, Parker Dam Project, P.O. Box 392, Phoenix, AZ 85073, PHX 080583, PHX 085708.
4. Bureau of Indian Affairs, Colorado River Agency, Power Section, Rt 1, Box 9–C, Parker, AZ 85344, AR 02975, A 9572, A 14738.
5. Buckskin Fire Department, Rt 1, Box 779, Parker, AZ 85344, A8493.

Grazing Lessee

6. Robert H. and James E. Jones, P.O. Box 924, Parker, AZ 85344,

Cooperative Agreement

7. Robert H. Jones: Fence; No. 4352.
T. 11 N., R. 18 W.

Withdrawals

1. SO 6/4/1930: Colorado River Storage Project.
2. SO 10/16/1931: Colorado River Storage Project.

Rights-of-Way

3. U.S. Bureau of Reclamation, Arizona Projects Office, 2200 Valley Bank Center, Phoenix, AZ 85073, PHX 080802.
4. Yuma County Board of Supervisors, P.O. Box 1112, Yuma, AZ 85364, A 1379.
5. Continental Telephone Company of California, 16071 Marjorie Drive, Victorville, CA 92392, A 11807.

Grazing Lessee

6. Arizona Ranch and Metals Company, c/o Walker Smith, 1518 Walker Bank Building, Salt Lake City, UT 84111.
T. 13 N., R. 19 W.

Grazing Lessee

1. Havasu Heights Ranch and Development Company, c/o John R. Snowberger, 1712 Guaranty Bank, Phoenix, AZ 85012.
T. 14 N., R. 20 W.

Withdrawals

1. SO 10/16/1981: Colorado River Storage Project.
2. SO 6/4/1930: Colorado River Storage Project.

Rights-of-Way

3. U.S. Bureau of Reclamation, Davis Dam Project, 2200 Valley Bank Center, Phoenix, AZ 85073, PHX 01868, PHX 085193.
4. Arizona Department of Transportation, 205 S. 17th Avenue, Phoenix, AZ 85007, A 4315.
5. Citizens Utilities Company, Hualapai Branch, Box 8128, Kingman, AZ 86401, PHX 034352, AR 033292, A 1626, A 7475, A 11483.
6. Southern Union Gas Co., 1800 First International Bldg., Dallas, TX 75270, AR 035651.
7. Mohave County Board of Supervisors, 315 Oak Street, Kingman, AZ 86401, A 11858.
8. Lake Havasu Irrigation and Drainage District, P.O. Box 1070, Kingman, AZ 86401, AR 034058.

Grazing Lessee

9. Havasu Heights Ranch and Development Co., c/o John R. Snowberger, 1712 Guaranty Bank, Phoenix, AZ 85012.

Oil and Gas Lease Application

10. NCC Energy, Inc., 1300 North 17th Street, Suite 1300, Rosslyn, VA 22209, A 16979.
T. 15 N., R. 10 W.

Rights-of-Way

1. Southern Union Gas Co., 1800 First International Bldg., Dallas, TX 75270, AR 035651, AR 035651–A.
2. Arizona Department of Transportation, 205 S. 17th Avenue, Phoenix, AZ 85007, A 4315.
3. U.S. Bureau of Reclamation, Davis Dam Project, 2200 Valley Bank Center, Phoenix, AZ 85073, PHX 085193.
4. Citizen's Utilities Co., P.O. Box 111, Kingman, AZ 85401, PHX 034352, A 7475.
5. Mohave County Board of Supervisors, 315 Oak Street, Kingman, AZ 86401, A 2690, A 4512.

Grazing Lessee

6. Havasu Heights Ranch and Development Company, c/o John R. Snowberger, 1712 Guaranty Bank, Phoenix, AZ 85012.

Oil and Gas Lease

7. J. Charles Hollimon, Suite 620, N. E. Loop 410, San Angelo, TX 78209, A 15364.
T. 20 N., R. 22 W.

Withdrawal

1. SO 10/16/1931: Colorado River Storage Project.

Rights-of-Way

2. Southwest Gas Corporation, 5241 Spring Mt. Road, P.O. Box 15015, Las Vegas, NV 89114, AR 035674.
3. American Telephone and Telegraph Company, 74 New Montgomery Street, San Francisco, CA 94119, AR 033057.
4. El Paso Natural Gas Co., P.O. Box 1492, El Paso, TX 79999, AR 032213, AR 035765, A 5979.
5. Citizens Utilities Company, P.O. Box 111, Kingman, AZ 86401, AR 032145, A 6380.
6. Mohave Electric Coop Inc., P.O. Box 1045, Bullhead City, AZ 86430, A 8880.
7. Mohave County Board of Supervisors, 315 Oak Street, Kingman, AZ 86401, A 9423, A 9974.
T. 1S., R. 23 W.

Withdrawal

1. SO 3/124/1929: Colorado River Storage Project.

Rights-of-Way

2. Yuma County Highway Department, 2703 South Avenue B, Yuma, AZ 85364, Cibola Road, R.S. 2477.
3. Francisco Grande Development Co., c/o Franklin Gibson, 525 W. Southern, Mesa, AZ 85702, A 11888.

Grazing Lessee

4. Lewis C. Biship, P.O. Box 111, Ehrenberg, AZ 853334.

Range Improvements

5. Lewis C. Biship: Windmill, well, corrals; No. 4146.

Oil and Gas Leases and Applications

6. Joe Lyon, Jr., 600 E. Capitol Street, Salt Lake City, Utah 84003, A 17183, A 17280.
7. Robert P. Kunkel, 757 Northcliffe Drive, Salt Lake City, UT 84103, A 17134.
T. 9 S., R. 25 W.

Withdrawals

1. SO 1/31/1903: Temporary Withdrawal Colorado River Survey.
2. SO 7/2/1902: Temporary Withdrawal Colorado River Survey.
3. SO 7/20/1905: Withdrawal for Yuma Project.

Rights-of-Way

4. U.S. Bureau of Reclamation, Yuma Projects Office, Yuma, AZ 85364, AR 092589, 1919 U.S.R.S. (levee).
5. Arizona Public Service Co., P.O. Box 21666, Station 3172, Phoenix, AZ 85036, A 9983.
6. U.S. Bureau of Reclamation, Lower Colorado Regional Office, P.O. Box 427, Boulder City, NV 89005, PHX 086549.

Agricultural Lease

7. Cocopah Indian Tribe, c/o Robert Barley, P.O. Bin G, Somerton, AZ 85350, 1A–10 (A).

Oil and Gas Lease

8. Inexco Oil Co., 1100 Milam Building, Suite 1900, Houston, TX 77002, A 16836.
T. 10 S., R. 25 W.

Withdrawals

1. SO 1/31/1903: Temporary Withdrawal Colorado River Survey.
2. SO 7/20/1905: Withdrawal for Yuma Project.

Rights-of-Way

3. Arizona Public Service Co., P.O. Box 21666, Station 3172, Phoenix, AZ 85036, A 9983.
4. U.S. Bureau of Reclamation, Lower Colorado Regional Office, P.O. Box 427, Boulder City, NV 89005, PHX 086549.

Agricultural Permit

H. D. and Phillip Sibley, Route 1, Box 147–A, Somerton, AZ 85350.

Oil and Gas Lease

6. Inexco Oil Company, 1100 Milam Building, Suite 1900, Houston, TX 77002, A 16836.

7. Rights-of-way granted by BLM will transfer with the land. Oil and gas leases will remain in effect under the terms and conditions of the lease. State Law and Land Department procedures (R 12–5–154 D Administrative Rules and Regulations, Arizona State Land Department) provide for the offering to holders of BLM grazing permits the first right to lease lands that are transferred to the State. This constitutes official notice to grazing lessees that their Bureau of Land Management leases will be terminated in part upon transfer of the land to the State of Arizona.

Dated: January 11, 1982.

W. K. Barker,

District Manager.

Dated: January 15, 1982.

Gary A. McVicker,

Assistant District Manager.

[FR Doc. 82–2651 Filed 2–1–82; 8:45 am]

BILLING CODE 4310–84–M

National Park Service

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before January 22, 1982. Pursuant to § 60.13 of 36 CFR Part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, U.S. Department of the Interior, Washington, DC 20243. Written comments should be submitted by February 27, 1982.

Carol D. Shull,

Acting Keeper of the National Register.

ALABAMA

Calhoun County

Anniston, *Parker-Reynolds House,* 330 E. 6th St.

Colbert County

Tuscumbia vicinity, *Belmont,* SE of Tuscumbia

Dale County

Ozark, *Holman, J. D., House,* 409 E. Broad St.

Greene County

Boligee vicinity, *Boligee Hill (Myrtle Hall)* SE of Boligee

Limestone County

Athens, *Old Athens, Alabama Main Post Office*, 310 W. Washington St.
Belle Mina vicinity, *Woodside*, SW of Belle Mina
Mooresville vicinity, *Cave Place*, AL 20

Madison County

Huntsville, *Phelps-Jones House*, 6112 Pulaski Pike

Mobile County

Mobile, *Miller-O'Donnell House*, 1102 Broad St.

Montgomery County

Montgomery, *Sayre Street School*, 506 Sayre St.
Mount Meigs, *Grace Episcopal Church*, Pike Rd.

ARIZONA

Maricopa County

Phoenix, *Hotel Westward Ho*, 618 N. Central Ave.

CALIFORNIA

Los Angeles County

Pasadena, *Longfellow-Hastings House*, 85 S. Allen Ave.
Pomona, *Pomona Fox Theater*, 102–144 3rd St.

Monterey County

Salinas, *Nesbitt, Sheriff William Joseph, House*, 66 Capitol St.

Napa County

Napa, *Old Napa Register Building*, 1202 1st St.

Orange County

Santa Ana, *Walkers Orange County Theater*, 308 N. Main St.

Sacramento County

Folsom, *Folsom Depot*, 200 Wool St.
Sacramento, *Goethe House*, 3731 T St.
Sacramento, *Howe, Edward P., Jr., House*, 2215 21st St.
Sacramento, *Libby McNeill and Libby Fruit and Vegetable Cannery*, 1724 Stockton Blvd.

San Benito County

San Juan Bautista, *Wilcox, Benjamin, House*, 315 The Alameda

San Francisco County

San Francisco, *Trinity Presbyterian Church*, 3261 23rd St.

San Joaquin County

Stockton, *Holt, Benjamin, House*, 548 Park St.
Stockton, *Sperry Office Building*, 146 W. Weber Ave.

San Luis Obispo County

Atascadero, *Archeological Site 4–SLO–834*

Santa Clara County

Morgan Hill vicinity, *Circles of Circles Archeological District*
Palo Alto, *Dunker House*, 420 Maple St.
San Jose, *Building at 27–29 Fountain Alley*
Santa Clara, *Landrum, Andrew J., House*, 1219 Santa Clara St.

Yolo County

Sacramento, *Tower Bridge*, CA 275 across the Sacramento River (also in Sacramento County)

CONNECTICUT

Hartford County

Hartford, *Washington Street School*, 461 Washington St.
Windsor, *Mills, Oliver W., House*, 148 Deerfield Rd.

New London County

Salem, *Fish, Abel H., House*, Buckley Hill and Rathbun Hill Rds.

INDIANA

Huntington County

Huntington vicinity, *LaFolier, Madame Margaret, House*, 3 mi. W of Huntington on U.S. 24

Marion County

Indianapolis, *Glossbrenner, Alfred M., Mansion*, 3202 N. Meridian St.
Indianapolis, *Merchants National Bank and Annex*, 11 S. Meridian St. and 7 E. Washington St.

Monroe County

Bloomington, *Abel, Elias, House*, 317 N. Fairview St.

Porter County

Valparaiso, *Immanuel Lutheran Church*, 308 N. Washington St.

Rush County

Rushville, *Durbin Hotel*, 137 W. 2nd St.

Steuben County

Fremont, *Michael, Enos, House*, 200 E. Toledo St.

Tippecanoe County

Lafayette, *Temple Israel*, 17 S. 7th St.

IOWA

Clayton County

McGregor, *Reynolds, Joseph "Diamond Jo", Office Building and House*, A and Main Sts.

Woodbury County

Sioux City, *Badgerow Building*, 622 4th St.

KANSAS

Douglas County

Lawrence, *Stephens, Judge Nelson T., House*, 340 N. Michigan St.

McPherson County

Marquette, *Hanson, Hans, House*, 211 E. 5th St.

Shawnee County

Topeka, *Central Motor and Finance Corporation Building*, 222 W. 7th St.
Topeka, *Woman's Club Building*, 420 W. 9th St.

Sumner County

Oxford vicinity, *Old Oxford Mill*, NE of Oxford

Wyandotte County

Kansas City, *Westheight Manor Historic District*, Roughly bounded by State and Wood Aves., 18th and 25th Sts. (Boundary increase)

MAINE

Cumberland County

Freeport, *Mallett, E. B., Office Building*, Mill St.

Hancock County

Bar Harbor, *Reverie Cove*, Harbor Lane

Kennebec County

Augusta, *Bangs, Algernon, House*, 16 E. Chestnut St.
Waterville, *Lombard, Alvin O., House*, 65 Elm St.
Waterville, *Professional Building*, 177 and 179 Main St.

Knox County

Camden, *American Boathouse*, Atlantic Ave.
Camden, *Norumbega Carriage House*, High St.
Vinalhaven, *Star of Hope Lodge*, Main St.

Lincoln County

Waldoboro, *Hutchins House*, 77 Main St.

Penobscot County

Kingman, *Kingman, Romanzo, House*, Main St.

Piscataquis County

Guilford, *Straw House*, Golda Ct.

Somerset County

Skowhegan, *Bloomfield Academy*, Main St.
Skowhegan, *Gould House*, 31 Elm St.
Skowhegan, *Skowhegan Historic District*, Water and Russell Sts. and Madison Ave.

Waldo County

Islesboro vicinity, *Archeological Site No. 29–64*

Washington County

Cherryfield, *Cherryfield Academy*, Main St.

York County

Kennebunkport vicinity, *Clock Farm*, ME 9 and Goose Rocks Rd.
Ocean Park, *Ocean Park Historic Buildings*, Temple Ave.
Parsonfield vicinity, *Blazo-Leavitt House*, ME 160

MINNESOTA

Rice County

Faribault, *Cathedral of Our Merciful Saviour and Guild House*, 515 NW. 2nd Ave.

Scott County

New Prague, *St. Wenceslaus Church Complex*, E. Main St.

Washington County

Lakeland, *Jackson, Mitchell, Farmhouse*, 16376 7th St. Lane South

Stillwater, *Hersey, Roscoe, House*, 416 S. 4th St.
Stillwater, *Wolf, Joseph, Brewery*, 402–414 S. Main St. and 211 E. Nelson St.

NEW HAMPSHIRE

Hillsborough County

Hillsborough Center, *Barnes, Jonathan, House*, North Rd.

NEW MEXICO

Bernalillo County

Albuquerque, *Hudson House*, 817 Gold Ave., SW.
Albuquerque, *Washington Apartments*, 1002–1008 Central Ave., SW.

UTAH

Cache County

Smithfield, *Douglass Dry Goods and Merchantile*, 100 S. Main St.

Utah County

Lehi, *Lehi City Hall*, 51 N. Center St.
Provo, *Provo Train Station*, 301 W. 600 South St.

VIRGIN ISLANDS

St. John Island

Maho Bay vicinity, *Francis Bay Archeological Site*
Maho Bay vicinity, *Petroglyph Site*

WASHINGTON

Clark County

Battle Ground vicinity, *Green, Albert and Letha, House and Barn*, 25716 NE. Lewisville Hwy.

King County

Median, *Eddy, James G., House and Grounds*, 100 Evergreen Point Rd.
Renton vicinity, *Newcastle Cemetery, N of Renton*
Seattle, *Wagner Houseboat (The Old Boathouse)* 2770 Westlake Avenue North

Pierce County

South Prairie, *Bisson, William, House*, Washington and Emery Sts.
Tacoma, *Boatman-Ainsworth House*, 6000 112th St., SW.

Walla Walla County

College Place vicinity, *Saturno-Breen Truck Garden*, E of College Place
Walla Walla, *Small-Elliott House*, 314 E. Poplar St.

Whatcom County

Bellingham, *Leopold Hotel*, 1224 Cornwall Ave.

WEST VIRGINIA

Taylor County

Grafton, *Grafton National Cemetery*, 431 Walnut St.

[FR Doc. 82-2556 Filed 2-1-82; 8:45 am]
BILLING CODE 4310-70-M

Office of the Secretary

Establishment of Organizations

This notice is issued in accordance with the provisions of 5 U.S.C. 552(a)(1). The Secretary of the Interior has issued an order establishing two new organizational units, namely, a Minerals Management Board and a Minerals Management Service. The Minerals Management Service will carry out the functions formerly assigned to the Conservation Division of the Geological Survey. The order making this organization change is published in its entirety below.

Additional information may be obtained from Richard R. Hite, Deputy Assistant Secretary—Policy, Budget and Administration, Department of the Interior, Washington, D.C. 20240, telephone 343–4502.

Dated: January 22, 1982

Richard R. Hite,

Deputy Assistant Secretary of the Interior.

January 19, 1982.

Order No. 3071

Subject: Establishment of the Minerals Management Board and the Minerals Management Service

Sec. 1 *Purpose.* This order establishes a Minerals Management Board and a Minerals Management Service which will be under the supervision of the Under Secretary. The purpose of this action is to improve the management of and provide greater management oversight and accountability for the minerals related activities previously carried out by the Conservation Division of the Geological Survey.

Sec. 2 *Authority.* This order is issued in accordance with the authority provided by Section 2 of Reorganization Plan No. 3 of 1950 (64 Stat. 1262).

Sec. 3 *Minerals Management Board.* There is hereby established a Minerals Management Board which will be chaired by the Under Secretary. Other members of the Board will be the Assistant Secretary—Energy and Minerals, and the Assistant Secretary—Policy, Budget and Administration. The Board will supervise and oversee the operations of the Minerals Management Service established in Section 4 of this order; develop appropriate policy and guidelines to implement the approved recommendations and findings of the Commission on Fiscal Accountability of the Nation's Energy Resources; and monitor program activities directed toward the improvement of the royalty management program.

Sec. 4 *Minerals Management Service.* There is hereby established a Minerals Management Service whose Director shall be under the supervision of the Minerals Management Board established in Section 3 above. All of the functions of the Conservation Division shall be exercised by the Minerals Management Service. The name Conservation Division is abolished. The Minerals Management Service will carry out the functions previously exercised by the Conservation Division and implement new policy and guidance developed by the Minerals Management Board.

Sec. 5 *Administrative Provisions.* The Director, Geological Survey will continue to provide administrative support (i.e., fiscal, personnel, property, procurement, etc.) to the Minerals Management Service.

Sec. 6 *Management Review.* By December 31, 1982, the Minerals Management Board will conduct a review with the purpose of restructuring the Minerals Management Service. The Board will also provide the Secretary with recommendations on the permanent disposition of its management and oversight functions.

Sec. 7 *Effective Date.* This order is effective immediately.

Dated: January 19, 1982

James G. Watt,

Secretary of the Interior.

[FR Doc. 82-2666 Filed 2-1-82; 8:45 am]
BILLING CODE 4310-10-M

INTERSTATE COMMERCE COMMISSION

Motor Carriers; Permanent Authority Decisions; Decision-Notice

The following applications, filed on or after February 9, 1981, are governed by Special Rule of the Commission's Rules of Practice, see 49 CFR 1100.251. Special Rule 251 was published in the **Federal Register** of December 31, 1980, at 45 FR 80109.

Persons wishing to oppose an application must follow the rules under 49 CFR 1100.252. A copy of any application, including all supporting evidence, can be obtained from applicant's representative upon request and payment to applicant's representative of $10.00.

Amendments to the request for authority are not allowed. Some of the applications may have been modified prior to publication to conform to the Commission's policy of simplifying grants of operating authority.

Findings

With the exception of those applications involving duly noted problems (e.g., unresolved common control, fitness, water carrier dual operations, or jurisdictional questions) we find, preliminarily, that each applicant has demonstrated a public need for the proposed operations and that it is fit, willing, and able to perform the service proposed, and to conform to the requirements of Title 49, Subtitle IV, United States Code, and the Commission's regulations. This presumption shall not be deemed to exist where the application is opposed. Except where noted, this decision is neither a major Federal action significantly affecting the quality of the human environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

In the absence of legally sufficient opposition in the form of verified statements filed on or before 45 days from date of publication, (or if the application later becomes unopposed) appropriate authorizing documents will be issued to applicants with regulated operations (except those with duly noted problems) and will remain in full effect only as long as the applicant maintains appropriate compliance. The unopposed applications involving new entrants will be subject to the issuance of an effective notice setting forth the compliance requirements which must be satisfied before the authority will be issued. Once this compliance is met, the authority will be issued.

Within 60 days after publication an applicant may file a verified statement in rebuttal to any statement in opposition.

To the extent that any of the authority granted may duplicate an applicant's other authority, the duplication shall be construed as conferring only a single operating right.

Note.—All applications are for authority to operate as a motor common carrier in interstate or foreign commerce over irregular routes, unless noted otherwise. Applications for motor contract carrier authority are those where service is for a named shipper "under contract."

Please direct status inquiries to the Ombudsman's Office, (202) 275–7326.

Volume No. OP2–16

Decided: January 20, 1982.

By the Commission, Review Board No. 1, Members Parker, Chandler, and Fortier.

MC 14252 (Sub-85), filed January 15, 1982. Applicant: COMMERCIAL LOVELACE MOTOR FREIGHT, INC., 3400 Refugee Rd., Columbus, OH 43227. Representative: William C. Buckham (same address as applicant) (614) 239–6000. Transporting *general commmodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in the U.S., under continuing contract(s) with J. C. Penney Company, Incorporated, of New York, NY.

MC 100892 (Sub-14), filed January 5, 1982. Applicant: TRANS-SOUTHWEST CARRIERS, INC., 1074 South 500 West, Salt Lake City, UT 84101. Representative: Billy L. Lindsey (same address as applicant) (801) 974–0600. Transporting *general commodities* (except classes A and B explosives, household goods and commodities in bulk), between those points in the U.S., in and west of MN, SD, NE, KS, OK and TX (except AK and HI).

MC 107012 (Sub-759), filed January 11, 1982. Applicant: NORTH AMERICAN VAN LINES, INC., 5001 U.S. Hwy 30 West, P.O. Box 988, Fort Wayne, IN 46801. Representative: Gerald A. Burns (same address as applicant) (219) 429–2234. Transporting *general commodities* (except classes A and B explosives), between points in the U.S., under continuing contract(s) with Motorola, Inc., of Schaumburg, IL.

MC 118612 (Sub-17), filed January 7, 1982. Applicant: COLUMBIA TRUCKING, INC., 700 131st Pl., Hammond, IN 46320. Representative: Richard A. Kerwin, 180 North La Salle St., Chicago, IL 60601; 312–332–5106. Transporting *petroleum or coal products,* between points in Lake County, IN, on the one hand, and, on the other, points in Madison County, IL.

MC 138782 (Sub-5), filed January 5, 1982. Applicant: KY. T.O.F.C. DELIVERY SERVICE, INC., P.O. Box 30, Princeton, KY 42445. Representative: William L. Willis, Suite 708, McClure Bldg., Frankfort, KY 40601 (502) 227–7384. Transporting *general commodities* (except classes A and B explosives), between points in IL, IN, KY, MO and TN.

MC 142543 (Sub-7), filed January 11, 1982. Applicant: L. D. FONTAINE, d.b.a. FONTAINE TRUCKING, 504 Riverview Blvd., Great Falls, MT 59404. Representative: Timothy R. Stivers, P.O. Box 1576, Boise, ID 83701 (208) 343–3071. Transporting *such commodities* as are dealt in by grocery and food business houses, between points in ID, MT, OR, and WA, on the one hand, and, on the other, points in AZ, CA, ID, IA, MN, MT, NE, ND, OR, TX, UT, WA, and WI.

MC 144693 (Sub-14), filed January 15, 1982. Applicant: GLENN'S TRUCK SERVICE, INC., #1 Produce Row, St. Louis, MO 63102. Representative: Ronald R. Adams, 600 Hubbell Bldg., Des Moines, IA 50309 (515) 244–2329. Transporting *rubber products,* between Cape Girardeau, MO, on the one hand, and, on the other, points in the U.S.

MC 147402 (Sub-10), filed January 5, 1982. Applicant: WACO DRIVERS SERVICE, INC., 138 Atando Ave., Charlotte, NC 28206. Representative: Archie B. Culbreth, Suite 202, 2200 Century Parkway, Atlanta, GA 30345 (404) 321–1765. Transporting *vitamins, cosmetics, nutritional products and cleaning compounds* between points in Fulton and DeKalb Counties, GA, on the one hand, and, on the other, points in NC, SC and TN.

MC 149343 (Sub-2), filed December 18, 1981. Published in the **Federal Register** issue of January 14, 1982, and republished, as corrected, this issue. Applicant: SOUTHERN PRIDE TRUCKING, INC., P.O. Box 84000, San Diego, CA 92138. Representative: Kenneth F. Dudley, P.O. Box 279, Ottumwa, IA 52501; 515–682–8154. Transporting (1) *aircraft engines, turbines, parts and accessories and ground support equipment,* between points in Maricopa County, AZ, Denver, CO, Miami, FL, Atlanta, GA, Minneapolis-St. Paul, MN, Portland, OR, Salt Lake City, UT, Seattle, WA, and points in CA, on the one hand, and, on the other, points in the U.S., (2) *machinery,* between points in CA, on the one hand, and, on the other, points in the U.S., and (3) *Displays, display equipment and materials, equipment and supplies* used in connection with the setting up of displays, between points in the U.S.

Note.—The purpose of this republication is to correct the commodity description.

MC 152813, filed January 11, 1982. Applicant: FRESH EXPRESS, INC., 55 Produce Row, St. Louis, MO 63103. Representative: Michael J. Ogborn, P.O. Box 82028, Lincoln, NE 68501; (402) 475–6761. Transporting *cleaning and washing products, toilet preparations, and food and related products,* between the facilities of Lever Bros. Co., at points in the U.S. (except AK and HI), on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 154732 (Sub-1), filed January 7, 1982. Applicant: HARPER TRANSPORT, INC., 3313 Concord Corner, Conyers, GA 30208. Representative: Clayton R. Byrd, 2870 Briarglen Dr., Doraville, GA 30340; 404–491–1696. Transporting *rubber and plastic products,* between points in the U.S., under continuing contract(s) with Cougar Oil, Inc., of Selma, AL.

MC 155793 (Sub-2), filed January 7, 1982. Applicant: CALIFORNIA/NEVADA BIG VALLEY EXPRESS, INC.,

2455 Walton Avenue, Central Valley, CA 96019. Representative: Robert G. Harrison, 4299 James Drive, Carson City, NV 89701, (702) 882–5649. Transporting *general commodities* (except household goods) between points in Washoe County, NV and Tehama, Trinity, Modoc, Plumas, Lassen and Shasta Counties, CA. Conditions: Any certificate issued in this proceeding to the extent that it authorizes the transportation of classes A and B explosives, shall be limited in term to a period expiring 5 years from its date of issuance.

MC 158742, filed January 13, 1982. Applicant: COLUMBIAN EXPRESS CO., INC., P.O. Box 123, Reading, PA 19603. Representative: John C. Fudesco, Suite 960, 1333 New Hampshire Ave., NW., Washington, DC 20036, (202) 659–5157. Transporting *such commodities* as are dealt in or used by manufacturers and distributors of hardware, between points in Berks County, PA, on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 159982, filed January 8, 1982. Applicant: O.L. EXPRESS, LTD., Box 327, Carlisle, IA 50047. Representative: William L. Fairbank, 2400 Financial Center, Des Moines, IA 50309; 515–282–3525. Transporting *food and related products*, between points in the U.S., under continuing contract(s) with Swift Independent Packing Company, of Chicago, IL.

MC 160002, filed January 7, 1982. Applicant: MITSUILINE TRAVEL SERVICE OF AMERICA, INC., 345 East Second St., Los Angeles, CA 90012. Representative: Richard G. Wallace, 555 South Flower St., 26th Fl., Los Angeles, CA 90071, 213–680–2222. As a *broker* at Los Angeles, CA, and New York, NY, in arranging for the transportation by motor vehicle of *passengers and their baggage*, in special and charter operations, beginning and ending at New York, NY, and points in CA, and extending to points in the U.S.

Volume No. OP3–016

Decided: January 27, 1982.

By the Commission, Review Board No. 2, Members Carleton, Fisher, and Williams.

MC 99455 (Sub-12), filed January 19, 1982. Applicant: M. H. HILLERY, INC., 90 Western Ave., Allston, MA 02134. Representative: Robert L. Cope, 1730 M St., NW., Suite 501, Washington, DC 20036, (202) 296–2900. Transporting *general commodities* (except classes A and B explosives, household goods as defined by the Commission, and commodities in bulk), between points in the U.S., under continuing contract(s) with Seacoast Shippers Association, Inc., of Allston, MA.

MC 117384 (Sub-12), filed January 19, 1982. Applicant: DAVIDSON BROTHERS, R.D. Route 3, Bellefonte, PA 16823. Representative: Theodore Polydoroff, Suite 301, 1307 Dolley Madison Blvd., McLean, Va. 22101, (703) 893–4924. Transporting *general commodities* (except household goods as defined by the Commission, and classes A and B explosives), between points in CT, DE, GA, IL, IN, KY, ME, MD, MA, MI, NH, NJ, NY, NC, OH, PA, RI, SC, TN, VT, VA, WV, WI, and DC, on the one hand, and, on the other, points in the U.S.

MC 119315 (Sub-37), filed January 19, 1982. Applicant: FREIGHTWAY CORPORATION, 131 Matzinger Rd., Tolego, OH 43612. Representative: Stephen L. Oliver, 275 East State St., Columbus, OH 43215, (614) 228–8575. Transporting *general commodities* (except classes A and B explosives), between points in OH, MI, IN, and IL, on the one hand, and, on the other, those points in the U.S. in and east of ND, SD, NE, KS, OK, and TX.

MC 123744 (Sub-99), filed January 19, 1982. Applicant: BUTLER TRUCKING COMPANY, a corporation, P.O. Box 88, Woodland, PA 16881. Representative: Dwight L. Koerber, Jr., P.O. Box 1320, 110 N. Second St., Clearfield, PA 16830, (814) 765–9611. Transporting *metals and metal products*, between points in the U.S., under continuing contract(s) with Metal Purchasing Co., Inc., of New York, NY.

MC 130475 (Sub-1), filed January 20, 1982. Applicant: YORK TOURS, 345 No. Bartlett, Medford, OR 97501. Representative: Eleanor B. York (same address as applicant), (503) 779–7571.Transporting *passengers and their baggage*, in charter and special operations, between points in the U.S.

MC 141914 (Sub-106), filed January 18, 1982. Applicant: FRANKS AND SON, INC., Rt. 1, Box 108A, Big Cabin, OK 74332. Representative: Kathrena J. Franks (same address as applicant), (918) 783–5180.Transporting *such commodities* as are dealt in or used by office supply houses, between points in Dallas County, TX, Middlesex County, MA, Wayne County, MI, Camden County, NJ and Cook County, IL, on the one hand, and, on the other, points in the U.S.

MC 142064 (Sub-7), filed January 18, 1982. Applicant: CAROLINA CARPET CARRIERS, INC., P.O. Box 6, Williamston, SC 29697. Representative: Mitchell King, Jr., P.O. Box 5711, Greenville, SC 29606, (803) 288–6000. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in the U.S. under continuing contract(s) with J. C. Penney Co., Inc., of New York, NY, Texize Division of Morton Norwich Inc., of Greenvile, SC, and Foremost McKesson, of Jersey City, NJ.

MC 144474 (Sub-4), filed January 20, 1982. Applicant: MORGAN MOVING & STORAGE, INC., 301 North St., Booneville, MS 38829. Representative: Robert J. Gallagher, 1000 Connecticut Ave., NW., Suite 1200, Washington, DC 20036, (202) 785–0024. Transporting *household goods*, (1) between points in AL, AR, DE, FL, GA, IL, IN, KS, KY, LA, MD, MI, MS, MO, NJ, NC, OH, OK, PA, SC, TN, TX, VA, WV, WI, and DC; and (2) between points named in (1) above, on the one hand, and, on the other, points in AZ, CA, CO, CT, ID, IA, ME, MA, MN, MT, NE, NV, NH, NM, NY, ND, OR, SD, UT, VT, WA, and WY.

MC 145494 (Sub-15), filed January 18, 1982. Applicant: EDINA CARTAGE CO., P.O. Box 42, Front St., Mauricetown, NJ 08329. Representative: Laurence J. Distefano, Jr., 1101 Wheaton Ave., Millville, NJ 08332, (609) 825–1400, Ext. 2414. Transporting *food and related products*, between Philadelphia, PA, on the one hand, and, on the other, points in the U.S.

MC 146624 (Sub-2), filed January 15, 1982. Applicant: MILLER BROS. TRUCKING, INC., 800 Cherry St., Liberty Center, OH 43532. Representative: A. Charles Tell, 100 E. Broad St., Columbus, OH 43215, (614) 228–1541. Transporting (1) *containers and container closures*, (2) *glassware*, (3) *packaging products*, (4) *container components*, and (5) *scrap materials*, between points in Lucas County, OH, on the one hand, and, on the other, points in MI.

MC 146724 (Sub-9), filed January 18, 1982. Applicant: DEAN RAPPLEYE, INC., 7444 S. 2200 W., West Jordan, UT 84084. Representative: Jack H. Blanshan, 205 W. Touhy Ave., Suite 200–A, Park Ridge, IL 60068, (312) 698–2235. Transporting *food and related products* (except commodities in bulk), (1) between Salem, OR, Kennewick, WA, points in Marion County, OR, Benton and Snohomish Counties, WA, Santa Clara, Santa Cruz, Stanislaus and Ventura Counties, CA, and Nez Perce County, ID, on the one hand, and, on the other, points in AZ, CA, CO, ID, IA, KS, MN, MO, NE, NV, NM, ND, OK, OR, SD, TX, UT and WA, and (2) between points in Salt Lake County, UT, on the one hand, and, on the other, points in CO, IA, KS, MN, MO, NE and SD.

MC 147354 (Sub-3), filed January 15, 1982. Applicant: FAUBION TRUCK LINES, INC., P.O. Box 5795, Alexandria, LA 71301. Representative: Donald Sharp, P.O. Box 6118, Alexandria, LA 71301, (318) 445–6471. Transporting (1) *beer,* (2) *food and related products,* and (3) *lubricating oil,* between points in the U.S. under continuing contracts with (a) Venture Marketing Corporation, and Coors of Central Louisiana, Inc., both of Alexandria, LA, (b) Joan of Arc Company, of Peoria, IL, and Bruce Foods Corporation, of New Iberia, LA, and (c) Westland Oil Company, of Shreveport, LA.

MC 150724 (Sub-7), filed January 20, 1982. Applicant: DONALD SANTISI TRUCKING COMPANY, 340 Victoria Rd., Youngstown, OH 44515. Representative: Andrew Jay Burkholder, 275 East State St., Columbus, OH 43215, (614) 228–8575. Transporting *food and related products,* between points in Hillsboro County, FL and New Castle County, DE, on the one hand, and, on the other, points in MD, PA, OH, NY, IN, IL, TN, KY, and WV.

MC 152905 (Sub-3), filed January 15, 1982. Applicant: DWAN'S MOVING & STORAGE CO., INC., 207 Hawthorne Ave., St. Joseph, MI 49085. Representative: Edward Malinzak, 900 Old Kent Bldg., Grand Rapids, MI 49503, (616) 459–6121. Transporting *electronic equipment,* between points in the U.S., under continuing contract(s) with Heath Company of St. Joseph, MI.

MC 153314 (Sub-5), filed January 15, 1982. Applicant: M & D TRANSPORTATION, INC., P.O. Box 775, Glendale, AZ 85311. Representative: Michael S. Varda, P.O. Box 2509, Madison, WI 53701, (608) 255–8891. Transporting *such commodities* as are dealt in or used by manufacturers and distributors of hydrotherapy spas and swimming pool products (except commodities in bulk), between points in the U.S. (except AK and HI).

MC 156384 (Sub-1), filed January 18, 1982. Applicant: TRANSPO, INCORPORATED, 9 Mill Plain Rd., Danbury, CT 06810. Representative: Sidney J. Leshin, 3 E. 54th St., New York, NY 10022, (212) 759–3700. Transporting *passengers and their baggage* in special operations, beginning and ending at points in Fairfield County, CT, Putnam and Dutchess Counties, NY, and extending to points in Westchester County, NY, and Fairfield County, CT.

MC 159555, filed January 19, 1982. Applicant: L. E. BLAIR TRUCKING, P.O. Box 247, Potosi, MO 63664. Representative: Lawrence E. Blair (same address as applicant), (314) 438–3602. Transporting *ore and ore concentrates,* in bulk, between points in Washington County, MO, on the one hand, and, on the other, points in AR, IL, KS, LA, OK, and TX.

MC 159735, filed January 19, 1982. Applicant: J.N.B. CARRIERS, INC., 11 Mount Marcy Ave., Farmingdale, NY 11738. Representative: George A. Olsen, P.O. Box 357, Gladstone, NJ 07934, (201) 435–7140. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in the U.S., under continuing contract(s) with E.Z.EM Company, Inc. of Westbury, NY.

MC 159845, filed January 18, 1982. Applicant: TRANSPORT SOUTH, INC., 2625 Cumberland Parkway, Suite 100, Atlanta, GA 30339. Representative: Guy H. Postell, Suite 713, 3384 Peachtree Rd., NE., Atlanta, GA 30326. Transporting *general commodities* (except household goods) between points in the U.S. (except AK and HI), under continuing contract(s) with Racetrac Petroleum, Inc., of Atlanta, GA.

Note.—To the extent the authority granted in this proceeding authorizes the transportation of classes A and B explosives it will expire 5 years from the date of issuance.

MC 160124, filed January 15, 1982. Applicant: FAST MOTOR EXPRESS, INC., 9100 Plainfield Road, Brookfield, IL 60513. Representative: Albert A. Andrin, 180 North La Salle Street, Chicago, IL 60601, (312) 332–5106. Transporting *general commodities* (except classes A and B explosives), between points in IL, IN, KY, MO, IA, MN, WI, MI and OH.

MC 160134, filed January 14, 1982. Applicant: A TOUR CENTRE, 3825 Coronado Avenue, San Diego, CA 92107. Representative: David B. Rosenman, 315 South Beverly Drive, Suite 315, Beverly Hills, CA 90212. As a *broker,* at San Diego County, CA, in arranging for the transportation of *passengers and their baggage,* in the same vehicle with passengers, in charter and special operations, between points in the U.S.

MC 160145, filed January 20, 1982. Applicant: TOMMIE STEVENS, d.b.a. NATIONAL WRECKER SERVICE, 1517 Pine St., Abilene, TX 79601. Representative: Timothy Mashburn, P.O. Box 2207, Austin, TX 78768–2207, (512) 476–6391. Transporting *transportation equipment,* in wrecker service, between points in Archer, Baylor, Borden, Brown, Coke, Callahan, Coleman, Comanche, Concho, Cottle, Dickens, Earth, Eastland, Fisher, Foard, Garza, Glasscock, Hamilton, Haskell, Howard, Irion, Jack, Jones, Kent, King, Knox, McCulloch, Menard, Mills, Mitchell, Noland, Palo Pinto, Runnels, San Saba, Schleicher, Scurry, Shackelford, Stephens, Sterling, Stonewall, Taylor, Throckmorton, Tom Green, Wilbarger and Young Counties, TX, on the one hand, and on the other, points in the U.S.

MC 160165, filed January 18, 1982. Applicant: APACHE WELLS TOUR CLUB, INC., 2348 N. 56th St., Mesa, AZ 85205. Representative: Howard L. Willcox (same address as applicant), (602) 832–3028. As a *broker,* at Mesa, AZ, in arranging for the transportation of *passengers and their baggage,* by motor vehicle, in charter and special operations, between points in AZ on the one hand, and, on the other, points in the U.S..

Volume No. OP4–26

Decided: January 26, 1982.

By the Commission, Review Board No. 2, Members Carleton, Fisher, and Williams.

MC 64806 (Sub-20), filed January 18, 1982. Applicant: R. P. THOMAS TRUCKING COMPANY, INC., 807 W. Fayette St., Martinsville, VA 24112. Representative: Terrel Clark, P.O. Box 25, Stanleytown, VA 24168, (703) 632–5658. Transporting *pulp, paper and related products; containers; container closures, ends, and components; glassware; packaging products;* and *scrap material,* between those points in the U.S. in and east of MN, IA, MO, OK, and TX.

MC 74416 (Sub-35), filed January 19, 1982. Applicant: LESTER M. PRANGE, INC., Box 1, Kirkwood, PA 17536. Representative: Chester A. Zyblut, 366 Executive Bldg., 1030 15th St., N.W., Washington, DC 20005, (202) 296–3555. Transporting *metal products,* between those points in the U.S. in and east of MN, IA, MI, AR, and LA.

MC 93396 (Sub-5), filed January 19, 1982. Applicant: YELLOW LIMOUSINE SERVICE, INC., 8001 Roosevelt Blvd., Philadelphia, PA 19152. Representative: Louis J. Carter, 7300 City Line Ave., Philadelphia, PA 19151, (215) 879–8665. Transporting *passengers and their baggage,* limited to the transportation of not more than 11 passengers (except the driver), in one vehicle at one time, between points in Montgomery and Bucks Counties, PA, on the one hand, and, on the other, points in NY, NJ, MD, and DC.

MC 94876 (Sub-21), filed January 18, 1982. Applicant: RICHARD ACERRA, INC., 38–39 Vernon Blvd., Long Island City, NY 11101. Representative: J. Aiden Connors, 325 East 201 St., New York, NY 10458, (212) 733–6965. Transporting *general commodities* (except classes A and B explosives), between those points in the U.S. in and east of WI, IL, KY, TN

and MS, under continuing contract(s) with Drake Bakeries, of Wayne, NJ, Casal Distributors, Inc., of Long Island City, NY, F.A.O. Schwarz, Inc., of New York, NY, Nabisco, Inc., of East Hanover, NJ, Interstate Safety Lines, Inc., of Newtonville, MA, and Nabisco Brands, Inc., of New York, NY.

MC 109376 (Sub-24), filed January 18, 1982. Applicant: SKINNER TRANSFER CORP., P.O. Box 284, Reedsburg, WI 53959. Representative: Richard A. Westley, 4506 Regent St., Suite 100, P.O. Box 5086, Madison, WI 53705–0086, (608) 238–3119. Transporting *lumber and wood products,* between points in the U.S., under continuing contract(s) with Louisiana Pacific Corporation, of Hayward, WI.

MC 140686 (Sub-5), filed January 18, 1982. Applicant: VSM TRUCKING, INC., 211 South Main St., Abingdon, IL 61410. Representative: Michael W. O'Hara, 300 Reisch Bldg., Springfield, IL 62701, (217) 544–5468. Transporting *plumbers' goods, bathroom and lavatory fixtures, plate and sheet steel,* between points in the U.S., under continuing contract(s) with Briggs Manufacturing Co., a Division of the Celotex Corporation, of Tampa, FL.

MC 151036 (Sub-6), filed January 12, 1982. Applicant: DECATUR TRANSIT, INC., 161 First Avenue N.E., Decatur, AL 35601. Representative: Eric G. Hancock (same address as applicant), (205) 353–9601. Transporting *salt and salt products,* between points in Morgan County, AL, on the one hand, and, on the other, points in AR, FL, GA, KY, LA, MS, NC, SC, TN, and VA.

MC 159556 (Sub-1), filed January 12, 1982. Applicant: COLE TRUCK LINE, INC., 9106 Talton, Houston, TX 77078. Representative: Claude W. Ferebee, 3910 FM 1960 W., Suite 106, Houston, TX 77068, (713) 537–8156. Transporting *automobile and truck parts, accessories and supplies,* between points in Harris and Travis Counties, TX, on the one hand, and, on the other, points in the U.S.

Volume No. OP4–27

Decided: January 26, 1982.

By the Commission, Review Board No. 2, Members Carleton, Fisher, and Williams.

MC 154436 (Sub-3), filed January 18, 1982. Applicant: MARILYN THOMAS, d.b.a. MAT TRUCKING, 2604 W. Pleasant Ridge Rd., Arlington, TX 76016. Representative: Billy R. Reid, 1721 Carl St., Fort Worth, TX 76103, (817) 332–4718. Transporting *rubber and plastic products,* between points in the U.S., under continuing contract(s) with Plastics Manufacturing Company, of Dallas, TX.

MC 158366 (Sub-1), filed January 19, 1982. Applicant: GUY A. GRANGER, d.b.a. GRANGER TRUCKING CO., 10203 64th Ave. So., Seattle, WA 98178. Representative: Guy A. Granger (same address as applicant), (206) 725–0554. Transporting *lumber and wood products,* between points in Grays Harbor County, WA, on the one hand, and, on the other, points in Orange and Los Angeles Counties, CA.

MC 160106, filed January 18, 1982. Applicant: A & L TRUCKING, ING., 145 N. 3rd St., Beech Grove, IN 46107. Representative: Donald W. Smith, P.O. Box 40248, Indianapolis, IN 46248, (317) 846–6655. Transporting *food and related products* between points in IA, IN, and KY.

MC 160146, filed January 18, 1982. Applicant: JHJ TRUCKING COMPANY, INC., 333 North Belt East, Suite 620, Houston, TX 77060. Representative: Donald R. Looper, 1100 Milam, Suite 1600, Houston, TX 77002, (713) 651–1300. Transporting *mercer commodities,* between points in MS, AL, LA, OK, and TX.

MC 160176, filed January 19, 1982. Applicant: JONES FOOD DISTRIBUTORS, INC., 450 S. Locust St., Twin Falls, ID 83301. Representative: Paul M. Beeks, P.O. Box 508, Twin Falls, ID 83301, (208) 733–6684. Transporting *wine, beer, and nonalcoholic mixes,* between points in CA, on the one hand, and, on the other, points in ID, under continuing contract(s) with Golden Beverage, of Twin Falls, ID, and Wood River Beverage Corp., of Hailey, ID.

Volume No. OP5–15

Decided: January 22, 1982.

By the Commission, Review Board No. 3, Members Krock, Joyce, and Dowell.

FF–568, filed September 9, 1981, previously noticed in the FR issue of September 30, 1981. Applicant: MISSION INTERNATIONAL, INC., 6750 Federal Blvd., Lemon Grove, CA 92045. Representative: Leonard J. Pellman (same address as applicant), (714) 287–4510. As a *freight forwarder* of (a) *used household goods,* (b) *unaccompanied baggage,* and (c) *used automobiles,* between points in the U.S.

Note.—This republication changes the territorial description of the previous publication.

MC 52858 (Sub-130), filed January 13, 1982. Applicant: CONVOY COMPANY, 3900 N. W. Yeon Ave., Portland, OR 97210. Representative: Patricia M. Schnegg, 707 Wilshire Blvd., Los Angeles, CA 90017, (213) 627–8471. Transporting *transportation equipment* between points in the U.S., under continuing contract(s) with Toyota Motor Sales, U.S.A., Inc., of Torrance, CA.

MC 72069 (Sub-43), filed January 12, 1982. Applicant: BLUE HEN LINES, INC., P.O. Box 280, Milford, DE 19963. Representative: Chester A. Zyblut, 366 Executive Bldg., 1030 Fifteenth St., N.W., Washington, DC 20005, 202–296–3555. Transporting *food and related products,* between points in the U.S. in and east of MN, IA, MO, AR, and TX.

MC 109448 (Sub-40), filed January 11, 1982. Applicant: PARKER TRANSFER COMPANY, P.O. Box 256, Elyria, OH 44036. Representative: David A. Turano, 100 E. Broad St., Columbus, OH 43215, 614–228–1541. Transporting *food and related products,* between Toledo, OH and points in Lorain County, OH, on the one hand, and, on the other, points in the U.S. in and east of WI, IL, KY, TN, and MS.

MC 113388 (Sub-136), filed January 12, 1982. Applicant: LESTER C. NEWTON TRUCKING CO., P.O. Box 618, Seaford, DE 19973. Representative: Chester A. Zyblut, 366 Executive Bldg., 1030 Fifteenth St., N.W., Washington, D.C. 20005, 202–296–3555. Transporting *food and related products,* between points in the U.S. (Including AK but excluding HI).

MC 123178 (Sub-9), filed January 12, 1982. Applicant: COLUMBIA COACHWAYS, INC., 6112 Fruit Valley Rd., Vancouver, WA 98660. Representative: David C. White, 2400 SW Fourth Ave., Portland, OR 97201, 503–226–6491. Transporting *passengers and their baggage* in the same vehicle with passengers, beginning and ending at points in Clackamas, Clatsop, Columbia, Multnomah, and Washington Counties, OR; and Clark Cowlitz, Pacific and Wahkiakum Counties, WA, and extending to points in the U.S. (except HI).

MC 124599 (Sub-1), filed January 11, 1982. Applicant: GIUFFRE BROS. BUS CO., INC., d.b.a. BROWN COACH, R.D. #5, Amsterdam, NY 12010. Representative: Neil D. Breslin, 11 North Pearl St., Albany, NY 12207, 518–434–1136. Transporting *passengers and their baggage* in the same vehicle with passengers, in special and charter operations, beginning and ending at points in Schenectady, Herkimer and Clinton Counties, NY, and extending to points in the U.S. (including AK but excluding HI).

MC 126159 (Sub-12), filed December 14, 1981, previously noticed (republication) in **Federal Register** on January 14, 1981. Applicant: APACHE EXPRESS, LTD., P.O. Box 341, Lannon, WI 53046. Representative: Richard C.

Alexander, 710 North Plankinton Ave., Milwaukee, WI 53203, (414) 273–7410. Transporting *salt and salt products,* between Chicago, IL, Duluth, MN, Dubuque, IA, points in Porter County, IN, and points in WI, on the one hand, and, on the other, points in IL, IN, IA, MI, MO, MN, NE, ND, SD, and WI.

Note.—Purpose of republication is to correct territorial description.

MC 133178 (Sub-6), filed January 11, 1982. Applicant: PAPER CARGO CORPORATION, P.O. Box 13, Grandville, MI 49418. Representative: Gregory G. Prasher, 500 Calder Plaza, Grand Rapids, MI 49503, (616) 459–9487. Transporting *paper and related products* between points in the U.S., under continuing contract(s) with Corrugated Supplies Corporation of Chicago, IL.

MC 134888 (Sub-11), filed December 29, 1981. Applicant: MOROSA BROS. TRANSPORTATION CO., 4800 Stine Road, Bakersfield, CA 93309. Representative: John C. Russell, 1545 Wilshire Blvd., Los Angeles, CA 90017, (213) 483–4700. Transporting (1) *fire protection equipment,* between points in Kern County, CA, on the one hand, and, on the other, points in CA, NV, and AZ, (2) *petroleum coke,* between points in Kern County, CA, on the one hand, and, on the other, points in AZ, AR, LA, NM, OK, and TX, and (3) *liquid feed,* between points in Kern County, CA, on the one hand, and, on the other, points in AZ, CO, ID, MT, NM, NV, OR, UT, WA, and WY.

MC 136429 (Sub-3), filed December 31, 1982. Applicant: FRANK A. HOFFMAN TRUCKING COMPANY, INC., 410 Predmore Ave., Lanoka Harbor, NJ 08734. Representative: A. David Millner, 7 Becker Farm Rd., P.O. Box Y, Roseland, NJ 07068, (201) 992–2200. Transporting *general commodities* (except classes A and B explosives, household goods as defined by the Commission, and commodities in bulk), between New York, NY, Philadelphia, PA, and points in NJ.

MC 136818 (Sub-141), filed January 8, 1982. Applicant: SWIFT TRANSPORTATION COMPANY, INC., 5601 W. Mohave, Phoenix, AZ 85031. Representative: Donald E. Fernaays, 4040 E. McDowell Rd., Suite 320, Phoenix, AZ 85008, (602) 275–3124. Transporting *such commodities* as are dealt in or used by wholesale, retail, and chain grocery and food business houses, hardware, discount, drug, variety, and department stores, between points in the U.S. (except AK and HI).

MC 138828 (Sub-10), filed January 12, 1982. Applicant: MAPLEWOOD EQUIPMENT COMPANY, 419 Anderson Ave., Fairview, NJ 07022. Representative: John F. Ward, McCarter Hwy & Market St., P.O. Box 10009, Newark, NJ 07101, (201) 648–6908. Over regular routes, transporting *passengers and their baggage and express,* in the same vehicle with passengers, (1) between Butler and Wayne, NJ: From junction NJ Hwy 23 and Kiel Avenue, Butler, over NJ Hwy 23 to junction NJ Hwy 23 and Black Oak Ridge Road, Wayne, NJ; (2) between Riverdale and Pompton Lakes, NJ: From junction Newark-Pompton Turnpike and Paterson-Hamburg Turnpike, Riverdale, over Paterson-Hamburg Turnpike to junction Wanaque Avenue, then over Wanaque Avenue to junction Colfax Avenue; then over Colfax Avenue to junction Lakeside Avenue, then over Lakeside Avenue to junction Wanaque Avenue, then over Wanaque Avenue to junction Colfax Avenue, Pompton Lakes, and return over the same route; (3) between points in Wayne, NJ: From junction Black Oak Ridge Road and Newark-Pompton Turnpike over Newark-Pompton Turnpike to junction NJ Hwy 23; (4) between points in Wayne and Hackensack, NJ, serving junction Interstate Hwy 80 and NJ Hwy 17 for joinder purposes: From junction Paterson-Hamburg Turnpike and Valley Road, Wayne, over Valley Road, French Hill Road, and Riverview Drive to junction U.S. Hwy 46, then over U.S. Hwy 46 to junction NJ Hwy 23, then over NJ Hwy 23 to junction Interstate Hwy 80, then over Interstate Hwy 80 to junction NJ Hwy 17, Hackensack, and return over the same route; (5) between points in Totowa, NJ: From junction Riverview Drive and Minnisink Road over Minnisink Road, Furler Street, and Union Boulevard to junction Interstate Hwy 80, and return over the same route; (6) between Pompton Lakes and Oakland, NJ, serving no intermediate points except for joinder at junction Skyline Drive and West Oakland Avenue in Oakland: From junction Wanaque Avenue and Colfax Avenue, Pompton Lakes, over Colfax Avenue and West Oakland Avenue to junction West Oakland Avenue and Skyline Drive, Oakland, NJ, and return over the same route, serving all intermediate points in routes (1) through (5)

MC 139858 (Sub-46), filed January 5, 1982. Applicant: AMSTAN TRUCKING, INC., 1255 Corwin Ave., Hamilton, OH 45015. Representative: Chandler L. van Orman, 1729 H St., NW., Washington, DC 20006, (202) 337–6500. Transporting *paper and related products* between points in the U.S., under continuing contract(s) with Orchids Paper Products/Concel, Inc., of La Palma, CA, and its subsidiaries, Ponderosa Paper Products Co., of Flagstaff, AZ, and Robel Tissue Mills, Inc., and Belco Tissue Mills, Inc., both of Pryor, OK.

MC 142189 (Sub-53), filed January 11, 1982. Applicant: C. M. BURNS, d.b.a. WESTERN TRUCKING, P. O. Box 980, Baker, MT 59313. Representative: James B. Hovland, 525 Lumber Exchange Bldg., 10 S. 5th St., Minneapolis, MN 55402, (612) 340–0808. Transporting *metal products,* between points in the U. S. in and west of OH, KY, TN, and MS.

Volume No. OP5–16

Decided: January 22, 1982.

By the Commission, Review Board No. 3, Members Krock, Joyce, and Dowell.

MC 143259 (Sub-5), filed January 11, 1982. Applicant: TOM DURKIN TRUCKING, 36 East Chestnut St., Walla Walla, WA 99362. Representative: Steve Van Wyk, 12012 NE Lonetree, Poulsbo, WA 98370, (206) 779–5789. Transporting *general commodities* (except classes A and B explosives) between points in Walla Walla, Columbia, Benton, Franklin, Grant, and Adams Counties, WA, and Umatilla, Union, and Morrow Counties, OR, on the one hand, and, on the other, points in the U.S.

MC 145748 (Sub-4), filed November 30, 1981, previously noticed in (REPUBLICATION) the **Federal Register** on December 18, 1981. Applicant: MEYERS TRANSFER, INC., Rt. 64, East, Mt. Morris, IL 61054. Representative: Abraham A. Diamond, 29 South La Salle Street, Chicago, IL 60603, (312) 236–0548. Transporting *machinery* and *machine parts,* between points in the U. S., under continuing contract(s) with Swenson Spreader, of Lindenwood, IL.

Note.—Purpose of republication is to show applicant's correct name and zip code.

MC 154789 filed January 12, 1982. Applicant: WHETSTONE CORPORATION, 615 E. Research Rd., Richmond, VA 23235. Representative: James R. Whetstone (same address as applicant), (804) 644–3460. Transporting *commodities,* the transportation of which, because of size or weight, require the use of special equipment, between points in the U.S., under continuing contract(s) with Bristol Steel and Iron Works, Inc., of Richmond, VA.

MC 155118 (Sub-2), filed January 12, 1982. Applicant: T.D.S. TRANSPORTATION, INC., 1700 South Wolf Road, Des Plaines, IL 60018. Representative: Julie L. Roper (same address as applicant), (312) 298–8800. Transporting *general commodities* (except classes A and B explosives), between points in the U.S. (except AK and HI), under continuing contract(s) with Visual Design Mfg. Co., of League

City, TX, Equitable Bag Co., Inc., of Orange, TX, Arvin Industries, Inc., of Columbus, IN, Libbey Glass Division of Owens-Illinois, Inc., of Toledo, OH, GTE Products Corporation of Seymour, IN, Disney Tire Company, of Louisville, KY, Gay Toys, Inc., of Walled Lake, MI, and Sparton Industries, of Brownstown, IN.

MC 158738, filed January 6, 1982. Applicant: LLOYD C. BYRD, d.b.a. OVERLAND FREIGHT LINES, 25 S.W. 10th St., Oklahoma City, OK 73125. Representative: C. L. Phillips, Room 248, Classen Terrace Bldg., 1411 N. Classen, Oklahoma City, OK 73106, 405–528–3884. Transporting *general commodities* (except classes A and B explosives, household goods as defined by the Commission and Commodities in bulk), (1) between Oklahoma City, OK, and the junction of Interstate Hwy 35 and U.S. Hwy 77 near Norman, OK, over Interstate Hwy 35; (2) between junction Interstate Hwy 35 and U.S. Hwy 77 near Norman, OK, and junction Interstate Hwy 35 and U.S. Hwy 77 near Thackerville, OK, (a) over Interstate Hwy 35, and (b) over U.S. Hwy 77; (3) between junction Interstate Hwy 35 and U.S. Hwy 77 near Thackerville, OK, and the junction of Interstate Hwy 35E and 35W near Denton, TX, over Interstate Hwy 35; (4) between junction Interstate Hwys 35E and 35W near Denton, TX, and Fort Worth, TX, over Interstate Hwy 35W; and, (5) between junction Interstate Hwys 35E and 35W near Denton, TX, and Dallas, TX, over Interstate Hwy 35E serving all intermediate points in routes 1 through 5 above, and the off route points of Alpers, Antioch, Baum, Clemscot, Cornish, County Line, Dickson, Dillard, Drake, Elmore City, Erin Springs, Foster, Fox, Graham, Healtdon, Hennepin, Katie, Lindsay, Lone Grove, Mannsville, Maysville, Mill Creek, Milo, Nebo, Parnell, Ratliff City, Ravia, Ringling, Sulphur, Tatums, Tishomingo, Troy, Tussy, Velma, White Bead, Wilson and Woodford, OK.

MC 159118, filed January 13, 1982. Applicant: ENERGY TRANSPORT, INC., 4801 S. Harlem Ave., Forest View, IL 60402. Representative: Phillip A. Lee, 120 W. Madison St., Chicago, IL 60602, 312–261–4020. Transporting *petroleum and petroleum products,* between Chicago, IL, on the one hand, and, on the other, points in Champaign, Crawford, Clair, Macon, Sangamon and Williamson Counties, IL.

MC 159759 (Sub-1), filed January 11, 1982. Applicant: ROYALTY DISTRIBUTION SERVICES, INC., Jeanne Drive, Newburgh, NY 12550. Representative: George A. Olsen, P.O. Box 357, Gladstone, NJ 07934, (201) 435–7140. Transporting *general commodities* (except classes A and B explosives, household goods as defined by the Commission, and commodities in bulk), between points in Orange County, NY, on the one hand, and, on the other, points in CT, NJ, PA, MA, NY, OH, DE, MD, VA, and DC.

MC 159789, filed December 21, 1981. Applicant: NU TREND LINES, INC., Route 2, Box 532, Dallas, NC 28034. Representative: Joseph T. Hughes, 205 Clayton St., Lawrenceville, GA 30425, (404) 963–1427. Transporting *general commodities* (except classes A and B explosives, commodities in bulk, and household goods as defined by the Commission), between points in NY, NJ, SC, NC, TX, CA, IL, MO, KS, OH, GA, and TN.

MC 160009, filed January 8, 1982. Applicant: AROUND THE TOWN, INC., 3405 Lacewood Road, Tampa, FL 33618. Representative: J. G. Dail, Jr., P.O. Box LL, McLean, VA 22101, (703) 893–3050. To engage in operations, as a *broker* at Tampa, FL, in arranging for the transportation of *Passengers and their baggage,* in special and charter operations, between points in the U.S.

MC 158209, filed January 11, 1982. Applicant: S.L.A. TRANSPORT, INC., 6 Spring St., Johnstown, NY 12095. Representative: David Earl Tinker, 1000 Connecticut Ave, N.W., Washington, D.C. 20036–5391, 202–887–5868. Transporting (1) *general commodities* (except classes A and B explosives, and household goods as defined by the Commission), between points in Fulton and Montgomery Counties, NY, on the one hand, and, on the other, points in the U.S.; (2) *Such commodities as are dealt in or used by tanneries,* (a) between points in Fulton County, NY, on the one hand, and, on the other, New York, NY, and points in Merrimack County, NH and Franklin County PA; (b) between New York, NY, on the one hand, and, on the other, points in Merrimack County, NH and Franklin County, PA; and (c) between points in Franklin County, PA, on the one hand, and, on the other, points in Merrimack County, NH; and (3) Transporting *machinery and equipment used in the tanning industry,* between Boston, MA, on the one hand, and, on the other, points in the U.S.

MC 160048, filed January 11, 1982. Applicant: HARTZ TRUCK LINE, INC., 120 Arnold Ave., P.O. Box 427, Thief River Falls, MN 56701. Representative: Robert P. Sack, P.O. Box 6010, West St. Paul, MN 55118, 612–457–6889. Transporting *such commodities* as are dealt in by food and grocery business houses, between points in the U.S. under continuing contract(s) with Hartz Wholesale, Inc. of Thief River Falls, MN, and Landy Packing Co., Inc. of St. Cloud, MN.

MC 160049, filed January 11, 1982. Applicant: H & P, INC., 13743 Jenny Drive, P.O. Box 3811, Centerline, MI 48093. Representative: William R. Ralls, 118 W. Ottawa, Suite B, Lansing, MI 48933, (517) 372–6622. Transporting *transportation equipment* between points in the U.S., under continuing contract(s) with Core Industries, Inc., of Mt Clemens, MI, Jartran, Inc., of Coral Gables, FL, McGraw Commercial Equipment Co., Inc., of Sterling Heights, MI, and Hoosier Equipment Company, of River Forest, IL.

MC 160058, filed January 11, 1982. Applicant: SPIKES COMMODITIES, INC., P.O. BOX 759, Hugoton, KS 67951. Representative: Larry E. Gregg, 641 Harrison St., P.O. Box 1979, Topeka, KS 66601, (913) 234–0565. Transporting *chemicals and related products* (except classes A and B explosives), between points in KS, NE, and OK, on the one hand, and, on the other, points in CO, KS, NE, NM, and those points in TX on and north of a line beginning at the TX-NM state line near Hobbs, NM, and extending along U.S. Hwy 180 to U.S. Hwy 277, and then along U.S. Hwy 277 to the TX-OK state line.

MC 160079, filed January 11, 1982. Applicant: PIEDMONT TRANSIT, INC., Route 4, Box 353, Burlington, NC 27215. Representative: Archie W. Andrews, 617 F Lynrock Terrace, Eden, NC 27288, (919) 627–0555. Transporting *passengers and their baggage,* in special and charter operations, beginning and ending at points in Alamance, Caswell, Lee, Orange, and Person Counties, NC., and extending to those points in the U.S. in and east of MN, IA, MO, AR, and TX.

MC 160099, filed January 12, 1982. Applicant: GLC TRANSPORTATION, INC., 9989 Kinsman Road, Newbury, OH 44065. Representative: Richard A. Zellner, 800 National City East 6th Bldg., Cleveland, OH 44114, (216) 621–0150. Transporting *food and related products,* between points in the U.S., under continuing contract(s) with Dell Products Corporation, of Hillside, NJ, and Kroger Company, Kluener Packing Co., and K.G.M. International Meats Company, Inc., all of Cincinnati, OH.

Volume No. OP5–19

Decided: January 25, 1982.

By the Commission, Review Board No. 3, members Krock, Joyce, and Dowell.

MC 114718 (Sub-2), filed January 11, 1982. Applicant: GEORGE R. MURPHY, d.b.a. MURPHY TRUCKING &

EXCAVATING CO., P.O. Box 378, Reno, OH 45773. Representative: John P. McMahon, 100 E. Broad St., Columbus, OH 43215, (614) 228–1541. Transporting *metal products, coal and coal products, ores and minerals, clay, concrete, gall or stone products, and waste or scrap materials,* between Washington and Ashtabula Counties, OH, Fayette County, WV, and Niagara Falls, NY, on the one hand, and, on the other, points in the U.S. in and east of MN, IA, MO, KS, AR, and LA.

MC 119118 (Sub-71), filed January 18, 1982. Applicant: HIGHLAND EXPRESS, INC., P.O. Box 388, Latrobe, PA 15650. Representative: Paul F. Sullivan, 711 Washington Bldg., Washington, DC 20005–2075, (202) 347–3987. Transporting *machinery and metal and wood products* between points in the U.S.

MC 152268 (Sub-2), filed January 8, 1982. Applicant: WILKINSON FREIGHT LINES, INC., 15 S. Main St., Belmont, NC 28012. Representative: Ken Wilkinson (same address as applicant.), (704) 825–1451. Transporting *textile products* between points in NC and SC.

MC 156168, filed January 15, 1982. Applicant: VOYAGER BUS LINES, INC., 13613 Engleman Drive, Laurel, MD 20708. Representative: Raymond P. Keigher, 401 E. Jefferson St., Rockville, MD 20850, (301) 424–2420. Transporting *passengers and their baggage* in same vehicle as passengers, in special and charter operations, beginning and ending at Washington, D.C., Alexandria, VA, and Baltimore, MD, and points in Anne Arundel, Baltimore, Howard, Montgomery, and Prince Georges Counties, MD, and Arlington and Fairfax Counties, VA, and extending to points in the U.S. (except HI).

MC 156939 (Sub-1), filed January 11, 1982. Applicant: KANATA CARRIERS, INC., 2203 Dunwin Drive, Mississauga, Ontario Canada L5L 1X2. Representative: Ronald N. Cobert, 1730 M St., NW, Suite 501, Washington, DC 20036, (202) 296–2900. Transporting *general commodities* (except classes A and B explosives, household goods as defined by the Commission, and commodities in bulk), between points in the U.S., under continuing contract(s) with Interamerican Transport System, Inc., of Mississauga, Ontario, Canada.

MC 157848 (Sub-1), filed January 15, 1982. Applicant: O.K.T., INC., 114 Raleigh St., Hamlet, NC 28345. Representative: Barry Weintraub, 8133 Leesburg Pike, Suite 510, Vienna, VA 22180, (703) 442–8330. Transporting *pulp, paper and related products* between points in the U.S. (except AK and HI), under continuing contract(s) with South Carolina Industries, Inc., of Florence, SC.

MC 158938 (Sub-1), filed January 11, 1982. Applicant: BOSWELL FARMS, INC., 403 South State Street, Lamoni, IA 50140. Representative: James M. Hodge, 3730 Ingersoll Ave., Des Moines, IA 50312, (515) 274–4985. Transporting *metal products,* (a) between Kansas City, MO and points in Decatur County, IA, on the one hand, and, on the other, points in the U.S., and (b) between points in Marshall County, OK on the one hand, and, on the other, points in AR, CO, IA, KS, LA, MN, MO, ND, NE, SD, TN, and TX.

MC 159189 (Sub-1), filed January 15, 1982. Applicant: MERRITT TRUCKING COMPANY, INC., P.O. Box 18346, Greensboro, NC 27419–8346. Representative: Ralph McDonald, P.O. Box 2246, Raleigh, NC 27602, (919) 828–0731. Transporting *fertilizer* between points in DE, MD, NC, NJ, PA, SC, TN, VA, and WV.

MC 160068, filed January 11, 1982. Applicant: MOBILE CHECK EXCHANGE, INC., 2660 Springhill Ave., Mobile, AL 36601. Representative: J. B. Ward (same address as applicant), 205–473–7346. Transporting (1) *such commercial papers,* documents, and written instruments as are used in the business of banks and banking institutions, (2) coin bullion, precious metals, and articles of unusual value, between points in Jackson, Harrison, Hancock, Pearl River, Stone, George, Greene, Perry, Forrest, Lamar, Marion, Jefferson Davis, Covington, Jones, and Wayne Counties, MS, on the one hand, and, on the other, points in Orleans Parish, LA.

MC 160148, filed January 18, 1982. Applicant: WADDLE BROS. AND SONS, INC., Hayes Route, Box 16C–1, Woodland, WA 98674. Representative: Kit S. Waddle (same address as applicant), (206) 225–8097. Transporting *such commodities* as are dealt in or used by grocery stores and food business houses and manufacturers of building materials, between points in AZ, CA, CO, ID, MT, NM, NV, OR, TX, UT, WA, and WY.

MC 160169, filed January 18, 1982. Applicant: L. G. TRUCKING, INC., 13612 South Lowe, Riverdale, IL 60627. Representative: Edward F. Stanula, 900 East 162nd St., P.O. Box 306, South Holland, IL 60473, (312) 596–8575. Transporting *iron and steel products* between points in the U.S., under continuing contract(s) with Keystone Tube Company of Chicago, IL.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82–2655 Filed 2–1–82; 8:45 am]

BILLING CODE 6450–01–M

[Docket No. AB–167 (Sub–No. 35N)]

Conrail Abandonment in Jeffersonville, IN; Findings

Notice is hereby given pursuant to Section 308(e) of the Regional Rail Reorganization Act of 1973 that the Commission, Review Board Number 1 has issued a certificate authorizing the Consolidated Rail Corporation to abandon its rail line between Jeffersonville and the end of the line in the County of Clark, IN, a total distance of 1.5 miles effective of January 6, 1982.

The net liquidation value of this line is $37,759. If, within 120 days from the date of this publication, Conrail receives a bona fide offer for the sale, for 75 percent of the net liquidation value, of this line it shall sell such line and the Commission shall, unless the parties otherwise agree, establish an equitable division of joint rates for through routes over such lines.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82–2619 Filed 2–1–82; 8:45 am]

BILLING CODE 7035–01–M

[Docket No. AB–167 (Sub-No. 54N)]

Conrail Abandonment Between Austin Lake and Vicksburg, MI; Findings

Notice is hereby given pursuant to Section 308(e) of the Regional Rail Reorganization Act of 1973 that the Commission, Review Board Number 1 has issued a certificate authorizing the Consolidated Rail Corporation to abandon its rail line between Austin Lake and Vicksburg in the County of Kalamazoo, MI, a total distance of 5.5 miles effective on January 6, 1982.

The net liquidation value of this line is $167,931. if, within 120 days from the date of this publication, Conrail receives a bona fide offer for the sale, for 75 percent of the net liquidation value, of this line it shall sell such line and the Commission shall, unless the parties otherwise agree, establish an equitable division of joint rates for through routes over such lines.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 81–2620 Filed 2–1–82; 8:45 am]

BILLING CODE 7035–01–M

[Docket No. AB-167 (Sub-No. 57N)]

Conrail Abandonment in Lockport, Niagara County, NY; Findings

Notice is hereby given pursuant to Section 308(e) of the Regional Rail Reorganization Act of 1973 that the Commission, Review Board Number 2 has issued a certificate authorizing the Consolidated Rail Corporation to abandon its rail line between milepost 21.0 and milepost 56.7 in Lockport, Niagara County, NY, a total distance of 1.2 miles effective on January 6, 1982.

The net liquidation value of this line is $109,055. If, within 120 days from the date of this publication, Conrail receives a bona fide offer for the sale, for 75 percent of the net liquidation value, of this line it shall sell such line and the Commission shall, unless the parties otherwise agree, establish an equitable division of joint rates for through routes over such lines.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-2633 Filed 2-1-82; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-167 (Sub-No. 37N)]

Conrail Abandonment In Newark, NJ; Findings

Notice is hereby given pursuant to Section 308(e) of the Regional Rail Reorganization Act of 1973 that the Commission, Review Board Number 1 has issued a certificate authorizing the Consolidated Rail Corporation to abandon its rail line from Hunter Street, Newark to the end of the line in the County of Essex, NJ, a total distance of 1.7 miles effective on January 6, 1982.

The net liquidation value of this line is $57,575. If, within 120 days from the date of this publication, Conrail receives a bona fide offer for the sale, for 75 percent of the net liquidation value, of this line it shall sell such line and the Commission shall, unless the parties otherwise agree, establish an equitable division of joint rates for through route over such lines.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-2617 Filed 2-1-82; 8:45 am]

BILLING CODE 7035-01-M

Docket No. AB-167 (Sub-No. 46N)

Conrail Abandonment Between Newark Transfer and The Passaic River, NJ; Findings

Notice is hereby given pursuant to Section 308(e) of the Regional Rail Reorganization Act of 1973 that the Commission, Review Board Number 3 has issued a certificate authorizing the Consolidated Rail Corporation to abandon its rail line between Newark Transfer and Passaic River in the County of Essex, NJ, a total distance of 0.3 miles effective on January 6, 1982.

The net liquidation value of this line is $64,927. If, within 120 days from the date of this publication, Conrail receives a bona fide offer for the sale, for 75 percent of the net liquidation value, of this line it shall sell such line and the Commission shall, unless the parties otherwise agree, establish an equitable division of joint rates for through routes over such lines.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-2625 Filed 2-1-82; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-167 (Sub-No. 36N)]

Conrail Abandonment in Warren County, N.J.; Findings

Notice is hereby given pursuant to Section 308(e) of the Regional Rail Reorganization Act of 1973 that the Commission, Review Board Number 1 has issued a certificate authorizing the Consolidated Rail Corporation to abandon its rail line between Pennsylvania-New Jersey State line and the eastern end of the line in the County of Warren, NJ, a total distance of 1.2 miles effective on January 6, 1982.

The net liquidation value of this line is $47,981. If, within 120 days from the date of this publication, Conrail receives a bona fide offer for the sale, for 75 percent of the net liquidation value, of this line it shall sell such line and the Commission shall, unless the parties otherwise agree, establish an equitable division of joint rates for through routes over such lines.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-2618 Filed 2-1-82; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-167 (Sub-No. 48N)]

Conrail Abandonment Between Dayton and Lytle, Ohio; Findings

Notice is hereby given pursuant to Section 308(e) of the Regional Rail Reorganization Act of 1973 that the Commission, Review Board Number 3 has issued a certificate authorizing the Consolidated Rail Corporation to abandon its rail line between Dayton and Lytle in the County of Montgomery, OH, a total distance of 1.7 miles effective on January 6, 1982.

The net liquidation value of this line is $236,239. If, within 120 days from the date of this publication, Conrail receives a bona fide offer for the sale, for 75 percent of the net liquidation value, of this line it shall sell such line and the Commission shall, unless the parties otherwise agree, establish an equitable division of joint rates for through route over such lines.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-2624 Filed 2-1-82; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-167 (Sub-No. 42N]

Conrail Abandonment In Allentown, Pa.; Findings

Notice is hereby given pursuant to Section 308(e) of the Regional Rail Reorganization Act of 1973 that the Commission, Review Board Number 2 has issued a certificate authorizing the Consolidated Rail Corporation to abandon its rail line from Union Boulevard, Allentown to the end of the line in the County of Lehigh, PA, a total distance of 0.5 miles effective on January 6, 1982.

The net liquidation value of this line is $96,585. If, within 120 days from the date of this publication, Conrail receives a bona fide offer for the sale, for 75 percent of the net liquidation value, of this line it shall sell such line and the Commission shall, unless the parties otherwise agree, establish an equitable division of joint rates for through routes over such lines.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-2630 Filed 2-1-82; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-167 (Sub-No. 51N]

Conrail Abandonment Between Brill and Passayunk Avenue, PA; Findings

Notice is hereby given pursuant to Section 308(e) of the Regional Rail Reorganization Act of 1973 that the Commission, Review Board Number 1 has issued a certificate authorizing the Consolidated Rail Corporation to abandon its rail line between Brill and Passayunk Avenue in the County of Philadelphia, PA, a total distance of 1.2 miles effective on January 6, 1982.

The net liquidation value of this line is $112,699. If, within 120 days from the date of this publication, Conrail receives a bona fide offer for the sale, for 75

percent of the net liquidation value, of this line it shall sell such line and the Commission shall, unless the parties otherwise agree, establish an equitable division of joint rates for through routes over such lines.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-2621 Filed 2-1-82; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-167 (Sub-No. 55N)]

Conrail Abandonment Between Burn and the Barber Quarry Branch, PA; Findings

Notice is hereby given pursuant to Section 308(e) of the Regional Rail Reorganization Act of 1973 that the Commission, Review Board Number 1 has issued a certificate authorizing the Consolidated Rail Corporation to abandon its rail line between Burn and the Barber Quarry Branch in the County of Lehigh, PA, a total distance of 1.5 miles effective on January 6, 1982.

The net liquidation value of this line is $481,925. If, within 120 days from the date of this publication, Conrail receives a bona fide offer for the sale, for 75 percent of the net liquidation value, of this line it shall sell such line and the Commission shall, unless the parties otherwise agree, establish an equitable division of joint rates for through routes over such lines.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-2632 Filed 2-1-82; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-167 (Sub-No. 49N)]

Conrail Abandonment Between Carlon and Nazareth, PA; Findings

Notice is hereby given pursuant to Section 308(e) of the Regional Rail Reorganization Act of 1973 that the Commission, Review Board Number 3 has issued a certificate authorizing the Consolidated Rail Corporation to abandon its rail line between Carlon and Nazareth in the County of Northampton, PA, a total distance of 1.8 miles effective on January 6, 1982.

The net liquidation value of this line is $44,505. If, within 120 days from the date of this publication, Conrail receives a bona fide offer for the sale, for 75 percent of the net liquidation value, of this line it shall sell such line and the Commission shall, unless the parties otherwise agree, establish an equitable division of joint rates for through routes over such lines.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-2623 Filed 2-1-82; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-167 (Sub-No. 45N)]

Conrail Abandonment in the City of Reno, PA; Findings

Notice is hereby given pursuant to Section 308(e) of the Regional Rail Reorganization Act of 1973 that the Commission, Review Board Number 3 has issued a certificate authorizing the Consolidated Rail Corporation to abandon its rail line between milepost 79.9 and 81.9 in the City of Reno, Venango County, PA, a total distance of 2.0 miles effective on January 6, 1982.

The net liquidation value of this line is $43,058. If, within 120 days from the date of this publication, Conrail receives a bona fide offer for the sale, for 75 percent of the net liquidation value, of this line it shall sell such line and the Commission shall, unless the parties otherwise agree, establish an equitable division of joint rates for through routes over such lines.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-2626 Filed 2-1-82; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-167 (Sub-No. 43N)]

Conrail Abandonment Between Catasaugua and Seiple, PA; Findings

Notice is hereby given pursuant to Section 308(e) of the Regional Rail Reorganization Act of 1973 that the Commission, Review Board Number 2 has issued a certificate authorizing the Consolidated Rail Corporation to abandon its rail line between Catasauqua and Seiple in the County of Lehigh, PA, a total distance of 2.5 miles effective on January 6, 1982.

The net liquidation value of this line is $179,848. If, within 120 days from the date of this publication, Conrail receives a bona fide offer for the sale, for 75 percent of the net liquidation value, of this line it shall sell such line and the Commission shall, unless the parties otherwise agree, establish an equitable division of joint rates for through routes over such lines.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-2629 Filed 2-1-82; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-167 (Sub-No. 34N)]

Conrail Abandonment Between Cresco and Mountain Home, PA; Findings

Notice is hereby given pursuant to Section 308(e) of the Regional Rail Reorganization Act of 1973 that the Commission, Review Board Number 1 has issued a certificate authorizing the Consolidated Rail Corporation to abandon its rail line between Cresco and Mountain Home in the County of Monroe, PA, a total distance of 1.0 miles effective on January 6, 1982.

The net liquidation value of this line is $10,977. If, within 120 days from the date of this publication, Conrail receives a bona fide offer for the sale, for 75 percent of the net liquidation value, of this line it shall sell such line and the Commission shall, unless the parties otherwise agree, establish an equitable division of joint rates for through route over such lines.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-2627 Filed 2-1-82; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-167 (Sub-No. 44N)]

Conrail Abandonment in Honeybrook, PA; Findings

Notice is hereby given pursuant to Section 308(e) of the Regional Rail Reorganization Act of 1973 that the Commission, Review Board Number 2 has issued a certificate authorizing the Consolidated Rail Corporation to abandon its rail line near Honeybrook in the Counties of Chester and Lancaster, PA, a total distance of 2.6 miles effective on January 6, 1982.

The net liquidation value of this line is $65,359. If, within 120 days from the date of this publication, Conrail receives a bona fide offer for the sale, for 75 percent of the net liquidation value, of this line it shall sell such line and the Commission shall, unless the parties otherwise agree, establish an equitable division of joint rates for through routes over such lines.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-2628 Filed 2-1-82; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-167 (Sub-No. 39N)]

Conrail Abandonment Between Phoenixville and Parkerford, PA; Findings

Notice is hereby given pursuant to Section 308(e) of the Regional Rail

Reorganization Act of 1973 that the Commission, Review Board Number 2 has issued a certificate authorizing the Consolidated Rail Corporation to abandon its rail line between Phoenixville and Parkerford in the Counties of Montgomery and Chester, PA, a total distance of 6.8 miles effective on January 6, 1982.

The net liquidation value of this line is $563,092. If, within 120 days from the date of this publication, Conrail receives a bona fide offer for the sale, for 75 percent of the net liquidation value, of this line it shall sell such line and the Commission shall, unless the parties otherwise agree, establish an equitable division of joint rates for through routes over such lines.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-2615 Filed 2-1-82; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-167 (Sub-No. 41N)]

Conrail Abandonment Between Newton Square Branch and Millbourne Mills, PA; Findings

Notice is hereby given pursuant to Section 308(e) of the Regional Rail Reorganization Act of 1973 that the Commission, Review Board Number 2 has issued a certificate authorizing the Consolidated Rail Corporation to abandon its rail line between Newton Square Branch and Millbourne Mills in the County of Delaware, PA, a total distance of 2.3 miles effective on January 6, 1982.

The net liquidation value of this line is $ -0-. If, within 120 days from the date of this publication, Conrail receives a bona fide offer for the sale, for 75 percent of the net liquidation value, of this line it shall sell such line and the Commission shall, unless the parties otherwise agree, establish an equitable division of joint rates for through route over such lines.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-2631 Filed 2-1-82; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-167 (Sub-No. 38N]

Conrail Abandonment Between Roosevelt Boulevard and Penn Street, in Philadelphia, PA; Findings

Notice is hereby given pursuant to Section 308(e) of the Regional Rail Reorganization Act of 1973 that the Commission, Review Board Number 1 has issued a certificate authorizing the Consolidated Rail Corporation to abandon its rail line between Roosevelt Boulevard and Penn Steet in the County of Philadelphia, PA, a total distance of 1.2 miles effective on January 6, 1982.

The net liquidation value of this line is $173,733. If, within 120 days from the date of this publication, Conrail receives a bona fide offer for the sale, for 75 percent of the net liquidation value, of this line it shall sell such line and the Commission shall, unless the parties otherwise agree, establish an equitable division of joint rates for through routes over such lines.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-2610 Filed 2-1-82; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-167 (Sub-No. 50N)]

Conrail Abandonment Between Lamokin and Upland, PA; Findings

Notice is hereby given pursuant to Section 308(e) of the Regional Rail Reorganization Act of 1973 that the Commission, Review Board Number 2 has issued a certificate authorizing the Consolidated Rail Corporation to abandon its rail line between Lamokin and Upland in the County of Delaware, PA, a total distance of 0.5 miles effective on January 6, 1982.

The net liquidation value of this line is $358,302. If, within 120 days from the date of this publication, Conrail receives a bona fide offer for the sale, for 75 percent of the net liquidation value, of this line it shall sell such line and the Commission shall, unless the parties otherwise agree, establish an equitable division of joint rates for through routes over such lines.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-2622 Filed 2-1-82; 8:45 am]

BILLING CODE 7035-01-M

[Ex Parte No. 311]

Expedited Procedures for Recovery of Fuel Costs; Decision

Decided: January 27, 1982.

In our recent decisions, an 18.0-percent surcharge was authorized on all owner-operator traffic, and on all truckload traffic whether or not owner-operators were employed. We ordered that all owner-operators were to receive compensation at this level.

The weekly figure set forth in the appendix for transportation performed by owner-operators and for truckload traffic is 18.0-percent. Accordingly, we are authorizing that the surcharge for this traffic remain at 18.0 percent. All owner-operators are to receive compensation at this level.

No change is authorized in the 3.1-percent surcharge on less-than-truckload (LTL) traffic performed by carriers not using owner-operators, or the 6.7-percent surcharge for the bus carriers. However, the UPS surcharge is ordered reduced to 2.0-percent.

Notice shall be given to the general public by mailing a copy of this decision to the Governor of each State having jurisdiction over transportation, by depositing a copy in the Office of the Secretary, Interstate Commerce Commission, Washington, D.C. for public inspection and by depositing a copy to the Director, Office of the Federal Register, for publication therein.

It is ordered:

This decision shall become effective Friday, 12:01 a.m. January 29, 1982.

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

Agatha L. Mergenovich,

Secretary.

APPENDIX.—FUEL SURCHARGE

Base date and price per gallon (including tax)

January 25, 1979 ..... 63.5¢

Date of current price measurement and price per gallon (including tax)

January 25, 1982 ..... 131.0¢

	Transportation performed by—			
	Owner operator [1]	Other [2]	Bus carrier	UPS
	(1)	(2)	(3)	(4)
Average percent: fuel expenses (including taxes) of total revenue	16.9	2.9	6.3	3.3
Percent surcharge developed	18.0	3.1	6.7	[3] 2.8
Percent surcharge allowed	18.0	3.1	6.7	[4] 2.0

[1] Apply to all truckload rated traffic.
[2] Including less-than-truckload traffic.
[3] The percentage surcharge developed for UPS is calculated by applying 81 percent of the percentage increase in the current price per gallon over the base price per gallon to UPS average percent of fuel expense to revenue figure as of January 25, 1979 (3.3 percent).
[4] The developed surcharge is reduced 0.8 percent to reflect fuel-related increases already included in UPS rates.

[FR Doc. 82-2612 Filed 2-1-82; 8:45 am]

BILLING CODE 7035-01-M

January 28, 1982.

Long- And Short-Haul Applications for Relief (Formerly Fourth Section Applications)

These applications for long-and-short-haul relief have been filed with the I.C.C.

Protests are due at the I.C.C. within 15 days from the date of publication of this notice.

No. 43956, Trans-Continental Freight Bureau, Agent, No. 565, relief is sought to maintain at higher-rated intermediate points of destination rates no higher than those determined on basis of the present rates on Lumber and related articles, from points in Canada to stations in Arkansas, Louisiana, Oklahoma, Mississippi, Texas and Tennessee, to be published in its Tariff ICC SWFB 4517, ICC SWFB 4518 and ICC SWFB 4570, item 50 series. Grounds for relief—destination rate relationship.

No. 43957, Southwestern Freight Bureau, Agent (No. B–149), reduced rates on asphalt (asphaltum), etc., from Machovec, TX to destinations in Illinois and Western Trunk Line Territories, in Supplement 153 to its Tariff ICC SWFB 4682, effective February 22, 1982. Ground for relief—Market Competition.

By the Commission.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82–2610 Filed 2–1–82; 8:45 am]

BILLING CODE 7035–01–M

Motor Carriers; Finance Applications; Decision Notice

As indicated by the findings below, the Commission has approved the following applications filed under 49 U.S.C. 10924, 10926, 10931 and 10932.

We find:

Each transaction is exempt from section 11343 (formerly section 5) of the Interstate Commerce Act, and complies with the appropriate transfer rules.

This decision is neither a major Federal action significantly affecting the quality of the human environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

Petitions seeking reconsideration must be filed within 20 days from the date of this publication. Replies must be filed within 20 days after the final date for filing petitions for reconsiderations; any interested person may file and serve a reply upon the parties to the proceeding. Petitions which do not comply with the relevant transfer rules at 49 CFR 1132.4 may be rejected.

If petitions for reconsideration are not timely filed, and applicants satisfy the conditions, if any, which have been imposed, the application is granted and they will receive an effective notice. The notice will indicate that consummation of the transfer will be presumed to occur on the 20th day following service of the notice, unless either applicant has advised the Commission that the transfer will not be consummated or that an extension of time for consummation is needed. The notice will also recite the compliance requirements which must be met before the transferee may commence operations.

Applicants must comply with any conditions set forth the following decision-notices within 30 days after publication, or within any approved extension period. Otherwise, the decision-notice shall have no further effect.

It is Ordered:

The following applications are approved, subject to the conditions stated in the publication, and further subject to the administrative requirements stated in the effective notice to be issued hereafter.

By the Commission, Review Board No. 3, Members Krock, Joyce, and Dowell.

MC–FC–79329. By decision of January 12, 1982 issued under 49 U.S.C. 10926 and the transfer rules at 49 CFR 1132, Review Board Number 3 approved the transfer to SPEED EXPRESS, INC. of a portion of Certificate No. MC–149554 (Sub-No. 1) issued to MOTOR TRANSPORT OF SOUTH DAKOTA, INC. authorizing the transportation of *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment) (a) between Cincinnati OH, and Hamilton, OH, over U.S. Hwy 127, serving no intermediate points, and (b) between points in OH and In within 40 miles of Oxford, OH. Representative: Carl L. Steiner, 39 South LaSalle St., Chicago, IL 60603.

Note.—Transferee is a non-carrier.

MC–FC–79399. By decision of January 20, 1982, issued under 49 U.S.C. 10926 and the transfer rules at 49 CFR 1132, Review Board Number 3 approved the tranfer to Jory Michael Lieberman, d/b/a J. Lieberman Movers, of Glen Head, NY, of a portion of MC–139808 (E–3), awarded to Coastal Van & Storage, Inc., of Newark, NJ. The operating rights to be transferred authorize the transportation of *household goods,* as defined by the Commission, (a) Between points in NJ on the one hand, and, on the other, points in CT, RI, MA, VT, NH, ME, GA and FL. (b) Between points in Essex, Morris, Passaic, Hudson, Union Counties, NJ, on the one hand, and, on the other, points in DC, VA, NC, SC, and those points in PA on and west of a line beginning at the PA–NY State line and extending along U.S. Hwy 11 to junction N.E. Extension of the PA Turnpike, then along to junction PA Hwy 320, then along PA Hwy 320 to the PA–DE State line. (c) Between points in Bergen County, NJ, on the one hand, and, on the other, points in PA. (d) Between points in Essex, Morris, Passaic, Hudson, Union, Mercer, Middlesex, Hunterdon, Monmouth, Somerset, Burlington, Camden, Cape May, Cumberland, Gloucester, Atlantic, Ocean and Salem Counties, NJ, on the one hand, and, on the other, points in OH, MI, IL, and those points in NY on and north of a line beginning at Lake Ontario and extending along NY Hwy 12 to junction NY Hwy 23, then along NY Hwy 23 to the NY–MA State line. (e) Between points in RI, on the one hand, and on the other, NJ, PA, DE, MD, VA, DC, OH, MI, and IL. (f) Between points in ME on the one hand, and, on the other, points in NJ, PA, DE, MD, VA, DC, OH, MI and IL. (g) Between points in VT, on the one hand, and, on the other, points in NJ, MD, DE, VA, OH, MI, IL and DC. (h) Between points in NH on the one hand, and, on the other, points in NJ, DE, MD, VA, DC, OH, MI and IL.

MC–FC 79486. By decision of January 12, 1982, issued under 49 U.S.C. 10926 and the transfer rules at 49 C.F.R. 1132, Review Board Number 3 approved the transfer to WENGERT TRANSPORTATION, INC., d.b.a. CITY DELIVERY of Certificate No. MC–21060 and Subs 6, 8, 9, 10, 13 and 17 thereunder issued to IOWA PARCEL SERVICE, INC., (BANKERS TRUST CO., ATTORNEY-IN-FACT) authorizing the transportation of (1) *general commodities* (with the usual exceptions) between points in 13 northwestern Iowa counties and between those same 13 northwestern Iowa counties and points in IA in Sub 6; between points in IA on the one hand, and, on the other, points in Harrison, Worth and Mercer Counties, MO in Sub 9; between the Des Moines Municipal Airport at Des Moines, IN, on the one hand, and, on the other, points in IA (except Marshalltown, Newton and points in their respective commercial zones) in Sub 10; between Epley Airfield at Omaha, NE on the one hand, and, on the other, points in IA in Sub 13; and between points in Rock Island County, IL and Scott County, IA in Sub 17; and (2) *motion picture films, film accessories, advertising material used in connection with the exhibition of such films, newspapers, magazines and periodicial publications* between Des Moines, IA and Omaha, NE; between Omaha, NE on the one hand, and, on the other, Fulton, IL, points in Polk, Humboldt, Pocahontas, Calhoun, Dallas, Cass, and Cedar Counties, IA, and those in northeastern Iowa; between Fulton, IL and points in the immediately preceding described territory; and between Des Moines, IA, Omaha, NE, Fulton, IL,

points in the Davenport, IA—Rock Island and Moline, IL commercial zone as defined by the Commission, and East Moline, Silvis, and Milan, IL, on the one hand, and, on the other, points in Worth and Scotland Counties, MO, and points in 43 Iowa counties in the Lead Certificate; between all points in Iowa in Sub 8; and between points in IA on the one hand, and, on the other, points in Harrison and Mercer Counties, MO in Sub 9. Representative: James M. Hodge, 1000 United Central Bank Bldg., Des Moines, IA 50309. TA lease is sought. Transferee is a carrier.

MC–FC–79511. By decision of January 13, 1982, Review Board Number 3 approved the transfer to A.M.A. Transportation Co., Inc., of Chelsea, MA, of a portion of Certificate No. MC–69275 to M&M Transportation Company, of Needham Heights, MA authorizing: *General commodities* (usual exceptions), between Boston, MA, and Philadelphia, PA, serving named intermediate and off-route points, over various described regular routes, with various restrictions. Representative: Joseph Wine, 54 Deronshire St., Boston, MA 02109. TA lease is sought. Transferee is not a carrier.

MC–FC–79516. By decision of January 18, 1982, issued under 49 U.S.C. 10926 and the transfer rules at 49 CFR 1132, Review Board Number approved the transfer to FRANCIS B. SHERIDAN, d.b.a. MOUND CITY TRUCK LINE, Route 2, Box 214, Mound City, KS 66056, of Certificate No. MC–119990 (Sub 11), issued November 21, 1980, to MERCHANTS DELIVERY CO., of Kansas City, MO, authorizing the transportation by irregular routes of *shipments weighing 100 pounds or less* if transported in a motor vehicle in which no package exceeds 100 pounds, from Wichita, KS, to Kansas City, MO. Representative is: Arthur J. Cerra, 2100 CharterBank Center, P.O. Box 19251, Kansas City, MO 64141. TA lease is not sought.

MC–FC–79522. By decision of December 29, 1981, issued under 49 U.S.C. 10926 and the transfer rules at 49 C.F.R. 1132, Review Board Number 3 approved the transfer to J. P. NOONAN TRANSPORTATION, INC. of West Bridgewater, MA of Certificate No. MC–113276 (Sub-Nos. 1, 5, 6, and 8) issued to ROMANO BROS. TRUCKING, INC., of Rutland, VT authorizing: the transportation of (1) grocery, grocery-store supplies, canned goods, and sugar (with specified exceptions), from Boston, MA to points in a defined area in Vermont; (2) marble, marble products, and limestone (with specific exceptions), from named points in Vermont to points in New Hampshire, Massachusetts, Connecticut, Rhode Island, New York, New Jersey, Pennsylvania, Delaware, Maryland, and the District of Columbia; (3) malt beverages, from New York, NY and Orange, NJ to Rutland, VT; (4) empty malt beverage containers, from Rutland, VT to NY, NY, and Orange, NJ; (5) malt and vinous beverages, from Willimanssett, MA to Rutland, VT; (6) empty malt and vinous beverage containers, from Rutland, VT to Willimansett, MA; (7) ground limestone, from Florence, VT, to Cumberland Mills, Lisbon, Sanford, and Winthrop, ME; (8) marble, marble products, and ground limestone, from New Haven Junction, VT, to Middlebury and Florence, VT; (9) and ground limestone (with exceptions), from Florence and New Haven Junction, VT, to Ashtabula, OH. Representatives: Frank J. Weiner, 15 Court Square, Boston, MA 02108; Robert S. Pratt, 64 N. Main St., Rutland, VT 05701. TA lease is sought. Transferee is a carrier.

MC–FC–79526. By decision of January 15, 1982 issued under 49 U.S.C. 10926 and the transfer rules at 49 CFR 1132, Review Board Number 3 approved the transfer to L&L Motor Freight, Inc. of Certificate of Registration Nos. MC–121826 and MC–121826 (Sub-No. 1) issued October 31, 1980 and January 21, 1981 to Ouachita Mountain Express, Inc. authorizing the transportation of common; regular (a) *general commodities* over the following routes: (1) between Oklahoma City, OK and McAlester, OK; from Oklahoma City, OK, east over Interstate Hwy 40 to its intersection with OK Hwy 99, thence south over OK Hwy 99 to its intersection with U.S. Hwy 270, thence southeast over U.S. Hwy 270 to McAlester, OK, serving all intermediate points; (2) from McAlester, OK to Poteau, OK; from McAlester, OK east on U.S. Hwy 270 to its intersection with OK Hwy 1, thence east on OK Hwy 1 to its intersection with U.S. Hwy 271, thence north on U.S. Hwy 271, serving all intermediate points; (3) From McAlester, OK to Wister, OK. From McAlester, OK via U.S. Hwy 270 to Wister, OK, serving all intermediate points and the off-route point of Damon, OK; (4) From Wister, OK via U.S. Hwy 270 to its intersection with U.S. Hwy 59, thence U.S. Hwy 59 to its intersection with U.S. Hwy 270 to Page, OK, serving all intermediate points; (5) From Wilburton, OK via OK Hwy 2 to its intersection with OK Hwy 1 and U.S. Hwy 63; (6) from Poteau, OK to Heavener, OK; From Poteau, OK via U.S. Hwy 59 to its intersection with OK Hwy 128, thence to Heavener, OK; (7) from McAlester, OK to the U.S. Naval Ammunition Depot. From McAlester, OK via U.S. Hwy 69 to the U.S. Naval Ammunition Depot. (b) *general commodities* (except commodities of unusual value, household goods, explosives, and commodities requiring the use of special equipment for loading, unloading, or transportation (1) between the intersection of Interstate Hwy 40 and OK Hwy 99 and the intersection of Interstate Hwy 40 and U.S. Hwy 69: from over Interstate Hwy 40 to serving no intermediate points or terminals (2) *for operating convenience only*, (a) between the intersection of Interstate Hwy 40 and U.S. Hwy 69 and Poteau, OK, from the intersection of Interstate Hwy 40 and U.S. Hwy 69 over Interstate Hwy 40 to its intersection with U.S. Hwy 59, thence over U.S. Hwy 59 to Poteau, OK and return over the same route, serving Poteau and all intermediate points and the off-route points of Checotah, Warner, Webber's Falls, Porum, Gore, Vian and Sallisaw; (b) between McAlester, OK and junction U.S. Hwy 69 and Interstate Hwy 40; over U.S. Hwy 69 serving all intermediate points. Representative: William P. Parker, P.O. Box 54657, Oklahoma City, OK 73154.

Notes.—(1) TA has not been filed. (2) Transferee is authorized to operate pursuant to Nos. MC–149152 (Sub Nos. 2, 3, and 4). In Sub Nos. 2 and 4, its holds regular route authority enabling operations over a network of regular routes within the State of OK. In Subs Nos. 3 authority transferee holds authority to transport general commodities over irregular routes between Oklahoma City, OK and Lubbock, TX. (3) MC–121826 (Sub-No. 2) is a directly regulated application to the certificate of registration being sold in MC–FC–79526 to a certificate of public convenience and necessity. It is being published in the same Federal Register issue.

MC–FC–79531. By decision of January 5, 1982 issued under 49 U.S.C. 10926 and the transfer rules at 49 CFR 1132, Review Board Number 3 approved the transfer to MALLIE KAY WEBSTER of Certificate No. MC–135348 (Sub-No. 2) issued to ELLIS B. WEBSTER authorizing operations as a *common carrier*, over irregular routes, of *lead, zinc, gold, and silver concentrates*, in bulk, from Black Claud Mine located at Iowa Gulch, (Lake County), CO, to the Denver and Rio Grande Railroad siding at Oro Jct., in Leadville, CO. Representative: William Andrew Wilson, Suite 1212, United Bank Bldg., 1700 Broadway, Denver, CO 80290. TA lease is not sought. Transferee is not a carrier.

MC–FC–79535. By decision of January 11, 1982, issued under 49 U.S.C. 10926 and the transfer rules at 49 CFR 1132, Review Board Number 3 approved the

transfer to GARYM LOOMIS d.b.a. LOOMIS FREIGHT of Certificate No. MC–135491 to THOMAS B. BILLING d.b.a. JORDAN FREIGHT authorizing the transportation of *general commodities* (usual exceptions) over regular routes, from Billings, MT, to Jordan, MT, serving the intermediate and off-route points of Winnett, Cat Creek, and Mosby, MT, from Billings over U.S. Hwy 87 to junction MT Hwy 244, then over MT Hwy 244 to MT Hwy 200, then over MT Hwy 200 to Jordan and return over the same route. Representative: H. David Cogley, 1025 3rd Street, Helena, MT 59601.

Note.—Transferee is a non-carrier.

MC–79544. By decision of 1–12–82 issued under 49 U.S.C. 10926 and the transfer rules at 49 C.F.R. 1132, Review Board Number 3 approved the transfer to Gaylord Combs and Josette Combs of Certificate No. MC–154855 issued to K.D., Inc. authorizing the transportation of (1) *household appliances* and (2) *equipment, materials and supplies* used in the manufacture and distribution of household appliances, between the facilities of General Electric Company, Appliance Park, at Louisville, KY, and points in IN and Cincinnati, OH. Note: Transferee is a non-carrier. Applicant's representative: James B. Murphy, Suite 102, Interchange Building, 835 West Jefferson Street, Louisville, KY 40202.

MC–FC–79555. By decision of 1–12–82 issued under 49 U.S.C. 10926 and the transfer rules at 49 C.F.R. 1132 Review Board Number 3 approved the transfer to Allstate Carriers, Inc. of Fort Worth, TX of Certificate No. MC–133095 (Sub-No. 306X) issued October 14, 1981 to Texas-Continental Express, Inc. of Fort Worth, TX authorizing the transportation over irregular routes of *food and related products, chemicals and related products, machinery, clay, concrete, glass or stone products, rubber and plastic products, pulp, paper and related products, lumber and wood products, metal products, petroleum, natural gas and petroleum products, ores and minerals, furniture and fixtures, transportation equipment, building materials, printed matter, textile mill products, such merchandise as is dealt in by retail stores, retail, auto and home supply stores, drug stores, discount and variety stores* between various points in the United States. Applicant's representatives are: Clayte Binion, 623 South Henderson, 2nd Fl., Fort Worth, TX and Marshall Kragen, 1919 Pennsylvania Avenue, NW, Suite 300, Washington, DC 20006.

MC–FC–79556. By decision of 1–12–82 issued under 49 U.S.C. 10924 and the transfer rules at 49 CFR 1045.11. Review Board Number 3 approved the acquisition of control by Southern Freightlines, Inc., a motor common carrier, of Freight Management Systems, Inc., a broker for the transportation of property, operating under License No. MC–131028 issued January 23, 1981, which authorizes the holder to arrange for the transportation of general commodities (except household goods), between points in the United States. Applicants' representative is: Robert J. Gallagher, Esquire, 1000 Connecticut Avenue, NW, Suite 1200, Washington, DC.

MC–FC–79558. By decision of 1–12–82 issued under 49 U.S.C. 10926 and the transfer rules at 49 C.F.R. 1132, Review Board Number 3 approved the transfer to Hosler Moving and Storage, Inc. of Certificate No. MC–129220 (Sub-No. 1) issued to Ted M. Hosler dba Hosler Moving & Storage authorizing the transportation of used household goods, between points in Geary, Riley, Saline and Dickinson Counties, KS. Restricted to the transportation of traffic having a prior or subsequent movement, in containers, beyond the points authorized and further restricted to the performance of pickup and delivery service in connection with packing, crating, and containerization or unpacking, uncrating, and decontainerization of such traffic. NOTE: TA application has been filed. Transfer is a non-carrier Applicants' representative: Erle W. Francis, 719 Capitol Federal Bldg., Topeka, KS 66603.

MC–FC–79559. By decision of January 15, 1982, issued under 49 U.S.C. 10926 and the transfer rules at 49 CFR 1132, Review Board Number 3 approved to the transfer to JAMES MATTAR, INC., d.b.a. EAGLE EXPRESS CO. of Certificate No. MC–97879 (Sub-No. 4) issued July 6, 1981 to Bab Transfer, Inc. authorizing the transportation of *General commodities*, except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk and those requiring special equipment between points in Massachusetts. Representative: David M. Marshall, 101 State Street, Suite 304, Springfield, MA 01103.

MC–FC 79562, By decision of Janaury 12, 1982 issued under 49 U.S.C. 10926 and the transfer rules at 49 CFR 1132, Review Board Number 3 approved the transfer to EDWARD SKINNER, JR., d.b.a. SKINNER TRUCKING of Twin Falls, ID of Permit No. MC–138977 (Sub-Nos. 1 and 3) issued August 16, 1974, and November 7, 1980 to Edward W. Skinner, Sr. and Edward W. Skinner, Jr., a Partnership d.b.a. Skinner Trucking of Twin Falls, ID authorizing transportation as a motor contract carrier over irregular routes transporting (1) *beekeepers' supplies and equipment, honey and beeswax* between points in AZ, CA, CO, ID, IL, IA, MN, MT, NE, NM, NV, ND, OK, OR, SD, TX, UT, WA, and WY under contract with Sioux Honey Ass's, Sioux City, IA, and (2) *irrigation pipe fittings* and *accessories* from Twin Falls, ID to points in AZ, CA, CO, MT, NV, OR, UT, WA and WY under contract with Aulmax Irrigation Products, Twin Falls, ID Representative: Timothy R. Stivers, P.O. Box 157, Boise, ID 83701.

MC–FC–79564. by decision of 1–15–82 Review Board 3 approved the transfer to A. D. McMULLEN, INC., of N. Dartmouth, MA, of Certificate No. MC–84463 issued to TANNER'S TRANSFER & STORAGE, INC. (Douglas O. Tice, Jr., Trustee in Bankruptcy) of Richmond, VA, authorizing household goods between points in AL, CT, DE, FL, GA, IL, IN, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, NH, NJ, NY, NC, OH, PA, RI, SC, TN, TX, VA, WV, WI, and DC. Representative; Andrew S. Kocser and Alfred John Chabior, P.O. Box 435, Dartmouth, MA 02747.

MC–FC–79568, filed January 12, 1982. J.T.I. TRANSPORTATION CO. (J.T.I.) (P.O. Box 78, Fairmont, NE 68354)—purchase—JACOBSEN TRANSFER, INC. (Jacobsen) (P.O. Box 47, Fairmont, NE 68354). Representative: Brian K. Ridenour, Nelson & Harding, P.O. Box 83028, 1200 N Street, 500 The Atrium, Lincoln, NE 68501. J.T.I., a corporation, seeks to purchase No. MC–85788 and subs thereunder issued to Jacobsen authorizing (1) food and related products between points in (a) San Mateo County, CA, on the one hand, and, on the other, points in the United States in and east of Montana, Wyoming, Utah and New Mexico; (b) York County, NE, on the one hand, and, on the other, points in Illinois, Wisconsin, Minnesota, Kansas, Missouri, Michigan, and Iowa; (c) Dawson County, NE on the one hand, and, on the other, points in Illinois (except Rockford and Chicago), Ohio, Michigan, and Wisconsin; (d) Kearney and Dawson Counties, NE on the one hand, and, on the other, Rockford and Chicago, IL, points in that part of Missouri on the north of U.S. Hwy 50, and points in Kansas and Kentucky; (e) York County, NE, on the one hand, and, on the other, points in Colorado, Indiana, Kentucky, Ohio, and South Dakota; and (f) Dawson County, NE, on the one hand, and, on the other, points in Colorado, Indiana, Iowa, Minnesota,

South Dakota, and points in that part of Missouri South of U.S. Hwy 50 as a common carrier and (2) (a) food and related products under a continuing contract(s) with Kelco Foods, Inc. of Deerfield, IL, (b) metal products and machinery under a continuing contract(s) with Geneva Concrete Company, Inc. of Geneva, NE; and (c) metal products under a continuing contract(s) with Wilkins Steel Building Company, Inc. of Geneva, NE, between points in the United States, as a contract carrier. An application for temporary authority has been filed. Representative: Brian K. Ridenour, 1200 N Street, 500 The Atrium, P.O. Box 82028 Lincoln, NE 68501.

Decision-Notice

The following operating rights applications, filed on or after July 3, 1980, are filed in connection with pending finance applications under 49 U.S.C. 10926, 11343 or 11344. The applications are governed by Special Rule 252 of the Commission's General Rules of Practice (49 CFR 1100.252).

Persons wishing to oppose an application must follow the rules under 49 CFR 1100.252. Persons submitting protests to applications filed in connection with pending finance applications are requested to indicate across the front page of all documents and letters submitted that the involved proceeding is directly related to a finance application and the finance docket number should be provided. A copy of any application, together with applicant's supporting evidence, can be obtained from any applicant upon request and payment to applicant of $10.00.

Amendments to the request for authority are not allowed. However, the Commission may have modified the application to conform to the Commission's policy of simplifying grants of operating authority.

Findings

With the exceptions of those applications involving duly noted problems (e.g., unresolved common control, unresolved fitness questions, and jurisdictional problems) we find, preliminarily, that each applicant has demonstrated that its proposed service warrants a grant of the application under the governing section of the Interstate Commerce Act. Each applicant is fit, willing, and able properly to perform the service proposed and to conform to the requirements of Title 49, Subtitle IV, United States Code, and the Commission's regulations. Except where specifically noted, this decision is neither a major Federal action significantly affecting the quality of the human environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

In the absence of legally sufficient protests in the form of verified statements as to the finance application *or* to the following operating rights applications directly related thereto filed within 45 days of publication of this decision-notice (or, if the application later becomes unopposed), appropriate authority will be issued to each applicant (except where the application involves duly noted problems) upon compliance with certain requirements which will be set forth in a notification of effectiveness of this decision-notice. Within 60 days after publication an applicant may file a verified statement in rebuttal to any statement in opposition.

Applicant(s) must comply with all conditions set forth in the grant or grants of authority within the time period specified in the notice by effectiveness of this decision-notice, or the application of a non-complying applicant shall stand denied.

To the extent that any of the authority granted may duplicate an applicant's other authority, the duplication shall be construed as conferring only a single operating right.

Dated: January 27, 1982.

By the Commission, Review Board Number 5, Members Krock, Taylor, and Williams.

MC 121826 (Sub-2), filed December 8, 1981. Applicant: OVACHITA MOUNTAIN EXPRESS, INC.—conversion, 1911 N.W. 1st Street, Oklahoma City, OK 73106. Representative: William P. Parker, P.O. Box 54657, Oklahoma City, OK 73154. (a) *general commodities* over the following routes: (1) between Oklahoma City, OK and McAlester, OK; from Oklahoma City, OK, east over Interstate Hwy 40 to its intersection with OK Hwy 99, thence south over OK Hwy 99 to its intersection with U.S. Hwy 270, thence southeast over U.S. Hwy 270 to McAlester, OK, serving all intermediate points; (2) from McAlester, OK to Poteau, OK, from McAlester. OK east on U.S. Hwy 270 to its intersection with OK Hwy 1, thence east on OK Hwy 1 to its intersection with U.S. Hwy 271, thence north on U.S. Hwy 271, serving all intermediate points; (3) From McAlester, OK to Wister, OK. From McAlester, OK via U.S. Hwy 270 to Wister, OK, serving all intermediate points and the off-route point of Damon, OK; (4) From Wister, OK via U.S. Hwy 270 to its intersection with U.S. Hwy 59, thence U.S. Hwy 59 to its intersection with U.S. Hwy 270 to Page, OK, serving all intermediate points; (5) From Wilburton, OK via OK Hwy 2 to its intersection with OK Hwy 1 and U.S. Highway 63; (6) from Poteau, OK to Heavener, OK; From Poteau, OK via U.S. Hwy 59 to its intersection with OK Hwy 128, thence to Heavener, OK; (7) from McAlester, OK to the U.S. Naval Ammunition Depot. From McAlester, OK via U.S. Hwy 69 to the U.S. Naval Ammunition Depot. (b) *general commodities* (except commodities of unusual value, household goods, explosives, and commodities requiring the use of special equipment for loading, unloading, or transportation (1) between the intersection of Interstate Hwy 40 and OK Hwy 99 and the intersection of Interstate Hwy 40 and U.S. Hwy 69; from over Interstate Hwy 40 to serving no intermediate points or terminals (2) *for operating convenience only*, (a) between the intersection of Interstate Hwy 40 and U.S. Hwy 69 and Poteau, OK, from the intersection of Interstate Hwy 40 and U.S. Highway 69 over Interstate Hwy 40 to its intersection with U.S. Hwy 59, thence over U.S. Hwy 59 to Poteau, OK and return over the same route, serving Poteau and all intermediate points and the off-route points of Checotah, Warner, Webber's Falls, Porum, Gore, Vian and Sallisaw; (b) between McAlester, OK and junction U.S. Hwy 69 and Interstate Hwy 40; over U.S. Hwy 69 serving all intermediate points.

Note.—The purpose of this application is to convert applicant's Certificate or Registration to a Certificate of Public Convenience and Necessity and is directly related to Finance Application MC-FC-79526 filed simultaneously.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-2611 Filed 2-1-82; 8:45 am]

BILLING CODE 7035-01-M

[Volume No. 225]

Motor Carriers; Permanent Authority Decisions, Restriction Removals; Decision-Notice

Decided: January 27, 1982.

The following restriction removal applications, filed after December 28, 1980, are governed by 49 CFR Part 1137. Part 1137 was published in the Federal Register of December 31, 1980, at 45 FR 86747.

Persons wishing to file a comment to an application must follow the rules under 49 CFR 1137.12. A copy of any application can be obtained from any applicant upon request and payment to applicant of $10.00.

Amendments to the restriction removal applications are not allowed.

Some of the applications may have been modified prior to publication to conform to the special provisions applicable to restriction removal.

Findings

We find, preliminarily, that each applicant has demonstrated that its requested removal of restrictions or broadening of unduly narrow authority is consistent with 49 U.S.C. 10922(h).

In the absence of comments filed within 25 days of publication of this decision-notice, appropriate reformed authority will be issued to each applicant. Prior to beginning operations under the newly issued authority, compliance must be made with the normal statutory and regulatory requirements for common and contract carriers.

By the Commission, Restriction Removal Board, Member Sporn, Ewing, and Shaffer.

Agatha L. Mergenovich,

Secretary.

MC 2228 (Sub-74)X, filed January 8, 1982. Applicant: MERCHANTS FAST MOTOR LINES, INC., East Highway 80, Abilene, TX 79604. Representative: Jerry Prestridge, P.O. Box 1148, Austin, TX 78767. Lead and Subs 43, 44 and 71F broaden: (1) to service at all intermediate points on regular routes lead and all subs, (2) remove restrictions (a) to service for purpose of joinder only at named intermediate points, lead (b) on southbound traffic to pickup and delivery of commodities other than articles of unusual value, classes A and B explosives, livestock, automobiles, commodities in bulk, commodities requiring special equipment, and those injurious or contaminating to other lading, moving to Anson, TX or to or from points north thereof; and those points between Anson and Claremont, except Roby and Rotan, restricted to pickup and delivery of eastbound traffic only, lead, sheet 4, (c) against serving the terminal point of Fredericksburg, TX, Sub 44, sheet 4, (d) against pickup and delivery of property moving between Hico and Hamilton on route between Dublin and Hamilton, TX, Sub 44, sheet 6, (e) against delivery of property originating at Waco or received in interline service at that point destined to any point between Waco and Carlton, TX on route between Hico and Waco, TX, Sub 44, sheet 6, (f) against serving Coleman, Brownwood, Ft. Worth, and Dallas, TX out of Abilene, TX and vice versa on routes between Abilene, TX and Coleman and Brownwood, TX Sub 44, sheet 7, (g) against service to a named terminal point, Sub 44, sheet 8, (h) against traffic moving radially between Houston, TX, Dallas, Ft. Worth and Waco, TX, Sub 44, sheet 8, (i) against using named routes to serve Waco, Gatesville, Ft. Hood and Temple, TX on traffic moving to or from Dallas, Ft. Worth and San Antonio, TX, and against service at Wichita Falls TX, Sub 44, sheet 9, (j) against transportation of freight over three described routes between Wildorado, Vega and Adrian, TX and other TX points moving by interline between Lubbock and Amarillo, TX, Sub 44, sheet 15, (k) prohibiting some intermediate point service except for interlining freight at named TX point, Sub 44, sheet 20, and (l) against freight moving radially between (1) Waco, TX, and, Dallas and Ft. Worth, TX, and, (2) Houston, TX, and Dallas, Ft. Worth and Waco, TX, Sub 44, sheet 22.

MC 2729 (Sub-3)X, filed January 21, 1982. Applicant: GLENWOOD TRANSIT LINE, INC., 207 S. Chestnut, Glenwood, IA 51534. Representative: Larry D. Knox, 600 Hubbell Building, Des Moines, IA 50309. Sub 2X broaden (1) from milk and cream to "food and related products"; and (2) service at off-route points to countywide authority points within 15 miles of Tabor, IA to Otoe and Cass Counties, NE and Fremont, Miles, Montgomery and Page Counties, IA; points within 25 miles of Tabor, IA to Dougas, Sarpy, Cass, and Otoe Counties, NE and Pottawattamie, Montgomery, Page, Fremont and Mills Counties, IA and; Pacific Junction, IA to Mills County.

MC 6607 (Sub-19)X, filed January 17, 1982. Applicant: ROCKINGHAM ENTERPRISES, INC., P.O. Box 466, Bellows Falls, VT 05101. Representative: Frederick T. O'Sullivan, P.O. Box 2184, Peabody, MA 01960. Sub-No. 18 permit: broaden (1) sugar to "food and related products" in parts 1, 4, 5, 7, 8, 10 liquid sugar, sugar syrup, and invert sugar, in bulk, in tank trucks, corn products, and blends of corn products, in bulk, in tank vehicles, and water, in bulk, in tank vehicles to "commodities in bulk" in parts 2, 16, 17, and 18; paper place mats to "pulp, paper, and related products" in part 15; (2) serve between all points in the US, under continuing contract(s) with named shippers.

MC 16903 (Sub-92)X, filed January 18, 1982. Applicant: MOON FREIGHT LINES, INC., P.O. Box 1275, Bloomington, IN. Representative: Donald W. Smith, P.O. Box 40248, Indianapolis, IN 46240. Subs 28 (paragraph 3) and 42, broaden: (1) rough sawn lumber, Sub 28 and treated and untreated lumber, cross ties, poles, pilings, switch ties and wood chips, Sub 42 to "lumber and wood products", (2) Clay City, Thorntown, Bloomington, Franklin, Terre Haute, and Wingate, IN to Clay, Boone, Monroe, Franklin, Vigo and Montgomery Counties, Sub 28, (3) remove originating at and destined to restrictions, Sub 28 and (4) to radial authority.

MC 44339 (Sub-1)X, filed January 18, 1982. Applicant: DONALD LEWIS GRAY, R.D. #5, Bloomsburg, PA 17815. Representative: Joseph A. Keating, Jr., 121 South Main St., Taylor, PA 18517. Lead certificate: broaden from (1) household goods to "household goods and furniture and fixtures", and (2) Bloomsburg, PA, and points within 25 miles thereof (Columbia, Montour, Union, Lycoming, Sullivan, Luzerne, Schuylkill, Northumberland, and Snyder Counties, PA).

MC 87523 (Sub-119)X, filed July 9, 1981, previously noticed in the **Federal Register** of August 4, 1981, republished as follows: Applicant: STEWART TRUCKING COMPANY, INC., P.O. Box 5155, Manchester, NH 03108. Representative: Edward J. Kiley, 1730 M Street, N.W., Suite 501, Washington, DC 20036. Applicant previously broadened its authorities in its lead and sub-nos. 93, 95, 96F, 97F, 99F, 108F, 109F, 110F, 112, 113F, 114F, and 116 certificates pursuant to 49 CFR 1137. In its request it proposed expanding Philadelphia, PA and its commercial zone in its Sub-No. 114 to the corresponding counties. The Board denied this request but on appeal, Division 1 in No. MC–87523 (Sub-No. 119F)X, Stewart Trucking Company, Inc.–Administrative Appeal (not printed) served 12–24–81, found such request to be appropriate and directed the Board to republish. Notice is hereby given that applicant proposes to broaden Philadelphia, PA to Philadelphia, Bucks, Montgomery, Chester, and Delaware Counties, PA, Salem, Gloucester, Burlington, Camden, Mercer, Hunterdon, and Monmouth Counties, NJ, and New Castle County, DE.

MC 127304 (Sub-22)X, filed January 21, 1982. Applicant: CLEAR WATER TRUCK COMPANY, INC., 9101 North West Street, Valley Center, KS 67148. Representative: Michael J. Ogborn, P.O. Box 82028, Lincoln, NE 68501. Lead permit: (1) broaden fluro-chloro hydrocarbons to "chemicals and related products" and to "metal products" from new containers, and (2) broaden the territorial authority to between points in the U.S. (except AK and HI), under continuing contract(s) with a named shipper.

MC 133532 (Sub-2)X, filed January 18, 1982. Applicant: BENRUS TRUCKING DIVISION, INC., P.O. Box 2665, Newburgh, NY 12550. Representative: Ronald I. Shapss, 450 Seventh Ave., New York, NY 10123. Sub 1M1F permit,

broaden: (1) pallet and storage racks, shelving, and sections, metal tubing, panels, grating, and angles, accessories, supplies and equipment used in the installation and erection of above commodities and advertising materials and displays to "metal products", and (2) to "between points in the United States," under continuing contract(s) with named shipper.

MC 143812 (Sub-25)X, filed January 19, 1982. Applicant: VAN DIEST TRUCKING, INC., 630 So. Indian Hill, Suite 7, Claremont, CA 91711. Representative: William J. Monheim, P.O. Box 1756, Whittier, CA 90609. Sub-Nos. 3, 7F, 12, 18, 20, 21, 22, and 23: (A) broaden (1) from (a) liquid sugar, in bulk, and foodstuffs, in bulk, Sub 3; grape juice, in bulk, Sub 7F; grape juice concentrate and grape brandy, in bulk, Sub 12; glycerine, in bulk, Sub 20; grape juice concentrate and grape wine, in bulk, Sub 21; and agricultural minerals, auxiliary soil nutrients, and commercial fertilizers, in bulk, Sub 22, to "commodities in bulk;" (b) liquid foodstuffs, in bulk, Sub 7F; and wine, in bulk, Sub 23, to "food and related products;" and (c) alcohol, in bulk, Sub 18, to "chemicals and related products;" (2) to countywide authority: (a) Sub 3, Crockett (Contra Costa County, CA); (b) Sub 7F, Prosser (Benton County, WA); (c) Sub 12, facilities, Fresno and Kingsburg (Fresno County, CA); Detroit and Paw Paw (Wayne and Van Buren Counties, MI); Niagara Falls (Niagara County, NY); Cincinnati, Geneva, and Orrville (Hamilton, Ashtabula, and Wayne Counties, OH); Memphis (Shelby County, TN); and Glendale (Milwaukee County, WI); (d) Sub 18, Bellingham (Whatcom County, WA); (e) Sub 20, Burbank (Los Angeles County, CA); and Cincinnati (Hamilton County, OH); and (f) Sub 22, Bakersfield (Kern County, CA); (B) remove "destined to Canada" restriction, Sub 23; and (C) broaden to radial authority, Subs 3, 7F, 12, 18, 20, 21, 22, and 23.

MC 143868 (Sub-12)X, filed January 21, 1982. Applicant: R.E.T.E.N.O. CARRIERS, INC., P.O. Box 1438, Willmar, MN 56201. Representative: William J. Monheim, P.O. Box 1756, Whittier, CA 90609. Subs 1F, 4F, 5F, 7F, 10F, and 11F permits. Broaden: Sub 5F, from part (1) agricultural pesticides and from part (2), ingredients for agricultural pesticides (except commodities in bulk), to "chemicals and related products"; Sub 4F, from plastic sheets and plastic sheeting to "rubber and plastic products"; Sub 1F, from coil steel and bar steel; Sub 7F, from steel; and Sub 11F, from bar steel, coil steel, and extruded steel, to "metal products"; and Sub 10F, from part (1), equipment, materials and parts used in the manufacture or assembly of components for chain saws, and from part (2), bar steel, coil steel, and extruded steel, to "machinery and metal products"; remove vehicles equipped with mechanical refrigeration restriction from Subs 1F, 7F, 10F, and 11F; and broaden all Subs to between points in the U.S., under continuing contract(s) with named shippers.

MC 144696 (Sub-12)X, filed January 12, 1982. Applicant: MEEUWSEN PRODUCE, INC., 9525 Ransom St., Zeeland, MI 49464. Representative: Edward N. Button, 635 Oak Hill Ave., Hagerstown, MD 21740. Sub-Nos. 3F, 4F, and 7F permits, broaden: (1) to "food and related products" from foodstuffs (except in bulk), frozen foods, and pet foods; and (2) to "between points in the United States," under continuing contract(s) with the named shippers.

MC 145648 (Sub-10)X, filed January 22, 1982. Applicant: DUDLEY TRUCKING, INC., P.O. BOX 1651, Tacoma, WA 98421. Representative: Kenneth R. Mitchell, 2320A Milwaukee Way, Tacoma WA 98421. Sub 3F, 4F, and 7F broaden (1) (a) iron and steel articles to "metal and metal products" Sub 3F, (b) crushed cars and scrap metal to "waste or scrap material," Sub 4F, and (c) treated poles, treated posts, treated lumber, and untreated lumber to "lumber and wood products," Sub 7F; (2) Tacoma, WA to Pierce County, and McMinnville, OR to Yamhill County, Sub 4; and facilities at Hayden Lake, ID to Kootenai County, Sub 7 (3) to radial authority, Sub 4F and 7F.

MC 146651 (Sub-4)X, filed January 15, 1982. Applicant: ARTHUR W. COULTER, d.b.a. A. W. COULTER TRUCKING, P.O. Box 504, Terra Bella, CA 93270. Representative: Earl N. Miles, 3704 Candlewood Dr., Bakersfield, CA 93306. Sub-No. 2F broaden: (1) lumber to "lumber and wood products", (2) to radial authority, and (3) facilities at Terra Bella, CA to Tulare County, CA.

MC 146912 (Sub-1)X, filed January 19, 1982. Applicant: MID-CITIES DELIVERY, INC., 324 Michigan St., St. Joseph, MO 64504. Representative: Tom B. Kretsinger, P.O. Box 258, Liberty, MO 64068. Lead permit: broaden to all points in the U.S. (except AK and HI), under continuing contract(s) with a named class of shippers.

MC 146984 (Sub-1)X, filed January 18, 1982. Applicant: PARAMOUNT TRUCKING, INC., P.O. Box 310, Washington, IN 47501. Representative: John F. Wickes, Jr., 1301 Merchants Plaza, Indianapolis, IN 46204-3491. Lead, broaden: coal to "commodities in bulk; Richmond to Wayne County, IN; and service to radial authority.

[FR Doc. 82-2614 Filed 2-1-82; 8:45 am]

BILLING CODE 7035-01-M

Motor Carriers; Permanent Authority Decisions, Decision-Notice

Correction

In FR Doc. 82-719 appearing at page 1343 in the issue for Tuesday, January 12, 1982, please make the following correction:

On page 1345, in the middle column, in the last paragraph, the first line should begin "MC 144503 Sub-44) * * *". The applicant in MC 144503 (Sub-44) is Adams Refrigerated Express, Inc.

BILLING CODE 1505-01-M

INTERNATIONAL COMMUNICATION AGENCY

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) and Executive Order 12047 of March 27, 1978 (43 FR 13359, March 29, 1978), I hereby determine that the objects in the exhibit, "The Heritage of Islam" (included in the list [1] filed as a part of this determination) imported from abroad for the temporary exhibition without profit within the United States are of cultural significance. These objects are imported pursuant to loan agreements between the foreign lenders and the National Committee to Honor the Fourteenth Centennial of Islam. I also determine that the temporary exhibition or display of the listed exhibit objects within the United States beginning on or about March 3, 1982, to on or about December 25, 1983, is in the national interest.

Public notice of this determination is ordered to be published in the **Federal Register.**

Dated: January 28, 1982.

Charles Z. Wick,

Director.

[FR Doc. 82-2663 Filed 2-1-82; 8:45 am]

BILLING CODE 8230-01-M

[1] An itemized list of objects included in the exhibit is filed as part of the original document.

DEPARTMENT OF LABOR

Employment and Training Administration

Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for adjustment assistance issued during the period.

In order for an affirmative determination to be made and a certification of eligibility to apply for adjustment assistance to be issued, each of the group eligibility requirements of section 222 of the Act must be met.

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated,

(2) That sales or production, or both, of the firm or subdivision have decreased absolutely, and

(3) That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Negative Determinations

In each of the following cases the investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-11,174; Crossville Rubber Products, Inc., Crossville, TN
TA-W-11,049; Inter-Lakes Steel Products Co., Pontiac, MI
TA-W-12,800; Keystone Group, Keystone Steel & Wire Division, Bartonville, IL
TA-W-12,206; Russell Gasket Co., Cleveland, OH
TA-W-11,304; Alatex, Inc., Andala Plant, Andalusia, AL
TA-W-11,305; Alatex, Inc., Andalusia Plant, Andalusia, AL
TA-W-11,306; Alatex, Inc., Enterprise Plant, Enterprise, AL
TA-W-11,307; Alatex, Inc., Montgomery Distribution Center, Montgomery, AL
TA-W-11,308; Alatex, Inc., Pike Plant, Troy, AL
TA-W-11,309; Alatex Inc., Troy Plant, Troy, AL

In each of the following cases the investigation revealed that criterion (3) has not been met. Increased imports did not contribute importantly to workers separations at the firm.

TA-W-11,760; Cleveland Metal Finishing Division, Cleveland Metal Products Co., Cleveland, OH
TA-W-12,674; Upland Cedar Products, Neilton, WA
TA-W-12,054; Chrysler Corp., Engine & Casting Division Office, Detroit, MI
TA-W-12,054A; Chrysler Corp., Engine & Casting Division, Warren, MI

In the following case the investigation revealed that criterion (3) had not been met. Aggregate U.S. imports of paper sanitary food containers are negligible.

TA-W-12,232; Lily Tulip Division, Owens Illinois, Inc., Old Town, ME

Affirmative Determinations

TA-W-12,098; Kransco Mfg., Inc., Morey Boogie Division, Oceanside, CA

A certification was issued in response to a petition received on January 12, 1981 covering all workers separated on or after January 9, 1980 and before March 31, 1981.

TA-W-12,587; MSM Coat Co., Inc., Oceanside, NY

A certification was issued in response to a petition received on April 1, 1981 covering all workers separated on or after May 2, 1980 and before April 30, 1981.

TA-W-11,484; National Fiber Glass Products, Inc., Yonkers, NY

A certification was issued in response to a petition received on October 22, 1980 covering all workers separated on or after October 16, 1979.

I hereby certify that the aforementioned determinations were issued during the period January 18–22, 1982. Copies of these determinations are available for inspection in Room 10,332, U.S. Department of Labor, 601 D Street, NW, Washington, D.C. 20213 during normal business hours or will be mailed to persons who write to the above address.

Dated: January 26, 1982.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 82-2698 Filed 2-1-82; 8:45 am]
BILLING CODE 4510-30-M

Mine Safety and Health Administration

[Docket No. M-81-222-C]

A and E Coal Company, Inc.; Petition for Modification of Application of Mandatory Safety Standard

A and E Coal Company, Inc., Box 85, Neon, Kentucky 41840, has filed a petition to modify the application of 30 CFR 75.1710 (cabs and canopies) to its No. 3 Mine located in Letcher County, Kentucky. The petition is filed under Section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statements follows:

1. The petition concerns the requirement that cabs or canopies be installed in the mine's electric face equipment.

2. The coal seam ranges from 48 to 55 inches in height with undulating top and bottom conditions.

3. Petitioner states that the installation of cabs or canopies on the mine's electric face equipment would result in a diminution of safety because the equipment operator's vision is impaired by the canopy, exposing both the operator and nearby miners to potential hazards.

4. For this reason, petitioner requests a modification of the standard.

Request for Comments

Persons interested in this petition may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before March 4, 1982. Copies of the petition are available for inspection at that address.

Dated: January 25, 1982.

Patricia W. Silvey,

Acting Director, Office of Standards, Regulations and Variances.

[FR Doc. 82-2699 Filed 2-1-82; 8:45 am]
BILLING CODE 4510-43-M

[Docket No. M-81-261-C]

Harlan-Cumberland Coal Co.; Petition for Modification of Application of Mandatory Safety Standard

Harlan-Cumberland Coal Co., Grays Knob, Kentucky 40829 has filed a petition to modify the application of 30 CFR 75.1704-1 (escapeways and escape facilities) to its H-1 Mine located in Harlan County, Kentucky. The petition is filed under Section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statements follows:

1. The petition concerns the requirement that escapeways be maintained at a height of at least 5 feet and a width of at least 6 feet.

2. A roof fall blocks the intake escapeway but ventilation over the fall is good and not interrupted in any way.

3. Petitioner states that cleaning up the fall and attempting to support the roof over it would expose miners to extremely hazardous conditions.

4. As an alternative method, petitioner proposes to timber off the fall area at all points and place "Danger" signs at those points. The escapeway route would detour around the fall area by following the belt entry. Conspicuous signs and markers would be placed at each exit and entry point to the belt entry.

5. Petitioner states that the proposed alternative method will provide the same degree of safety for the miners affected as that afforded by the standard.

Request for Comments

Persons interested in this petition may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before March 4, 1982. Copies of the petition are available for inspection at that address.

Dated: January 25, 1982.

Patricia W. Silvey,

Acting Director, Office of Standards, Regulations and Variances.

[FR Doc. 82-2700 Filed 2-1-82; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-81-235-C]

Preston Energy, Inc.; Petition for Modification of Application of Mandatory Safety Standard

Preston Energy, Inc., 202 East High Street, Kingwood, West Virginia 26537, has filed a petition to modify the application of 30 CFR 75.1710 (cabs and canopies) to its No. 1 Mine located in Preston County, West Virginia. The petition is filed under Section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statements follows:

1. The petition concerns the requirement that cabs or canopies be installed on the mine's electric face equipment.

2. Petitioner states that the installation of cabs or canopies on the mine's electric face equipment would result in a diminution of safety for the miners affected because:

a. Equipment operator visibility is hampered, increasing the chances of an accident; and

b. The chance of the cab striking the roof exists, which damages the electrical trailing cables, the roof support system and the mine's lighting system.

3. For these reasons, petitioner requests a modification of the standard.

Request for Comments

Persons interested in this petition may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before March 4, 1982. Copies of the petition are available for inspection at that address.

Dated: January 25, 1982.

Patricia W. Silvey,

Acting Director, Office of Standards, Regulations and Variances.

[FR Doc. 82-2701 Filed 2-1-82; 8:45 am]

BILLING CODE 4510-43-M

Office of Pension and Welfare Benefit Programs

[Prohibited Transaction Exemption 81-28; (Exemption Application No. D-2584)]

Exemption From the Prohibitions for Certain Transactions Involving the American Medical Association Members Retirement Plan Located in Chicago, Ill.

AGENCY: Office of Pension and Welfare Benefit Programs

ACTION: Grant of Individual Exemption.

SUMMARY: This exemption permits the provision of services by the American Medical Association (the AMA) to the American Medical Association Members Retirement Plan (the Plan).

FOR FURTHER INFORMATION CONTACT: Mr. Robert Sandler of the Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-4526, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20216. (202) 523-8195. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On October 27, 1981, notice was published in the **Federal Register** (46 FR 52448) of the pendency before the Department of Labor (the Department) of a proposal to grant an exemption from the restrictions of section 406(b) (1) and (2) of the Employee Retirement Income Security Act of 1974 (the Act) and from the sanctions resulting from the application of section 4975 of the Internal Revenue Code of 1954 (the Code) by reason of section 4975(c)(1)(E) of the Code, for the above-described transaction. The notice set forth a summary of facts and representations contained in the application for exemption and referred interested persons to the application for a complete statement of the facts and representations. The application has been available for public inspection at the Department in Washington, D.C. The notice also invited interested persons to submit comments on the requested exemption to the Department. In addition the notice stated that any interested person might submit a written request that a public hearing be held relating to this exemption. The applicant has represented that a copy of the notice was distributed in accordance with the requirements set forth in the proposed exempton. No requests for a hearing were received by the Department; however, the Department received six public comments. One commentator made a general statement that the exemption should not be granted. Each of the other commentators claimed that the proposed fees to be paid to the AMA by the Plan would be excessive. Both the Bank of New York (BONY), the Plan's trustee, and Mr. Charles Custer of the law firm of Vedder, Price, Kaufman and Kammholz which is independent of the AMA and the Plan, have examined the management contract (the Contract) to be entered into by the AMA and the Plan and have determined that the terms and conditions of the Contract, including the fees to be paid thereunder, are reasonable and comparable to management contracts and fees charged by independent third parties performing similar services. Furthermore, BONY will monitor the Contract on the Plan's behalf, to ensure compliance with all terms and conditions contained therein and ensure that the AMA's fees continue to be reasonable. Because of these independent safeguards, the Department believes that the Plan is adequately protected with regard to the fees to be charged by the AMA and has therefore decided to grant the exemption as proposed.

The notice of pendency was issued and the exemption is being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption granted under section 408(a) of the Act and section 4975(c)(2) of the Code does not relieve a

fiduciary or other party in interest or disqualified person with respect to a plan to which the exemption is applicable from certain other provisions of the Act and the Code. These provisions include any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his or her duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does the fact the transaction is the subject of an exemption affect the requirement of section 401(a) of the Code that a plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries.

(2) This exemption does not extend to transactions prohibited under section 406(a) and 406(b)(3) of the Act and section 4975(c)(1) (A), (B), (C), (D) and (F) of the Code.

(3) This exemption is supplemental to, and not in derogation of, any other provisions of the Act and the Code, including statutory or administrtive exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption or transitional rule is not dispositive of whether the transaction is, in fact, a prohibited transaction.

Exemption

In accordance with section 408(a) of the Act and section 4975(c)(2) of the Code and the procedures set forth in ERISA Procedure 75–1 (40 FR 18471, April 28, 1975), and based upon the entire record, the Department makes the following determinations:

(a) The exemption is administratively feasible;

(b) It is in the interests of the Plan and of its participants and beneficiaries; and

(c) It is protective of the rights of the participants and beneficiaries of the Plan.

Accordingly the restrictions of section 406(b)(1) and (2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(E) of the Code, shall not apply to the provision of services by the AMA to the Plan, provided that the terms and conditions of the AMA's provision of services remain at least as favorable to the Plan as those the Plan could secure from an unrelated party.

The availability of this exemption is subject to the express conditions that the material facts and representations contained in the application are true and complete, and that the application accurately describes all material terms of the transaction to be consummated pursuant to this exemption.

Signed at Washington, D.C., this 25th day of January, 1982.

Alan D. Lebowitz,

Assistant Administrator for Fiduciary Standards, Pension and Welfare Benefit Programs, Labor-Management Services Administration, U.S. Department of Labor.

[FR Doc. 82-2668 Filed 2-1-82; 8:45 am]

BILLING CODE 4510-29-M

[Prohibited Transaction Exemption 82-22; Exemption Application No. D-2614]

Exemption From the Prohibitions for Certain Transactions Involving the Bellco Glass, Inc. Salaried Employees Pension Plan Located in Vineland, N.J.

AGENCY: Office of Pension and Welfare Benefit Program.

ACTION: Grant of individual exemption.

SUMMARY: This exemption exempts: (1) The proposed loan (the Plan Loan) of money by the Bellco Glass, Inc. Salaried Employees Pension Plan (the Plan) to Bellco Glass, Inc. (the Employer), a party in interest with respect to the Plan; and (2) a guarantee of repayment by the prinicpal shareholders (the Principal Shareholders) of the Employer.

FOR FURTHER INFORMATION CONTACT: Horace C. Green of the Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C–4526, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20216. (202) 523–8196. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On December 11, 1981, notice was published in the **Federal Register** (46 FR 60672) of the pendency before the Department of Labor (the Department) of a proposal to grant an exemption from the restrictions of section 406(a), 406(b)(1) and (b)(2) of the Employee Retirement Income Security Act of 1974 (the Act) and from the sanctions resulting from the application of section 4975 of the Internal Revenue Code of 1954 (the Code) by reason of section 4975(c)(1)(A) through (E) of the Code, for the above-described transactions. The notice set forth a summary of facts and representations contained in the application for exemption and referred interested persons to the application for a complete statement of the facts and representations. The application has been available for public inspection at the Department in Washington, D.C. The notice also invited interested persons to submit comments on the requested exemption to the Department. In addition the notice stated that any interested person might submit a written request that a public hearing be held relating to this exemption. The applicant has represented that he has complied with the notice to interested persons requirement as set forth in the notice of pendency. No public comments and no requests for a hearing were received by the Department. The notice of pendency was issued and the exemption is being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption granted under section 408(a) of the Act and section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person with respect to a plan to which the exemption is applicable from certain other provisions of the Act and the Code. These provisions include any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his or her duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does the fact the transaction is the subject of an exemption affect the requirement of section 401(a) of the Code that a plan must operate for the exclusive benefit of the empoloyees of the employer maintaining the plan and their beneficiaries.

(2) This exemption does not extent to transactions prohibited under section 406(b)(3) of the Act and section 4975(c)(1)(F) of the Code.

(3) This exemption is supplemental to, and not in derogation of, any other provisions of the Act and the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption or transitional rule is not dispositive of whether the

transaction is, in fact, a prohibited transaction.

Exemption

In accordance with section 408(a) of the Act and section 4975(c)(2) of the Code and the procedures set forth in ERISA Procedure 75–1 (40 FR 18471, April 28, 1975), and based upon the entire record, the Department makes the following determinations:

(a) The exemption is administratively feasible;

(b) It is in the interests of the Plan and of its participants and beneficiaries; and

(c) It is protective of the rights of the participants and beneficiaries of the Plan.

Accordingly, the restrictions of section 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to: (1) the Plan Loan, provided that the terms and conditions of the Plan Loan will be and remain at least as favorable to the Plan as an arm's-length transaction would be with an unrelated party; and (2) the guarantee of repayment by the Principal Shareholders should the Employer default on the Plan Loan.

The availability of this exemption is subject to the express condition that the material facts and representations contained in the application are true and complete, and that the application accurately describes all material terms of the transaction to be consummated pursuant to this exemption.

Signed at Washington, D.C., this 27th day of January 1982.

Alan D. Lebowitz,

Assistant Administrator for Fiduciary Standards, Pension and Welfare Benefit Programs, Labor-Management Services Administration, U.S. Department of Labor.

[FR Doc. 82-2669 Filed 2-1-82; 8:45 am]

BILLING CODE 4510-29-M

[Prohibited Transaction Exemption 81-21; Exemption Application No. D-2425]

Exemption From the Prohibitions for Certain Transactions Involving City Investing Co. and its Affiliates Located in New York, New York

AGENCY: Office of Pension and Welfare Benefit Programs, Labor.

ACTION: Grant of individual exemption.

SUMMARY: This exemption permits the reinsurance by Federal Home Life Insurance Company (the Reinsurer), a party in interest with respect to certain welfare plans (the Plans) for employees of City Investing Company and its affiliates (the Employers), of insurance contracts issued by the Prudential Insurance Company of America (the Insurer) to fund benefits under the Plans.

EFFECTIVE DATE: This exemption is effective January 1, 1978.

FOR FURTHER INFORMATION CONTACT: Mrs. Miriam Freund, of the Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C–4526, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20216. (202) 523–8671. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On June 26, 1981, notice was published in the Federal Register (46 FR 33138) of the pendency before the Department of Labor (the Department) of a proposal to grant an exemption from the restrictions of section 406(a) and (b) of the Employee Retirement Income Security Act of 1974 (the Act) for transactions described in an application filed on behalf of the Reinsurer. The notice set forth a summary of facts and representations contained in the application for exemption and referred interested persons to the application for a complete statement of the facts and representations. The application has been available for public inspection at the Department in Washington, D.C. The notice also invited interested persons to submit comments on the requested exemption to the Department. In addition the notice stated that any interested person might submit a written request that a public hearing be held relating to this exemption. The applicant has represented that a copy of the notice has been furnished to interested persons in compliance with the provisions of the notice of proposed exemption, except that the notice was not furnished until July 27, 1981. The notice also advised that the comment period was extended until August 26, 1981, pursuant to discussions with the Department.

The Department received five written comments on the notice of proposed exemption. Two of these commentators also requested a hearing on the proposed exemption but subsequently withdrew their requests for a hearing. One of the five commentators approved of granting the proposed exemption. The other four commentators objected to same, but three of them subsequently withdrew their objections. The remaining single objection asks for denial of the proposed exemption if the arrangement in question does not provide a reinsurer of equal status and a guarantee that no damage will result to the Plan participants and beneficiaries. With respect to this objection, the Department believes that, regardless of the size of the Reinsurer, the safeguards relating to the Reinsurer, which were described in the notice of proposed exemption, are sufficient to protect the rights of the Plan participants and beneficiaries. Furthermore, as described in the notice of proposed exemption, the reinsurance arrangement does not affect the rights of Plan participants and beneficiaries under the insurance contracts being reinsured and also does not affect the liabilities of the Insurer under these contracts. Thus, the amounts of benefits and premiums paid to or by Plan participants and beneficiaries and the procedures for submitting claims would remain the same, whether or not the insurance contracts are reinsured.

Therefore, the Department does not believe the proposed exemption should be denied on the basis of the issues raised in the single remaining objection.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption granted under section 408(a) of the Act does not relieve a fiduciary or other party in interest with respect to a plan to which the exemption is applicable from certain other provisions of the Act. These provisions include any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his or her duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act.

(2) This exemption is supplemental to, and not in derogation of, any other provisions of the Act, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption or transitional rule is not dispositive of whether the transaction is, in fact, a prohibited transaction.

Exemption

In accordance with section 408(a) of the Act and the procedures set forth in ERISA Procedure 75–1 (40 FR 18471, April 28, 1975), and based upon the entire record, the Department makes the following determinations:

(a) The exemption is administratively feasible;

(b) It is in the interests of the Plans and of their participants and beneficiaries; and

(c) It is protective of the rights of the participants and beneficiaries of the Plans.

Accordingly the restrictions of section 406 (a) and (b) of the Act shall not apply to the reinsurance of risks and the receipt of premiums therefrom by the Reinsurer from the group health and group life insurance contracts sold by the Insurer to the Employers to provide benefits to the Plans, subject to the conditions set forth in the notice of proposed exemption.

The availability of this exemption is subject to the express condition that the material facts and representations contained in the application are true and complete, and that the application accurately describes all material terms of the transaction which is the subject of this exemption.

Signed at Washington, D.C., this 27th day of January 1982.

Alan D. Lebowitz,

Assistant Administrator for Fiduciary Standards, Pension and Welfare Benefit Programs, Labor-Management Services Administration, U.S. Department of Labor.

[FR Doc. 82-2670 Filed 2-1-82; 8:45 am]

BILLING CODE 4510-29-M

[Prohibited Transaction Exemption 82-23; Exemption Application No. D-2705]

Exemption From the Prohibitions for Certain Transactions Involving the Farnsworth Realty and Development Company Profit-Sharing Thrift Plan Located in Mesa, Ariz.

AGENCY: Office of Pension and Welfare Benefit Programs, Labor.

ACTION: Grant of Individual Exemption.

SUMMARY: This exemption exempts the cash sale of certain unimproved real property (the Property) by the Farnsworth Realty and Development Company Profit Sharing Thrift Plan (the Plan) to Farnsworth Realty and Development Company (the Employer).

FOR FURTHER INFORMATION CONTACT: Ms. Jan Broady of the Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-4526, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20216. (202) 523-7222. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On October 27, 1981, notice was published in the Federal Register (46 FR 52454) of the pendency before the Department of Labor (the Department) of a proposal to grant an exemption from the restrictions of section 406(a), 406 (b)(1) and (b)(2) of the Employee Retirement Income Security Act of 1974 (the Act) and from the sanctions resulting from the application of section 4975 of the Internal Revenue Code of 1954 (the Code) by reason of section 4975(c)(1) (A) through (E) of the Code, for a transaction described in an application filed on behalf of the Employer. The notice set forth a summary of facts and representations contained in the application for exemption and referred interested persons to the application for a complete statement of the facts and representations. The application has been available for public inspection at the Department in Washington, D.C. The notice also invited interested persons to submit comments on the requested exemption to the Department. In addition, the notice stated that any interested person might submit a written request that a public hearing be held relating to this exemption. The applicant has represented that a copy of the notice has been furnished to all interested persons in compliance with the requirements set forth in the notice of proposed exemption.

On public comment, which included a request for a hearing, was received by the Department. The commentator questioned the effect of the proposed transaction on the interests of those persons participating in the Plan. Following a discussion of this issue with a Department representative, the commentator withdrew the hearing request.

The notice of pendency was issued and the exemption is being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption granted under section 408(a) of the Act and section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person with respect to a plan to which the exemption is applicable from certain other provisions of the Act and the Code. These provisions include any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his or her duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fasion in accordance with section 404(a)(1)(B) of the Act; nor does the fact the transaction is the subject of an exemption affect the requirement of section 401(a) of the Code that a plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries.

(2) This exemption does not extend to transactions prohibited under section 406(b)(3) of the Act and section 4975(c)(1)(F) of the Code.

(3) This exemption is supplemental to, and not in derogation of, any other provisions of the Act and the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption or transitional rule is not dispositive of whether the transaction is, the fact, a prohibited transaction.

Exemption

In accordance with section 408(a) of the Act and section 4975(2) of the Code and the procedures set forth in ERISA Procedures 75-1 (40 FR 18471, April 28, 1975), and based upon the entire record, the Department makes the following determinations:

(a) The exemption is administratively feasible;

(b) It is in the interests of the Plan and of its participants and beneficiaries; and

(c) It is protective of the rights of the participants and beneficiaries of the Plan.

Accordingly the restrictions of section 406(a), 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, shall not apply to the cash sale of the Property by the Plan to the Employer for the greater of $306,950 or the fair market value of the Property at the time of the sale.

The availability of this exemption is subject to the express condition that the material facts and representations contained in the application are true and complete, and that the application accurately describes all material terms of the transaction to be consummated pursuant to this exemption.

Signed at Washington, D.C., this 27th day of January, 1982.

Alan D. Lebowitz,

Assistant Administrator for Fiduciary Standards, Pension and Welfare Benefit Programs, Labor-Management Services Administration, U.S. Department of Labor.

[FR Doc. 82-2671 Filed 2-1-82; 8:45 am]

BILLING CODE 4510-29-M

[Prohibited Transaction Exemption 82-27; Exemption Application No. D-2817]

Exemption From the Prohibitions for Certain Transactions Involving Flournoy Electric Co., Inc., Money Purchase Pension Plan and Trust, Located in Clearwater, Fla.

AGENCY: Office of the Pension and Welfare Benefit Programs, Labor.

ACTION: Grant of Individual Exemption.

SUMMARY: This exemption will permit the sale of a parcel of unimproved real property as described in the notice of proposed exemption (the Property) from the Flournoy Electric Company, Inc. Money Purchase Pension Plan and Trust (the Plan) to Mr. Roscoe C. Wooten, Jr. (Mr. Wooten), a party in interest with respect to the Plan.

FOR FURTHER INFORMATION CONTACT: Mr. David Stander of the Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-4526, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20216, (202) 523-8881. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On December 4, 1981, notice was published in the **Federal Register** (46 FR 59331) of the pendency before the Department of Labor (the Department) of a proposal to grant an exemption from the restrictions of section 406(a), 406 (b)(1) and (b)(2) of the Employee Retirement Income Security Act of 1974 (the Act) and from the sanctions resulting from the application of section 4975 of the Internal Revenue Code of 1954 (the Code) by reason of section 4975(c)(1) (A) through (E) of the Code, for the above described transaction. The notice set forth a summary of facts and representations contained in the application for exemption and referred interested persons to the application for a complete statement of the facts and representations. The application has been available for public inspection at the Department in Washington, D.C. The notice also invited interested persons to submit comments on the requested exemption to the Department. In addition the notice stated that any interested person might submit a written request that a public hearing be held relating to this exemption. The applicant has represented that a copy of the notice was provided to all interested persons in compliance with the requirements set forth in the notice of proposed exemption. No public comments and no requests for a hearing were received by the Department.

The notice of pendency was issued and the exemption is being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption granted under section 408(a) of the Act and section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person with respect to a plan to which the exemption is applicable from certain other provisions of the Act and the Code. These provisions include any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his or her duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does the fact the transaction is the subject of an exemption affect the requirement of section 401(a) of the Code that a plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries.

(2) This exemption does not extend to transactions prohibited under section 406(b)(3) of the Act and section 4975(c)(1)(F) of the Code.

(3) This exemption is supplemental to, and not in derogation of, any other provisions of the Act and the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption or transitional rule is not dispositive of whether the transaction is, in fact, a prohibited transaction.

Exemption

In accordance with section 408(a) of the Act and section 4975(c)(2) of the Code and the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975), and based upon the entire record, the Department makes the following determinations:

(a) The exemption is administratively feasible;

(b) It is in the interests of the Plan and of its participants and beneficiaries; and

(c) It is protective of the rights of the participants and beneficiaries of the Plan.

Accordingly the restrictions of section 406(a), 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the cash sale of the Property by the Plan to Mr. Wooten for the higher of $31,800 or the fair market value of the Property as of the date of sale.

The availability of this exemption is subject to the express condition that the material facts and representations contained in the application are true and complete, and that the application accurately describes all material terms of the transaction to be consummated pursuant to this exemption.

Signed at Washington, D.C., this 27th day of January 1982.

Alan D. Lebowitz,

Assistant Administrator for Fiduciary Standards, Pension and Welfare Benefit Programs, Labor-Management Services Administration, U.S. Department of Labor.

[FR Doc. 82-2672 Filed 2-1-82; 8:45 am]

BILLING CODE 4510-29-M

[Prohibited Transaction Exemption 82-24; Exemption Application No. D-2714]

Exemption From the Prohibitions for Certain Transactions Involving Henderson, Franklin, Starnes & Holt P.A. Second-Amended Employee Profit-Sharing Plan and Trust Located in Fort Myers, Fla.

AGENCY: Office of Pension and Welfare Benefit Programs, Labor.

ACTION: Grant of Individual Exemption.

SUMMARY: This exemption will permit (1) the loan of $120,000 (the Loan) by the Henderson, Franklin, Starnes & Holt P.A. Second-Amended Employee Profit Sharing Plan and Trust (the Plan) to 2100 Second Street Partnership (the Partnership), a party in interest with respect to the Plan; and (2) the joint and several guarantee of the Partnership's obligations under the Loan by the eleven partners of the Partnership.

FOR FURTHER INFORMATION CONTACT: Mr. David Stander of the Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-

4526, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20216. (202) 523-8881. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On December 11, 1981, notice was published in the **Federal Register** (46 FR 60688) of the pendency before the Department of Labor (the Department) of a proposal to grant an exemption from the restrictions of section 406(a), 406 (b)(1) and (b)(2) of the Employee Retirement Income Security Act of 1974 (the Act) and from the sanctions resulting from the application of section 4975 of the Internal Revenue Code of 1954 (the Code) by reason of section 4975(c)(1) (A) through (E) of the Code, for the above-described transactions. The notice set forth a summary of facts and representations contained in the application for exemption and referred interested persons to the application for a complete statement of the facts and representations. The application has been available for public inspection at the Department in Washington, D.C. The notice also invited interested persons to submit comments on the requested exemption to the Department. In addition the notice stated that any interested person might submit a written request that a public hearing be held relating to this exemption. The applicant has represented that it did not provide notice to interested persons by the date stated in the notice, December 21, 1981, but instead provided notice on December 22, 1981. The Department notes this action and has determined that since the comment period expired on January 25, 1982, interested persons have had adequate time to comment on and/or request a hearing with regard to the proposed exemption. No public comments and no requests for a hearing have been received by the Department.

The notice of pendency was issued and the exemption is being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption granted under section 408(a) of the Act and section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person with respect to a plan to which the exemption is applicable from certain other provisions of the Act and the Code. These provisions include any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his or her duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does the fact the transaction is the subject of an exemption affect the requirement of section 401(a) of the Code that a plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries.

(2) This exemption does not extend to transactions prohibited under section 406(b)(3) of the Act and section 4975(c)(1)(F) of the Code.

(3) This exemption is supplemental to, and not in derogation of, any other provisions of the Act and the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption or transitional rule is not dispositive of whether the transaction is, in fact, a prohibited transaction.

Exemption

In accordance with section 408(a) of the Act and section 4975(c)(2) of the Code and the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975), and based upon the entire record, the Department makes the following determinations:

(a) The exemption is administratively feasible;

(b) It is in the interests of the Plan and of its participants and beneficiaries; and

(c) It is protective of the rights of the participants and beneficiaries of the Plan.

Accordingly the restrictions of section 406(a), 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to (1) the Loan by the Plan to the Partnership as described above provided that the terms and conditions of the Loan are not less favorable to the Plan than those obtainable in a similar transaction with an unrelated third party; and (2) the personal guarantees of the Partnership's obligations under the Loan by the eleven partners of the Partnership.

The availability of this exemption is subject to the express condition that the material facts and representations contained in the application are true and complete, and that the application accurately describes all material terms of the transaction to be consummated pursuant to this exemption.

Signed at Washington, D.C., this 27th day of January 1982.

Alan D. Lebowitz,

Assistant Administrator for Fiduciary Standards, Pension and Welfare Benefit Programs, Labor-Management Services Administration, U.S. Department of Labor.

[FR Doc. 82-2673 Filed 2-1-82; 8:45 am]

BILLING CODE 4510-29-M

[Prohibited Transaction Exemption 82-25; Exemption Application No. D-2766]

Exemption From the Prohibitions for Certain Transactions Involving Merrill Lynch, Hubbard, Inc., and Its Affiliates Located in New York, N.Y.

AGENCY: Office of Pension and Welfare Benefit Programs.

ACTION: Grant of Individual Exemption.

SUMMARY: This exemption would exempt: (1) Transactions relating to the origination, maintenance and termination of mortgage pool investment trusts (Mortgage Pools) sponsored by Merrill Lynch, Hubbard, Inc. and its affiliate (Merrill Lynch Hubbard); and (2) the acquisition and holding of certain multi-family dwelling mortgage-backed pass-through certificates (Certificates) of Mortgage Pools under certain circumstances by employee benefit plans (Plans) when Merrill Lynch Hubbard or a trustee (Trustee) of a Mortgage Pools is a party in interest with regard to the Plans.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Sandler of the Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-4526, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20216. (202) 523-8195. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On November 20, 1981, notice was published in the **Federal Register** (46 FR 57186) of the pendency before the Department of Labor (the Department) of a proposal to grant an exemption from the restrictions of sections 406(a), 406(b) (1) and (2) and 407(a) of the Employee Retirement Income Security Act of 1974 (the Act) and from the sanctions resulting from the application of section 4975 of the Internal Revenue Code of 1954 (the Code) by reason of section 4975(c)(1) (A) through (E) of the Code, for the above-described transactions. The notice set forth a

summary of facts and representations contained in the application for exemption and referred interested persons to the application for a complete statement of the facts and representations. The application has been available for public inspection at the Department in Washington, D.C. The notice also invited interested persons to submit comments on the requested exemption to the Department. In addition the notice stated that any interested person might submit a written request that a public hearing be held relating to this exemption. No public comments and no requests for a hearing were received by the Department. The notice of pendency was issued and the exemption is being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption granted under section 408(a) of the act and section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person with respect to a plan to which the exemption is applicable from certain other provisions of the Act and the Code. These provisions include any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his or her duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does the fact the transaction is the subject of an exemption affect the requirement of section 401(a) of the Code that a plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries.

(2) This exemption does not extend to transaction prohibited under section 406(b)(3) of the Act and section 4975(c)(1)(F) of the Code.

(3) This exemption is supplemental to, and not in derogation of, any other provisions of the Act and the Code, including statutory or administrtive exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption or transitional rule is not dispositive of whether the transaction is, in fact, a prohibited transaction.

Exemption

In accordance with section 408(a) of the Act and section 4975(c)(2) of the Code and the procedures set forth in ERISA Procedure 75–1 (40 FR 18471, April 28, 1975), and based upon the entire record, the Department makes the following determinations:

(a) The exemption is administratively feasible;

(b) It is in the interests of the Plans and their participants and beneficiaries; and

(c) It is protective of the rights of the participants and beneficiaries of the Plans.

Accordingly, the following exemption is hereby granted under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75–1.

I. Transactions

A. Effective July 29, 1981, the restrictions of sections 406(a) and 407(a) of the Act and the taxes imposed by section 4975(a) and (b) of the Code by reason of section 4975(c)(1)(A) through (D) of the Code shall not apply to the following transactions involving Mortgage Pools:

(1) The direct or indirect sale, exchange or transfer of Certificates in the initial issuance of Certificates between Merrill Lynch Hubbard and the Plan when Merrill Lynch Hubbard or the Trustee of such Pool is a party in interest with respect to such Plan, provided that the Plan pays no more than fair market value for such Certificates, and provided further that the rights and interests evidenced by such Certificates are not subordinated to the rights and interests evidenced by other Certificates of the same Mortgage Pool; and

(2) The continued holding of Certificates acquired by a Plan pursuant to subparagraph (1), above.

B. Effective July 29, 1981, the restrictions of sections 406(a), 406(b)(1) and (2) and 407(a) of the Act and the taxes imposed by section 4975(a) and (b) of the Code by reason of section 4975(c)(1)(A) through (E) of the Code shall not apply to the direct or indirect sale, exchange or transfer of Certificates in the initial issuance of Certificates of a Mortgage Pool between Merrill Lynch Hubbard and a Plan, and the continued holding of such Certificates, when Merrill Lynch Hubbard or the Trustee of such Mortgage Pool is a fiduciary with respect to such Plan, provided that:

(1) The Plan pays no more than fair market value for such Certificates;

(2) The rights and interests evidenced by such Certificates are not subordinated to the rights and interests evidenced by other Certificates of the same Mortgage Pool:

(3) Such sale, exchange or transfer is expressly approved by a fiduciary independent of Merrill Lynch Hubbard or the Trustee or any affiliate thereof, who has authority to manage and control those Plan assets being invested in the Certificates;

(4) The total value of Certificates purchased by a Plan does not exceed 25% of the amount of the issue; and

(5) At least 50% of the aggregate amount of the issue is acquired by persons independent of Merrill Lynch Hubbard or the Trustee.

C. Effective July 29, 1981, the restrictions of sections 406(a), 406(b)(1) and (2) and 407(a) of the Act and the taxes imposed by section 4975(a) and (b) of the Code by reason of section 4975(c)(1)(A) through (E) of the Code shall not apply to transactions in connection with the servicing and operation of the Mortgage Pool provided that:

(1) such transactions are carried out in accordance with the terms of a binding Pooling and Servicing Agreement; and

(2) such Pooling and Servicing Agreemeent is made available to investors before they purchase Certificates in a Mortgage Pool.

D. Effective July 29, 1981, the restrictions of sections 406(a) and 407(a) of the Act and the taxes imposed by section 4975(a) and (b) of the Code by reason of seciton 4975(c)(1)(A) through (D) of the Code shall not apply to any transactions to which such restrictions or taxes would otherwise apply merely because a person is deemed to be a party in interest (including a fiduciary) with respect to a Plan by virtue of providing services to the Plan (or who has a relationship to such service provider descirbed in section 3(14)(F), (G), (H) or (I) of the Act), solely because of the ownership by such Plan of a Certificate.

II. General Conditions

A. The relief provided under section I, above, is available only if the following conditions are met:

(1) The Trustee for each Mortgage Pool must not be an affiliate of Merrill Lynch Hubbard provided, however, the Trustee shall not be considered to be an affiliate of Merrill Lynch Hubbard solely because the Trustee has succeeded to

the rights and responsibilities of Merrill Lynch Hubbard pursuant to the terms of the Pooling and Servicing Agreement providing for such succession upon the occurrence of one or more events of default by Merrill Lynch Hubbard; and

(2) The sum of all payments made to and retained by Merrill Lynch Hubbard in connection with a Mortgage Pool, and all funds inuring to the benefit of Merrill Lynch Hubbard as a result of the administration of the Mortgage Pool, must represent not more than adequate consideration for selling the Certificates and underwriting the sale of the Certificates, plus reasonable compensation for services provided by Merrill Lynch Hubbard to the Mortgage Pool.

III. Definitions

A. For the purposes of this exemption, the term "Mortgage Pool" means an investment pool the corpus of which

(1) Is held in trust; and

(2) Consists solely of

(a) Interest bearing obligations secured by multi-family residential property;

(b) Property which had secured such obligations and which has been acquired by foreclosure; and

(c) Undistributed cash.

B. For the purposes of this exemption, the term "Certificate" means a certificate representing a beneficial undivided fractional interest in a Mortgage Pool and entitling the holder of such certificate to pass-through payment of principal and interest from the pooled mortgage loans, less any fees retained by Merrill Lynch Hubbard.

C. For the purposes of this exemption, the term "affiliate" of another person means:

(1) Any person directly or indirectly, through one or more intermediaries, controlling, controlled by, or under common control with such other person;

(2) Any officer, director partner, employee, or relative (as defined in section 3(15) of the Act) of such other person; and

(3) Any corporation or partnership of which such other person is an officer, director, or partner.

For purposes of this paragraph, the term "control" means the power to exercise a controlling influence over the management or policies of a person other than an individual.

D. For the purposes of this exemption, a person will be "independent of Merrill Lynch Hubbard or the Trustee" only if:

(1) Such person is not an affiliate (as defined in paragraph III(C) of this exemption) of Merrill Lynch Hubbard or the Trustee; and

(2) Neither Merrill Lynch Hubbard nor the Trustee, nor any affiliate thereof, is a fiduciary who has investment management authority or renders investment advice with respect to any of the assets of such person.

The availability of this exemption is subject to the express condition that the material facts and representations contained in the application are true and complete, and that the application accurately describes all material terms of the transactions that are the subject of this exemption.

Signed at Washington, D.C., this 27th day of January, 1982.

Alan D. Lebowitz,

Assistant Administrator for Fiduciary Standards, Pension and Welfare Benefit Programs, Labor-Management Services Administration, U.S. Department of Labor.

[FR Doc. 82-2674 Filed 2-1-82; 8:45 am]

BILLING CODE 4510-29-M

[Prohibited Transaction Exemption 82-26; Exemption Application Nos. D-2785 and D-2786]

Exemption From the Prohibitions for Certain Transactions Involving R. M. Bradley Co., Inc., Located in Boston, Massachusetts, and the First City National Bank of Houston, Located in Houston, Texas

AGENCY: Office of Pension and Welfare Benefit Programs, Labor.

ACTION: Grant of individual exemption.

SUMMARY: This exemption permits certain aspects of the proposed provision of real estate services by the R. M. Bradley Co., Inc. (Bradley) to the First City National Bank of Houston (the Bank) as trustee of certain employee benefit plans.

FOR FURTHER INFORMATION CONTACT: Gary H. Lefkowitz of the Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-4526, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20216, (202) 523-8881. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On December 18, 1981, notice was published in the **Federal Register** (46 FR 61757) of the pendency before the Department of Labor (the Department) of a proposal to grant an exemption from the restrictions of section 406(b) of the Employee Retirement Income Security Act of 1974 (the Act) and from the sanctions resulting from the application of section 4975 of the Internal Revenue Code of 1954 (the Code) by reason of section 4975(c)(1) (E) and (F) of the Code, for transactions described in an application filed on behalf of Bradley and the Bank.

The notice set forth a summary of facts and representations contained in the application for exemption and referred interested persons to the application for a complete statement of the facts and representations. The application has been available for public inspection at the Department in Washington, D.C. The notice also invited interested persons to submit comments on the requested exemption to the Department. In addition the notice stated that any interested person might submit a written request that a public hearing be held relating to this exemption. No public comments and no requests for a hearing were received by the Department.

The notice of pendency was issued and the exemption is being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption granted under section 408(a) of the Act and section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person with respect to a plan to which the exemption is applicable from certain other provisions of the Act and the Code. These provisions include any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his or her duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does the fact the transaction is the subject of an exemption affect the requirement of section 401(a) of the Code that a plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries.

(2) This exemption does not extend to transactions prohibited under section 406(a) of the Act and section 4975(c)(1) (A) through (D) of the Code.

(3) This exemption is supplemental to, and not in derogation of, any other provisions of the Act and the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction

is subject to an administrative or statutory exemption or transitional rule is not dispositive of whether the transaction is, in fact, a prohibited transaction.

Exemption

In accordance with section 408(a) of the Act and section 4975(c)(2) of the Code and the procedures set forth in ERISA Procedure 75–1 (40 FR 18471, April 28, 1975), and based upon the entire record, the Department makes the following determinations:

(a) The exemption is administratively feasible;

(b) It is in the interests of the Plan and of its participants and beneficiaries; and

(c) It is protective of the rights of the participants and beneficiaries of the Plan.

Accordingly the restrictions of section 406(b) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (E) and (F) of the Code, shall not apply to the provision of real estate services as described in the notice of pendency and the receipt of fees with respect to such services by Bradley.

The availability of this exemption is subject to the express condition that the material facts and representations contained in the application are true and complete, and that the application accurately describes all material terms of the transactions to be consummated pursuant to this exemption.

Signed at Washington, D.C., this 27th day of January, 1982.

Alan D. Lebowitz,

Assistant Administrator for Fiduciary Standards, Pension and Welfare Benefit Programs, Labor-Management Services Administration, U.S. Department of Labor.

[FR Doc. 82-2675 Filed 2-1-82; 8:45 am]

BILLING CODE 4510-29-M

[Prohibited Transaction Exemption 82-20; Exemption Application No. D-2247]

Exemption From the Prohibitions for Certain Transactions Involving the Teamsters Local No. 20 Insurance, Health and Welfare Plan and Trust Located in Toledo, Ohio

AGENCY: Office of Pension and Welfare Benefit Programs.

ACTION: Grant of individual exemption.

SUMMARY: This exemption permits the assignment of a lease by the Teamsters Local No. 20 Insurance, Health and Welfare Plan and Trust (the Plan) to Dental Plans, Inc. (DPI), a party in interest with respect to the Plan, and the cash sale of furniture, equipment and leasehold improvements by the Plan to DPI.

FOR FURTHER INFORMATION CONTACT: Gary H. Lefkowitz of the Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-4526, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20216, (202) 523-8881. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On November 20, 1981, notice was published in the **Federal Register** (46 FR 57172) of the pendency before the Department of Labor (the Department) of a proposal to grant an exemption from the restrictions of section 406(a) of the Employee Retirement Income Security Act of 1974 (the Act), for transactions described in an application filed on behalf of the trustees of the Plan. The notice set forth a summary of facts and representations contained in the application for exemption and referred interested persons to the application for a complete statement of the facts and representations. The application has been available for public inspection at the Department in Washington, D.C. The notice also invited interested persons to submit comments on the requested exemption to the Department. The applicants have represented that they have complied with the requirements of the notice to interested persons as set forth in the notice of pendency. No public comments were received by the Department.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption granted under section 408(a) of the Act does not relieve a fiduciary or other party in interest with respect to a plan to which the exemption is applicable from certain other provisions of the Act. These provisions include any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his or her duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act.

(2) This exemption does not extend to transactions prohibited under section 406(b) of the Act.

(3) This exemption is supplemental to, and not in derogation of, any other provisions of the Act including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption or transitional rule is not dispositive of whether the transaction is, in fact, a prohibited transaction.

Exemption

In accordance with section 408(a) of the Act and the Procedures set forth in ERISA Procedure 75–1 (40 FR 18471, April 28, 1975), and based upon the entire record, the Department makes the following determinations:

(a) The exemption is administratively feasible;

(b) It is in the interests of the Plan and of its participants and beneficiaries; and

(c) It is protective of the rights of the participants and beneficiaries of the Plan.

Accordingly the restrictions of section 406(a) of the Act shall not apply to the assignment by the Plan to DPI of a lease with Forty Four Corporation as owner-lessor for the premises in the basement of 435 S. Hawley Street, Toledo, Ohio (the Dental Care Center), and the cash sale of the furniture, equipment and leasehold improvements in the Dental Care Center by the Plan to DPI for a total of $174,935, provided such amount is not less than their fair market value at the time of the sale.

The availability of this exemption is subject to the express condition that the material facts and representations contained in the application are true and complete, and that the application accurately describes all material terms of the transactions to be consummated pursuant to this exemption.

Signed at Washington, D.C., this 27th day of January 1982.

Alan D. Lebowitz,

Assistant Administrator for Fiduciary Standards, Pension and Welfare Benefit Programs, Labor-Management Services Administration, U.S. Department of Labor.

[FR Doc. 82-2676 Filed 2-1-82; 8:45 am]

BILLING CODE 4510-29-M

Wage and Hour Division

[Administrative Order No. 656]

Special Industry Committee for All Industry in American Samoa; Appointment; Convention; Notice of Hearing

1. Pursuant to sections 5 and 6(a)(3) of the Fair Labor Standards Act of 1938, as amended (29 U.S.C. 205, 206(a)(3)), and Reorganization Plan No. 6 of 1950 (3 CFR, 1949–53 Comp., p. 1004) and 29 CFR 511. I hereby appoint special

Industry Committee No. 15 for American Samoa.

2. Pursuant to section 6(a)(3) and Section 8 of the Act, as amended (29 U.S.C. 206(a)(3), 208), Reorganization Plan No. 6 of 1950 (3 CFR 1949–53 Comp., p. 1004), and 29 CFR 511, I hereby:

(a) Convene the above-appointed industry committee.

(b) Refer to the industry committee the question of the minimum rate or rates for all industry in American Samoa to be paid under section 6(a)(3) of the Act, as amended.

(c) Give notice of the hearing to be held by the committee at the time and place indicated.

The industry committee shall investigate conditions in such industry and the committee, or any authorized subcommittee thereof, shall hear such witnesses and receive such evidence as may be necessary or appropriate to enable the committee to perform its duties and functions under the Act.

The Committee shall meet in executive session to commence its investigation at 9 a.m. and begin its public hearing at 11 a.m. on April 26, 1982 in the Rainmaker Hotel, Pago Pago, American Samoa.

3. The rate or rates recommended by the committee shall not exceed the rates prescribed by sections 6(a) and 6(b) of the Act, as amended by the Fair Labor Standards Amendments of 1977. The rate has been $3.35 since January 1, 1981.

The committee shall recommend to the Administrator of the Wage and Hour Division of the Department of Labor the highest minimum rate or rates of wages for such industry which it determines, having due regard to economic and competitive conditions, will not substantially curtail employment in such industry, and will not give any industry in American Samoa a competitive advantage over any industry in the United States outside of Puerto Rico, the Virgin Islands, and American Samoa.

4. Where the committee finds that a higher minimum wage may be determined for employees engaged in certain activities or in the manufacture of certain products in such industry than may be determined for other employees in such industry, the committee shall recommend such reasonable classifications within such industry as it determines to be necessary for the purpose of fixing for each classification the highest minimum wage rate that can be determined for it under the principles set forth herein and in 29 CFR 511.10, which will not substantially curtail employment in such classification and will not give a competitive advantage to any group in the industry. No classification shall be made, however, and no minimum wage rate shall be fixed solely on a regional basis or on the basis of age or sex. In determining whether there should be classifications within industry, in making such classifications and in determining the minimum wage rates for such classifications, the committee shall consider, among other relevant factors, the following: (a) Competitive conditions as affected by transportation, living, and production costs; (b) wages established for work of like or comparable character by collective labor agreements negotiated between employers and employees by representatives of their own choosing; and (c) wages paid for work of like or comparable character by employers who voluntarily maintain minimum wage standards in the industry.

5. The Administrator of the Wage and Hour Division, U.S. Department of Labor, shall prepare an economic report containing the information he has assembled pertinent to the matters referred to the committee. Copies of this report may be obtained at the Office of the Governor, Pago Pago, American Samoa, and the National Office of the Wage and Hour Division, U.S. Department of Labor, Washington, D.C. 20210, as soon as it is completed. The committee will take official notice of the facts stated in this report. Parties, however, shall be afforded an opportunity to refute such facts by evidence received at the hearing.

6. The procedure of this industry committee will be governed by the provisions of Title 29, Code of Federal Regulations, Part 511. Copies of this part of the regulations will be available at the Office of the Governor, Pago Pago, American Samoa, and at the National Office of the Wage and Hour Division. The proceedings will be conducted in English but in the event a witness should wish to testify in Samoan, an interpreter will be provided. As a prerequisite to participation as a party, interested persons shall file six copies of a prehearing statement at the aforementioned Office of the Governor of American Samoa and six copies at the National Office of the Wage and Hour Division, U.S. Department of Labor, Washington, D.C. 20210. Each prehearing statement shall contain the data specified in § 511.8 of the regulations and shall be filed not later than April 16, 1982. If such statements are sent by airmail between American Samoa and the mainland, such filing shall be deemed timely if postmarked within the time provided.

Signed at Washington, D.C., this 29th day of January 1982.

Raymond J. Donovan,

Secretary of Labor.

[FR Doc. 82-2806 Filed 2-1-82; 8:45 am]

BILLING CODE 4510-27-M

MERIT SYSTEMS PROTECTION BOARD

Employee Responsibilities and Conduct

AGENCY: Merit Systems Protection Board.

ACTION: Notice.

SUMMARY: The Merit Systems Protection Board ("the Board") publishes notice of the adoption of the rules and regulations contained in Part 735 of Title 5 of the Code of Federal Regulations. Part 735 of Title 5 prescribes standards of conduct and responsibilities and governs statements of employment and financial interests for officers, employees and special government employees. This action is being taken pursuant to the requirements of 5 CFR 735.104 (a) and (f).

EFFECTIVE DATE: February 2, 1982.

FOR FURTHER INFORMATION CONTACT: Kenneth Goshorn, (202) 653–7171.

SUPPLEMENTARY INFORMATION: The Merit Systems Protection Board, pursuant to 5 CFR 735.104 issues this notice adopting Part 735 of 5 CFR as its standards of employee conduct and responsibilities. This notice adopting the standards and requirements established by the Office of Personnel Management ("OPM") has been approved by OPM pursuant to 5 CFR 735.104(f) and is being published in the **Federal Register** for immediate effect.

The Board finds that this action relates solely to rules governing agency procedure or practice and, accordingly, that notice and prior publication for comments under the Administrative Procedure Act, 5 U.S.C. 551 *et seq.*, are unnecessary. See 5 U.S.C. 553(b).

Regulatory Flexibility Act

The Chairman, Merit Systems Protection Board, certifies that the Board is not required to prepare an initial or final regulatory analysis of this rule, pursuant to section 603 or 604 of the Regulatory Flexibility Act, because of his determination that this rule would not have a significant economic impact on a substantial number of small entities, including small business, small organizational units and small governmental jurisdictions.

Accordingly, the Merit Systems Protection Board pursuant to 5 CFR 1205(g) and 5 CFR 735.104(f) publishes its employee responsibilities and conduct standards to read as follows:

Employee responsibilities and conduct.

The Merit Systems Protection Board hereby adopts the rules and regulations contained in Part 735 of Title 5 of the Code of Federal Regulations, prescribing standards of conduct and responsibilities, and governing statements reporting employment and financial interests for officers and employees, including special government employees. These adopted rules and regulations shall be applied, as appropriate, to the officers and employees, including special government employees, of the Board.

For the Board.

Dated: January 21, 1982.

Herbert E. Ellingwood,

Chairman.

[FR Doc. 82-2468 Filed 2-1-82; 8:45 am]

BILLING CODE 7400-01-M

MOTOR CARRIER RATEMAKING STUDY COMMISSION

Public Hearing; Collective Ratemaking

DATE: February 12, 1982.

PLACE: State Building, 350 McAllister Street, Room 1194, San Francisco, California.

TIME: 9:30 a.m.

PURPOSE: To receive testimony from various parties on collective ratemaking.

The Motor Carrier Act of 1980, Public Law 96-296, directs the Motor Carrier Ratemaking Study Commission (Commission) to make a full and complete investigation and study of the collective ratemaking process for all rates of motor common carriers and of the need or lack of need for continued antitrust immunity thereof. The Commission is specifically directed to estimate the impact of the elimination of such immunity upon the rate levels and rate structures and to describe the impact of such on the Interstate Commerce Commission and its staff. Also, the Commission has been directed to give special consideration to the impact of the elimination of such immunity upon rural areas and small communities.

The Commission, through its Hearings Committee, calls this regional hearing for the purpose of exploring alternatives to the current collective ratemaking process and to discuss advantages and disadvantages of the status quo.

Anyone who is interested in submitting written testimony for the record of the Commission may do so by sending same to: Larry F. Darby, Executive Director, Motor Carrier Ratemaking Study Commission, 214 Massachusetts Avenue, N.E., Washington, D.C. 20002.

FOR FURTHER INFORMATION, CONTACT: Name: J. Kent Jarrell; Title: General Counsel; Phone No.: (202) 724-9600.

Submitted this, the 28th day of January, 1982.

Larry F. Darby,

Executive Director.

[FR Doc. 82-2713 Filed 2-1-82; 8:45 am]

BILLING CODE 6820-BD-M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[82-3]

Intent To Grant an Exclusive Patent License

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of intent to grant an exclusive patent license.

SUMMARY: NASA hereby gives notice of intent to grant to D.F.M. Company, Norman, Oklahoma, a limited, exclusive, royalty-bearing, revocable license to practice the invention described in U.S. Patent No. 3,360,972 for "Magnetomotive Metal Working Device," issued January 2, 1968, to the Administrator of the National Aeronautics and Space Administration on behalf of the United States of America. The proposed exclusive license wil be for a limited number of years and will contain appropriate terms and conditions to be be negotiated in accordance with the NASA Patent Licensing Regulations, 14 CFR Part 1245 Subpart 2. NASA will negotiate the final terms and conditions and grant the exclusive license unless, within 60 days of the date of this Notice, the Director of Patent Licensing receives written objections to the grant, together with supporting documentations. The Director of Patent Licensing will review all written responses to the Notice and then recommend to the Assistant General Counsel for Patent Matters whether to grant the exclusive license.

DATE: Comments to this notice must be received on or before April 5, 1982..

ADDRESS: National Aeronautics and Space Administration, Code GP-4, Washington, D.C. 20546.

FOR FURTHER INFORMATION CONTACT: Mr. John G. Mannix, (202) 755-3954.

Dated: January 26, 1982.

S. Neil Hosenball,

General Counsel.

[FR Doc. 82-2652 Filed 2-1-82; 8:45 am]

BILLING CODE 7510-01-M

[82-4]

Intent To Grant Partially Exclusive Patent Licenses

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of intent to grant partially exclusive patent licenses.

SUMMARY: Notice is hereby given that consideration is being given to granting both LIXI Research Limited Partnership, Downers Grove, Illinois; and Biomet, Inc., Warsaw, Indiana, limited, partially exclusive, revocable licenses to practice the radioactive isotope version of the invention described in claims 3, 5, 7-11, 13-28, 30, 32-35, and 37 of U.S. Patent No. 4,142,101 for "Low Intensity X-Ray and Gamma-Ray Imaging Device," issued February 27, 1979, to the Administrator of the National Aeronautics and Space Administration on behalf of the United States of America. The proposed partially exclusive licenses will be for a limited number of years and will contain appropriate terms and conditions to be negotiated in accordance with the NASA Patent Licensing Regulations, 14 CFR Part 1245, subpart 2. NASA will negotiate the final terms and conditions and grant the partially exclusive licenses unless, within 60 days of the date of this Notice, the Director of Patent Licensing receives in writing any of the following, together with supporting documentations: (a) a statement from any person setting forth reasons why it would not be in the best interest of the United States to grant the proposed partially exclusive licenses; or (b) an application for a nonexclusive license for the radioactive isotope versions of the invention, in accordance with § 1245.205(b) in which applicant states that he/she has already brought or is likely to bring the radioactive isotope version of the invention to practical application within a reasonable period. The Director of Patent Licensing will review all written responses to the Notice and then recommend to the Assistant General Counsel for Patent Matters whether to grant the partially exclusive licenses.

DATE: Comments to this notice must be received on or before April 5, 1982.

ADDRESS: National Aeronautics and Space Administration, Code GP–4, Washington, D.C. 20546.

FOR FURTHER INFORMATION CONTACT: Mr. John G. Mannix, (202) 755–3954.

Dated: January 26, 1982.

S. Neil Hosenball,

General Counsel.

[FR Doc. 82–2653 Filed 2–1–82; 8:45 am]

BILLING CODE 7510–01–M

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Behavioral and Neural Sciences; Subcommittee on Neurobiology; Meeting

In accordance with the Federal Advisory Committee Act, as amended, Pub. L. 92–463, the National Science Foundation announces the following meeting:

Name: Subcommittee on Neurobiology of the Advisory Committee for Behavioral and Neural Sciences.

Date and Time: February 18–19, 1982, 9:00 a.m. to 5:00 p.m. each day.

Place: Room 1224, National Science Foundation, 1800 G Street, NW. Washington, D.C.

Type of Meeting: Closed.

Contact: Dr. John K. Harting, Developmental Neurosciences Panel, Room 320, National Science Foundation, Washington, D.C. 20550 Telephone (202–357–7428).

Purpose of Subcommittee: To provide advice and recommendations concerning support for research in Developmental Neurosciences.

Agenda: To review and evaluate research proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary of confidential nature, including technical information: financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are within exemptions (4) and (6) of 5 U.S.C. 552b(c), Government in the Sunshine Act.

Authority to Close Meeting: This determination was made by the Committee Management Officer pursuant to provisions of Section 10(d) of Pub. L. 92–463. The Committee Management Officer was delegated the authority to make such determinations by the Director, NSF, on July 6, 1979.

Dated: January 28, 1982.

M. Rebecca Winkler,

Committee Management Coordinator.

[FR Doc. 82–2667 Filed 2–1–82; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–397]

Washington Public Power Supply System, WPPSS Nuclear Plant No. 2; Order Extending Construction Completion Date

Washington Public Power Supply System (WPPSS) is the holder of Construction Permit No. CPPR–93 issued by the Atomic Energy Commission [1] on March 19, 1973 and extended on August 29, 1978, for construction of the WPPSS Nuclear Plant No. 2 which is presently under construction at the Permittee's site in Benton County, Washington. On September 4, 1981, the Permittee filed a request pursuant to the Code of Federal Regulations, Title 10, Part 50 § 50.55(b) for an extension of the construction completion date for WNP–2 because construction has been delayed due to the following factors:

1. Changes in the scope of the project including increases in the amount of material and engineering required as a result of regulatory actions, in particular those subsequent to the TMI–2 accident.

2. Construction delays and lower than estimated productivity, which resulted in delays in installation of material and equipment and delays in completing of systems necesssitating rescheduling of preoperational testing.

3. Strikes by portions of the construction work force.

4. Changes in plant design.

5. Delays in delivery of equipment and materials.

This action involves no significant hazards consideration; good cause has been shown for the delays; and the requested extension is for a reasonable period, the bases for which are set forth in the staff's evaluation of the request for extension.

The Commission has determined that this action will not result in any significant environmental impact and, pursuant to 10 CFR 51.5(d)(4), an environmental impact statement, or negative declaration and environmental impact appraisal, need not be prepared in connection with this action.

The NRC staff evaluation of the request for extension of the construction permit is available for public inspection at the Commission's Public Document Room 1717, H Street, NW., Washington, D.C. 20555 and at the Richland Public Library, Richland, Washington 99352.

It is hereby ordered that the latest completion date for CPPR–93 is extended from December 1, 1981 to February 1, 1984.

Date of Issuance: January 27, 1982.

For The Nuclear Regulatory Commission.

Darrell G. Eisenhut,

Director, Division of Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 82–2696 Filed 2–1–82; 8:45 am]

BILLING CODE 7590–01–M

[1] Effective January 19, 1975, the Atomic Energy Commission became the Nuclear Regulatory Commission and Permits in effect on that day were continued under the authority of the Nuclear Regulatory Commission.

Privacy Act of 1974; Minor Amendments and Corrections to Systems of Records

AGENCY: Nuclear Regulatory Commission.

ACTION: Minor amendments and corrections to NRC Systems of Records.

SUMMARY: This document makes minor corrective amendments to the NRC Systems of Records, NRC–16, NRC–22, NRC–40, and Addendum I, Part 1. It adds certain information in NRC–22 and NRC–40, which was inadvertently omitted when these notices were submitted for publication in the **Federal Register** in 1979. It also clarifies and updates the information in NRC–16 and Addendum I, Part 1.

EFFECTIVE DATE: February 2, 1982.

FOR FURTHER INFORMATION CONTACT: Sarah N. Wigginton, FOI/PA Branch, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492–8133.

SUPPLEMENTARY INFORMATION: The Commission is amending its Systems of Records Notices, NRC–16, by clarifying the paragraph entitled "Routine uses of records maintained in the system, including categories of users and the purposes of such uses," and by updating the location of NRC Headquarters Offices on Addendum I, Part 1. The amendments also correct Systems of Records Notices, NRC–22 and NRC–40, by adding the "Systems exempted from certain provisions of the act" paragraph in each notice. This paragraph was inadvertently omitted from the amendments to these two Systems of Records published on July 9, 1979 (44 FR 40158).

1. In NRC–16, Facility Operator Licensees Records Files (10 CFR Part 55)—NRC, the paragraph entitled

"Routine uses of records maintained in the system, including categories of users and the purposes of such uses" is revised to read as follows:

NRC–16

SYSTEM NAME:

Facility Operator Licensees Records Files (10 CFR Part 55)—NRC.

* * * * *

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information in these records may be used:

a. To determine if the individual meets the requirements of 10 CFR Part 55 to take an examination to be issued an operator's license;

b. To provide researchers with information for statistical evaluations related to selections, training and examination of facility operators;

c. To provide for examination and testing material and obtain results from contractors;

d. To provide facility management with sufficient information to enroll the individuals in the licensed operator requalification program; and

e. For any of the routine uses specified in the Prefactory Statement, except paragraph number 3.

In addition, information related to the application, certification of competency, and license or denial letter may be made available in the NRC's Public Document Room.

* * * * *

2. In NRC–22, Personnel Performance Appraisals—NRC: Part A, GG–15 Employees and below; Part B, Senior Executive Service and Equivalent employees, the following paragraph should be inserted after the paragraph which is entitled "Record source categories" to read as follows:

NRC–22

SYSTEM NAME:

Personnel Performance Appraisals—NRC: Part A, GG–15 employees and below; Part B, Senior Executive Service and equivalent employees.

* * * * *

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

Pursuant to 5 U.S.C. 552a(k)(1) and (5), the Commission has exempted portions of this system of records from 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H) and (I) and (f). The exemption rule is contained in 10 CFR 9.95 of the NRC regulations.

* * * * *

3. In NRC–40, Facility Security Support Files and Associated Reports—NRC, the following paragraph should be inserted after the paragraph which is entitled "Record source categories" to read as follows:

NRC–40

SYSTEM NAME:

Facility Security Support Files and Associated Reports—NRC.

* * * * *

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

Pursuant to 5 U.S.C. 552a(k)(5) and (6), the Commission has exempted portions of this system of records from 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H) and (I) and (f). The exemption rule is contained in 10 CFR 9.95 of the NRC regulations.

* * * * *

4. Addendum I, List of U.S. Nuclear Regulatory Commission Locations, Part 1, NRC Headquarters Offices, is revised to read as follows:

Addendum I

List of U.S. Nuclear Regulatory Commission Locations

Part 1—NRC Headquarters Offices

a. Willste Building, 7915 Eastern Avenue, Silver Spring, Maryland.

b. East-West Towers Building, 4340 East-West Highway, Bethesda, Maryland.

c. East-West Towers Building, 4350 East-West Highway, Bethesda, Maryland.

d. Lugenbeel Building, 4922 Fairmont Avenue, Bethesda, Maryland.

e. Landow Building, 7910 Woodmont Avenue, Bethesda, Maryland.

f. Maryland National Bank Building, 7735 Old Georgetown Road, Bethesda, Maryland.

g. Phillips Building, 7920 Norfolk Avenue, Bethesda, Maryland.

h. Nicholson Lane Building, 5650 Nicholson Lane, Rockville, Maryland.

i. Matomic Building, 1717 H Street, NW., Washington, D.C.

j. Air Rights III Building, 4550 Montgomery Avenue, Bethesda, Maryland.

* * * * *

Dated at Bethesda, Maryland, this 22d day of January 1981.

For the Nuclear Regulatory Commission.

William J. Dircks,

Executive Director for Operations.

[FR Doc. 82–2717 Filed 2–1–82; 8:45 am]

BILLING CODE 7590–01–M

SECURITIES EXCHANGE COMMISSION

[Rel. No. 12184; 811–2800]

Anplan Variable Account and Anchor National Life Insurance Co.; Filing of Application

January 26, 1982.

Notice is hereby given that Anchor National Life Insurance Company ("Anchor National") and Anplan Variable Account ("Applicant"), Camelback at 22nd Street, Phoenix, Arizona 85016, a separate account of Anchor National registered under the Investment Company Act of 1940 ("Act") as a unit investment trust, filed an application on December 24, 1981, pursuant to section 8(f) of the Act, for an order declaring that Applicant has ceased to be an investment company. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein, which are summarized below.

Applicant was established pursuant to a resolution of the Board of Directors of Anchor National in November of 1977 and registered with the Commission on January 3, 1978. Applicant's registration statement under the Securities Act of 1933 was amended on September 28, 1978. According to the application, that registration statement was never declared effective. Thus, the application represents that Applicant has not made a public offering of its securities.

Applicant states that it has no shareholders. Applicant further states that it has no assets; that it has no outstanding debts or other liabilities; that it is not a party to any litigation or administrative proceeding; and that it has not, for any reason, transferred any of its assets to a separate trust, the beneficiaries of which were or are securityholders of Applicant. Applicant also states that it is not now engaged, and does not propose to engage, in any business activities other than those necessary for the winding-up of its affairs.

Section 8(f) of the Act provides, in pertinent part, that whenever the Commission, on its own motion or upon application, finds that a registered investment company has ceased to be an investment company, it shall so declare by order, and upon the effectiveness of such order the registration of such company shall cease to be in effect.

Notice is further given that any interested person may, not later than February 22, 1982, at 5:30 p.m., submit to the Commission in writing a request for

a hearing on the application accompanied by a statement as to the nature of his interest, the reasons for such request, and the issues, if any, of fact or law proposed to be controverted, or he may request that he be notified if the Commission shall order a hearing thereon. Any such communication should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request shall be served personally or by mail upon Applicant at the address stated above. Proof of such service (by affidavit or, in case of an attorney-at-law, by certificate) shall be filed contemporaneously with the request. As provided by Rule 0–5 of the Rules and Regulations promulgated under the Act, an order disposing of the application herein will be issued as of course following said date unless the Commission thereafter orders a hearing upon request or upon the Commission's own motion. Persons who request a hearing or advice as to whether a hearing is ordered, will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82–2680 Filed 2–1–82; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. 12185; 812–5003]

Chestnut Street Cash Fund, Inc.

January 26, 1982.

Notice is hereby given that Chestnut Street Cash Fund, Inc. ("Applicant"), #6 The Commons, 3512 Silverside Road, Wilmington, Del. 19803, filed an appliction on October 26, 1981, and an amendment thereto on January 20, 1982, for an order of the Commission pursuant to section 6(c) of the Investment Company Act of 1940 ("Act") exempting Applicant from the provisions of section 2(a)(41) of the Act and Rules 2a–4 and 22c–1 under the Act to the extent necessary to permit Applicant to compute its net asset value per share using the amortized cost method of valuing portfolio securities. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein, which are summarized below.

Applicant was organized under the laws of the State of Maryland in 1981, and is registered under the Act as an open-end, diversified, management investment company. It is a no-load, money market fund offering its shares to customers of Provident National Bank ("Provident"), including clients of its trust division and individuals and businesses which maintain Provident accounts. Applicant will have two separate portfolios, A and B, each having the investment objective of seeking current income and stability of principal.

Applicant states that the securities held in each portfolio will have remaining maturities of one year or less. Portfolios A and B differ only with respect to their permitted investments; portfolio A will invest exclusively in obligations issued or guaranteed by the United States Government, its agencies of instrumentalities, while portfolio B will consist of other high quality "money market" instruments in addition to direct and indirect United States Government obligations, and may include certificates of deposit, banker's acceptances, and commercial paper including variable amount master demand notes. Applicant represents that it will not purchase certificates of deposit from Provident.

Applicant seeks an order of the Commission pursuant to section 6(c) of the Act exempting it from the provisions of section 2(a)(41) of the Act and Rules 2a–4 and 22c–1 thereunder to the extent necessary to permit Applicant's assets to be valued according to the amortized cost valuation method. Under the amortized cost valuation method, portfolio instruments are valued at their cost as of the date of acquisition and thereafter assuming a constant rate of amortization to maturity of any discount or permium, regardless of the impact of fluctuating interest rates on the market value of such instruments.

As here pertinent, section 2(a)(41) of the Act defines value to mean: (1) with respect to securities for which market quotations are readily available, the market value of such securities, and (2) with respect to other securities and assets, fair value as determined in good faith by the board of directors. Rule 22c–1 adopted under the Act provides, in part, that no registered investment company or principal underwriter therefor issuing any redeemable security shall sell, redeem or repurchase any such security except at a price based on the current net asset value of such security which is next computed after receipt of a tender of such security for redemption or of an order to purchase or sell such security.

Rule 2a–4 adopted under the Act provides, as here relevant, that the "current net asset value" of a redeemable security issued by a registered investment company used in computing its price for the purposes of distribution, redemption and repurchase shall be an amount which reflects calculations made substantially in accordance with the provisions of that rule, with estimates used where necessary or appropriate. Rule 2a–4 further states that portfolio securities with respect to which market quotations are readily available shall be valued at current market value, and other securities and assets shall be valued at fair value as determined in good faith by the board of directors of the investment company. Prior to the filing of the application, the Commission expresed its view that, among other things, (1) Rule 2a–4 under the Act requires that portfolio instruments of "money market" funds be valued with reference to market factors, and (2) it would be inconsistent, generally, with the provisions of Rule 2a–4 for a "money market" fund to value its portfolio instruments on an amortized cost basis (Investment Company Act Release No. 9786, May 31, 1977).

Section 6(c) of the Act provides, in pertinent part, that the Commission, by order upon application, may conditionally or unconditionally exempt any person, security or transaction, or any class or classes of persons, securities or transactions, from any provision or provisions of the Act or of any rule or regulation thereunder, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

In support of the relief requested, Applicant states that it believes that its potential shareholders are not concerned with the theoretical differences which might occur between the yield achieved through market pricing and the yield computed on the basis of amortized cost as described above. On the other hand, Applicant states that it believes that those potential shareholders are vitally concerned that (1) the net asset value of their interests remain stable; and (2) that the daily net income declared on their investment be steady and not exhibit the volatility which can occur when change in market prices cause changes in yield on a daily or weekly basis.

By maintaining its portfolios of high quality instruments, having short maturities, Applicant believes that it will be possible to provide the required stability to individuals and institutional investors. Applicant has determined that

maintaining an average maturity of 120 days or less in each portfolio will accomplish the aims of Applicant's investors by reducing the risk of significant volatility in the value of portfolio instruments and at the same time producing a yield commensurate with those available in the market in which each portfolio will invest.

Applicant's requests for exemption is based on its proposed investment policies and Applicant has agreed that the following conditions may be imposed in any order of the Commission granting the exemptive relief requested:

1. In supervising the operations of Applicant and delegating special responsibilities involving portfolio management to Applicant's investment adviser, Applicant's board of directors undertakes—as a particular responsibility within its overall duty of care owed to Applicant's shareholders—to establish procedures reasonably designed, taking into account current market conditions and the investment objectives of each of Applicant's portfolios to stabilize Applicant's net asset value per share, as computed for the purpose of distribution, redemption and repurchase, at $1.00 per share.

2. Included within the procedures to be adopted by the board of directors shall be the following:

(a) Review by the board of directors, as it deems appropriate and at such intervals as are reasonable in light of current market conditions, to determine the extent of deviation, if any, of the net asset value per share as determined by using available market quotations from each portfolio's $1.00 amortized cost price per share, and maintenance of records of such review.[1]

(b) In the event such deviation from Applicant's $1.00 amortized cost price per share exceeds ½ of 1 percent, a requirement that the board of directors will promptly consider what action, if any, should be initiated.

(c) Where the board of directors believes that the extent of any deviation from Applicant's $1.00 amortized cost price per share may result in material dilution or other unfair results to investors or existing shareholders, it shall take such action as it deems appropriate to eliminate or to reduce to the extent reasonably practicable such dilution or unfair results, which action may include: redeeming shares in kind; selling portfolio instruments prior to maturity to realize capital gains or losses, or to shorten Applicant's average portfolio maturity of the relevant portfolio; reducing or withholding dividends; or utilizing a net asset value per share as determined by using available market quotations.

3. Applicant will maintain a dollar-weighted average portfolio maturity appropriate to each portfolio objective of maintaining a stable net asset value per share, provided, however, that Applicant will neither (a) purchase any instrument with a remaining maturity of greater than one year except for instruments subject to repurchase agreements effective not more than 7 days from date of purchase nor (b) maintain in each portfolio a dollar-weighted average portfolio maturity which exceeds 120 days.[2]

4. Applicant will record, maintain and preserve permanently in an easily accessible place a written copy of the procedures (and any modifications thereto) described in condition 1 above, and Applicant will include in the minutes of its directors' meetings and will record, maintain and preserve for a period of not less than six years (the first two years in an easily accessible place) a written record of the board of directors' considerations and actions taken in connection with the discharge of its responsibilities, as set forth above. The documents preserved pursuant to this condition shall be subject to inspection by the Commission in accordance with section 31(b) of the Act as though such documents were records required to be maintained pursuant to rules adopted under section 31(a) of the Act.

5. Applicant will limit its portfolio investments, including repurchase agreements, to those United States dollar-denominated instruments which the board of directors determines present minimal credit risks, and which are of high quality as determined by any major rating service, or, in the case of any instrument that is not rated, of comparable quality as determined by the board of directors.

6. Applicant will include in each quarterly report, as an attachment to Form N–1Q, a statement as to whether any action pursuant to condition 2(c) was taken during the preceding fiscal quarter, and, if any action was taken, Applicant will describe the nature and circumstances of such action.

Prior to adopting the amortized cost method of valuation, Applicant represents that its board of directors will determine in good faith that in light of characteristics described above, including the conditions to which Applicant must adhere as set forth in any order of the Commission, absent unusual or extraordinary circumstances, the amortized cost method of valuing portfolio securities will reflect the fair value of such securities. Applicant submits that granting its requested exemptive order is appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Notice is further given that any interested person may, not later than February 22, 1982, at 5:30 p.m., submit to the Commission in writing a request for a hearing on the application accompanied by a statement as to the nature of his interest, the reasons for such request, and the issues, if any, of fact or law proposed to be controverted, or he may request that he be notified if the Commission shall order a hearing thereon. Any such communication should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request shall be served personally or by mail upon Applicant at the address stated above. Proof of such service (by affidavit or, in the case of an attorney-at-law, by certificate) shall be filed contemporaneously with the request. As provided by Rule 0–5 of the Rules and Regulations promulgated under the Act, an order disposing of the application herein will be issued as of course following said date unless the Commission thereafter orders a hearing upon request or upon the Commission's own motion. Persons who request a hearing, or advice as to whether a hearing is ordered, will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82–2681 Filed 2–1–82; 8:45 am]

BILLING CODE 8010–01–M

[1] To fulfill this condition, Applicant states that it intends to use actual quotations or estimates of market value reflecting current market conditions chosen by its board of directors in the exercise of its discretion to be appropriate indicators of value, which may include, among others, (i) quotations or estimates of market value reflecting current market conditions, or (ii) values obtained from yield data relating to classes of money market instruments published by reputable sources.

[2] In fulfilling this condition, if the disposition of a portfolio instrument results in a dollar-weighted average portfolio maturity in excess of 120 days, Applicant will invest its available cash in such a manner as to reduce the dollar-weighted average portfolio maturity to 120 days or less as soon as reasonably practicable.

Cincinnati Stock Exchange; Application for Unlisted Trading Privileges and of Opportunity for Hearing

January 27, 1982.

The above named national securities exchange has filed an application with the Securities and Exchange Commission pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f–1 thereunder, for unlisted trading privileges in the common stock of:

Conquest Exploration Co.
Common Stock, $.20 Par Value (File No. 7–6120)

This security is listed and registered on one or more other national securities exchanges and is reported on the consolidated transaction reporting system.

Interested persons are invited to submit on or before February 18, 1982, written data, views and arguments concerning the above-referenced application. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, Washington, D.C. 20549. Following this opportunity for hearing, the Commission will approve the application if it finds, based upon all the information available to it, that the extension of unlisted trading privileges pursuant to such application is consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82–2694 Filed 2–1–82; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. 12188; 812–5042]

Delaware Fund, Inc., et al; Filing of Application

January 26, 1982.

Notice is hereby given that Delaware Fund, Inc.; Decatur Income Fund, Inc.; Delta Trend Fund, Inc.; Delchester Bond Fund, Inc.; DMC Tax-Free Income Trust-Pennsylvania; Delaware Cash Reserve, Inc. ("Delaware Cash"); Delaware Tax-Free Money Fund, Inc. ("Delaware Tax-Free"); each registered under the Investment Company Act of 1940 ("Act") as a diversified, open-end, management investment company, and any other member fund to be formed in the Delaware Group of Funds at a later date (collectively, ("Funds"); and Delaware Management Co., Inc. ("DMC") and its wholly-owned subsidiary, Delaware Investment Advisors, Inc. ("DIA"), Seven Penn Center Plaza, Philadelphia, Pennsylvania 19103, each registered under the Investment Adviser's Act of 1940 (hereinafter, the Funds, DMC, and DIA are referred to as "Applicants") filed an application on November 27, 1981, for an order of the Commission pursuant to section 6(c) of the Act exempting Applicants from certain provisions of section 22(d) of the Act and Rule 22d–1 thereunder to the extent necessary to permit sales of the shares of certain of the Funds and of funds which may in the future become members of the Delaware Group of Funds, at net asset value without a sales charge to certain directors and affiliated employees of Applicants on terms, and in the circumstances, described below. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein, which are summarized below.

The application states that the Funds maintain continuous offerings of their shares to the public pursuant to effective registration statements under the Securities Act of 1933. DMC, which acts as adviser to each of the Funds, is also registered as a broker-dealer under the Securities Exchange Act of 1934, and acts as the principal underwriter for certain of the Funds. DIA, acts as the investment adviser to a number of pension and retirement accounts, and to various private clients. The Funds other than Delaware Cash and Delaware Tax-Free, assess a sales charge in connection with the purchase of their shares.

Applicants represent that the existing Funds have boards of directors (or boards of trustees) consisting of the same 10 persons, and the Funds have, collectively, 12 employees. DMC, has a board of directors of 6 persons, and DIA, has a board of directors of 5 persons. DMC and DIA together employed approximately 219 persons as of October 31, 1981. Such directors, trustees, employees, and employees of any new fund or future DMC subsidiary are hereinafter denoted "Affiliated Employees."

Applicants propose to permit the Affiliated Employees to purchase, on their own behalf, and on behalf of a spouse or their children under the age of 21 years, either directly or through retirement or employee benefit plans (as applicable), the shares of Funds or of any other registered investment companies which may hereafter become members of the Delaware Group at the net asset value determined in accordance with Rule 22c–1 under the Act without the imposition of a sales charge as otherwise applied pursuant to the prospectuses of certain of the Funds. Purchases on behalf of a spouse or child will be eligible for purchase at net asset value only if that purchase is directed by the Affiliated Employee.

Applicants assert that no individual or in-person group sales solicitations or presentations concerning the Funds will be made. According to the application, all Affiliated Employees will receive, at least annually, notice from their employers concerning the availability of shares of the Funds at the net asset value of the shares without a sales charge. This notice, which will be furnished at the expense of their employers, will describe the Funds and their investment objectives, indicate that investments would be at net asset value without a sales charge and detail the various ways in which investments could be made. This notice would also indicate that additional information concerning the Funds could be obtained from DMC and would inform employees of the availability of prospectuses of the Funds from DMC. Applicants state that participants will agree not to resell Fund shares acquired thereunder except by repurchase by or for the account of the fund issuing such shares.

Section 22(d) of the Act provides, in pertinent part, that no registered investment company shall sell any redeemable security issued by it to any person except at a current public offering price described in the prospectus, and if such class of security is being currently offered to the public by or through an underwriter, no principal underwriter of such security and no dealer shall sell any such security to any person except at a current public offering price described in the prospectus. Rule 22d–1 exempts certain transactions in, or elimination of, the sales load charged upon the sale of shares under certain circumstances. Applicants submit that the sale of Fund shares to Affiliated Employees at net asset value under the Plan may conflict with the provisions of section 22(d) of the Act and Rule 22d–1 thereunder.

Applicants state that while Rule 22d–1(i) provides an exemption from section 22(d) of the Act and permits sales without any sales charge to certain employees of affiliated persons of the Funds, this exemption is not available to Affiliated Employees who are employed in positions that do not directly provide investment advice to, or distribute shares of, the Funds. Applicants also point out that an argument maybe made that purchases of Fund shares at net

asset value by Affiliated Employees under an employee benefit plan are permitted by Rule 22d–1(f), which permits elimination of sales charges upon the sale pursuant to a uniform offer described in the prospectus and made to certain employee benefit plans provided such plans satisfy uniform criteria relating to the realization of economies of scale in sales effort and sales-related expense. Applicants submit that it is not clear, however, that net asset value sales to the Affiliated Employees covered by a plan would meet the "uniform offer" requirement of Rule 22d–1(f).

Section 6(c) of the Act provides, in pertinent part, that the Commission, by order upon application, may conditionally or unconditionally exempt any person, security or transaction, or any class or classes of persons, securities or transactions, from any provision of the Act or of any rule under the Act, if and to the extent such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Applicants submit that investment by Affiliated Employees in shares of the Funds at net asset value is supported by policy considerations, that such sales should result in demonstrable economies in sales efforts and sales related expenses as compared with other sales and would not be unjustly discriminatory, and that the grant of the exemption requested by the Applicants is appropriate in the public interest and consistent with the protection of investors and the purposes of the Act. Applicants further sumbit that the affiliation of the Funds with DMC and DMC subsidiaries is the basis for a unique relationship of these DMC companies to the Funds, which can be expected to result in economies of sales effort and sales charges on Fund shares purchased by Affiliated Employees without discrimination against other employee benefit plans or other purchasers of the Fund's shares.

Applicants further submit that the anticipated economies of scale will result from the fact that there will not be any effort expended by the Funds or DMC personally to solicit investments, that money for purchases of Fund shares by Affiliated Employees through any retirement or other employee benefit plan or payroll deduction program will be aggregated by DMC for payment to the respective Funds in which Affiliated Employees or their plans are investing, and all employees will receive, at least annually and at the expense of the employer, a notice of this program. Applicants believe that the proposed ability to allow such investments in Fund shares will serve valid business purposes for the Funds because it will promote among Affiliated Employees incentive, goodwill, and loyalty which will benefit the Funds as well as DMC and its subsidiaries.

Notice is further given that any interested person may, not later than February 22, 1982, at 5:30 p.m., submit to the Commission in writing a request for a hearing on the application accompanied by a statement as to the nature of his interest, the reasons for such request, and the issues, if any, of fact or law proposed to be controverted, or he may request that he be notified if the Commission shall order a hearing thereon. Any such communication should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request shall be served personally or by mail upon Applicant at the address stated above. Proof of such service (by affidavit or, in the case of an attorney-at-law, by certificate) shall be filed contemporaneously with the request. As provided by Rule 0–5 of the Rules and Regulations promulgated under the Act, an order disposing of the application herein will be issued as of course following said date unless the Commission thereafter orders a hearing upon request or upon the Commission's own motion. Persons who request a hearing, or advice as to whether a hearing is ordered, will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82–2682 Filed 2–1–82; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. 12186; 812–5018]

Massachusetts Financial International Trust, et al.; Filing of Application

January 26, 1982.

Notice is hereby given that Massachusetts Financial International Trust ("MFI"), Massachusetts Financial Bond Fund, Inc., Massachusetts Income Development Fund, Inc., Massachusetts Investors Trust, Massachusetts Investors Growth Stock Fund, Inc., Massachusetts Financial High Income Trust, Massachusetts Capital Development Fund, Inc., Massachusetts Financial Emerging Growth Trust, (collectively, the "Member Funds"), each registered under the Investment Company Act of 1940 ("Act"), Massachusetts Financial Services Company ("MFS"), 200 Berkeley Street,, Boston, Massachusetts 02116, the principal underwriter for each of the Member Funds and any other load funds ("Future Funds") which may ultimately be created and managed by MFS and registered under the Act (the Member Funds, MFS and the Future Funds are collectively referred to as the "Applicants") filed an application on November 20, 1981, for an order of the Commission pursuant to Section 6(c) of the Act exempting Applicants from the provisions of Section 22(d) of the Act to the extent necessary to permit participants in the State of Washington Deferred Compensation Plan ("Plan") to purchase shares of the Member Funds and the Future Funds at a price other than the current public offering price described in the applicable prospectus of each Member Fund or any Future Fund. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein which are summarized below.

Applicant states that MFI is an open-end, non-diversified, management investment company registered under the Act. MFI is a series company with one bond portfolio series outstanding. Applicants state that each of the other Member Funds is an open-end, diversified, management investment company registered under the Act. MFS serves as the principal underwriter for each of the Member Funds. Applicants state that the public offering price of the shares of the Member Funds is the net asset value per share next computed after the sale plus a sales charge of 7.25% (as a percentage of the offering price) when the amount of the purchase is less than $10,000. Applicants state that the sales charge reduces by scheduled amounts with purchases over $10,000 to a sales charge of 0.1% at amounts of purchase of $5,000,000 or more.

Applicants represent that the exemption is requested to permit participants in the Plan to purchase shares of the Member Funds and any Future Funds at net asset value with no additional sales charge. Applicants state that this purchase price is less than the current offering price described in the prospectus for each Member Fund, and less than the expected offering price to be described in any prospectus of a Future Fund.

National Plan Coordinators of Washington, Inc. ("NPC") is the administrator and coordinator for the Plan and its affiliate, NPC Securities, Incorporated, will effect the actual sales of shares in the Member Funds and Future Funds to participants in the Plan.

Applicants state that the Plan was established by statute to provide a system of deferred compensation for state employees. Applicants state that a deferred compensation committee ("Committee") was established to effectuate the Plan. The Committee engaged NPC to administer and coordinate the Plan, established various criteria to be met by any funding media to be used by the Plan, and authorized NPC to establish a bidding procedure for funding media interested in participation. One of the criteria established by the Committee was that no fees or expenses were to be charged to, or collected from the State of Washington in connection with the sale of securities of any funding medium. MFS submitted a bid to NPC which, on September 22, 1981, accepted the bid subject to MFS and the Member Funds obtaining an exemptive order from the Commission authorizing the Member Funds to sell shares to the Plan at net asset value.

Applicants represent that none of the Member Funds has any minimum investment requirement. Applicants further represent that none of the Member Funds have any power to redeem any shareholder's shares without his consent, nor does any Member Fund currently contemplate seeking such power.

Section 22(d) of the Act provides, in pertinent part, that no registered investment company shall sell any redeemable security issued by it except to or through a principal underwriter for distribution or at a current public offering price described in the prospectus, and, if such class of security is being currently offered to the public by or through an underwriter, no principal underwriter of such security and no dealer shall sell any such security to any person, except a dealer, a principal underwriter, or the issuer, except at a current public offering price described in the prospectus. Applicants request an order of exemption from the provisions of section 22(d) of the Act to permit participants in the Plan to purchase shares of the Member Funds and Future Funds at net asset value.

Applicants state that the purposes of section 22(d) are to prevent sales of investment company securities by unauthorized dealers at prices less than those offered by authorized distributors, which would hinder distribution of the securities, to prevent dilution of existing shareholder equity, and to prevent discrimination in favor of insiders.

In support of their request, Applicants argue that the largest portion of a sales charge on shares of the trust is attributable to soliciting the investor, ascertaining his financial requirements and providing backup sales services. Applicants state that in this case they were approached by the administrator of the Plan, which is expected to be a multi-million dollar, professionally managed deferred compensation plan for thousands of employees. Thus, the Applicants state that they did not have to engage in extensive solicitation efforts, nor did they have to engage in detailed investigation of financial suitability or financial requirements. Applicants state that much of the effort ordinarily made in connection with such sales of securities has been assumed by NPC in its role as coordinator for the enrollment of participants in the Plan. Applicants also state that they will not be supplying normal backup sales services, the cost of which is customarily covered by the proceeds of sales charges. Applicants argue that it is not unreasonable under such circumstances for the participants in the Plan, rather than MFS, to receive the complete benefit of the reduction in costs.

Section 6(c) of the Act provides, in pertinent part, that the Commission may, upon application, conditionally or unconditionally exempt any person, security, or transaction, or any class or classes of persons, securities or transactions, from any provision of the Act or of any rule or regulation under the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Notice is further given that any interested person may, not later than February 22, 1982, at 5:30 p.m. submit to the Commission in writing a request for a hearing on the application accompanied by a statement as to the nature of his interest, the reasons for such request, and the issues, if any, of fact or law proposed to be controverted, or he may request that he be notified if the Commission shall order a hearing thereon. Any such communication should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request shall be served personally or by mail upon Applicants at the address stated above. Proof of such service (by affidavit or, in the case of an attorney-at-law, by certificate) shall be filed contemporaneously with the request. As provided by Rule 0–5 of the Rules and Regulations promulgated under the Act, an order disposing of the application herein will be issued as of course following said date unless the Commission thereafter orders a hearing upon request or upon the Commission's own motion, persons who request a hearing, or advice as to whether a hearing is ordered, will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82–2683 Filed 2–1–82; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. 12187; 811–1457]

Pegasus Income & Capital Fund, Inc.; Filing of Application

January 26, 1982.

Notice is hereby given that Pegasus Income & Capital Fund, Inc. ("Applicant"), 1800 Century Park East, Suite 204B, Los Angles, CA 90067, a Delaware corporation, registered as an open-end, deversified management investment company under the Investment Company Act of 1940 ("Act"), filed an application on November 30, 1981, for an order pursuant to Section 8(f) of the Act declaring that Applicant has ceased to be an investment company. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein, which are summarized below.

Applicant represents that at a special meeting of Applicant's shareholders held on January 6, 1981, Applicant's shareholders authorized (1) the sale by Applicant of substantially all of its assets to St. Paul Income Fund, Inc. ("St. Paul") in exchange for shares of voting stock of St. Paul, and (2) the creation of a litigation trust (the "Litigation Trust") to pursue certain claims of Applicant (the "Litigation") and the distribution of interests in the Litigation Trust to the shareholders of Applicant in liquidation of Applicant. On January 7, 1981, Applicant transferred substantially all of its assets to St. Paul in exchange for shares of voting stock of St. Paul.

Applicant further represents that the shares of St. Paul received by Applicant in connection with the sale of its assets

have been distributed pro rata to Applicant's shareholders, and that the Litigation heretofore conducted by Applicant and assets to continue such litigation have been distributed to a Litigation Trust, which is subject to supervision of the United States District Court for the Central District of California (No. CV 74–2527–ALS).

Applicant represents that, on the basis of a Certificate of Dissolution filed with the Secretary of the State of Delaware on January 8, 1981, it is a dissolved corporation under Delaware law. Applicant further represents that it presently has no shareholders and is not now engaged and does not propose to engage in any business activities other than those necessary for the winding up of its affairs. In addition, Applicant states that as of October 31, 1981, its only assets consisted of $29,682.43 in cash, which have been retained to meet certain liabilities of Applicant consisting primarily of attorneys fees.

Section 8(f) of the Act provides, in part, that whenever the Commission, upon application, finds that a registered investment company has ceased to be an investment company, it shall so declare by order and upon the taking effect of such order, the registration of such company shall cease to be in effect.

Notice is further given that any interested person may, not later than February 22, 1982, at 5:30 p.m., submit to the Commission in writing a request for a hearing on the matter accompanied by a statement as to the nature of his interest, the reason for such request, and the issues, if any, of fact or law proposed to be controverted, or he may request that he be notified if the Commission shall order a hearing thereon. Any such communication should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request shall be served personally or by mail upon Applicant at the address stated above. Proof of such service (by affidavit or, in the case of an attorney-at-law, by certificate) shall be filed contemporaneously with the request. As provided by Rule 0–5 of the Rules and Regulations promulgated under the Act, an order disposing of the application will be issued as of course following said date unless the Commission thereafter orders a hearing upon request or upon the Commission's own motion. Persons who request a hearing, or advice as to whether a hearing is ordered, will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82–2684 Filed 2–1–82; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. 22368; 70–6409]

Southern Ohio Coal Co. and Ohio Power Co.; Proposed Financing for Coal Mining Subsidiary

January 26, 1982.

Ohio Power Company ("Ohio Power"), 301 Cleveland Avenue, S.W., Canton, Ohio 44702, an electric utility subsidiary of American Electric Power Company, Inc. ("AEP"), a registered holding company, and Southern Ohio Coal Company ("SOCCO"), P.O. Box K, Moundsville, West Virginia 26401, a coal mining subsidiary of Ohio Power, have filed with this Commission a post-effective amendment to the application-declaration previously filed in this proceeding pursuant to sections 6, 7, 9, 10 and 12 of the Public Utility Holding Company Act of 1935 ("Act") and Rule 50(a)(3) thereunder.

By orders dated April 25, 1980 (HCAR No. 21537) and July 13, 1981 (HCAR No. 22129), Ohio Power and SOCCO were authorized to finance the installation of coal preparation facilities at SOCCO's Meigs Mine No. 1 and Raccoon Mine No. 3 through capital contributions and long-term loans by Ohio Power to SOCCO in aggregate amounts of $40,600,000 and $14,000,000, respectively. Included in the former amount was a sum of $5,542,000 for partial construction costs of a coal preparation plant at Raccoon Mine No. 3.

After reviewing the necessary fine refuse dewatering and waste disposal systems, a determination of the total construction cost of the preparation plant at Raccoon Mine No. 3 has been made. It has been determined that the cost for such systems, plus the cost of certain other design additions which are intended to improve further the quality of coal and to increase the total plant capacity, will raise the total cost of the preparation plant and ancillary facilities at Raccoon Mine No. 3 to $13,684,000, an increase of $8,142,000.

In concert with the additions and modifications proposed to be made at the preparation plant, it has been determined that it would be desirable to construct a rail loadout system at Raccoon Mine No. 3 including a coal handling facility at the mine and an overland conveyor to connect the coal handling facility with a coal-loading tipple to be constructed on the Chesapeake and Ohio Railroad line near Minerton, Ohio. The construction of such a rail loadout system will enable SOCCO to ship coal from Raccoon Mine No. 3 by rail (as opposed to its present movement by truck) to the Gavin Plant.

It is projected that the rail loadout system will be able to load rail cars at a rate of 2,000 tons of coal per hour. Plans call for loading and shipping one fifty-seven (57) car train to the Gavin Plant each workday. It is anticipated that the cost per ton of rail transportation in the start-up year will be almost the same as the cost per ton of truck transportation. However, as shipments from Raccoon Mine No. 3 increase, the cost differential is expected to increase in favor of rail transportation, and it has been estimated that, by 1990, the savings realized by rail delivery will be $3.00 per ton based on constant 1980 dollars.

In preparation for the proposed rail delivery of coal to the Gavin Plant, it will be necessary for the railroad to rehabilitate approximately 33 miles of railroad track from the Minerton siding to the Gavin Plant in Cheshire, Ohio. This expenditure currently anticipated to be $1,921,440 will be recorded in Ohio Power's utility plant account and will not be reflected in the cost of coal delivered to the Gavin Plant. The cost of the rail loadout system, not including the cost of rehabilitating the railroad track from Minerton to Cheshire, is estimated to be $5,877,000. This cost and the additional cost of $8,142,000 for improvements to the preparation plant will necessitate additional investments by Ohio Power in SOCCO in an aggregate amount of $14,019,000.

It is proposed that the additional investments will be financed through a combination of long-term loans and cash capital contributions by Ohio Power to SOCCO of $14,019,000. It is expected that Ohio Power will make its investment in SOCCO in one or more increments prior to June 30, 1982. The investments made by Ohio Power in SOCCO will be made in the same proportion as the debt-equity ratio of Ohio Power at the end of the year prior to the investment. As of December 31, 1980, the debt-equity ratios of Ohio Power were 55.9% long-term debt, 11.8% preferred stock, and 32.3% common equity.

In exchange for the long-term loans of Ohio Power, SOCCO will issue to Ohio Power promissory notes for the principal amount of such loans. Each of the notes will mature and become payable on December 31, 2011. It is proposed that the interest rate per annum on each note issued by SOCCO shall, in each case, be equal to the effective interest cost of

Ohio Power's most recently issued series of First Mortgage Bonds. The most recently issued series of Ohio Power's First Mortgage Bonds, the 15¼% Series due March 1, 1988 issued in March 1981, has an effective interest cost to Ohio Power of 15.4% per annum.

The capital contribution to be made by Ohio Power to SOCCO would equal the equity component of the debt-equity ratio of Ohio Power as of December 31, 1980. It is proposed that the return on equity applicable to this capital contribution shall be based on the weighted cost of money of Ohio Power's last issue of preferred stock (Ohio Power's last issue of preferred stock was the $2.27 series with a cost to Ohio Power equal to 9.46%) and the rate of return on common equity determined and allowed by the Federal Energy Reguatory Commission (FERC) in the most recent wholesale rate proceeding involving Ohio Power. Since there is presently no such applicable FERC order, it is proposed that the cost of common equity capital of SOCCO to be included in a return on equity be set at 13%, which is not more than the level allowed in the most recent order of the Public Utilities Commission of Ohio in a retail rate proceeding involving Ohio Power. At such time as FERC should take action specifying a rate of return in a wholesale rate proceeding involving Ohio Power, the rate established by FERC shall become applicable on a prospective basis to the then total common equity investment of Ohio Power in SOCCO. The allowed rate of return on common equity shall not be applied to any of SOCCO's retained earnings. No return allowance will be applied to such retained earnings. Based on Ohio Power's debt equity ratio, and on the interest rate on the long-term promissory notes and the return on equity state above, the overall cost of capital to SOCCO would be 13.93%.

The amended application-declaration and any further amendments thereto are available for public inspection through the Commission's Office of Public Reference. Interested persons wishing to comment or request a hearing should submit their views in writing by February 18, 1982 to the Secretary, Securities and Exchange Commission, Washington, D.C. 20549, and serve a copy on the applicant-declarants at the addresses specified above. Proof of service (by affidavit or, in the case of an attorney at law, by certificate) should be file with the request. Any request for a hearing shall indentify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in this matter. After said date the amended application-declaration, as filed or as it may be amended, may be granted and permitted to become effective.

For the Commission, by the Division of Corporate Regulation, pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82-2685 Filed 2-1-82; 8:45 am]

BILLING CODE 8010-01-M

[Rel. No. 12189; 812-5017]

State Bond Cash Management Fund, Inc.; Filing of Application

January 26, 1982.

Notice is hereby given that State Bond Cash Management Fund, Inc. ("Applicant"), 100–106 North Minnesota Street, New Ulm, Minnesota 56073, a no-load, open-end, diversified management investment company registered under the Investment Company Act of 1940 ("Act"), filed an application on November 18, 1981, requesting an order of the Commission, pursuant to section 6(c) of the Act, exempting Applicant from the provisions of section 2(a)(41) of the act and Rules 2a–4 and 22c–1 thereunder to the extent necessary to permit Applicant to value its portfolio securities using the amortized cost valuation method. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein, which are summarized below.

Applicant states it is a "money market fund," designed to be an investment vehicle for investors who desire to place assets in money market investments where the primary considerations are high current income, preservation of capital, and liquidity. Applicant maintains that it seeks to provide a convenient means of investing short-term funds where the direct purchase of money market instruments may be undesirable or impractical. Applicant represents that its portfolio may be invested exclusively in a variety of high-quality short-term money market instruments, consisting of obligations issued or guaranteed by the U.S. Government or its agencies or instrumentalities (whether or not subject to repurchase agreements); obligations, or instruments secured by such obligations, including certificates of deposits, bankers' acceptances, fixed time deposits, and letters of credit, issued by (1) U.S. domestic banks (including foreign branches) and savings institutions having total assets of over one billion dollars and subject to regulatory supervision by the U.S. Government or state governments, (2) the fifty largest foreign banks in terms of assets, having branches or agencies in the United States (including their U.S. branches or agencies), and (3) domestic banks and savings institutions, which obligations or instruments are fully insured by the Federal Deposit Insurance Corporation or the Federal Savings and Loan Insurance Corporation; high-grade commercial paper rated at the time of investment within the two highest grades by Standard & Poor's Corporation or by Moody's Investors Services, Inc., or such other rating organizations as may be approved by Applicant's Board of Directors, or if not rated, issued and guaranteed as to payment of principal and interest by companies which have an existing debt security rated at the time of investment within the two highest grades by Standard & Poor's or Moody's or such other rating organization as may be approved by Applicant's Board of Directors; and corporate debt securities (other than commercial paper) rated within the two highest grades by Standard & Poor's or Moody's or such other rating organizations as may be approved by Applicant's Board of Directors at the time of investment. Applicant states that all of its investments will consist of obligations maturing within one year from the date of acquisition, and the average maturity of all its investments will be 120 days or less. Applicant maintains that the foregoing policies are not fundamental, and may be changed by the Board of Directors without shareholder approval. Applicant represents, however, that shareholder approval would be required to change a limitation that it invest no more than 25% of the market value of its total assets in securities of issuers of any one industry, except that Applicant reserves the right to concentrate investments in money market instruments issued by the U.S. Government or its agencies or instrumentalities or by banks or bank holding companies.

As here pertinent, section 2(a)(41) of the Act defines value to mean: (1) with respect to securities for which market quotations are readily available, the market value of such securities, and (2) with respect to other securities and assets, fair value as determined in good faith by the board of directors. Rule 22c–1 adopted under the Act provides, in part, that no registered investment company or principal underwriter therefor issuing any redeemable security shall sell, redeem or repurchase any

such security except at a price based on the current net asset value of such security which is next computed after receipt of a tender of such security for redemption or of an order to purchase or to sell such security. Rule 2a–4 adopted under the Act provides, as here relevant, that the "current net asset value" of a redeemable security issued by a registered investment company used in computing its price for the purposes of distribution, redemption and repurchase shall be an amount which reflects calculations made substantially in accordance with the provisions of that rule, with estimates used where necessary or appropriate. Rule 2a–4 states further that portfolio securities with respect to which market quotations are readily available shall be valued at current market value, and other securities and assets shall be valued at fair value as determined in good faith by an investment company's board of directors. Prior to the filing of this application, the Commission expressed its view that, it was, generally, inconsistent with Rule 2a–4 for money market funds to value their portfolio securities on an amortized cost basis and that such valuation should be made with reference to market factors.

Section 6(c) of the Act provides, in pertinent part, that the Commission, by order upon application, may conditionally or unconditionally exempt any person, security or transaction, or any class or classes of persons, securities, or transactions from any provision of the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

In support of the relief requested, Applicant states that the experience of the money market fund industry tends to show that two qualities are helpful to attract investment: (1) Stability of principal and (2) steady flow of investment income. Applicant believes that by utilizing high quality money market instruments of short maturities combined with a stable net asset value, preferably $1.00 per share, it would be possible to provide these features to a variety of investors. Applicant expresses its view that investors can be expected to be concerned that the daily income declared by Applicant reflects income as earned and that the sales and redemption prices not change. For this reason, Applicant contends that it would have a significant competitive disadvantage over other money market funds, if its net asset value fluctuations were reflected in the price or included in dividends. Applicant states that it has an investment policy that investments are made only in instruments having a remaining maturity of one year or less. Applicant submits that its management has determined that an average portfolio maturity of 120 days or less combined with a stable price may accomplish both of the above aims of investors, that is, it somewhat obviates the possiblity of a change in the price per share, while at the same time providing a yield on portfolio instruments more or less related to yields available in the general debt market, otherwise unavailable with a portfolio having an average maturity of a shorter duration.

Applicant states further that given the nature of its policies and operations, there will normally be a relatively negligible discrepancy between market value and amortized cost value of such securities. Applicant expresses its belief that on the basis of the foregoing, it believes that the valuation of its portfolio securities on the amortized cost basis will benefit its shareholders by enabling Applicant to maintain more effectively a stable price per share while providing shareholders with the opportunity to receive a flow of investment income less subject to fluctuation than under procedures whereby its dividend would be adjusted by all realized and unrealized gains and losses on its portfolio securities. Applicant submits that its Board of Directors has determined in good faith that in light of the Characteristics of Applicant as generally described in the application, absent unusual or extraordinary circumstances, the amortized cost method of valuing portfolio securities is appropriate and preferable for Applicant and reflects fair value of such securities.

Applicant states that its request for the exemption specified in its application is made based on the existing management policies of Applicant set forth in the application. Applicant states further that as a condition to the granting of the exemption requested therein, Applicant agrees that the following conditions may be made conditions of the order:

1. In supervising Applicant's operations and in delegating special responsibilities involving portfolio management to Applicant's investment adviser, Applicant's Board of Directors undertakes—as a particular responsibility within the overall duty of care owed to shareholders—to establish procedures reasonably designed, taking into account current market conditions and Applicant's investment objectives, to stabilize Applicant's net asset value per share, as computed for the purpose of distribution, redemption and repurchase, at $1.00 per share.

2. Included within the procedures to be adopted by Applicant's Board of Directors shall be the following:

(a) Review by the Board of Directors, as it deems appropriate and at such intervals as are reasonable in light of current market conditions, to determine the extent of deviation, if any, of the net asset value per share as determined by using available market quotations from Applicant's $1.00 amortized cost price per share, and maintenance of records of such review. To fulfill this condition, Applicant intends to use actual quotations or estimates of market value reflecting current market conditions chosen by the Board in the exercise of its discretion to be appropriate indicators of value which may include, *inter alia*, (i) quotations or estimates of market value for individual portfolio instruments or (ii) values obtained from yield data relating to classes of money market instruments published by reputable sources;

(b) In the event such deviation from Applicant's $1.00 amortized cost price per share exceeds one-half of one percent, a requirement that the Board will promptly consider what action, if any, should be initiated; and

(c) Where the Board of Directors believes the extent of any deviation from Applicant's $1.00 amortized cost price per share may result in material dilution or other unfair results to investors or existing shareholders, it shall take such action as it deems appropriate to eliminate or to reduce to the extent reasonably practicable such dilution or unfair results which may include: redeeming shares in kind; selling portfolio instruments prior to maturity to realize capital gains or losses or to shorten Applicant's average portfolio maturity; withholding dividends; or utilizing a new asset value per share as determined by using available market quotations.

3. Applicant will maintain a dollar-weighted average portfolio maturity appropriate to its objective or maintaining a stable net asset value per share; provided, however, that Applicant will not (a) purchase any instrument with a remaining maturity of greater than one year, or (b) maintain a dollar-weighted average portfolio maturity that exceeds 120 days. In fulfilling this condition, if the disposition of a portfolio instrument results in a dollar-weighted average portfolio maturity in excess of 120 days, Applicant will invest its available cash

in such a manner as to reduce its dollar-weighted average portfolio maturity to 120 days or less as soon as reasonably practicable.

4. Applicant will record, maintain and preserve permanently in an easily accessible place a written copy of the procedures (and any modifications thereto) described in condition 1 above; and Applicant will record, maintain and preserve for a period of not less than six years (the first two years in an easily accessible place) a written record of its Board of Directors' considerations and actions taken in connection with the discharge of its responsibilities, as set forth above, to be included in the minutes of Directors' meetings. The documents preserved pursuant to this condition shall be subject to inspection by the Commission in accordance with section 31(b) of the Act, as though such documents were records required to be maintained pursuant to rules adopted under section 31(a) of the Act.

5. Applicant will limit its portfolio investments, including repurchase agreements, to those United States dollar denominated instruments that its Board of Directors determines present minimal credit risks, and that are of high quality as determined by Standard & Poor's of Moody's at the time of investment or, in the case of any instrument that is not rated, of comparable quality as determined by its Board of Directors.

6. Applicant will include in each quarterly report, as an attachment to Form N–1Q, a statement as to whether any action pursuant to condition 2(c) above was taken during the preceding fiscal quarter, and, if any such action was taken, Applicant will describe the nature and circumstances of such action.

Notice is further given that any interested persons may, no later than February 18, 1982, at 5:30 p.m., submit to the Commission in writing a request for a hearing on the application accompanied by a statement as to the nature of his interest, the reasons for such request, and the issues, if any, of fact or law proposed to be controverted, or he may request that he be notified if the Commission shall order a hearing thereon. Any such communication should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request shall be served personally or by mail upon Applicant at the address stated above. Proof of such service (by affidavit, or in the case of an attorney-at-law by certificate) shall be filed contemporaneously with the request. As provided by Rule 0–5 of the Rules and Regulations promulgated under the Act, an order disposing of the application herein will be issued as of course following said date unless the Commission thereafter orders a hearing upon request or upon the Commission's own motion. Persons who request a hearing, or advice as to whether a hearing is ordered, will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82–2686 Filed 2–1–82; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. 18445; SR–Amex–82–1]

American Stock Exchange, Inc.; Filing and Order Granting Accelerated Approval of Proposed Rule Change

January 27, 1982.

The American Stock Exchange, Inc. ("Amex"), 86 Trinity Place, New York, New York 10006, submitted on January 26, 1982, copies of a proposed rule change pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act") and Rule 19b–4 thereunder, to obtain authorization to list and trade standardized put and call options on 5 to 10 year U.S. Treasury notes.

Interested persons are invited to submit written data, views and arguments concerning the proposed rule change on or before February 23, 1982. Persons desiring to make written comments should file six copies thereof with the Secretary of the Commission, Securities and Exchange Commission, 500 North Capitol Street, Washington, D.C. 20549. Reference should be made to File No. SR–Amex–82–1.

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change which are filed with the Commission and all written communications relating to the proposed rule change between the Commission and any person, other than those which may be withheld from the public in accordance with the provisions of 5 U.S.C. 552 will be available for inspection and copying at the Commission's Public Reference Room, 1100 L Street, N.W., Washington, D.C. Copies of the filing and of any subsequent amendments also will be available at the principal office of the above-mentioned self-regulatory organization.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to national securities exchanges and in particular, the requirements of section 6 and the rules and regulations thereunder.

The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of notice of filing thereof, in that the Amex rules governing the trading of the proposed options contract previously have been approved by the Commission after notice and a full opportunity for public comment.[1]

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the proposed rule change referenced above be, and hereby is, approved.

For the Commission, by the Division of Market Regulation pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82–2687 Filed 2–1–82; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–18444; File No. SR–CBOE–82–01]

Self-Regulatory Organizations; Proposed Rule Change by Chicago Board Options Exchange, Inc.

In the matter of rule change relating to priority of bids and offers; comments requested on or after February 23, 1982.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on January 22, 1982, the Chicago Board Options Exchange, Incorporated filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Item 1. Text of Proposed Rules Change

Additions are italicized; deletions are bracketed.

Priority of Bids and Offers

Rule 21.14. No Change.

* * * Interpretations and Policies:

01 A Market-Maker's bid and offer for a Treasury security option covering $100,000 principal amount of underlying

[1] Securities Exchange Act Release No. 18371 (December 23, 1981), 46 FR 63423 (December 31, 1981)

security automatically shall include a bid and offer for a "mini-series" Treasury security option covering $20,000 principal amount of the same underlying security that is no worse than 1/32 less on the bid and 1/32 more on the offer. Only regular series, and not "mini-series," quotations shall be disseminated.

Rule 21.14 replaces Rule 6.45 and 6.46; *Interpretation and Policy .01 to Rule 21.14 supplements Rule 6.44.*

Obligations of Market-Makers (Treasury bonds and notes)

Rule 21.19. No change.

* * * Interpretations and Policies:

.01 No Change.

.02 No Change.

.03 Rule 21.19 and its interpretations and policies shall be deemed complied with if a Market-Maker's bid and offer for a "mini-series" Treasury security option covering $20,000 principal amount of underlying security complies with interpretation and policy .01 of Rule 21.14, that is, is no worse than 1/32 less on the bid and 1/32 more on the offer, and if the bid and offer for the Treasury security option covering $100,000 principal amount of the same underlying security complies with Rule 21.19 and interpretations and policies .01 and .02.

Rule 21.19 and Interpretations and Policies .01 [and], .02 *and .03* supplement paragraph (b) of Rule 8.7.

II. A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of only disseminating regular, and not "mini-series," security option quotations is to simplify quotation procedures in order to save on costs and on quotation-reporting screen space. At the same time, by automatically including a 1/32 differential requirement for related "mini-series" Treasury security option quotations, the public is protected because there always will be a market available in the "mini-series" at that differential or better. The Exchange's surveillance systems are not affected by this proposed rule change.

The proposed change was discussed informally with a number of member firms. The firms were all in favor of the change because it would avoid confusion and would keep the quotation in the regular and "mini-series" markets in line.

The statutory basis for the proposed amendment is section 6(b)(5) of the Securities Exchange Act of 1934, in that it will help to implement the Exchange's already-approved Treasury security options market, while including protections for investors and the public interest.

(B) *Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe that the proposed rule change would impose a burden on competition.

(C) *Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others*

Formal comments on the proposed rule change were neither solicited not received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

On or before March 9, 1982 or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 500 North Capitol Street, Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section, 1100 L Street, N.W., Washington, D.C. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted on or before February 23, 1982.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

January 27, 1982.

[FR Doc. 82-2688 Filed 2-1-82; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-18443; File No. SR-MSE-81-7]

Self-Regulatory Organizations; Proposed Rule Change by Midwest Stock Exchange, Inc.

In the matter of rule change relating to the duties of the Chairman, Vice Chairman and President; comments requested on or before February 23, 1982.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on June 19, 1981 [1] the Midwest Stock Exchange, Incorporated, filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II, and III below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change deals with the duties and responsibilities of the Chairman, Vice Chairman and President of the exchange. First, the Chairman and President would lose their status as ex-officio members, with right to vote, on the exchange's Audit and Compensation Committees. Second, the authority to vote the securities of other corporations held by the MSE would be transferred from the President to the Chairman. Finally, the Vice Chairman alone, rather than together with the Chairman, would be responsible for the appointment of exchange committees.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received

[1] The MSE submitted an amendment to the filing on January 15, 1982, notifying the Commission that its membership approved the proposed changes at its annual meeting of members held on January 11, 1982.

on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C), below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The proposed amendments are designed in part, to bring the Constitution and the Rules of the Exchange in line with what was intended when the Audit and Compensation Committees were created. Although the Constitution and the Rules have not prohibited the Chairman and President from voting as members of these committees, the Chairman and President have recognized what the intent was and have not voted in committee sessions. The amendments also are designed to make the provisions of the MSE constitution and rules concerning the role of the Vice Chairman consistent.

The amendments to the Constitution and Rules of the Exchange are consistent with section 6(b)(1) of the Act since they relate to the organization of the Exchange and the capacity of the Exchange to be able to carry out the purposes of the Securities Exchange Act of 1934 as amended.

(b) Self-Regulatory Organization's Statement on Burden on Competition

The Midwest Stock Exchange, Incorporated does not believe that any burdens will be placed on competition as a result of the proposed rule change.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

Comments have neither been solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3) of the Securities Exchange Act of 1934 and subparagraph (e) of Securities Exchange Act Rule 19b–4. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Securities Exchange Act of 1934.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 500 North Capitol Street, Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 1100 L Street, NW., Washington, D.C. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted on or before February 23, 1982.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

Dated: January 25, 1982.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82–2689 Filed 2–1–82; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–18439; File No. SR–PCC–81–4]

Self-Regulatory Organization; Proposed Rule Change by Pacific Clearing Corp.

In the matter of rule change relating to revision of fees for clearing services; comments requested on or before February 23, 1982.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on January 19, 1982, Pacific Clearing Corporation filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Pacific Clearing Corporation is instituting revisions in fees for clearing services applicable to its Participants.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for the Proposed Rule Change

The purpose of the proposed rule change is to offset, in part, the increased costs of supplying services provided by Pacific Clearing Corporation. These costs include labor and systems associated with providing clearing services. No significant fee increases have been effected for over three years, with some fees remaining unchanged since 1973. The basis under the act for the proposed rule change is section 17A(b)(3)(D) providing for the equitable allocation of reasonable dues, fees and other charges among clearing agency participants.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change imposes no burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Comments on the proposed rule change were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3) of the Securities Exchange Act of 1934 and subparagraph (e) of the Securities Exchange Act Rule 19b–4. At any time within 60 days of the filing of such proposed rule change, the Commission

may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Securities Exchange Act of 1934.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 500 North Capitol Street, Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 1100 L Street, NW., Washington, D.C. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned, self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted on or before February 23, 1982.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

Dated: January 22, 1982.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82-2690 Filed 2-1-82; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-18438; File No. SR-PSD-81-1]

Self-Regulatory Organization; Proposed Rule Change by Pacific Securities Depository Trust Co.

In the matter of rule change relating to revision of fees for depository services; comments requested on or before February 23, 1982.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78d(b)(1), notice is hereby given that on January 19, 1982, Pacific Securities Depository Trust Company filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Pacific Securities Depository Trust Company is instituting revisions in fees for depository services applicable to its Participants.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections (A), (B), and (c) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for the Proposed Rule Change

The purpose of the proposed rule change is to offset, in part, the increased costs of supplying services provided by Pacific Securities Depository Trust Company. These costs include labor and systems associated with providing depository services. No significant fee increases have been effected for over three years. The basis under the Act for the proposed rule change is section 17A(b)(3)(D) providing for the equitable allocation of reasonable dues, fees and other charges among clearing agency participants.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change imposes no burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

Comments on the proposed rule change were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3) of the Securities Exchange Act of 1934 and subparagraph (e) of the Securities Exchange Act Rule 19b-4. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Securities Exchange Act of 1934.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 500 North Capitol Street, Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 1100 L Street, NW., Washington, D.C. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned, self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted on or before February 23, 1982.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

Dated: January 22, 1982.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82-2691 Filed 2-1-82; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 18410; File No. SR-PSE-81-25]

Self-Regulatory Organizations; Filing of Proposed Rule Change by the Pacific Stock Exchange

January 11, 1982.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on January 4, 1982, the Pacific Stock Exchange Inc. ("PSE") filed with the Securities and Exchange Commission the proposed rule change as described herein. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

The terms of substance of the proposed rule change would require that admission to the PSE's San Francisco Equities Trading Floor be by badge only. Repeated failures by members or member firm personnel to wear badges would be grounds for fines ranging up to $50.00. Special arrangements would be made for the admission of visitors, who would be issued temporary badges. The access of any visitor to the trading floor, however, could be restricted if such visitor interferes with orderly floor procedure. The PSE's stated purpose in adopting this proposal is to enhance trading floor security and in the PSE's opinion the proposal is consistent with section 6(b) of the Act.

In order to assist the Commission in determining whether to approve the proposed rule change or institute proceedings to determine whether the proposed rule change should be disapproved, interested persons are invited to submit written data, views and arguments concerning the submission on or before February 23, 1982. Persons desiring to make written comments should file six copies thereof with the Secretary of the Commission, Securities and Exchange Commission, 500 North Capitol Street, Washington, D.C. 20549. Reference should be made to File No. SR–PSE–81–25.

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change which are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those which may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room, 1100 L Street, NW., Washington, D.C. Copies of the filing and of any subsequent amendments also will be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization.

For the Commission, by the Division of Market Regulation pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82-2692 Filed 2-1-82; 8:45 am]

BILLING CODE 8010-01-M

[Rel. No. 18412; File No. SR-PSE-81-26]

Self-Regulatory Organizations; Filing of Proposed Rule Change by the Pacific Stock Exchange, Inc.

January 12, 1982.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on January 8, 1982, the Pacific Stock Exchange, Inc. ("PSE") filed with the Securities and Exchange Commission the proposed rule change as described herein. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

The proposed rule change would amend Rule II, Section 3(g) of the PSE rules, relating to specialists accepting orders before the opening. The proposed amendment, which would add Commentary .03 to the above rule, requires a specialist to accept round lot orders for executions prior to the reopening of a stock in which trading has been halted until two minutes prior to the reopening of trading by the specialist, thereby allowing the specialist to establish the price of the stock on reopening. The PSE states in its submission that the statutory basis for the proposed rule change is section 6(b) of the Securities Exchange Act of 1934 ("Act"), in general, and section 6(b)(5) of the Act, in particular, in that the proposed rule change is intended to promote a fair and orderly marketplace and to facilitate transactions in securities.

In order to assist the Commission in determining whether to approve the proposed rule change or institute proceedings to determine whether the proposed rule change should be disapproved, interested persons are invited to submit written data, views and arguments concerning the submission on or before February 23, 1982. Persons desiring to make written comments should file six copies thereof with the Secretary of the Commission, Securities and Exchange Commission, 500 North Capitol Street, Washington, D.C. 20549. Reference should be made to File No. SR–PSE–81–26.

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change which are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those which may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room, 1100 L. Street, NW., Washington, D.C. Copies of the filing and of any subsequent amendments also will be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization.

For the Commission, by the Division of Market Regulation pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82-2693 Filed 2-1-82; 8:45 am]

BILLING CODE 8010-01-M

SMALL BUSINESS ADMINISTRATION

[License No. 05/07-5086]

CEDCO Capital Corp.; Filing of an Application for an Exemption Under the Conflict of Interest Regulation

Notice is hereby given that CEDCO Capital Corporation (CEDCO), 180 North Michigan Avenue, Suite 333, Chicago, Illinois 60601, a Federal Licensee under the Small Business Investment Act of 1958, as amended (the Act), has filed an application with the Small Business Administration (SBA) pursuant to Section 107.1004(b) of the Regulations governing small business investment companies (13 CFR 107.1004(b) (1982)) for an exemption from the provisions of the Regulation.

This exemption, if granted, will permit CEDCO to provide financing in the amount of $100,000 to Fort Dearborn Paper Company (FDPC), 2901 West 36th Place, Chicago, Illinois 60632. Mr. Charles T. Grant, a director of CEDCO, is the President and majority stockholder of FDPC.

CEDCO is one of several participants in the financing of FDPC which was formed for the purpose of acquiring the assets and business operations of Fort Dearborn Paper, a division of Mead Corporation. Mr. Grant is presently the Vice President and General Manager of this division.

Pursuant to Paragraph (f) of the definition of "associate of a Licensee" in § 107.3 of the SBA Regulations, FDPC is considered to be an Associate of CEDCO. As such, the transaction will

require an exemption from the provisions of § 107.1004(b)(1) of the Regulations.

Notice is hereby given that any interested person may, not later than fifteen (15) days from the date of publication of this Notice, submit written comments on the proposed transaction to the Acting Deputy Associate Administrator for Investment, Small Business Administration, 1441 "L" Street, NW., Washington, D.C. 20416.

A copy of this Notice shall be published in a newspaper of general circulation in Chicago, Illinois.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Dated: January 26, 1982.

Robert G. Lineberry,

Acting Deputy Associate Administrator for Investment.

[FR Doc. 82-2712 Filed 2-1-82; 8:45 am]

BILLING CODE 8025-01-M

Sunshine Act Meetings

Federal Register
Vol. 47, No. 22
Tuesday, February 2, 1982

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

CONTENTS

1

CIVIL AERONAUTICS BOARD

[M-341, Amdt. 2, January 28, 1982]

Addition and Closure of Item to the January 29, 1982 Board Meeting

TIME AND DATE: 10 a.m. (after open meeting), January 29, 1982.

PLACE: Room 1027 (open), room 1012 (closed), 1825 Connecticut Avenue, NW., Washington, D.C. 20428.

SUBJECT: 39. Report on ECAC. (BIA)

STATUS: Closed.

PERSON TO CONTACT: Phyllis T. Kaylor, the Secretary (202) 673–5068.

[S-148-82 Filed 1-29-82; 3:53 am]

BILLING CODE 6320-01-M

2

CIVIL AERONAUTICS BOARD

[M-341, Amdt 3, January 28, 1982]

Addition and Closure of Item to the January 29, 1982 Board Meeting.

TIME AND DATE: 10 a.m. (after open meeting), January 29, 1982.

PLACE: Room 1027 (open), room 1012 (closed), 1825 Connecticut Avenue, NW., Washington, D.C. 20428.

SUBJECT: Report on Negotiations with Chile. (BIA).

STATUS: Closed.

PERSON TO CONTACT: Phyllis T. Kaylor, the Secretary (202) 673–5068.

[S-149-82 Filed 1-29-82; 3:53 pm]

BILLING CODE 6320-01-M

3

CIVIL AERONAUTICS BOARD

[M-341, Amdt 4, January 28, 1982]

Deletion from the January 29, 1982 Board Meeting.

TIME AND DATE: 10 a.m., January 29, 1982.

PLACE: Room 1027 (open), room 1012 (closed), 1825 Connecticut Avenue, NW., Washington, D.C. 20428.

SUBJECT: 2. Docket 39634, U.S. London Case (1982), Instructions to staff (OGC).

STATUS: Open.

PERSON TO CONTACT: Phyllis T. Kaylor, the Secretary (202) 673–5068.

[S-150-82 Filed 1-29-82; 3:53 pm]

BILLING CODE 6320-01-M

4

CIVIL AERONAUTICS BOARD

[M-342, January 28, 1982]

TIME AND DATE: 10 a.m. (open), February 4, 1982.

PLACE: Room 1027 (open), 1825 Connecticut Avenue, NW., Washington, D.C. 20428.

SUBJECT:

1. Ratification of items adopted by notation.
2. Docket 39634, U.S.-London Case (1982), Instructions to staff.
3. Docket EAS-653, Appeal of Macon, Georgia, of its essential air transportation determination. (BDA, OCCR, OGC)
4. Docket EAS-813, Appeal of Essential Air Transportation Determination filed by Pierre, South Dakota. (OGC, OCCR, BDA)
5. Docket EAS-759, Bowling Green's appeal of BDA's denial of eligibility under section 419(b). (BDA, OCCR, OGC)
6. Docket 40225, Notice of Frontier Airlines to terminate service at Cody and Worland, Wyoming. (BDA, OCCR)
7. Commuter carrier fitness determination of Nolan Enterprise, Inc. d.b.a. Piper Air Center. (BDA)
8. Docket 40109, Southeast Air Cargo, Inc.—Application for a section 418 All-Cargo Air Service Certificate. (BDA)
9. Docket 40302, Application of Global International Airways Corp. for a certificate of public convenience and necessity under section 401 of the Federal Aviation Act of 1958, as amended, to operate United States-Germany scheduled service. (BIA, OGC)

STATUS: Open.

PERSON TO CONTACT: Phyllis T. Kaylor, the Secretary (202) 673–5068.

[S-151-82 Filed 1-29-82; 3:53 pm]

BILLING CODE 6320-01-M

5

FEDERAL HOME LOAN MORTGAGE CORPORATION

The Corporation having provided by regulation that a majority of its meetings or portions thereof may properly be closed to the public pursuant to paragraphs (4), (6), (8), 9(A), or (10) of subsection (c) of U.S.C. 552b, or any combination thereof, public announcement is made of the following closed meeting:

DATE: January 8, 1982.

TIME: 2 p.m.

PLACE: 1776 G Street, NW., Washington, D.C., 4G, fourth floor.

SUBJECT MATTER:

Minutes of November 23, 1981 Board of Directors' Meeting (closed) (5 U.S.C. 552b(c)(9)(A))
President's Report (closed) (5 U.S.C. 562b(c)(9)(A))
Complete October Financial Statements; Partial November Financial Statements (closed) (5 U.S.C. 552b(c)(9)(A))

[S-41-82 Filed 1-11-82; 10:19 am]

BILLING CODE 6720-01-M

6

INTERSTATE COMMERCE COMMISSION

TIME AND DATE: 9 a.m., Tuesday, February 9, 1982.

PLACE: Hearing Room A, Interstate Commerce Commission, 12th & Constitution Avenue, NW., Washington, D.C. 20423.

STATUS: Open Special Conference.

MATTER TO BE DISCUSSED: Ex Parte No. MC-88, *Detention of Motor Vehicles.*

CONTACT PERSON FOR MORE INFORMATION: Robert R. Dahlgren, Director, Office of Communications; Telephone: (202) 275–7252.

January 27, 1982.

[S-145-82 Filed 1-29-82; 12:24 pm]

BILLING CODE 7035-01-M

7

NATIONAL TRANSPORTATION SAFETY BOARD

[NM-82-2]

TIME AND DATE: 9 a.m., Tuesday, February 9, 1982.

PLACE: NTSB Board Room, National Transportation Safety Board, 800

Independence Avenue, SW., Washington, D.C. 20594.

STATUS: The first four items will be open to the public; items five and six will be closed under Exemption 10 of the Government in the Sunshine Act.

MATTERS TO BE CONSIDERED:

1. *Marine Accident Report:* Collision of the U.S. Tankship *Pisces with the Greek Bulk Carrier Trade Master,* Mile 124, Lower Mississippi River, December 27, 1980, and *Recommendations* to the U.S. Coast Guard, the Federal Communications Commission, the New Orleans Port Safety Council, the Waterways Journal, and the American Waterways Operators, Inc.

2. *Aircraft Accident Report:* McDonnell Douglas, Inc., DC-9-80, N980DC, Edwards Air Force Base, California, May 2, 1980, and *Recommendations* to the Federal Aviation Administration.

3. *Marine Accident Report:* Collision of the U.S. Barge Carrier, *SS Lash Atlantico* and Greek Freighter *Hellenic* Carrier in the Atlantic Ocean 13 nmi Northeast of Kitty Hawk, North Carolina, May 6, 1981, and *Recommendations* to the U.S. Coast Guard, Hellenic Lines, Ltd., and Prudential Lines, Inc.

4. *Recommendations* to the Federal Aviation Administration regarding runway safety area obstacle and midfield arrestment barrier, runway 30R, Lambert-St. Louis International Airport.

5. *Opinion and Order:* Administrator v. Moore, Dkt. SE-4776; disposition of Administrator's appeal.

6. *Opinion and Order:* Administrator v. Tracy, Dkt. 5194; disposition of respondent's appeal.

CONTACT PERSON FOR MORE INFORMATION: Sharon Flemming 202-382-6525.

January 29, 1982.

[S-146-82 Filed 1-29-82; 1:20 pm]

BILLING CODE 4910-58-M

8

NUCLEAR REGULATORY COMMISSION

DATE: Week of February 1, 1982 (revised).

PLACE: Commissioners' Conference Room, 1717 H Street, NW., Washington, D.C.

STATUS: Open/closed.

MATTERS TO BE CONSIDERED: Tuesday, February 2:

2:00 p.m.
Briefing on Status of Committee for Review of Generic Requirements (public meeting) (as announced)

Thursday, February 4:

10:00 a.m.
Meeting with FEMA on Rulemaking on Frequency of Exercises (public meeting) (as announced)

2:00 p.m.
Briefing by Industry on Plans for Quality Assurance Improvement (public meeting) (approximately 1½ hours) (as announced)

3:30 p.m.
Affirmation/Discussion Session (public meeting) (items revised)
Items to be affirmed and/or discussed:
a. Final Rule for Eliminating Need for Power and Alternative Energy Sources as Issues in OL Proceedings
b. Amendments to Part 1 and 2 to Implement the Commission's Delegation of OL Antitrust Determination to Directors of NRR AND NMSS
c. Diablo Canyon Physical Security—Governor Brown's Request for Public Disclosure of Non-Protection Information

4:15 p.m.
Briefing on Proposed Enforcement Action (closed meeting)

Friday, February 5:

10:30 a.m.
Meeting with ACRS (public meeting) (as announced)

2:00 p.m.
Discussion of Phase I of Diablo Canyon Report (closed meeting)

ADDITIONAL INFORMATION:

Discussion of Region V Report on Diablo Canyon (Closed Meeting), held at 9:50 a.m. on January 21 was continued at 1:50 that afternoon

By a vote of 5-0 on January 27, 1982, the Commission determined pursuant to 5 U.S.C. 552b(e)(1) and § 9.107(a) of the Commission's Rules, that Commission business required that Discussion of Enforcement Matters (Closed Meeting) and, by a vote of 5-0 on January 28, that Report on Ginna Incident, held those days respectively, be held on less than one week's notice to the public

Affirmations of Revised General Statement of Policy and Procedure for Enforcement Actions and Dr. George V. Taplin's Petition (PRM 35-1) Regarding 10 CFR Part 35, "Human Uses of Byproduct Material," scheduled for January 28 were cancelled

Discusion of Management-Organization and Internal Personnel Matters, scheduled for January 25 was postponed to January 28

Discussion of Contested Issues in TMI-1 Restart Proceeding, announced for February 3 was cancelled

Briefing by Regulatory Reform Task Force, announced for February 5, was cancelled

AUTOMATIC TELEPHONE ANSWERING SERVICE FOR SCHEDULE UPDATE: (202) 634-1498. Those planning to attend a meeting should reverify the status on the day of the meeting.

CONTACT PERSON FOR MORE INFORMATION: Gary M. Gilbert (202) 634-1410.

January 28, 1982.

Gary M. Gilbert,

Office of the Secretary.

[S-147-82 Filed 1-29-82; 3:45 pm]

BILLING CODE 7590-01-M

federal register

Tuesday
February 2, 1982

Part II

Department of Health and Human Services

Food and Drug Administration

Clinical Chemistry and Clinical Toxicology Devices; General Provisions and Classification of 206 Devices

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. 78N-2285]

Clinical Chemistry and Clinical Toxicology Devices; General Provisions and Classification of 206 Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing general rules applicable to the classification of all clinical chemistry and clincal toxicology devices. The Medical Device Amendments of 1976 require FDA to classify all medical devices intended for human use into three categories: class I, general controls; class II, performance standards; and class III, premarket approval. In the preamble to this proposal, FDA describes the development of the proposed regulation classifying 206 clinical chemistry and clinical toxicology devices. The preamble also describes the activities of the Clinical Chemistry Device Section and the Clinical Toxicology Device Section of the Clinical Chemistry and Hematology Devices Panel (formerly the Clinical Chemistry Device Classification Panel and the Clinical Toxicology Device Classification Panel), an FDA advisory committee that makes recommendations to FDA concerning the classification of clinical chemistry and clinical toxicology devices.

DATES: Comments by April 5, 1982. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

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

FOR FURTHER INFORMATION CONTACT: Eugene W. Rice, Bureau of Medical Devices (HFK-440), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Device Classification System

The Medical Device Amendments of 1976 (Pub. L. 94-295, hereinafter called the amendments) establish a comprehensive system for the regulation of medical devices intended for human use. One provision of the amendments, section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories are as follows: class I, general controls; class II, performance standards; and class III, premarket approval.

Most devices are not classified under section 513 of the act until after FDA has (1) received a recommendation from a device panel (an FDA advisory committee); (2) published the Panel's recommendation for comment along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. These steps must precede the classification of any device that was in commercial distribution before May 28, 1976 (the date of enactment of the amendments) and that was not previously regarded by FDA as a new drug under section 505 of the act (21 U.S.C. 355). A device that is first offered for commercial distribution after May 28, 1976, and that is substantially equivalent to a device classified under this scheme, is classified in the same class as the device to which it is substantially equivalent.

A device that FDA previously regarded as a new drug, or a newly offered device that is not substantially equivalent to a device that was in commercial distribution before the amendments, is classified by statute into class III. These two types of devices are classified into class III without any FDA rulemaking proceedings. The agency determines whether new devices are substantially equivalent to previously offered devices by means of the premarket notification procedure in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the regulations (21 CFR Part 807).

Related Regulations

In the **Federal Register** of July 28, 1978 (43 FR 32988), the agency issued final regulations describing the procedures for classifying devices intended for human use. These regulations, which were proposed in the **Federal Register** of September 13, 1977 (42 FR 46028), supplement the agency's regulations in Part 14 (21 CFR Part 14) governing the use of advisory committees. The agency also issued interim device classification procedures in a notice published in the **Federal Register** of May 19, 1975 (40 FR 21848).

Clinical chemistry and clinical toxicology devices are subject to labeling requirements in § 809.10 (21 CFR 809.10) for in vitro diagnostic products. As defined in § 809.3(a) (21 CFR 809.3(a)), in vitro diagnostic products are those reagents, instruments, and systems intended for use in the diagnosis of disease or in the determination of the state of health in order to cure, mitigate, treat, or prevent disease or its sequelae. These products are intended for use in the collection, preparation, and examination of specimens taken from the human body. Before the enactment of the amendments, FDA regarded in vitro diagnostic products as drugs or devices, or as combinations of drugs and devices. Since the enactment of the amendments, with the expanded definition of "device" in section 201(h) of the act, FDA regards in vitro diagnostic products as devices.

Activities of Panels

Anticipating enactment of the amendments, FDA established several advisory committees to make preliminary recommendations on device classification. The Clinial Chemistry Device Classification Panel and the Clinical Toxicology Device Classification Panel were originally chartered on October 15, 1974, as the Clinical Chemistry and the Clinical Toxicology Subcommittee of the Diagnostic Products Advisory Committee.

On August 9, 1976, the Subcommittees were rechartered as the Clinical Chemistry Device Classification Panel and the Clinical Toxicology Device Classification Panel to reflect their new responsibilities under the amendments. The agency directed each panel to reconsider its preamendments classification recommendations in light of the new requirements. In 1976 and 1977, the Panels reviewed all devices that FDA had referred to them to make certain that their recommendations were in accord with the amendments. Throughout the Panels' deliberations, interested persons were given an opportunity to present their views, data, and other information concerning the classification of clinical chemistry and clinical toxicology devices. The Panels also invited experts to testify and sought information on many devices from the published literature.

In October 1977, the Panels submitted to FDA preliminary reports of their recommendations. The reports included rosters of current and former Panel members and consultants and listed all meeting dates. The agency placed copies of the reports in the office of the Dockets Management Branch (HFA-305), Food and Drug Administration, and announced their availability to the public by notice published in the **Federal**

Register of November 29, 1977 (42 FR 60792). Also available in the Dockets Management Branch are summary minutes from all Panel meetings, verbatim transcripts of meetings held after May 28, 1976 (the date of enactment of the amendments), and all references cited in this proposal.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the Federal Register of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). The Clinical Chemistry Device Classification Panel and the Clinical Toxicology Device Classification Panel were terminated, and their functions are now conducted by the Clinical Chemistry Device Section and the Clinical Toxicology Device Section of the Clinical Chemistry and Hematology Devices Panel.

Relationship Between the Device Names in the Device Registration and Listing Codes and the Device Names in Classification Regulations

Some manufacturers have become accustomed to identifying a device by its registration and listing name and three-letter code used for purposes of device listing under section 510 of the act (21 U.S.C. 360). However, FDA is still making changes in the names and identifications of generic types of devices in the classification regulations for all devices for which final regulations have not been published. Because FDA has not used the present device registration and listing names in the proposed and final classification regulations, FDA has prepared an index of names of generic types of medical devices used in classification regulations to aid a manufacturer in matching its device with the proper classification regulation. The index shows the device registration and listing product code for each device reviewed by a classification panel and the corresponding name of the generic type of device and classification panel in which the device classification will be published in the Federal Register. The agency announced the availability of this index in the Federal Register of March 6, 1979 (44 FR 12269). If necessary, this index will be updated and the availability of the revised index will be reannounced in the Federal Register. FDA believes that, because this index is available, it is unnecessary to include or cross-reference the present device registration and listing name and product code in the classification regulations. In the future, following publication of most of the device classification regulations, the agency will revise and the reissue the device registration and listing product code, so the device names to be used for registration and listing correspond to the device names in the final device classification regulations.

List of Clinical Chemistry and Clinical Toxicology Devices

In 1972 FDA surveyed device manufacturers to identify the devices for which classification regulations would be needed. Following this survey, FDA developed a list of clinical chemistry and clinical toxicology devices. The Panels supplemented the list using their members' knowledge of clinical chemistry and clinical toxicology devices in use. Devices that were solely for experimental or investigational use or that were not generally available were not included.

FDA is proposing to establish a new Part 862 in Title 21 of the Code of Federal Regulations. Part 862 will consist of sections identifying each clinical chemistry and clinical toxicology device with a brief narrative description and stating the classification of that device. A list of the clinical chemistry and clinical toxicology devices appears elsewhere in this preamble.

Clinical Chemistry and Clinical Toxicology Device Classifications

The agency is proposing to classify 31 clinical chemistry and clinical toxicology devices into class I (general controls) and 175 clinical chemistry and clinical toxicology devices into class II (performance standards). The agency is not proposing to classify any clinical chemistry products or clinical toxicology products into class III (premarket approval). FDA is also publishing the recommendations of the two Sections of the Clinical Chemistry and Hematology Devices Panel regarding these devices, as required by section 513 (c)(2) and (d)(1) of the act (21 U.S.C. 360c (c)(2) and (d)(1)).

Panel Recommendations

The Panel recommendation concerning a clinical chemistry or clinical toxicology device includes the information described below.

1. *Identification.* Both the Panel recommendation and the proposed FDA classification include a brief narrative identification of the device. The identification statement is necessarily broad because it applies to a category or type of device rather than to a specific device. As explained in proposed § 862.1, any manufacturer of a newly offered device who files a premarket notification submission under section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 (21 CFR Part 807) of the regulations cannot show merely that the device is accurately described by the section title and identification provisions of a classification regulation. Although a newly offered device may be described accurately by the title and identification in a classification regulation, it is nevertheless in class III under section 513(f) of the act if it is not substantially equivalent to a preamendments device (or to a postamendments device that has already been reclassified from class III into class I or class II). It is not practical for FDA to publish an idenfication of each type of device that is so detailed as to anticipate every product feature that may be relevant in determining whether a new device is substantially equivalent to devices previously classified by the regulation. FDA believes that this problem was recognized in, and addressed by, the premarket notification procedures in section 510(k) of the act. Accordingly, any manufacturer who submits a premarket notification submission should state why the manufacturer believes the device is substantially equivalent to other devices in commercial distribution, as required by § 807.87 (21 CFR 807.87), and whether the device is described in a classification regulation.

2. *Recommended classification.* Each Panel's recommendation describes whether the device is recommended for classification into class I (general controls) or class II (performance standards).

For each device recommended for classification into class I, the Panel considered whether the device should be exempt from any requirements under certain sections of the act: section 510 (21 U.S.C. 360, registration), section 519 (21 U.S.C. 360i, records and reports), and section 520(f) (21 U.S.C. 360j(f), good manufacturing practice requirements). Although the Panels did not recommend that any device be exempted at this time from section 519 of the act, the Panels did recommend that the manufacturers of several class I devices be exempted from the good manufacturing practice regulation in Part 820 of the regulations (21 CFR Part 820) in the manufacture of these devices. The Clinical Chemistry Panel recommended that those class I clinical chemistry devices which are exempted from the good manufacturing practice regulation also be exempted from premarket notification procedures under section 510(k) of the act and Part

807 of the regulations (21 CFR Part 807). FDA's policy concerning these exemption recommendations is discussed below in the seciton of this proposal concerning "Exemptions for Class I Devices."

A Panel recommendation that a device be classified into class II includes the Panel's recommended priority ("high," "medium," or "low") for establishing a performance standard for the device. As explained below in the section of this notice concerning "Priorities for Class II Devices," FDA is not, however, proposing the establishment of FDA priorities at this time.

3. *Summary of reasons for recommendation.* The summary of reasons for the Panel's recommendation explains why the Panel believes that a particular device meets the statutory critieria for classification into class I or II.

Except in those instances in which FDA's classification proposal differs from the Panel's recommendation, FDA is adopting the Panel's summary of reasons as the agency's statement of the reasons for issuing the regulations, as required by section 517(f) of the act (21 U.S.C. 360g(f)).

The Panels and FDA have not identified any device subject to this proposal as implants or as life-supporting or life-sustaining devices.

4. *Summary of data on which the recommendation is based.* In many cases, the Sections of the Panel based their recommendations on Panel members' personal knowledge of, and clinical experience with, the devices under review. The Panel particularly relied upon clinical experience and judgment when considering a simple device that had been used extensively and was accepted widely before the amendments were enacted. The legislative history of the amendments makes clear that the term "data" has a special meaning in section 513(c)(2)(A) of the act, which requires that a Panel recommendation summarize the data upon which a recommendation is based. As used in that section, "data" refers not only to the results of scientific experiments, but also to less formal evidence, other scientific information, or judgments of experts (House Committee on Interstate and Foreign Commerce, Medical Device Amendments of 1976, H.R. Rept. No. 94–853, 94th Congress, 2d Session 40 (1976)). FDA has determined that clinical experience and judgment is valid scientific evidence for classifying certain devices.

In many cases, FDA sought more data and information concerning the classification of a device than were cited by the Panel. References to these data and information are found in the section for each clinical chemistry and clinical toxicology device under the heading "Panel Recommendations and FDA's Proposed Classifications." FDA is adopting, as the agency's statement of the basis for issuing the regulation under section 517(f) of the act, the Panel's summary of the data on which a recommendation to classify a device is based, together with any additional data and information cited in the preamble to the proposed classification regulation.

5. *Risks to health.* In identifying the risks to health presented by clinical chemistry and clinical toxicology devices, the Panel recognized that few devices are completely free of risk. The Panel listed the risks they considered most significant, especially those that are unique to the individual device.

Because the Panel's classification recommendations and FDA's proposed classification may not identify all risks to health presented by clinical chemistry and clinical toxicology devices, future regulations establishing performance standards under section 514 of the act (21 U.S.C. 360d) or requiring premarket approval under section 515(b) of the act (21 U.S.C. 360e(b)) may identify additional risks to health to be addressed by FDA requirements.

Proposed Classification

Each section for a clinical chemistry or a clinical toxicology device states under the heading "Panel Recommendations and FDA's Proposed Classifications" whether FDA agrees with the Panel's recommendation and describes the agency's proposed classification of the device.

FDA cautions that the final classification of a device may differ from the proposal. Factors that may cause such a change include comments, the agency's reconsideration of existing data and information, and the agency's consideration of new data and information.

Priorities for Class II Devices

For devices that the Panel recommends be classified into class II, section 513(c)(2)(A) of the act requires that the Panel's recommendation include, to the extent practicable, a recommendation for the assignment of a priority for application to the device of a performance standard or premarket approval requirements. In developing its advice concerning priorities ("high," "medium," or "low") of devices recommended for classification into class II, the Panel compared the device with other clinical chemistry and clinical toxicology devices, based on information available to the Panel members concerning the relative importance of use of the device and the relative risks presented by the device. The Panel recommended assignment of a "high priority" only to those class II devices that the Panel believed should receive the agency's immediate attention.

FDA is not proposing at this time to establish priorities for development of performance standards for all class II devices. Section 513(d)(3) of the act authorizes, but does not require, establishment of these priorities. In the **Federal Register** of February 1, 1980 (45 FR 7489 and 45 FR 7493), FDA published notices identifying which class II devices the agency found to warrant a high priority for the development of performance standards. At a later date, the agency will establish priorities for the development of standards for the remaining class II devices. All priorities established by the agency are based on the Panel's recommendations, available resources, and other relevant factors. The agency's priorities will be reflected in the agency's annual budget request and other publicly available documents and may be published in the **Federal Register.**

Products That Have Both Medical and Nonmedical Uses

Some products have both medical and nonmedical uses. FDA will regulate a multi-purpose product as a medical device if it is intended for a medical purpose, i.e., for "use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease," or "to affect the structure or any function of the body." Section 201(h) of the act (21 U.S.C. 321(h)). FDA will determine the intended use of a product based upon the expressions of the person legally responsible for its labeling and by the circumstances surrounding its distribution. The most important factors the agency will consider in determining the intended use of a particular product are the labeling, advertising, and other representations accompanying the product. Products that have medical uses only are clearly intended for medical purposes and, therefore, will be regulated as medical devices whether or not medical claims are made for them.

Exemptions for Class I Devices

Section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) provides that FDA may exempt a device recommended for classification into class I from a requirement under the following sections of the act: Section 510

(21 U.S.C. 360), registration; section 519 (21 U.S.C. 360i), records and reports; and section 520(f) (21 U.S.C. 360j(f)), good manufacturing practices.

Under section 510 of the act, a person "engaged in the manufacture, preparation, propagation, compounding or processing of * * * a device or devices" must register with FDA (section 510 (b) through (i)), file a list of devices (section 510(j)), and notify FDA at least 90 days before beginning commercial distribution of a device (section 510(k)). (See Part 807 (21 CFR Part 807).) Section 510(g)(4) authorizes the agency to exempt a device from section 510 if it finds that compliance with that section is not necessary for the protection of the public health. In § 807.65 (21 CFR 807.65), FDA has exempted certain classes of persons from section 510 of the act. Several device classification panels have recommended that manufacturers of certain class I devices also be exempted from all or some of the requirements of section 510. The agency has determined that protection of the public health requires that manufacturers of medical devices, other than those already exempt under § 807.65, register and list their products with FDA to ensure that the agency can identify these manufacturers and their products and conduct necessary inspections.

The agency has determined, however, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions for certain devices. Thus, the agency has proposed to exempt manufacturers of certain devices from Subpart E of Part 807 of the regulations, which implements section 510(k) of the act. The agency does not, at this time, anticipate that premarket approval will be required for these devices. The agency believes that the semiannual updating of device listing under section 510(j)(2) of the act will provide FDA with adequate notice of new products within these generic types of devices.

Section 519 of the act authorizes FDA to issue regulations requiring device manufacturers, importers, and distributors to establish and maintain such records, make such reports, and provide such information as the agency may reasonably require to assure that devices are not adulterated or misbranded and to otherwise assure their safety and effectiveness. The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation under Part 820 (21 CFR Part 820), published in the Federal Register of July 21, 1978 (43 FR 31508). In the future, FDA may publish other regulations in accordance with section 519 of the act, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. Whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempted from the requirements, and FDA will issue exemptions that are appropriate.

The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from most requirements of the device GMP regulation. As explained below, the exemption will not extend to two device GMP records requirements.

The device GMP regulation was published in final form in the Federal Register of July 21, 1978. At the time of the Panel's recommendations, the GMP regulation had not yet been promulgated, and the agency had not yet developed criteria for exempting manufacturers of a class I device from GMP requirements. The agency has now decided that, if any one of the following criteria is met, FDA will consider exempting from the GMP regulation manufacturers of a class I device that is not labeled or otherwise represented as sterile. The agency will not, however, exempt manufacturers of a device from general requirements concerning records or complaint files. The criteria are:

1. FDA has determined, based on adequate information about current practices in the manufacture of the device and about user experience with the device, that application of the GMP regulation is unlikely to improve the safety and effectiveness of the device.

2. FDA has determined that all possible defects relating to the safety and effectiveness of the device are readily detectable before use, either through visual examination by the user or routine testing before use, e.g., testing a clinical laboratory reagent with positive and negative controls.

3. FDA has determined that any defect in the device that is not readily detectable will not result in a device failure that could have an adverse effect on the patient or other user.

FDA has determined that no device that is labeled or otherwise represented as sterile will be exempted from the device GMP regulation. A sterile device must be subject to the entire GMP regulation to ensure that manufacturers adequately reduce the bioburden (number of microorganisms) on the device and its components during the manufacturing process. This reduction is accomplished through adherence to a comprehensive quality assurance program as is required by the GMP regulation, with adequate environmental controls, trained personnel, appropriate maintenance and calibration of sterilization equipment, recordkeeping concerning lot sterility, strick packaging and labeling controls, and other quality assurance measures.

The agency also has determined that no exemption from the device GMP regulation will extend to § 820.180, with respect to general requirements concerning records, or § 820.198, with respect to complaint files. The agency believes that granting exemptions from these sections would not be in the public interest, and that compliance with these sections is not unduly burdensome for device manufacturers. To ensure that device manufacturers have adequate systems for complaint investigation and followup, all manufacturers are required to comply with the complaint file requirements. All device manufacturers also are required to comply with the general requirements concerning records to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

In general, FDA has not initiated proposals to exempt manufacturers of devices from requirements under section 510 or 520(f) of the act, but has acted on the basis of exemption recommendations of the device classification panels. However, FDA has proposed occasionally to exempt manufacturers of certain devices classified into class I or class II from the requirements of certain sections of the GMP regulation, according to the above exemption criteria. Manufacturers and other interested persons may submit comments on the appropriateness of the proposed exemptions of manufacturers of devices, whether the exemptions are proposed in response to recommendations of the panels or on the agency's initiative. Comments requesting additional exemptions should be supported by information showing that the exemption of manufacturers of a

device from the premarket notification requirements or the GMP regulation is consistent with the criteria discussed above.

Guidelines for Preparing Petitions Requesting Exemption or Variance From the Device GMP Regulation for Devices Classified Into Class I or Class II

FDA has prepared guidelines on the procedures that should be followed by persons who wish to submit petitions for exemption or variance from the device GMP regulation. These petitions may be submitted in accordance with provisions of section 520(f)(2) of the Act (21 U.S.C. 360j(f)(2)). The agency announced the availability of the guidelines in a notice published in the **Federal Register** of January 18, 1980 (45 FR 3671).

List of Clinical Chemistry and Clinical Toxicology Devices

The following is a list of clinical chemistry and clinical toxicology devices that FDA is proposing to classify, the section and subpart of Part 862 in Title 21 of the Code of Federal Regulations under which the regulation classifying the device will be codified, the docket number of the proposed classification regulation, and the proposed classification of each device.

Section	Device	Docket No.	Class
	Subpart B—Clinical Chemistry Test Systems		
862.1020	Acid phosphatase (total or prostatic) test system.	78N-2287	II.
862.1025	Adrenocorticotropic hormone (ACTH) test system.	78N-2288	II.
862.1030	Alanine amino transferase (ALT/SGPT) test system.	78N-2289	II.
862.1035	Albumin test system	78N-2290	II.
862.1040	Aldolase test system	78N-2291	II.
862.1045	Aldosterone test system	78N-2292	II.
862.1050	Alkaline phosphatase of isoenzymes test system.	78N-2293	II.
862.1060	*Delta*-aminolevulinic acid test system.	78N-2295	II.
862.1065	Ammonia test system	78N-2296	II.
862.1070	Amylase test system	78N-2297	II.
862.1075	Androstenedione test system	78N-2298	II.
862.1080	Androsterone test system	78N-2299	II.
862.1085	Angiotensin I and renin test system.	78N-2300	II.
862.1095	Ascorbic acid test system	78N-2301	II.
862.1100	Aspartate amino transferase (AST–SGOT) test system.	78N-2302	II.
862.1110	Bilirubin (total or direct) test system.	78N-2203	II.
862.1115	Urinary bilirubin and its conjugates (nonquantitative) test system.	78N-2304	II.
862.1120	Blood gases (P_{CO_2}, P_{O_2}) and blood pH test system.	78N-2305	II.
862.1130	Blood volume test system	78N-2307	II.
862.1135	C-peptides of proinsulin test system.	78N-2308	II.
862.1140	Calcitonin test system	78N-2309	II.
862.1145	Calcium test system	78N-2310	II.
862.1150	Calibrator	78N-2311	II.
862.1155	Human chorionic gonadotropin (HCG) test system for use in early detection of pregnancy.	78N-2312	II.
862.1160	Bicarbonate/carbon dioxide test system.	78N-2313	II.
862.1165	Catecholamines (total) test system.	78N-2314	II.
862.1170	Chloride test system	78N-2315	II.
862.1175	Cholesterol (total) test system.	78N-2316	II.
862.1180	Chymotrypsin test system	78N-2317	II.
862.1185	Compound S (11-deoxycortisol) test system.	78N-2318	II.
862.1190	Copper test system	78N-2319	II.
862.1195	Corticoids test system	78N-2320	II.
862.1200	Corticosterone test system	78N-2321	II.
862.1205	Cortisol (hydrocortisone and hydroxycorticosterone) test system.	78N-2322	II.
862.1210	Creatine test system	78N-2323	II.
862.1215	Creatine phosphokinase/creatine kinase or isoenzymes test system.	78N-2324	II.
862.1225	Creatinine test system	78N-2326	II.
862.1230	Cyclic AMP or cyclic GMP test system.	78N-2327	II.
862.1240	Cystine test system	78N-2329	II.
862.1245	Dehydroepiandrosterone (free and sulfate) test system.	78N-2330	II.
862.1250	Desoxycorticosterone test system.	78N-2331	II.
862.1255	2,3-Diphosphoglyeric acid test system.	78N-2332	II.
862.1260	Estradiol test system	78N-2333	II.
862.1265	Estriol test system	78N-2334	II.
862.1270	Estrogens (total, in pregnancy) test system.	78N-2335	II.
862.1275	Estrogens (total, nonpregnancy) test system.	78N-2336	II.
862.1280	Estrone test system	78N-2337	II.
862.1285	Etiocholanolone test system	78N-2338	II.
862.1290	Fatty acids test system	78N-2339	II.
862.1295	Folic acid test system	78N-2340	II.
862.1300	Follicle-stimulating hormone test system.	78N-2341	II.
862.1305	Formiminoglutamic acid (FIGLU) test system.	78N-2342	II.
862.1310	Galactose test system	78N-2343	II.
862.1315	Galactose-1-phosphate uridyl transferase test system.	78N-2344	II.
862.1320	Gastric acidity test system	78N-2345	II.
862.1325	Gastrin test system	78N-2346	II.
862.1330	Globulin test system	78N-2347	II.
862.1335	Glucagon test system	78N-2348	II.
862.1340	Urinary glucose (non-quantitative) test system.	78N-2349	II.
862.1345	Glucose test system	78N-2350	II.
862.1360	*Gamma*-glutamyl transpeptidase and isoenzymes test system.	78N-2353	II.
862.1365	Glutathione test system	78N-2354	II.
862.1370	Human growth hormone test system.	78N-2355	II.
862.1375	Histidine test system	78N-2356	II.
862.1380	Hydroxybutyric dehydrogenase test system.	78N-2357	II.
862.1385	17-Hydroxycorticosteroids (17-ketogenic steroids) test system.	78N-2358	II.
862.1390	5-Hydroxyindole acetic acid/serotonin test system.	78N-2359	II.
862.1395	17-Hydroxyprogesterone test system.	78N-2360	II.
862.1400	Hydroxyproline test system	78N-2361	II.
862.1405	Immunoreactive insulin test system.	78N-2362	II.
862.1410	Iron (non-heme) test system	78N-2363	II.
862.1415	Iron-binding capacity test system.	78N-2364	II.
862.1420	Isocitric dehydrogenase test system.	78N-2365	II.
862.1430	17-Ketosteroids test system	78N-2367	II.
862.1435	Urinary ketones (nonquantitative) test system.	78N-2368	II.
862.1440	Lactate dehydrogenase test system.	78N-2369	II.
862.1445	Lactate dehydrogenase isoenzymes test system.	78N-2370	II.
862.1450	Lactic acid test system	78N-2371	II.
862.1455	Lecithin-sphingomyelin ratio in amniotic fluid test system.	78N-2372	II.
862.1460	Leucine aminopeptidase test system.	78N-2373	II.
862.1465	Lipase test system	78N-2374	II.
862.1470	Lipid (total) test system	78N-2375	II.
862.1475	Lipoprotein test system	78N-2376	II.
862.1485	Luteinizing hormone test system.	78N-2378	II.
862.1490	Lysozyme (muramidase) test system.	78N-2379	II.
862.1495	Magnesium test system	78N-2380	II.
862.1500	Malic dehydrogenase test system.	78N-2381	II.
862.1505	Mucopolysaccharides test system.	78N-2382	II.
862.1510	Urinary nitrite (nonquantitative) test system.	78N-2383	II.
862.1515	Nitrogen (amino-nitrogen) test system.	78N-2384	II.
862.1520	5'-Nucleotidase test system	78N-2385	II.
862.1530	Plasma oncometry test system.	78N-2387	II.
862.1535	Ornithine carbamyl transferase test system.	78N-2388	II.
862.1540	Osmolality test system	78N-2389	II.
862.1545	Parathyroid hormone test system.	78N-2390	II.
862.1550	Urinary pH (nonquantitative) test system.	78N-2391	II.
862.1555	Phenylalanine test system	78N-2392	II.
862.1560	Urinary phenylketones (nonquantitative) test system.	78N-2393	II.
862.1565	6-Phosphogluconate dehydrogenase test system.	78N-2394	II.
862.1570	Phosphohexose isomerase test system.	78N-2395	II.
862.1575	Phospholipid test system	78N-2396	II.
862.1580	Phosphorus (inorganic) test system.	78N-2397	II.
862.1585	Human placental lactogen test system.	78N-2398	II.
862.1590	Porphobilinogen test system	78N-2399	II.
862.1595	Porphyrins test system	78N-2400	II.
862.1600	Potassium test system	78N-2401	II.
862.1605	Pregnanediol test system	78N-2402	II.
862.1610	Pregnanetriol test system	78N-2403	II.
862.1615	Pregnenolone test system	78N-2404	II.
862.1620	Progesterone test system	78N-2405	II.
862.1625	Prolactin (lactogen) test system.	78N-2406	II.
862.1630	Protein (fractionation) test system.	78N-2407	II.
862.1635	Total protein test system	78N-2408	II.
862.1640	Protein-bound iodine test system.	78N-2409	II.
862.1645	Urinary protein or albumin (nonquantitative) test system.	78N-2410	II.
862.1650	Pyruvate kinase test system	78N-2411	II.
862.1655	Pyruvic acid test system	78N-2412	II.
862.1660	Quality control material (assayed and unassayed).	78N-2413	I.
862.1665	Sodium test system	78N-2414	II.
862.1670	Sorbitol dehydrogenase test system.	78N-2415	II.
862.1675	Blood specimen collection device.	78N-2416	II.
862.1680	Testosterone and dihydrotestosterone test system.	78N-2417	II.
862.1685	Thyroxine-binding globulin test system.	78N-2418	II.
862.1690	Thyroid-stimulating hormone test system.	78N-2419	II.
862.1695	Free thyroxine test system	78N-2420	II.
862.1700	Total thyroxine test system	78N-2421	II.
862.1705	Triglyceride test system	78N-2422	II.
862.1710	Total triiodothyronine test system.	78N-2423	II.
862.1715	Triiodothyronine uptake test system.	78N-2424	II.
862.1720	Triose phosphate isomerase test system.	78N-2425	II.
862.1725	Trypsin test system	78N-2426	II.
862.1730	Free tyrosine test system	78N-2427	II.
862.1770	Urea nitrogen test system	78N-2428	II.
862.1775	Uric acid test system	78N-2429	II.
862.1780	Urinary calculi (stones) test system.	78N-2430	II.
862.1785	Urinary urobilinogen (nonquantitative) test system.	78N-2431	II.
862.1790	Uroporphyrin test system	78N-2432	II.
862.1795	Vanilmandelic acid test system.	78N-2433	II.
862.1805	Vitamin A test system	78N-2435	II.
862.1810	Vitamin B_{12} test system	78N-2436	II.
862.1815	Vitamin E test system	78N-2437	II.
862.1820	Xylose test system	78N-2438	II.

Section	Device	Docket No.	Class
	SUBPART C—CLINICAL LABORATORY INSTRUMENTS		
862.2050	General purpose laboratory equipment.	78N-2439	I.
862.2100	Calculator/data processing module for clinical use.	78N-2441	I.
862.2140	Centrifugal chemistry analyzer for clinical use.	78N-2443	I.
862.2150	Continuous flow sequential multiple chemistry analyzer for clinical use.	78N-2444	I.
862.2160	Discrete photometric chemistry analyzer for clinical use.	78N-2445	I.
862.2170	Micro chemistry analyzer for clinical use.	78N-2446	I.
862.2230	Chromatographic separation material for clinical use.	78N-2450	I.
862.2250	Gas liquid chromatography system for clinical use.	78N-2452	I.
862.2260	High-pressure liquid chromatography system for clinical use.	78N-2453	I.
862.2270	Thin-layer chromatography system for clinical use.	78N-2454	I.
862.2300	Colorimeter, photometer, or spectrophotometer for clinical use.	78N-2455	I.
862.2310	Clinical sample concentrator	78N-2456	I.
862.2320	*Beta* or *gamma* counter for clinical use.	78N-2457	I.
862.2400	Densitometer/scanner (intergrating, reflectance, thin-layer chromatography, or radiochromatogram) for clinical use.	78N-2459	I.
862.2485	Electrophoresis apparatus for clinical use.	78N-2463	I.
862.2500	Enzyme analyzer for clinical use.	78N-2464	I.
862.2540	Flame emission photometer for clinical use.	78N-2467	I.
862.2560	Fluormeter for clinical use	78N-2468	I.
862.2680	Microtitrator for clinical use	78N-2472	I.
862.2700	Nephelometer for clinical use	78N-2474	I.
862.2720	Plasma oncometer for clinical use.	78N-2475	I.
862.2730	Osmometer for clinical use	78N-2476	I.
862.2750	Pipetting and diluting system for clinical use.	78N-2477	I.
862.2800	Refractometer for clinical use	78N-2481	I.
862.2850	Atomic absorption spectrophotometer for clinical use.	78N-2483	I.
862.2860	Mass spectrophotometer for clinical use.	78N-2484	I.
862.2900	Automated urinalysis system	78N-2487	I.
862.2920	Plasma viscometer for clinical use.	78N-2488	I.
	SUBPART D—CLINICAL TOXICOLOGY TEST SYSTEMS		
862.3040	Alcohol test system	78N-2490	II.
862.3050	Breath-alcohol test system	78N-2491	I.
862.3100	Amphetamine test system	78N-2495	II.
862.3110	Antimony test system	78N-2496	II.
862.3120	Arsenic test system	78N-2497	II.
862.3150	Barbiturate test system	78N-2498	II.
862.3170	Benzodiazepine test system	78N-2499	II.
862.3200	Clinical toxicology calibrator	78N-2501	II.
862.3220	Carbon monoxide test system	78N-2503	II.
862.3240	Cholinesterase test system	78N-2505	II.
862.3250	Cocaine and cocaine metabolite test system.	78N-2506	II.
862.3270	Codeine test system	78N-2508	II.
862.3280	Clinical toxicology control material.	78N-2509	I.
862.3300	Digitoxin test system	78N-2511	II.
862.3320	Digoxin test system	78N-2513	II.
862.3350	Diphenylhydantoin test system.	78N-2515	II.
862.3380	Ethosuximide test system	78N-2516	II.
862.3450	Gentamicin test system	78N-2518	II.
862.3520	Kanamycin test system	78N-2522	II.
862.3550	Lead test system	78N-2523	II.
862.3560	Lithium test system	78N-2377	II.
862.3580	Lysergic acid diethylamide (LSD) test system.	78N-2526	II.
862.3600	Mercury test system	78N-2527	II.
862.3610	Methamphetamine test system.	78N-2528	II.
862.3620	Methadone test system	78N-2529	II.
862.3640	Morphine test system	78N-2531	II.
862.3650	Opiate test system	78N-2532	II.
862.3660	Phenobarbital test system	78N-2533	II.
862.3670	Phenothiazine test system	78N-2534	II.
862.3680	Primidone test system	78N-2535	II.
862.3700	Propoxyphene test system	78N-2537	II.
862.3750	Quinine test system	78N-2540	II.
862.3830	Salicylate test system	78N-2541	II.
862.3850	Sulphanimide test system	78N-2542	II.
862.3870	Cannabinoid test system	78N-2543	II.
862.3900	Tobramycin test system	78N-2545	II.

Devices Considered by Two or More Panels

Many devices were reviewed by two or more device classification panels. For these devices, FDA will publish each panel's recommendations and a single proposed classification of the device.

Device	Other panels or sections
Colorimetric, occult blood in urine.	Hematology and Pathology Device Section of the Clinical Chemistry and Hematology Devices Panel.
Enzymatic method, occult blood in urine.	Do.
Fluorescence, visual observation, (qual., U.V.), glutathione reductase.	Do.
Electrophoretic, glucose-6-phosphate dehydrogenase isoenzymes.	Do.
NADP reduction (U.V.) glucose-6-phosphate dehydrogenase.	Do.
Visual, semi-quant (colorimetric), glucose-6-phosphate dehydrogenase.	Do.
Immunochemical, Bence-Jones protein.	Immunology and Microbiology Devices Panel.
Immunochemical ceruloplasmin	Do.
Indirect copper assay, ceruloplasmin.	Do.
p-Phenylenediamine/EDTA (spectrophotometric) ceruloplasmin.	Do.
Immunochemical, transferrin	Do.
Immunochemical, thyroglobulin autoantibody.	Do.
Immunodiffusion method, immunoglobulins (G,A,M).	Do.
Immunoelectrophoretic method, immunoglobulins (G,A,M).	Do.
Radioimmunoassay method, immunoglobulins (G,A,M).	Do.
Nephelometric method, immunoglobulins (G,A,M).	Do.
Radioimmunoassay, (two-site solid phase).	Do.
Radioimmunoassay, immunoglobulins (D,E,).	Do.
Incubator/water bath for clinical use.	Do.

The recommendations of the Clinical Chemistry Device Section of the Clinical Chemistry and Hematology Devices Panel and the proposed classification regulations for the devices listed above were published in the **Federal Register** of September 11, 1979 (44 FR 52950–53063) when FDA published the recommendations of the Hematology and Pathology Device Section of the Clinical Chemistry and Hematology Devices Panel and April 22, 1980 (45 FR 27204–27359) when FDA published the recommendations of the Immunology and Microbiology Devices Panel that also reviewed the devices. The following table shows the current structure of the advisory committees involved with the classification of medical devices and a list of all proposed and final classification regulations published to date:

Panel/section name	Publication date in FEDERAL REGISTER
Circulatory Systems Devices Panel.	Mar. 9, 1979, 44 FR 13284–13434 (proposals); Feb. 5, 1980, 45 FR 7904–7971 (final regulations).
Clinical Chemistry and Hematology Devices Panel:	
Clinical Chemistry Device Section.	Feb. 2, 1982 (proposals).
Clinical Toxicology Device Section.	Do.
Hematology and Pathology Device Section.	Sept. 11, 1979, 44 FR 52950–53063 (proposals); Sept. 12, 1980, 45 FR 60576–60651 (final regulations).
General Medical Devices Panel:	
General Hospital and Personal Use Device Section.	Aug. 24, 1979, 44 FR 49844–49954 (proposals); Oct. 21, 1980, 45 FR 69678–69737 (final regulations).
Gastroenterology-Urology Device Section.	Jan. 23, 1981, 46 FR 7562–7641 (proposals).
Immunology and Microbiology Devices Panel:	
Immunology Device Section.	Apr. 22, 1980, 45 FR 27204–27359 (proposals).
Microbiology Device Section.	Apr. 22, 1980, 45 FR 27204–27359 (proposals).
Obstetrics-Gynecology and Radiologic Devices Panel:	
Obstetrics-Gynecology Device Section.	Apr. 3, 1979, 44 FR 19894–19971 (proposals); Feb. 26, 1980, 45 FR 12682–12720 (final regulations).
Radiology Device Section	Do.
Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel:	
Dental Device Section	Dec. 30, 1980, 45 FR 85962–86168 (proposals).
Ear, Nose, and Throat Device Section.	
Ophthalmic Device Section.	
Respiratory and Nervous System Devices Panel:	
Anesthesiology Device Section.	Nov. 2, 1979, 44 FR 63292–63426 (proposals).
Neurological Device Section.	Nov. 28, 1978, 43 FR 54640–55732 (proposals); Sept. 4, 1979, 44 FR 51726–51778 (final regulations).
Surgical and Rehabilitation Devices Panel:	
General and Plastic Surgery Device Section.	
Orthopedic Device Section	
Physical Medicine Device Section.	Aug. 28, 1979, 44 FR 50458–50537 (proposals).

Devices Not in Commercial Distribution as Test Systems

The Clinical Chemistry and Hematology Devices Panel made classification recommendations concerning several reagents that are marketed as general purpose laboratory reagents but are not in commercial distribution as a test system. FDA is not now publishing proposals to classify these products:

1. Bromide test reagents used to measure bromide in human serum by photometry.

2. Chloral hydrate test reagents used to measure chloral hydrate (an anticonvulsant drug) in human specimens (e.g., blood and urine) by spectrophotometry.

3. Fluoride test reagents used to measure fluoride in human specimens by photometry.

4. Methyl alcohol test reagents used to measure methyl alcohol in human specimens (e.g., serum, whole blood, and urine) by spectrophotometry.

5. Microcrystalline forming reagents for alkaloids used to measure any of the alkaloids (e.g., cocaine, codeine, morphine, nicotine, and quinine) in human specimens by crystal formation.

6. Ouabain test reagents used to measure ouabain (a cardiac glycoside used to control congestive heart failure) in human specimens by chemical color reactions.

7. Zinc test reagents used to measure zinc in human specimens (e.g., blood and urine).

The Clinical Chemistry and Hematology Devices Panel recommended that the heavy metal free radical assay be classified into class II. Heavy metal free radical assay is used to measure any heavy metal (e.g., lead, mercury, bismuth, antimony, arsenic) in human specimens. Because this technique is available only as a research tool and is not in commercial distribution as a medical device, FDA is not now publishing a proposal to classify this product.

Panel Recommendations and FDA's Proposed Classifications

Section 862.1020; Docket No. 78N-2287; Acid phosphatase (total or prostratic) test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of acid phosphatase (total or prostatic) test systems:

1. Identification: An acid phosphatase (total or prostatic) test system is a device used to measure the activity of the acid phosphatase enzyme in plasma, serum, vaginal washings, and seminal fluid by methods such as *beta*-glycerophosphate, disodium phenyl phosphate, naphthyl phosphate, nitrophenylphosphate, thymol blue monophosphate, thymolphthalein monophosphate, or tartrate inhibition. Acid phosphatase measurements are used in the diagnosis and treatment of prostatic carcinoma. This device is also used to develop legal evidence to demonstrate the presence of seminal fluids in specimens collected from victims of alleged rape and other sex-related crimes.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that acid phosphatase (total or prostatic) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Because many patients with prostatic carcinoma have elevated serum prostatic acid phosphatase enzyme activity, measurements obtained by this test system are used in diagnosing and treating patients with this disease. The test system is also used to develop legal evidence to demonstrate the presence of seminal fluid in specimens collected from victims of alleged rape and other sex-related crimes. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *1* through *6*). Serum may contain numerous related acid phosphatase enzymes in addition to those of prostatic origin. Because total acid phosphatase enzyme activity can be elevated due to conditions other than carcinoma of the prostate, it is desirable to differentiate specifically between an increase in the enzyme of prostatic origin and an increase in the enzyme of nonprostatic origin. The activity of the enzyme of prostatic origin is strongly inhibited by tartrate ions, while the activity of the anzyme of nonprostatic origin in not. Therefore, the acid phosphatase (prostatic) test is usually performed both in the presence of, and in the absence of, tartarate ions, comparing the results. The acid phosphatase (prostatic) test system was developed to provide a more specific test for the diagnosis and treatment of prostatic carcinoma. Use of the specific acid phosphatase (prostatic) test system provides more accurate information.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis and treatment of patients with prostatic carcinoma. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that acid phosphatase (total or prostatic) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1025; Docket No. 78N-2288; Adrenocorticotropic hormone (ACTH) test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of adrenocorticotropic hormone (ACTH) test systems:

1. Identification: An adrenocorticotropic hormone (ACTH) test system is a device used to measure adrenocorticotropic hormone in plasma and serum by methods such as radioimmunoassay. ACTH measurements are used in the differential diagnosis and treatment of certain disorders or the adrenal glands such as Cushing's syndrome, adrenocortical insufficiency, and the ectopic ACTH syndrome.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that adrenocorticotropic hormone (ACTH) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in

inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of certain disorders of the adrenal glands such as Cushing's syndrome and adrenocortical insufficiency, and, in the ectopic ACTH syndrome, in assessting tumor activity following surgical tumor removal, cytotoxic therapy, or radiotherapy. Test results can indicate the need for further therapy before clinical signs occur. To assure reliable data, the Panel believes it important that the device be able to distinguish between the entire hormone and the split products resulting from metabolic deactivation, and that specific information as to what is being measured be included in the labeling. Therefore, the Panel recommends that labeling include information concerning the source of calibrator and standardization material, the method the manufacturer used to obtain stated values, and the method's specificity as it relates to precursors, subunits, and other features specific to the method. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *7*, *8*, and *9*).

5. Risks to health: Misdiagnosis and inappropriate therapy. Failure of the device to perform satisfactorily may lead to error in the diagnosis and treatment of adrenocortical disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that adrenocorticotropic hormone (ACTH) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1030; Docket No. 78N-2289; Alanine amino transferase (ALT/SGPT) test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of alanine amino transferase (ALT/SGPT) test systems:

1. Identification: An alanine amino transferase (ALT/SGPT) test system is a device used to measure the activity of the enzyme alanine amino transferase (ALT) (also known as serum glutamic pyruvic transaminase or SGPT) in serum and plasma by methods such as diazo, hydrazone colorimetry, nicotinamide adenine dinucleotide (NAD), reduction/nicotinamide adenine dinucleotide (reduced form) (NADH) oxidation, or vanillin pyruvate. Alanine amino transferase measurements are used in the diagnosis and treatment of certain liver diseases (e.g., viral hepatitis and cirrhosis) and heart diseases.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that alanine amino transferase (ALT/SGPT) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropirate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with certain liver diseases, myocardial infarction, and infectious mononucleosis. Markedly elevated levels of this serum enzyme occur in viral hepatitis, severe liver disease, and in circulatory failure with shock. Moderately raised levels are seen in cirrhosis, liver involvement secondary to heart failure, and extensive trauma and muscle diseases. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based. The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *10*, *11*, and *12*). Following myocardial infarction, ALT serum levels begin to rise about 6 to 8 hours after the onset of pain. Peak values are reached after 48 to 60 hours, and the level falls to within the normal range by the fourth or fifth day. The peak values are approximately proportional to the amount of cardiac tissue damage.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of possible liver and cardiac diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that alanine amino transferase (ALT/SGPT) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this advice because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1035; Docket No. 78N-2290; Albumin test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of albumin test systems:

1. Identification: An albumin test system is a device used to measure the albumin concentration in serum and plasma. This device uses methods such as bromcresol green dye-binding, bromcresol purple dye-binding, hydroxyazo-benzene benzoic acid, radial immunodiffusion, tetrabromo-*m*-cresolsulfonphthalein, or tetrabromophenolphthalein. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that albumin test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy,

precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with numerous disease states involving primarily the liver or kidneys. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *13* and *14*). Many plasma proteins, notably albumin, are synthesized by the liver. Causes of low plasma albumin (hypoalbuminemia) generally involve: (a) decreased hepatic synthesis, (b) loss via kidney diseases or after extensive burns, (c) diet defects, (d) nonspecific, apparently minor, illnesses, and (e) hemodilution (reduced ratio of blood cells to plasma).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis and treatment of certain liver and kidney diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that albumin test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1040; Docket No. 78N-2291; Aldolase test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of aldolase test systems:

1. Identification. An aldolase test system is a device used to measure the activity of the enzyme aldolase in serum and plasma by methods such as hydrazone colorimetry or ultraviolet determination employing fructose-1, 6-diphosphate and nicotinamide adenine dinucleotide (reduced form) (NADH). Aldolase measurements are used in the diagnosis and treatment of the early stages of acute hepatitis and for certain muscle diseases such as progressive, Duchenne-type muscular dystrophy.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that aldolase test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of serum aldolase are used to assist in the diagnosis and treatment of the early stages of acute hepatitis and for certain muscle diseases (e.g., progressive, Duchenne-type muscular dystrophy). The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *15* and *16*). Serum aldolase measurements are most useful and of greatest clinical interest in diagnosing and treating diseases involving muscle disintegration. Values 10 to 50 times the upper level may be seen in some disorders, with the highest levels found in progressive, Duchenne-type muscular dystrophy. The highest serum levels of aldolose occur early in the disease, but as the capacity of the body cells to synthesize the enzyme decreases, serum levels also decrease. Trichinosis, gangrene, and prostate tumors are among other disease states in which elevated aldolase levels may be found.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of muscle disease or the early stages of hepatitis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that aldolase test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1045; Docket No. 78N-2292; Aldosterone test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of aldosterone test systems:

1. Identification: An aldosterone test system is a device used to measure the hormone aldosterone in serum and urine by methods such as radioimmunoassay (RIA) or chromatographic separation followed by RIA. Aldosterone measurements are used in the diagnosis and treatment of primary aldosteronism (a disorder caused by the excessive secretion of aldosterone by the adrenal gland), hypertension caused by primary aldosteronism, selective hypo-aldosternoism, edematous states, and other conditions of electrolyte imbalance.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that aldosterone test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitively, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Hypertension is a major clinical indication of malfunction in aldosterone physiology. Aldosterone measurements are used in the diagnosis and evaluation of primary aldosteronism, hypertension caused by

primary aldosteronism, selective hypoaldosteronism, edamatous states, and other conditions of electrolyte imbalance. Determination of aldosterone in adrenal vein plasma is of value in locating aldosterone-producing tumors. When used with suppression tests of plasma renin activity, measurement of aldosterone provides a decisive means of diagnosing primary aldosteronism. Test results are influenced by a large number of factors related to patient condition such as drug treatment, sodium intake, serum potassium levels, physical activity, and any factor that affects the effective extracellular fluid volume. The Panel believes that careful control of these factors is essential for optimum diagnosis and treatment. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature. (Ref. *17*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of hypertension caused by primary aldosteronism and other conditions. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that aldosterone test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1050; Docket No. 78N–2293; Alkaline phosphatase or isoenzymes test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of alkaline phosphatase or isoenzymes test systems:

1. Identification: An alkaline phosphatase or isoenzymes test system is a device used to measure alkaline phosphatase or its isoenzymes (a group of enzymes with similar biological activity) in serum and plasma by methods such as electrophoretic separation, *alpha*-naphthyl phosphate, *beta*-glycerophosphate, disodium phenyl phosphate, nitrophenyl phosphate, phenolphthalein phosphate, phenyl phosphate, thymol blue monophosphate, or thymolphthalein monophosphate. Measurements of alkaline phosphatase or its isoenzymes are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that alkaline phosphatase or isoenzymes test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with numerous disease states primarily involving the liver, bones, parathyroid gland, and intestines. The Panel believes that general controls would not provide sufficienf control over the device's accuracy precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *18* through *21*). Alkaline phosphatase measurement in plasma or serum is useful in the diagnosis and prognosis of liver, bone, parathyroid, and intestinal diseases, including metastatic cancers and viral and toxic hepatitis. Alkaline phosphatase enzymes hydrolyze phosphates at an alkaline pH. They are found in the bones, liver, kidneys, intestinal wall, lactating mammary glands, and placenata. The activity measured as total alkaline phosphatase in plasma is composed of the activity of several isoenzymes. Serum isoenzymes are multiple forms of a given enzyme from the patient; they originate in different body tissues and organs. Identification and measurement of individual alkaline phosphatase isoenzymes in plasma or serum help to establish whether an increased total alkaline phosphatase enzyme level originates in a patient's liver, bone, parathyroid gland, or intestines. Pathologically elevated plasma levels of alkaline phosphatase usually occur in liver disease or bone disease. Increases in the plasma levels of this enzyme normally occur in children until about the age of puberty, due to developing bones, and in the last trimester of pregnancy, from the placenta.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of liver, bone, parathyroid, and intestinal diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that alkaline phosphatase or isoenzymes test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1060; Docket No. 78N–2295; Delta-aminolevulinic acid test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *delta*-aminolevulinic acid test systems:

1. Identification: A *delta*-aminolevulinic acid test system is a device used to measure the level of *delta*-aminolevulinic acid (a precursor of porphyrin) in urine by methods such as ion exchange columns with colorimetry. *Delta*-aminolevulinic acid measurements are used in the diagnosis and treatment of lead poisoning and certain prophyrias (diseases affecting the liver, gastrointestinal, and nervous systems that are accompanied by increased urinary excretion of various heme compounds including *delta*-aminolevulinic acid).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that *delta*-aminolevulinic acid test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of lead poisoning and certain prophyrias. Test results can be affected by color formation due to substances other than *delta*-aminolevulinic acid. False-positive results may occur due to interferences from other constituents in the sample such as amino acids, ammonia, drug metabolites of barbiturates, alcohol and sulfonamides, and glucosamine, which may condense with the test reagent to form colored products. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *22* and *23*). *Delta*-aminolevulinic acid measurements are used to confirm lead poisoning and in the differential diagnosis of various types of porphyrias. Excessive urinary excretion of aminolevulinic acid is characteristic of porphyrin metabolism.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of lead poisoning and certain prophyrias. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that *delta*-aminolevulinic acid test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1065; Docket No. 78N–2296; Ammonia test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ammonia test systems:

1. Identification: An ammonia test system is a device used to measure ammonia levels in blood, serum, and plasma by methods such as enzymatic, ion exchange, ion-specific electrode, or photometric. Ammonia measurements are used in the diagnosis and treatment of severe liver disorders, such as cirrhosis, hepatitis, and Reye's syndrome.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that ammonia test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with severe liver disorders accompanied with existing or impending hepatic coma, such as cirrhosis, hepatitis, and Reye's syndrome. Treatment with dietary proteins may be monitored by this test. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *24, 25,* and *26*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of severe liver disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that ammonia test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1070; Docket No. 78N–2297; Amylase test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of amylase test systems:

1. Identification: An amylase test system is a device used to measure the activity of the enzyme amylase in serum and urine by methods such as amyloclastic, nephelometric, nitro-salicylate reduction, radial diffusion, saccharogenic, or starch-dye bound polymer. Amylase measurements are used primarily for diagnosis and treatment of pancreatitis (inflammation of the pancreas).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that amylase test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are primarily used for diagnosing and treating patients with pancreatitis, but they also are used for detecting mumps and perforated ulcers. Elevated amylase levels may also be found in a variety of disorders. Plasma amylase measurements are of limited diagnostic use for uremia, diabetic ketoacidosis, acute abdominal disorders, mumps, after morphine and alcohol administration, and occasionally

after myocardial infarction. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *27* through *30*). Amylase is an enzyme involved with the breakdown of dietary starch and glycogen into maltose. It is present in pancreatic juice and saliva, as well as in the liver and muscle. The enzyme also is excreted in the urine.

5. Risks to health: Misdiagnosis and inappropriate therapy. Failure of the device to perform satisfactorily may lead to error in the diagnosis of pancreatitis and other disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that amylase test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1075; Docket No. 78N–2298; Androstenedione test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of androstenedione test systems:

1. Identification: An androstenedione test system is a device used to measure androstenedione (a substance secreted by the testes, ovary, and adrenal glands) in serum by methods such as radioimmunoassay. Androstenedione measurements are used in the diagnosis and treatment of females with excessive levels of androgen (male sex hormone) production.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that androstenedione test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therepy that places the patient at risk unnecessarily. Test results are used for diagnosing and treating excessive levels of androgen production in females demonstrating hirsutism (abnormal hairiness), virilism (masculinity) or both. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *31* and *32*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of female patients with excessive levels of androgen production. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that adrostenedione test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is a sufficient information to establish a performance standard for this device.

Section 862.1080; Docket No. 78N–2299; Androsterone test systems.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of androsterone test systems:

1. Identification: An androsterone test system is a device used to measure the hormone androsterone in serum, plasma, and urine by methods such as radioimmunoassay. Androsterone measurements are used in the diagnosis and treatment of gonadal and adrenal diseases.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that androsterone test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used for diagnosing and treating patients with gonadal and adrenal disorders. Decreased values are found in persons with hypogonadism and hypoadrenalism, and increased values are found in persons with testicular tumors and adrenal carcinomas. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *33* and *34*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of gonadal and adrenal diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that androsterone test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient

information to establish a performance standard for this device.

Section 862.1085; Docket No. 78N-2300; Angiotensin I and renin test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of angiotensin I and renin test systems:

1. Identification: An angiotensin I and renin test system is a device used to measure the level of angiotensin I generated by renin in plasma by methods such as radiommunoassay. Angiotensin I measurements are used in the diagnosis and treatment of certain types of hypertension.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that angiotensin I and renin test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with hypertension disorders due to altered aldosterone physiology. Comparative measurements of renin activity in blood from the left and the right renal veins can assist in the diagnosis of unilateral renal disease, a treatable cause of hypertension. The Panel believes that the labeling of the device should include information on the source of the calibrator and standardization material, on the source of the stated values, and on the specificity of the device as it relates to precursors, subunits, and other features specific to the method. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *35* and *36*). Renin is a proteolytic enzyme secreted by a cellular complex in the kidneys. In the bloodstream it acts on a renin substrate (an alpha 2-globulin) to form angiotensin I. This decapeptide is further split by peptidase, located predominantly in the lungs, to form angiotensin II. Angiotensin II has two actions: (a) It acts directly on blood vessel walls causing vasoconstriction, and therefore helps to maintain blood pressure. (b) It stimulates the adrenal cortex to secrete aldosterone, which affects the sodium-potassium ion (and possibly the sodium-hydrogen ion) exchange across cell membranes. Aldosterone secretion is the most important factor affecting levels of body sodium. Aldosterone secretion is controlled by the renin-angiotensin mechanism which responds to changes in renal blood flow.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of hypertensive diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that angiotensin I and renin test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone be insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1095; Docket No. 78N-2301; Ascorbic acid test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ascorbic acid test systems:

1. Identification: An ascorbic acid test system is a device used to measure the level of ascorbic acid (vitamin C) in plasma, serum, and urine by methods such as 2,4-dinitrophenylhydrazine (spectrophotometric). Ascorbic acid measurements are used in the diagnosis and treatment of ascorbic acid dietary deficiencies.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that ascorbic acid test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with a dietary deficiency of ascorbic acid. A chronic deficiency of this essential nutrient may lead to scurvy. Supplemental intake of ascorbic acid may also affect certain other diagnostic tests. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *37* and *38*).

5. Risks to health: Misdiagnosis and inappropriate therapy. Failure of the device to perform satisfactorily may lead to error in the diagnosis of ascorbic acid deficiency. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that ascorbic acid test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1100; 78N-2302; Aspartate amino transferase (AST/SGOT) test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of aspartate amino transferase (AST/SGOT) test systems:

1. Identification: An aspartate amino transferase (AST/SGOT) test system is

a device used to measure the activity of the enzyme aspartate amino transferase (AST) (also known as serum glutamic oxaloacetic transaminase or SGOT) in serum and plasma by methods such as diazo, hydrazone colorimetry, nicotinamide adenine dinucleotide (NAD) reduction/nicotinamide adenine dinucleotide (reduced form) (NADH) oxidation, or the vanillin pyruvate method. Aspartate amino transferase measurements are used in the diagnosis and treatment of certain types of liver and heart disease.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that aspartate amino transferase (AST/SGOT) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of certain liver diseases (e.g., viral hepatitis) and myocardial infarction. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *39* through *42*). Test results are useful when evaluated in conjunction with other liver and cardiac tests. Aspartate amino transferase is a transaminase, a class of enzymes involved in the transfer of an amino group from an alpha-amino to an alpha-oxo acid. Transaminases are widely distributed in the body. Aspartate amino transferase is present in high concentrations in the heart, liver, skeletal muscle, kidney, and erythrocytes. Damage to any of these tissues may cause elevated levels of aspartate amino transferase in plasma. Some examples of conditions that can cause elevation of the enzyme are myocardial infarction, numerous liver disorders, skeletal muscle diseases, hemolytic anemias after trauma or surgery, and circulatory failure due to shock.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of liver or cardiac diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that aspartate amino transferase (AST/SGOT) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1110; Docket No. 78N-2303; Bilirubin (total or direct) test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of bilirubin (total or direct) test systems:

1. Identification: A bilirubin (total or direct) test system is a device used to measure the levels of bilirubin (total or direct) in plasma and serum by methods such as diazo colorimetry or enzymatic. Measurement of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, is used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder block.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that bilirubin (total or direct) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used for diagnosing and treating patients with liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder block. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *42a*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of liver, hemolytic, hematological, and metabolic disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that bilirubin (total or direct) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1115; Docket No. 78N-2304; Urinary bilirubin and its conjugates (nonquantitative) test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of urinary bilirubin and its conjugates (nonquantitative) test systems:

1. Identification: A urinary bilirubin and its conjugates (nonquantitative) test system is a device used to measure the levels of bilirubin conjugates in urine by methods such as azo-dyes colorimetric. Measurements of urinary bilirubin and its conjugates (nonquantitative) are used in the diagnosis and treatment of certain liver diseases.

2. Recommended classification: Class II (performance standards). The Panel

recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that urinary bilirubin and its conjugates (nonquantitative) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with certain liver diseases. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *42b*). Conjugated bilirubin is excreted in the urine when a patient has any kind of hepatitis that involves impairment or destruction of liver cells, in transportation defects such as Dubin-Johnson syndrome, and in obstructive jaundice.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of liver diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that urinary bilirubin and its conjugates (nonquantitative) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1120; Docket No. 78N-2305; Blood gases (P_{CO_2}, P_{O_2}) and blood pH test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of blood gases (P_{CO_2}, P_{O_2}) and blood pH test systems:

1. Identification: A blood gases (P_{CO_2}, P_{O_2}) and blood pH test system is a device used to measure certain gases in blood, serum, and plasma or the pH of blood, serum and plasma by methods such as electrode measurement with standard buffers. Measurements of blood gases (P_{CO_2}, P_{O_2}) and blood pH are used in the diagnosis and treatment of life-threatening acid-based disturbances.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that blood gases (P_{CO_2}, P_{O_2}) and blood pH test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of blood gases (P_{CO_2}, P_{O_2}) and blood pH are used to determine the acid-base status of critically ill patients with numerous metabolic and pulmonary diseases. Inaccurate test results may contribute to improper adjustment of respirators by health professionals. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *43* through *46*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of acid-base disturbances. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that blood gases (P_{CO_2}, P_{O_2}) and blood pH test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1130; Docket No. 78N-2307; Blood volume test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of blood volume test systems:

1. Identification: A blood volume test system is a device used to measure the circulating blood volume by methods such as ^{51}Cr labeling. Blood volume measurements are used in the diagnosis and treatment of shock, hemorrhage, and polycythemia vera (a disease characterized by an absolute increase in erythrocyte mass and total blood volume).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that blood volume test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used for diagnosing and treating patients with various disease states, including shock, hemorrhage and polycythemia vera. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel

based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *47*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in diagnosis of shock, hemorrhage, and polycythemia vera. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that blood volume test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1135; Docket No. 78N–2308; C-peptides of proinsulin test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of C-peptides of proinsulin test systems:

1. Identification: A C-peptides of proinsulin test system is a device used to measure C-peptide levels in serum, plasma, and urine by methods such as radioimmunoassay. Measurements of C-peptides of proinsulin are used in the diagnosis and treatment of patients with abnormal insulin secretion, including diabetes mellitus.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that C-peptides of proinsulin test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of abnormal insulin secretion, as in diabetes mellitus. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *48, 49,* and *50*). Because C-peptides are secreted by the pancreas in a 1:1 ratio with insulin, measurement of C-peptides of proinsulin is useful in assessment of pancreatic beta-cell secretory capacity, i.e., insulin secretion.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of diseases of abnormal insulin secretion, including diabetes mellitus. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that C-peptides of proinsulin test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1140; Docket No. 78N–2309; Calcitonin test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of calcitonin test systems:

1. Identification: A calcitonin test system is a device used to measure the thyroid hormone calcitonin (thyrocalcitonin) levels in plasma and serum by methods such as radioimmunoassay. Calcitonin measurements are used in the diagnosis and treatment of diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyroidism (excessive activity of the parathyroid gland).

2. Recommended classification: Class I (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that calcitonin test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in diagnosing and treating patients with thyroid and parathyroid diseases, including carcinoma and hyperparathyroidism. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *51* and *52*). Calcitonin measurement is most useful in assessing patients with hyperparathyroidism and thyroid carcinoma. Calcitonin is produced in the thyroid and it lowers levels of plasma calcium. Normally its secretion is stimulated by high serum ionized calcium levels. However, patients with carcinoma of the thyroid may have high levels of calcitonin in plasma.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of thyroid and parathyroid diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that calcitonin test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1145; Docket No. 78N–2310; Calcium test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following

recommendation regarding the classification of calcium test systems:

1. Identification: A calcium test system is a device used to measure the total calcium level in serum by methods such as alizarin sulfonate, atomic absorption, azo dye, cresolphthalein complexone, di(*O*-hydroxyphenylimine) ethane, fluorometric, ion specific electrode, methylthymol blue, permanganate and bromophenol blue titration, or titration with ethylenediaminetetraacetic acid (EDTA) and indicator. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease, and tetany (intermittent muscular contractions or spasms).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that calcium test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases including metastatic carcinoma, chronic renal disease, and tetany. Measurement of serum calcium is important in a variety of serious conditions. Tetany from hypocalcemia (abnormally low levels of serum calcium) may lead to death; lethargy and coma may result from hypercalcemia (abnormally high levels of serum calcium), and inaccurate measurement of serum calcium may lead to performance of inappropriate surgery. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *53*, *54*, and *55*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of parathyroid disease, a variety of bone diseases, chronic renal disease, and tetany. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that calcium test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1150; Docket No. 78N-2211; Calibrator.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of calibrators:

1. Identification: A calibrator is a device intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substance in human specimens.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that calibrators be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of purity concentration, stability, uniformity and reliability and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that the performance of a calibrator affects all related test results and may indirectly lead to misdiagnosis by causing results to be too high or too low. The Panel believes that general controls would not provide sufficient control over the device's purity, concentration, stability, uniformity, and reliability. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device, and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, calibrators and on the availability of standards prepared by the National Committee for Clinical Laboratory Standards (Approved Standard: ASC–2, Calibration reference materials and control materials in clinical chemistry). The Panel also noted that standards for calibration and control materials have been proposed by the International Federation of Clincial Chemistry and by the World Health Organization.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead indirectly to misdiagnosis based on improper calibration of test systems. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the panel recommendation and is proposing that calibrators be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1155; Docket No. 78N-2312; Human chorionic gonadotropin (HCG) test system for use in early detection of pregnancy.

The Clinical Chemistry Device Classification Panel and the Immunology Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of human chorionic gonadotropin (HCG) test systems:

1. Identification: A human chorionic gonadotropin (HCG) test system is a device used to measure HCG, a placental hormone, in plasma and urine by methods such as agglutination and radioimmunoassay. Measurements of HCG are used in the early detection of pregnancy and in the diagnosis and management of treatment of various conditions, such as trophoblastic tumors which may secrete HCG.

2. Recommended classification: Both Panels recommend classification of the device into class II (performance

standards). The Clinical Chemistry Device Classification Panel recommends that establishing a performance standard for this device be a medium priority. The Immunology Device Classification Panel recommends that establishing a performance standard for HCG test systems be a high priority.

3. Summary of reasons for recommendation: Both Panels recommend that HCG test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Tests results are used in the early detection of pregnancy or of trophoblastic tumors. The Clinical Chemistry Device Classification Panel believes that accuracy, precision, and specificity are characteristics associated with the safe and effective performance of the device. The Immunology Device Classification Panel believes that the device's reliability is influenced by the sensitivity, specificity, and stability of reagents. The Panels believe that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panels believe that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on their Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *56* and *57*). HCG is secreted by the placenta and is found in urine, plasma, amniotic fluid, colostrum, milk, and fetal tissues. This placental hormone appears within a few days after conception, and early confirmation of pregnancy is possible through its detection in urine or plasma. If HCG is present in the absence of pregnancy, it may indicate the presence of an HCG producing tumor. The accurate and sensitive measurement of HCG may allow these devices to be used to determine whether all of an HCG producing tumor has been removed surgically. Certain investigators have reported the use of anti-HCG serum in semi-quantitative and quantitative assays as an aid in dianosing choriocarcinoma and hydatidiform mole and have suggested its use in monitoring HCG levels in urine and serum to determine the effectiveness of cancer treatment (Refs. *58*, *59*, and *60*).

5. Risks to health: Misdiagnosis and inappropiate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of pregnancy or tumors. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA partially agrees with the recommendations of the Panels and is proposing that human chorionic gonadotropin (HCG) test systems intended for use in the early detection of pregnancy be classified into class II (performance standards). The agency believes that a performance standard is necessary for the device intended for this use because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device intended for this use. The agency also believes that there is sufficient information to establish a performance standard for the device intended for this use.

However, FDA disagrees with the recommendations of the Panels to classify into class II human chorionic gonadotropin (HCG) test systems intended for uses other than in the early detection of pregnancy, such as use in the diagnosis and management of treatment of trophoblastic tumors and carcinomas of the stomach, liver, pancreas, and breast (Refs. *58* and *59*). Because human chorionic gonadotrophin (HCG) test systems intended for these other uses are investigational, and are not in commercial distribution, the systems intended for these other uses are already classified into class III (premarket approval) by section 513(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)). Accordingly, these uses of the systems other than in the early detection of pregnancy are subject to premarket approval without the 30-month grace period applicable to class III devices of a type that were in commerical distribution on May 28, 1976, the enactment date of the Medical Device Amendments. If FDA approves for commercial distribution any use of human chorionic gonadotropin (HCG) test systems for other than in early pregnancy detection, or if FDA reclassifies the device by order following a petition under section 513(f)(2) and 21 CFR 860.134 justifying less stringent regulation of certain uses, the agency will amend § 862.1155 to add provisions describing, as appropriate, the statutory classification into class III of these additional approved uses of human chorionic gonadotropin (HCG) test systems, or any reclassification. FDA believes that investigations are still being done to show whether the device is safe and effective when intended for these other uses.

Anti-HCG serum intended for use in the determination of pregnancy was formerly regulated as a licensed biological under section 351 of the Public Health Service Act (42 U.S.C. 262). In a **Federal Register** notice published on February 16, 1979 (44 FR 10133), FDA announced the transfer of the administrative responsibility for the regulation of anti-HCG serum intended for this use from the Bureau of Biologics (BOB), FDA, to the Bureau of Medical Devices (BMD), FDA.

BMD is now responsible also for the regulation of human chorionic gonadotropin (HCG) test systems for uses other than pregnancy detection. This responsibility is consistent with its regulation of certain other biological in vitro diagnostic devices used as aids for the detection and management of cancer in humans; FDA announced the transfer from BOB to BMD of responsibility for these other devices in a notice published in the **Federal Register** of September 5, 1980 (45 FR 58964).

Section 862.1160; Docket No. 78N-2313; Bicarbonate/carbon dioxide test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of bicarbonate/carbon dioxide test systems:

1. Identification: A bicarbonate/carbon dioxide test system is a device used to measure bicarbonate/carbon dioxide in plasma, serum, and whole blood by methods such as coulometric, cresol red colorimetry, enzymatic, pH rate measurement, phenolphthalein colorimetry, titrimetric phenol red, or volumetric/manometric. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially life-threatening disorders associated with changes in body acid-base balance.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that bicarbonate/carbon dioxide test systems be classified into class II because there is a need for a performance standard that prescribes

for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with acid-base disorders (acidosis and alkalosis) and other potentially life-threatening metabolic and respiratory disorders. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 61 through 65). In normal healthy persons, the pH (hydrogen ion activity) of the extracellular fluid is 7.4, plus or minus 0.05. Even very small changes in the pH of the body fluid are important and result in physiological disturbances. Disturbances of hydrogen ion balance involve bicarbonate, and its measurement using a bicarbonate/carbon dioxide test system is vital in assessing this balance.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of acid-base disturbances. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that bicarbonate/carbon dioxide test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1165; Docket No. 78N-2314; Catecholamine (total) test system.

The Clinical Chemistry Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of catecholamine (total) test systems:

1. Identification: A catecholamine (total) test system is a device used to determine whether a group of similar hormone compounds (epinephrine, norepinephrine, and dopamine) are present in urine and plasma by methods such as chromatographic/fluorometric or electrophoretic. Catecholamine determinations are used in the diagnosis and treatment of adrenal medulla and hypertensive disorders, and for catecholamine-secreting tumors (pheochromocytoma, neuroblastoma, ganglioneuroma, and retinoblastoma).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that catecholamine (total) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at rish unnecessarily. Test results are used in the diagnosis and treatment of patients with adrenal medulla hypertensive disorders and for catecholamine-secreting tumors (pheochromocytoma, neuroblastoma, ganglioneuroma, and retinoblastoma). The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *66, 67,* and *68*). Adrenaline (epinephrine) and noradrenaline (norepinephrine) are catecholamines. Adrenaline is almost exclusively a product of the adrenal gland, while most noradrenaline is formed at certain nerve endings. Both catecholamines act on the cardiovascular system producing hypertension (high blood pressure). Certain tumors, whether adrenal or extra-adrenal, can produce catecholamines. These tumors include pheochromocytomas and neuroblastomas. Chemical diagnosis of such tumors can often be made by measuring the urinary levels of catecholamines.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of adrenal medulla and hypertensive disorders and catecholamine-secreting tumors. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that catecholamine (total) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1170; Docket No. 78N-2315; Chloride test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of chloride test systems:

1. Identification: A chloride test system is a device used to measure the level of chloride in plasma, serum, sweat, and urine by methods such as coulometric, ion-specific electrode, mercuric nitrate and diphenyl carbazone (titrimetric), mercuric thiocyanate, or phosphoric-tungstic acid (spectrophotometric). Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that chloride test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily.

Test results are used in the diagnosis and treatment of patients with electrolyte and metabolic disorders, including cystic fibrosis and diabetic acidosis. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *69* and *70*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to preform satisfactorily may lead to error in the diagnosis of electrolyte and metabolic disorders. Inappropriate therapy based on inaccurate diagnotic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that chloride test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1175; Docket No. 78N-2316; Cholesterol (total) test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of cholesterol (total) test systems:

1. Identification: A cholesterol (total) test system is a device used to measure cholesterol in plasma and serum by methods such as enzymatic/esterase-oxidase, ferric ion-sulfuric acid, or Lieberman-Burchard/Abell-Kendall colorimetric. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that cholesterol (total) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with a variety of disorders involving excess cholesterol in the blood and for evaluation of disorders of lipid and lipoprotein metabolism. Many medical experts believe that excess cholesterol in the blood is associated with coronary or vascular diseases. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *71* and *72*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of disorders involving excess cholesterol in the blood, many of which are believed to be associated with coronary or vascular diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that cholesterol (total) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1180; Docket No. 78N-2317; Chymotrypsin test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of chymotrypsin test systems:

1. Identification: A chymotrypsin test system is a device used to measure the activity of the enzyme chymotrypsin in blood and other body fluids and in feces by methods such as *N*-acetyl-*L*-tyrosine ethyl ester (ultraviolet) or *N*-benzoyl-*L*-tyrosine ethyl ester (ultraviolet). Chymotrypsin measurements are used in the diagnosis and treatment of pancreatic exocrine insufficiency.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that chymotrypsin test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with pancreatic exocrine insufficiency. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *73*, *74*, and *75*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diangosis of pancreatic exocrine insufficiency. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that chymotrypsin test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable

assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1185; Docket No. 78N-2318; Compound S (11-deoxycortisol) test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of compound S (11-deoxycortisol) test systems:

1. Identification: A compound S (11-deoxycortisol) test system is a device used to measure the level of compound S in plasma by methods such as radioimmunoassay. Compound S is a steroid intermediate in the biosynthesis of the adrenal hormone cortisol. Measurements of compound S are used in the diagnosis and treatment of certain adrenal and pituitary gland disorders resulting in clinical symptoms of masculinization and hypertension.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that compound S (11-deoxycortisol) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with certain adrenal and pituitary gland disorders resulting in clinical symptoms of masculinization and hypertension. Test results are also used for evaluating pituitary function together with the metyrapone test. The individual steroids measured in plasma most often are cortisol, 17-hydroxyprogesterone, and 11-deoxycortisol. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *76*). Measurements of compound S may be used to locate an enzymatic block in the synthesis of adrenal steroids and to evaluate pituitary function.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of adrenal and pituitary gland disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that compound S (11-deoxycortisol) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1190; Docket No. 78N-2319; Copper test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of copper test systems:

1. Identification: A copper test system is a device used to measure copper levels in plasma, serum, and urine by methods such as diethyldithiocarbamate (colorimetric) or oxalydihydrazide (colorimetric). Measurements of copper are used in the diagnosis and treatment of anemia, infections, inflammations, and Wilson's disease (a hereditary disease primarily of the liver and nervous system). Test results are also used in monitoring patients with Hodgkin's disease (a potentially fatal disease primarily of the lymph system).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that copper test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with anemia, Wilson's disease and numerous infections and inflammation. Test results are also used in monitoring patients with Hodgkin's disease. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *77, 78,* and *79*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of Wilson's disease, anemia, and infections. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that copper test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1195; Docket No. 78N-2320; Corticoids test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of corticoids test systems:

1. Identification: A corticoids test system is a device used to measure the level of corticoids (hormones of the adrenal cortex) in serum and plasma by methods such as radioassay. Measurements of corticoids are used in the diagnosis and treatment of disorders of the cortex of the adrenal glands, especially those associated with hypertension and electrolyte disturbances.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a

performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that corticoids test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnositic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used for diagnosis and treatment of patients with adrenal disorders, especially those associated with hypertension and electrolyte disturbances. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *80* and *81*). The adrenal cortex secretes three types of hormones that exert physiological action: glucocorticoids, affecting carbohydrate, protein, and lipid metabolism; mineralcorticoids, with effects on sodium and potassium distribution; and androgens that exert effects on reproductive function and promote growth by a nitrogen-retaining action.

5. Risks to health: Misdiagnosis and inappropriate therapy. Failure of the device to perform satisfactorily may lead to error in the diagnosis of adrenal dysfunction. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that corticoids test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1200; Docket No. 78N–2321; Corticosterone test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of corticosterone test systems:

1. Identification: A corticosterone test system is a device used to measure corticosterone (a steroid secreted by the adrenal gland) levels in plasma by methods such as radioimmunoassay. Measurements of corticosterone are used in the diagnosis and treatment of adrenal disorders such as adrenal cortex disorders and blocks in cortisol synthesis.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that corticosterone test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with adrenal cortex disorders due to suspected adrenal hormone excess and in locating blocks in the synthesis of cortisol. Corticosterone levels are elevated by administration of estrogens and during pregnancy. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *82* and *83*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of certain adrenal disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that corticosterone test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1205; Docket No. 78N–2322; Cortisol (hydrocortisone and hydroxycorticosterone) test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of cortisol (hydrocortisone and hydroxycorticosterone) test systems:

1. Identification: A cortisol (hydrocortisone and hydroxycorticosterone) test system is a device used to measure the cortisol hormones secreted by the adrenal gland in plasma and urine by methods such as fluorometric or radioimmunoassay. Measurements of cortisol are used in the diagnosis and treatment of disorders of the adrenal gland.

2. Recommended classification Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that cortisol (hydrocortisone and hydroxycorticosterone) test systems be classified into Class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with adrenal disorders, such as Cushing's syndrome (adrenal overactivity), Addison's disease (adrenal insufficiency), and adrenogenital syndromes. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity and specificity. The Penal believes that a standard would provide reasonable assurance of the safety and

effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data in which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *84*). Measurements of cortisol are useful in evaluating adrenocortical function. Cortisol in the blood is mostly protein-bound to a specific cortisol-binding globulin and to albumin. Only the unbound free fraction cortisol is physiologically active. Cortisol is metabolized in the liver and excreted in the urine. Cortisol has physiologic actions that influence carbohydrate, lipid and protein metabolism, body water distribution, electrolyte balance, and blood pressure regulation. It also has anti-inflammatory and immuno-suppressant actions. Plasma levels of cortisol are elevated by estrogens or aldactone therapy, and during pregnancy. Normal levels of cortisol depend on the proper functional relationship between the hypothalamus, pituitary, and adrenal cortex.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of adrenal and adrenogenital disorders. Inappropropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that cortisol (hydrocortisone and hydroxycorticosterone) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1210; Docket No. 78N-2323; Creatine test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of creatine test systems:

1. Identification: a Creatine test system is a device used to measure creatine (a substance synthesized in the liver and pancreas and found in biological fluids) in plasma, serum, and urine by methods such as adenosine triphosphate (ATP) creatine kinase (enzymatic) or conversion to creatinine. Measurements of creatine are used in the diagnosis and treatment of muscle diseases and endocrine disorders including hyperthyroidism.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that creatine test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with diseases associated with extensive muscle destruction, hyperthyroidism, and other endocrine diseases. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. the Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *85, 86,* and *87*). Creatine is synthesized in the liver and pancreas from three amino acids. After synthesis, creatine diffuses into the vascular system and is thus supplied to many kinds of cells, particularly those of muscle, where it is converted to creatine phosphate by the addition of phosphorous. Each day about 2 percent of the body's creatine and creatine phosphate are converted spontaneously into creatinine, a waste product excreted by the kidneys. Disease conditions associated with extensive muscle destruction may result in elevated levels of serum creatine as well as creatinuria (presence of creatine in urine).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of muscle diseases and endocrine disorders, such as hyperthyroidism. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that creatine test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1215; Docket No. 78N-2324; Creatine phosphokinase/creatine kinase or isoenzymes test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of creatine phosphokinase/creatine kinase or isoenzymes test systems:

1. Identification: A creatine phosphokinase/creatine kinase or isoenzymes test system is a device used to measure the activity of the enzyme creatine phosphokinase or its isoenzymes (a group of enzymes with similar biological activity) in serum and plasma by methods such as chromatographic separation, differential rate kinetic, fluorometric *N*-acetyl-*L*-cysteine, or nicotinamide adenine dinucleotide (NAD) reduction/nicotinamide adenine dinucleotide (reduced form) (NADH) oxidation. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infaraction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that creatine phosphokinase/creatine kinase or isoenzymes test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of creatine phosphokinase and of the several types of creatine phosphokinase

isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases, such as progressive Duchenne-type muscular dystrophy. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *88* through *92*). Creatine phosphokinase/creatine kinase (CPK/CK) is an enzyme found primarily in heart tissue, skeletal muscle, and the brain. The enzyme catalyzes the reversible transfer of high-energy phosphate from creatine phosphate to adenosine diphosphate (ADP) to form adenosine triphosphate (ATP). Serum CPK activity is elevated in muscle diseases, such as various types of muscular dystrophy. If skeletal muscle and brain disease may be ruled out, an increase in the CPK level is probably due to heart disease. Serum CPK begins to rise within 3 to 6 hours after a myocardial infarction. It returns to normal levels in about 3 to 4 days, earlier than other enzymes used in the diagnosis of infarction. The activity measured as total serum CPK includes that of several isoenzymes. Measurement of CPK isoenzymes is another useful tool in the diagnosis of myocardial infarction. Because different CPK isoenzymes predominate in nerve tissue, in smooth muscle (heart muscle) and in skeletal muscle, comparative measurements of these isoenzymes can be used as markers to detect and specifically locate damaged tissues or cell types. Following myocardial infarction, the rise in CPK activity is accompanied by the appearance in serum of one specific CPK isoenzyme, the MB isoenzyme, which, some experts feel, is specially indicative of infarction. Raised total CPK levels may result from other causes such as muscle injury, surgery, intramuscular injections, severe physical exertion, hypothyroidism, alcoholism acute psychotic episodes, and some cases of stroke and head injury.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of certain heart and muscle diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that creatine phosphokinase/creatine kinase or isoenzymes test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1225; Docket No. 78N-2326; Creatinine test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of creatinine test systems:

1. Identification: A creatinine test system is a device used to measure creatinine levels in plasma, serum, and urine, by methods such as alkaline picrate colorimetry, enzymatic, or ion-electrode-based enzymatic. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that creatinine test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Creatinine is the final product of the breakdown of creatine, an organic acid. Creatinine measurements are used in the diagnosis and treatment of patients with renal diseases, to monitor renal dialysis as a sign of rejection of a renal transplant, and as a calculation basis for measuring other urine analytes. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *93* and *94*). Automated methods for measuring creatinine levels have a plus or minus 14 percent day-to-day precision at 1.2 milligrams per deciliter (mg/dL), and about plus or minus 7.2 percent within-day precision at 1.3 mg/dL concentration.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of renal diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that creatinine test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1230; Docket No. 78N-2327; Cyclic AMP or cyclic GMP test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of cyclic AMP or cyclic GMP test systems:

1. Identification: A cyclic AMP or a cyclic GMP test system is a device used to measure the level of adenosine 3', 5'-monophosphate (cyclic AMP) or guanosine 3', 5'-monophosphate (cyclic GMP) in plasma, urine, and other body fluids by methods such as radio-immunoassay. Cyclic AMP and cyclic GMP measurements are used in the diagnosis and treatment of endocrime disorders, including hyperparathyroidism (overactivity of the parathyroid gland Cyclic AMP measurements may also be used in the diagnosis and treatment of Graves' disease (a disorder of the thyroid) and in the differentiation of causes of hypercalcemia (elevated levels of serum calcium).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that cyclic AMP of cyclic GNP test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results have diagnostic value in disorders of parathyroid function, mainly in hyperparathyroidism. Cyclic AMP measurements may also be used in the diagnosis and treatment of Gravers' disease, and in the differentiation of causes of hypercalcemia. Cyclic AMP is recognized as a regulator of hormones, enzymes, and other biologically active substances. The Panel believes that general controls would not provide sufficient control over the accuracy, precision, sensitivity, and specificity of these devices. The Panel believes that a standard would provide reasonable assurance of the safety and effectivenes of these devices and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *95, 96,* and *97*). Clinical significance is attached mostly to the levels of urinary cyclic AMP. Plasma cyclic AMP levels are mainly used in conjuction with urinary cyclic AMP measurements and are useful in the calculation of the renal fraction of total urinary cyclic AMP.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of these devices to perform satisfactorily may lead to error in the diagnosis of endocrine disorders including hyperparathyroidism and Graves' disease and in the differentiation of causes of hypercalcemia. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that cyclic AMP or cyclic GMP test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1240; Docket No. 78N–2329; Cystine test system.

The Clinical Chemistry Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of cystine test systems:

1. Identification: A cystine test system is a device used to measure the amino acid cystine in urine by methods such as chromatography or nitroprusside reaction (qualitative). Cystine measurements are used in the diagnosis of cystinuria (occurrence of cystine in urine). Patients with cystinuria frequently develop kidney calculi (stones).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that cystine test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with cystinuria as a cause of kidney calculi. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *98* and *99*). Normal cystine excretion varies with the amount of protein in the diet. Loss of cystine through precipitation in acidic urine may lead to stone formation. Elevations occur only in urine and not in plasma.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of cystinuria. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that cystine test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1245; Docket No. 78N–2330; Dehydroepiandrosterone (free and sulfate).

The Clinical Chemistry Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of dehydroepiandrosterone (free and sulfate) test systems:

1. Identification: A dehydroepiandrosterone (free and sulfate) test system is a device used to measure dehydroepiandrosterone (DHEA) and its sulfate in urine, serum, plasma, and amniotic fluid by methods such as radioimmunoassay. DHEA measurements are used in the diagnosis and treatment of DHEA-secreting adrenal carcinomas.

2. Recommended classification: Class II (performance standards).The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that DHEA (free and sulfate) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of DHEA-secreting adrenal carcinomas. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that

a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *100*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of patients with DHEA-secreting adrenal carcinomas. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that dehydroepiandrosterone (free and sulfate) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1250; Docket No. 78N–2331; Desoxycorticosterone test system.

The Clinical Chemistry Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of desoxycorticosterone test systems:

1. Identification: A desoxycorticosterone test system is a device used to measure desoxycorticosterone (DOC) in plasma and urine by methods such as radioimmunoassay. DOC measurements are used in the diagnosis and treatment of patients with hypermineralocorticoidism (excess retention of sodium and loss of potassium) and other disorders of the adrenal gland.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that desoxycorticosterone test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with hypermineralocorticoidism and other disorders of the adrenal gland. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *101*, *102*, and *103*). DOC is an active mineralocorticoid steroid secreted in small amounts (50 to 100 milligrams per day) by the adrenal cortex. Although it has a marked effect on the metabolism of water and electrolytes, it does not influence carbohydrate metabolism and cannot be used as a complete substitute for the secretion of hormones by the adrenal cortex. Measurement of DOC is useful in evaluating patients with suspected hypermineralocorticoidism in the presence of low plasma renin activity and low or normal aldosterone levels.

5. Risks to health: therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of patients with suspected hypermineralocorticoidism and other disorders of the adrenal gland. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that desoxycorticosterone test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1255; Docket No. 78N–2332; 2,3-diphosphoglyceric acid test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of 2,3-diphosphoglyceric acid test systems:

1. Identification: A 2,3-diphosphoglyceric acid test system is a device used to measure 2,3-diphosphoglyceric acid (2,3-DPG) in erythrocytes (red blood cells) by methods such as nicotinamide adenine dinucleotide (reduced form) (NADH)/phosphoglycerate mutase/adenosine triphosphate (ATP) (ultraviolet), or phosphoglycerate mutase (colorimetric). Measurements of 2,3-diphosphoglyceric acid are used in the diagnosis and treatment of blood disorders that affect the delivery of oxygen by erythrocytes to tissues and in monitoring the quality of stored blood.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that 2,3-diphosphoglyceric acid test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with blood disorders that cause defective oxygen transport to tissues. Results may also be used in monitoring of preservation of blood during storage. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *104* and *105*). The oxygen affinity of hemoglobin within the erythrocyte is lower than that of hemoglobin in solution. In erythrocytes, 2,3-diphosphoglycerate is present in high concentrations, and this compound has a substantial effect on oxygen binding by hemoglobin. Because it is preferentially bound to deoxyhemoglobin, it lowers the oxygen

affinity of hemoglobin and thus facilitates oxygen unloading. The unspecified second effect is due to intercellular pH changes.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of blood disorders that cause inadequate oxygen transport to tissues. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. Failure of the device to perform satisfactorily may cause error in the evaluation of the quality of stored blood.

FDA agrees with the Panel recommendation and is proposing that 2,3-diphosphoglyceric acid test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1260; Docket No. 78N-2333; Estradiol test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of estradiol test systems:

1. Identification: An estradiol test system is a device used to measure estradiol, an estrogenic steroid, in plasma by methods such as radioimmunoassay. Estradiol measurements are used in the diagnosis and treatment of various hormonal sexual disorders and in assessing placental function in complicated pregnancy.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that estradiol test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of various hormonal sexual disorders and in assessing placental function in complicated pregnancy. Measurement of estradiol is most useful in evaluating production of estrogens (estrone, estradiol, estriol) by the male and female gonads. Plasma estradiol measurements are also useful in establishing the time of ovulation and in assessing placental function. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *106*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of complicated pregnancy. Inappropriate therapy based on inaccurate diagnostic data may place the patient or fetus at risk.

FDA agrees with the Panel recommendation and is proposing that estradiol test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1265; Docket No. 78N-2334; Estriol test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of estriol test systems:

1. Identification: An estriol test system is a device used to measure estriol, an estrogenic steroid, in plasma, serum, and urine of pregnant females by methods such as radioimmunoassay. Estriol measurements are used in the diagnosis and treatment of fetoplacental distress in certain cases of high-risk pregnancy.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that estriol test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used to diagnose and treat fetoplacental distress in certain cases of high-risk pregnancy. Estriol measurements are most useful in the evaluation of intrauterine fetal viability. Estriol in maternal plasma during pregnancy is derived from fetal precursors that the placenta converts into estriol. After about the 24th gestational week, the intact fetoplacental unit synthesizes sufficient levels of estriol to provide a clinically useful means of monitoring its viability. Measurement of estriol in plasma is a sensitive diagnostic test for detecting fetoplacental distress in certain high-risk pregnancies. Plasma estriol levels rise until parturition in uncomplicated, normal pregnancies. However, in high-risk pregnancies where placental insufficiency becomes a factor, a significant, acute decline in maternal plasma estriol is observed. Low plasma estroil levels have been observed also in cases of anencephaly (congenital absence of the skull) and in intrauterine fetal death. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clincial experience with, the device and upon a review of the literature (Ref. *107*).

5. Risks to health: Misdiagnosis and inappropriate therapy. Failure of the device to perform satisfactorily may lead to error in the diagnosis of fetoplacental distress. Inappropriate thereapy based on inaccurate diagnostic data may place the patient or fetus at risk.

FDA agrees with the Panel recommendation and is proposing that estriol test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are

insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1270; Docket No. 78N-2335; Estrogens (total, in pregnancy) test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of estrogens (total, in pregnancy) test systems:

1. Identification: An estrogens (total, in pregnancy) test system is a device used to measure total estrogens in plasma, serum, and urine during pregnancy by methods such as radioimmunoassay. The device primarily measures estrone plus estradiol. Measurements of total estrogens are used in the diagnosis and treatment of fetoplacental distress in certain cases of high-risk pregnancy.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that estrogens (total, in pregnancy) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of total estrogens in maternal plasma, serum, or urine are used in the diagnosis and treatment of fetoplacental distress in certain cases of high-risk pregnancy. After about the 24th gestational week, the intact fetoplacental unit synthesizes sufficient levels of estrogens to provide a clinically useful means of monitoring its viability. Plasma estrogen levels rise until parturition in uncomplicated, normal pregnancies. However, in high-risk pregnancies where placental insufficiency becomes a factor, a significant, acute decline in total estrogens in maternal plasma is observed. Low plasma estrogen levels have been observed also in cases of anencephaly (congenital absence of the skull) and in intrauterine fetal death. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *107*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device may lead to error in the diagnosis of fetoplacental distress. Inappropriate therapy based on inaccurate diagnostic data may place the patient or fetus at risk.

FDA agrees with the Panel recommendation and is proposing that estrogens (total, in pregnancy) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1275; Docket No. 78N-2336; Estrogens (total, nonpregnancy) test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of estrogens (total, nonpregnancy) test systems:

1. Identification: An estrogens (total, nonpregnancy) test system is a device used to measure the level of estrogens (total estrone, estradiol, and estriol) in plasma, serum, and urine of males and nonpregnant females by methods such as radioimmunoassay. Measurement of estrogens (total, nonpregnancy) is used in the diagnosis and treatment of numerous disorders, including infertility, amenorrhea (absence of menses), differentiation of primary and secondary ovarian malfunction, estrogen secreting testicular and ovarian tumors, and precocious puberty in females.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that estrogens (total, nonpregnancy) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of numerous disorders, including infertility, amenorrhea (absence of menses), differentiation of primary and secondary ovarian malfunction, estrogen secreting testicular and ovarian tumors and precocious puberty in females. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *108*). In males secreting excessive estrogen, measurement of total estrogen may produce more valuable diagnostic information than measurement of estradiol because estrone sometimes is the primary estrogen being secreted. The importance of estrone in circulating plasma is uncertain. Measurement of plasma unconjugated estrogens (principally estrone and estradiol) is useful for evaluating ovarian function, differentiating primary and secondary ovarian malfunction in females, and in diagnosing, excessive estrogen secretion in males.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of estrogenic disturbance. Inapproporiate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that estrogens (total, nonpregnancy) test system be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the

device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1280; Docket No. 78N–2337; Estrone test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of estrone test systems:

1. Identification: An estrone test system is a device used to measure estrone, an estrogenic steroid, in plasma by methods such as radioimmunoassay. Estrone measurements are used in the diagnosis and treatment of numerous disorders, including infertility, amenorrhea, differentiation of primary and secondary ovarian malfunction, estrogen secreting testicular and ovarian tumors, and precocious puberty in females.

2. Recommended classification: Class II (performance stndards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that estrone test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of numerous disorders, including infertility, amenorrhea (absence of menses), differentiation of primary and secondary ovarian malfunction, estrogen secreting testicular and ovarian tumors, and precocious puberty in females. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *108*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of estrogenic disturbances. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that estrone test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1285; Docket No. 78N–2338; Etiocholanolone test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of etiocholanolone test systems:

1. Identification: An etiocholanolone test system is a device used to measure etiocholanolone in serum and urine by methods such as radioimmunoassay. Etiocholanolone is a metabolic product of the hormone testosterone and is excreted in the urine. Etiocholanolone measurements are used in the diagnosis and treatment of disorders of the testes and ovaries.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that etiocholanolone test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of numerous disorders of gonadal function. The 17-ketosteroid androgen etiocholanolone is a reduced form of testosterone excreted in the urine of both males and females. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *109*, *110*, and *111*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of testosterone disturbances. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that etiocholanolone test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1290; Docket No. 78N–2339; Fatty acids test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of fatty acids test systems:

1. Identification: A fatty acids test system is a device used to measure fatty acids in plasma and serum by methods such as conversion to ferric hydroxymates (colorimetric) or titrimetric. Measurements of fatty acids are used in the diagnosis and treatment of various disorders of lipid metabolism.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that fatty acids test systems be classified into class II because there is a need for a performance standard that prescribed for this device acceptable ranges of accuracy, precision, sensititivy, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with numerous disorders of lipid

metabolism. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *112*). Measurement of fatty acids is useful in the evaluation of stress and lipid metabolism. Measurements of fatty acids are generally used in conjunction with other lipid tests. Fatty acids are straight chain compounds, and in the blood the free fatty acids (FFA) or nonesterified fatty acids (NEFA) are carried by the plasma albumin. One molecule of albumin can carry as much as 10 molecules of fatty acid. All but one-third is readily removable under physiological conditions. The normal level of NEFA in human plasma is low, but the flux is very large and quite sensitive to exercise or other physical work, to the level of blood glucose, or to excitement or other emotional stress that liberates epinephrine. The NEFA are readily taken up by most tissues to satisfy energy requirements.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of lipid disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that fatty acids test systems be classified into class II (performing standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1295; Docket No. 78N–2340; Folic acid test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of folic acid test systems:

1. Identification: A folic acid test system is a device used to measure the vitamin folic acid in plasma and serum by methods such as radioimmunoassay. Folic acid measurements are used in the diagnosis and treatment of megaloblastic anemia, which is characterized by the presence of megaloblasts (an abnormal red blood cell series) in the bone marrow.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that folic acid test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with megaloblastic anemia. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient informaiton to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs, *113, 114,* and *115*). Folic acid (folate) and vitamin B12 are both essential for the normal maturation of the erythrocytes (red blood cells). Deficiency of either causes megaloblastic anemia, an anemia characterized by the presence of megaloblasts in the bone marrow. Both vitamins are important in purine and pyrimidine (and therefore nucleic acids) synthesis. Deficiency of folic acid, like that of vitamin B12, causes megaloblastic anemia; unlike that of vitamin B12, folate deficiency does not result in degeneration of the spinal cord.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of anemias. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that folic acid test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1300; Docket No. 78N–2341; Follicle-stimulating hormone test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of follicle-stimulating hormone test systems:

1. Identification: A follicle-stimulating hormone test system is a device used to measure follicle-stimulating hormone (FSH) in plasma, serum, and urine by methods such as radioimmunoassay. FSH measurements are used in the diagnosis and treatment of pituitary gland and gonadal disorders.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that follicle-stimulating hormone test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with pituitary and pituitary/gonadal dysfunction. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. 116). Measurement of follicle-stimulating hormone (FSH) is useful in the

evaluation of primary and secondary gonadal failure and pituitary function. FSH acts directly to stimulate follicular development in the ovary and gametogenesis in the testes. Primary ovarian failure can be differentiated from secondary failure, which results from decreased pituitary activity. FSH levels are increased in severe testicular damage, menopause, ovarian agenesis, and male climacteric. They are decreased in anorexia nervosa, estrogen administration, hypogonadotropic eunuchoidism, and neoplasms of the adrenal, ovary, or testis which secrete estrogens or androgens. The Panel recommended that the labeling of the device include information on the source of calibrator and standardization material, on the methods used to obtain stated values, and on the specificity of the method as it relates to precursors, subunits, and other features specific to the method.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of pituitary gland and gonadal disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that follicle-stimulating hormone test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1305; Docket No. 78N–2342; Formiminoglutamic acid (FIGLU) test system.

The Clinical Chemistry Device Classification Panel, an FDA Advisory committee, made the following recommendation regarding the classification of formiminoglutamic acid (FIGLU) test systems:

1. Identification: A formiminoglutamic acid (FIGLU) test system is a device used to measure formiminoglutamic acid in urine by methods such as tetrahydrofolate enzymatic (ultraviolet). FIGLU measurements obtained by this device are used in the diagnosis of anemias, such as pernicious anemia and congenital hemolytic anemia.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that formiminoglutamic acid (FIGLU) test systems be classified into class II because there is a need for a performance standard that prescribed for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with folic acid (folate) deficiency occurring in a variety of conditions, including anemias such as pernicious anemia and congenital hemolytic anemia. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *117* and *118*). Measurements of FIGLU are most useful in the evaluation of folate deficiency conditions. If a dose of histidine is given to a patient deficient in folic acid, urinary excretion of FIGLU is increased. Measurement of FIGLU excretion is useful in the diagnosis of megaloblastic anemias.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of anemias such as pernicious anemia (folate deficiency). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that formiominoglutamic acid (FIGLU) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1310; Docket No. 78N–2343; Galactose test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of galactose test systems:

1. Identification: A galactose test system is a device used to measure galactose in blood and urine by methods such as colorimetric, enzymatic, or ultraviolet. Galactose measurements are used in the diagnosis and treatment of the hereditary disease galactosemia (a disorder of galactose metabolism) in infants.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that galactose test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of newborn and infant patients with galactosemia, a rare congenital metabolic disorder that occurs once in 20,000 to 50,000 live births. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *119* and *20*). Galactose (a sugar) is necessary for the formation of cerebrosides and certain glycoproteins, and during lactation. Normally, an excess of galactose is converted rapidly to glucose. Deficiency of the enzyme galactose-phosphate uridyl transferase results in an inability to make this conversion, with resulting galactosemia (galactose in blood) and galactosuria (galactose in urine). Galactosesemia becomes apparent only after cow's milk has been added to the infant's diet. The

main features of the condition are vomiting and diarrhea with failure to thrive, hepatomegaly (swelling of the liver), jaundice and cirrhosis, cataract formation, mental retardation, renal tubular damage, and hypoglycemia. The condition is diagnosed by identifying galactose in the blood or urine and by demonstrating a deficiency of the enzyme in the erythrocytes (red blood cells).

5. Risks to health: Misdiagnosis and inappropriate therapy. Failure of the device to perform satisfactorily may lead to error in the diagnosis of hereditary galactosemia. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that galactose test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1315; Docket No. 78N–2344; Galactose-1-phosphate uridyl transferase test system.

The Clinical Chemistry Device Classification Panel an FDA advisory committee, made the following recommendation regarding the classification of galactose-1-phosphate uridyl transferase test systems:

1. Identification: A galactose-1-phosphate uridyl transferase test system is a device used to measure the activity of the enzyme galactose-1-phosphate uridyl transferase in erythrocytes (red blood cells) by methods such as uridine-5-diphosphoglucose/nicotinamide adenine dinucleotide (reduced form) (NADH) (ultraviolet). Measurements of galactose-1-phosphate uridyl transferase are used in the diagnosis and treatment of the hereditary disease galactosemia (a disorder of galactose metabolism) in infants.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that galactose-1-phosphate uridyl transferase test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of newborn and infant patients with galactosemia, a rare congential metabolic disorder that occurs once in 20,000 to 50,000 live births. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *121* and *122*). Galactose (a sugar) is necessary for the formation of cerebrosides and certain glycoproteins, and during lactation. Normally an excess of galactose is converted rapidly to glucose. Deficiency of the enzyme galactose-1-phosphate uridyl transferase results in an inability to make this conversion, with resulting galactosemia (galactose in blood) and galactosuria (galactose in urine). The condition becomes apparent only after cow's milk has been added to the infant's diet. The main features of the condition are vomiting and diarrhea with failure to thrive, hepatomegaly (swelling of the liver), jaundice and cirrhosis, cataract formation, mental retardation, renal tubular damage, and hypoglycemia. The condition is diagnosed by identifying galactose in the blood or urine and by demonstrating a deficiency of the enzyme in the erythrocytes (red blood cells). The latter test should be done on cord blood in all newborn infants with siblings who had galactosemia.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of hereditary galactosemia. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that galactose-1-phosphate uridyl transferase test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1320; Docket No. 78N–2345; Gastric acidity test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gastric acidity test systems:

1. Identification: A gastric acidity test system is a device used to measure the acidity of gastric fluid by methods such as sodium hydroxide/phenol red (titrimetric) or tubeless analysis. Measurements of gastric acidity are used in the diagnosis and treatment of patients with peptic ulcer, gastric carcinoma, Zollinger-Ellison snydrome (peptic ulcer due to gastrin-secreting tumor of the pancreas), and related gastric disorders.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that gastric acidity test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with peptic ulcer, gastric carcinoma, Zollinger-Ellison syndrome (pancreatic cell carcinoma), and related gastric disorders. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *123* and *124*). Hydrochloric acid is the

constituent of gastric juice that is most commonly tested in the laboratory. Achlorhydria (absence of hydrochloric acid) is associated with pernicious anemia or carcinoma of the stomach. Achlorhydria is also seen in certain apparently healthy older people. Increase in hydrochloric acid secretion is often associated with gastric ulcers. Additionally, in many functioning pancreatic cell adenomas and carcinomas (Zollinger-Ellison syndrome), the tumor cells produce increased and prolonged secretion of gastric acids.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of gastric disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that gastric acidity test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1325; Docket No. 78N-2346; Gastrin test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gastrin test systems:

1. Identification: A gastrin test system is a device used to measure the hormone gastrin in plasma and serum by methods such as radioimmunoassay. Measurements of gastrin are used in the diagnosis and treatment of patients with ulcers, pernicious anemia, and the Zollinger-Ellison syndrome (peptic ulcer due to a gastrin-secreting tumor of the pancreas).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that gastrin test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with ulcers, pernicious anemia, and the Zollinger-Ellison syndrome (peptic ulcer due to a gastrin-secreting tumor of the pancreas). The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *125* and *126*). Gastrin stimulates secretion of gastric acid, pepsin, intrinsic factor (a glycoprotein secreted by gastric glands), electrolytes, and water by the pancreas and liver. Gastrin also stimulates enzyme secretion by the pancreas, contraction of smooth muscle of the lower esophageal sphincter, stomach, intestines, gall bladder, and uterus.

5. Risks to health: Misdiagnosis and inappropriate therapy. Failure of the device to perform satisfactorily may lead to error in the diagnosis of gastric disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that gastrin test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1330; Docket No. 78N-2347; Globulin test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of globulin test systems:

1. Identification: A globulin test system is a device used to measure globulins (proteins) in plasma and serum by methods such as electrophoretic, nephelometric, tryptophan measurement, or turbidimetric. Measurements of globulins are used in the diagnosis and treatment of patients with numerous illnesses, including severe liver and renal disease, multiple myeloma, and other disorders of blood globulins.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that globulin test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with numerous illnesses, including severe liver and renal disease, multiple myeloma, and other disorders of blood globulins. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *127* and *128*). Globulins are a group of proteins relatively insoluble in water and soluble in salt solutions. Plasma globulins tend to increase when there is active tissue damage. Certain globulins (gamma group) are involved in antibody formation.

These immunoglobulins, or paraproteins, may be associated with myeloma disease and liver disorders. A normal person's globulin level varies about plus or minus 3 to 4 percent. The laboratory precision of the globulin test system is about plus or minus 9 percent at 3.5 grams per liter, and the medically significant precision at this level is about plus or minus 7 percent (Ref. *128*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of numerous generalized illnesses. Inappropriate therapy based on

inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that globulin test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1335; Docket No. 78N–2348; Glucagon test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of glucagon test systems:

1. Identification: A glucagon test system is a device used to measure the pancreatic hormone glucagon in plasma and serum by methods such as radioimmunoassay. Glucagon measurements are used in the diagnosis and treatment of patients with various disorders of carbohydrate metabolism, including diabetes mellitus, hypoglycemia, and hyperglycemia.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that glucagon test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with various disorders of carbohydrate metabolism, including diabetes mellitus, hypoglycemia, and hyperglycemia. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *129* and *130*). Glucagon, a single chain polypeptide consisting of 29 amino acids, is synthesized in the pancreas. Glucagon secretion, in contrast with that of insulin, is suppressed by hyperglycemia and stimulated by hypoglycemia. Proteins and amino acids stimulate production of both glucagon and insulin. Glucagon raises the blood glucose level and, paradoxically, stimulates insulin secretion. Determination of glucagon in serum or plasma is used for the differential diagnosis of hyperglycemia. A relationship appears to exist between glucagon and insulin in controlling glucose levels in circulating blood. Increased glucagon secretion has been associated with insulin resistance and impaired glucose tolerance in some diabetic patients. Measurement of glucagon is also useful in diagnosing idiopathic hypoglycemia caused by inadequate glucagon secretion, in drug related hypoglycemia, in hyperglycemia resulting from causes other than diabetes mellitus, and in screening for prediabetes.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of carbohydrate metabolism abnormalities. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that glucagon test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1340; Docket No. 78N–2349; Urinary glucose (nonquantitative) test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of urinary glucose (nonquantitative) test systems:

1. Identification: A urinary glucose (nonquantitative) test system is a device used to measure glucosuria (glucose in urine) by methods such as enzymatic or metallic reduction. Urinary glucose (nonquantitative) measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, hypoglycemia, and hyperglycemia.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that urinary glucose (nonquantitative) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatments of patients with various disorders of carbohydrate metabolism, including diabetes mellitus, hypoglycemia, and hyperglycemia. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *131*). Except for the very rare cases of galactosuria (galactose in the urine), glycose is the only sugar found in urine that is of pathological significance.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of carbohydrate metabolism abnormalities. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that urinary glucose (nonquantitative) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of

the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1345; Docket No. 78N–2350; Glucose test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of glucose test systems:

1. Identification: A glucose test system is a device used to measure glucose quantitatively in blood and other body fluids by methods such as copper reduction, ferricyanide, glucose oxidase, hexokinase or orthotoluidine. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that glucose test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagosis and treatment of patients with carbohydrate metabolism disorders, including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

In discussing this proposal, the Panel has been concerned with variability of results obtained with the same methods in different applications. This variability was demonstrated by an interlaboratory survey by Gochman, et al. (Ref. *133*) and illustrates the influence of various instrumental applications on analytical methods.

The Panel believes that general controls would not provide sufficient control over the device's accuracy precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *132* and *133*). Diabetes is a potentially fatal disease if proper treatment is not provided. A laboratory finding of low blood sugar is crucial in the diagnosis of pancreatic islet cell carcinoma. Failure to diagnose and treat neonatal hypoglycemia can lead to irreversible brain damage.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of carbohydrate metabolism disorders, including diabetes mellitus, idiopathic hypoglycemia, and neonatal hypoglycemia, and of pancreatic islet cell carcinoma. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that glucose test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1360; Docket No. 78N–2353; Gamma-glutamyl transpeptidase and isoenzymes test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *gamma*-glutamyl transpeptidase and isoenzymes test systems:

1. Identification: A *gamma*-glutamyl transpeptidase and isoenzymes test system is a device used to measure the activity of the enzyme *gamma*-glutamyl transpeptidase (GGTP) in plasma and serum by methods such as colorimetric, kinetic, or electrophorectic/isoenzymes. *Gamma*-glutamyl transpeptidase and isoenzyme measurements are used in the diagnosis and treatment of liver diseases such as alcoholic cirrhosis and primary and secondary liver tumors.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that *gamma*-glutamyl transpeptidase and isoenzymes test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with liver diseases such as alcoholic cirrhosis and primary and secondary liver tumors. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *134* through *138*). Measurement of *gamma*-glutamyl transpeptidase is useful in the evaluation of liver diseases. *Gamma*-glutamyl transpeptidase is found mainly in the liver, kidney, and pancreas. GGTP plasma levels are elevated in the same diseases that affect levels of liver alkaline phosphatase enzyme. GGTP, however, is a more sensitive indicator of liver disease, particularly for detection of cirrhosis, metastatic carcinoma, and hepatic infiltrations. Plasma *gamma*-glutamyl transferase is elevated in chronic alcoholism, and plasma levels correlate with alcohol consumption. Levels of GGTP also may be elevated in patients on anticonvulsant therapy.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of liver diseases, such as alcoholic cirrhosis and primary and secondary liver tumors. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that *gamma*-glutamyl transpeptidase and isoenzymes test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health

presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1365; Docket No. 78N–2354; Glutathione test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of glutathione test systems:

1. Identification: A glutathione test system is a device used to measure glutathione (the tripeptide of glycine, cysteine, and glutamic acid) in erythrocytes (red blood cells) by methods such as chromatographic or enzymatic (glutathione reductase). Glutathione measurements are used in the diagnosis and treatment of certain drug-induced hemolytic (erythrocyte destroying) anemias due to an inherited enzyme deficiency.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that glutathione test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with certain drug-induced hemolytic anemias due to erythrocyte sensitivity because of an inherited glucose-6-phosphate dehydrogenase (G-6-PD) deficiency. Other methods are available for diagnosis of these anemias, and the determination of reduced glutathione is an additional diagnostic aid. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *139*). This disorder may be detected by the glutathione stability test in which the glutathione content of blood is determined before and after aerobic incubation with acetylphenylhydrazine and glucose. A positive test shows a marked decrease in erythrocyte glutathione upon incubation and a slight change or no change in the case of nonsensitive erythrocytes.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of hemolytic anemias due to G-6-PD deficiency. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that glutathione test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1370; Docket No. 78N–2355; Human growth hormone test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of human growth hormone test systems:

1. Identification: A human growth hormone test system is a device used to measure the levels of human growth hormone in plasma by methods such as radioimmunoassay. Human growth hormone measurements are used in the diagnosis and treatment of disorders involving the anterior lobe of the pituitary gland.

2. Recommended classification: Class II performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that human growth hormone test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of disorders involving the anterior lobe of the pituitary gland. Because circulating levels of human growth hormone are normally low, diagnosis cannot be made by baseline hormone assay alone, but must be achieved by various suppression and stimulation tests with multiple sampling. The Panel recommended that the device's labeling contain information on physiological interferences, the sources of calibrator and standardization material, methods used to obtain stated values, and the specificity of the method as it relates to precursors, subunits, and other features specific to the method. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based. The Panel based its recommendation on the Panel memebers' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *140*). Measurement of human growth hormone, one of the major polypeptide hormones secreted and released by the pituitary gland, is important in evaluating anterior pituitary function. Hyposecretion during the human growth years results in dwarfism, whereas hypersecretion causes gigantism. In adulthood, hypersecretion results in enlargement of the skeletal extremities. It is important to diagnose pituitary dwarfism as early as possible to initiate treatment.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of anterior pituitary dysfunction. Inappropriate therapy based on inaccurate diagnosis data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that human growth hormone test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency

also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1375; Docket No. 78N–2356; Histidine test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of histidine test systems:

1. Identification: A histidine test system is a device used to measure free histidine (an amino acid) in plasma and urine by methods such as chromatographic or microbiological. Histidine measurements are used in the diagnosis and treatment of hereditary histidinemia characterized by excess histidine in the blood and urine often resulting in mental retardation and disordered speech development.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that histidine test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with the rate hereditary disease histidinemia. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *141, 142,* and *143*). Histidinemia is associated with deficiency of the enzyme histidase, which is required for the normal metabolism of histidine. Blood levels of histidine are raised, and histidine and a metabolite, imidazole pyruvic acid, appear in increased amounts in the urine. About half of the cases reported have shown mental retardation and speech defects, and the remainder appear normal. The results of dietary therapy are inconclusive.

5. Risks to health: Misdiagnosis and inappropriate therapy. Failure of the device to perform satisfactorily may lead to error in the diagnosis of hereditary histidinemia. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that histidine test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1380; Docket No. 78N–2357; Hydroxybutyric dehydrogenase test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hydroxybutyric dehydrogenase test systems:

1. Identification: A hydroxybutyric dehydrogenase test system is a device used to measure the activity of the enzyme *alpha*-hydroxybutric dehydrogenase (HBD) in plasma and serum by methods such as *alpha*-ketobutyric acid/nicotinamide adenine dinucleotide (reduced form) (ultraviolet), or by dinitrophenyl hydrazone measurement (colorimetric). HBD measurements are used in the diagnosis and treatment of myocardial infarction, renal damage (such as rejection of transplants), certain hematological diseases (such as acute leukemias and megaloblastic anemias) and, to a lesser degree, liver disease.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that hydroxybutyric dehydrogenase test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. HBD measurements are useful in the evaluation of myocardial infarctions, although these measurements are seldom used as the sole test for the diagnosis or confirmation of myocardial infarctions. Levels of the enzyme HBD are raised in myocardial infarction, megaloblastic anemias, acute leukemias, severe active renal damage (such as rejection of transplants) and, to a lesser degree, in liver disease. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *144*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of myocardial infarction, kidney damage, certain hematological diseases, and liver disease. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that hydroxybutyric dehydrogenase test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1385; Docket No. 78N–2358; 17-Hydroxycorticosteroids (17-ketogenic steroids) test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of 17-hydroxycorticosteroids (17-ketogenic steroids) test system:

1. Identification; A 17-hydroxycorticosteroids (17-ketogenic steroids) test system is a device used to measure corticosteroids that possess a dihydroxy acetone

$$(CH_2OHCOH)$$
$$\|$$
$$O$$

side chain on carbon 17 in urine by methods such as fluorometric, Porter Silber hydrazone, radioassay, or chromatography separation/Zimmerman and Zimmerman/Norymberski. Corticosteroids with this chemical configuration include cortisol, cortisone, 11-desoxycortisol, desoxycorticosterone and their tetra-hydroderivatives. This group of hormones is synthesized by the adrenal glands. Measurements of 17-hydroxycorticosteroids (17-ketogenic steroids) are used in the diagnosis and treatment of various diseases of the adrenal or pituitary glands and gonadal disorders.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends 17-hydroxycorticosteroids (17-ketogenic steroids) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with diseases of the adrenal or pituitary glands and gonadal disorders. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *145* through *150*). Measurement of 17-hydroxycorticosteroids is useful in the evaluation of adrenal cortex and anterior pituitary dysfunctions. Increased excretion of 17-hydroxycorticosteroids is sometimes observed in patients with severe stress, in persons with Cushing's syndrome (overactivity of the cortex of the adrenal gland), and in women with masculinization. Abnormally low levels of 17-hydroxycorticosteroids in urine are often found in patients with Addison's disease (underactivity of the adrenal gland) or hypofunction of the anterior pituitary gland.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of adrenal and gonadal disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that 17-hydroxycorticosteroids (17-ketogenic steroids) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1390; Docket No. 78N-2359; 5-Hydroxyindole acetic acid/serotonin test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of 5-hydroxyindole acetic acid/serotonin test systems:

1. Identification: A 5-hydroxyindole acetic acid/serotonin test system is a device used to measure 5-hydroxyindole acetic acid/serotonin in urine by methods such as the nitrous acid/nitrosonapthal. Measurements of 5-hydroxyindole acetic acid/serotonin are used in the diagnosis and treatment of carcinoid tumors of endocrine tissue.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that 5-hydroxyindole acetic acid/serotonin test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of carcinoid tumors. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *151*). Carcinoid tumors produce excessive amounts of serotonin. The presence of the metabolite of serotonin, 5-hydroxyindole acetic acid (5-HIAA) in the urine provides a diagnostic test for the carcinoid syndrome. Ingestion of foods containing serotonin and some drugs such as phenothiazines and cough syrup containing guaiacolate may cause falsely elevated values. When dietary interferences are excluded, a urinary excretion of more than 25 milligrams of 5-HIAA daily is diagnostic of carcinoid tumor.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of carcinoid tumors. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that 5-hydroxyindole acetic acid/serotonin test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1395; Docket No. 78N-2360; 17-Hydroxyprogesterone test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of 17-hydroxyprogesterone test systems:

1. Identification: A 17-hydroxyprogesterone test system is a device used to measure 17-hydroxyprogesterone (a Steroid) in plasma and serum by methods such as radioimmunoassay. Measurements of 17-hydroxyprogesterone are used in the diagnosis and treatement of various

disorders of the adrenal glands or the ovaries.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that 17-hydroxyprogesterone test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of various disorders of the adrenal glands and the ovary including congenital adrenal hyperplasia. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *152* and *153*). Measurement of the steroid 17-hydroxyprogesterone is most useful in the evaluation of adrenal C–21 hydroxylase deficiency. Clinical applications of 17-hydroxyprogesterone test systems are limited and apply to investigations of blocks in synthesis of corticosteroids. 17-hydroxyprogesterone is secreted by the adrenal glands and ovaries and is an intermediate in the formation of androgens, estrogens, and corticosteroids.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of adrenal and ovarian diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that 17-hydroxyprogesterone test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1400; Docket No. 78N–2361; Hydroxyproline test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hydroxyproline test systems:

1. Identification: A hydroxyproline test system is a device used to measure the amino acid hydroxyproline in urine by methods such as column chromatography and color development, or extraction plus chromatography with color by ninhydrin. Hydroxyproline measurements are used in the diagnosis and treatment of various collagen (connective tissue) diseases, bone diseases such as Paget's disease, and endocrine disorders such as hyperparathyroidism and hyperthyroidism.

2. Recommended classification: Class I (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation. The Panel recommends that hydroxyproline test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with certain collagen (connective tissue) disorders, bone diseases (e.g., Paget's disease), and endocrine disorders such as hyperparathyroidism and hyperthyroidism. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *154*). Collagen is a main supportive protein of skin, tendon, bone, cartilage, and connective tissue. The collagen diseases are a group of diseases that, although clinically distinct and not necessarily related etiologically, have in common widespread pathological changes in the collagen (connective tissue). The amino acid hydroxyproline is found especially in collagen proteins. Test results are very dependent on diet.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of bone and endocrine disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that hydroxyproline test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1405; Docket No. 78N–2362; Immunoreactive insulin test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of immunoreactive isulin test systems:

1. Identification: An immunoreactive insulin test system is a device used to measure immunoreactive insulin in serum and plasma by methods such as radioimmunoassay. Immunoreactive insulin measurements are used in the diagnosis and treatment of various carbohydrate metabolism disorders, including diabetes mellitus and hypoglycemia.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that immunoreactive insulin test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information.

Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of various carbohydrate metabolism disorders such as diabetes mellitus and hypoglycemia. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *155*). Simultaneous performance of the glucose tolerance test and insulin measurements by radioimmunoassay have been used in investigations of prediabetics and classification of diabetic patients for adequate therapy. In cases of hypoglycemia, when used with challenge tests, insulin measurement is helpful in differential diagnosis. Normally, insulin levels in plasma increase and decrease is parallel with blood glucose levels. However, patients with reactive hypoglycemia may have elevated levels of plasma insulin with normal levels of plasma glucose.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of various carbohydrate metabloism disorders, failure in proper assessment of prediabetics, or improper classification of diabetic patients for therapy. Additionally, failure to determine the cause of hypoglycemia could cause proper treatment to be delayed. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that immunoreactive insulin test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1410; Docket No. 78N–2363; Iron (non-heme) test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of iron (non-heme) test systems:

1. Identification: An iron (non-heme) test system is a device used to measure iron (non-heme) in serum and plasma by methods such as atomic absorption, bathophenanthroline colorimetry, photometric, or radiolabeled iron. Iron (non-heme) measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that iron (non-heme) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used, together with total iron binding capacity measurements and bone marrow studies, in the diagnosis and treatment of iron deficiency anemia, hemochromatosis, or chronic renal disease. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with the device and upon a review of the literature (Refs. *156, 157,* and *158*). Elevated serum iron levels may be found in conditions involving increased erythrocyte (red blood cell) destruction, decreased blood formation, or increased release of iron from body stores. Decreased values may be found in iron deficiency anemia or chronic renal disease. Iron is bound to transferrin, a protein, when it circulates in blood plasma. Transferrin is measured by the amount of iron which it can bind; this measurement is referred to as the total iron-binding capacity. Although measurement of serum iron alone does not usually provide adequate information for diagnosis, when used with iron-binding capacity determinations, the serum iron measurement is useful in evaluation of patients with disorders involving low or high levels of iron.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of iron deficiency anemia, hemochromatosis, or chronic renal disease. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that iron (non-heme) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1415; Docket No. 78N–2364; Iron-binding capacity test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of iron-binding capacity test systems:

1. Identification: An iron-binding capacity test system is a device used to measure iron-binding capacity in serum by methods such as bathophenanthroline, ferrozine (colorimetric), ion exchange resin with ascorbic acid, ion exchange resin with thioglycolic acid, or radiometric with ^{59}Fe. Iron-binding capacity measurements are used in the diagnosis and treatment of anemia.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that iron-binding capacity test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity and

specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of anemia. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *159, 160,* and *161*). Measurements of serum iron-binding capacity levels are useful in the differential diagnosis of anemia and as nonspecific indications of chronic disease. Although the serum iron level is reduced both in iron deficiency anemia and in association with chronic disorders, the iron-binding capacity is often increased in anemia, while it falls below normal in chronic disorders.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of anemia. Inappropriate therapy based on inaccurate data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that iron-binding capacity test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1420; Docket No. 78N-2365; Isocitric dehydrogenase test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of isocitric dehydrogenase test systems:

1. Identification. An isocitric dehydrogenase test system is a device used to measure the activity of the enzyme isocitric dehydrogenase in serum and plasma by methods such as hydrazone derivative of *alpha*-ketoglutarate (colorimetry) or *L*-isocitrate and nicotinamide adenine dinucleotide phosphate (NADP) (ultraviolet). Isocitric dehydrogenase measurements are used in the diagnosis and treatement of liver diseases such as viral hepatitis, cirrhosis, or acute inflammation of the biliary tract; pulmonary disease such as pulmonary infarction (local arrest or sudden insufficiency of the blood supply to the lungs); and diseases associated with pregnancy.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that isocitric dehydrogenase test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of liver disease such as viral hepatitis, cirrhosis, or acute inflammation of the biliary tract. Test results are also used in evaluation of pulmonary disease such as pulmonary infarction (local arrest or sudden insufficiency of the blood supply to the lungs) and diseases connected with pregnancy. During pregnancy, a sudden increase in isocitric dehydrogenase levels suggests possible placental damage. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: the Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *162* and *163*). Test results can be affected by a large variety of factors. Activity of isocitric dehydrogenase varies greatly with temperature, which needs to be carefully controlled to ensure greater accuracy of the test results. For example, 10° C change in temperature causes a 2.4-fold difference in enzyme activity. In addition, calcium chloride and sodium chloride inhibit activity of isocitric dehydrogenase. Because of the low activity of this enzyme in serum, the test requires great sensitivity.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of certain liver, pulmonary, and pregnancy associated diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that isocitric dehydrogenase test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1430; Docket No. 78N-2367; 17-Ketosteroids test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of 17-ketosteroids test systems:

1. Identification: A 17-ketosteroids test system is a device used to measure 17-ketosteroids in urine by methods such as chromatographic separation/ Zimmerman, or Zimmerman (spectrophotometric). Measurements of 17-ketosteroids are used in the diagnosis and treatment of disorders of the adrenal cortex and gonads and of other endocrine disorders, including hypertension, diabetes, and hypothyroidism.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that 17-ketosteroids test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk

unnecessarily. Test results are used in the diagnosis and treatment of patients with disorders of the adrenal cortex and gonads and with other endocrine disorders, including hypertension, diabetes, and hypothyroidism. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *164, 165,* and *166*). In men, total 17-ketosteroid values consist of androgens from the testes and steroids from the adrenal cortex. In women, most 17-ketosteroids originate in the adrenal cortex. Increased urinary excretion of 17-ketosteroids occurs in patients with severe stress, virilism (masculinization) in women, adrenal enlargement, hirsutism, and testicular tumors. Abnormally low levels occur in patients with nephrosis (disease of the kidneys), myxedema (a form of hypothyroidism), Addison's disease (a disease caused by hypofunction of the adrenal glands), gout, diabetes mellitus, and hypertension.

5. Risk to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of adrenal, gonadal, and endocrine diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that 17-ketosteroids test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1435; Docket No. 78N-2368; Urinary ketones (nonquantitative) test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of urinary ketones (nonquantitative) test systems:

1. Identification: A urinary ketones (nonquantitative) test system is a device used to identify ketones in urine by using reagents such as nitroprusside. Identification of urinary ketones is used in the diagnosis and treatment of acidosis (a condition characterized by abnormally high acidity of body fluid) or ketosis (a condition characterized by increased production of ketone bodies such as acetone) and for monitoring patients on ketogenic diets and patients with diabetes.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that urinary ketones (nonquantitative) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of acidosis or ketosis, and for monitoring patients on ketogenic diets and patients with diabetes. A ketone is an organic substance with a carbonyl or ketone group (–CO–) linking two carbon atoms. There are a number of ketones, the simplest being acetone, which is found in extremely small amounts in normal urine but in larger quantities in urine and blood of diabetic patients. The Panel believes that general controls would not provide control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *167, 168,* and *169*). Ketone bodies are products of incomplete fat metabolism. Their presence is indicative of acidosis. Marked increases of urinary ketones are observed in a variety of abnormal states, such as diabetes mellitus. Measurements of ketones in urine are very useful when changes in diabetic therapy are prescribed.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of acidosis or ketosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that urinary ketones (nonquantitative) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1440; Docket No. 78N-2369; Lactate dehydrogenase test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of lactate dehydrogenase test systems:

1. Identification: A lactate dehydrogenase test system is a device used to measure the activity of the enzyme lactate dehydrogenase in serum by methods such as tetrazolium INT (2-*p*-iodophenyl-3-*p*-nitrophenyl tetrazolium chloride) dye-diaphorase, 2,4-dinitrophenylhydrazine, or nicotinamide adenine dinucleotide (NAD) reduction/nicotinamide adenine dinucleotide (reduced form) (NADH) oxidation. Lactate dehydrogenase measurements are used in the diagnosis and treatment of liver diseases such as acute viral hepatitis, cirrhosis, and metastatic carcinoma of the liver, cardiac diseases such as myocardial infarction, and tumors of the lungs or kidneys.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that lactate dehydrogenase test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate

inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of liver diseases such as acute viral hepatitis, cirrhosis, and metastatic carcinoma of the liver, cardiac diseases such as myocardial infarction, and tumors of the lungs or kidneys. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificicity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *170, 171,* and *172*). Lactate dehydrogenase (LDH) measurements are used widely to diagnose liver diseases such as acute viral hepatitis and cirrhosis in which levels of LDH often a moderately elevated. High serum levels of LDH may be found in metastatic carcinoma of the liver. Test results are also used in diagnosis of tumors in lungs or kidneys, as well as in diagnosis of such cardiac diseases as myocardial infarction. Highly elevated levels are observed shortly after the onset of myocardial infarction and persist for a longer time than elevated GOT (glutamic oxaloacetic transaminase) values. For this reason, comparing the levels of LDH and GOT is useful in the recognition of myocardial infarction.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of certain cardiac and liver diseases and malignant tumors. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that lactate dehydrogenase test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1445; Docket No. 78N-2370; Lactate dehydrogenase isoenzymes test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of lactate dehydrogenase isoenzymes test systems:

1. Identification: A lactate dehydrogenase isoenzymes test system is a device used to measure the activity of lactate dehydrogenase isoenzymes (a group of enzymes with similar biological activity) in serum by methods such as chromatographic separation, differential rate kinetic, or electrophoretic. Measurement of lactate dehydrogenase isoenzymes is used in the diagnosis and treatment of liver diseases, such as viral hepatitis, and myocardial infarction.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that lactate dehydrogenase isoenzymes test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of liver disorders, such as viral hepatitis, and myocardial infarction. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *173, 174,* and *175*). The enzyme lactate dehydrogenase (LDH) is present in almost all the tissues of the body (liver, heart, kidney, skeletal muscle) in significantly larger concentrations than those normally found in serum. Thus, in tissue destroying disease, even a small mass of damaged tissue can increase the serum level of LDH. The LDH of human serum consists of five enzymes (LDH isoenzymes) that are very similar in their biological activity but that may be differentiated by variations in physical properties. Because each tissue contains various ratios of the 5 isoenzymes, diffusion from a given tissue may change the ratio of the enzymes found in the serum. LDH1 and LDH5 are the most significant LDH isoenzymes in identifying the tissue responsible for the increased serum LDH levels. The LDH1 isoenzyme is elevated in myocardial infarction and hemolytic anemia. LDH5 isoenzyme is elevated in diseases of the liver.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of myocardial infarction or liver disease. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that lactate dehydrogenase isoenzymes test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1450; Docket No. 78N-2371; Lactic acid test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of lactic acid test systems:

1. Identification: A lactic acid test system is a device used to measure lactic acid in whole blood and plasma by methods such as enzymatic. Lactic acid measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that lactic acid test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of

accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in evaluating the acid-base status of patients who are suspected of having lactic acidosis. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *176* and *177*). An elevated blood lactic acid level is a characteristic of conditions associated with anoxia (oxygen deprivation), such as shock, pneumonia, and congestive heart failure. Results of lactic acid measurements are influenced by the blood specimen collection procedure employed, the stability of the specimen, and the temperature and the pH of the reaction mixture.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of lactic acidosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that lactic acid test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1455; Docket No. 78N-2372; Lecithin-sphingomyelin ratio in amniotic fluid test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of lecithin-sphingomyelin ratio in amniotic fluid test systems:

1. Identification: A lecithin-sphingomyelin ratio in amniotic fluid test system is a device used to measure the lecithin-sphingomyelin ratio in amniotic fluid by methods such as chromatographic separation, electrophoretic, or colorimetric. Lecithin and sphingomyelin are phospholipids (fats or fat-like substances contaning phosphorus). Measurements of the lecithin-sphingomyelin ratio in amniotic fluid are used in evaluating fetal maturity.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that lecithin-sphingomyelin ratio in amniotic fluid test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the evaluation of fetal maturity. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *178* and *179*). Fetal lung maturity is related to the lecithin-sphingomyelin (L/S) ratio, with increased lecithin occurring after the 34th week of gestation in a normal pregnacy. L/S ratio measurements are very useful in the management of high-risk pregnancies with maternal diseases, e.g., toxemia, renal disease, or diabetes mellitus, in which fetal lung development may deviate significantly from that in normal gestation. Signs of fetal distress (e.g., abnormal fetal heart rate) or severe fetal jeopardy (e.g., lessening levels of maternal estriol, an estrogenic hormone) are indications for L/S ratio measurements and for consideration of early delivery if the ratio shows adequate pulmonary maturity. Lecithin appears to be essential to proper lung development. An L/S ratio of less than 1.0 shows that the newborn will probably develop respiratory distress. An L/S ratio above 2.0 usually indicates adequate fetal lung maturity.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an inaccurate clinical diagnosis and incorrect timing of delivery. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that lecithin-sphingomyelin ratio in amniotic fluid test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1460; Docket No. 78N-2373; Leucine aminopeptidase test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of leucine aminopetidase test systems:

1. Identification: A leucine aminopeptidase test system is a device used to measure the activity of the enzyme leucine aminopeptidase in serum, plasma, and urine by methods such as *L*-leucine-4-nitroanilide (colorimetric) or *L*-leucyl-*beta*-naphthylamide. Leucine aminopeptidase measurements are used in the diagnosis and treatment of liver diseases such as viral hepatitis and obstructive jaundice.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that leucine aminopeptidase test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test

results are used in the diagnosis and treatment of patients with liver disorders such as viral hepatitis and obstructive jaundice. The Panel belives that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable asssurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *180* through *183*). LAP measurement is a sensitive and reasonably specific indication of hepatobiliary disease (diseases pertaining to the liver and the bile or the biliary ducts). Determination of LAP is of greatest value in discrimination between hepatobiliary tract and other diseases. However, because LAP test results overlap in various intraextrahepatic diseases (diseases within the liver and outside the liver), differentiation of these conditions cannot be based solely on this single test.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to perform satisfactorily may lead to error in the diagno;sis of certain liver diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that leucine aminopeptidase test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1465; Docket No. 78N-2374; Lipase test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of lipase test systems:

1. Identification: A lipase test system is a device used to measure the activity of the enzyme lipase in serum by methods such as oil emulsion/ thymolphthalein (titrimetric), olive oil emulsion (turbidimetric), or lipase-esterase, enzymatic (photometric). Lipase measurements are used in diagnosis and treatment of diseases of the pancreas such as acute pancreatitis and obstruction of the pancreatic duct.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that lipase test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of acute pancreatitis and obstruction of the pancreatic duct. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *184* through *190*). Significantly elevated lipase values may be found in acute pancreatitis and obstruction of the pancreatic ducts. In acute pancreatitis, serum levels of lipase and amylase are elevated. However elevation of lipase values may be more accentuated, and these levels remain elevated for a longer period. Lipase hydrolyzes fats into fatty acids and glycerol. Serum lipase is usually determined by measurement of the fatty acids liberated. Technical difficulties have been associated with the development of methods used to assay lipase activity. Lipase test results can vary depending on the different fat emulsions used as substrates, such as olive oil or tributyrin, and on a number of other factors related to the substrate and conditions of analysis.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of pancreatic disease. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that lipase test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1470; Docket No. 78N-2375; Lipid (total) test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of lipid (total) test systems:

1. Identification: A lipid (total) test system is a device used to measure total lipids (fats or fat-like substances) in serum and plasma by methods such as chromatographic derivative or sulfophosphovanillin colorimetry. Lipid (total) measurements are used in the diagnosis and treatment of various diseases involving lipid metabolism and atherosclerosis.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that lipid (total) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with various diseases involving lipid metabolism and atherosclerosis. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel

members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *191*). Plasma total lipids may be measured directly or as the sum of cholesterol, triglycerides, and phospholipids. Although findings of total lipids at levels above normal (about 1 gram per deciliter) are associated with increased incidence of atherosclerosis, these findings are too nonspecific and cannot compare in clinical utility to separate measurements of levels of plasma cholesterol and triglycerides.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of lipid disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that lipid (total) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1475; Docket No. 78N–2376; Lipoprotein test system.

The Clinical Chemistry Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of lipoprotein test systems:

1. Identification: A lipoprotein test system is a device used to measure lipoprotein in serum and plasma by methods such as colorimetric, electrophoretic separation, microdensitometry, nephelometric, radial immunodiffusion, or turbidimetric. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that lipoprotein test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Lipoprotein measurements are used in the evaluation of hyperlipoproteinemia (increased lipoprotein levels) and in the diagnosis and treatment of patients with numerous diseases affecting lipid metabolism, including diabetes mellitus, artherosclerosis, and liver and renal diseases. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity, the Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 192 through 195). Hyperlipoproteinemia may be considered as a primary inherited disease, while hyperbetalipoproteinemia (increased beta, or low density, lipoprotein) may be secondary to one of a variety of disorders such as liver cirrhosis, kidney nephrosis, pancreatitis, or severe diabetes mellitus. Serum beta lipoprotein acts as a transporter of cholesterol or triglycerides. Increased levels of serum beta lipoprotein, as well as increased cholesterol levels, are believed to be a causative factor in atherosclerosis. Because measurements of lipoprotein alone may not provide an accurate diagnosis, they should be considered with other measurements such as those of plasma cholesterol. Physicians who have diagnosed a patient as having primary hyperlipoproteinemia should determine whether the patient has the heritable or the nonheritable form.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of lipid disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that lipoprotein test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1484; Docket No. 78N–2378; Luteinizing hormone test system.

The Clinical Chemistry Device Classification Panel and the Immunology Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of luteinizing hormone test systems:

1. Identification: A luteinizing hormone test system is a device used to measure luteinizing hormone in serum and urine by methods such as radioimmunoassay. Luteinizing hormone measurements are used in the diagnosis and treatment of gonadal dysfunction.

2. Recommended classification: Class II (performance standards). The Clinical Chemistry Device Classification Panel recommends that establishing a performance standard for this device be a low priority. The Immunology Device Classification Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panels recommend that luteinizing hormone (LH) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of gonadal dysfunction. The major use of LH measurement is to track the physiological events preceding ovulation. In the male, LH measurements are used to evaluate gonadal dysfunction. LH measurements are also used in assessment of gonadotropin-producing tumors, in evaluation of pituitary function, and in the differential diagnosis of amenorrhea (absence or abnormal cessation of menstruation). Test results are also used in evaluation of infertility, anovulatory cycles, and as a measurement of response to clomiphene (a drug used to stimulate ovarian function) administration. Because of the immunological cross-reactivity of luteinizing hormone with related glycoprotein hormones, the Clinical Chemistry Panel believes that it is essential that the labeling of the product

include information concerning source of calibrator and standardization material as well as information concerning methods the manufacturer used to obtain stated values and information concerning specificity as it relates to precursors, subunits, and other features specific to the method. The Clinical Chemistry Panel also believes that the labeling should also include warnings about interference in test results due to the effects of estrogens, birth control pills, and pregnancy. The Panels believe that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panels believe that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *196* through *199*). Luteinizing hormone (LH) in the female causes ovulation and steroid production. In the male, LH stimulates production of androgens and estrogens. LH is elevated and follicle-stimulating hormone (FSH) is low in conditions such as Stein-Leventhal syndrome (a disease of the ovary) and FSH deficiency. Both LH and FSH are elevated in primary ovarian failure and low in primary hypopituitarism. Numerous cross-reactivity problems have been encountered in LH assays. Immunologic cross-reactivity is present between LH and the related glycoprotein hormones FHS, TSH, and HCG due to structural similarities. All four contain two peptide chains, or subunits, designated alpha and beta. Each of the beta-subunits is distinct in composition and appears to confer biologic specificity on the hormone. The alpha-subunits, however, appear sufficiently similar to be interchangeable with one another, causing test cross-reactivity. This structural similarity has contributed to problems in obtaining specific antisera. Although biologic activity and immunologic activity of the hormone do not always correlate, radioimmunoassay is recognized as offering the greatest sensitivity and precision.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of gonadal dysfunction. In appropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panels' recommendation and is proposing that luteinizing hormone test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1490; Docket No. 78N–2379; Lysozyme (muramidase) test system.

The Clinical Chemistry Device Classification Panel and the Immunology Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of lysozyme (muramidase) test systems:

1. Identification: A lysozyme (muramidase) test system is a device used to measure the activity of the bacteriolytic enzyme lysozyme (muramidase) in serum, plasma, leukocytes, and urine by methods such as immunochemical or spectrophotometric (*Micrococcus lysodeikticus*). Lysozyme measurements are used in the diagnosis and treatment of monocytic leukemia and kidney disease.

2. Recommended classification: The Immunology Device Classification Panel recommends that the device be classified into class I (general controls) and that there be no exemptions. The Clinical Chemistry Device Classification Panel recommends that the device be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Immunology Device Classification Panel recommends that lysozyme (muramidase) test systems be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Clinical Chemistry Device Classification Panel recommends that lysozyme (muramidase) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with leukemia (using leucocytes to distinguish monocytic leukemia from other types of leukemia), and kidney diseases using urinary tests. The Clinical Chemistry Device Classification Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *200* through *203*). Determination of lysozymes is useful in the evaluation of leukemia. Leukocytes contain significant amounts of lysozymes. The basic enzyme is also present in saliva, tears, and many body fluids and functions as an antibacterial agent. Lysozyme catalyzes the hydrolysis (breakdown) of cell walls of several types of bacteria, with maximum activity toward *Micrococcus lysodeikticus*. The degree of cell wall breakdown (as measured by a spectrophotometer) is proportional to the amount of lysozyme present in the sample. Serum and urine lysozyme estimations are useful in classifying acute monocytic leukemia (in which the predominating white cells are identified as monocytes) and in assessing the degree of remission achieved as a result of treatment.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of leukemia and renal disease. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Clinical Chemistry Device Classification Panel's recommendation and is proposing that lysozyme (muramidase) test systems be classified into class II (performance standards). FDA disagrees with the Immunology Device Classification Panel recommendation that this device be classified into class I. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of

the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

§862.1495; Docket No. 78N–2380; Magnesium test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of magnesium test systems:

1. Identification: A magnesium test system is a device used to measure magnesium levels in serum and plasma by methods such as atomic absorption, ion-specific electrode, photometric, or titrimetric. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnesemia (abnormally high plasma levels of magnesium).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that magnesium test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of hypomagnesemia and hypermagnesemia. Hypomagnesemia can result in tetany (muscle spasms), while hypermagnesemia can lead to possible neuromuscular irritability. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *204* through *207*). Magnesium is present with calcium in bone salts and tends to move in and out of bone with calcium. It is also present in all cells of the body in much higher concentrations than those in the extracellular fluid, and tends to enter and leave cells under the same conditions as do potassium and phosphate. A patient who has diarrhea can lose large quantities of magnesium in the feces. Diarrhea is the most common cause of significantly low plasma mangesium levels. Certain drugs, such as calcium gluconate or mercurial diuretics, interfere with magnesium measurements. The accuracy of the photometric method is only plus or minus 10 percent; the preferred method is atomic absorption spectrophotometry.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of hypomagnesemia, which may lead to tetany, and hypermagnesemia, which may lead to possible neuromuscular irritability. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that magnesium test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and efectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1500; Docket No. 78N–2381; Malic dehydrogenase test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of malic dehydrogenase test systems:

1. Identification: A malic dehydrogenase test system is a device that is used to measure the activity of the enzyme malic dehydrogenase in serum and plasma by methods such as oxalacetic acid/nicotinamide adenine dinucleotide (reduced form) (NADH) oxidation (ultraviolet). Malic dehydrogenase measurements are used in the diagnosis and treatment of muscle and liver diseases, myocardial infarctions, cancer, and blood disorders such as myelogenous (produced in the bone marrow) leukemias.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that malic dehydrogenase test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with muscle and liver diseases. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *208*). Measurements of malic dehydrogenase are useful in the evaluation of muscle and liver disorders. Elevated serum values occur in patients with heart attacks, liver and blood disorders, and cancer. This enzyme test is of limited clinical usefulness because it is not specific.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of cancer, heart attacks, and muscle, liver, and blood disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that malic dehydrogenase test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1505; Docket No. 78N–2382; Mucopolysaccharides test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the

classification of mucopolysaccharides test systems:

1. Identification: A mucopolysaccharides test system is a device used to measure the levels of mucopolysaccharides in serum, plasma, and urine by methods such as colorimetric. Mucopolysaccharide measurements are used in the diagnosis and treatment of various inheritable disorders that affect bone and connective tissues, such as Hurler's, Hunter's Sanfilippo's Scheie's Morquio's and Maroteaux-Lamy syndromes.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The panel recommends that mucopolysaccharides test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in evaluation of inheritable disorders including Hurler's Hunter's, Sanfilippo's, Scheie's, Morquio's, and Maroteaux-Lamy syndromes. These diseases, which have in common an error in the metabolism of mucopolysaccharides (complexes of proteins and sugars), are characterized by abnormality in bone development due to various defects of bone, cartilage, and connective tissue. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *209, 210,* and *211*). Test results are used to confirm the diagnosis of inheritable disorders of mucopolysaccharide metabolism. Usually, mucopolysaccharide levels are determined by measurement of uronic acid. However, in some mucopolysaccharides that lack uronic acid, analyses are limited to hexosamine measurement. Erroneous results are possible because of interferences due to the presence of hexosamines in glycoproteins and glycolipids.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis or evaluation of certain inheritable diseases affecting bone and connective tissues. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that mucopolysaccharides test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1510; Docket No. 78N-2383; Urinary nitrite (nonquantitative) test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of urinary nitrite (nonquantitative) test systems:

1. Identification: A urinary nitrite (nonquantitative) test system is a device used to identify nitrite in urine by methods such as diazo (colorimetric). Urinary nitrite identification is used in the diagnosis and treatment of urinary tract infection of bacterial origin.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that urinary nitrite (nonquantitative) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of urinary tract infection of bacterial origin. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *212, 213,* and *214*). Urinary nitrite test systems detect nitrite produced by bacteria causing infection that may be present in the urinary tract. Although these devices do not have complete sensitivity (i.e., they may give some false-negative results), they have been found to have excellent specificity (i.e., they seldom give a false-positive result). If used on early morning urine specimens, when the bacterial count is expected to be the highest, the nitrite test will detect almost 90 percent of cases of persistent bacteriuria (abnormally high levels of bacteria in the urine) without false positive results.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in diagnosis and treatment of urinary tract infection of bacterial origin. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that urinary nitrite (nonquantitative) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1515; Docket No. 78N-2384; Nitrogen (amino-nitrogen) test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nitrogen (amino-nitrogen) test systems:

1. Identification: A nitrogen (amino-nitrogen) test system is a device used to measure amino acid nitrogen levels in serum, plasma, and urine by methods such as ninhydrin, trinitrobenzene sulfonate (spectroscopic), or 2,4-dinitrofluorobenzene (spectroscopic).

Nitrogen (amino-nitrogen) measurements are used in the diagnosis and treatment of certain forms of severe liver disease and renal disorders.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that nitrogen (amino-nitrogen) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with severe liver disease and some forms of renal disorders. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *215*). The measurement of nitrogen (amino-nitrogen) levels is useful in the evaluation of severe liver disease and certain renal disorders. It is now known that the changes in concentrations of certain individual amino acids, or groups of related amino acids, are significant in many disease states. Despite the importance of amino acids in many aspects of human biochemistry, determination of amino acid nitrogen levels in serum is not very useful in clinical diagnosis. Low values of total amino acids are rarely encountered. A significantly large increase in serum amino acid nitrogen levels is found only in very severe liver disease. Measurement of levels of amino acid nitrogen in urine is of more clinical interest than measurement of levels of this substance in plasma. Amino acids may increase in the urine due to elevated blood levels of amino acids, because of liver failure, kidney disease, heavy metal poisoning, severe muscle degeneration, or a congenital disease.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of liver and renal diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that nitrogen (amino-nitrogen) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1520; Docket No. 78N–2385; 5'-Nucleotidase test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of 5'-nucleotidase test systems

1. Identification: A 5'-nucleotidase test system is a device used to measure the activity of the enzyme 5'-nucleotidase in serum and plasma by methods such as 5-adenosine monophosphate(AMP)-phosphate release (colorimetric). Measurement of 5'-nucleotidase is used in the diagnosis and treatment of liver diseases and treatment of liver diseases and in the differentiations between liver and bone diseases in the presence of elevated serum alkaline phosphatase activity.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that 5'-nucleotidase test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with liver or bone diseases. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members; personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *216* and *217*). The measurement of the enzyme 5'-nucleotidase is useful in the evaluation of liver disease and in the differentiation between liver and bone diseases in the presence of elevated serum alkaline phosphate activity. 5'-Nucleotidase is a specific enzyme occurring in serum. In liver diseases, the activity of the enzyme parallels that of serum alkaline phophatase. In such bone diseases as rickets of Paget's disease, however, the activity of the enzyme is not increased while serum alkaline phosphatase acitivty is elevated. 5'-Nucleotidase measurements are particularly valuable in the diagnosis of diseases in children.

5. Risks to health: Misdiagnosis and inappropriate therapy; Failure of the device to perform satisfactorily may lead to error in the diagnoais of liver or bone diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that 5'-nucleotidase test systems be classified into class II (performance standards). the agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurnace of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1530; Docket No. 78N–2387; Plasma oncometry test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of plasma oncometry test systems:

1. Identification: A plasma oncometry test system is a device used to measure plasma oncotic pressure by methods such as membrane oncometry. Plasma oncotic pressure is that portion of the total fluid pressure contributed by proteins and other molecules too large to pass through a specified membrane. Measurements of plasma oncotic

pressure are used in the diagnosis and treatment of dehydration and circulatory disorders related to low serium protein levels and increased capillary permeability, such as edema and shock.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that plasma oncometry test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of circulatory disorders related to low serum protein levels and increased capillary permeability, such as edema and shock. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *218* and *219*). Plasma proteins are large molecules that are nondiffusible (cannot move through thin membranes). When trapped in the vascular system, plasma proteins exert oncotic pressure which serves to maintain normal blood volume and water content in the tissues.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of this device to perform satisfactorily may lead to failure to diagnose dehydration and circulatory disorders related to low serum protein levels and increased capillary permeability, such as edema and shock. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that plasma oncometry test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectivensess of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1535; Docket No. 78N–2388; Ornithine carbamyl transferase test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ornithine carbamyl transferase test systems:

1. Identification: An ornithine carbamyl transferase test system is a device used to measure the activity of the enzyme ornithine carbamyl transferase (OCT) in serum by methods such as citrulline/arsenate/Nessler (colorimetry). Ornithine carbamyl transferase measurements are used in the diagnosis and treatment of liver diseases, such as infectious hepatitis, acute cholecystitis (inflammation of the gall bladder), cirrhosis, and liver metastases.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that ornithine carbamyl transferase test systems be classified into class II because there is a need for a performance standardr that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurement of ornithine carbamyl transferase levels is useful in evaluation of liver diseases such as infectious hepatitis, acute cholecystitis, cirrhosis, and liver metastases. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *220, 221,* and *222*). Ornithine carbamyl transferase (OCT), a very stable enzyme almost specific to the liver, is a sensitive index of liver cell damage. Very high serum activity, one hundred times normal, is found in infectious hepatitis and in acute cholecystitis. Moderate serum elevations of OCT are observed in cirrhosis and liver metastases. However, OCT is one of several enzymes that is elevated in all groups of hepatic and pancreatic disorders. Therefore, for differential diagnosis, measurements of OCT should be supplemented by other enzyme tests. The suggestion that some elevation in serum enzyme values may reflect nonspecific stress reactions (Ref. *222*) seems pertinent to OCT, which is frequently elevated in conditions when liver complication would not be expected. OCT measurements may be too sensitive. It is possible that the value of the upper normal limit for this enzyme should be increased.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of liver diseases such as hepatitis, acute cholecystitis, and cirrhosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that ornithine carbamyl transferase test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1540; Docket No. 78N–2389; Osmolality test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of osmolality test systems:

1. Identification: An osmolality test system is a device used to measure ionic and nonionic solute concentration in body fluids, such as serum and urine, by methods such as vapor pressure or freezing point depression measurement. Osmolality measurement is used as an adjunct to other tests in the evaluation of a variety of diseases, including kidney diseases (e.g., chronic

progressive renal failure), diabetes insipidus, other endocrine and metabolic disorders, and fluid imbalances.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that osmolality test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used as an adjunct to other tests in the evaluation of the kidneys' ability to concentrate urine and of the tonicity (a state of normal tension) of serum in a variety of diseases, including renal diseases (e.g., chronic progressive renal failure), diabetes insipidus, other endocrine and metabolic disorders, and fluid imbalances (e.g., dehydration or overhydration). The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *223* and *224*). The freezing point of a solution is related to the osmotic concentration of that solution or to the concentration of particles of solute per unit amount of solvent (water). Increased concentration of solute lowers the freezing point of the solution. Because measurements of osmolality indicate the concentrating ability of the kidney, the measurements help practitioners to follow the course of kidney and endocrine diseases and to evaluate the effectiveness of therapy.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of renal disease, diabetes insipidus, other endocrine and metabolic disorders, and fluid imbalances. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that osmolality test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1545; Docket No. 78N–2390; Parathyroid hormone test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of parathyroid hormone test systems:

1. Identification: A parathyroid horomone test system is a device used to measure the levels of parathyroid hormone in serum and plasma by methods such as radioimmunoassay. Measurements of parathyroid hormone levels are used in the differential diagnosis of hypercalcemia (abnormally high levels of calcium in the blood) and hypocalcemia (abnormally low levels in calcium in the blood) resulting from disorders of calcium metabolism.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that parathyroid hormone test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of levels of parathyroid hormones (PTH) are used in the laboratory differential diagnosis of hypercalcemia (abnormally high levels of calcium in the blood) or hypocalcemia (abnormally low levels of calcium in the blood) resulting from disorders of calcium metabolism. Because more than one immunoreactive form of PTH is present in serum, the Panel believes that it is essential for the labeling of the device to include information concerning the source of calibrator and standardization material, methods the manufacturer used to obtain stated values, and information concerning specificity relating precursors, subunits, and other features specific to the method. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *225, 226,* and *227*). In hypercalcemic conditions, PTH measurements can be used to distinguish patients with primary hyperparathyroidism (a condition due to an increase in the secretion of the parathyroids caused by tumors of the parathyroid glands) from those with hypercalcemia due to other causes. In hypocalcemic conditions, PTH measurement can serve to distinguish between parathyroid and nonparathyroid causes of the hypocalcemia.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the evaluation of patients with disorders of calcium metabolism. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that parathyroid hormone test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1550; Docket No. 78N–2391; Urinary pH (nonquantitative) test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of urinary pH (nonquantitative) test systems:

1. Identification: A urinary pH (nonquantitative) test system is a device used to estimate the pH of urine by use of methods such as a dye-indicator.

Estimations of pH are used to evaluate the acidity or alkalinity of urine as it relates to numerous renal and metabolic disorders and in the monitoring of patients with certain diets.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that urinary pH (nonquantitative) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with a variety of renal and metabolic disorders and in the monitoring of patients with certain diets. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *228*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the disgnosis of renal and metabolic disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that urinary pH (nonquantitative) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1555; Docket No. 78N–2392; Phenylalanine test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of Phenylalanine test systems:

1. Identification: A phenylalanine test system is a device used to measure free phenylalanine (an amino acid) in serum, plasma, and urine by methods such as column or paper chromatography plus ninhydrin, or fluorometric procedure using *L*-leucyl-*L*-alanine with ninhydrin. Measurements of phenylalanine are used in the diagnosis and treatment of congenital phenylketonuria which, if untreated, may cause mental retardation.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that phenylalanine test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of phenylketonuria, a congenital metabolism disorder of newborns. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *229* through *232*). Measurements of phenylalanine levels, usually performed on blood, are used extensively in screening of newborns for phenylketonuria. This disorder is caused by a congential deficiency of an enzyme that results in the accumulation of phenylalanine or its metabolites in blood and tissues. A serum level of 4 milligrams (mg) phenylalanine/10 milliliter (mL) is generally considered the division between normal individuals and those who need to be investigated further. The precision of the fluorometric method is plus or minus 7 percent at the 5 mg/100 mL level. Compounds other than phenylalanine that react to give fluoroscence under the conditions of the test can influence results by causing phenylalanine levels to be overestimated by 1.0 to 2.4 mg/100 mL in the newborn and by 1.0 to 2.2 mg/100 mL in adults. Diagnosis of the disease shortly after birth allows treatment by appropriate diet, reducing risk of abnormalities, which may include mental retardation.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of this device to perform satisfactorily may lead to error in the diagnosis of phenylketonuria. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that phenylalanine test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1560; Docket No. 78N–2393; Urinary phenylketones (nonquantitative) test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of urinary phenylketones (nonquantitative) test systems:

1. Identification: A urinary phenylketones (nonquantitative) test system is a device used to identify phenylketones (such as phenylpyruvic acid) in urine by methods such as chromogenesis or ferric chloride. The identification of urinary phenylketones is used in the diagnosis and treatment of congenital phenylketonuria which, if untreated, may cause mental retardation.

2. Recommended classification: Class II (performance standards). The Panel recommends the establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that urinary phenylketones (nonquantitative) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable

ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of phenylketonuria, a congenital metabolism disorder of newborns. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *233* and *234*). Phenylketonuria is caused by a congenital deficiency of an enzyme that results in the accumulation of the amino acid phenylalanine in the blood and tissues. Phenylalanine is excreted in the urin together with phenylpyruvic acid (phenylketone). The high circulating levels of phenylalanine or its metabolites may damage the brain. Diagnosis of the disease shortly after birth allows treatment by appropriate diet, reducing risk of abnormalities, which may include mental retardation.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of phenylketonuria. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that urniary phenylketones (nonquantitative) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1565; Docket No. 78N-2394; 6-Phosphogluconate dehyrogenase test system.

The Clinical Chemistry Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of 6-phosphogluconate dehyrogenase test systems:

1. Identification: A 6-phosphogluconate dehydrogenase test system is a device used to measure the activity of the enzyme 6-phosphogluconate dehydrogenase (6 PGD) in serum and erythrocytes by methods such as nicotinamide adenine dinucleotide phosphate (NADP) reduction. Measurements of 6-phosphogluconate dehydrogenase are used in the diagnosis and treatment of certain liver diseases (such as hepatitis) and anemias.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that 6-phosphogluconate dehydrogenase test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with certain liver diseases, such as hepatitis, and inherited anemias. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *235* and *236*). Measurements of the enzyme 6 PGD are useful in the evaluation of anemias. Certain individuals have hereditary hemolytic anemias with specific erythrocyte enzyme deficiencies. About 14 different enzyme deficiencies are associated with hemolytic anemias. A common factor in many of these anemias is 6-phosphogluconate dehydrogenase deficiency. A 6 PGD erythrocyte deficiency is a congenial hemolytic anemia in which hemolysis (destruction of red blood cells) occurs when an individual is exposed to certain chemical compounds. The abnormality is distributed in populations throughout the world. The three major types of 6 PGD deficiency are: (1) type A, found in Africans; (2) Mediterranean type, found in Caucasians and Orientals; and (3) the rare congenital, nonspherocytic type.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of certain liver diseases and anemias. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that 6-phosphogluconate dehyrogenase test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1570; Docket No. 78N-2395; Phosphohexose isomerase test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of phosphohexose isomerase test systems:

1. Identification: A phosphohexose isomerase test system is a device used to measure the activity of the enzyme phosphohexose isomerase in serum by methods such as glucose-6-phosphate (colormetric) or nicotinamide adenine dinucleotide (NAD) reduction (ultraviolet). Measurements of phosphohexose isomerase are used in the diagnosis and treatment of muscle diseases such as muscular dystrophy, liver diseases such as hepatitis or cirrhosis, and metastatic carcinoma.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that phosphohexose isomerase test systems to classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate

inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used to substantiate clinical findings of muscular dystrophy, hepatitis or cirrhosis of the liver, and metastatic carcinoma. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *237* through *240)*. Measurement of the enzyme phosphohexose isomerase (PHI) using this sensitive test system provides data that may be used to monitor the response to treatment of patients with active metastatic breast carcinomas. Measurement of PHI is also used as an indicator of metastases in cases of carcinoma of the breast or prostate. However, the diagnosis of cancer should not be based solely on a high PHI value, because some increase in serum PHI may be caused by such conditions as acute hepatitis. On the other hand, the absence of an increase in serum PHI levels may confirm that a patient does not have cancer. Therefore, this test should be used in conjunction with other biochemical tests.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of certain muscle diseases, liver diseases, and metastatic carcinoma. In appropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that phosphohexose isomerase test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1575; Docket No. 78N-2396; Phospholipid test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of phospholipid test systems:

1. Identification: A phospholipid test system is a device used to measure phospholipids in serum and plasma by methods such as ammonium molybdate/ammonium vanadate, chromatographic, molybdenum blue, or stannous chloride/hydrazine. Measurements of phospholipids are used in the diagnosis and treatment of disorders involving lipid (fat) metabolism.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that phospholipid test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with disorders involving lipid metabolism. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *241* and *242*). Phospholipids are complex lipids containing phosphate and a nitrogenous base. The major phospholipids in plasma are lecithin and sphingomyelin. The phosphate and base portions of the molecules are water soluble, a fact that is important in lipid transport. Plasma phospholipids are derived mainly from synthesis in the liver. Although the role of phospholipids is uncertain, they seem to be involved with blood coagulation. Plasma lecithin is the source of fatty acids for esterification of cholesterol in alpha lipoproteins. Because abnormalities in blood lipids are a major cause of coronary artery disease, practitioners often try to detect lipid disorders to predict coronary artery disease. The important blood lipids for gauging hyperlipidemia are cholesterol and triglycerides, rather than phospholipids. A phospholipid/cholesterol ratio has been calculated, with a normal range of 0.7 to 1.8. Lower values are associated with early development of coronary artery disease. However, measurements of phospholipids are not very useful and are rarely done.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of diseases affecting lipid metabolism. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that phospholipid test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1580; Docket No. 78N-2397; Phosphorus (inorganic) test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of phosphorus (inorganic) test systems:

1. Identification: A phosphorus (inorganic) test system is a device used to measure inorganic phosphorus in serum, plasma, and urine by methods such as phosphomolybdate. Measurements of phosphorus (inorganic) are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that phosphorus (inorganic) test systems be classified into class II because there is a need for a performance standard that prescribes

for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *243*). Measurement of inorganic phosphorus is performed and evaluated in conjunction with a variety of other diagnostic procedures, such as measurements of plasma proteins and calcium and various tests of renal function. There is a reciprocal relationship between calcium and phosphorus; any increase in the serum phosphorus causes a decrease in serum calcium. Hyperphosphatemia (increased serum phosphorus levels) may be found in hypervitaminosis (a condition caused by ingestion of excessive levels of vitamin D), hypoparathyroidism, and renal failure. Hypophosphatemia (low serum phosphorus levels) may be seen in ricketts (vitamin D deficiency), in hyperparathyroidism, and in the Fanconi syndrome, which is associated with a defect in reabsorption of phosphorus from the glomerular filtrate.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance. Inappropriate therapy based on inaccurate diagnosis data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that phosphorus (inorganic) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficent to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1585; Docket No. 78N–2398; Human placental lactogen test system.

The Clinical Chemistry Device Classification Panel and the Immunology Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of human placental lactogen test systems:

1. Identification: A human placental lactogen test system is a device used to measure the hormone human placental lactogen (HPL), (also known as human chorionic somatomammotrophin (HCS)) in maternal serum and maternal plasma by methods such as radioimmunoassay. Measurements of human placental lactogen are used in the diagnosis and clinical management of highrisk pregnancies involving fetal distress associated with placental insufficiency. Measurements of HPL are also used in pregnancies complicated by hypertension, proteinuria, edema, post-maturity, placental insufficiency or possible miscarriage.

2. Recommended classification: Class II (performance standards). The Clinical Chemistry Device Classification Panel recommends that establishing a performance standard for this device be a medium priority. The Immunology Device Classification Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panels recommend that human placental lactogen test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of HPL are used in the diagnosis and management of high risk pregnancies, such as pregnancies involving fetal distress associated with placental insufficiency. The Clinical Chemistry Device Classification Panel stressed that because absolute plasma HPL levels may vary in individuals throughout pregnancy, this test should be used serially, and also that it should not be used as the single index of fetal well being. Because of the immunologic cross-reactivity of HPL with other hormones, the Clinical Chemistry Device Classification Panel believes that it is essential that the labeling of the device include information on the source of calibrator and standardization material, the method(s) the manufacturer used to obtain stated values, and information concerning specificity as it relates to precursors, subunits, and other features specific to the method. The Panels believe that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panels believe that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *244, 245,* and *246*). Measurement of HPL in maternal blood plasma provides an index of placental function and fetal distress when associated with placental insufficiency. Plasma HPL values rises progressively during pregnancy. Based upon the normal reference range, dramatically decreasing values, as well as low levels of plasma HPL, indicate a risk to the fetus. Low concentrations of HPL after 30 weeks of gestation have been associated with high fetal mortality in patients with toxemia. The incidence of fetal complications accompanied by abnormal maternal levels of plasma estriol and human placental lactogen is consistently greater than 66 percent.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of complicated pregnancies. Inappropriate therapy based on inaccurate diagnostic data may place the patient or fetus at risk.

FDA agrees with the Panels' recommendations and is proposing that human placental lactogen test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient

information to establish a performance standard for this device.

The agency has reviewed the Panels' recommendations for human placental lactogen test systems and has concluded that the classification of this device should be published in the part of the Code of Federal Regulations for clinical chemistry devices.

Section 862.1590; Docket No. 78N-2399; Porphobilinogen test system.

The Clinical Chemistry Device Classification Panel, an FDA advosory committee, made the following recommendation regarding the classification of porphobilinogen test systems:

1. Identification: A porphobilinogen test system is a device used to measure porphobilinogen (one of the derivatives of hemoglobin which can make the urine a red color) in urine by methods such as ion exchange resin/Ehrlich's reagent. Measurements obtained by this device are used in the diagnosis and treatment of porhyrias (primarily inherited diseases associated with disturbed porphyrin metabolism), lead poisoning, and other diseases characterized by alterations in the heme pathway.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that porphobilinogen test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of porphobilinogen are used in the diagnosis and treatment of patients with lead poisoning or one of the group of diseases named porphyrias (acute intermittent porphyria, porphyria variegata, and heriditary coproporphyria) that are accompanied by excessive urinary excretion of various heme compounds. Acute attacks with abdominal or neurological symptoms are a feature of the inherited hepatic porphyrias. Such attacks are potentially fatal and may be provoked by a number of drugs (notably barbiturates). Other causes of abnormalities in porphyrin excretion are lead poisoning, liver diseases, and upper gastrointestinal bleeding. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *247* and *248*).

5. Risks to health: Misadiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of lead poisoning and porphyrias, Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that porphobilinogen test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1595; Docket No. 78N-2400; Porphyrins test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of porphyrins test systems:

1. Identification: A porphyrins test system is a device used to measures porphyrins (compounds formed during the biosynthesis of heme, a constituent of hemoglobin, and related compounds) in urine and feces by methods such as fluorometric measurement. Measurements obtained by this device are used in the diagnosis and treatment of lead poisoning, porphyrias (primarily inherited diseases associated with disturbed porphyrin metabolism), and other diseases characterized by alterations in the heme pathway.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that porphyrins test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance uon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of porphyrins are used in the diagnosis and treatment of patients with lead poisoning or one of the group of diseases named porphyrias (acute intermittent porphyria, porphyria variegata, and hereditary coproporphyria) that are accompanied by excessive urinary excretion of various heme compounds. Acute attacks with abdominal or neurological symptoms are a feature of the inherited hepatic porphyrias. Such attacks are potentially fatal and may be provoked by a number of drugs (notable barbiturates). Other causes of abnormalities in porphyrin excretion are lead poisoning, liver diseases, and upper gastrointestinal bleeding. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *249* and *250*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of lead poisoning and prophyrias. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that porphyrins test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1600; Docket No. 78N-2401; Potassium test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory

committee, made the following recommendation regarding the classification of potassium test systems:

1. Identification: A potassium test system is a device used to measure potassium in serum, plasma, and urine by methods such as flame photometry, ion selective electrode, or tetraphenyl borate colorimetry. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that potassium test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of potassium are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels. Erroneous measurements lead to improper treatment, possibly causing hypokalemia (abnormally low potassium concentration in the blood) and resultant alteration in muscle function, or causing hyperkalemia (abnormally high potassium concentration in the blood), which may in turn cause changes in muscle irritability, respiration or myocardial function.

The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *251* through *254*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of lead poisoning and prophyrias. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that potassium test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1605; Docket No. 78N–2402; Pregnanediol test system.

The Clinical Chemsitry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of pregnanediol test systems:

1. Identification: A pregnanediol test system is a device used to measure pregnanediol (a major urinary metabolic product of progesterone) in urine by methods such as spectrophotometric. Measurements obtained by this device are used in the diagnosis and treatment of disorders of the ovaries or placenta.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that pregnanediol test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of pregnanediol are used in the diagnosis and treatment of ovarian or placental dysfunction. Administration of contraceptives, estrogens, and androgens may interfere with test results. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *255*). The levels of excretion of pregnanediol provide an indication of endogenous production of progesterone. In nonpregnant women, measurement of pregnanediol provides a means for determining duration and functional activity of the corpus luteum (a yellow glandular mass formed in the ovary in the site of a ruptured ovarian follicle). In pregnancy, levels of pregnanediol reflect placental function, and in patients with a history of repeated spontaneous abortions, measurements early in pregnancy may be helpful. The Panel noted that to provide accuracy for proper evaluation, measurements of pregnanediol should be performed serially during the pregnancy.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of ovarian or placental dysfunction. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that pregnanediol test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1610; Docket No. 78N–2403; Pregnanetriol test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of pregnanetriol test systems:

1. Identification: A pregnanetriol test system is a device used to measure pregnanetriol (a precursor in the biosynthesis of the adrenal hormone cortisol) in urine by methods such as spectrophotometry or gas chromatography. Measurements obtained by this device are used in the diagnosis and treatment of congenital adrenal hyperplasia (congenital enlargement of the adrenal gland).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that pregnanetriol test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of pregnanetriol are used in the diagnosis and treatment of congenital adrenal hyperplasia, which results from a deficiency of 21-hydroxylase (an enzyme) in the biosynthesis of cortisol. Failure to diagnose congenital adrenal hyperplasia at an early stage of life may result in later complications such as growth abnormalities and sexual dysfunction. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *256*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of congenital adrenal hyperplasia. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that pregnanetriol test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1615; Docket No. 78N–2404; Pregnenolone test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of pregnenolone test systems:

1. Identification: A pregnenolone test system is a device used to measure pregnenolone (a precursor in the biosynthesis of the adrenal hormone cortisol and adrenal androgen) in serum and plasma by methods such as radioimmunoassay. Measurements obtained by this device are used in the diagnosis and treatment of diseases of the adrenal cortex or the gonads.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that pregnenolone test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of pregnenolone are used in the diagnosis and treatment of patients with adrenal or gonadal disorders. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *257* and *258*). The adrenal steroids are synthesized via cholesterol, which loses its side chain to form pregnenolone.

There are two major pathways for pregnenolone biosynthesis. The first (C21 pathway) leads to cortisol. Each step is controlled by a specific enzyme, and absence of one of these enzymes gives rise to the condition of congenital adrenal hyperplasia (enlargement of the adrenal gland), with low plasma cortisol levels and elevated adrenocorticotrophic hormone (ACTH), and androgen overproduction. The second (C19 pathway) produces the adrenal androgens. The circulating hormones are further metabolized in the liver and excreted in the urine.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of adrenal and gonadal diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that pregnenolone test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1620; Docket No. 78N–2405; Progesterone test system.

The Clinical Chemistry Device Classification Panel, an advisory committee, made the following recommendation regarding the classification of progesterone test systems:

1. Identification: A progesterone test system is a device used to measure progesterone (a female hormone) in serum and plasma by methods such as radioimmunoassay. Measurements obtained by this device are used in the diagnosis and treatment of disorders of the ovaries or placenta.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that progesterone test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of progesterone are used in the diagnosis and treatment of ovarian or placental dysfunction. They are especially useful for detection of ovulation. Measurements are also valuable in the evaluation of menstrual disorders, problems of infertility, ovarian response to therapy with clomiphene or gonadotropins, and placental function during complicated pregnancies (e.g., pregnancies in patients with toxemia, diabetes mellitus, or threatened spontaneous abortions). Administration of contraceptives, estrogens, and androgens may interfere with test results. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *259*). Progesterone, the major steroid possessing progestational activity, is secreted by the corpus luteum (a yellow glandular mass formed in the ovary in the site of a ruptured ovarian follicle) during the normal menstrual cycle. The placenta becomes the primary source of progesterone secretion during pregnancy. Inadequate progesterone secretion by the corpus luteum during the menstrual cycle prevents development of the secretory endometrium (thickened uterine lining), causing uterine bleeding and infertility. Abnormally low progesterone levels during pregnancy can lead to threatened or recurrent spontaneous abortion and intrauterine fetal death.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of ovarian

or placental dysfunction. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that progesterone test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1625; Docket No. 78N-2406; Prolactin (lactogen) test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of prolactin (lactogen) test systems:

1. Identification: A prolactin (lactogen) test system is a device used to measure the anterior pituitary polypeptide hormone prolactin in serum and plasma by methods such as radioimmunoassay. Measurements obtained by this device are used in the diagnosis and treatment of disorders of the anterior pituitary gland or of the hypothalamus portion of the brain.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that prolactin (lactogen) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with various hypothalamic or pituitary disorders. The Panel noted also that labeling should include information on source of calibrator and standardization material, source of stated values, and specificity as it relates to precursors, subunits, and other features specific to the method. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *260*). Measurement of lactogen is useful as a sensitive test showing hypothalamic tumors, in which a patient would be expected to have elevated levels of lactogen but not of other anterior pituitary hormones. Prolactin, a polypeptide hormone secreted by the anterior pituitary gland, acts on the mother's mammary glands to stimulate its growth and the secretion of milk shortly after an infant's birth. Elevated values have been found in patients who are lactating, who have galactorrhea (galactose in the feces), in patients with certain pituitary tumors, and in some patients with hypthyroidism associated with elevated thyroid stimulating hormone (TSH) levels.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of hypothalamic or pituitary disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that prolactin (lactogen) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1630; Docket No. 78N-2407; Protein (fractionation) test system.

The Clinical Chemistry Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of protein (fractionation) test systems:

1. Identification: A protein (fractionation) test system is a device used to measure protein fractions in blood, urine, cerebrospinal fluid, and other body fluids by methods such as densitometric, electrophoretic, or immunodiffusion. Protein fractionation

is used as an aid in recognizing abnormal proteins in body fluids and genetic variants of proteins produced in diseases with tissue destruction.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that protein (fractionation) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used as an aid in the diagnosis and treatment of abnormal proteins in body fluids and genetic variants of proteins produced in diseases with tissue destruction. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *261*). Protein fractionation is used in measuring albumin values and in detecting and quantitating immunoglobulins in diseases such as multiple myeloma (a disorder characterized by abnormalities in formation of plasma protein). Protein fractionation is also used in detecting agammaglobulinemia or hypogammaglobulinemia and for measuring the severity of the acute phase reaction (change in serum protein composition following tissue damage as occurs in injury or acute infection) and of inflammation.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of this device to perform satisfactorily could lead to error in the diagnosis of disproteinemia or abnormal protein patterns in body fluids. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that protein (fractionation) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1635; Docket No. 78N–2408; Total protein test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of total protein test systems:

1. Identification: A total protein test system is a device used to measure total protein(s) in serum and plasma by methods such as biuret (colorimetric), Lowry (colorimetric), refractometric, or turbidimetric. Measurements obtained by this device are used in the diagnosis and treatment of a variety of diseases involving the liver, kidneys, or bone marrow as well as other metabolic or nutritional disorders.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that total protein test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of total protein(s) are used in the diagnosis and treatment of hypoproteinemic (low-protein level) patients with a variety of diseases involving the liver, kidneys, or bone marrow, as well as other metabolic or nutritional disorders. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *262, 263,* and *264*). Plasma contains a complex mixture of proteins at a concentration of about 6 to 7 grams per deciliter. The different proteins have different functions and originate from several different cell types. Changes in the total proteins measured by total protein test systems are frequently nonspecific for a particular disease, but the test results can be of diagnostic value in a limited number of conditions. Many proteins, notably albumin, some blood coagulation factors, carrier proteins, and lipoproteins, are synthesized in the liver. Plasma protein concentrations are altered in hepatic disease. Changes in one protein fraction may be masked by opposite changes in another. The day-to-day (intraindividual) variation in levels of total protein is about plus or minus 3 percent, and laboratory precision is about plus or minus 2 to 3 percent (Ref. *263*). A recommended biuret method has been described and is under further development at the Center for Disease Control (Ref. *264*)..

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of liver, renal, and metabolic diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that total protein test systems be classified into class II (performance standards). The agency believes that a standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1640; Docket No. 78N–2409; Protein-bound iodine test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of protein-bound iodine test systems:

1. Identification: A protein-bound iodine test system is a device used to measure protein-bound iodine in serum by methods such as dry ash or wet ash. Measurements of protein-bound iodine obtained by this device are used in the

diagnosis and treatment of thyroid disorders.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that protein-bound iodine test systems be classified into Class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of protein-bound iodine are used in the diagnosis and treatment of thyroid disorders. Such measurements are rarely used currently for the diagnosis of hypothroidism or hyperthyroidism because they have been superseded by more specific assays for thyroxine and triiodothyronine. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *265* and *266*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of thyroid diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that protein-bound iodine test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1645; Docket No. 78N-2410; Urinary protein or albumin (nonquantitative) test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of urinary protein or albumin (nonquantitative) test systems:

1. Identification: A urinary protein or albumin (nonquantitative) test system is a device used to identify proteins or albumin in urine by methods such as indicator or tubidimetric. Identification of urinary protein or albumin (nonquantitative) is used in the diagnosis and treatment of disease conditions such as renal or heart diseases or thyroid disorders, which are characterized by proteinuria or albuminuria.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that urinary protein or albumin (nonquantitative) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of proteinuria or albuminuria shown by patients with various conditions, such as renal or heart diseases or thyroid disorders. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *267*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of proteinuria or albuminuria. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that urinary protein or albumin (nonquantitative) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1650; Docket No. 78N-2411; Pyruvate kinase test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of pyruvate kinase test systems:

1. Identification: A pyruvate kinase test system is a device used to measure the activity of the enzyme pyruvate kinase in erythrocytes (red blood cells) by methods such as phosphoenol pyruvate/adenosine diphosphate (ADP)/nicotinamide adenine dinucleotide (reduced form) (NADH). Measurements obtained by this device are used in the diagnosis and treatment of various inherited anemias due to pyruvate kinase deficiency or of acute leukemias.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that pyruvate kinase test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of pyruvate kinuse activity are used in the diagnosis and treatment of various inherited anemias due to pyruvate kinase deficiency or of acute leukemias. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the

device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *268* and *269*). Measurement of pyruvate kinase is most useful in the evaluation of hemolytic anemia due to pyruvate kinase deficiency. Limits of "normal" have been difficult to define. Elevated values of the enzyme are found in blood from the umbilical cord and in reticulocytes (young red cells) while low levels are found in patients with acute leukemias.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of hemolytic anemias or acute leukemias. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that pyruvate kinase test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1655; Docket No. 78N–2412; Pyruvic acid test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of pyruvic acid test systems:

1. Identification: A pyruvic acid test system is a device used to measure pyruvic acid (an intermediate compound in the metabolism of carbohydrate) in plasma by methods such as enzymatic (ultraviolet). Measurements obtained by this device are used in the evaluation of electrolyte metabolism and in the diagnosis and treatment of acid-base and electrolyte disturbances of anoxia (the reduction of oxygen in body tissues).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation. The Panel recommends that pyruvic acid test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Pyruvic acid measurements are used in the diagnosis and treatment of acid-base and electrolyte disturbances of anoxia (the reduction of oxygen in body tissues). The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *270* and *271*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of acid-base and electrolyte disturbances. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that pyruvic acid test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1660; Docket No. 78N–2413; Quality control materials (assayed and unassayed).

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of quality control materials (assayed and unassayed):

1. Identification: A quality control material (assayed and unassayed) for clinical chemistry is a device intended for use in a test system to estimate test precision and to detect systematic analytical deviations that may arise from reagent or analytical instrument variation. A quality control material (assayed and unassayed) may be used for proficiency testing in interlaboratory surveys. This generic type of device includes controls (assayed and unassayed) for blood gases, electrolytes, enzymes, multianalytes (all kinds), single (specified) analytes, or urinalyis controls.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that quality control materials (assayed and unassayed) be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that quality control materials (assayed and unassayed) be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 862.1665; Docket No. 78N–2414; Sodium test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of sodium test systems:

1. Identification: A sodium test system is a device used to measure sodium in serum, plasma, and urine by methods such as flame photometry, ion selective electrode, or uranyl acetate/zinc acetate. Measurements obtained by this device are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

2. Recommended classification: Class II (performance standard). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that sodium test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Sodium measurements are used in the diagnosis and treatment of aldosteronism, dehydration, diabetes insipidus, adrenal hypertension, inappropriate antidiuretic hormone (ADH) secretion, Addison's disease, or other diseases involving electrolyte imbalance. Delay in the diagnosis of Addison's disease and inappropriate ADH hormone secretion may be hazardous to the patient. Improper treatment of dehydrated infants may lead to death. Current sodium measurements are fairly accurate. Within-day variations of about plus or minus 1 percent and interlaboratory variations of about plus or minus 2 percent have been reported. Despite the good performance of the test, the Panel recommended high priority for the development of a standard because in the serious conditions described above, sodium measurements are among the primary factors used in making a diagnosis. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *272* through *275*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of aldosteronism, diabetes insipidus, adrenal hypertension, dehydration, inappropriate antidiuretic hormone secretion, Addison's disease, or other diseases involving electrolyte imbalance. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that sodium test systems be classified into class II (performance standards). The agency belives that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1670; Docket No. 78N–2415; Sorbitol dehydrogenase test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of sorbitol dehydrogenase test systems:

1. Identification: A sorbitol dehydrogenase test system is a device used to measure the activity of the enzyme sorbitol dehydrogenase in serum by methods such as *beta*-D-fructose and incotinamide adenine dinucleotide (reduced form) (NADH) oxidation (ultraviolet). Measurements obtained by this device are used in the diagnosis and treatment of liver disorders such as cirrhosis or acute hepatitis.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that sorbitol dehydrogenase test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of sorbitol dehydrogenase are used in the diagnosis and treatment of liver disorders such as cirrhosis or acute hepatitis. Specificity of this test system is essential because any sorbitol dehydrogenase detected in serum indicates the presence of liver damage. Sorbitol dehydrogenase activity is elevated in acute hepatitis (10 to 30 times the normal level), cirrhosis of the liver, or any parenchymal liver cell damage (Ref. *276*). The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *276*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of liver disorders such as cirrhosis or acute hepatitis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that sorbitol dehydrogenase test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1675; Docket No. 78N–2416; Blood specimen collection device.

The Clinical Chemistry Device Classification Panel and the Hematology Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of blood specimen collection devices:

1. Identification: A blood specimen collection device is a device intended for medical purposes that is used to collect and to handle blood specimens and to separate serum from nonserum (cellular) components prior to further testing. This generic type device may include blood collection tubes, vials, systems, serum separators, blood collection trays, or vacuum sample tubes.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panels recommend that blood specimen collection devices be classified into class II because there is a need for a

performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. One type of blood specimen collection device, the serum separator, is a vacuum-sealed blood-drawing tube containing an inert material which, during centrifugation, forms a barrier between the serum and the blood clot. Evaluation of this device has shown that it can affect the values obtained in some analytes, e.g., lactate dehydrogenase. The Clinical Chemistry Device Classification Panel was also concerned that other blood specimen collection devices may affect analyses of trace elements due to the possible leaching of interfering substances from the sample container (vial, vacuum tube, etc.) into the blood sample. The Hematology Device Classification Panel believed that difficulties have arisen in the use of evacuated (vacuum sealed) blood collection tubes containing anticoagulants to collect blood for coagulation testing. Due to differences in the manufacture of these tubes blood samples collected using tubes from different manufacturers do not give comparable results when used for coagulation testing. The Hematology Panel believes that a performance standard addresssing tube characteristics such as the glass, stopper, anticoagulant, and sterility would minimize the risks to health presented by the device. The Panels believe that general controls would not provide sufficient control over the blood specimen collection device's accuracy, precision, sensitivity, and specificity. The Panels believe that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The National Committee for Clinical Laboratory Standards (NCCLS) has approved standards for evacuated (vacuum sealed) tubes used for the collection of blood and blood collection systems. Both Panels based their recommendations on the proposed NCCLS standards, the Panel members' personal knowledge of, and clinical experience with, this device, and upon a review of the literature (Refs. *227* and *278*).

5. Risks to health: Misdiagnosis and inappropriate therapy: If the blood sample collected and handled in this device is partially absorbed by a device component or contaminated by materials leached from the device, the test results for one or more analytes may be erroneous, leading to an error in the diagnosis of coagulation disorders or other various disease conditions. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panels' recommendations and is proposing that blood specimen collection devices be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

The agency has reviewed the Panels' recommendations for blood specimen collection devices and has concluded that the classification of this device should be published in the part of the Code of Federal Regulations for clinical chemistry devices.

Section 862.1680; Docket No. 78N-2417; Testosterone and dihydrotestosterone test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of testosterone and dihydrotestosterone test systems:

1. Identification: A testosterone and dihydrotestosterone test system is a device used to measure testosterone and dihydrotestosterone (two male sex hormones) in serum, plasma, and urine by methods such as radioimmunoassay. Measurements of testosterone and dihydrotestosterone are used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and, in females, hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that testosterone and dihydrotestosterone test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with androgen (male sex hormone) dysfunctions, including impotence in males, primary and secondary hypogonadism, delayed and precocious puberty, and, in females, hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *279* and *280*). The testes secrete testosterone under the influence of the pituitary luteinizing hormone (LH). Before puberty, levels of LH are low. LH is responsible for the development, at puberty, of the mature male's physical and sexual characteristics. In females, the main ovarian androgen is androstenedione, which is converted peripherally to testosterone. Normal testosterone levels in women are about a tenth of those in men. Androgenic activity is usually assessed through measurements of testosterone in plasma, although measurement in urine also has been used. When testosterone reaches the cells of the target glands (such as the prostate), an enzyme transforms testosterone into dihydrotestosterone into dihydrotestosterone (DHT). Also, the testes produce about 10 percent of the total DHT produced. The Panel recommended that the labeling of the device state the expected ranges.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of androgen disorders. Inappropriate

therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that testosterone and dihydrotestosterone test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1685; Docket No. 78N-2418; Thyroxine-binding globulin test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of thyroxine-binding globulin test systems:

1. Identification: A thyroxine-binding globulin test system is a device used to measure thyroxine (thyroid)-binding globulin (TBG), a plasma protein which binds thyroxine, in serum and plasma by methods such as radioimmunoassay. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that thyroxine-binding globulin test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with thyroid diseases. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *281* and *282*). Measurements of thyroxine-binding globulin are especially useful in the evaluation of patients whose clinical status is not consistent with the level of thyroxine (T4) in their serum. The biosynthesis of thyroxine (the thyroid hormone) is complex. Each step is controlled by specific enzymes, and congenital deficiency of any of tthese enzymes can lead to hypthyroidism. Thyroxine occurs in the plasma in free and protein-bound forms.

Several plasma proteins, including albumin, bind thyroxine, but the main plasma protein involved is an alpha globulin named thyroxine-binding globulin (TBG). Altough most thyroxine in plasma is bound, the thyroxine that is free (0.1 percent or less) is the physiologically active fraction. Free thyroxine controls pituitary secretion of thyroid stimulating hormone. Increased TBG concentration occurs in pregnancy and with administration of estrogen or oral contraceptives. Decreased TBG concentration occurs in cases of protein loss, administration of androgens and anabolic steriods and, rarely, in congenital TBG deficiency. Certain drugs, notably salicylates and dilantin, interfere with the performance of thyroxine-binding test systems by occupying TBG binding sites.

5. Risks to health: Misdiagnosis and inapproriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of thyroid disease. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that thyroxine-binding globulin test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1690; Docket No. 78N-2419; Thyroid stimulating hormone test system:

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of thyroid stimulating hormone test systems:

1. Identification: A thyroid stimulating hormone test system is a device used to measure thyroid stimulating hormone, also known as thyrotrophin and thyrotrophic hormone, in serum and plasma by methods such as radioimmunoassay. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium-priority.

3. Summary of reasons for recommendation: The Panel recommends that thyroid stimulating hormone (TSH) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements obtained by thyroid stimulating hormone test systems are used in the diagnosis and treatment of patients with thyroid or pituitary disorders. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *283* and *284*). Measurements of TSH are useful in the evaluation of thyroid or pututiary disorders. TSH, which is secreted by the anterior pituitary, regulates the thyroid by stimulating thyroidal iodide metabolism and thyroid hormone synthesis and release. Patients with primary hypothyroidism have elevated TSH levels, and those with secondary (pituitary) hypothyroidism have low TSH levels. TSH levels are low in most patients with untreated conditions involving hyperthyroidism.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of thyroid

or putuitary disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that thyroid stimulating hormone test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assuance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1695; Docket No. 78N-2420; Free thyroxine test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of free thyroxine test systems:

1. Identification: A free thyroxine test system is a device used to measure free (not protein bound) thyroxine (thyroid hormone) in serum and plasma by methods such as radioimmunoassay. Levels of free thyroxine in plasma are thought to reflect the amount of thyroxine hormone available to the cells and may therefore determine the clinical metabolic status of thyroxine. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that free thyroxine test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of free thyroxine are used in the diagnosis and treatment of patients with thyroid diseases. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *285* and *286*). The biosynthesis of thyroxine (the thyroid hormone) is complex. Each step is controlled by specific enzymes, and congenital deficiency of any of these enzymes can lead to hypothroidism. The principal usefulness of measurement of free thyroxine lies in two diagnostic areas: (1) cases in which total thyroxine hormone levels do not correlate with thyrometabolic status, usually characterized either by idiopathic (unknown) or congenital thyroxine binding globulin (TBG) abnormalities, and (2) cases in which induced abnormalities in thyroxine binding globulin (protein) levels are present. Elevated thyroxine binding globulin (TBG) levels occur in pregnancy and during administration of estrogens or oral contraceptives. Administration of androgens and anabolic steroids result in low TBG levels.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of thyroid diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that free thyroxine test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1700; Docket No. 78N-2421; Total thyroxine test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of total thyroxine test systems:

1. Identification: A total thyroxine test system is a device used to measure total (free and protein bound) thyroxine (thyroid hormone) in serum and plasma by methods such as radioimmunoassay or nonradiolabeled enzyme immunoassay. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that total thyroxine test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therepy that places the patient at risk unnecessarily. Measurements of total thyroxine are used in the diagnosis and treatment of patients with thyroid disease. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *287, 288,* and *289*). The biosynthesis of thyroxine (the thyroid hormone) is complex. Each step is controlled by specific enzymes, and congenital deficiency of any of these enzymes can lead to hypothyroidism. Measurement of total thyroxine is the most valuable single test for the evaluation of thyroid function. In most patients, total thyroxine levels correlate well with the degree of hypo- or hyperthyrodism. However, exceptions are found in patients who have elevated levels of thyroxine-binding globulin (TBG) and in patients with triiodothyronine toxicosis, where normal thyroxine values may be found in clinically hyperthyroid (thyrotoxic) patients.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of thyroid diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that total thyroxine test systems be classified

into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1705; Docket No 78N–2422; Triglyceride test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of triglyceride test systems:

1. Identification: A triglyceride test system is a device used to measure triglyceride (neutral fat) in serum and plasma by methods such as colorimetric, fluorometric, lipase hydrolysis/glycerol kinase enzyme, thin-layer chromatographic separation, or turbidimetric. Measurements obtained by this device are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that triglyceride test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of triglyceride are used in the diagnosis and treatment of patients with diseases involving lipid metabolism, including diabetes mellitus, nephrosis, liver obstruction, or various endocrine disorders. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literatur (Ref. *290*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of diseases involving lipid metabolism or various endocrine disorders. Inappropriate thereapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that triglyceride test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1710; Docket No. 78N–2423; Total triiodothyronine test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of total triiodothyronine test systems:

1. Identification: A total triiodothyronine test system is a device used to measure the hormone triiodothyronine in serum and plasma by methods such as radioimmunoassay. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases such as hyperthyroidism.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device by a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that total triiodothyronine test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of total triiodothyronine are used in the diagnosis and treatment of patients with thyroid diseases. Such measurements are particularly useful in evaluating patients with suspected hyperthyroidism due to toxic nodules and with myxedema (a swelling of tissue associated with hyperthyroidism). The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *291, 292,* and *293*). Triiodothyronine in plasma is secreted by the thyroid and also is converted from circulating plasma thyroxine. Like thyroxine, about 99 percent of triiodothyronine is carried on thyroxine-binding globulin (protein), but by a weaker binding mechanism. Triiodothyronine is metabolically more active than thyroxine. A rare condition, triiodothyronine thyrotoxicosis, should be suspected if a patient has normal thyroxine levels, the thyroid gland has normal uptake of iodine, elevated triiodothyronine levels are found, and the patient is clinically hyperthyroid.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactory may lead to error in the diagnosis of thyroid disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that total triiodothyronine test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard to provide this assurance.

Section 862.1715; Docket No. 78N–2424; Triiodothyronine uptake test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of triiodothyronine uptake test systems:

1. Identification: A triiodothyronine uptake test system is a device used to

measure by methods such as radioassay the total amount of binding sites available for binding thyroid hormone on the thyroxine-binding proteins, thyroid-binding globulin, thyroxine-binding prealbumin, and albumin of serum and plasma. The device provides an indirect measurement of thryoxine levels in serum and plasma. Measurements of triiodothyronine uptake are used in the diagnosis and treatment of thyroid disorders.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that triiodothyronine uptake test systems be classified into class II because there is a need for a performance standard that prescribed for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Triiodothyronine uptake measurement is used in the diagnosis and treatment of patients with thyroid diseases. Triiodothyronine uptake measurement is used only in conjunction with plasma thyroxine measurement. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *291, 292,* and *293*). Measurement of triiodothyronine uptake is useful in the evaluation of the thyroid status of individuals with abnormal plasma thyroxine-binding globulin concentrations. Clinical conditions characterized by an increase or decrease in thyroxine-binding globulin will demonstrate an inverse relationship to the level of triiodothyronine uptake.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of thyroid disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that triiodothyronine uptake test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1720; Docket No. 78N-2425; Triose phosphate isomerase test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of triose phosphate isomerase test systems:

1. Identification: A triose phosphate isomerase test system is a device used to measure the activity of the enzyme triose phosphate isomerase in erythrocytes (red blood cells) by methods such as glyceraldehyde-3-phosphate nicotinamide adenine dinucleotide (reduced form) (NADH) (enzymatic). Triose phosphate isomerase is an enzyme important in glycolysis (the energy-yielding conversion of glucose to lactic acid in various tissues). Measurements obtained by this device are used in the diagnosis and treatment of congenital triose phosphate isomerase enzyme deficiency, which causes a type of hemolytic anemia.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that triose phosphate isomerase test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of triose phosphate isomerase are used in the diagnosis and treatment of patients with congenital triose phosphate isomerase enzyme deficiency, which causes a type of hemolytic anemia. The enzyme deficiency occurs in erythrocytes, leukocytes (white blood cells), and skeletal muscle. Hemolytic anemia is characterized by abnormal destruction of erythrocytes in the body, accompanied by progressive neuromuscular disorders and recurrent infections. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *294* and *295*). Certain individuals have congenital hemolytic anemias with specific erythrocyte enzyme deficiencies. Patients with hemolytic anemia due to pyruvate kinase deficiency have no distinguishing clinical features. Anemia, varying degrees of jaundice, slight-to-moderate splenomegaly (increased spleen size), and temporary hemolytic episodes following intercurrent illness or surgery have been noted.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of congenital triosephosphate isomerase deficiency. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that triose phosphate isomerase test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1725; Docket No. 78N-2426; Trypsin test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of trypsin test systems:

1. Identification: A trypsin test system is a device used to measure the activity of trypsin (a pancreatic enzyme important in digestion for the

breakdown of proteins) in blood and other body fluids and in feces by methods using *n*-benzoyl-L-arginine ethyl ester or *p*-toluene-sulphonyl-arginine methyl ester. Measurements obtained by this device are used in the diagnosis and treatment of pancreatic disease.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that trypsin test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of trypsin are used in the diagnosis and treatment of pancreatic disease. A high incidence of false-positive and false-negative values has been associated with trypsin measurements. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *296, 297,* and *298*). Although some studies have found that in the presence of pancreatic disease there is a significant elevation of serum trypsin, the usefulness of blood trypsin assays has been subject to controversy. However, fecal trypsin tests have long been used as an aid in the diagnosis of cystic fibrosis of the pancreas, where in most cases trypsin activity is very low or absent.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of pancreatic disease. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that trypsin test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1730; Docket No. 78N-2427; Free tyrosine test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of free tyrosine test systems:

1. Identification: A free tyrosine test system is a device used to measure free tyrosine (an amino acid) in blood and urine by methods such as 1-nitroso-2-naphthol (fluorometic). Measurements obtained by this device are used in the diagnosis and treatment of diseases such as congenital tyrosinemia (a disease that can cause liver or kidney disorders) and as an adjunct to the measurement of phenylalanine in detecting congenital phenylketonuria (a disease that can cause brain damage).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that free tyrosine test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of free tyrosine are used in the diagnosis and treatment of congenital diseases such as tyrosinemia and as an adjunct to the measurement of phenylalanine in detecting congenital phenylketonuria. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *299, 300,* and *301*). Measurements of free tyrosine are used as an adjunct to the measurement of phenylalanine (one of the common amino acids) in detecting congenital phenylketonuria. Diagnosis of this disease shortly after birth can allow treatment by appropriate diet, reducing the risk of abnormalities, which may include mental retardation in children. Measurement of serum tyrosine levels, in combination with measurement of phenylalanine levels, may also be useful in the detection of carriers of phenylketonuria. Elevated serum and urine tyrosine levels are found in congenital tyrosinemia, which causes hepatic cirrhosis, renal disease, and rickets (a deficiency disease characterized by defective bone growth occurring in infants and young children). The fluorometric test is nonspecific in urine due to interfering tyrosine derivatives and indicates only parasubstituted phenols.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of congenital phenylketonuria and tyrosinemia. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agreeés with the Panel recommendation and is proposing that free tyrosine test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1770; Docket No. 78N-2428; Urea nitrogen test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of urea nitrogen test systems:

1. Identification: A urea nitrogen test system is a device used to measure urea nitrogen (an end-product of nitrogen metabolism) in whole blood, serum, plasma, and urine by methods such as diacetylmonoxime, *o*-phthalaldehyde, urease (photometric), urease and glutamic dehydrogenase, ion-specific electrode, or Berthelot indophenol

reaction. Measurements obtained by this device are used in the diagnosis and treatment of certain renal and metabolic diseases.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that urea nitrogen test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of urea nitrogen, together with measurements of creatinine in the patient's serum, are used in the diagnosis and treatment of renal disease and in the confirmation of diagnosis of decreased circulation to the kidney caused by shock or by prerenal causes of renal malfunction. Delay in treatment of renal and metabolic disease may cause continued poor health and death. Measurements of urea nitrogen in serum and urine are used also in estimation of urea clearance as a crude test of kidney function. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *302* through *305).* Although the level of performance of urea nitrogen test systems has improved in recent years, the test results still are subject to an interlaboratory variation of about 10 percent coefficient of variation.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of renal and metabolic disease. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that urea nitrogen test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1775; Docket No. 78N–2429; Uric acid test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of uric acid test systems:

1. Identification: A uric acid test system is a device used to measure uric acid in serum, plasma, and urine by methods such as phosphotungstate reduction, and uricase (colorimetric, coulometric, gasometric, oxygen rate, or ultraviolet). Measurements obtained by this device are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that uric acid test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Uric acid measurements are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation, or other wasting conditions, and of patients receiving cytotoxic drugs. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *306, 307,* and *308*). Gout is a hereditary form of arthritis, affecting mostly men, characterized by an excess of uric acid in the blood and by recurrent attacks of acute arthritis, usually involving a single joint, followed by remission. The attacks result from deposits of crystals of sodium urate around the joint. The elevated blood uric acid may be caused by an increased rate of synthesis of uric acid precursors and/or by decreased excretion of uric acid by the kidneys.

5. Risks of health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of numerous renal and metabolic disorders, such as gout, leukemia, or psoriasis. Inappropriate therapy based on inaccurate diagnositic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that uric acid test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1780; Docket No. 78N–2430; Urinary calculi (stones) test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of urinary calculi (stones) test systems:

1. Identification: A urinary calculi (stones) test system is a device used for the analysis of urinary calculi by methods such as infrared spectroscopy measurement or qualitative chemical reactions. Analysis of urinary calculi is used in the diagnosis and treatment of calculi of the urinary tract.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that urinary calculi (stones) test systems be classified into class II because there is a need for a performance standard that prescribes

for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Analyses of urinary calculi are used in the diagnosis and treatment of patients with calculi of the urinary tract. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *309*, *310*, and *311*). Analyses of urinary calculi are useful in evaluating the cause and treatment of the formation of urinary calculi such as kidney stones. The formation of urinary calculi is favored by: (a) high urinary concentration of the constituents of the calculi that may be due to low urine volume or a high rate of excretion of the relevant substances; (b) a pH of the urine that favors precipitation of the constituents of the calculi; and (c) urinary stagnation. The cause of calculi containing calcium is generally unknown. Some 10 percent of urinary calculi develop from uric acid while cystine and xanthine crystals are rare components of such calculi. Tests should be conducted to exclude as a cause elevated serum calcium, especially that associated with primary hyperparathyroidism.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactory may lead to error in the diagnosis of urinary calculi. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that urinary calculi (stones) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1785; Docket No. 78N-2431; Urinary urobilinogen (nonquantitative) test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of urinary urobilinogen (nonquantitative) test systems:

1. Identification: A urinary urobilinogen (nonquantitative) test system is a device used to detect and estimate urobilinogen (a bile pigment degradation product of red cell hemoglobin) in urine by methods such as diazonium colorimetry. Estimations obtained by this device are used in the diagnosis and treatment of liver diseases and hemolytic (red cell) disorders.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that urinary urobilinogen (nonquantitative) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensititity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the diagnosis and treatment of patients with liver disease or hemolytic diseases. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *312*). Urobilinogen is formed in the intestine from bilirubin, a bile pigment degradation product of red blood cell hemoglobin. In the normal individual, part of the urobilinogen is excreted in the feces, and a small amount is excreted in the urine. Because increased amounts of urobilinogen are excreted by the kidneys in various forms of liver disease, the measurement of elevated levels of urobilinogen in urine is a sensitive test for detecting the early stages of hepatitis. A patient with obstructive jaundice has greatly reduced excretion of bilirubin into the intestine and a corresponding reduction of urobilinogen levels in urine.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of liver diseases and hemolytic anemias. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that urinary urobilinogen (nonquantitative) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1790; Docket No. 78N-2432; Uroporphyrin test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of uroporphyrin test systems:

1. Identification: A uroporphyrin test system is a device used to measure uroporphyrin in urine by methods such as fluorometric or spectrophotometric. Measurements obtained by this device are used in the diagnosis and treatment of porphyrias (primarily inherited diseases associated with disturbed porphyrin metabolism), lead poisoning, and other diseases characterized by alteration in the heme pathway.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that uroporphyrin test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate

inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of uroporphyrin are used in the diagnosis and treatment of patients with porphyrias (primarily inherited diseases associated with disturbed porphyrin metabolism), lead poisoning, and other diseases characterized by alterations in heme pathway. The clinical features of some of the diseases include abdominal and neurological symptoms and skin lesions. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *313* and *314*). Measurements of uroporphyrins are useful in the evaluation of porphyrias. The porphyrins are complex ring compounds synthesized in the liver and bone marrow. Abnormalities of porphyrins metabolism are included in the diseases termed porphyrias and are accompanied by increased urinary and fecal excretion of various porphyrins of their precursors, or both. Urinary porphyrins are of two types: (a) coproporphyrins and (b) uroporphyrins. Small to moderate increases in output of uroporphyrins are found in hepatic porphyria, and massive output occurs in congenital porphyria.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of porphyrias and porphyrinurias. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that uroporphyrin test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1795; Docket No. 78N-2433; Vanilmandelic acid test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of vanilmandelic acid test systems:

1. Identification: A vanilmandelic acid test system is a device used to measure vanilmandelic acid in urine by methods such as diazo, *p*-nitroaniline/vanillin, or electrophoretic separation. Measurements of vanilmandelic acid obtained by this device are used in the diagnosis and treatment of neuroblastoma, pheochromocytoma, and certain hypertensive conditions.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that vanilmandelic acid (VMA) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of vanilmandelic acid are used in the diagnosis and treatment of neuroblastoma, pheochromocytoma (a tumor characterized by the secretion of catecholamines resulting in hypertension), and of certain hypertensive conditions. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *315* through *320*). Elevated urinary VMA levels are considered indicative of pheochromocytoma. In a study of 6 patients with pheochromocytoma and a group of 32 patients with essential hypertension (high blood pressure of unknown cause), urinary VMA levels invariably were found to be higher in patients with pheochromocytoma than in those who did not have the tumor (Ref. *321*). However, false indications of pheochromocytoma can result from elevated levels of VMA from ingestion of certain foods, and drugs such as aspirin or antihypertensive agents; therefore, strict control of the diet and drug regimen of patients on whom the test is done is necessary to minimize interferences (Ref. *320*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of neuroblastoma, pheochromocytoma, and certain hypertensive conditions. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that vanilmandelic acid test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1805; Docket No. 78N-2435; Vitamin A test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of vitamin A test systems:

1. Identification: A vitamin A test system is a device used to measure vitamin A in serum and plasma by methods such as hexane extraction/trifluoroacetic acid. Measurements obtained by this device are used in the diagnosis and treatment of vitamin A deficiency conditions, including night blindness, or skin, eye, or intestinal disorders.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that vitamin A test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility

that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of vitamin A are used in the diagnosis and treatment of patients with vitamin A deficiency conditions including night blindness or skin, eye, or intestinal disorders. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *321, 322,* and *323*). Carotenes, precursors of the fat soluble vitamin A, occur in plants and are transformed into the vitamin in the intestinal mucosa. Vitamin A is stored in the liver and is essential for normal mucus formation and for maintaining normal levels of the retinal pigment rhodopsin. Thus, clinical effects of vitamin A deficiency include night blindness and drying of certain tissues of the eys, which may lead to blindness. In large doses, vitamin A is toxic. The symptoms of acute vitamin A poisoning are nausea and vomiting, abdominal pain, drowsiness, and headache. Chronic excess of the vitamin results in fatigue, insomnia, bone pains, and loss of hair with skin pigmentation.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of vitamin A deficiency. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that vitamin A test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1810; Docket No. 78N–2436; Vitamin B_{12} test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of vitamin B_{12} test systems:

1. Identification: A vitamin B_{12} test system is a device used to measure vitamin B_{12} in serum, plasma, and urine by methods such as radioassay. Measurements obtained by this device are used in the diagnosis and treatment of anemias or gastrointestinal malabsorption.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that vitamin B_{12} test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of vitamin B_{12} are used in the diagnosis and treatment of patients with gastrointestinal malabsorption or macrocytic, megaloblastic anemia (a deficiency of red cells characterized by the presence of a large abnormal red cell series). The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *324, 325* and *326*). The vitamins folic acid and B_{12} are included in the B group and are essential for the normal maturation of the erythrocyte (red blood cell). A deficiency of either causes megaloblastic anemia. Both vitamins are important in purine and pyrimidine (and therefore nucleic acid) synthesis. Vitamin B_{12} (cyanocobalamin) is believed to be required for normal metabolism of folic acid. Vitamin B_{12} is absorbed in the ileum. In malabsorption syndromes affecting the ileum, vitamin B_{12} deficiency can occur.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of anemias or gastrointestinal malabsorption. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that vitamin B^{12} test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1815; Docket No. 78N–2437; Vitamin E test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of vitamin E test systems:

1. Identification: A vitamin E test system is a device used to measure vitamin E (tocopherol) in serum by methods such as hexane extraction/fluorescence. Measurements obtained by this device are used in the diagnosis and treatment of infants with vitmain E deficiency syndrome.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that vitamin E test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of vitamin E are used in the diagnosis and treatment of infants with vitamin E deficiency syndrome associated with hemolytic anemia and low birth weight. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and

effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *327* and *328*). Vitamin E (tocopherol) is a fat soluble vitamin. In experimental animals, vitamin E deficiency causes fetal death and sterility in both sexes and is related to muscular dystrophy. Vitamin E deficiency has not been shown to produce definite clinical effects in humans, and therapeutric trials for various conditions have produced disappointing results.

5. Risks of health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of vitamin E deficiency in infants. Inappropriate therpy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that vitamin E test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.1820; Docket No. 78N-2438; Xylose test system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of xylose test sysetms:

1. Identification: A xylose test system is a device used to measure xylose (a sugar) in serum, plasma, and urine by methods such as para-bromoaniline (colorimetric). Measurements obtained by this device are used in the diagnosis and treatment of gastrointestinal malabsorption syndrome (a group of disorders in which there is subnormal absorption of dietary constituents and thus excessive loss from the body of the nonabsorbed substances).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that xylose test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnositc information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of xylose are used in the diagnosis and treatment of patients with gastrointestinal disorders of malabsorption. The xylose test is peformed to determine the level of xylose present in a patient's blood and urine at a specified time following oral ingestion of a dose of xylose. Low absorption of xylose (low urine level) is observed in intestinal malabsorption. Simultaneous measurement of the patient's blood xylose helps to differentiate low urinary xylose levels which may be due to decreased excretion of xylose by the kidneys rather than to intestinal malabsorption. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonalbe assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *329*, *330* and *31*).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of intestinal malabsorption syndromes. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that xylose test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.2050; Docket No. 78N-2439; General purpose laboratory equipment.

The Clinical Chemistry Device Classification Panel, the Clinical Toxicology Device Classification Panel, the Hematology Device Classification Panel, and the Pathology Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of general purpose laboratory equipment:

1. Identification: General purpose laboratory equipment are devices that have general applications and that are intended to prepare and examine specimens from the human body. Labeling for these devices does not make reference to a use in a specific diagnostic procedure.

2. Recommended classification: Class I (general controls). The Clinical Chemistry Device Classification Panel and the Hematology Device Classification Panel recommend that manufacturers of the analytical balance, blender/mixer, thermostated cuvette, dialyzer, drying unit, ion selective electrode (nonspecified), evaporator, membrane filter unit, freezer, heating block, micro mixer, micro pipette, pH meter, polarimeter, shaker/stirrer, temperature regulator, general laboratory timer and water purifier (absorption, deionization, membrane filtration)/reagent grade water system (reverse osmosis) be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) and, in the manufacture of these devices, from the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)). The Clinical Chemistry Device Classification Panel and the Hematology Device Classification Panel recommend that the centrifuge (micro, refrigerated, ultra) and blood tube mixer be classified into class I with no exemptions. The Pathlogy Device Classification Panel recommends that the general centrifuge be classified into class I with no exemptions. The Clinical Toxicology Device Classification Panel recommends that the general use centrifuge, general use balance, and pH meter be classified into class I with no exemptions.

3. Summary of reasons for recommendation: The Panels recommend that general purpose laboratory equipment be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices. The Clinical Chemistry Device Classification Panel and the Hematology Device Classification Panel made the recommendation described above that

manufacturers of the named devices be exempted from premarket notification under section 510(k) of the act and, in the manufacture of these devices, from the GMP regulation under section 520(f) of the act because these devices are widely used and have a history of satisfactory performance. These two Panels recommend that the manufacturers of the named devices be exempt from the good manufacturing practice requirements in the manufacture of these devices because adherence to the good manufacturing practice regulation would not improve the safety and effectiveness of the device. The Panels believe that the reliability of current manufacturing practice for these devices has been well established, and that these devices present no risks to health when used by persons trained in their use.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, these devices.

5. Risks to health: None identified.

FDA agrees with the Panels' recommendations and is proposing that general purpose laboratory equipment be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the recommendation of the Clinical Chemistry Device Classification Panel and the Hematology Device Classification Panel that manufacturers of general purpose laboratory equipment be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration and device listing under section 510 (a) through (j) of the act, but exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration and listing by manufacturers of general purpose laboratory equipment, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing these devices and to conduct necessary inspections. The agency has determined, however, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning general purpose laboratory equipment. The agency does not at this time anticipate that premarket approval will be required for these devices. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

In response to the recommendation of the Clinical Chemistry Device Classification Panel and the Hematology Device Classification Panel that manufacturers of general purpose laboratory equipment be exempt from the device GMP regulation under section 520(f) of the act, FDA is proposing that a manufacturer of these devices be exempt, in the manufacture of the devices, from all requirements in the GMP regulation except § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files. Based on available information about current practices used in the manufacture of the devices and user experience with the devices, the agency has determined that application of the GMP regulation, other than § 820.180 and § 820.198, is unlikely to improve the safety and effectiveness of the devices. The agency believes, however, that manufacturers of general purpose laboratory equipment must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of general purpose laboratory equipment must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturers' corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate. See the discussion above in this preamble under the heading "Exemption's for Class I Devices" for further discussion of the agency's policies concerning exemptions.

The agency has reviewed the Panels' recommendations for general purpose laboratory equipment and has concluded that the classification of these generic types of devices should be published in the part of the Code of Federal Regulations for clinical chemistry devices.

Section 862.2100; Docket No. 78N-2441; Calculator/data processing module for clinical use.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of calculators/data processing modules for clinical use:

1. Identification: A calculator/data processing module for clinical use is an electronic device used to store, retrieve, and process laboratory data by means of programmable cassettes.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that calculators/data processing modules for clinical use be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that calculators/data processing modules for clinical use be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 862.2140; Docket No. 78N-2443; Centrifugal chemistry analyzer for clinical use.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of centrifugal chemistry analyzers for clinical use:

1. Identification: A centrifugal chemistry analyzer for clinical use is an automatic device that centrifugally mixes a sample and a reagent and spectrophotometrically measure concentrations of the sample constituents. This device is used in conjunction with certain materials to measure a variety of analytes.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that centrifugal chemistry analyzers for clinical use be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that centrifugal chemistry analyzers for clinical use be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 862.2150; Docket No. 78N-2444; continuous flow sequential multiple chemistry analyzer for clinical use.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of continuous flow sequential multiple chemistry analyzers for clinical use:

1. Identification: A continuous flow sequential multiple chemistry analyzer for clinical use is a modular analytical instrument that, using the principles of automated continuous flow systems, can simultaneously perform multiple chemical procedures. This device is used in conjunction with certain materials to measure a variety of analytes.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that continuous flow sequential multiple chemistry analyzers for clinical use be classified into class I (general controls) because the panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that continuous flow sequential multiple chemistry analyzers for clinical use be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 862.2160; Docket No. 78N-2445; Discrete photometric chemistry analyzer for clinical use.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of discrete photometric chemistry analyzers for clinical use:

1. Identification: A discrete photometric chemistry analyzer for clinical use is a device that duplicates manual analytical procedures by performing automatically various steps such as pipetting, preparing filtrates, heating, and measuring color intensity. This device is used in conjunction with certain materials to measure a variety of analytes. Different models of the device incorporate various instrumentation such as micro analysis apparatus, double beam, single, or dual channel photometers, and bichromatic two-wavelength photometers. Some models of the device may include reagent-containing components that may also serve as reaction units.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that discrete photometric chemistry analyzers for clinical use be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that discrete photometric chemistry analyzers for clinical use be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 862.2170; Docket No. 78N-2446; Micro chemistry analyzer for clinical use.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of micro chemistry analyzers for clinical use:

1. Identification: A micro chemistry analyzer for clinical use is a device that duplicates manual analytical procedures by performing automatically various steps such as pipetting, preparing filtrates, heating, and measuring color intensity. The distinguishing characteristic of the device is that it requires only micro volumes of samples, which facilitates the analysis of the very small volume samples obtainable from pediatric patients. This device is used in conjunction with certain materials to measure a variety of analytes.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that micro chemistry analyzers for clinical use be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that micro chemistry analyzers for clinical use be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 862.2230; Docket No. 78N-2450; Chromatographic separation material for clinical use.

The Clinical Toxicology Device Classification Panel and the Pathology Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of chromatographic separation materials for clinical use:

1. Identification: A chromatographic separation material for clinical use is a device accessory (e.g., ion exchange absorbents, ion exchange resins, and ion papers) used in ion exchange chromatography, a procedure in which a compound is separated from a solution.

2. Recommended classification: Class I (general controls). The Clinical Toxicology Device Classification Panel recommends that manufacturers of chromatographic separation materials for clinical use be exempt, in the manufacture of these devices, from the good manufacturing practice (GMP) regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)). The Pathology Device Classification Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panels recommend that chromatographic separation materials for clinical use be

classified into class I (general controls) because the Panels believe that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Clinical Toxicology Device Classification Panel recommends that manufacturers of chromatographic separation materials be exempt, in the manufacture of these devices, from the GMP regulation under section 520(f) of the act because current manufacturing practices and user experience show that application of the GMP regulation would not improve the safety and effectiveness of these devices.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panels' recommendations and is proposing that chromatographic separation materials for clinical use be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. However, the agency disagrees with the Clinical Toxicology Device Classification Panel's recommendation that manufacturers of chromatographic separation materials be exempt, in the manufacture of these devices, from the GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)). The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent production of chromatographic separation materials having defects that could harm users.

The agency has reviewed the Panels' recommendations for chromatographic separation materials and has concluded that the classification of this device should be published in the part of the Code of Federal Regulations for clinical chemistry devices.

Section 862.2250; Docket No. 78N-2452; Gas liquid chromatography system for clinical use.

The Clinical Toxicology Device Classification Panel, the Clinical Chemistry Device Classification Panel, and the Microbiology Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of gas liquid chromatography systems for clinical use:

1. Identification: A gas liquid chromatography system for clinical use is a device used to separate one or more drugs or compounds from a mixture. Each of the constituents in a vaporized mixture of compounds is separated according to its vapor pressure. The device may include accessories such as columns, gases, column supports and liquid coating.

2. Recommended classification: Class I (general controls). The Panels recommend that there be no exemptions.

3. Summary of reasons for recommendation: The Panels recommend that gas liquid chromatography systems for clinical use be classified into class I (general controls) because the Panels believe that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, these devices.

5. Risks to health: The Microbiology Device Classification Panel identified the following risks to health presented by the device: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of the presence of a human pathogen(s). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. The Clinical Toxicology and Clinical Chemistry Device Classification Panels did not identify any risks to health presented by the device.

FDA agrees with the Panels' recommendations and is proposing that gas liquid chromatography systems for clinical use be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

The agency has reviewed the Panels' recommendations for gas liquid chromatograph systems and has concluded that the classification of this device should be published in the part of the Code of Federal Regulations for clinical chemistry devices.

Section 862.2260; Docket No. 78N-2453; High-pressure liquid chromatography system for clinical use.

The Clinical Toxicology Device Classification Panel and the Clinical Chemistry Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of high pressure liquid chromatography systems for clinical use:

1. Identification: A high pressure liquid chromatography system for clinical use is a device used to separate one or more drugs or compounds from a solution by processing the mixture of compounds (solutes) through a column packed with materials of uniform size (stationary phase) under the influence of a high pressure liquid (mobile phase). Separation of the solutes occurs either by absorption, sieving, partition, or selective affinity.

2. Recommended classification: Class I (general controls). The Panel recommend that there be no exemptions.

3. Summary of reasons for recommendation: The Panels recommend that high pressure liquid chromatography systems for clinical use be classified into class I (general controls) because the Panels believe that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panels members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panels' recommendations and is proposing that high pressure liquid chromatography systems for clinical use be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 862.2270; Docket No. 78N-2454; Thin-layer chromatography system for clinical use.

The Clinical Toxicology Device Classification Panel and the Clinical Chemistry Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of thin-layer chromatography systems for clinical use:

1. Identification: A thin-layer chromatography (TLC) system for clinical use is a device used to separate one or more drugs or compounds from a mixture. The mixture of compounds is absorbed onto a stationary phase or thin layer of inert material (e.g., cellulose, alumina, etc.) and eluted off by a moving solvent (moving phase) until equilibrium occurs between the two phases.

2. Recommended classification: Class I (general controls). The Clinical Toxicology Device Classification Panel recommends that manufacturers of particular components of the device, the thin-layer chromatography (TLC) apparatus for clinical use, the TLC atomizer, the TLC developing tanks, and the TLC ultraviolet (UV) light, be exempt, in the manufacture of these components, from the good manufacturing practice (GMP) regulation under section 520(f) of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)). The Clinical Chemistry Device Classification Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panels recommend that thin-layer chromatography systems be classified into class I (general controls) because the Panels believe that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Clinical Toxicology Device Classification Panel recommends that manufacturers of particular components of the device, the thin-layer chromatography apparatus general use, the TLC atomizer, the TLC developing tanks and the TLC UV light be exempt, in the manufacture of these components, from the GMP regulation under section 520(f) of the act because user experience shows that application of the GMP regulation would not improve the safety and effectiveness of these particular components of TLC systems.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panels' recommendations and is proposing that thin layer chromatography systems be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Clinical Toxicology Device Classification Panel recommendation that manufacturers of particular components of thin layer chromatography (TLC) systems, the thin layer chromatography apparatus, TLC atomizer, TLC developing tanks, and TLC UV light be exempt from the good manufacturing practice (GMP) regulation under section 520(f) of the act, FDA is proposing that manufacturers of these particular components of TLC systems be exempt, in the manufacture of these components, from all requirements in the GMP regulation except § 820.180 regarding general requirements concerning records, and § 820.198, regarding complaint files. See the preamble at § 862.2050 *General purpose laboratory equipment* for further discussion of the agency's policies concerning exemptions.

Section 862.2300; Docket No. 78N-2455; Colorimeter, photometer, or spectrophotometer for clinical use.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of colorimeters, photometers, or spectrophotometers for clinical use:

1. Identification: A colorimeter, a photometer, or a spectrophotometer for clinical use is a electronic device used to measure the light absorbance of solutions. The device may include a monochromator to produce light of a specific wavelength.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the colorimeters, photometers, or spectrophotometers for clinical use be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that colorimeters, photometers, or spectrophotometers for clinical use be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 862.2310; Docket No. 78N-2456; Clinical sample concentrator.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of clinical sample concentrators:

1. Identification: A clinical sample concentrator is a device used to concentrate (by dialysis, evaporation, etc.) serum, urine, cerebrospinal fluid, and other body fluids before the fluids are analyzed.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that clinical sample concentrators be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that clinical sample concentrators be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 862.2320; Docket No. 78N-2457; beta or *gamma* counter for clinical use.

The Clinical Chemistry Device Classification Panel and the Clinical Toxicology Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of *beta* or *gamma* counters for clinical use:

1. Identification: A *beta* or *gamma* counter for clinical use is a device used to detect and count *beta* or *gamma* radiation emitted by clinical samples. The radiation emitted by a sample, following a chemical reaction with a radioactive reagent, is proportional to the concentration of the analyte being measured. These measurements are useful in the diagnosis and treatment of various disorders.

2. Recommended classification: The Clinical Chemistry Device Classification Panel recommends that a *beta* or *gamma* counter for clinical use be classified into class I with no exemptions. The Clinical Toxicology Device Classification Panel recommends that *gamma* counters for clinical use and liquid scintillation counters for clinical use be classified into class I with no exemptions. The Clinical Toxicology Device Classification Panel recommends that radioimmunoassay (RIA) procedure *gamma* counters for clinical use be classified into class II with a medium priority for establishing a performance standard.

3. Summary of reasons for recommendation: The Clinical Chemistry Device Classification Panel and Clinical Toxicology Device Classification Panel recommend that *beta* or *gamma* counters for clinical use be classified into class I because both Panels believe that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Clinical Toxicology Device Classification Panel recommends that radioimmunoassay procedure *gamma* counters for clinical use be classified into class II because

there is a need for a performance standard that prescribes for the device acceptable ranges of accuracy, precision, sensitivity, and specificity, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over this device's accuracy, precision, sensitivity and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Both the Clinical Chemistry Device Classification Panel and the Clinical Toxicology Device Classification Panel did not identify any risks to health presented by *beta* or *gamma* counters for clinical use. The Clinical Toxicology Device Classification Panel identified the following risk to health prosented by radioimmunoassay procedure *gamma* counters for clinical use: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may result in findings of erroneously high or low levels of *gamma* radiation emitted by clinical samples, thereby providing an incorrect diagnosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panels' recommendations and is proposing that *beta* or *gamma* counters for clinical use be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. For this reason, the agency disagrees with the Clinical Chemistry Device Classification Panel's recommendation that the RIA procedure *gamma* counter for clinical use be classified into class II.

FDA has reviewed the Panels' recommendations and the literature relating to *beta* or *gamma* counters for clinical use and RIA procedure *gamma* counters for clinical use (Ref. 334). The agency believes that the RIA procedure *gamma* counter is the same generic type of device as the *beta* or *gamma* counter for clinical use considered by the Clinical Chemistry Device Classification Panel and the Clinical Toxicology Device Classification Panel.

Section 862.2400; Docket No. 78N-2459; Densitometer/scanner (intergrating, reflectance, thin-layer chromatography, or radiochromatogram) for clinical use.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of densitometers/scanners (integrating, reflectance, TLC, or radiochromatogram) for clinical use:

1. Identification: A densitometer/scanner (integrating, reflectance, thin-layer chromatography, or radiochromatogram) for clinical use is a device used to measure the concentration of a substance on the surface of a film or other support media by either a photocell measurement of the light transmission through a given area of the medium or, in the case of the radiochromatogram scanner, by measurement of the distribution of a specific radioactive element on a radiochromatogram.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that densitometers/scanners (integrating, reflectance, TLC, or radiochromatogram) for clinical use be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the panel recommendation and is proposing that densitometers/scanners (integrating, reflectance, TLC, or radiochromatogram) for clinical use be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 862.2485; Docket No. 78N-2463; Electrophoresis apparatus for clinical use.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of electrophoresis apparatus for clinical use:

1. Identification: A electrophoresis apparatus for clinical use is a device used to separate molecules or particles, including plasma proteins, lipoproteins, enzymes, and hemoglobins, on the basis of their net charge in specified buffered media. This device is used in conjunction with certain materials to measure a variety of analytes as an aid in the diagnosis and treatment of certain disorders.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that electrophoresis apparatus for clinical use be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that electrophoresis apparatus for clinical use be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 862.2500; Docket No. 78N-2464; Enzyme analyzer for clinical use.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of enzyme analyzers for clinical use:

1. Identification: An enzyme analyzer for clinical use is a device used to measure enzymes in blood plasma or serum by nonkinetic or kinetic measurement of enzyme-catalyzed reactions. This device is used in conjunction with certain materials to measure a variety of enzymes as an aid in the diagnosis and treatment of certain enzyme related disorders.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that enzyme analyzers for clinical use be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel

based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that enzyme analyzers for clinical use be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 862.2540; Docket No. 78N-2467; Flame emission photometer for clinical use.

The Clinical Chemistry Device Classification Panel, and the Clinical Toxicology Device Classificastion Panel, FDA advisory committees, made the following recommendations regarding the classification of flame emission photometers for clinical use:

1. Identification: A flame emission photometer for clinical use is a device used to measure the concentration of sodium, potassium, lithium, and other metal ions in body fluids. Abnormal variations in the concentration of these substances in the body are indicative of certain disorders (e.g., electrolyte imbalance and heavy metal intoxication) and are, therefore, useful in diagnosis and treatment of those disorders.

2. Recommended classification: Class I with no exemptions. The Clinical Chemistry Device Classification Panel recommends that flame emission photometers for clinical use be classified into class I with no exemptions. The Clinical Toxicology Device Classification Panel recommends that flame photometers, general use, be classified into class I with no exemptions. The Clinical Toxicology Device Classification Panel recommends that heavy metals flame photometers be classified into class II and recommends that establishing a performance standard be a high priority.

3. Summary of reasons for recommendation: The Clinical Chemistry Device Classification Panel and the Clinical Toxicology Device Classification Panel recommend that flame emission photometers for clinical use be classified into class I (general controls) because the panels believe that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Clinical Toxicology Device Classification Panel recommends that heavy metals flame photometers be classified into class II (performance standards) because there is is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, specificity, and sensitivity and thereby minimizes the possibility that the device may state inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls alone would not provide sufficient control over the heavy metals flame photometers' stability. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Clinical Chemistry Device Classification Panel and the Clinical Toxicology Device Classification Panel based their recommendations on the Panel members' personal knowledge of, and clinical experience with this device and upon a review of the literature (Refs. *333, 334,* and *335*). Flame emission photometers are used for the measurement of life-supporting elements (e.g., sodium, potassium, magnesium, and calcium), as well as heavy metals. These life-supporting elements are responsible for electrolyte (salt) balance in normal human physiology. Heavy metals in the body can produce toxic reactions and electrolyte imbalance. Interference from biological materials, the environment, or variations of the flame may affect the accuracy of the test results. Persons who use flame emission photometers should be appropriately trained to recognize the influence of these factors and adjust the device to eliminate the possibility that they will interfere with test results.

5. Risks to health: The Clinical Chemistry Device Classification Panel and the Clinical Toxicology Device Classification Panel did not identify any risks to health presented by flame emission photometers. The Clinical Toxicology Device Classification Panel identified the following risk to health presented by heavy metals flame photometers: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may result in an error in the measurement of heavy metals in body fluids. Inappropriate therapy based on inaccurate diagnosis data may place the patient at risk.

FDA agrees with the Panels' recommendations regarding the flame emission photometer and the flame photometer, general use and is proposing that the generic type of device named flame emission photometers for clinical use be classified into class I (general controls) with no exemptions. FDA believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. FDA disagrees with the recommendation of the Clinical Toxicology Device Classification Panel that heavy metals flame photometers be classified into class II (performance standards). FDA has reviewed the Panels' recommendations and the literature relating to the flame emission photometer for clinical use and the heavy metals flame photometer and has concluded they are essentially the same generic type of device. FDA believes that all flame emission photometers for clinical use, whether for the measurement of essential elements or heavy metals, can be adequately controlled by general controls (class I).

Section 862.2560; Docket No. 78N-2468; Fluorometer for clinical use.

The Clinical Chemistry Device Classification Panel and the Clinical Toxicology Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of fluorometers for clinical use:

1. Identification: A fluorometer for clinical use is a device used to measure by fluorescence certain analytes. Fluorescence is the property of certain substances of radiating, when illuminated, a light of a different wavelength. This device is used in conjunction with certain materials to measure a variety of analytes.

2. Recommended classification: Class I (general controls). The Panels recommend that there be no exemptions.

3. Summary of reasons for recommendation: The Panels recommend that fluorometers for clinical use be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel does not believe that this device requires performance standards to control the identified risks to health.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *336*).

5. Risk to health: The Clinical Chemistry Device Classification Panel identified no risks to health presented by the device. The Clinical Toxicology Device Classification Panel identified a possible potential hazard to users from the ultraviolet light source.

FDA agrees with the Panels' recommendations and is proposing that fluorometers for clinical use be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 862.2680; Docket No. 78N-2472; Microtitrator for clinical use.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of microtitrators for clinical use:

1. Identification: A Microtitrator for clinical use is a device used in microanalysis to measure the concentration of a substance by reacting it with a measured "micro" volume of a known standardized solution.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that microtitrators for clinical use be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that microtitrators for clinical use be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 862.2700; Docket No. 78N-2474; Nephelometer for clinical use.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nephelometers for clinical use:

1. Identification: A nephelometer for clinical use is a device used to estimate the concentration of particles in a suspension by measuring their light scattering properties (the deflection of light rays by opaque particles in their path). The device is used in conjunction with certain materials to measure the concentration of a variety of analytes.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that nephelometers for clinical use be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that nephelometers for clinical use be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 862.2720; Docket No. 78N-2475; Plasma oncometer for clinical use.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of plasma oncometers for clinical use:

1. Identification: A plasma oncometer for clinical use is a device used to measure plasma oncotic pressure, which is that portion of the total plasma osmotic pressure contributed by protein and other molecules too large to pass through a specified semipermeable membrane. Because variations in plasma oncotic pressure are indications of certain disorders, measurements of these variations are useful in the diagnosis and treatment of these disorders.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that plasma oncometers for clinical use be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recoimmendation on the members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that plasma oncometers for clinical use be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 862.2730; Docket No. 78N-2476; Osmometer for clinical use.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of osmometers for clinical use:

1. Identification: An osmometer for clinical use is a device used to measure the osmotic pressure of body fluids. Osmotic pressure is the pressure required to prevent the passage of a solution with a lesser solute concentration into a solution with greater solute concentration when the two solutions are separated by a semipermeable membrane. The concentration of a solution affects its osmotic pressure, freezing point, and other physiochemical properties. Osmometers determine osmotic pressure by methods such as the measurement of the freezing point. Measurements obtained by this device are used in the diagnosis and treatment of body fluid disorders.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that osmometers for clinical use be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and a review of the literature (Ref. *337*).

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that osmometers for clinical use be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 862.2750; Docket No. 78N-2477; Pipetting and diluting system for clinical use.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of pipetting and diluting systems for clinical use:

1. Identification: A pipetting and diluting system for clinical use is a device that provides an accurately measured volume of liquid at a specified temperature that may be used in certain test procedures. This generic type of device system includes serial, manual, automated, and semi-automated dilutors, pipettors, dispensers, and pipetting stations.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that pipetting and diluting systems for clinical use be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that pipetting and diluting systems for clinical use be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 862.2800; Docket No. 78N-2481; Refractometer for clinical use.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of refractometers for clinical use:

1. Identification: A refractometer for clinical use is a device used to determine the amount of solute in a solution by measuring the index of refraction (the ratio of the velocity of light in a vacuum to the velocity of light in the solution). The index of refraction is used to measure the concentration of certain analytes (solutes), such as plasma total proteins and urinary total solids. Measurements obtained by this device are used in the diagnosis and treatment of certain conditions.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that refractometers for clincial use be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation is proposing that refractometers for clinical use be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 862.2850; Docket No. 78N-2483; Atomic absorption spectrophotometer for clinical use.

The Clinical Toxicology Device Classification Panel and the Clinical Chemistry Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of atomic absorption spectrophotometers for clinical use:

1. Identification: An atomic absorption spectrophotometer for clinical use is a device used to identify and measure elements and metals (e.g., lead and mercury) in human specimens. The metal elements are identified according to the wavelength and intensity of the light that is absorbed when the specimen is converted to the atomic vapor phase. Measurements obtained by this device are used in the diagnosis and treatment of certain conditions.

2. Recommended classification: Class I (general controls). Both Panels recommend that there be no exemptions.

3. Summary of reasons for recommendation: The Panels recommend that atomic absorption spectrophotometers for clincial use be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panels recommendations and is proposing that refractometers for clinical use be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 862.2860; Docket No. 78N-2484; Mass spectrophotometer for clinical use.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of mass spectrophotometers for clinical use:

1. Identification: A mass spectrophotometer for clinical use is a device used to identify metallic or organic compounds (e.g., lead, mercury, and drugs) in human specimens by ionizing the compound under investigation and separating the resulting ions by means of an electrical and a magnetic field according to their mass.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that mass spectrophotometers for clinical use be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that mass spectrophotometers for clinical use be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 862.2900; Docket No. 78N-2487; Automated urinalysis system.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of automated urinalysis systems:

1. Identification: An automated urinalysis sytem is a device used to measure certain of the physical properties and chemical constituents of urine by procedures that duplicate manual urinalysis test systems. This device is used in conjunction with certain materials to measure a variety of urinary analytes.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that automated urinalysis systems be classified into class I (general controls) because the panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that automated urinalysis systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 862.2920; Docket No. 78N-2488; Plasma viscometer for clinical use.

The Clinical Chemistry Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of plasma viscometers for clinical use;

1. Identification: A plasma viscometer for clinical use is a device used to measure the viscosity of blood plasma by determining the time period required for the plasma to flow a measured distance through a calibrated glass tube. Measurements obtained by this device are used to monitor changes in the amount of solids present in plasma in various disorders.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panels recommends that plasma viscometers for clincial use be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that plasma viscometers for clinical use be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 862.3040; Docket No. 78N-2490; Alcohol test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of alcohol test systems:

1. Identification: An alcohol test system is a device used to measure alcohol (e.g., ethanol, methanol, isopropanol, etc.) in human body fluids (e.g., serum, whole blood, and urine) by methods such as alcohol dehydrogenase (ADH) enzymatic method, gas chromatography, or potassium dichromate method. Measurements obtained by this device are used in the diagnosis and treatment of alcohol intoxication and poisoning.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that alcohol test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: the Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *338* through *344*). Comatose patients entering hospital emergency rooms are routinely screened for alcohol intoxication because it is necessary to determine whether alcohol caused the comatose condition and, if so, to identify the type of alcohol specifically. The dectection and measurement of ethanol must be controlled to assure that a toxic nonbeverage type alcohol (e.g., isopropanol, propanol, and ethylene glycol) is not identified as ethanol. Cross-reactivity is a major concern in the diagnosis for alcohol, and any positive result should be confirmed by a second diagnostic test.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may result in findings of erroneously high or low levels of alcohol in specimens or the identification of the incorrect type of alcohol. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that alcohol test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3050; Docket No. 78N-2491; Breath-alcohol test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of breath-alcohol test systems:

1. Identification: A breath-alcohol test system is a device used to measure alcohol in the human breath. The device utilizes qualitative gas chromatography to distinguish between various alcohols (i.e., ethanol, methanol, isopropanol, and acetone). Measurements obtained by this device are used in the diagnosis of alcohol intoxication.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that breath-alcohol test systems be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that breath alcohol test systems be classified

into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 862.3100; Docket No. 78N-2495; Amphetamine test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of amphetamine test systems:

1. Identification: An amphetamine test system is a device used to measure amphetamine, a central nervous system stimulating drug, in plasma and urine by methods such as gas chromatography, liquid chromatography, thin-layer chromatography, enzyme immunoassay, or radioimmunoassay. Measurements obtained by this device are used in the diagnosis and treatment of amphetamine overdose and in monitoring levels of amphetamine to ensure appropriate therapy.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device by a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that amphetamine test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance fo the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *345, 346,* and *347*). Amphetamines are used as a central nervous system (CNS) stimulant in the treatment of narcolepsy (uncontrolled sleepiness), attention deficit disorders and as an adjunct in the treatment of exogenous obesity. Amphetamines can produce toxic reactions (e.g., restlessness, insomnia, and cardiac failure with severe over stimulation), and addiction.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactory may result in findings of erroneously high or low levels of amphetamine. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that amphetamine test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3110; Docket No. 78N-2496; Antimony test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of antimony test systems:

1. Identification: An antimony test system is a device used to measure antimony, a heavy metal, in urine, blood, vomitus, and stomach contents by methods such as atomic absorption spectroscopy or colorimetry. Measurements obtained by this device are used in the diagnosis and treatment of antimony poisoning.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that antimony test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *348* and *349*). Antimony is a heavy metal that is used in various drugs and pesticides. Antimony is not normally present in the human body. Antimony poisoning can result from ingestion of insecticides and contaminated food or through occupational poisoning. Chronic or acute toxicity can result in nausea, vomiting, dermatitis, abdominal pain, cyanosis (a bluish discoloration of skin and mucous membranes), liver damage, coma, and death due to cardiac failure. The clinical symptoms of antimony poisoning and arsenic poisoning are very similar. The colorimetric assay method (i.e., Reinsch test) is a screening test for heavy metals, particularly arsenic, antimony, bismuth, and mercury. Antimony can be quantitatively measured by this procedure as well as the atomic absorption procedure.

5. Risks of health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may result in findings of erroneously high or low levels of antimony. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that antimony test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3120; Docket No. 78N-2497; Arsenic test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of arsenic test systems:

1. Identification: An arsenic test system is a device used to measure arsenic, a poisonous heavy metal, in urine, vomitus, stomach contents, nails, hair, and blood by methods such as atomic absorption spectrophotometry, ultraviolet spectrophotometry, or colorimetry. Measurements obtained by this device are used in the diagnosis and treatment of arsenic poisoning.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that arsenic test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *350* through *353*). Arsenic poisoning can result from ingestion of drugs, pesticides, herbicides, contaminated food, and paints and dyes. Acute toxicity can result in gastric pain, diarrhea, shock, coma, and death within 24 hours after ingestion. Chronic toxicity can result in weakness, loss of appetite, nausea, increased pigmentation, pain in joints, and motor paralysis. Acute and chronic symptoms of arsenic poisoning are dependent on the oxidative state (the ability of arsenic to lose electrons) of the arsenic, making arsenic (III) more toxic than arsenic (V). Distinguishing these oxidative states is essential in accurately diagnosing arsenic toxicity. All reagents used in the diagnostic test should be analyzed for arsenic to prevent false-positive results.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may result in findings of erroneously high or low levels of arsenic. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that arsenic test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3150; Docket No. 78N-2498; Barbiturate test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of barbiturate test systems:

1. Identification: A barbiturate test system is a device used to measure barbiturates, a class including hypnotic/sedative and anticonvulsant drugs, in serum, urine, and gastric contents by methods such as thin-layer chromatography, gas chromatography, colorimetry, enzyme immunoassay, high pressure liquid chromatography, hemagglutination inhibition, or radioimmunoassay. Measurements obtained by this device are used in the diagnosis and treatment of barbiturate overdose and in monitoring levels of barbiturate to ensure appropriate therapy.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that barbiturate test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *354* and *355*). Barbiturates have several therapeutic uses (e.g., anticonvulsant, sedative, hypnotic, and analgesic). Large doses can result in toxic reactions (e.g., lethargy, depression, coma, and death due to respiratory arrest).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may result in findings of erroneously high or low levels of barbiturates. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that barbiturate test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3170; Docket No. 78N-2499; Benzodiazepine test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of benzodiazepine test systems:

1. Identification: A benzodiazepine test system is a device used to measure any of the benzodiazepine compounds, sedative and hypnotic drugs, in blood, plasma, and urine by methods such as enzyme immunoassay, ultraviolet spectrophotometry, gas chromatography, high pressure liquid chromatography, or thin-layer chromatography. The benzodiazepine compounds include chlordiazepoxide, diazepam, oxazepam, chlorazepate, flurazepam, and nitrazepam. Measurements obtained by this device are used in the diagnosis and treatment of benzodiazepine overdose.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that benzodiazepine test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information.

Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *356* and *357*). Benzodiazepine compounds are used in the treatment of anxiety or alcohol withdrawal syndrome, and as a muscle relaxant, but may be addictive if used excessively. The compounds may be detected in the plasma and urine for several days after administration due to their long half-life and conversion to active metabolites. Substances with similar chemical structure and metabolites of the benzodiazepine compounds may interfere with the test and can result in erroneous findings.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may result in findings of erroneously high or low levels of benzodiazepine compounds. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that benzodiazepine test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device

Section 862.3200; Docket No–78N–2501; Clinical toxicology calibrator.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of clinical toxicology calibrators:

1. Identification: A clinical toxicology calibrator is a device that is used as a reference material for equipment set-up and that is used to determine the accuracy of a device by measuring the variation from a standard or by developing a standard curve for a diagnostic assay. A clinical toxicology calibrator can be a mixture of drugs or a specific material for a particular drug (e.g., ethanol, lidocaine, etc.).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that clinical toxicology calibrators be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device. Clinical toxicology calibrators used in developing a standard curve for a particular diagnostic test must be sufficiently sensitive and specific to determine correctly the amounts of analyte present in the sample.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may result in findings of erroneously high or low levels of analyte. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that clinical toxicology calibrators be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3220; Docket No. 78N–2503; Carbon monoxide test system.

The Clinical Toxicology Device Classification Panel, the Clinical Chemistry Device Classification Panel and the Anesthesiology Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of carbon monoxide test systems:

1. Identification: A carbon monoxide test system is a device used to measure carbon monoxide or carboxyhemoglobin (carbon monoxide bound to the hemoglobin in the blood) in blood by methods such as microdiffusion analysis, spectrophotometric determination, or gas chromatography. Measurements obtained by this device are used in the diagnosis and treatment of or confirmation of carbon monoxide poisoning.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panels recommend that carbon monoxide test systems be classified into class II because there is need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The measurement is necessary to assess the decrease in the oxygen-carrying capacity of the patient's blood to assure proper diagnosis of the patient's condition. The Panels believe that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panels believe that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *358* through *361*). Carbon monoxide analysis is used mainly in governmental investigations of injuries or deaths resulting from fires or suicides. The normal value for carbon monoxide in the blood is 0.5 percent saturation, with 40 to 80 percent saturation being considered a fatal concentration.

Postmortem blood or blood with desaturated hemoglobin cannot be used to obtain accurate results using the spectrophotometric method. Gas chromatography can be used in postmortem specimens.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may result in findings of erroneous high or low levels of carbon monoxide. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panels' recommendations and is proposing that carbon monoxide test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3240; Docket No. 78N-2505; Cholinesterase test system.

The Clinical Toxicology Device Classification Panel and the Clinical Chemistry Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of cholinesterase test systems:

1. Identification: A cholinesterase test system is a device used to measure cholinesterase (an enzyme that catalyzes the hydrolysis of acetylcholine to choline) in human specimens by methods such as test paper colorimetry or electrometry. There are two principal types of cholinesterase in human tissues. True cholinesterase is present at nerve endings and in erythrocytes (red blood cells) but is not present in plasma. Pseudo cholinesterase is present in plasma and liver but is not present in erythrocytes. Measurements obtained by this device are used in the diagnosis and treatment of cholinesterase inhibition disorders (e.g., insecticide poisoning and succinylcholine poisoning).

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panels recommend that cholinesterase test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *362* through *365*). Cholinesterase analysis is used in the diagnosis and treatment of poisonings associated with certain organophosphorus insecticides and of prolonged apnea (no breathing) in patients given the muscle relaxant succinylcholine. Serum proteins and temperature variations can interfere with cholinesterase measurements. The indicator of the colorimetric method may deviate from the normal standards, resulting in an erroneous result.

5. risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may result in findings of erroneously high or low levels of cholinesterase. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panels' recommendations and is proposing that cholinesterase test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3250; Docket No. 78N-2506; Cocaine and cocaine metabolite test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of cocaine and cocaine metabolite test systems:

1. Identification: A cocaine and cocaine metabolite test system is a device used to measure cocaine and a cocaine metabolite (benzoylecgonine) in serum, plasma, and urine by methods such as gas chromatography, thin-layer chromatography, enzyme immunoassay, free radical assay, high pressure liquid chromatography, radioimmunoassay, or hemagglutination. Measurements obtained by this device are used in the diagnosis and treatment of cocaine overdose and in monitoring levels of cocaine and its metabolite to ensure appropriate therapy.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that cocaine and cocaine metabolite test systems be classified into class II because there is a need for a performance standard that prescribed for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *366, 367,* and *368*). The use of small amounts of cocaine can produce toxic reactions, addiction, and death. Cocaine is readily absorbed by the mucous membranes and is detoxified to its metabolite, benzoylecgonine, by the liver. Cocaine derivatives (e.g., norcocaine, benzoylecgonine, pseudobensoylecogonine, and pseudococaine) may cross-react with cocaine antibody in the immunologic test methods (e.g., enzyme immunoassay and radioimmunoassay) giving a false-positive result. A second nonimmunoassay test (e.g., gas chromatography or thin-layer chromatography) may be required to confirm positive findings.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the

device to perform satisfactorily may result in findings of erroneously high or low levels of cocaine and cocaine metabolite. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that cocaine and cocaine metabolite test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3270; Docket No. 78N–2508; Codeine test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of codeine test systems:

1. Identification: A codeine test system is a device used to measure codeine, a narcotic pain-relieving drug, in serum and urine by methods such as thin-layer chromatography, enzyme immunoassay, gas chromatography, high pressure liquid chromatography, or hemagglutination inhibition. Measurements obtained by this device are used in the diagnosis and treatment of codeine overdose and in monitoring levels of codeine to ensure appropriate therapy.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that codeine test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *369* and *370*). Codeine (methylmorphine) is a narcotic analgesic (pain-relieving drug which may become addictive) and antitussive drug that is chemically converted from morphine (a naturally occurring narcotic that is isolated from opium). There is minimal cross-reactivity with substances derived from opium in the enzyme immunoassay. Cross-reactivity with other drugs such as chlorpromazine or dextromethorphan can result in a false-positive test. Positive immunoassay for codeine should be confirmed by an additional nonimmunoassay method. Technical errors in thin layer chromatography (e.g., extraction of the drug from the specimen) can result in a false-negative test.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may result in findings of erroneously high or low levels of codeine. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that codeine test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3280; Docket No. 78N–2509; Clinical toxicology control material.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of clinical toxicology control materials:

1. Identification: A clinical toxicology control material is a device used to provide an estimation of the precision of a device test system and to detect and monitor systematic deviations from accuracy resulting from reagent or instrument defects. This generic type of device includes various control materials, such as alcohol, digoxin, digitoxin, theophylline, lidocaine, methotrexate, *N*-acetylprocainamide, procainamide, drug mixtures, and heavy metals.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that clinical toxicology control materials be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that clinical toxicology control materials be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 862.3300; Docket No. 78N–2511; Digitoxin test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of digitoxin test systems:

1. Identification: A digitoxin test system is a device used to measure digitoxin, a cardiovascular drug, in serum and plasma by radioimmunoassay. Measurements obtained by this device are used in the diagnosis and treatment of digitoxin overdose and in monitoring levels of digitoxin to ensure appropriate theray.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that digitoxin test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision,

sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *371* through *375*). Digitoxin (a drug derived from the plant Digitalis purpurea) is one of several widely prescribed cardiac gylcosides used to control congestive heart failure and other abnormalities that affect cardiac rhythm. Digitoxin and digoxin are structurally similar cardiac glycosides but are derived from different plants and have different pharmokinetic properties. Digitoxin has a narrow range between an effective therapeutic and a toxic level with toxicity resulting in arrhythmia (variations from normal heartbeat), bradycardia (slowness of the heartbeat), anorexia (loss of appetite), and fatigue. Accurate measurement of serum concentrations of digitoxin is a necessary aid in the regulation of digitoxin cardiac therapy. Establishing an effective but nontoxic therapeutic dosage is difficult due to patients' physiological variations (i.e., in patient size and renal, hepatic, and gastrointestinal functions) and the narrow difference between the therapeutic range and the toxic range of digitoxin. Accuracy of the assay method is dependent on the specificity of the antibody and the standards used in preparing the standard curve. Inadequate antibody preparation resulting in a low affinity constant of the antibody is the most common source of error in radioimmunoassay.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may result in findings of erroneously high or low levels of digitoxin. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that digitoxin test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3320; Docket No. 78N–2513; Digoxin test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of digoxin test systems:

1. Identification: A digoxin test system is a device used to measure digoxin, a cardiovascular drug, in serum and plasma by radioimmunoassay. Measurements obtained by this device are used in the diagnosis and treatment of digoxin overdose and in monitoring levels of digoxin to ensure appropriate therapy.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that digoxin test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *376* through *379*). Digoxin (a drug derived from the plant *digitalis lanata*) is one of several prescribed cardiac glycocides used to control congestive heart failure and certain abnormalities of cardiac rhythm (atrial fibrillation and flutter and paroxysmal atrial tachycardia). Digoxin and digitoxin are structurally similar cardiac glycosides but are derived from different plants and have different pharmacokinetic properties. The toxic and effective therapeutic levels of digoxin are not far apart. Toxicity can be severe and includes potentially fatal arrhythmias (irregular heartbeat), bradycardia (slow heartbeat), and heart block (interference with the electrical transmission of the heart beat). Accurate measurement of serum concentrations of digoxin is necessary to aid in the regulation of digoxin cardiovascular therapy. Establishing an effective but nontoxic therapeutic dosage is difficult due to patients' physiological variations (e.g., in patient size and reanal, hepatic, and gastrointestinal functions) and the narrow difference between the therapeutic range and the toxic range of digoxin. Accuracy of the assay method is dependent on the specificity of the antibody and the standards used in preparing the standard curve. Inadequate antibody preparation due to variations of the antibody's affinity for digoxin is the most common source of error in radioimmunoassay.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may result in findings of erroneously high or low levels of digoxin. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that digoxin test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3350; Docket No. 78N–2515; diphenylhydantoin test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of diphenylhydantoin test systems:

1. Identification: A diphenylhydantoin test system is a device used to measure diphenylhydantoin, and antiepileptic drug, in human specimens by methods such as enzyme immunoassay, radioimmunoassay, gas chromatography, and thin-layer chromatography. Measurements obtained by this device are used in the diagnosis and treatment of diphenylhydantoin overdose and in monitoring levels of diphenylhydantoin to ensure appropriate therapy.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that diphenylhydantoin test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *380* through *383*). Diphenylhydantoin is an antiepileptic drug capable of producing toxic reactions (e.g., slurred speech, mental confusion, dizziness, insomnia, and muscle incoordination) which are dose-related. The immunoassay is not specific for diphenylhydantoin and shows cross-reactivity of the phenytoin antibody with other drugs. Concurrent administration of certain drugs (e.g., chloramphenicol, dicumarol, disulfiram, isoniazid, or sulthiane) produces variations in diphenylhydantoin plasma concentration. A decrease in diphenylhydantoin plasma concentration can occur in the presence of carbamazepine, an antiepileptic drug. The Panel considered the voluntary standard being developed by the International Union of Immunological Societies (Enzyme Immunoassay Standardization Committee) for enzyme immunoassay determination of diphenylhydantoin. The Panel also considered voluntary guidelines established by the Nuclear Regulatory Commission on how handle radioactive compounds.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may result in findings of erroneously high or low levels of diphenylhydantoin. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that diphenylhydantoin test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3380; Docket No. 78N-2516; Ethosuximide test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ethosuximide test systems:

1. Identification: An ethosuximide test system is a device used to measure ethosuximide, an antiepileptic drug, in human specimens by such methods as thin-layer chromatography, liquid chromatography, gas chromatography, radioimmunoassay, or enzyme immunoassay. Measurements obtained by this device are used in the diagnosis and treatment of ethosuximide overdose and in monitoring levels of ethosuximide to ensure appropriate therapy.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that ethosuximide test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *384, 385,* and *386*). Ethosuximide is often administered in conjunction with other antiepileptics in the treatment of epilepsy. Toxic levels of ethosuximide may cause agranulocytosis (decreased number of granulocytes and lesions in the throat and other mucous membranes) and pancytopenia (deficiency of all cell elements of the blood). The Panel considered the voluntary guidelines established by the Nuclear Regulatory Commission on how to handle radioactive compounds. The Panel also considered the voluntary standards being developed by the International Union of Immunological Societies (Enzyme-Immunological Standardization Committee) for the enzyme-immunoassay determination of ethosuximide.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may result in findings of erroneously high or low levels of ethosuximide. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that ethosuximide test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3450; Docket No. 78N-2518; Gentamicin test system.

The Clinical Toxicology Device Classification Panel and the Microbiology Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of gentamicin test systems:

1. Identification: A gentamicin test system is a device used to measure gentamicin, an antibiotic drug, in human specimens by methods such as hemagglutination inhibition, agar gel diffusion discs, radioimmunoassay gentamicin (125_I) second antibody separation, *Bacillus subtlis* microbiology assay, or enzymatic radiochemical assay. Measurements obtained by this device are used in the diagnosis and treatment of gentamicin overdose and in monitoring gentamicin to ensure appropriate therapy.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panels recommend that gentamicin test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *387* through *392*). Gentamicin is used in the treatment of serious infections caused by certain bacteria. The Panel notes that the crossreactivity of the gentamicin antibody with other antibiotics limits the specificity of gentamicin test systems. Gentamicin has a very narrow range between an effective therapeutic and a toxic level with toxicity resulting in damage to hearing and the kidneys. Frequent monitoring of serum or plasma concentrations of gentamicin can help prevent toxicity. Comparative studies between microbiological and radioimmunoassay methods for the measurement of gentamicin indicate that although the methods are equivalent, radioimmunoassay offers the advantages of rapidity, specificity, and precision.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may result in findings of erroneously high or low levels of gentamicin. Inappropriate therapy based on inaccurate diagnositc data may place the patient at risk.

FDA agrees with the Panels' recommendations and is proposing that gentamicin test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3520; Docket No. 78N–2522; Kanamycin test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of kanamycin test systems:

1. Identification: A kanamycin test system is a device used to measure kanamycin, an antibiotic drug, in plasma and serum by radio immunoassay. Measurements obtained by this device are used in the diagnosis and treatment of kanamycin overdose and in monitoring levels of kanamycin to ensure appropriate therapy.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that kanamycin test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *393* and *394*). Kanamycin is an aminoglycoside (a bacterial antibiotic which acts by interfering with the function of the bacterial ribosomes) used in the treatment of infections caused by certain bacteria. The drug has narrow a range between an effective therapeutic and a toxic level with toxicity resulting in damage to hearing and the kidneys. The safe and effective use of kanamycin depends upon establishing an adequate dosage to control the infection without producing toxicity by performing frequent measurements of serum or plasma concentrations of kanamycin.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may result in findings of erroneously high or low levels of kanamycin. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that kanamycin test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3550; Docket No. 78N–2523; Lead test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of lead test systems:

1. Identification: A lead test system is a device used to measure lead, a heavy metal, in blood and urine by methods such as atomic absorption spectroscopy, *delta*-aminolevulinic acid, fluorometric protoporphyrin zinc, or fluorometric protoporphyrin. Measurements obtained by this device are used in the diagnosis and treatment of lead poisoning.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that lead test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that

a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *395* through *399*). Lead poisoning is a major problem in children who come in contact with leaded interior paint. Lead poisoning can also result from auto emissions from burning leaded gasoline, and industrial emissions, especially smelter dust. Toxicity can range from mild neurological disability to severe acute encephalopathy (brain disorder). Lead is normally present in the human body at trace levels. Intoxication is usually of a chronic nature because lead is absorbed slowly and excreted even more slowly from the body. Screening and diagnostic testing in children and some industrial workers, followed by appropriate action, can prevent serious tissue damage since clinical manifestations do not always appear at toxic levels of lead. Diagnosis of lead poisoning by measuring the level of porphyrins in the blood can be difficult because elevated concentrations of porphyrins in the red blood cell can indicate other disease states (i.e., iron-deficiency anemia) as well as lead poisoning. The best indication of whether lead is absorbed by the body is the direct measurement of the lead level in blood or urine. Low-rate accumulation of lead over a long period may give erroneous diagnostic results because lead can be deposited in bones and soft tissues as well as in the blood and urine. Interference from lead present in the atmosphere, laboratory glassware, or blood anticoagulants may produce erroneously high results.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may result in findings of erroneously high or low levels of lead. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that lead test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3560; Docket No. 78N-2377; Lithium test system.

The Clinical Chemistry Device Classification Panel and the Clinical Toxicology Device Classification Panel, FDA advisory committees, made the following recommendation regarding the classification of lithium test systems:

1. Identification: A lithium test system is a device used to measure lithium (from the drug lithium carbonate) in serum and plasma by methods such as atomic absorption or flame photometry. Measurements of lithium are used to assure that the proper drug dosage is administered in the treatment of patients with mental disturbances, such as manic-depressive illness (bipolar disorder).

2. Recommended classification: Class II (performance standards). The two Panels recommended that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panels recommended that lithium test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate information. Reliance upon inaccurate information could result in inappropriate therapy that places the patient at risk unnecessarily. Test results are used in the treatment of manic-depressive illness (bipolar disorder). The Panels believe that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panels believe that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *400* and *401*). The drug lithium carbonate is widely used in the treatment of manic-depressive illness (bipolar disorder). A patient's serum lithium level must be tested regularly to assure that the proper therapeutic dosage is administered and to safeguard against untoward toxic side effects due to the narrow range between therapeutic and toxic lithium serum levels.

5. Inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the amount of lithium administered to the patient, resulting in inappropriate therapy or possible toxic effects.

FDA agrees with the recommendations of both of the Panels and is proposing that lithium test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because there is sufficient information to establish a performance standard for this device.

Section 862.3580; Docket No. 78N-2526; Lysergic acid diethylamide (LSD) test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of lysergic acid diethylamide (LSD) test systems:

1. Identification: A lysergic acid diethylamide (LSD) test system is a device used to measure lysergic acid diethylamide, a hallucinogenic drug, in serum, urine, and gastric contents by methods such as free radical assay or radioimmunoassay. Measurements obtained by this device are used in the diagnosis and treatment of LSD use.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that lysergic acid diethylamide (LSD) test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *402*

through *405*). Lysergic acid diethylamide (LSD) has no therapeutic use and is considered a drug of abuse due to its hallucinogenic properties. LSD can cause severe toxic reactions such as psychosis (mental disorder) and possibly chromosome damage. Detection and measurement are difficult because usually only small amounts of the drug are ingested, and it is rapidly metabolized in the liver with only 1 percent of the LSD that is consumed being excreted unchanged in the urine. Radioimmunoassay can detect LSD or its metabolites in urine, serum, or other biological fluids. Cross-reactivity with structurally related compounds can cause false-positive data. Fluorometry or high pressure liquid chromatography has greater specificity, but larger amounts of the sample specimen are needed. Nonspecific constituents present in the urine can cause false-positives in the fluorometric techniques.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may result in findings of erroneously high or low levels of LSD. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that lysergic acid diethylamide (LSD) test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3600; Docket No. 78N-2527; Mercury test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of mercury test systems:

1. Identification: A mercury test system is a device used to measure mercury, a heavy metal, in human specimens by atomic absorption spectroscopy. Measurements obtained by this device are used in the diagnosis and treatment of mercury poisoning.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that mercury test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *406, 407,* and *408*). Mercury is not normally found in the human body, but it can be present in a concentration range of 0 to 20 micrograms/100 milliliter of blood, depending on the person's occupation and diet. Mercury is a cumulative poison, and traces may be found in the urine several months after exposure. Chronic mercury poisoning can result in inflammation of the mouth, muscular tremors, and mental and nervous behavioral changes. Acute mercury poisoning can result in burning of the mouth and throat, abdominal pain, vomiting, diarrhea, increased urine volume, kidney and liver damage, and death due to renal failure.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may result in findings of erroneously high or low levels of mercury. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that mercury test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3610; Docket No. 78N-2528; Methamphetamine test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of methamphetamine test systems:

1. Identification: A methamphetamine test system is a device used to measure methamphetamine, a central nervous system stimulating drug, in serum, plasma, and urine by methods such as thin-layer chromatography, gas chromatography, or high-pressure liquid chromatography. Measurements obtained by this device are used in the diagnosis and treatment of methamphetamine overdose.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that methamphetamine test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *409* through *412*). Methamphetamine is a mild central nervous system (CNS) stimulant used in the treatment of attention deficit disorders and as an adjunct in the treatment of exogenous obesity. The drug can produce toxic reactions and addiction when used excessively. Screening for methamphetamines is used in drug-abuse treatment programs because continued use of methamphetamine can cause addiction. Thin-layer chromatography is highly specific for methamphetamine and its metabolite.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may result in findings of erroneously high or

low levels of methamphetamine. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that methamphetamine test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3620; Docket No. 78N–2529; Methadone test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of methadone test systems:

1. Identification: A methadone test system is a device used to measure methadone, an addictive narcotic pain-relieving drug, in serum and urine, by methods such as thin-layer chromatography, liquid chromatography, gas chromatography, enzyme immunoassay, free radical assay, spectrophotometry, hemagglutination inhibition, or radioimmunoassay. Measurements obtained by this device are used in the diagnosis and treatment of methadone overdose and to determine compliance with regulations in methadone maintenance treatment.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that methadone test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *413* through *417*). Methadone is a narcotic analgesic with qualitative properties similar to those of morphine (Ref. *417*). Methadone is used in treatment of morphine and heroin addiction. Methadone toxicity can result in nausea, coma, respiratory failure, and death. Direct analysis of the specimen by immunoassay techniques shows no cross-reaction with other drugs or methadone's metabolites. Methadone and its metabolites are detected by the spectrophotometric method as a qualitative measurement. The use of another technique (e.g., gas chromatography) in conjunction with spectrophotometry improves the test's specificity for methadone.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may result in findings of erroneously high or low levels of methadone. Inappropriate therapy based on inaccurate diagnosis data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that methadone test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3640; Docket No. 78N–2531; Morphine test system.

The Clinical Toxicology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of morphine test systems:

1. Identification: A morphine test system is a device used to measure morphine, an addictive narcotic pain-relieving drug, and its analogs in serum, urine, and gastric contents by methods such as fluorometry, free radical assay, gas chromatography, hemagglutination inhibition, liquid chromatography, radio immunoassay or thin-layer chromatography. Measurements obtained by this device are used in the diagnosis and treatment of morphine overdose.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that morphine test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon review of the literature (Refs. *418* through *423*). Morphine is a narcotic analgesic capable of producing toxic reactions and addiction. Morphine is metabolized in the liver and is excreted rapidly in the urine within 24 hours. The immunoassays (free radical assay and hemagglutination inhibition) are capable of detecting the free drug and its conjugate form (morphine glucuronide) up to 48 hours, and possibly 72 hours, after administration of a dose. Codeine, heroin, dihydromorphine, and 1-morphine may cross-react with morphine antibody resulting in false-positive values. A second nonimmunoassay test may be required to confirm positive findings.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may result in findings of erroneously high or low levels of morphine. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agree with the Panal recommendation and is proposing that morphine test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable

assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3650; Docket No. 78N-2532; Opiate test system.

The Clinical Toxicology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of opiate test systems:

1. Identification: An opiate test system is a device used to measure any of the addictive narcotic pain-relieving opiate drugs in blood, serum, urine, gastric contents, and saliva by methods such as enzyme immunoassay, gas chromatography, thin-layer chromatography, high pressure liquid chromatography, free radical assay, or hemagglutination inhibition. An opiate is any natural or synthetic drug that has morphine-like pharmacological actions. The opiates include drugs such as morphine, morphine glucuronide, methadone, heroin, codeine, nalorphine, and meperedine. Measurements obtained by this device are used in monitoring the levels of opiate administration to ensure appropriate therapy and the diagnosis of possible drug dependence.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that opiate test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *424, 425,* and *426*). Opiates are substances having addiction-forming or addiction-sustaining actions similar to morphine, The immunoassays for opiates are highly sensitive but are not specific. Codeine is more reactive than morphine in the opiate immunoassay. Interference from urine constituents (e.g., enzyme inhibitors, salts, H positive, or OH negative ions), unknown biochemical and nutritional factors, unidentified drugs or metabolites, and technical error can result in positive findings. A second nonimmunoassay test may be needed to confirm any positive findings.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may result in findings of erroneously high or low levels of opiates. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that opiate test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3660; Docket No. 78N-2533; Phenobarbital test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of phenobarbital test systems:

1. Identification: A phenobarbital test system is a device used to measure phenobarbital, an antiepileptic and sedative-hypnotic drug, in human specimens by methods such as radioimmunoassay, enzyme immunoassay, liquid chromatography, or gas chromatography. Measurements obtained by this device are used in the diagnosis and treatment of phenobarbital overdose and in monitoring levels of phenobarbital to ensure appropriate therapy.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that phenobarbital test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *427* through *431*). Phenobarbital is a long-lasting sedative-hypnotic and antiepileptic drug with addicting properties. The drug is used in the treatment of epilepsy and is often given in conjunction with other antiepileptics (e.g., primidone). Phenobarbital is a drug subject to abuse. Patients receiving primidone may appear to have high phenobarbital levels because in the body primidone is oxidized, at least in part, to phenobarbital. If phenobarbital and primidone are given simultaneously, the level of each drug should be differentiated to assure that the patient is not maintaining a toxic level of phenobarbital or primidone. The Panel considered guidelines established by the Nuclear Regulatory Commission on how to handle radioactive compounds. The Panel also considered the voluntary standards being developed by the International Union of Immunological Societies (Enzyme-Immunoassay Standardization Committee) for the enzyme-immunoassay determination of phenobarbital.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may result in findings of erroneously high or low levels of phenobarbital. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that phenobarbital test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable

assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3670; Docket No. 78N–2534; Phenothiazine test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of phenothiazine test systems:

1. A phenothiazine test system is a device used to measure any of the drugs of the phenothiazine class in human specimens by methods such as thin-layer chromatography or the ferric choloride/perchloric acid/nitric acid color test. Measurements obtained by this device are used in the diagnosis and treatment of phenothiazine overdose.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that phenothiazine test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *432* and *433*). Phenothiazine compounds are used as antipsychotic agents (drugs used in certain severe nervous system disorders), anxiolytics, antihistamines (drugs used to reduce the physiological effects associated with allergies and colds), and analgesics (pain-relieving drugs) and can produce toxic reactions. Many anxiolytic drugs are derivatives of phenothiazine (chlorpromazine, promazine, prochlorperazine, etc.). Caution is necessary when administering phenothiazines to patients with impaired liver function (e.g., increased urinary levels of urobilinogen) because metabolism of phenothiazine compounds may be modified or delayed.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the product to perform satisfactorily may result in findings of erroneously high or low levels of phenothiazine. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that phenothiazine test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device. FDA has reviewed the literature relating to these devices and has found that phenothiazines are used in the treatment of psychiatric patients, for control of nausea, vomiting, and hiccups and as an antihistamine. Phenothiazines are relatively safe drugs, but can produce toxic reactions affecting the central nervous system, cardiovascular system, and endocrine functions. The most hazardous effects of the phenothiazines are hypersensitivity reactions and tardive dyskemia (delayed impairment of the power of voluntary motion). When administered concurrently, tricyclic antidepressants (e.g., amitriptyline) may block antihypertensive effects of phenothiazine. The FPN test is valuable as a rapid test for the qualitative determination of phenothiazine. Thin layer chromatography is specific and sensitive (Refs. *434* and *435*).

Section 862.3680; Docket No. 78N–2535; Primidone test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of primidone test systems:

1. Identification: A primidone test system is a device used to measure primidone, an antiepileptic drug, in human specimens by methods such as thin-layer chromatography, liquid chromatography, gas chromatography, radioimmunoassay, or enzyme immunoassay. Measurements obtained by this device are used in the diagnosis and treatment of primidone overdose and in monitoring levels of primidone to ensure appropriate therapy.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that primidone test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *436*, through *439*). Primidone is an antiepileptic often given in conjunction with anticonvulsants, such as phenobarfital, in the treatment of generalized tonicoclonic or complex partial epileptic seizures in children as well as adults. Primidone is oxidized in the body, at least in part, to phenobarbital. The phenobarbital derivative accumulates during prolonged therapy and produces plasma levels equivalent to those occurring during therpay with phenobarbital alone. If phenobarbital and primidone are given simultaneously, the level of each drug should be differentiated to assure that the patient is not maintaining a toxic level of phenobarbital. Primidone toxicity is manifested as respiratory or central nervous system depression. The Panel considered voluntary guidelines established by the Nuclear Regulatory Commission on how to handle radioactive compounds. The Panel also considered the voluntary standards being developed by the International Union of Immunological Societies (Enzyme-Immunoassay Standardization Committee) for enzyme-immunoassay determination of primidone.

5. Risk to health: Misdiagnosis and inappropriate therapy: Failure of the product to perform satisfactorily may result in findings of erroneously high or low levels of primidone. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that primidone test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3700; Docket No. 78N-2537; Propoxyphene test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of propoxyphene test systems:

1. Identification: A propoxyphene test system is a device used to measure propoxyphene, a pain-relieving drug, in serum, plasma, and urine by methods such as enzyme immunoassay or thin-layer chromatography. Measurements obtained by this device are used in the diagnosis and treatment of propoxyphene overdose and in monitoring levels of propoxyphene to ensure appropriate therapy.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that propoxyphene test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device. Propoxyphene is an analgesic that acts on the central nervous system for the relief of mild to moderate pain. It does not have fever reducing or antiinflammatory activity.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the product to perform satisfactorily may result in findings of erroneously high or low levels of propoxyphene. Inappropriate therapy based on inaccurate diagnosis data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that propoxyphene test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

FDA has reviewed the literature relating to these devices and has found that high doses of propoxyphene can produce side effects (i.e., dizziness, headache, gastrointestinal irritations, and skin rashes), with toxic doses producing depression of the respiratory and the central nervous system, convulsions, hallucinations, and death (Ref. *440*). The enzyme immunoassay technique is sensitive but lacks specificity for propoxyphene. A false-positive test can result from error in the quantitative assay due to lysozyme activity (an enzyme that functions as an antibacterial agent) in the urine, unknown biochemical and nutritional factors, and unidentified drugs (Ref. *442*). Thin layer chromatography is sensitive and specific with good separation of the various propoxyphene drugs (Ref. *441*).

Section 862.3750; Docket No. 78N-2540; Quinine test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of quinine test systems:

1. Identification: A quinine test system is a device used to measure quinine, a fever-reducing and pain-relieving drug used in the treatment of malaria, in serum and urine by methods such as thin-layer chromatography, high-pressure liquid chromatography, spectrophotofluorometry, or gas chromatography. Measurements obtained by this device are used in the diagnosis and treatment of quinine overdose and malaria.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that quinine test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device. Quinine is used in the treatment of falciparum malaria, a severe form of malaria caused by Plosmodiumfalciparum.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the product to perform satisfactorily may result in findings of erroneously high or low levels of quinine. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that quinine test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

The agency has reviewed the literature relating to quinine test

systems and has found that accurate measurement of quinine levels in the patient's plasma or urine is necessary to establish an adequate therapeutic concentration of quinine without subjecting the patient to its toxic effects (Ref. *447*). Toxicity due to clinical overdosage or hypersensitivity can result in headache, tinnitus (ringing in the ear), liver malfunction, renal damage, coma and death due to respiratory paralysis, and/or heart paralysis (Ref. *446*). Quinine toxicity can also result from the use of illicit heroin preparations where a large proportion of the purported heroin is quinine (Refs. *443* through *446*).

Section 862.3830; Docket No. 78N–2541; Salicylate test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of salicylate test systems:

1. Identification: A salicylate test system is a device used to measure salicylates, a class of analgesic, antiinflammatory drugs that includes aspirin, in human specimens by methods such as the paper strip test or colorimetry. Measurements obtained by this device are used in diagnosis and treatment of salicylate overdose and in monitoring salicylate levels to ensure appropriate therapy.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that salicylate test systems be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *448* through *451*). Salicylates are used in the treatment of inflammatory conditions (e.g., rheumatoid arthritis), thromboembolic phenomena (obstruction in blood vessel by an aggregation of blood factors), fever, and pain. Salicylates have a narrow range between an effective therapeutic and a toxic level with toxicity resulting in kidney damage, extreme lethargy (lack of energy), sweating with resultant dehydration, hypernea (over breathing), low blood pressure, and convulsions. Accidental poisoning can occur in adult or geriatric patients who are taking several medications containing salicylates concurrently or in patients with chronic conditions requiring continuous aspirin therapy. The Panel considered the voluntary standards being developed by the World Health Organization for salicylate measurement by paper-strip and colorimetry methodologies.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the product to perform satisfactorily may result in findings of erroneously high or low levels of salicylates. Inappropriate therapy based on inaccurate diagnostic data my place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that salicylate test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3850; Docket No. 78N–2542; Sulfonamide test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of sulfonamide test systems:

1. Identification: A sulfonamide test system is a device used to measure sulfonamides, any of the antibacterial drugs derived from sulfanilamide, in human specimens by colorimetry. Measurements obtained by this device are used in the diagnosis and treatment of sulfonamide overdose and in monitoring levels of sulfonamide to ensure appropriate therapy.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that sulfonamide test systems be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members's personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. *452*). Sulfonamides are used to control disease caused by specific microbial organisms (e.g., Group A beta-hemolytic streptococci, cause of rheumatic fever; meningococci, cause of meningitis; and *Escherichia coli*, a frequent cause of certain urinary tract infections). Sulfonamides are also used in the treatment of bacillary dysentery, caused by the *Shigella* bacteria, and in conjunction with other antibiotics against the resistant strains of the *Shigella* bacteria (i.e., *S. sonnei*). Sulfonamides have been found to cause toxic reactions (e.g., leukopenia, decreased number of white blood cells, and renal malfunction) during therapy.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the product to perform satisfactorily may result in findings of erroneously high or low levels of sulfonamides. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that sulfonamide test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and

effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

FDA has reviewed the literature relating to sulfonamide test systems and has found that sulfonamides inhibit both gram-positive and gram-negative bacteria and can cause toxic reactions (Ref. *452* and *454*). Detection levels of sulfonamides will vary with the type of specimen analyzed because of variation in rates of sulfonamide absorption and excretion. The colorimetric procedure is not specific for sulfonamides (Ref. *453*).

Section 862.3870; Docket No. 78N–2543; Cannabinoid test system.

The Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of cannabinoid test systems:

1. Identification: A cannabinoid test system is a device used to measure by radioimmunoassay any of the cannabinoids, hallucinogenic compounds endogenous to marihuana, in serum, plasma, saliva, and urine. Cannabinoid compounds include *delta*-9-tetrahydrocannabinol, cannabidiol, cannabinol, and cannabichromene. Measurements obtained by this device are used in the diagnosis and treatment of cannabinoid abuse and in monitoring levels of cannabinoids during clinical investigational use.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that cannabinoid test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *455* through *459*). Cannabinoid compounds have no substantiated indications for use as therapeutic agents. However, these compounds are being investigated for certain therapeutic uses. When used as a social drug, cannabinoid compounds can cause sedation, confusion, mood alterations, increased heart rate and blood pressure, visual changes and reddening of the eyes, mild hallucinations, and impairment of psychomotor skills. Marihuana usually contains *delta*-9-tetrahydrocannabinol (*delta*-9-THC), cannabidiol (CBD), cannabinol (CBN), and cannabichromene (CBC). *Delta*-9-THC is one of the compounds responsible for the pyschotomimetic properties of marihuana. Because highly selective antibodies for *delta*-9-THC are difficult to obtain, radioimmunoassay is specific for all cannabinoids in urine. Nonspecific compounds present in plasma or serum may interfere with the radioimmunoassay.

5. Risk to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may result in findings of erroneously high or low levels of any of the cannabinoid compounds. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the Panel recommendation and is proposing that cannabinoid test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 862.3900; Docket No. 78N–2545; Tobramycin test system.

The Clinical Toxicology Device Classification Panel and the Microbiology Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of tobramycin test systems:

1. Identification: A tobramycin test system is a device used to measure tobramycin, an aminoglycoside antibiotic drug, in plasma and serum by methods such as radioimmunoassay or *Bacillus subtilis* microbiology assay. Measurements obtained by this device are used in the diagnosis and treatment of tobramycin overdose and in monitoring levels of tobramycin to ensure appropriate therapy.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: Both Panels recommend that tobramycin test systems be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panels believe that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, and specificity. The Panels believe that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *460* through *464*). Tobramycin is an aminoglycoside antibiotic used in the treatment of certain bacterial infections. Tobramycin has a narrow range between an effective therapeutic level and a toxic level, with toxicity resulting in hearing and renal impairment. Safe and effective use of tobramycin is dependent upon establishing an adequate dosage to control infection without producing toxicity. Frequent monitoring of serum or plasma concentrations of tobramycin can help prevent toxicity.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the product to perform satisfactorily may result in findings of erroneously high or low levels of tobramycin. Inappropriate therapy based on inaccurate diagnosis data may place the patient at risk.

FDA agrees with the Panels' recommendations and is proposing that tobramycin test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable

assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the Dockets Management Branch (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

(*1*) Ishibe, T., T. Usui, and H. Nihara, "Prognostic Usefulness of Serum Acid Phosphatase Levels in Carcinoma of the Prostate," *Journal of Urology*, 112:237–240, 1974.

(*2*) Murphy, G. P., "The Diagnosis of Prostatic Cancer," *Cancer*, 37:589–596, 1976.

(*3*) Gomez, R. R., C. D. Wunsch, J. H. Davis, and D. J. Hicks, "Qualitative and Quantitative Determinations of Acid Phosphatase Activity in Vaginal Washings," *American Journal of Clinical Pathology*, 64:423–432, 1975.

(*4*) Walther, G., "Acid Phosphatase, Its Significance in the Determination of Human Seminal Traces," *Journal of Forensic Medicine*, 18:15–17, 1971.

(*5*) Fishman, W. H., C. D. Bonner, and F. Homburger, "Serum 'Prostatic' Acid Phosphatase and Cancer of the Prostate," *New England Journal of Medicine*, 255:925–933, 1956.

(*6*) Schwartz, M. K., "Enzymes in Cancer," *Clinical Chemistry*, 19:10–22, 1973.

(*7*) Liddle, G. W., "The Adrenal Cortex," *in* "Textbook of Endocrinology," 5th Ed., Edited by Williams, R. H., W. B. Saunders Co., Philadelphia, pp. 233–283, 1974.

(*8*) Besser, G. M. and C. R. W. Edwards, "Cushing's Syndrome," *Clinics in Endocrinology and Metabolism*, 1:451–489, 1972.

(*9*) Steinbeck, A. W. and H. M. Thiele, "The Adrenal Cortex," *Clinics in Endocrinology and Metabolism*, 3:557–587, 1974.

(*10*) Erhardt, L. R., A. Sjogren, and U. Sawe, "Late Rise in SGPT after Acute Myocardial Infarction," *Acta Medica Scandinavica*, 196:47–51, 1974.

(*11*) Latner, A. L., (ed.), "Cantarow and Trumper, Clinical Biochemistry," W. B. Saunders Co., Philadelphia, pp. 553–554, 1975.

(*12*) Trip, J. A. J., et al., "Investigations on Correlations Between Serum Enzymes and Histological Findings in Liver Disease, with Special Reference to Transaminases and Urocanase," *Acta Medica Scandinavica*, 193:113, 1973.

(*13*) Peters, T. Jr., "Serum Albumin" *in* "Advances in Clinical Chemistry," Vol. 13, Academic Press, New York, pp. 37–111, 1971.

(*14*) Tietz, N. W., (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 336–338, 1976.

(*15*) Raphael, S. S., et al., "Lynch's Medical Laboratory Technology," 3d Ed., W. B. Saunders Co., Philadelphia, pp. 255–256, 1976.

(*16*) Tietz, N.W., (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 690–692, 1976.

(*17*) Laragh, J. H., "The Renin-Aldosterone Axis in Blood Pressure and Electrolyte Homeostasis," in "Textbook of Endocrinology," 5th Ed., Edited by Williams, R. W., W. B. Saunders Co., Philadelphia, 1974.

(*18*) Fishman, W. H., "Perspectives on Alkaline Phosphatase Isoenzymes," *American Journal of Medicine*, 56:617–649, 1974.

(*19*) Bowers, G. N., Jr., and R. B. McComb, "Measurement of Alkaline Phosphatase Activity In Human Serum," *Clinical Chemistry*, 22: 1988–1995, 1975.

(*20*) Schwartz, M. K., "Laboratory Aids to Diagnosis," *Cancer*, 37:542–548, 1976.

(*21*) Schwartz, M. K., "Enzymes in Cancer," *Clinical Chemistry*, 19:10–22, 1973.

(*22*) Wintrobe, M. M., et al., "Clinical Hematology," 7th Ed., Lea and Febiger, Philadelphia, pp. 1021–1039, 1974.

(*23*) Henry, R. J., D. C. Cannon, and J. W. Winkelman (eds.), "Clinical Chemistry, Principles and Technics," 2d Ed., Harper and Row, Hagerstown, MD, pp. 1226–1227 and 1233–1239, 1974.

(*24*) Henry, R. J., D. C. Cannon, and J. W. Winkelman (eds.), "Clinical Chemistry, Principles and Technics," 2d Ed., Harper and Row, New York, pp. 518–526, 1974.

(*25*) Corey, L., R. J. Rubin, and M. A. W. Hattwick, "Reye's Syndrome: Clinical Progression and Evaluation of Therapy," *Pediatrics*, 60(5):708–714, 1977.

(*26*) Conn, H. D., *in* "Standard Methods of Clinical Chemistry," Vol. 5, Academic Press, New York, pp. 43–54, 1965.

(*27*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders, Co., Philadelphia, pp. 943–949, 1976.

(*28*) Warshaw, A. L. and P. B. Lesser, "Amylase Clearance in Differentiating Acute Pancreatitis from Peptic Ulcer with Hyperamylasemia," *Annals of Surgery*, 181:314–316, 1975.

(*29*) Berk, J. E. and L. Fridhandler, "Clinical Application of Amylase Isoenzyme Analysis," *The American Journal of Gastroenterology*, 63:457–463, 1975.

(*30*) Lesser, P. B., et al., "Differentiation of Pancreatitis from Common Bile Duct Obstruction with Hyperamylasemia," *Gastroenterology*, 68:636–641, 1975.

(*31*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d. Ed., W. B. Saunders Co., Philadelphia, pp. 741–745, 1976.

(*32*) Williams, R. H. (ed.), "Textbook of Endocrinology," 5th Ed., W. B. Saunders Co., Philadephia, p. 481, 1974.

(*33*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., Chapter 13, W. B. Saunders Co., Philadelphia, 1976.

(*34*) Davidsohn, I. and J. B. Henry (eds.), "Todd-Sanford, Clinical Diagnosis by Laboratory Methods," 15th Ed., W. B. Saunder Co., Philadelphia, pp. 709, 716, and 736, 1974.

(*35*) Laragh, J. H., "The Renin-Aldosterone Axis in Blood Pressure and Electryolyte Homeostasis," *in* "Textbook of Endocrinology," 5th Ed., edited by Williams, R. W., W. B. Saunders Co., Philadelphia, pp. 948–962, 1974.

(*36*) Wallach, L., I. Nyarai, and K. G. Dawson, "Stimulated Renin: A Screening Test for Hypertension," *Annals of Internal Medicine*, 82:27–34, 1975.

(*37*) Tietz, N. W., (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp 547–551, 1976.

(*38*) Henry, R. J., D. C. Cannon, and J. W. Winkelman (eds.), "Clinical Chemistry, Principles and Technics," 2d Ed., Harper and Row, Hagerstown, pp. 1393–1398, 1974.

(*39*) Davidsohn, I. and J. B. Henry (eds.), "Todd-Sanford Clinical Diagnosis by Laboratory Methods," 15th Ed., W. B. Saunders Co., Philadelphia, pp. 848–851 and 824–828, 1974.

(*40*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," W. B. Saunders Co., Philadelphia, pp. 674–675, 1976.

(*41*) Barnett, R. N., N. S. Erving, and S. B. Skodon, "Performance of 'Kits' Used for Clinical Chemical Analysis of GOT (Aspartate Aminotransferase)," *Clinical Biochemistry*, 9:78–84, 1976.

(*42*) Grannis, G. F., "Interlaboratory Survey of Enzyme Analyses 1. Preliminary Studies," *American Journal of Clinical Pathology*, 66:206–226, 1976.

(*42a*) Tietz, N. W. (ed.) "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, Ch. 19, 1976.

(*42b*) Tietz, N. W., (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 1043–1045, 1976.

(*43*) Koo, K. W., D. S. Sax, and D. L. Snider, "Arterial Blood Gases and pH During Sleep in Chronic Obstructive Pulmonary Disease," *American Journal of Medicine*, 58:663–670, 1975.

(*44*) Komjathy, Z. C., J. C. Mathies, J. A. Parker, and H. A. Schreiber, "Stability and Precision of a New Ampuled Quality Control System for pH and Blood Gas Measurements," *Clinical Chemistry*, 22:1399–1401, 1976.

(*45*) Figueras, J., L. Stein, V. Diez, M. H. Weil, and H. Shubin, "Relationship Between Pulmonary Hemodynamics and Arterial pH and Carbon Dioxide Tension in Critically Ill Patients," *Chest*, 70:466–472, 1976.

(*46*) Dharan, M., "A Simplified Method of Interpretative Reporting of Blood Gas Analysis and Acid-Base Balance," *Laboratory Medicine*, 6:41–42, 1975.

(*47*) Gray, S. J., and K. Sterling, "Determination of Circulating Red Cell Volume by Radioactive Chromium," *Science*, 112:179–180, 1950.

(*48*) Horwitz, D. L., A. H. Rubenstein, and A. I. Katz, "Quantitation of Human Pancreatic Beta-Cell Function by Immunoassay of C–Peptide in Urine," *Diabetes*, 26:30–35, 1977.

(*49*) Horwitz, D. L., et al., "Proinsulin, Insulin and C-Peptide Concentrations in Human Portal and Peripheral Blood," *The Journal of Clinical Investigations*, 55:1278–1283, 1975.

(*50*) Heding, L. G., "Radioimmunological Determination of Human C-Peptide in Serum," *Diabetologia*, 11:541–548, 1975.

(*51*) Copp, D. H., E. C. Cameron, B. A. Cheney, A. G. F. Davidson, and K. G. Henze, "Evidence of Calcitonin—A New Hormone From the Parathyroid That Lowers Blood Calcium," *Endocrinology*, 79:638–649, 1962.

(*52*) Foster, G. V., P. G. H. Byfield, and T. V. Gudmundsson, "Calcitonin," *Clinics in Endocrinology and Metabolism*, 1:93–124, March 1972.

(*53*) Cali, J. P., G. N. Bowers, and D. S. Young, "A Reference Method for the

Determination of Total Calcium in Serum," *Clinical Chemistry*, 19:1208–1213, 1973.

(*54*) Pickup, J. F., M. J. Jackson, E. M. Price, and S. S. Brown, "Assessment of the Reference Method for Determination of Total Calcium in Serum," *Clinical Chemistry*, 20:1324–1330, 1974.

(*55*) Pickup, J. F., M. J. Jackson, E. M. Price, M. J. R. Healy, and S. S. Brown, "Use of the Reference Method for Determination of Serum Calcium in a Quality Assurance Survey," *Clinical Chemistry*, 21:1416–1421, 1975.

(*56*) Horowitz, C. A., et. al., "A Comparative Study of Five Immunologic Pregnancy Tests: An Analysis of 1,863 cases," *American Journal of Clinical Pathology*, 58:305, 1972.

(*57*) Crain, J. L., et al., "Differential Testing for Low Levels of Human Chorionic Gonadotropin and/or Pituitary Gonadotropins: Follow-up Studies of Choriocarcinoma," *Obstetrics and Gynecology*, 41:640, 1973.

(*58*) Glenn D. Braunstein, et al., "Ectopic Production of Human Chorionic Gonadotropin by Neoplasms," *Annals of Internal Medicine*, 78:39–45, 1973.

(*59*) M. Yusoff Dawood, et al., "Human Chorionic Gonadotropin and its subunits in Hydatidiform Mole and Choriocarcinoma," *Obstetrics and Gynecology*, Vol. 50, No. 2, August, 1977.

(*60*) C. Paul Morrow, et al., "Clinical and Laboratory Correlates of Molar Pregnancy and Trophoblastic Disease," *American Journal of Obstetrics and Gynecology*, 128:424, 1977.

(*61*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, Ch. 16, 1976.

(*62*) Koo, K. W., D. S. Sax, and D. L. Saunder, "Arterial Blood Gases and pH During Sleep in Chronic Obstructive Pulmonary Disease," *American Journal of Medicine*, 58:663–670, 1975.

(*63*) Komjathy, Z. L., J. C. Mathies, J. A. Parker, and H. A. Schreiber, "Stability and Precision of a New Ampuled Quality-Control System for pH and Blood Gas Measurements," *Clinical Chemistry*, 22:1399–1401, 1976.

(*64*) Figueras, J., L. Stein, V. Diez, M. H. Weil, and H. Shubin, "Relationship Between Pulmonary Hemodynamics and Arterial pH and Carbon Dioxide Tension in Critically Ill Patients," *Chest*, 70:466–472, 1976.

(*65*) Dharan, M., "A Simplified Method of Interpretative Reporting of Blood Gas Analysis and Acid-Base Balance," Laboratory Medicine, 6:41–42, 1975.

(*66*) Sobel, C., and R. J. Henry, "Determination of Catecholamines (Adrenaline and Noradrenaline) in Urine and Tissue," *American Journal of Clinical Pathology*, 27:240–245, 1957.

(*67*) Jacobs, J. L., C. Sobel, and R. J. Henry, "Specificity of the Trihydroxyindole Method for Determination of Urinary Catecholamines," *Journal of Clinical Endocrinology and Metabolism*, 21:305–314, 1961.

(*68*) Weil-Malherbe, H., "The Estimation of Total (Free + Conjugated) Catecholamines and Some Catecholamine Metabolites in Human Urine," *Methods of Biochemical Analysis*, 16:293–329, 1968.

(*69*) Henry, R. J., D. C. Cannon, and J. W. Winkelman (eds.), "Clinical Chemistry, Principles and Technics," 2d Ed., Harper and Row, Hagerstown, MD, pp. 712–720, 1974.

(*70*) Gilbert, R. K., "Progress and Analytic Goals in Clinical Chemistry," *Journal of Clinical Pathology*, 63:960–973, 1975.

(*71*) Henry, R. J., D. C. Cannon, J. W. Winkelman, (eds.), "Clinical Chemistry: Principles and Technics," 2d Ed., Harper and Row, pp. 1428–1449, 1974.

(*72*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Ch. 10, pp. 474–451, 1976.

(*73*) Dyck, W., and R. Ammann, "Quantitative Determination of Fecal Chymotrypsin as a Screening Test for Pancreatic Exocrine Insufficiency," *American Journal of Digestive Diseases*, 10:530–544, 1965.

(*74*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, p. 1071, 1976.

(*75*) Ammann, R. W., et al., "Diagnostic Value of Fecal Chymotrypsin and Trypsin Assessment for Detection of Pancreatic Disease," *American Journal of Digestive Diseases*, 13:123–146, 1968.

(*76*) Steinbeck, A. W. and H. M. Theile, "The Adrenal Cortex (Excluding Aldosteronism)," *Clinics in Endocrinology and Metabolism*, 3:557–591, 1974.

(*77*) Henry, R. J., D. C. Cannon, and J. W. Winkelman (eds.), "Clinical Chemistry, Principles and Technics," 2d Ed., Harper and Row, Hagerstown, pp. 695–703, 1974.

(*78*) Osaki, S., D. A. Johnson, and E. Frieden, "The Possible Significance of the Ferrous Oxidase Activity of Ceruloplasmin in Normal Human Serum," *The Journal of Biological Chemistry*, 241(12):2746–2751, 1966.

(*79*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 929–932, 1976.

(*80*) Bacon, G. E., R. George, S. T. Koeff, and W. F. Howatt, "Plasma Corticoids in the Respiratory Distress Syndrome and in Normal Infants," *Pediatrics*, 55:500–512, 1975.

(*81*) Giodano, N. D., R. J. Koletsky, and S. Koletsky, "Simultaneous Determination of Plasma Aldosterone, Corticosterone, 11-Deoxycorticosterone, 18-Hydroxydeoxycorticosterone, Cortisol and 11-Deoxycortisol," *American Journal of Clinical Pathology*, 66:588–597, 1976.

(*82*) Leaf, A. and G., W. Liddle, "The Adrenals," *in* "Textbook of Endocrinology," 5th Ed., Edited by Williams, R. H., W. B. Saunders Co., Philadelphia, 1974.

(*83*) Newsome, H. H., Jr., A. S. Clements, and E. H. Borum, "The Simultaneous Assay of Cortisol, Corticosterone, 11-Deoxycortisol, and Cortisone in Human Plasma," *Journal of Clinical Endocrinology*, 34:473–483, 1972.

(*84*) Steinbeck, A. W. and H. M. Theile, "The Adrenal Cortex (Excluding Aldosteronism)," *Clinics in Endocrinology and Metabolism*, 3:557–591, 1974.

(*85*) Henry, R. J., D. C. Cannon, and J. W. Winkelman (eds.), "Clinical Chemistry, Principles and Technics," 2d Ed., Harper and Row, Hagerstown, MD, pp. 541–552, 1974.

(*86*) Davidsohn, I. and J. B. Henry (eds.), "Todd-Sanford's Clinical Diagnosis by Laboratory Methods," 5th Ed., W. B. Saunders Co., Philadelphia, pp. 594–596, 1974.

(*87*) Searcy, R.L. "Diagnostic Biochemistry," McGraw-Hill, New York pp. 193–201, 1969.

(*88*) Galen, R. S., J. A. Reiffel, and S. R. Gambino, "Diagnosis of Relative Myocardial Infarction—Relative Efficiency of Serum Enzyme and Isoenzyme Measurements," *Journal of the American Medical Association*, 232:145, 1975.

(*89*) Elevitch, F. R., "Fluoremetric Techniques in Clinical Chemistry," Little, Brown and Co., Boston, pp. 244:246, 1973.

(*90*) Tietz, N. W., (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 682–690, 1976.

(*91*) Davidsohn, I., and J. B. Henry, "Todd-Sanford Clinical Diagnosis by Laboratory Methods," 15th Ed., W. B. Saunders Co., Philadelphia, p. 860, 1974.

(*92*) Grannis, G. F., "Interlaboratory Survey of Enzyme Analysis," 1. Prelimianry Studies Pathology, 66:206–222, 1976.

(*93*) Henry, R. J., D. C. Cannon, and J. W. Winkelman, "Clinical Chemistry, Principles and Technics," 2d Ed., Harper and Row, Hagerstown, MD, pp. 541–553, 1974.

(*94*) Schwartz, M. K., et al., "Chemical and Clinical Evaluation of the Continuous Flow Analyzer 'SMAC'," *Clinical Chemistry*, 20: 1062–1070, 1974.

(*95*) Murad, F. and C. Y. C. Pak, "Urinary Excretion of Adenosine 3', 5' Monophosphate and Guanosine 3', 5' Monophosphate," *The New England Journal of Medicine*, 286:1382–1387, 1972.

(*96*) Bernstein, R. A., et al., "Decreased Urinary Adenosine 3', 5' Monophosphate (Cyclic AMP) in Asthmatics," *Journal of Laboratory and Clinical Medicine*, 80:772–779, 1972.

(*97*) Rosen, O. M., "Urinary Cyclic AMP in Graves' Disease," *The New England Journal of Medicine*, 287:670–671, 1972.

(*98*) Henry, R. J., D. C. Cannon, and J. W. Winkelman (eds.), "Clinical Chemistry, Principles and Technics," 2d Ed., Harper and Row, Hagerstown, MD, p 589, 1974.

(*99*) Tietz, N. W., "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, p. 386, 1976.

(*100*) Liddle, G. W., "The Adrenal Cortex" *in* "Textbook of Endocrinology," 5th Ed., Edited by Williams, R. H., p. 245, 1974.

(*101*) Schoneshofer, M., W. Oelkers, and H. Harendt, "Radioimmunoassay for Serum Desoxycorticosterone: Normal Values and Changes in Serum Desoxycorticosterone After Adrenal Stimulation," *Zeitschrift fur Klinische Chemie und Klinische Biochemie*, 13(4):143–147, April 1975.

(*102*) Mantero, F., N. Sonino, and P. Masarotto, "Plasma Desoxycorticosterone Radioimmunoassay (DOC): Method and Clinical Applications," *The Journal of Nuclear Biology and Medicine*, 19(4):186–194, Oct.–Dec., 1975.

(*103*) Honda, M., et al., "Plasma Desoxycorticosterone and Aldosterone in Essential Hypertension," *Journal of Steroid Biochemistry*, 7:565–569, May 1976.

(*104*) Benesch, R. and R. E. Benesch, "Intracellular Organic Phosphates as Regulators of Oxygen Release by Hemoglobin," *Nature*, 221:618–621, 1969.

(*105*) Duhm, J., "The Effect of 2,3–DPG and Other Organic Phosphates on the Donnan

Equilibrium and the Oxygen Affinity of Human Blood," *in* "Affinity of Hemoglobin and Red Cell Acid Base Status," (Alfred Benzon Symposium, IV), Roth, M. and R. Astrup, (eds.), New York Academic Press, New York, pp. 583–594, 1972.

(*106*) Williams, R. H., (ed.), "Textbook of Endocrinology," 5th Ed., W. B. Saunders Co., Philadelphia, pp. 379–382, 392–393, 1047–1049, 1974.

(*107*) Podoba, W., T. H. Rizkallah and W. G. Kelly, "Radioimmunoassay of Estrogens in Maternal Blood in Late Pregnancy: Values in Normal and Complicated Pregnancy," *American Journal of Obstetrics and Gynecology*, 117:321–330, 1973.

(*108*) Williams, R. H. (ed.), "Textbook of Endocrinology," 5th Ed., W. B. Saunders Co., Philadelphia, pp. 379–382, 392–393, and 1047–1049, 1974.

(*109*) Chattoriu, S. C., "Endocrine Function," *in* "Fundamentals of Clinical Chemistry," Tietz, N. W. (ed.), 2d Ed., W. B. Saunders Co., Philadelphia, p. 748, 1976.

(*110*) Frolich, M., et al., "Serum Levels of Unconjugated Aetiocholanolone, Androstenedione, Testosterone, Dehydroepiandrosterone, Aldosterone, Progesterone, and Estrogens During the Normal Menstrual Cycle," *Acta Endrocrinologica*, (Kbn), 81(3):548–562, March 1976.

(*111*) Youssefnejadian, E., S. S. Virdee, and I. F. Sommerville, "Radioimmunoassay of Plasma Aetiocholanolone," *Journal of Steroid Biochemistry*, 5(5):529–532, August 1974.

(*112*) Lattner, A., "Canterow and Trumper, Clinical Biochemistry," W. B. Saunders Co., Philadelphia, pp. 21–22, 25, 119, 125, 1975.

(*113*) Waxman, S. and C. Schreiber, "Measurement of Serum Folate Levels and Serum Folic Acid-Binding Protein by 3H–PGA Radioimmunoassay," *Blood*, 42:281–290, 1973.

(*114*) Dunn, R. T. and L. B. Foster, "Radioimmunoassay of Serum Folate," *Clinical Chemistry*,, 19:1101–1105, 1973.

(*115*) Archibald, E. L., E. K. Mincey, and R. T. Morrison, "Estimation of Serum Folate Levels by Competitive Protein Binding Assay," *clinical Biochemistry*, 5:232–241, 1972.

(*116*) Williams, R. H. (ed.), "Textbook of Endocrinology," 5th Ed., W. B. Saunders Co., Philadelphia, pp. 40–44, 1974.

(*117*) Henry, Cannon, and Winkelman, "Clinical Chemistry," Harper and Row, pp. 626–633, 1974.

(*118*) Searcy, R. L., "Diagnostic Biochemistry," McGraw Hill, pp. 223–228, 1969.

(*119*) Shih, V. E., et al., "Galactosemia Screening of Newborns in Massachusetts," *The New England Journal of Medicine*, 284:753–757, 1971.

(*120*) Fenson, A. H., P. F. Benson, and S. Blunt, "Prenatal Diagnosis of Galactosemia," *British Medical Journal*, 4:386–387, 1974.

(*121*) Shih, V. E., et al., "Galactosemia Screening of Newborns in Massachusetts," *New England Journal of Medicine*, 284:753–759, 1971.

(*122*) Segal, S., "Disorders of Galactose Metabolism," *in*, "The Metabolic Basis of Inherited Disease," 3d Ed., Edited by Stanbury, J. B., J. B. Wyngaarden, and D. S. Fredrickson, McGraw Hill Book Co., New York, pp. 174–195, 1972.

(*123*) Helmer, O. M., "Gastric Acidity", *in* "Standard methods of Clinical Chemistry," Vol. 3, Edited by Seligson, D., Academic Press, Inc., New York, pp. 124–130, 1961.

(*124*) Henry, R. J., D. C. Cannon, and J. W. Winkelman, (eds.), "Clinical Chemistry, Principles and Technics," 2d Ed., Harper and Row, Hagerstown, MD, Ch. 31, 1974.

(*125*) Warner, A. and H. George, "Comparison of Results by Three Kit Methods for Assay of Serum Gastrin," *Clinical Chemistry*, 22:1705–1709, 1976.

(*126*) McGuigan, J. E., "The Gastrointestinal Hormones," *in* "Textbook of Endocrinology" 5th ed., R. H. Williams, Editor, W. B. Saunders Co., Philadelphia, pp. 842–846, 1974.

(*127*) Henry, R. J., D. C. Cannon, and J. W. Winkelman (eds.), "Clinical Chemistry: Principles and Technics," Harper and Row, Publishers, Hagerstown, Md., pp. 448–455, 1974.

(*128*) Barnett, R. N., "Medical Significance of Laboratory Results," *The American Journal of Clinical Pathology*, 50:671–676, 1968.

(*129*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 242, 786, 1066, 1976.

(*130*) Latner, A. L. (ed.), "Cantarow and Trumper, Clinical Biochemistry," 7th Ed., W. B. Saunders Co., Philadelphia, pp. 26–27, 1975.

(*131*) Henry, R. J., D. C. Cannon, and J. W. Winkelman (eds.), "Clincial Chemistry: Principles and Technics," 2d. Ed., Harper and Row, Hagerstown, Md., pp. 1294–1299, 1974.

(*132*) Henry, R. J., D. C. Cannon, and J. W. Winkelman (eds.), "Clinical Chemistry: Principles and Techniques," 2d Ed., Harper and Row, Hagerstown, Md., pp. 1271–1294, 1974.

(*133*) Gochman, N., et al., "Interlaboratory Comparison of Enzymatic Methods for Serum Glucose Determination," *Clinical Chemistry*, 21:356–361, 1975.

(*134*) Schwartz, M. K., "Laboratory Aides to Diagnosis," *Cancer*, 37:542–548, 1976.

(*135*) Zein, M. and G. Discombe, "Serum Gamma-Glutamyl Transpeptidase as a Diagnostic Aid," *Lancet*, II:748–750, 1970.

(*136*) Lum, G. and S. R. Gambino, "Serum Gamma-Glutamyl Transpeptidase Activity as an Indicator of Disease of Liver, Pancreas, or Bone," *Clinical Chemistry*, 18:358–362, 1972.

(*137*) Martin, J. V., P. B. Gray, and D. M. Goldberg, "Pitfalls in Assay and Interpretation of Serum Gamma-Glutamyl Transpeptidase Activity," *Clinica Chimica Acta*, 61:99–101, 1975.

(*138*) Szasz, G., "A Kinetic Photometric Method for Serum Gamma-Glutamyl Traspeptidase," *Clinical Chemistry*, 15:124–136, 1969.

(*139*) Henry, R. J., D. C. Cannon, and J. W. Winkelman (eds.), "Clinical Chemistry, Principles and Technics," Harper and Row, Hagerstown, Md., pp. 614–618, 1974.

(*140*) Edwards, C. R. W., and G. M. Besser, "Diseases of the Hypothalamus and Pituitary Gland," *Clinics in Endocrinology and Metabolism*, 3:475–505, 1974.

(*141*) Bond and Rosenberg, "Duncan's Diseases of Metabolism," 7th Ed., W. B. Saunders Co., Philadelphia, pp. 534–538, 1974.

(*142*) Stanbury, J. B., J. B. Wyngaarden, and D. S. Fredrickson (eds.), "Metabolic Basis of Inherited Disease," 3d Ed., McGraw Hill, pp. 338–339, 345–346, 1972.

(*143*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 268 and 555, 1976.

(*144*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., p. 655, 1976.

(*145*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 730–734, 1976.

(*146*) Mattingly, D. and C. Tyler, "Simple Screening Test for Cushing's Syndrome," *British Medical Journal*, 4:394–397, 1976.

(*147*) Pavlatos, F. C., R. P. Smilo, and P. H. Forsham, "A Rapid Screening Test for Cushing's Syndrome," *The Journal of the American Medical Association*, 193(9):720–723, 1965.

(*148*) Metcalf, M. G., "A Rapid Method for Measuring 17-Hydroxycorticosteroids in Urine," *Journal of Endocrinology*, 26:415–423, 1963.

(*149*) Sobel, C., et al., "Study of the Norymberski Methods for Determination of 17-Ketogenic Steriods (17-Hydroxycorticosteroids) in Urine," *Journal of Clinical Endocrinology and Metabolism*, 18:208–221, 1958.

(*150*) Rutherford, E. R. and D. H. Nelson, "Determination of Urinary 17-Ketogenic Steroids by Means of Sodium Metaperiodate Oxidation," *Journal of Clinical Endocrinology and Metabolism*, 23:533–538, 1963.

(*151*) Oates, J. A., "The Carcinoid Syndrome," *in* "Harrision's Principles of Internal Medicine," 7th Ed., Edited by Wintrobe, M. M., et al., McGraw Hill, New York, pp. 604–607, 1974.

(*152*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 699–766, 1976.

(*153*) Lucis, O. G., "Progesterone and Metabolites" *in* "Biochemistry of Women: Methods for Clinical Investigations," A. S. Curry and J. V. Hewitt (eds), CRC Press, 1974.

(*154*) Henry, R. J., D. C. Cannon, and J. W. Winkelman (eds.), "Clinical Chemistry, Principles and Technics," 2d Ed., Harper and Row, Hagerstown, Md., p. 608, 1974.

(*155*) "GTT Plus Insulin by RIA: A New Guide to Diagnosis," Laboratory Management, 12:19, 1974.

(*156*) Frankel, S., S. Reitman, and A. C. Sonnenwirth (eds.), "Gradwohl's Clinical Laboratory Methods and Diagnosis," 7th Ed., C. V. Mosby Co., St. Louis, pp. 204–208 and 436–442, 1970.

(*157*) Wintrobe, M. M., et al. (eds.), "Harrison's Principles of Internal Medicine," 7th Ed., McGraw Hill, New York, pp. 1581–1583, 1974.

(*158*) Davidsohn, I., and J. B. Henry (eds.), "Todd-Sanford, Clinical Diagnosis by Laboratory Methods," 15th Ed., W. B. Saunders Co.,Philadelphia, pp. 652–656, 1974.

(*159*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 926–928, 1976.

(*160*) Wintrobe, M. M. and G. R. Lee, *in* "Harrison's Principles of Internal Medicine," 7th Ed., McGraw-Hill, New York, pp. 1581–1583, 1974.

(*161*) Davidsohn, I. and J. B. Henry (ed.), "Todd-Sanford, Clinical Diagnosis by

Laboratory Methods," 15th Ed., W. B. Saunders Co., pp. 652–656, 1974.

(*162*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., pp. 660–664, 1976.

(*163*) Henry, R. J., D. C. Cannon, and J. W. Winkelman (eds.), "Clinical Chemistry, Principles and Technics," 2d Ed., Harper and Row, Hagerstown, MD, pp. 837–842, 1974.

(*164*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 699–766, 1976.

(*165*) Glenn, E. M. and D. H. Nelson, "Chemical Method for the Determination of 17-Hydroxycorticosteroids and 17-Ketosteroids in Urine Following Hydrolysis with B-Glucuronidase," *Journal of Clinical Endocrinology and Metabolism*, 13:911–921, 1953.

(*166*) Golub, O. J., C. Sobel, and R. J. Henry, "Comparative Study of the 17-Ketogenic (Norymberski), Glenn-Nelson and Reddy Methods for the Determination of C21 Urinary Steroids," *Journal of Clinical Endocrinology and Metabolism*, 18:522–530, 1958.

(*167*) Latner, A. L. (ed.), "Cantarow and Trumper, Clinical Biochemistry," 7th Ed., W. B. Saunders Co., Philadelphia, p. 477, 1975.

(*168*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 933–935, 1976.

(*169*) Bradley, G. M. and E. S. Benson, *in* "Todd-Sanford, Clinical Diagnosis by Laboratory Methods," 15th Ed., edited by Davidsohn, I. and J. B. Henry, W. B. Saunders Co., Philadelphia, pp. 68–70, 1964.

(*170*) Sekiya, S., et al., "Serum Lactate Dehydrogenase Activity in Patients with Trophoblastic Neoplasms," *American Journal of Obstetrics and Gynecology*, 121(8):1119–1120, 1975.

(*171*) Wroblewski, F. and J. S. LaDue, "Lactic Dehydrogenase Activity in Blood," *Proceedings of the Society for Experimental Biology and Medicine*, 90:210–213, 1955.

(*172*) Zimmerman, H. J. and J. B. Henry, *in* "Clinical Diagnosis by Laboratory Methods," 15th Ed., W. B. Saunders Co., Philadelphia, pp. 852–853, 1974.

(*173*) Davidsohn, I. and J. B. Henry (eds.), "Todd-Sanford, Clinical Diagnosis by Laboratory Methods," 15th Ed., W. B. Saunders Co., Philadelphia, pp. 853–855, 1974.

(*174*) Nerenberg, S. T. and G. Pogojeff, "Laboratory Diagnosis of Specific Organ Diseases by Means of Combined Serum Isoenzyme Patterns," *The American Journal of Clinical Pathology*, 51:429–439, 1969.

(*175*) Warburton, F. G., E. Allen, G. S. Laing, and J. Waddecar, "Increased Lactate Dehydrogenase 3 in Serum After Myocardial Infarction," *Nature*, 215:287–289, 1967.

(*176*) Lubran, M., "Measurement of Lactic and Pyruvic Acids in Biological Fluids," *in* "Laboratory Diagnosis of Endocrine Diseases," Sunderman, F. W., Sr., and F. W. Sunderman, Jr. (eds.), W. H. Green, St. Louis, pp. 401–408, 1971.

(*177*) Wolf, P. L., et al., "Methods and Techniques in Clinical Chemistry," Wiley-Interscience, New York, pp. 252–257, 1972.

(*178*) Gluck, L. and M. V. Kulovich, "Lecithin/Sphingomyelin Ratios in Amniotic Fluid in Normal and Abnormal Pregnancy," *American Journal of Obstetrics and Gynecology*, 115:539–546, 1973.

(*179*) Nelson, G. H., "Relationship Between Amniotic Fluid Lecithin Concentration and Respiratory Distress Syndrome," *American Journal of Obstetrics and Gynecology*, 112:827–833, 1972.

(*180*) Davidsohn, I. and J. B. Henry, "Todd-Sanford Clinical Diagnosis by Laboratory Methods," 14th Ed., W. B. Saunders Co., Philadelphia, pp. 734–735, 1969.

(*181*) Toro, G. and P. G. Ackerman, "Practical Clinical Chemistry," Little, Brown, and Co., Boston, pp. 516–519, 1975.

(*182*) Bressler, R., et al., "Serum Leucine Aminopeptidase Activity in Hepatobiliary and Pancreatic Disease," *Journal of Laboratory and Clinical Medicine*, 56:417–430, 1960.

(*183*) Rong, J., "Practical Clinical Enzymology," Van Nostrand, New York, pp. 245–252, 1965.

(*184*) Shihabi, Z. K. and C. Bishop, "Simplified Turbidimetric Assay for Lipase Activity," *Clinical Chemistry*, 1:1150–1153, 1971.

(*185*) Henry, R. J., "Pancreatitis-Lipase," *in* "Standard Methods of Clinical Chemistry," Vol. 2, Edited by Seligson, D., Academis Press, New York, pp. 86–90, 1958.

(*186*) Saifer, A. and G. Perle, "Photometric Microdetermination of Serum Lipase with a Phenyl Substrate," *Clinical Chemistry*, 7:178, 1961.

(*187*) MâcDonald, R. P. and R. O. LeFave, "Serum Lipase Determination With an Olive Oil Substrate Using a Three-Hour Incubation Period," *Clinical Chemistry*, 8:509–519, 1962.

(*188*) Vogel, W. C. and L. Zieve, "A Rapid and Sensitive Turbidimetric Method for Serum Lipase Based Upon Differences Between the Lipases of Normal and Pancreatitis Serum," *Clinical Chemistry*, 9:168–181, 1963.

(*189*) Wilson, A. G., "An Improved Colorimetric Method for the Estimation of Lipase in Serum Using Phenyl Laurate as a Substrate," *New Zealand Journal of Medical Laboratory-Technology*, 18:119–124, 1964.

(*190*) Massion, C. G. and D. Seligson, "Serum Lipase, a Rapid Photomeric Method," *American Journal of Clinical Pathology*, 48:307–313, 1967.

(*191*) Tietz, N. W., ed., "Fundamentals of Clinical Chemistry," 2d. Ed., W. B. Saunders, Philadelphia, pp. 492–494, 1976.

(*192*) Levy, R. I., "Hyperlipoproteinemia; Some Basic Concepts on Diagnosis and Management" *Journal of the American Medical Association*, 226(6):648–649, 1973.

(*193*) Ravel, R., "Clinical Laboratory Medicine; Application of Laboratory Data," 2d Ed., Year Book Medical Publishers, Inc., Chicago, pp. 254–256, 260, and 322, 1973.

(*194*) Murphy, B. F., "Management of Hyperlipidemias" *Journal of the American Medical Association*, 230:1683–1691, 1974.

(*195*) Tietz, N. W., (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 482–483, 529–540, 1976.

(*196*) Hunter, W. M. and J. G. Bennie, "Validation of Specific RIA for H-FSH and H-LH", *Hormone and Metabolic Research*, 7:142–148, 1975.

(*197*) Rabinowitz, D., R. Benveniste, and J. Bell, "Heterogeneity of Human Luteinizing Hormone," *Israel Journal of Medical Sciences*, 10:1272–1279, 1974.

(*198*) Qazi, M. H., P. Romani, and E. Diczfalusy, "Discrepancies in Plasma LH Activities as Measured by Radioimmunoassay and an In Vitro Bioassay," *Acta Endocrinologica*, 77:672–685, 1974.

(*199*) "Textbook of Endocrinology," 5th Ed., edited by Williams, R. H., W. B. Saunders Co., Philadelphia, pp. 40–44, 1974.

(*200*) Catovsky, D., D. A. G. Galton, and C. Griffin, "The Significance of Lysozyme Estimations in Acute Myeloid and Chronic Monocytic Leukemia," *British Journal of Hematology*, 21:565–579, 1971.

(*201*) Briggs, R. S., P. E. Perillie, and S. C. Finch, "Lysozyme in Bone Marrow and Peripheral Blood Cells," *The Journal of Histochemistry and Chemistry*, 14:167–170, 1966.

(*202*) Perillie, P. E., S. C. Finch, "Muramidase Studies in Philadelphia—Chromosome-Positive and Chromosome-Negative Chronic Granulocytic Leukemia," *The New England Journal of Medicine*, 283:456–459, 1970.

(*203*) Syren, E. and A. M. Raeste, "Identification of Blood Monocytes by Demonstration of Lysozyume and Peroxidase Activity," *Acta Haematologica*, 45:29–35, 1971.

(*204*) Latner, A. L., "Cantarow and Trumper Clinical Biochemistry," 7th Ed., W. B. Saunders Co., Philadelphia, pp. 316–318, 1975.

(*205*) Weisberg, H. R., *in* "Todd and Sanford's Clinical Diagnosis by Laboratory Methods," Davidsohn, I. and J. B. Henry (eds.), 15th Ed., W. B. Saunders Co., Philadelphia, p. 776, 1974.

(*206*) Weisman, N. and V. J. Pileggi, *in* "Clinical Chemistry Principles and Techniques," 2d Ed., Henry, R. J., D. C. Canno, and J. W. Winkelman (eds.), Harper and Row, Hagerstown, MD. pp. 670–679, 1974.

(*207*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 918–921, 1976.

(*208*) Davidsohn, I. and J. B. Henry (eds.), "Todd-Sanford, Clinical Diagnosis by Laboratory methods," 14th Ed., W. B. Saunders Co., Philadelphia, PA, p. 731, 1969.

(*209*) Latner, A. L., "Canterow and Trumper, Clinical Biochemistry," W. B. Saunders Co., pp. 232–234, 1975.

(*210*) Stanbury, J. B., J. B. Wyngaarden, and D. S. Fredrickson, (eds.), "The Metabolic Basis of Inherited Disease," 3rd Ed., MrGraw Hill, pp. 1233–1236 and 1246–1249, 1972.

(*211*) Davidsohn, I. and J. B. Henry, (eds.), "Todd and Sanford, Clinical Diagnosis by Laboratory Methods," 15th Ed., W. B. Saunders Co., Philadelphia, pp. 70–71, 1974.

(*212*) Kunin, C. M. and J. E. DeGroot, "Self Screening for Significant Bacteriuria," *Journal of The American Medical Association*, 231:1349–1353, 1975.

(*213*) Alwall, N. and A. Lohi, "Factors Affecting the Reliability of Screening Tests for Bacteriuria," *Acta Medica Scandinavica*, 193:499–503, 1973.

(*214*) Alwall, N., "Factors Affecting the Reliability of Screening Tests for Bacteriuria," *Acta Medica Scandinavica*, 193:505–509, 1973.

(215) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 378–386 and 1051, 1976.

(216) Schwartz, M. K., "Measurement of 5'-Nucleotidase Activity in Serum," *Standard Methods of Clinical Chemistry*, Vol. 7, Academic Press, New York, pp. 1–7, 1975.

(217) Schwartz, M. K., "Enzymes in Cancer," *Clinical Chemistry*, 19:10–22, 1973.

(218) Davidsohn, I. and J. B. Henry (eds.), "Todd and Sanford, Clinical Diagnosis by Laboratory Methods," 15th Ed., W. B. Saunders Co., Philadelphia, pp. 782–785, 1974.

(219) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 298, 951, 1976.

(220) King, J., "Practical Clinical Enzymology," Van Nostrand, New York, pp. 154–160, 1965.

(221) Reichard, H., "A New Specific Liver Test: Determination of Ornithine Carbamyl Transferase in Human Serum," *Scandinavian Journal of Clinical and Laboratory Investigation*, 9:103–104, 1957.

(222) Norberg, B., "Serum Enzyme Studies in Some Icteric Conditions," *Clinica Chimica Acta*, 6:264–271, 1961.

(223) White, W. W., M. M. Erickson, and S. C. Stevens, "Chemistry for Medical Technologists," 3d Ed., C. V. Mosbey, St. Louis, pp. 216–219, 1970.

(224) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 1008–1014, 1976.

(225) Arnaud, C. D., H. S. Tsao, and T. Littledike, "Radioimmunoassay of Human Parathyroid Hormone in Serum," *Journal of Clinical Investigation*, 50:21–34, 1971.

(226) Arnaud, C. D., "Parathyroid Hormone: Coming of Age in Clinical Medicine," *American Journal of Medicine*, 55:577–581, 1973.

(227) Aurbach, G. D., L. E. Mallette, B. M. Patten, D. A. Heath, J. L. Doppman, and J. P. Bilezikian, "Hyperparathyroidism: Recent Studies," *Annals of Internal Medicine*, 79:566–581, 1973.

(228) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, p. 982, 1976.

(229) Henry, R. J., D. C. Cannon, and J. W. Winkelman (eds.), "Clinical Chemistry, Principles and Technics," 2d Ed., Harper and Row, Hagerstown, MD pp. 596–600, 1974.

(230) Latner, A. L. (ed.), "Canterow and Trumper, Clinical Biochemistry," 7th Ed., W. B. Saunders Co., pp. 225–226, 1975.

(231) Wolf, P., et al., "Methods and Techniques in Clinical Chemistry," Wiley-Interscience, New York, pp. 298–302, 1972.

(232) Stanbury, Wyngaarden, and Frederickson, "Metabolic Basis of Inherited Disease," 3d Ed., McGraw Hill, pp. 273–275, 1972.

(233) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d, Ed., W. B. Saunders Co., Philadelphia, pp. 390–394, 1976.

(234) Bradley, G. M. and E. Benson, in "Todd-Sanford, Clinical Diagnosis by Laboratory Methods," Edited by Davidsohn, I., and J. B. Henry, 15th Ed., W. B. Saunders Co., Philadelphia, pp. 19, 48, and 52, 1974.

(235) Heller, P., H. G. Weinstein, M. West, and H. J. Zimmerman, "Glycolytic, Citric Acid Cycle, and Hexosemonophosphate Shunt Enzymes of Plasma and Erythrocytes in Megaloblastic Anemia," *Journal of Laboratory and Clinical Medicine*, 55: 425–434, 1960.

(236) Henry, R. J., D. C. Cannon, and J. W. Winkelman (eds.), "Clinical Chemistry: Principles and Technics," 2d Ed., Harper and Row, Hagerstown, MD, pp. 849–853, 1974.

(237) "Lynch's Medical Laboratory Technology," 3d Ed., W. B. Saunders Co., Philadelphia, pp. 263–264, 1976.

(238) Rao, Y. M., M. Chakravorty, and N. N. Khanna, "Serum Phosphohexose Isomerase in Cancer," *Indian Journal of Cancer*, 13(4):361–366, December 1976.

(239) Munjal, D., et al., "Carcinoembryonic Antigen and Phosphohexose Isomerase, Gamma-Glutamyl Transpeptidase and Lactate Dehydrogenase Levels in Patients With and Without Liver Metastases," *Cancer*, 37(4):1800–1807, 1976.

(240) Davidsohn, I. and J. B. Henry (eds.), "Todd and Sanford, Clinical Diagnosis by Laboratory Methods," 15th Ed., W. B. Saunders Co., Philadelphia, p. 851, 1974.

(241) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 478 and 516–521, 1976.

(242) Raven, R. B., "The Clinical Laboratory in Heart Diseases," *in* "The Laboratory in Clinical Medicine—Interpretation and Application," Edited by J. A. Halsted, W. B. Saunders Co., Philadelphia, pp. 285–287, 1976.

(243) Henry, R. J., D. C. Cannon, and J. W. Winkelman (eds.), "Clinical Chemistry, Principles and Technics," 2d Ed., Harper and Row, Hagerstown, MD, pp. 720–728, 1974.

(244) Spellacy, W. N., E. S. Teoh, W. C. Buhi, S. A. Birk, and S. A. McCreary, "Value of Human Chorionic Somatomammotrophin in Managing High-Risk Pregnancies," *American Journal of Obstetrics and Gynecology*, 109: 588–598, 1971.

(245) Spellacy, W. N., W. C. Buhi, J. D. Schram, S. A. Birk, and S. A. McCreary, "Control of Human Chorionic Somatomammotrophin Levels During Pregnancy," *Obstetrics and Gynecology*, 37:567–573, 1971.

(246) Harrigan, J. T., et al., "Predictive Value of Human Placental Lactogen Determinations in Pregnancy," *Obstetrics and Gynecology*, 47(4):443–445, 1976.

(247) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 455–473, 1976.

(248) Henry, R. J., D. C. Cannon, and J. W. Winkelman (eds.), "Clinical Chemistry, Principles and Technics," 2d Ed., Harper and Row, Hagerstown, MD, pp. 1226–1227 and 1233–1239, 1974.

(249) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 455–473, 1976.

(250) Henry, R. J., D. C. Cannon, and J. W. Winkelman (eds.), "Clinical Chemistry, Principles and Technics," 2d Ed., Harper and Row, Hagerstown, MD, pp. 1226–1227 and 1233–1239, 1974.

(251) Weisberg, H. F., *in* "Todd and Sanford's Clinical Diagnosis by Laboratory Methods," Davidsohn, I. and J. B. Henry (eds.), 15th Ed., Philadelphia, W. B. Saunders Co., pp. 775–776, 1974.

(252) Latner, A. L. (ed.), "Cantarow and Trumper, Clinical Biochemistry," 7th Ed., Philadelphia, W. B. Saunders Co., pp. 383–391, 1975.

(253) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., Philadelphia, W. B. Saunders, Co., pp. 876–879, 1976.

(254) Weissman, N. and V. J. Pileggi, "Clinical Chemistry, Principles and Technics," Henry, R. J., D. C. Cannon, and J. W. Winkelman (eds.), 2d Ed., Harper and Row, Hagerstown, MD. pp. 644–646, 1974.

(255) Lucis, O. J., "Progesterone and Metabolites" *in* "Biochemistry of Women: Methods for Clinical Investigation," Edited by Curry, A. S. and J. V. Hewitt, CRC Press, Columbus, OH, pp. 45–78, 1974.

(256) Liddle, G. W. and K. L. Melmon, "The Adrenals" *in* Textbook of Endocrinology," 5th Ed., Edited by Williams, R. H., W. B. Saunders Co., Philadelphia, pp. 233–322, 1974.

(257) McKenna, J. J. et al., "Pregnenolone, 17-OH-pregnenolone and Testosterone in Plasma of Patients with Congenital Adrenal Hyperplasia," *Journal of Clinical Endocrinology and Metabolism*, 42:918–925, 1976.

(258) Tietz, N. W., (ed.), "Fundamentals of Clinical Chemistry," 2d. Ed., W. B. Saunders Co., Philadelphia, pp. 742–743, 1976.

(259) Ross, G. T. and R. L. Van de Wiele, "The Ovaries," *in* "Testbook of Endocrinology," 5th Ed., Edited by Williams, R. H., pp. 368–422, 1974.

(260) Buckman, M. T. and G. T. Peake, "Prolactin in Clinical Practice," *Journal of the American Medical Association*, 236:871–874, 1976.

(261) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 308–312, 1976.

(262) Tietz, N. W. (ed.), "Fundamentals of Clinical Chcmistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 298–305, 1976.

(263) Schwartz, M. K., et al., "Chemical and Clinical Evaluation of the Continuous Flow Analyzer 'SMAC'," *Clinical Chemistry*, 20:1062–1070, 1974.

(264) Doumas, B. T., "Standards for Total Serum Protein Assays—A Collaborative Study," *Clinical Chemistry*, 21:1159–1166, 1975.

(265) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 824–848, 1976.

(266) Davidsohn, I. and J. B. Henry (eds.), "Todd-Sanford, Clinical Diagnosis by Laboratory Methods," 15th Ed., W. B. Saunders Co., Philadelphia, pp. 755–756, 1974.

(267) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 358–360, 1976.

(268) Henry, R. J., J. W. Winkelman, and D. C. Cannon (eds.), "Clinical Chemistry, Principles and Technics," 2d Ed., Harper and Row, Hagerstown, MD, pp. 893–898, 1974.

(269) Wintrobe, M. M., "Clinical Hematology," Lea and Febiger, Philadelphia, pp. 769–774, 1974.

(270) Henry, R. J., D. C. Cannon, and J. W. Winkelman (eds.), "Clinical Chemistry, Principles and Technics, 2d Ed., Harper and Row, Hagerstown, MD, pp. 1335–1340, 1974.

(271) Wolf, P. L., et al., "Methods and Techniques in Clinical Chemistry," Wiley-Interscience, New York, pp. 332–337, 1972.

(272) Frankel, S., S. Reitman, and A. C. Sonnenwirth (eds.), "Gradwohl's Clinical

Laboratory Methods and Diagnosis," 7th Ed., Mosby Co., St. Louis, pp. 169–170, 1970.

(*273*) Wintrobe M. M., et al. (eds.), "Harrison's Principles of Internal Medicine," 7th Ed., McGraw Hill, New York, pp. 1343–1355, 1974.

(*274*) Davidson, I. and J. B. Henry (eds.), "Todd-Sanford, Clinical Diagnosis by Laboratory Methods," 15th Ed., W. B. Saunders Co., Philadelphia, pp. 773–775, 1974.

(*275*) Gilbert, R. K., "Progress and Analytic Goals in Clinical Chemistry," *American Journal of Clinical Pathology*, 63:960–973, 1975.

(*276*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 665–666, 1976.

(*277*) Spencer, W. W., G. H. Nelson, and K. A. Konicki, "Evaluation of a New System ("Corvac") in Separating Serum from Blood for Routine Laboratory Procedures," *Clinical Chemistry*, 22:1012–1016, 1976.

(*278*) Laessig, R. H., et al., "Assessment of a Serum Separator Device for Obtaining Serum Specimens Suitable for Clinical Analyses," *Clinical Chemistry*, 22:235–239, 1976.

(*279*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 741–758, 1976.

(*280*) Paulsen, C. A., "The Testes," *in* "Textbook of Endocrinology," 5th Ed., Edited by Williams, R. H., W. B. Saunders Co., Phildelphia, pp. 323–332, 481–485, 1974.

(*281*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 824–848, 1976.

(*282*) Henry, J. B. and A. F. Krieg, "Endocrine Measurements," in "Todd-Sanford, Clinical Diagnosis by Laboratory Methods," 15th Ed., Edited by Davidsohn, I. and J. B. Henry, W. B. Saunders Co., Philadelphia, pp. 758–761, 1974.

(*283*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 824–848, 1976.

(*284*) Thorn, G. W., et al., "Harrison's Principles of Internal Medicine," 8th Ed., McGraw-Hill Book Co., New York, pp. 484, 503, 505, and 506, 1977.

(*285*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 824–848, 1976.

(*286*) Kessler, G. and V. J. Pileggi, "A Semiautomated Nonincineration Technique for Determining Serum Thyroxine," *Clinical Chemistry*, 16:382–389, 1970.

(*287*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 824–848, 1976.

(*288*) Kessler, G., and V. J. Pileggi, "A Semiautomated Nonincineration Technique for Determining Serum Thyroxine," *Clinical Chemistry*, 16:382–389, 1970.

(*289*) Demetriou, J. A., et al., "An Improved Semimicromethod for Thyroxine Measurement by Competitive Protein Binding," *Clinical Chemistry*, 17:650, 1971 (abstract).

(*290*) Henry, R. J., D. C. Cannon, J. W. Winkelman (eds.), "Clinical Chemistry, Principles and Technics," 2d Ed., Harper & Row, Hagerstown, MD, pp. 1452–1464, 1974.

(*291*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 824–848, 1976.

(*292*) Larsen, P. R., "Triiodothyronine: Review of Recent Studies of Its Physiology and Pathophysiology in Man," *Metabolism*, 21:1073–1092, 1973.

(*293*) Kirkegaard, C., T. Friis, and K. Siersbaek-Nielsen, "Measurement of Serum Triiodothyronine by Radioimmunoassay," *Acta Endocrinologica*, 77:71–81, 1974.

(*294*) Schneider, A. S., et al., "Triosephosphate Isomerase Deficiency A. A Multi-System Inherited Enzyme Disorder. Clincial and Genetic Aspects," *in* "Hereditary Disorders of Erythrocyte Metabolism," edited by Beutler, E., Greene and Stratton, New York, pp. 265–272, 1969.

(*295*) Beutler, E., "Red Cell Metabolism," 1st Ed., Green and Stratton, New York, pp. 47–50, 1975.

(*296*) Schwartz, M. K., and M. Fleisher, "Diagnostic Biochemical Methods in Pancreatic Disease," *Advances in Clinical Chemistry*, 13:113–159, 1970.

(*297*) Nardi, J. L., and C. W. Lees, "Serum Trypsin: A New Diagnostic Test for Pancreatic Disease," *New England Journal of Medicine*, 258:797–798, 1958.

(*298*) Amman, R. W. W., et al., "Diagnostic Value of Fecal Chymotrypsin and Trypsin Assessment for Detection of Pancreatic Disease," *American Journal of Digestive Diseases*, 13:123–146, 1968.

(*299*) Henry, R. J., D. C. Cannon, and J. W. Winkelman (eds.), "Clinical Chemistry, Principles and Technics," 2d Ed., Harper and Row, Hagerstown, MD, pp. 604–608, 1974.

(*300*) Stanbury, J. B., J. B. Wyngaarden, and D. S. Fredrickson, "Metabolic Basis of Inherited Disease," 3d Ed., McGraw-Hill, New York, pp. 296–302, 1972.

(*301*) Tietz, N., "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, p. 396, 1976.

(*302*) "Gradwohl's Clinical Laboratory Methods and Diagnosis," 7th Ed., Frankel, S., et al. (eds.), Mosby Co., St. Louis, pp. 57–60, 1970.

(*303*) "Harrison's Principles of Internal Medicine," 8th Ed., Thorn, G. W., et al. (eds.) McGraw Hill, New York, pp. 1422–1423, 1425–1426, 1977.

(*304*) "Todd-Sanford, Clinical Diagnosis by Laboratory Methods," 15th Ed., Davidsohn, I. and J. B. Henry (eds.), W. B. Saunders Co., Philadelphia, pp. 591–594, 1974.

(*305*) Gilbert, R. K., "Progress and Analytical Goals in Clinical Chemistry," *American Journal of Clinical Pathology*, 63:960–973, 1975.

(*306*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 999–1002, 1976.

(*307*) Lum, G. and S. R. Gambino, "Comparison of Four Methods for Measuring Uric Acid: Copper-Chelate, Phosphotungstate, Manual Uricase, and Automated Kinetic Uricase," *Clinical Chemistry*, 19:1184–1186, 1973.

(*308*) Radin, N., et al., "Uric Acid: An Annotated Bibliography," Center for Disease Control, Atlanta, 1975.

(*309*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, Chapter 18, 1976.

(*310*) Prien, E. L., "The Analysis of Urinary Calculi," *in* "Urologic Clinics of North America," 1:229–246, June 1974.

(*311*) Herring, L. C., "Observations on the Analysis of Ten Thousand Urinary Calculi," *Journal of Urology*, 80:545–562, 1962.

(*312*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 1045–1049, 1976.

(*313*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 455–473, 1976.

(*314*) Scott, C. R., R. F. Labbe, and J. Nutter, "A Rapid Assay for Urinary Porphyrins by Thin-Layer Chromatography," *Clinical Chemistry*, 13:493–501, 1967.

(*315*) Carney, J. A., G. W. Sizemore, and S. G. Sheps, "Adrenal Medullary Disease in Multiple Endocrine Neoplasia, Type 2, Pheochromocytoma and its Precursors," *American Journal of Clinical Pathology*, 66:279–290, 1976.

(*316*) Cytryn, L., et al., "Biochemical Correlates of Affective Disorders in Children", *Archives of General Psychiatry*, 31:659–661, 1974.

(*317*) Renelt, P., et al., "Vanilmandelic Acid Urinary Excretion in the Diagnosis of Retino Blastoma," *Albrecht von Graefes Archiv Fur Klinische und Experimentelle Opthalmologie*, 188:281–283, 1973.

(*318*) Richards, D. A., "Determination of 4-hydroxy-3-methoxymandelic acid (HMMA) in urine," *Medical Laboratory Sciences*, 33:155–160, 1976.

(*319*) Sullivan, J. M. and H. S. Solomon, "The Diagnosis of Pheochromocytoma, Overnight Excretion of Catecholamine Metabolites," *Journal of the American Medical Association*, 231:618–619, 1975.

(*320*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 815–817, 1976.

(*321*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 542–547, 1089–1090, 1976.

(*322*) Reddy, V., et al., "Color Vision in Vitamin A Deficiency," *British Medical Journal*, 1(6053):81, 8, January 1977.

(*323*) Thompson, J. N., et al., "Fluorometric Determination of Vitamin A in Human Blood and Liver," *Biochemical Medicine*, 5:67, 1971.

(*324*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 555–558, 1976.

(*325*) Adams, J. F., K. Boddy, and A. S. Douglas, "Interrelation of Serum Vitamins B12, Total Body Vitamin B12, Peripheral Blood Morphology and the Nature of Erythropoiesis," *British Journal of Hematology*, 23:297–305, 1972.

(*326*) Liu, Y. K. and L. W. Sullivan, "An Improved Radioisotope Dilution Assay for Serum Vitamin B12 Using Hemoglobin-Coated Charcoal," *Blood*, 39:426–432, 1972.

(*327*) Horwitt, M. K., "Status of Human Requirements for Vitamin E," *The American Journal of Clinical Nutrition*, 27(10):1182–1193, 1974.

(*328*) Schrauzer, G. N., et al., "Sudden Infant Death Syndrome: Plasma Vitamin E Levels and Dietary Factors," *Annals of Clinical and Laboratory Science*, 5(1):31–37, 1975.

(*329*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 1091–1094, 1976.

(*330*) Broitman, S. A. et al., "Absorption and Disposition of D-Xylose in Thyrotoxicosis and Myxedema," *New*

England Journal of Medicine, 270:333–337, 1960.

(*331*) Kendall, M. J., S. Nutter, and C. S. Hawkins, "Bacteria and the Xylose Test," *Lancet*, 1:1017–1018, 1972.

(*332*) Curteus, H. C. and M. Roth (eds.), "Radioimmunoassays," *in* "Clinical Biochemistry Principles and Methods," Vol. I, Walter de Gruyter and Co., Berlin, pp. 361–365, 1974.

(*333*) Berman, E., "Biochemical Applications of Flame Emission and Atomic Absorption Spectroscopy," *Applied Spectroscopy*, 29(1):1–8, 1975.

(*334*) Todd-Sanford, "Clinical Diagnosis by Laboratory Methods," 15th Ed., W. B. Saunders Co., Philadelphia, PA, pp. 510–512, 1974.

(*335*) Caraway, W. T., *in* "Fundamentals of Clinical Chemistry," Edited by Tietz, N. W., 2d Ed., W. B. Saunders Co., Philadelphia, pp. 119–122, 1976.

(*336*) Martinek, R., "Fluorometry," *Medical Electronics and Data*, 1:118–127, 1970.

(*337*) Johnson, R. B., Jr., and H. Hoch, "Osmolality of Serum and Urine," *in* "Standard Methods of Clinical Chemistry," Vol. 5, Edited by S. Meites, Academic Press, New York, pp. 159–168, 1965.

(*338*) Curry, A. S., G. W. Walker, and G. S. Simpson, "Determinationn of Ethanol in Blood by Gas Chromatography," *Analyst*, 91:742–743, 1966.

(*339*) Frankel, S., S. Reitman, and A. C. Sonnenwirth, "Gradwohl's Clinical Laboratory Methods and Diagnosis," 7th Ed., C. V. Mosby Co., St. Louis, MO, p. 306, 1970.

(*340*) Redetzki, H. M. and W. L. Dees, "Comparison of Four Kits for Enzymatic Determinatin of Ethanol in Blood," *Clinical Chemistry*, 22(1):83–86, 1976.

(*341*) Teitz, N. W., "Fundamentals of Clinical Chemistry," W. B. Saunders Co., Philadelphia, pp. 1110–1111, 1976.

(*342*) Wallace, J. E. and E. V. Dahl, "Rapid Vapor Phase Method for Determining Ethanol in Blood and Urine by Gas Chromatography," *American Journal of Clinical Pathology*, 46:152, 1966.

(*343*) Jain, N. C., "Direct Blood-Injection Method for Gas Chromatographic Determination of Alcohols and Other Volatile Compounds," *Clinical Chemistry*, 17(2):82–85, 1971.

(*344*) Sunshine, I., "Methodology for Analytical Toxicology," CRC Press Inc., Cleveland, Ohio, pp. 145–148, 1975.

(*345*) Bost, R. O., C. A. Sutheimer, and I. Sunshine, "Relative Merits of Some Methods for Amphetamine Assay in Biological Fluids," *Clinical Chemistry*, 22(6):789–801, 1976.

(*346*) Cleeland, R., J. Christenson, M. Usatequi-Gomez, J. Heveran, R. Davis, and E. Grubergn, "Detection of Drugs of Abuse by Radioimmunassay: A Summary of Published Data and Some New Information," *Clinical Chemistry*, 22(6):712–725, 1976.

(*347*) Meyers, F. H., T. E. Jawete, and M. A. Goldfien, "CNS Stimulants and Antidepressants," *in* "Review of Medical Pharmacology," 5th Ed., Lange Medical Publications, Los Altos, CA, pp. 288–296, 1976.

(*348*) Berman, E., "Biochemical Applications of Flame Emission and Atomic Absorption Spectroscopy," *Applied Spectroscopy*, 29(1):1–9, 1975.

(*349*) Frankel, S., S. Reitman, And A. C. Sonnenwirth, "Gradwohl's Clinical Laboratory Methods and Diagnosis," Vol. I., C. V. Mosby Co., St. Louis, MO, pp. 312–313, 1970.

(*350*) Agett, J. and A. C. Spell, "The Determination of Arsenic (III) and Total Arsenic by Atomic Absorption Spectroscopy," *Analyst*, 101:341–347, 1976.

(*351*) Berman, E., "Biochemical Applications of Flame Emission and Atomic Absorption Spectroscopy," *Applied Spectroscopy*, 29:1–9, 1975.

(*352*) Morrell, G., "Arsenic Poisoning," *Lab Management*, 16(5):54–55, 1978.

(*353*) Sunshine, I., "Methodology for Analytical Toxicology," CRC Press, Inc., Cleveland, Ohio, pp. 30–33, 1975.

(*354*) Cleeland, R., J. Christenson, M. Usategui-Gomez, J. Heverau, R. Davis, and E. Grunberg, "Detection of Drugs of Abuse by Radioimmunoassay: A Summary of Published Data and Some New Information," *Clinical Chemistry*, 22(6):712–725, 1976.

(*355*) Meyers, F. H., E. Jawetz, and A. Goldfien, "Review of Medical Pharmacology," 5th Ed., Lange Medical Publications, Los Altos, CA, pp. 222–231, 1976.

(*356*) Goodman, S. and A. Gilman, "The Pharmacological Basis of Therapeutics," MacMillian Publishing Co., New York, pp. 186–192, 1975.

(*357*) Sunshine, I., "Methodology for Analytical Toxicology," CRC Press, Cleveland, Ohio, pp. 45–47, 1975.

(*358*) Trender, P. and F. E. Harper, "A Colorimetric Method for the Determination of Carboxyhemoglobin Over a Wide Range of Concentrations," *Journal of Clinical Pathology*, 15:82–84, 1962.

(*359*) Rowan, T. and F. C. Coleman, "Carbon Monoxide Poisoning," *Journal of Forensic Science*, 7:103–130, 1962.

(*360*) Sunshine, I., "Methodology for Analytical Toxicology," CRC Press, Cleveland, OH pp. 64–71, 1975.

(*361*) Tietz, N. W., "Fundamentals of Clinical Chemistry," W. B. Saunders Co., Philadelphia, PA, pp. 1104–1109, 1976.

(*362*) Witter, F. F., "Measurement of Blood Cholinesterase," *Archives of Environmental Health*, 6:537–563, 1963.

(*363*) Mayer, F. W. and N. Schlackman, "Organophosphates—A Pediatric Hazard," *American Family Physician*, 2(5):121–124, 1975.

(*364*) Sunderman, F. W. and F. W. Sunderman, Jr., "Laboratory Diagnosis of Diseases Caused by Toxic Agents," W. H. Green, Inc., St. Louis, MO, Chapters 18, 19A, 19B, 1970.

(*365*) Frankel, S., S. Reitman, and A. Sonnenwirth, "Gradwohl's Clinical Laboratory Methods and Diagnosis," 7th Ed., C. V. Mosby Co., St. Louis, MO, pp. 140–141, 1970.

(*366*) Goodman, L. S. and A. Gilman, "The Pharmacological Basis of Therapeutics," MacMillan Publishing Co., New York, pp. 386–388, 1975.

(*367*) Mule, S. J., D. Jukofsky, M. Kogan, M. D. Pace, and K. Vereby, "Evaluation of the Radioimmunoassay for Benzoylecgnone (a Cocaine Metabolite) in Human Urine," *Clinical Chemistry*, 23(5):796–801, 1977.

(*368*) Van Kyke, C., R. Byck, P. G. Barash, and P. Jatlow, "Urinary Excretion of Immunologically Reactive Metabolite After Intranasal Administration of Cocaine, as Followed by Enzyme Immunoassay," *Clinical Chemistry*, 23(2):241–244, 1977.

(*369*) Kaistha, K. K. and R. Tadrus, "Thin-Layer Chromatographic Detection of Quinine, Morphine, and Poly-Drugs," *Clinical Chemistry*, 22(11):1936–1937, 1976.

(*370*) Meyers, F. H., E. Jawetz, and A. Goldfien, "Review of Medical Pharmacology," 5th Ed., Lange Medical Publications, Los Altos, CA, pp. 261–271, 1976.

(*371*) Beller, G. A., T. W. Smith, W. H. Abelmann, E. Haber, and W. B. Hood, "Digitalis Intoxication, A Prospective Clinical Study with Serum Level Correlations," *New England Journal of Medicine*,, 284:989–997, 1971.

(*372*) Noble, R. J., D. A. Rothbaum, A. M. Watanbe, H. R. Besch, and C. Fisch, "Limitations of Serum Digitalis Levels," *Cardiovascular Clinics*, 6:299–311, 1974.

(*373*) Ryan, S. A. and B. D. Clayton, "Handbook of Practical Pharmacology," C. V. Mosby Co., St. Louis, MO, pp. 44–47, 1977.

(*374*) Sheiner, L. B., "The Use of Serum Concentrations of Digitalis for Quantitative Therapeutic Decisions," *Cardiovascular Clinics*, 6:141–152, 1974.

(*375*) Smith, T. W. and E. Haber, "Clinical Value of the Radioimmunoassay of the Digitalis Glycosides," *Pharmacological Reviews*, 25:219–228, 1973.

(*376*) Beller, G. A., T. W. Smith, W. H. Abelmann, E. Haber, and W. B. Hood, "Digitalis Intoxication, A Prospective Clinical Study with Serum Level Correlations," *New England Journal of Medicine*, 284:989–997, 1971.

(*377*) Noble, R. J., D. A. Rothbaum, A. M. Watanbe, H. R. Besch, and C. Fisch, "Limitations of Serum Digitalis Levels," *Cardiovascular Clinics*, 6:299–311, 1974.

(*378*) Sheiner, L. B., "The Use of Serum Concentrations of Digitalis for Quantitative Therapeutic Decisions," *Cardiovascular Clinics*, 6:141–152, 1974.

(*379*) Smith, T. W. and E. Haber, "Clinical Value of the Radioimmunoassay of the Digitalis Glycocides," *Pharmacology Review*, 25:219–228, 1973.

(*380*) Goodman, L. S. and A. Gilman, "The Pharmacological Basis of Therapeutics," 5th Ed., MacMillan Publishing Co., New York, pp. 207–208, 1975.

(*381*) Adams, R. F. and R. L. Vandemark, "Simultaneous High-Pressure Liquid Chromatographic Determination of Some Anticonvulsants in Serum," *Clinical Chemistry*, 22(1):25–31, 1976.

(*382*) Wilson, J. T. and G. R. Wilkinson, "Chronic and Severe Phenobarbital Intoxication in a Child Treated with Primidone and Phenylhydantoin," *Journal of Pediatrics*, 83(3):484–489, 1973.

(*383*) Pippenger, C. E. and H. Kutt, "Common Errors in the Detection of Anticonvulsant Drugs by Gas Liquid Chromatography," *Clinical Chemistry*, 19:666, 1973.

(*384*) Myers, F. H., E. Jawetz, and A. Goldfien, "Review of Medical

Pharmacology," 5th Ed., Lange Medical Publications, Los Altos, CA, p. 306, 1976.

(*385*) Goodman, S. and A. Gilman, "The Pharmacological Basis of Therapeutics," 5th Ed., Macmillan Publishing Co. Inc., New York, pp. 212–213, 1975.

(*386*) Pippenger, E. E., et al., "Interlaboratory Variability in Determination of Plasma Antiepileptic Drug Concentrations," *Archives of Neurology*, 33:351–355, 1976.

(*387*) Lewis, J. Z., J. C. Nelson, and H. A. Elder, "Radioimmunoassay of an Antibiotic Gentamicin," *Nature New Biology*, 239:214–216, 1972.

(*388*) Mahon, W. A., J. Ezer, and T. W. Wilson, "Radioimmunoassay for Measurement of Gentamicin in Blood," *Antimicrobial Agents and Chemotherapy*, 3(5):505–509, 1973.

(*389*) Stevens, P., L. S. Young, and W. L. Hewitt, "Radioimmunoassay, Acetylating Radio-enzymatic Assay, and Microbioassay of Gentamicin: A Comprehensive Study," *Journal of Laboratory and Clinical Medicine*, 86:349, 1975.

(*390*) Sabath, L. D. et al., "Rapid Microassay of Gentamicin, Kanamycin, Neomycin, Streptomycin, and Vancomycin in Serum or Plasma," *Journal of Laboratory and Clinical Medicine*, 78(3):457–463, 1971.

(*391*) Riff, L. J. and G. G. Jackson, "Pharmacology of Gentamicin in Man," *Journal of Infectious Diseases*, 124 (Supplement):98–105, 1971.

(*392*) Kahlgren, J. G. Z. T. Anderson, and W. L. Hewitt, "Gentamicin Blood Levels: A Guide to Nephrotoxicity," *Antimicrobial Agents and Chemotherapy*, 8(1):58–62, 1975.

(*393*) Steven, P., L. S. Young, and W. L. Hewitt, "125 I-Radioimmunoassay of Amikacin and Comparison with a Microbiassay," *Journal of Antibiotics*, 29(8):829–32, 1976.

(*394*) Ryna, S. A. and B. D. Clayton, "Handbook of Practical Pharmacology," C. V. Mosby Co., St. Louis, MO, pp. 13–16, 1977.

(*395*) Berman, E., "Biochemical Application of Flame Emission and Atomic Absorption Spectroscopy," *Applied Spectroscopy*, 29(1):1–9, 1975.

(*396*) Center for Disease Control, "Increased Lead Absorption and Lead Poisoning in Young Children," *Journal of Pediatrics*, 87(5):824–830, 1975.

(*397*) Piomelli, S., B. Davidow, V. P. Guinee, P. Young, and G. Gay, "The FEP (Free Erythrocyte Porphyrine) Test: A Screening Micromethod for Lead Poisioning," *Pediatrics*, 51(2):254–259, 1973.

(*398*) Sassa, S., J. L. Granick, S. Granick, A. Kappas, and R. D. Levere, "Studies in Lead Poisoning," *Biochemical Medicine*, 8:135–148 1973.

(*399*) Tietz, N. W., "Fundamentals of Clinical Chemistry," W. B. Saunders Co., Philadelphia, PA, pp. 1121–1125, 1976.

(*400*) Tietz, N. W. (ed.), "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co., Philadelphia, pp. 899–901, 1976.

(*401*) Phybus, J. and G. N. Bowers, Jr., "Serum Lithium Determination by Atomic Absorption Spectroscopy," *in* "Standard Methods of Clinical Chemistry," Vol. 6, Edited by MacDonald, R. P., Academic Press, New York, pp. 189–192, 1970.

(*402*) Egozeue, J., S. Irwin, and C. A. Maruffo, "Chromosomal Damage in LSD Users," *American Medical Association*, 204(3):214–218, 1968.

(*403*) Ratcliffe, W. A., S. M. Fletcher, A. C. Moffat, J. G. Ratcliffe, W. A. Harland, and T. E. Levitt, "Radioimmunoassay of Lysergic Acid Diethylamide (LSD) in Serum and Urine by Using Antisera of Different Specificities," *Clinical Chemistry*,, 23(2):169–174, 1977.

(*404*) Castro, A., and H. Malkus, "Radioimmunoassay of Drugs of Abuse in Humans: A Review," *Research Communications in Chemical Pathology and Pharmacology*, 16(2):291–309, 1977.

(*405*) Meyers, F. H., E. Jawetz, and A. Goldfein, "Review of Medical Pharmacology," Lange Medical Publications, Los Altos, CA, pp. 48–50, 1976.

(*406*) Berman, E., "Biochemical Applications of Flame Emission and Atomic Absorption Spectroscopy," *Applied Spectroscopy*, 29(1):1–9, 1975.

(*407*) Magos, L., "Selective Atomic Absorption Determination of Inorganic Mercury and Methylmercury in Undigested Biological Samples," *Analyst*, 96:847–853, 1971.

(*408*) Sunshine, I., "Methodology for Analytical Toxicology," CRC Press, Inc., Cleveland, Ohio, pp. 224–230, 1975.

(*409*) Bost, R. O., C. A. Sutheimer, and I. Sunshine, "Relative Merits of Some Methods for Amphetamine Assay in Biological Fluids," *Clinical Chemistry*, 22(6):789–801, 1976.

(*410*) Galconer, M. W., H. R. Patterson, E. A. Gustofson, and E. Sheridan, "Current Drug Handbook, 1978–1980," W. B. Saunders Co., Philadelphia, pp. 88–89, 1978.

(*411*) Gatlin, D. H., "A Guide to Urine Testing for Drugs of Abuse," Special Action Office Monograph, Series B, No. 2, November 1973.

(*412*) Mule, S. J., "Identification of Narcotics, Barbiturates, Amphetamines, Tranquilizers and Psychotomimetics in Human Urine," *Journal of Chromatography*, 39:302–314, 1969.

(*413*) Cleeland, R., J. Christenson, M. Usategui-Gomez, J. Heveran, R. Davis, and E. Grunberg, "Detection of Drugs of Abuse by Radioimmunoassy: A Summary of Published Data and Some New Information," *Clinical Chemistry*, 22(6):712–725, 1976.

(*414*) Hamilton, H. E., J. E. Wallace and K. Blum, "Improved Methods for Quantitative Determination of Methadone," *Journal of Pharmaceutical Sciences*, 63:741–745, 1974.

(*415*) Inturrisi, C. E. and K. Verebely, "A Gas-Liquid Chromatographic Method for the Quantitative Determination of Methadone in Human Plasma and Urine," *Journal of Chromatography*, 65:361–369, 1972.

(*416*) Sunshine, I., "Methodology for Analytical Toxicology," CRC Press, Cleveland, Ohio, pp. 231–235, 1975.

(*417*) Goodman, L. S. and A. Gilman, "The Pharmacological Basis of Therapeutics," Macmillan Publishing Co., New York, pp. 268–270, 1975.

(*418*) Catlin, D. H., "A Comparison of Five Current Methods for Detecting Morphine," *American Journal of Clinical Pathology*, 60:719–728, 1973.

(*419*) Kokoski, R. J. and M. Jain, "Comparison of Results for Morphine Urinalysis by Radioimmunoassay and Thin-Layer Chromatography in Narcotic Clinical Setting," *Clinical Chemistry*, 21(3):417–419, 1975.

(*420*) Cleeland, R. J. Christenson, M. Usategui-Gomez, J. Heveran, R. Davis, and E. Grunberg, "Detection of Drugs of Abuse by Radioimmunoassays: A Summary of Published Data and Some New Information," *Clinical Chemistry*, 22(6): 712–725, 1976.

(*421*) Mule, S. J., E. Whitlock, and D. Jukofsky, "Radioimmunoassay of Drugs Subject to Abuse: Critical Evaluation of Urinary Morphine-Barbiturate, and Amphetamine Assays," *Clinical Chemistry*, 21(1):81–86, 1975.

(*422*) Van Der Slootin, E. P. T. and H. J. Van Der Helm, "Comparison of Mass Spectrometric Determination of Morphine and Codeine in Urine," *Clinical Chemistry*, 22(7):1110–1111, 1976.

(*423*) Jain, N. C., T. C. Sneath, W. J. Leung, and R. D. Budd, "Mass Screening and Confirmation of Codeine and Morphine in Urine by Radioimmunoassay-GLC," *Journal of Pharmaceutical Sciences*, 66(1):66–69, 1977.

(*424*) Goodman, L. S. and A. Gilman, "The Pharmacological Basis of Therapeutics," Macmillian Publishing Co., New York, pp. 246–263, 1975.

(*425*) Mule, S. J., M. L. Bastos, and D. Jukofsky, "Evaluation of Immunoassay Methods for Detection in Urine, of Drugs Subject to Abuse," *Clinical Chemistry*, 20(2):243–248, 1974.

(*426*) Van Der Slotten, E. P. J. and H. J. Van Der Helm, "Comparison of the EMIT (Enzyme Multiplied Immunoassay Technique) Opiate Assay and a Gas-Chromatographic-Mass-Spectrophotometer Determination of Morphone and Codeine in Urine," *Clinical Chemistry*, 22(7):1110–1111, 1976.

(*427*) Meyers, F. H., E. Jawetz, and A. Golfien, "Review of Medical Pharmacology," 5th Ed., Lange Medical Publications, Los Altos, CA, pp. 301–303, 1976.

(*428*) Pippenger, C. E. et al., "Interlaboratory Variability in Determination of Plasma Antiepileptic Drug Concentrations," *Archives of Neurology*, 33:351–355, 1976.

(*429*) Garretson, L. K., "Pharmacology of Anticonvulsants," *Pediatric Clinics of North America*, 19:179–191, 1972.

(*430*) Bogan, J. and H. Smith, "Relation between Primidone and Phenobarbital Blood Levels," *Journal of Pharmacy and Pharmacology*, 20:64, 1968.

(*431*) Swindler, G. D., "Handbook of Drug Interactions," John Wiley and Sons, Inc., New York, pp. 25–28, 1971.

(*432*) Forrest, I. S. and F. M. Forest, "Urine Color Test for the Detection of Phenothiazine Compounds," *Clinical Chemistry*, 6:11–15, 1960.

(*433*) Sunshine, I., "Methodology for Analytical Toxicology," CRC Press, Cleveland, OH, p. 301, 1975.

(*434*) Goodman, L. S. and A. Gilman, "The Pharmacological Basis of Therapeutics," 5th Ed., Macmillan Publishing Co., Inc., New York, pp. 157–166, 1975.

(*435*) Frankel, S., S. Rietman, and A. C. Sonnenwirth, "Gradwohl's Clinical

Laboratory Methods and Diagnosis," 7th Ed., C. V. Mosby Co., St. Louis, MO, p. 317, 1970.

(436) Adams, R. F., and F. L. Vandemark, "Simultaneous High Pressure Liquid-Chromatographic Determination of Some Anticonvulsants in Serum," *Clinical Chemistry*, 22(1):25–31, 1976.

(437) Wilson, J. T., and R. G. Wilkinson, "Chronic and Severe Phenobarbital Intoxication in a Child Treated with Primidone and Diphenylhydantoin," *Journal of Pediatrics*, 83(3):484–489, 1973.

(438) Pippenger, C. E. et al., "Interlaboratory Variability in Determination of Plasma Antiepileptic Drug Concentrations," *Archives of Neurology*, 33:351–355, 1976.

(439) Garrettson, L. K., "Pharmacology of Anticonvulsants," *Pediatric Clinics of North America*, pp. 179–191, Feb. 19, 1972.

(440) Goodman, L. S. and A. Gilman, "The Pharmacological Basis of Therapeutics," 5th Ed., Macmillan Publishing Co., Inc., New York, pp. 270–271, 1975.

(441) Kaistha, K. K. and J. H. Jaffe, "TLC Techniques for Identification of Narcotics, Barbiturates and CNS Stimulants in a Drug Abuse Urine Screening Program," *Journal of Pharmacological Science*, 61:679–689, 1972.

(442) Mule, S. J., M. L. Bastos, and D. Jukofsky, "Evaluation of Immunoassay Methods for Detection, in Urine, or Drugs Subject to Abuse," *Clinical Chemistry*, 20(2):243–248, 1974.

(443) Karawya, M. S. and A. M. Diab, "Colorimetric Assay of Quinine and Quinidine in Raw Materials, Formulations, and Biological Fluids," *Journal of Pharmaceutical Sciences*, 66(9):1317–1319, 1977.

(444) Mule, S. J. and P. L. Huskin, "Semi-automated Fluorometric Assay for Sub-microgram Quantities of Morphine and Quinine in Human Biological Material," *Analytical Chemistry*, 43(6):708–711, 1971.

(445) Sunshine, I., "Methodology for Analytical Toxicology," CFR Press, Inc., Cleveland, Ohio, pp. 336–341, 1975.

(446) Goodman, L. S. and M. M. Gilman, "The Pharmacological Basis of Therapeutics," Macmillan Publishing Co., New York, pp. 1062–1065, 1975.

(447) Hall, A. P., "Human Plasma and Urine Quinine Levels Following Tablets, Capsules and Intravenous Infusion," *Clinical Pharmacology and Therapeutics*, 14(4): 580–585, 1973.

(448) Tietz, N., "Fundamentals of Clinical Chemistry," W. B. Saunders Co., Philadelphia, PA, pp 1147–1148, 1976.

(449) Frankel, S., S. Reitman, and A. Sonnenwirth, "Gradwohl's Clinical Laboratory Methods and Diagnosis," 7th Ed., C. V. Mosby Co., St. Louis, MO, pp. 301–303, 1970.

(450) Hyunchul, K., et al., "Performance of Kits Used for the Clinical Chemical Analysis of Salicylates in Serum," *American Journal of Clinical Pathology*, 61(6):936, 1974.

(451) Hill, J. B., "Current Concepts: Salicylate Intoxication," *New England Journal of Medicine*, 228(21):1110–1113, 1973.

(452) Weinstein, L., N. A. Madoff, and C. A. Sament, "The Sulfonamides," *New England Journal of Medicine*, 263(18):900–907, 1960.

(453) Sunshine, I., "Methodology for Analytical Toxicology," CRC Press, Cleveland, Ohio, pp. 352–353, 1975.

(454) Goodman, L. S. and A. Gilman, "The Pharmacological Basis of Therapeutics," 5th Ed., Macmillan Publishing Co., New York, pp. 1113–1127, 1975.

(455) Chase, A. R., P. R. Kelley, A. Tauton-Rigby, R. T. Jones, and T. Harwood, "Quantitation of Cannabinoids in Biological Fluids by Radioimmunoassay," *in* "Cannabinoid Assays in Humans," NIDA Research Monograph 7, pp. 1–9, 1976.

(456) Cook, C. E., M. L. Hawes, E. W. Amerson, C. G. Pitt, and D. Williams, "Radioimmunoassay of Delta 9—Tetrahydrocannabinol," *in* "Cannabinoid Assays in Humans," NIDA Research Monograph 7, pp. 15–27, 1976.

(457) Marks V., D. Teale, and D. Fry, "Detection of Cannabis Products in Urine by Radioimmunoassay," *British Medical Journal* 13:348–349, 1975.

(458) Meyers, F. H., E. Jawety, and A. Goldien, "Review of Medical Pharmacology," Lange Medical Publications, Canada, pp. 46–48, 1976.

(459) Gross, S. J. and J. R. Soares, "Validated Direct Blood delta 9-THC Radioimmune Quantitation," *Journal of Analytical Toxicology*, 2:98–100, 1978

(460) Broughton, A., J. E. Strong, L. K. Pickering, and G. P. Bodey, "Radioimmunoassay of Iodinated Tobramycin," *Antimicrobial Agents and Chemotherapy*, 10(4): 652–656, 1976.

(461) Fry, T. L., F. A. Fried, and B. A. Goven, "Renal Toxicity, Tobramycin and Gentamicin," *Investigative Urology*, 15(2):100–103, 1977.

(462) Kucers, A. and N. McK. Bennett, "The Use of Antibiotics," William Heinemann Medical Books, London, pp. 222–228, 1975.

(463) Maitra, S. K., T. T. Yoshikawa, L. B. Guze, and M. C. Schotz, "Determination of Aminoglycoside Antibiotics in Biological Fluids: A Review," *Clinical Chemistry*, 25(8):1361–1367, 1979.

(464) Ryan, S. A., and B. D. Clayton, "Handbook of Practical Pharmacology, "C. V. Mosby Company, St. Louis, MO, pp. 13–19, 1977.

Environmental Impact

The agency has determined pursuant to 21 CFR 25.24(b)(12) (proposed December 11, 1979, 44 FR 71742) that this proposed action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), the Commissioner proposes that Chapter I of Title 21 of the Code of Federal Regulations be amended by adding new Part 862 to read as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

Supart A—General Provisions

Subpart B—Clinical Chemistry Test Systems

Subpart C—Clinical Laboratory Instruments

Subpart D—Clinical Toxicology Test Systems

Authority: Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).

Subpart A—General Provisions

§ 862.1 Scope.

(a) This part sets forth the classification of clinical chemistry and clinical toxicology devices intended for human use.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 cannot show merely that the device is accurately described by the section title and identification provision of a regulaiton in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

Subpart B—Clinical Chemistry Test Systems

§ 862.1020 Acid phosphatase (total or prostatic) test system.

(a) *Identification.* An acid phosphatase (total or prostatic) test system is a device used to measure the activity of the acid phosphatase enzyme in plasma, serum, vaginal washings, and seminal fluid by methods such as *beta*-glycerophosphate, disodium phenyl phosphate, naphthyl phosphate, nitrophenylphosphate, thymol blue monophosphate, thymolphthalein monophosphate, or tartrate inhibition. Acid phosphatase measurements are used in the diagnosis and treatment of prostatic carcinoma. This device is also used to develop legal evidence to demonstrate the presence of siminal fluids in specimens collected from victims of alleged rape and other sex-related crimes.

(b) *Classification.* Class II (performance standards).

§ 862.1025 Adrenocorticotropic hormone (ACTH) test system.

(a) *Identification.* An adrenocorticotropic hormone (ACTH) test system is a device used to measure adrenocorticotropic hormone in plasma and serum by methods such as radioimmunoassay. ACTH measurements are used in the differential diagnosis and treatment of certain disorders of the adrenal glands such as Cushing's syndrome, adrenocortical insufficiency, and the ectopic ACTH syndrome.

(b) *Classification.* Class II (performance standards).

§ 862.1030 Alanine amino transferase (ALT/SGPT) test system.

(a) *Identification.* An alanine amino transferase (ALT/SGPT) test system is a device used to measure the activity of the enzyme alanine amino transferase (ALT) (also known as serum glutamic pyruvic transaminase or SGPT) in serum and plasma by methods such as diazo, hydrazone colorimetry, nicotinamide adenine dinucleotide (NAD) reduction/nicotinamide adenine dinucleotide (reduced form) (NADH) oxidation, or vanillin pyruvate. Alanine amino transferase measurements are used in the diagnosis and treatment of certain liver diseases (e.g., viral hepatitis and cirrhosis) and heart diseases.

(b) *Classification.* Class II (performance standards).

§ 862.1035 Albumin test system.

(a) *Identification.* An albumin test system is a device used to measure the albumin concentration in serum and plasma. This device uses methods such as bromcresol green dye-binding, bromcresol purple dye-binding, hydroxyazo-benzene benzoic acid, radial immunodiffusion, tetrabromo-*m*-cresolsulfonphthalein, or tetrabromophenolphthalein. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

(b) *Classification.* Class II (performance standards).

§ 862.1040 Aldolase test system.

(a) *Identification.* An aldolase test system is a device used to measure the activity of the enzyme aldolase in serum and plasma by methods such as hydrazone colorimetry or ultraviolet determination employing fructose-1,6-diphosphate and nicotinamide adenine dinucleotide (reduced form) (NADH). Aldolase measurements are used in the diagnosis and treatment of the early stages of acute hepatitis and for certain muscle diseases such as progressive, Duchenne-type muscular dystrophy.

(b) *Classification.* Class II (performance standards).

§ 862.1045 Aldosterone test system.

(a) *Identification.* An aldosterone test system is a device used to measure the hormone aldosterone in serum and urine by methods such as radioimmunoassay (RIA) or chromatographic separation followed by RIA. Aldosterone measurements are used in the diagnosis and treatment of primary aldosteronism (a disorder caused by the excessive secretion of aldosterone by the adrenal gland), hypertension caused by primary aldosteronism, selective hypoaldosteronism, edematous states, and other conditions of electrolyte imbalance.

(b) *Classification.* Class II (performance standards).

§ 862.1050 Alkaline phosphatase or isoenzymes test system.

(a) *Identification.* An alkaline phosphatase or isoenzymes test system is a device used to measure alkaline phosphatase or its isoenzymes (a group of enzymes with similar biological activity) in serum and plasma by methods such as electrophoretic separation, *alpha*-naphthyl phosphate, *beta*-glycerophosphate, disodium phenyl phosphate, nitrophenyl phosphate, phenolphthalein phosphate, phenyl phosphate, thymol blue monophosphate, or thymolphthalein monophosphate. Measurements of alkaline phosphatase or its isoenzymes are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

(b) *Classification.* Class II (performance standards).

§ 862.1060 Delta-aminolevulinic acid test system.

(a) *Identification.* A *delta*-aminolevulinic acid test system is a device used to measure the level of *delta*-aminolevulinic acid (a precursor of porphyrin) in urine by methods such as ion exchange columns with colorimetry. *Delta*-aminolevulinic acid measurements are used in the diagnosis and treatment of lead poisoning and certain porphyrias (diseases affecting the liver, gastrointestinal, and nervous systems that are accompanied by increased urinary excretion of various heme compounds including *delta*-aminolevulinic acid).

(b) *Classification.* Class II (performance standards).

§ 862.1065 Ammonia test system.

(a) *Identification.* An ammonia test system is a device used to measure ammonia levels in blood, serum, and plasma by methods such as enzymatic, ion exchanger, ion-specific electrode, or photometric. Ammonia measurements are used in the diagnosis and treatment of severe liver disorders, such as cirrhosis, hepatitis, and Reye's syndrome.

(b) *Classification.* Class II (performance standards).

§ 862.1070 Amylase test system.

(a) *Identification.* An amylase test system is a device used to measure the activity of the enzyme amylase in serum and urine by methods such as

amyloclastic, nephelometric, nitro-salicylate reduction, radial diffusion, saccharogenic, or starch-dye bound polymer. Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas).

(b) *Classification.* Class II (performance standards).

§ 862.1075 Androstenedione test system.

(a) *Identification.* An androstenedione test system is a device used to measure androstenedione (a substance secreted by the testes, ovary, and adrenal glands) in serum by methods such as radioimmunoassay. Androstenedione measurements are used in the diagnosis and treatment of females with excessive levels of androgen (male sex hormone) production.

(b) *Classification.* Class II (performance standards).

§ 862.1080 Androsterone test system.

(a) *Identification.* An androsterone test system is a device used to measure the hormone androsterone in serum, plasma, and urine by methods such as radioimmunoassay. Androsterone measurements are used in the diagnosis and treatment of gonadal and adrenal diseases.

(b) *Classification.* Class II (performance standards).

§ 862.1085 Angiotensin I and renin test system.

(a) *Identification.* An angiotensin I and renin test system is a device used to measure the level of angiotensin I generated by renin in plasma by methods such as radioimmunoassay. Angiotensin I measurements are used in the diagnosis and treatment of certain types of hypertension.

(b) *Classification.* Class II (performance standards).

§ 862.1095 Ascorbic acid test system.

(a) *Identification.* An ascorbic acid test system is a device used to measure the level of ascorbic acid (vitamin C) in plasma, serum, and urine by methods such as 2,4-dinitrophenylhydrazine (spectrophotometric). Ascorbic acid measurements are used in the diagnosis and treatment of ascorbic acid dietary deficiencies.

(b) *Classification.* Class II (performance standards).

§ 862.1100 Aspartate amino transferase (AST/SGOT) test system.

(a) *Identification.* An aspartate amino transferase (AST/SGOT) test system is a device used to measure the activity of the enzyme aspartate amino transferase (AST) (also known as serum glutamic oxaloacetic transaminase or SGOT) in serum and plasma by methods such as diazo, hydrazone colorimetry, nicotinamide adenine dinucleotide (NAD) reduction/nicotinamide adenine dinucleotide (reduced form) (NADH) oxidation, or the vanillin pyruvate method. Aspartate amino transferase measurements are used in the diagnosis and treatment of certain types of liver and heart disease.

(b) *Classification.* Class II (performance standards).

§ 862.1110 Bilirubin (total or direct) test system.

(a) *Identification.* A bilirubin (total or direct) test system is a device used to measure the levels of bilirubin (total or direct) in plasma and serum by methods such as diazo colorimetry or enzymatic. Measurement of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, is used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder block.

(b) *Classification.* Class II (performance standards).

§ 862.1115 Urinary bilirubin and its conjugates (nonquantitative) test system.

(a) *Identification.* A urinary bilirubin and its conjugates (nonquantitative) test system is a device used to measure the levels of bilirubin conjugates in urine by methods such as azo-dyes colorimetric. Measurements of urinary bilirubin and its conjugates (nonquantitative) are used in the diagnosis and treatment of certain liver diseases.

(b) *Classification.* Class II (performance standards).

§ 862.1120 Blood gases (P_{CO2}, P_{O2}) and blood pH test system.

(a) *Identification.* A blood gases (P_{CO2}, P_{O2}) and blood pH test system is a device used to measure certain gases in blood, serum, and plasma or the pH of blood, serum, and plasma by methods such as electrode measurement with standard buffers. Measurements of blood gases (P_{CO2}, P_{O2}) and blood pH are used in the diagnosis and treatment of life-threatening acid-base disturbances.

(b) *Classification.* Class II (performance standards).

§ 862.1130 Blood volume test system.

(a) *Identification.* A blood volume test system is a device used to measure the circulating blood volume by methods such as ^{51}Cr labeling. Blood volume measurements are used in the diagnosis and treatment of shock, hemorrhage, and polycythemia vera (a disease characterized by an absolute increase in erythrocyte mass and total blood volume).

(b) *Classification.* Class II (performance standards).

§ 862.1135 C-Peptides of proinsulin test system.

(a) *Identification.* A C-peptides of proinsulin test system is a device used to measure C-peptide levels in serum, plasma, and urine by methods such as radioimmunoassay. Measurements of C-peptides of proinsulin are used in the diagnosis and treatment of patients with abnormal insulin secretion, including diabetes mellitus.

(b) *Classification.* Class II (performance standards).

§ 862.1140 Calcitonin test system.

(a) *Identification.* A calcitonin test system is a device used to measure the thyroid hormone calcitonin (thyrocalcitonin) levels in plasma and serum by methods such as radioimmunoassay. Calcitonin measurements are used in the diagnosis and treatment of diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyrodism (excessive activity of the parathyroid gland).

(b) *Classification.* Class II (performance standards).

§ 862.1145 Calcium test system.

(a) *Identification.* A calcium test system is a device used to measure the total calcium level in serum by methods such as alizarin sulfonate, atomic absorption, azo dye, cresolphthalein complexone, di(*O*-hydroxphenylimine) ethane, fluorometric, ion specific electrode, methylthymol blue, permanganate and bromophenol blue titration, or titration with ethlyenediaminetetraacetic acid (EDTA) and indicator. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

(b) *Classification.* Class II (performance standards).

§ 862.1150 Calibrator.

(a) *Identification.* A calibrator is a device intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens.

(b) *Classification.* Class II (performance standards).

§ 862.1155 Human chorionic gonadotropin (HCG) test system for use in the early detection of pregnancy.

(a) *Identification.* A human chorionic gonadotropin (HCG) test system is a device intended to measure HCG, a placental hormone, in plasma and urine by methods such as agglutination and radioimmunoassay, for use in the early detection of pregnancy.

(b) *Classification.* Class II (performance standards).

§ 862.1160 Bicarbonate/carbon dioxide test system

(a) *Identification.* A bicarbonate/carbon dioxide test system is a device used to measure bicarbonate/carbon dioxide in plasma, serum, and whole blood by methods such as coulometric, cresol red colorimetry, enzymatic, pH rate measurement, phenolphthalein colorimetry, titrimetric phenol red, or volumetric/manometric. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially life-threatening disorders associated with changes in body acid-base balance.

(b) *Classification.* Class II (performance standards).

§ 862.1165 Catecholamine (total) test system.

(a) *Identification.* A catecholamine (total) test system is a device used to determine whether a group of similar hormone compounds (epinephrine, norepinephrine, and dopamine) are present in urine and plasma, by methods such as chromatographic/fluorometric or electrophoretic. Catecholamine determinations are used in the diagnosis and treatment of adrenal medulla and hypertensive disorders, and for catecholamine-secreting tumors (pheochromocytoma, neuroblastoma, ganglioneuroma, and retinoblastoma).

(b) *Classification.* Class II (performance standards).

§862.1170 Chloride test system.

(a) *Identification.* A chloride test system is a device used to measure the level of chloride in plasma, serum, sweat, and urine by methods such as coulometric, ion-specific electrode, mercuric nitrate and diphenyl carbazone (titrimetric), mercuric thiocyanate, or phosphoric-tungstic acid (spectrophotometric). Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

(b) *Classification.* Class II (performance standards).

§ 862.1175 Cholesterol (total) test system.

(a) *Identification.* A cholesterol (total) test system is a device used to measure cholesterol in plasma and serum by methods such as enzymatic/esterase-oxidase, ferric ion-sulfuric acid, or Lieberman-Burchard/Abell-Kendall colorimetric. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.

(b) *Classification.* Class II (performance standards).

§ 862.1180 Chymotrypsin test system.

(a) *Identification.* A chymotrypsin test system is a device used to measure the activity of the enzyme chymotrypsin in blood and other body fluids and in feces by methods such as *N*-acetyl-*L*-tyrosine ethyl ester (ultraviolet) or *N*-benzoyl-*L*-tyrosine ethyl ester (ultraviolet). Chymotrypsin measurements are used in the diagnosis and treatment of pancreatic exocrine insufficiency.

(b) *Classification.* Class II (performance standards).

§ 862.1185 Compound S (11-deoxycortisol) test system.

(a) *Identification.* A compound S (11-deoxycortisol) test system is a device used to measure the level of compound S (11-deoxycortisol) in plasma by methods such as radioimmunoassay. Compound S is a steroid intermediate in the biosynthesis of the adrenal hormone cortisol. Measurements of compound S are used in the diagnosis and treatment of certain adrenal and pituitary gland disorders resulting in clinical symptoms of masculinization and hypertension.

(b) *Classification.* Class II (performance standards).

§ 862.1190 Copper test system.

(a) *Identification.* A copper test system is a device used to measure copper levels in plasma, serum, and urine by methods such as diethyldithiocarbamate (colorimetric) or oxalydihydrazide (colorimetric). Measurements of copper are used in the diagnosis and treatment of anemia, infections, inflammations, and Wilson's disease (a hereditary disease primarily of the liver and nervous system). Test results are also used in monitoring patients with Hodgkin's disease (a potentially fatal disease primarily of the lymph system).

(b) *Classification.* Class II (performance standards).

§ 862.1195 Corticoids test system.

(a) *Identification.* A corticoids test system is a device used to measure the level of corticoids (hormones of the adrenal cortex) in serum and plasma by methods such as radioassay. Measurements of corticoids are used in the diagnosis and treatment of disorders of the cortex of the adrenal glands, especially those associated with hypertension and electrolyte disturbances.

(b) *Classification.* Class II (performance standards).

§ 862.1200 Corticosterone test systems

(a) *Identification.* A corticosterone test system is a device used to measure corticosterone (a steroid secreted by the adrenal gland) levels in plasma by methods such as radioimmunoassay. Measurements of corticosterone are used in the diagnosis and treatment of adrenal disorders such as adrenal cortex disorders and blocks in cortisol synthesis.

(b) *Classification.* Class II (performance standards).

§ 862.1205 Cortisol (hydrocortisone and hydroxycorticosterone) test system.

(a) *Identification.* A cortisol (hydrocortisone and hydroxycorticosterone) test system is a device used to measure the cortisol hormones secreted by the adrenal gland in plasma and urine by methods such as fluorometric or radioimmunoassay. Measurements of cortisol are used in the diagnosis and treatment of disorders of the adrenal gland.

(b) *Classification.* Class II (performance standards).

§ 862.1210 Creatine test system.

(a) *Identification.* A creatine test system is a device used to measure creatine (a substance synthesized in the liver and pancreas and found in biological fluids) in plasma, serum, and urine by methods such as adenosine triphosphate (ATP) creatine kinase (enzymatic) or conversion to creatinine. Measurements of creatine are used in the diagnosis and treatment of muscle diseases and endocrine disorders including hyperthyroidism.

(b) *Classification.* Class II (performance standards).

§ 862.1215 Creatine phosphokinase/creatine kinase or isoenzymes test system.

(a) *Identification.* A creatine phosphokinase/creatine kinase or isoenzymes test system is a device used to measure the activity of the enzyme creatine phosphokinase or its isoenzymes (a group of enzymes with similar biological activity) in plasma and serum by methods such as chromatographic separation, differential rate kinetic, fluorometric, *N*-acetyl-*L*-cysteine, or nicotinamide adenine

dinucleotide (NAD) reduction/ nicotinamide adenine dinucleotide (reduced form) (NADH) oxidation. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

(b) *Classification.* Class II (performance standards).

§ 862.1225 Creatinine test system.

(a) *Identification.* A creatinine test system is a device used to measure creatinine levels in plasma, serum, and urine, by methods such as alkaline picrate colorimetry, enzymatic, or ion-electrode-based enzymatic. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

(b) *Classification.* Class II (performance standards).

§ 862.1230 Cyclic AMP or cyclic GMP test system.

(a) *Identification.* A cyclic AMP or a cyclic GMP test system is a device used to measure the level of adenosine 3',5'-monophosphate (cyclic GMP) in plasma, urine, and other body fluids by methods such as radioimmunoassay. Cyclic AMP and cyclic GMP measurements are used in the diagnosis and treatment of endocrine disorders, including hyperparathyroidism (overactivity of the parathyroid gland). Cyclic AMP measurements may also be used in the diagnosis and treatment of Graves' disease (a disorder of the thyroid) and in the differentiation of causes of hypercalcemia (elevated levels of serum calcium).

(b) *Classification.* Class II (performance standards).

§ 862.1240 Cystine test system.

(a) *Identification.* A cystine test system is a device used to measure the amino acid cystine in urine by methods such as chromatography or nitroprusside reaction (qualitative). Cystine measurements are used in the diagnosis of cystinuria (occurrence of cystine in urine). Patients with cystinuria frequently develop kidney calculi (stones).

(b) *Classification.* Class II (performance standards).

§ 862.1245 Dehydroepiandrosterone (free and sulfate) test system.

(a) *Identification.* A dehydroepiandrosterone (free and sulfate) test system is a device used to measure dehydroepiandrosterone (DHEA) and its sulfate in urine, serum, plasma, and amniotic fluid by methods such as radioimmunoassay. Dehydroepiandrosterone measurements are used in the diagnosis and treatment of DHEA-secreting adrenal carcinomas.

(b) *Classification.* Class II (performance standards).

§ 862.1250 Desoxycorticosterone test system.

(a) *Identification.* A desoxycorticosterone test system is a device used to measure desoxycorticosterone (DOC) in plasma and urine by methods such as radioimmunoassay. DOC measurements are used in the diagnosis and treatment of patients with hypermineralocorticoidism (excess retention of sodium and loss of potassium) and other disorders of the adrenal gland.

(b) *Classification.* Class II (performance standards).

§ 862.1255 2,3-Diphosphoglyceric acid test system.

(a) *Identification.* A 2,3-diphosphoglyceric acid test system is a device used to measure 2,3-diphosphoglyceric acid (2,3-DPG) in erythrocytes (red blood cells) by methods such as nicotinamide adenine dinucleotide (reduced form) (NADH/ phosphoglycerate mutase/adenosine triphosphate (ATP) (ultraviolet), or phosphoglycerate mutase (colorimetric). Measurements of 2,3-diphosphoglyceric acid are used in the diagnosis and treatment of blood disorders that affect the delivery of oxygen by erythrocytes to tissues and in monitoring the quality of stored blood.

(b) *Classification.* Class II (performance standards).

§ 862.1260 Estradiol test system.

(a) *Identification.* An estradiol test system is a device used to measure estradiol, an estrogenic steriod, in plasma by methods such as radioimmunoassay. Estradiol measurements are used in the diagnosis and treatment of various hormonal sexual disorders and in assessing placental function in complicated pregnancy.

(b) *Classification.* Class II (performance standards).

§ 862.1265 Estriol test system.

(a) *Identification.* An estriol test system is a device used to measure estriol, an estrogenic steriod, in plasma, serum, and urine of pregnant females by methods such as radioimmunoassay. Estriol measurements are used in the diagnosis and treatment of fetoplacental distress in certain cases of high-risk pregnancy.

(b) *Classification.* Class II (performance standards).

§ 862.1270 Estrogens (total, in pregnancy) test system.

(a) *Identification.* An estrogens (total, in pregnancy) test system is a device used to measure total estrogens in plasma, serum, and urine during pregnancy by methods such as radioimmunoassay. The device primarily measures estrone plus estradiol. Measurements of total estrogens are used in the diagnosis and treatment of fetoplacental distress in certain cases of high-risk pregnancy.

(b) *Classification.* Class II (performance standards).

§ 862.1275 Estrogens (total, nonpregnancy) test system.

(a) *Identification.* An estrogens (total, nonpregnancy) test system is a device used to measure the level of estrogens (total estrone, estradiol, and estriol) in plasma, serum, and urine of males and nonpregnant females by methods such as radioimmunoassay. Measurement of estrogens (total, nonpregnancy) is used in the diagnosis and treatment of numerous disorders, including infertility, amenorrhea (absence of menses), differentiation of primary and secondary ovarian malfunction, estrogen secreting testicular and ovarian tumors, and precocious puberty in females.

(b) *Classification.* Class II (performance standards).

§ 862.1280 Estrone test system.

(a) *Identification.* An estrone test system is a device used to measure estrone, an estrogenic steroid, in plasma by methods such as radioimmunoassay. Estrone measurements are used in the diagnosis and treatment of numerous disorders, including infertility, amenorrhea, differentiation of primary and secondary ovarian malfunction, estrogen secreting testicular and ovarian tumors, and precocious puberty in females.

(b) *Classification.* Class II (performance standards).

§ 862.1285 Etiocholanolone test system.

(a) *Identification.* An etiocholanolone test system is a device used to measure etiocholanolone in serum and urine by methods such as radioimmunoassay. Etiocholanolone is a metabolic product of the hormone testosterone and is excreted in the urine. Etiocholanolone measurements are used in the diagnosis and treatment of disorders of the testes and ovaries.

(b) *Classification.* Class II (performance standards).

§ 862.1290 Fatty acids test system.

(a) *Identification.* A fatty acids test system is a device used to measure fatty acids in plasma and serum by methods such as conversion to ferric hydroxymates (colorimetric) or titrimetric. Measurements of fatty acids are used in the diagnosis and treatment of various disorders of lipid metabolism.

(b) *Classification.* Class II (performance standards).

§ 862.1295 Folic acid test system.

(a) *Identification.* A folic acid test system is a device used to measure the vitamin folic acid in plasma and serum by methods such as radioimmunoassay. Folic acid measurements are used in the diagnosis and treatment of megaloblastic anemia, which is characterized by the presence of megaloblasts (an abnormal red blood cell series) in the bone marrow.

(b) *Classification.* Class II (performance standards).

§ 862.1300 Follicle-stimulating hormone test system.

(a) *Identification.* A follicle-stimulating hormone test system is a device used to measure follicle-stimulating hormone (FSH) in plasma, serum, and urine by methods such as radioimmunoassay. FSH measurements are used in the diagnosis and treatment of pituitary gland and gonadal disorders.

(b) *Classification.* Class II (performance standards).

§ 862.1305 Formiminoglutamic acid (FIGLU) test system.

(a) *Identification.* A formiminoglutamic acid (FIGLU) test system is a device used to measure formiminoglutamic acid in urine by methods such as tetrahydrofolate enzymatic (ultraviolet). FIGLU measurements obtained by this device are used in the diagnosis of anemias, such as pernicious anemia and congenital hemolytic anemia.

(b) *Classification.* Class II (performance standards).

§ 862.1310 Galactose test system.

(a) *Identification.* A galactose test system is a device used to measure galactose in blood and urine by methods such as colorimetric, enzymatic, or ultraviolet. Galactose measurements are used in the diagnois and treatment of the hereditary disease galactosemia (a disorder of galactose metabolism) in infants.

(b) *Classification.* Class II (performance standards).

§ 862.1315 Galactose-1-phosphate uridyl transferase test system.

(a) *Identification.* A galactose-1-phosphate uridyl transferase test system is a device used to measure the acitvity of the enzyme galactose-1-phosphate uridyl transferase in erythrocytes (red blood cells) by methods such as uridine-5-diphosphoglucose/nicotinamide adenine dinucleotide (reduced form) (NADH) (ultraviolet). Measurements of galactose-1-phosphate uridyl transferase are used in the diagnosis and treatment of the hereditary disease galactosemia (a disorder of galactose metabolism) in infants.

(b) *Classification.* Class II (performance standards).

§ 862.1320 Gastric acidity test system.

(a) *Identification.* A gastric acidity test system is a device used to measure the acidity of gastric fluid by methods such as sodium hydroxide/phenol red (titrimetric) or tubeless analysis. Measurements of gastric acidity are used in the diagnosis and treatment of patients with peptic ulcer, gastric carcinoma, Zollinger-Ellison syndrome (peptic ulcer due to gastrin-secreting tumor of the pancreas), and related gastric disorders.

(b) *Classification.* Class II (performance standards).

§ 862.1325 Gastrin test system.

(a) *Identification.* A gastrin test system is a device used to measure the hormone gastrin in plasma and serum by methods such as radioimmunoassay. Measurements of gastrin are used in the diagnosis and treatment of patients with ulcers, pernicious anemia, and the Zollinger-Ellison syndrome (peptic ulcer due to a gastrin-secreting tumor of the pancreas).

(b) *Classification.* Class II (performance standards).

§ 862.1330 Globulin test system.

(a) *Identification.* A globulin test system is a device used to measure globulins (proteins) in plasma and serum by methods such as electrophoretic, nephelometric, tryptophan measurement, or turbidimetric. Measurements of globulin are used in the diagnosis and treatment of patients with numerous illnesses, including severe liver and renal disease, multiple myeloma, and other disorders of blood globulins.

(b) *Classification.* Class II (performance standards).

§ 862.1335 Glucagon test system.

(a) *Identification.* A glucagon test system is a device used to measure the pancreatic hormone glucagon in plasma and serum by methods such as radioimmunoassay. Glucagon measurements are used in the diagnosis and treatment of patients with various disorders of carbohydrate metabolism, including diabetes mellitus, hypoglycemia, and hyperglycemia.

(b) *Classification.* Class II (performance standards).

§ 862.1340 Urinary glucose (nonquantitative) test system.

(a) *Identification.* A urinary glucose (nonquantitative) test system is a device used to measure glucosuria (glucose in urine) by methods such as enzymatic or metallic reduction. Urinary glucose (nonquantitative) measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, hypoglycemia, and hyperglycemia.

(b) *Classification.* Class II (performance standards).

§ 862.1345 Glucose test system.

(a) *Identification.* A glucose test system is a device used to measure glucose quantitatively in blood and other body fluids by methods such as copper reduction, ferricyanide, glucose oxidase, hexokinase, or orthotoluidine. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

(b) *Classification.* Class II (performance standards).

§ 862.1360 Gamma-glutamyl transpeptidase and isoenzymes test system.

(a) *Identification.* A gamma-glutamyl transpeptidase and isoenzymes test system is a device used to measure the activity of the enzyme gamma-glutamyl transpeptidase (GGTP) in plasma and serum by methods such as colorimetric, kinetic, or electrophoretic/isoenzymes. Gamma-glutamyl transpeptidase and isoenzyme measurements are used in the diagnosis and treatment of liver diseases such as alcoholic cirrhosis and primary and secondary liver tumors.

(b) *Classification.* Class II (performance standards).

§ 862.1365 Glutathione test system.

(a) *Identification.* A glutathione test system is a device used to measure glutathione (the tripeptide of glycine, cysteine, and glutamic acid) in erythrocytes (red blood cells) by methods such as chromatographic or enzymatic (glutathione reductase). Glutathione measurements are used in the diagnosis and treatment of certain

drug-induced hemolytic (erythrocyte destroying) anemias due to an inherited enzyme deficiency.

(b) *Classification.* Class II (performance standards).

§ 862.1370 Human growth hormone test system.

(a) *Identification.* A human growth hormone test system is a device used to measure the levels of human growth hormone in plasma by methods such as radioimmunoassay. Human growth hormone measurements are used in the diagnosis and treatment of disorders involving the anterior lobe of the pituitary gland.

(b) *Classification.* Class II (performance standards).

§ 862.1375 Histidine test system.

(a) *Identification.* A histidine test system is a device used to measure free histidine (an amino acid) in plasma and urine by methods such as chromatographic or microbiological. Histidine measurements are used in the diagnosis and treatment of hereditary histidinemia characterized by excess histidine in the blood and urine often resulting in mental retardation and disordered speech development.

(b) *Classification.* Class II (performance standards).

§ 862.1380 Hydroxybutyric dehydrogenase test system.

(a) *Identification.* A hydroxybutyric dehydrogenase test system is a device used to measure the activity of the enzyme *alpha*-hydroxybutric dehydrogenase (HBD) in plasma or serum by methods such as *alpha*-ketobutyric acid/nicotinamide adenine dinucleotide (reduced form) (ultraviolet), or by dinitrophenyl hydrazone measurement (colorimetric). HBD measurements are used in the diagnosis and treatment of myocardial infarction, renal damage (such as rejection of transplants), certain hematological diseases (such as acute leukemias and megaloblastic anemias) and, to a lesser degree, liver disease.

(b) *Classification.* Class II (performance standards).

§ 862.1385 17-Hydroxycorticosteriods (17-ketogenic steriods) test system.

(a) *Identification.* A 17-hydroxycorticosteroids (17-ketogenic steroids) test system is a device used to measure corticosteroids that possess a dihydroxy acetone

$$(CH_2OHCOH)$$
$$\parallel$$
$$O$$

side chain on carbon 17 in urine by methods such as fluorometric, Porter Silber hyrazone, radioassay, or chromatography separation/Zimmerman and Zimmerman/Norymberski. Corticosteroids with this chemical configuration include cortisol, cortisone, 11-desoxycortisol, desoxycorticosterone and their tetra-hydroderivatives. This group of hormones is synthesized by the adrenal glands. Measurements of 17-hydroxycorticosteriods (17-ketogenic steriods) are used in the diagnosis and treatment of various diseases of the adrenal or pituitary glands and gonadal disorders.

(b) *Classification.* Class II (performance standards).

§ 862.1390 5-Hydroxyindole acetic acid/serotonin test system.

(a) *Identification.* A 5-hydroxyindole acetic acid/serotonin test system is a device used to measure 5-hydroxyindole acetic acid/serotonin in urine by methods such as the nitrous acid/nitrosonaphthol. Measurements of 5-hydroxyindole acetic acid/serotonin are used in the diagnosis and treatment of carcinoid tumors of endocrine tissue.

(b) *Classification.* Class II (performance standards).

§ 862.1395 17-Hydroxyprogesterone test system.

(a) *Identification.* A 17-hydroxyprogesterone test system is a device used to measure 17-hydroxyprogesterone (a steroid) in plasma and serum by methods such as radioimmunoassay. Measurements of 17-hydroxyprogesterone are used in the diagnosis and treatment of various disorders of the adrenal glands or the ovaries.

(b) *Classification.* Class II (performance standards).

§ 862.1400 Hydroxyproline test system.

(a) *Identification.* A hydroxyproline test system is a device used to measure the amino acid hydroxyproline in urine by methods such as column chromatography and color development, or extraction plus chromatography with color by ninhydrin. Hydroxyproline measurements are used in the diagnosis and treatment of various collagen (connective tissue) diseases, bone diseases such as Paget's disease, and endocrine disorders such as hyperparathyroidism and hyperthyroidism.

(b) *Classification.* Class II (performance standards).

§ 862.1405 Immunoreactive insulin test system.

(a) *Identification.* An immunoreactive insulin test system is a device used to measure immunoreactive insulin in serum and plasma by methods such as radioimmunoassay. Immunoreactive insulin measurements are used in the diagnosis and treatment of various carbohydrate metabolism disorders, including diabetes mellitus and hypoglycemia.

(b) *Classification.* Class II (performance standards).

§ 862.1410 Iron (non-heme) test system.

(a) *Identification.* An iron (non-heme) test system is a device used to measure iron (non-heme) in serum and plasma by methods such as atomic absorption, bathophenanthroline colorimetry, photometric, or radio-labeled iron. Iron (non-heme) measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease.

(b) *Classification.* Class II (performance standards).

§ 862.1415 Iron-binding capacity test system.

(a) *Identification.* An iron-binding capacity test system is a device used to measure iron binding capacity in serum by methods such as bathophenanthroline, ferrozine (colorimetric), ion exchange resin with ascorbic acid, ion exchange resin with thioglycolic acid, or radiometric with ^{59}Fe. Iron-binding capacity measurements are used in the diagnosis and treatment of anemia.

(b) *Classification.* Class II (performance standards).

§ 862.1420 Isocitric dehydrogenase test system.

(a) *Identification.* An isocitric dehydrogenase test system is a device used to measure the activity of the enzyme isocitric dehydrogenase in serum and plasma by methods such as hydrazone derivative of *alpha*-ketoglutarate (colorimetry) or *L*-isocitrate and nicotinamide adenine dinucleotide phosphate (NADP) (ultraviolet). Isocitric dehydrogenase measurements are used in the diagnosis and treatment of liver disease such as viral hepatitis, cirrhosis, or acute inflammation of the biliary tract; pulmonary disease such as pulmonary infarction (local arrest or sudden insufficiency of the blood supply to the lungs), and diseases associated with pregnancy.

(b) *Classification.* Class II (performance standards).

§ 862.1430 17-Ketosteroids test system.

(a) *Identification.* A 17-ketosteroids test system is a device used to measure 17-ketosteroids in urine by methods such as chromatographic separation/Zimmerman or Zimmerman (spectrophotometric). Measurements of 17-ketosteroids are used in the diagnosis and treatment of disorders of the adrenal cortex and gonads and of other endocrine disorders, including hypertension, diabetes, and hypothyroidism.

(b) *Classification.* Class II (performance standards).

§ 862.1435 Urinary ketones (nonquantitative) test system.

(a) *Identification.* A urinary ketones (nonquantitative) test system is a device used to identify ketones in urine by using reagents such as nitroprusside. Identification of urinary ketones is used in the diagnosis and treatment of acidosis (a condition characterized by abnormally high acidity of body fluids) or ketosis (a condition characterized by increased production of ketone bodies such as acetone) and for monitoring patients on ketogenic diets and patients with diabetes.

(b) *Classification.* Class II (performance standards).

§ 862.1440 Lactate dehydrogenase test system.

(a) *Identification.* A lactate dehydrogenase test system is a device used to measure the activity of the enzyme lactate dehydrogenase in serum by methods such as tetrazolium INT (2-*p*-iodophenyl-3-*p*-nitrophenyl tetrazolium chloride (dye-diaphorase, 2,4-dinitrophenylhydrazine, or nicotinamide adenine dinucleotide (NAD) reduction/nicotinamide adenine dinucleotide (reduced form) (NADH) oxidation. Lactate dehydrogenase measurements are used in the diagnosis and treatment of liver diseases such as acute viral hepatitis, cirrhosis, and metastatic carcinoma of the liver, cardiac diseases such as myocardial infarction, and tumors of the lungs or kidneys.

(b) *Classification.* Class II (performance standards).

§ 862.1445 Lactate dehydorgenase isoenzymes test system.

(a) *Identification.* A lactate dehydrogenase isoenzymes test system is a device used to measure the activity of lactate dehydrogenase isoenzymes (a group of enzymes with similar biological activity) in serum by methods such as chromatographic separation, differential rate kinetic, or electrophoretic. Measurement of lactate dehydrogenase isoenzymes is used in the diagnosis and treatment of liver diseases, such as viral hepatitis, and myocardial infarction.

(b) *Classification.* Class II (performance standards).

§ 862.1450 Lactic acid test system.

(a) *Identification.* A lactic acid test system is a device used to measure lactic acid in whole blood and plasma by methods such as enzymatic. Lactic acid measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).

(b) *Classification.* Class II (performance standards).

§ 862.1455 Lecithin-sphingomyelin ratio in amniotic fluid test system.

(a) *Identification.* A lecithin-spingomyelin ratio in amniotic fluid test system is a device used to measure the lecithin-spinogomyelin ratio in amniotic fluid by methods such as chromatographic separation, electrophoretic, or colorimetric. Lecithin and spingomyelin are phospholipids (fats or fat-like substances containing phosphorus). Measurements of the lecithin-spingomyelin ratio in amniotic fluid are used in evaluating fetal maturity.

(b) *Classification.* Class II (performance standards).

§ 862.1460 Leucine aminopeptidase test system.

(a) *Identification.* A leucine aminopeptidase test system is a device used to measure the activity of the enzyme leucine aminopeptidase in serum, plasma, and urine by methods such as *L*-leucine-4-nitroanilide (colorimetric) or *L*-leucyl-*beta*-naphthylamide. Leucine aminopeptidase measurements are used in the diagnosis and treatment of liver diseases such as viral hepatitis and obstructive jaundice.

(b) *Classification.* Class II (performance standards).

§ 862.1465 Lipase test system.

(a) *Identification.* A lipase test system is a device used to measure the activity of the enzyme lipase in serum by methods such as oil emulsion/thymolphthalein (titrimetric), olive oil emulsion (turbidimetric), or lipase-esterase, enzymatic (photometric). Lipase measurements are used in diagnosis and treatment of diseases of the pancreas such as acute pancreatitis and obstruction of the pancreatic duct.

(b) *Classification.* Class II (performance standards).

§ 862.1470 Lipid (total) test system.

(a) *Identification.* A lipid (total) test system is a device used to measure total lipids (fats or fat-like substances) in serum and plasma by methods such as chromatographic derivative or sulfophosphovanillin colorimetery. Lipid (total) measurements are used in the diagnosis and treatment of various diseases involving lipid metabolism and atherosclerosis.

(b) *Classification.* Class II (performance standards).

§ 682.1475 Lipoprotein test system.

(a) *Identification.* A lipoprotein test system is a device used to measure lipoprotein in serum and plasma by methods such as colorimetric, electrophoretic separation, microdensitometry, nephelometric, radial immunodiffusion, or turbidimetric. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

(b) *Classification.* Class II (performance standards).

§ 862.1485 Luteinizing hormone test system.

(a) *Identification.* A luteinizing hormone test system is a device used to measure luteinizing hormone in serum and urine by methods such as radioimmunoassay. Luteinizing hormone measurements are used in the diagnosis and treatment of gonadal dysfunction.

(b) *Classification.* Class II (performance standards).

§ 862.1490 Lysozyme (muramidase) test system.

(a) *Identification.* A lysozyme (muramidase) test system is a device used to measure the activity of the bacteriolytic enzyme lysozyme (muramidase) in serum, plasma, leukocytes, and urine by methods such as immunochemical or spectrophotometric (*Micrococcus lysodeikticus*). Lysozyme measurements are used in the diagnosis and treatment of monocytic leukemia and kidney disease.

(b) *Classification.* Class II (performance standards).

§ 862.1495 Magnesium test system.

(a) *Identification.* A magnesium test system is a device used to measure magnesium levels in serum and plasma by methods such as atomic absorption, ion-specific electrode, photometric, or titrimetric. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low plasma levels of magnesium) and

hypermagnesemia (abnormally high plasma levels of magnesium).

(b) *Classification.* Class II (performance standards).

§ 862.1500 Malic dehydrogenase test system.

(a) *Identification.* A malic dehydrogenase test system is a device that is used to measure the activity of the enzyme malic dehydrogenase in serum and plasma by methods such as oxalacetic acid/nicotinamide adenine dinucleotide (reduced form) (NADH) oxidation (ultraviolet). Malic dehydrogenase measurements are used in the diagnosis and treatment of muscle and liver diseases, myocardial infarctions, cancer, and blood disorders such as myelogenous (produced in the bone marrow) leukemias.

(b) *Classification.* Class II (performance standards).

§ 862.1505 Mucopolysaccharides test system.

(a) *Identification.* A mucopolysaccharides test system is a device used to measure the levels of mucopolysaccharides in serum, plasma, and urine by methods such as colorimetric. Mucopolysaccharide measurements are used in the diagnosis and treatment of various inheritable disorders that affect bone and connective tissues, such as Hurler's, Hunter's, Sanfilippo's, Scheie's, Morquio's, and Maroteaux-Lamy syndromes.

(b) *Classification.* Class II (performance standards).

§ 862.1510 Urinary nitrite (nonquantitative) test system.

(a) *Identification.* A urinary nitrite (nonquantitative) test system is a device used to identify nitrite in urine by methods such as diazo (colorimetric). Urinary nitrite identification is used in the diagnosis and treatment of urinary tract infection of bacteria origin.

(b) *Classification.* Class II (performance standards).

§ 862.1515 Nitrogen (amino-nitrogen) test system.

(a) *Identification* A nitrogen (amino-nitrogen) test system is a device used to measure amino acid nitrogen levels in serum, plasma, and urine by methods such as ninhydrin, trinitrobenzene sulfonate (spectroscopic), or 2,4-dinitrofluorobenzene (spectroscopic). Nitrogen (amino-nitrogen) measurements are used in the diagnosis and treatment of certain forms of severe liver disease and renal disorders.

(b) *Classification.* Class II (performance standards).

§ 862.1520 5'-Nucleotidase test system.

(a) *Identification.* A 5'-nucleotidase test system is a device used to measure the activity of the enzyme 5'-nucleotidase in serum and plasma by methods such as 5-adenosine monophosphate(AMP)-phosphate release (colorimetric). Measurement of 5'-nucleotidase is used in the diagnosis and treatment of liver diseases and in the differentiations between liver and bone diseases in the presence of elevated serum alkaline phosphatase activity.

(b) *Classification.* Class II (performance standards).

§ 862.1530 Plasma oncometry test system.

(a) *Identification.* A plasma oncometry test system is a device used to measure plasma oncotic pressure by methods such as membrane oncometry. Plasma oncotic pressure is that portion of the total fluid pressure contributed by proteins and other molecules too large to pass through a specified membrane. Measurements of plasma oncotic pressure are used in the diagnosis and treatment of dehydration and circulatory disorders related to low serum protein levels and increased capillary permeability, such as edema and shock.

(b) *Classification.* Class II (performance standards).

§ 862.1535 Ornithine carbamyl transferase test system.

(a) *Identification.* An ornithine carbamyl transferase test system is a device used to measure that activity of the enzyme ornithine carbamyl transferase (OCT) in serum by methods such as citrulline/arsenate/Nessler (colorimetry). Ornithine carbamyl transferase measurements are used in the diagnosis and treatment of liver diseases, such as infectious hepatitis, acute cholecystitis (inflammation of the gall bladder), cirrhosis, and liver metastases.

(b) *Classification.* Class II (performance standards).

§ 862.1540 Osmolality test system.

(a) *Identification.* An osmolality test system is a device used to measure ionic and nonionic solute concentration in body fluids, such as serum and urine, by methods such as vapor pressure or freezing point depression measurement. Osmolality measurement is used as an adjunct to other tests in the evaluation of a variety of diseases, including kidney diseases (e.g., chronic progressive renal failure), diabetes insipidus, other endocrine and metabolic disorders, and fluid imbalances.

(b) *Classification.* Class II (performance standards).

§ 862.1545 Parathyroid hormone test system.

(a) *Identification.* A parathyroid hormone test system is a device used to measure the levels of parathyroid hormone in serum and plasma by methods such as radioimmunoassay. Measurements of parathyroid hormone levels are used in the differential diagnosis of hypercalcemia (abnormally high levels of calcium in the blood) and hypocalcemia (abnormally low levels of calcium in the blood) resulting from disorders of calcium metabolism.

(b) *Classification.* Class II (performance standards).

§ 862.11550 Urinary pH (nonquantitative) test system.

(a) *Identification.* A urinary pH (nonquantitative) test system is a device used to estimate the pH of urine by use of methods such as a dye-indicator. Estimations of pH are used to evaluate the acidity or alkalinity of urine as it relates to numerous renal and metabolic disorders and in the monitoring of patients with certain diets.

(b) *Classification.* Class II (performance standards).

§ 862.1555 Phenylalanine test system.

(a) *Identification.* A phenylalanine test system is a device used to measure free phenylalanine (an amino acid) in serum, plasma, and urine, by methods such as column or paper chromatography plus ninhydrin, or fluorometric procedure using *L*-leucyl-*L*-alanine with ninhydrin. Measurements of phenylalanine are used in the diagnosis and treatment of congenital phenylketonuria which, if untreated, may cause mental retardation.

(b) *Classification.* Class II (performance standards).

§ 862.1560 Urinary phenylketones (nonquantitative test system.

(a) *Identification.* A urinary phenylketones (nonquantitative) test system is a device used to identify phenylketones (such as phenylpyruvic acid) in urine by methods such as chromogenesis or ferric chloride. The identification of urinary phenylketones is used in the diagnosis and treatment of congenital phenylketonuria which, if untreated, may cause mental retardation.

(b) *Classification.* Class II (performance standards).

§ 862.1565 6-Phosphogluconate dehyrogenase test system.

(a) *Identification.* A 6-phosphoguluconate dehydrogenase test system is a device used to measure the activity of the enzyme 6-phosphogluconate (6 PGD) in serum and erythrocytes by methods such as nicotinamide adenine dinucleotide phosphate (NADP) reduction. Measurements of 6-phosphogluconate dehydrogenase are used in the diagnosis and treatment of certain liver diseases (such as hepatitis) and anemias.

(b) *Classification.* Class II (performance standards).

§ 862.1570 Phosphohexose isomerase test system.

(a) *Identification.* A phosphohexose isomerase test system is a device used to measure the activity of the enzyme phosphohexose isomerase in serum by methods such as glucose-6-phosphate (colorimetric) or nicotinamide adenine dinucleotide (NAD) reduction (ultraviolet). Measurements of phosphohexose isomerase are used in the diagnosis and treatment of muscle diseases such as muscular dystrophy, liver diseases such as hepatitis or cirrhosis, and metastatic carcinoma.

(b) *Classification.* Class II (performance standards).

§ 862.1575 Phospholipid test system.

(a) *Identification.* A phospholipid test system is a device used to measure phospholipids in serum and plasma by methods such as ammonium molybdate/ammonium vanadate, chromatographic, molybdenum blue, or stannous chloride/hydrazine. Measurements of phospholipids are used in the diagnosis and treatment of disorders involving lipid (fat) metabolism.

(b) *Classification.* Class II (performance standards).

§ 862.1580 Phosphorus (inorganic) test system.

(a) *Identification.* A phosphorus (inorganic) test system is a device used to measure inorganic phosphorus in serum, plasma, and urine by methods such as phosphomolybdate. Measurements of phosphorus (inorganic) are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.

(b) *Classification.* Class II (performance standards).

§ 862.1585 Human placental lactogen test system.

(a) *Identification.* A human placental lactogen test system is a device used to measure the hormone human placental lactogen (HPL), (also known as human chorionic somatomammotrophin (HCS)) in maternal serum and maternal plasma by methods such as radioimmunoassay. Measurements of human placental lactogen are used in the diagnosis and clinical management of high-risk pregnancies involving fetal distress associated with placental insufficiency. Measurements of HPL are also used in pregnancies complicated by hypertension, proteinuria, edema, post-maturity, placental insufficiency, or possible miscarriage.

(b) *Classification.* Class II (performance standards).

§ 862.1590 Porphobilinogen test system.

(a) *Identification.* A porphobilinogen test system is a device used to measure porphobilinogen (one of the derivatives of hemoglobin which can make the urine a red color) in urine by methods such as ion exchange resin/Ehrlich's reagent. Measurements obtained by this device are used in the diagnosis and treatment of porphyrias (primarily inherited diseases associated with disturbed porphyrin metabolism), lead poisoning, and other diseases characterized by alterations in the heme pathway.

(b) *Classification.* Class II (performance standards).

§ 862.1595 Porphyrins test system.

(a) *Identification.* A porphyrins test system is a device used to measure porphyrins (compounds formed during the biosynthesis of heme, a constituent of hemoglobin, and related compounds) in urine and feces by methods such as fluorometric measurement. Measurements obtained by this device are used in the diagnosis and treatment of lead poisoning, porphyrias (primarily inherited diseases associated with disturbed porphyrin metabolism), and other diseases characterized by alterations in the heme pathway.

(b) *Classification.* Class II (performance standards).

§ 862.1600 Potassium test system.

(a) *Identification.* A potassium test system is a device used to measure potassium in serum, plasma, and urine by methods such as flame photometry, ion selective electrode, or tetraphenyl borate colorimetry. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.

(b) *Classification.* Class II (performance standards).

§ 862.1605 Pregnanediol test system.

(a) *Identification.* A pregnanediol test system is a device used to measure pregnanediol (a major urinary metabolic product of progesterone) in urine by methods such as spectrophotometric. Measurements obtained by this device are used in the diagnosis and treatment of disorders of the ovaries or placenta.

(b) *Classification.* Class II (performance standards).

§ 862.1610 Pregnanetriol test system.

(a) *Identification.* A pregnanetriol test system is a device used to measure pregnanetriol (a precursor in the biosynthesis of the adrenal hormone cortisol) in urine by methods such as spectrophotometry or gas chromatography. Measurements obtained by this device are used in the diagnosis and treatment of congenital adrenal hyperplasia (congenital enlargement of the adrenal gland).

(b) *Classification.* Class II (performance standards).

§ 862.1615 Pregnenolone test system.

(a) *Identification.* A pregnenolone test system is a device used to measure pregnenolone (a precursor in the biosynthesis of the adrenal hormone cortisol and adrenal androgen) in serum and plasma by methods such as radioimmunoassay. Measurements obtained by this device are used in the diagnosis and treatment of diseases of the adrenal cortex or the gonads.

(b) *Classification.* Class II (performance standards).

§ 862.1620 Progesterone test system.

(a) *Identification.* A progesterone test system is a device used to measure progesterone (a female hormone) in serum and plasma by methods such as radioimmunoassay. Measurements obtained by this device are used in the diagnosis and treatment of disorders of the ovaries or placenta.

(b) *Classification.* Class II (performance standards).

§ 862.1625 Prolactin (lactogen) test system.

(a) *Identification.* A prolactin (lactogen) test system is a device used to measure the anterior pituitary polypeptide hormone prolactin in serum and plasma by methods such as radioimmunoassay. Measurements obtained by this device are used in the diagnosis and treatment of disorders of the anterior pituitary gland or of the hypothalamus portion of the brain.

(b) *Classification.* Class II (performance standards).

§ 862.1630 Protein (fractionation) test system.

(a) *Identification.* A protein (fractionation) test system is a device

used to measure protein fractions in blood, urine, cerebrospinal fluid, and other body fluids by methods such as densitometric, electrophoretic, or immunodiffusion. Protein fractionation is used as an aid in recognizing abnormal proteins in body fluids and genetic variants of proteins produced in diseases with tissue destruction.

(b) *Classification.* Class II (performance standards).

§ 862.1635 Total protein test system.

(a) *Identification.* A total protein test system is a device used to measure total protein(s) in serum and plasma by methods such as biuret (colorimetric), Lowry (colorimetric), refractometric, or turbidimetric. Measurements obtained by this device are used in the diagnosis and treatment of a variety of diseases involving the liver, kidney, or bone marrow as well as other metabolic or nutritional disorders.

(b) *Classification.* Class II (performance standards).

§ 862.1640 Protein-bound iodine test system.

(a) *Identification.* A protein-bound iodine test system is a device used to measure protein-bound iodine in serum by methods such as dry ash or wet ash. Measurements of protein-bound iodine obtained by this device are used in the diagnosis and treatment of thyroid disorders.

(b) *Classification.* Class II (performance standards).

§ 862.1645 Urinary protein or albumin (nonquantitative) test system.

(a) *Identification.* A urinary protein or albumin (nonquantitative) test system is a device used to identify proteins or albumin in urine by methods such as indicator or turbidimetric. Identification of urinary protein or albumin (nonquantitative) is used in the diagnosis and treatment of disease conditions such as renal or heart diseases or thyroid disorders, which are characterized by proteinuria or albuminuria.

(b) *Classification.* Class II (performance standards).

§ 862.1650 Pyruvate kinase test system.

(a) *Identification.* A pyruvate kinase test system is a device used to measure the activity of the enzyme pyruvate kinase in erythorcytes (red blood cells) by methods such as the phosphoenol pyruvate/adenosine diphosphate (ADP)/nicotinamide adenine dinucleotide (reduced form) (NADH). Measurements obtained by this device are used in the diagnosis and treatment of various inherited anemias due to pyruvate kinase deficiency or of acute leukemias.

(b) *Classification.* Class II (performance standards).

§ 862.1655 Pyruvic acid test system.

(a) *Identification.* A pyruvic acid test system is a device used to measure pyruvic acid (an intermediate compound in the metabolism of carbohydrate) in plasma by methods such as enzymatic (ultraviolet). Measurements obtained by this device are used in the evaluation of electrolyte metabolism and in the diagnosis and treatment of acid-base and electrolyte disturbances or anoxia (the reduction of oxygen in body tissues).

(b) *Classification.* Class II (performance standards).

§ 862.1660 Quality control material (assayed and unassayed).

(a) *Identification.* A quality control material (assayed and unassayed) for clinical chemistry is a device intended for use in a test system to estimate test precision and to detect systematic analytical deviations that may arise from reagent or analytical instrument variation. A quality control material (assayed and unassayed) may be used for proficiency testing in interlaboratory surveys. This generic type of device includes controls (assayed and unassayed) for blood gases, electrolytes, enzymes, multianalytes (all kinds), single (specified) analytes, or urinalysis controls.

(b) *Classification.* Class I (general controls).

§ 862.1665 Sodium test system.

(a) *Identification.* A sodium test system is a device used to measure sodium in serum, plasma, and urine by methods such as flame photometry, ion selective electrode, or uranyl acetate/zinc acetate. Measurements obtained by this device are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretaion, or other diseases involving electrolyte imbalance.

(b) *Classification.* Class II (performance standards).

§ 862.1670 Sorbitol dehyrogenase test system.

(a) *Identification.* A sorbitol dehydrogenase test system is a device used to measure the activity of the enzyme sorbitol dehydrogenase in serum by methods such as *beta*-D-fructose and nicotinamide adenine dinucleotide (reduced form) (NADH) oxidation (ultraviolet). Measurements obtained by this device are used in the diagnosis and treatment of liver disorders such as cirrhosis or acute hepatitis.

(b) *Classification.* Class II (performance standards).

§ 862.1675 Blood specimen collection device.

(a) *Identification.* A blood specimen collection device is a device intended for medical purposes that is used to collect and to handle blood specimens and to separate serum from nonserum (cellular) components prior to further testing. This generic type device may include blood collection tubes, vials, systems, serum separators, blood collection trays, or vacuum sample tubes.

(b) *Classification.* Class II (performance standards).

§ 862.1680 Testosterone and dihydrotestosterone test system.

(a) *Identification.* A testosterone and dihydrotestosterone test system is a device used to measure testosterone and dihydrotestosterone (two male sex hormones) in serum, plasma, and urine by methods such as radioimmunoassay. Measurements of Testosterone and dihydrotestosterone are used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and, in females, hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes.

(b) *Classification.* Class II (performance standards).

§ 862.1685 Thyroxine-binding globulin test system.

(a) *Identification.* A thyroxine-binding globulin test system is a device used to measure thyroxine (thyroid)-binding globulin (TBG), a plasma protein which binds thyroxine, in serum and plasma by methods such as radioimmunoassay. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases.

(b) *Classification.* Class II (performance standards).

§ 862.1690 Thyroid stimulating hormone test system.

(a) *Identification.* A thyroid stimulating hormone test system is a device used to measure thyroid stimulating hormone, also known as thyrotrophin and thyrotrophic hormone,

in serum and plasma by methods such as radioimmunoassay. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.

(b) *Classification.* Class II (performance standards).

§ 862.1695 Free thyroxine test system.

(a) *Identification.* A free thyroxine test system is a device used to measure free (not protein bound) thyroxine (thyroid hormone) in serum and plasma by methods such as radioimmunoassay. Levels of free thyroxine in plasma are thought to reflect the amount of thyroxine hormone available to the cells and may therefore determine the clinical metabolic status of thyroxine. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases.

(b) *Classification.* Class II (performance standards).

§ 862.1700 Total thyroxine test system.

(a) *Identification.* A total thyroxine test system is a device used to measure total (free and protein bound) thyroxine (thyroid hormone) in serum and plasma by methods such as radioimmunoassay or nonradiolabeled enzyme immunoassay. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases.

(b) *Classification.* Class II (performance standards).

§ 862.1705 Triglyceride test system.

(a) *Identification.* A triglyceride test system is a device used to measure triglyceride (neutral fat) in serum and plasma by methods such as colorimetric, fluorometric, lipase hydrolysis/glycerol kinase enzyme, thin-layer chromatographic separation, or turbidimetric. Measurements by this device are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.

(b) *Classification.* Class II (performance standards).

§ 862.1710 Total triiodothyronine test system.

(a) *Identification.* A total triiodothyronine test system is a device used to measure the hormone triiodothyronine in serum and plasma by methods such as radioimmunoassay. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases such as hyperthyroidism.

(b) *Classification.* Class II (performance standards).

§ 862.1715 Triiodothyronine uptake test system.

(a) *Identification.* A triiodothyronine uptake test system is a device used to measure by methods such as radioassay the total amount of binding sites available for binding thyroid hormone on the thyroxine-binding proteins thyroid-binding globulin, thyroxine-binding prealbumin, and albumin of serum and plasma. The device provides an indirect measurement of thyroxine levels in serum and plasma. Measurements of triiodothyronine uptake are used in diagnosis and treatment of thyroid disorders.

(b) *Classification.* Class II (performance standards).

§ 862.1720 Triose phosphate isomerase test system.

(a) *Identification.* A triose phosphate isomerase test system is a device used to measure the activity of the enzyme triose phosphate isomerase in erythrocytes (red blood cells) by methods such as glyceraldehyde-3-phosphate nicotinamide adenine dinucleotide (reduced form) (NADH) (enzymatic). Triose phosphate isomerase is an enzyme important in glycolysis (the energy-yielding conversion of glucose to lactic acid in various tissues). Measurements obtained by this device are used in the diagnosis and treatment of congenital triose phosphate isomerase enzyme deficiency, which causes a type of hemolytic anemia.

(b) *Classification.* Class II (performance standards).

§ 862.1725 Trypsin test system.

(a) *Identification.* A trypsin test system is a device used to measure the activity of trypsin (a pancreatic enzyme important in digestion for the breakdown of proteins) in blood and other body fluids and in feces by methods using *n*-benzoyl-*L*-arginine ethyl ester or *p*-toluenesulphonyl-*L*-arginine methyl ester. Measurements obtained by this device are used in the diagnosis and treatment of pancreatic disease.

(b) *Classification.* Class II (performance standards).

§ 862.1730 Free tyrosine test system.

(a) *Identification.* A free tyrosine test system is a device used to measure free tyrosine (an amino acid) in serum and urine by methods such as 1-nitroso-2-naphthol (fluorometric). Measurements obtained by this device are used in the diagnosis and treatment of diseases such as congenital tyrosinemia (a disease that can cause liver/kidney disorders) and as an adjunct to the measurement of phenylalanine in detecting congenital phenylketonuria (a disease that can cause brain damage).

(b) *Classification.* Class II (performance standards).

§ 862.1770 Urea Nitrogen test system.

(a) *Identification.* A urea nitrogen test system is a device used to measure urea nitrogen (an end-product of nitrogen metabolism) in whole blood, serum, plasma, and urine by methods such as diacetylmonoxime, *o*-phthalaldehyde, urease (photometric), urease and glutamic dehydrogenase, ion-specific electrode, or Berthelot indophenol reaction. Measurements obtained by this device are used in the diagnosis and treatment of certain renal and metabolic diseases.

(b) *Classification.* Class II (performance standards).

§ 862.1775 Uric acid test system.

(a) *Identification.* A uric acid test system is a device used to measure uric acid in serum, plasma, and urine by methods such as phosphotungstate reduction and uricase (colorimetric, coulometric, gasometric, oxygen rate, or ultraviolet). Measurements obtained by this device are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.

(b) *Classification.* Class II (performance standards).

§ 862.1780 Urinary calculi (stones) test system.

(a) *Identification.* A urinary calculi (stones) test system is a device used for the analysis of urinary calculi by methods such as infrared spectroscopy measurement of qualitative chemical reactions. Analysis of urinary calculi is used in the diagnosis and treatment of calculi of the urinary tract.

(b) *Classification.* Class II (performance standards).

§ 862.1785 Urinary urobilinogen (nonquantitative) test system.

(a) *Identification.* A urinary urobilinogen (nonquantitative) test system is a device used to detect and estimate urobilinogen (a bile pigment degradation product of red cell hemoglobin) in urine by methods such as diasonium colorimetry. Estimations obtained by this device are used in the diagnosis and treatment of liver diseases and hemolytic (red cell) disorders.

(b) *Classification.* Class II (performance standards).

§ 862.1790 Uroporphyrin test system.

(a) *Identification.* A uroporphyrin test system is a device used to measure uroporphyrin in urine by methods such as fluorometric or spectrophotometric. Measurements obtained by this device are used in the diagnosis and treatment of porphyrias (primarily inherited diseases associated with disturbed porphyrin metabolism), lead poisoning, and other diseases characterized by alterations in the heme pathway.

(b) *Classification.* Class II (performance standards).

§ 862.1795 Vanilmandelic acid test system.

(a) *Identification.* A Vanilmandelic acid test system is a device used to measure vanilmandelic acid in urine by methods such as diazo, *p*-nitroaniline/vanillin or electrophoretic separation. Measurements of vanilmandelic acid obtained by this device are used in the diagnosis and treatment of neuroblastoma, pheochromocytoma, and certain hypertensive conditions.

(b) *Classification.* Class II (performance standards).

§ 862.1805 Vitamin A test system.

(a) *Identification.* A vitamin A test system is a device used to measure vitamin A in serum and plasma by methods such as hexane extraction/trifluoroacetic acid. Measurements obtained by this device are used in the diagnosis and treatment of vitamin A deficiency conditions, including night blindness, or skin, eye, or intestinal disorders.

(b) *Classification.* Class II (performance standards).

§ 862.1810 Vitamin B_{12} test system.

(a) *Identification.* A vitamin B_{12} test system is a device used to measure vitamin B_{12} in serum, plasma, and urine by methods such as radioassay. Measurements obtained by this device are used in the diagnosis and treatment of anemias of gastrointestinal malabsorption.

(b) *Classification.* Class II (performance standards).

§ 862.1815 Vitamin E test system.

(a) *Identification.* A vitamin E test system is a device used to measure vitamin E (tocopherol) in serum by methods such as hexane extraction/fluorescence. Measurements obtained by this device are used in the diagnosis and treatment of infants with vitamin E deficiency syndrome.

(b) *Classification.* Class II (performance standards).

§ 862.1820 Xylose test system.

(a) *Identification.* A xylose test system is a device used to measure xylose (a sugar) in serum, plasma, and urine by methods such as para-bromoaniline (colorimetric). Measurements obtained by this device are used in the diagnosis and treatment of gastrointestinal malabsorption syndrome (a group of disorders in which there is subnormal absorption of dietary constituents and thus excessive loss from the body of the nonabsorbed substances).

(b) *Classification.* Class II (performance standards).

Subpart C—Clinical Laboratory Instruments

§ 862.2050 General purpose laboratory equipment.

(a) *Identification.* General purpose laboratory equipment are devices that have general applications and that are intended to prepare and examine specimens from the human body. Labeling for these devices does not make reference to a use in a specific diagnostic procedure.

(b) *Classification.* Class I (general controls). The devices are exempt from the premarket notification procedures in Subpart E of Part 807. The devices also are exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 862.2100 Calculator/data processing module for clinical use.

(a) *Identification.* A calculator/data processing module for clinical use is an electronic device used to store, retrieve, and process laboratory data by means of programmable cassettes.

(b) *Classification.* Class I (general controls).

§ 862.2140 Centrifugal chemistry analyzer for clinical use.

(a) *Identification.* A centrifugal chemistry analyzer for clinical use is an automatic device that centrifugally mixes a sample and a reagent and spectrophotometrically measures concentrations of the sample constituents. This device is used in conjunction with certain materials to measure a variety of analytes.

(b) *Classification.* Class I (general controls).

§ 862.2150 Continuous flow sequential multiple chemistry analyzer for clinical use.

(a) *Identification.* A continuous flow sequential multiple chemistry analyzer for clinical use is a modular analytical instrument that, using the principles of automated continuous flow systems, can simultaneously perform multiple chemical procedures. This device is used in conjunction with certain materials to measure a variety of analytes.

(b) *Classification.* Class I (general controls).

§ 862.2160 Discrete photometric chemistry analyzer for clinical use.

(a) *Identification.* A discrete photometric chemistry analyzer for clinical use is a device that duplicates manual analytical procedures by performing automatically various steps such as pipetting, preparing filtrates, heating, and measuring color intensity. This device is used in conjunction with certain materials to measure a variety of analytes. Different models of the device incorporate various instrumentation such as micro analysis apparatus, double beam, single, or dual channel photometers, and bichromatic two-wavelength photometers. Some models of the device may include reagent-containing components that may also serve as reaction units.

(b) *Classification.* Class I (general controls).

§ 862.2170 Micro chemistry analyzer for clinical use.

(a) *Identification.* A micro chemistry analyzer for clinical use is a device that duplicates manual analytical procedures by performing automatically various steps such as pipetting, preparing filtrates, heating, and measuring color intensity. The distinguishing characteristic of the device is that it requires only micro volumes of samples, which facilitates the analysis of the very small volume samples obtainable from pediatric patients. This device is used in conjunction with certain materials to measure a variety of analytes.

(b) *Classification.* Class I (general controls).

§ 862.2230 Chromatographic separation material for clinical use.

(a) *Identification.* A chromatographic separation material for clinical use is a device accessory (e.g., ion exchange absorbents, ion exchange resins, and ion papers) used in ion exchange chromatography, a procedure in which a compound is separated from a solution.

(b) *Classification.* Class I (general controls).

§ 862.2250 Gas liquid chromatography system for clinical use.

(a) *Identification.* A gas liquid chromatography system for clinical use is a device used to separate one or more

drugs or compounds from a mixture. Each of the constituents in a vaporized mixture of compounds is separated according to its vapor pressure. The device may include accessories such as columns, gases, column supports, and liquid coating.

(b) *Classification.* Class I (general controls).

§ 862.2260 High pressure liquid chromatography system for clinical use.

(a) *Identification.* A high pressure liquid chromatography system for clinical use is a device used to separate one or more drugs or compounds from a solution by processing the mixture of compounds (solutes) through a column packed with materials of uniform size (stationary phase) under the influence of a high pressure liquid (mobile phase). Separation of the solutes occurs either by absorption, sieving, partition, or selective affinity.

(b) *Classification.* Class I (general controls).

§ 862.2270 Thin-layer chromatography system for clinical use.

(a) *Identification.* A thin-layer chromatography (TLC) system for clinical use is a device used to separate one or more drugs or compounds from a mixture. The mixture of compounds is absorbed onto a stationary phase or thin layer of inert material (e.g., cellulose, alumina, etc.) and eluted off by a moving solvent (moving phase) until equilibrium occurs between the two phases.

(b) *Classification.* Class I (general controls). Particular components of TLC system, i.e., the thin-layer chromatography apparatus, TLC atomizer, TLC developing tanks, and TLC ultraviolet light, are exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 862.2300 Colorimeter, photometer, or sepectrophotometer for clinical use.

(a) *Identification.* A colorimeter, a photometer, or a spectrophotometer for clinical use is an electronic device used to measure the light absorbance of solutions. The device may include a monochromator to produce light of a specific wavelength.

(b) *Classification.* Class I (general controls).

§ 862.2310 Clinical sample concentrator.

(a) *Identification.* A clinical sample concentrator is a device used to concentrate (by dialysis, evaporation, etc.) serum, urine, cerebrospinal fluid, and other body fluids before the fluids are analyzed.

(b) *Classification.* Class I (general controls).

§ 862.2320 Beta or gamma counter for clinical use.

(a) *Identification.* A beta or gamma counter for clinical use is a device used to detect and count beta or gamma radiation emitted by clinical samples. The radiation emitted by a sample, following a chemical reaction with a radioactive reagent, is proportional to the concentration of the analyte being measured. These measurements are useful in the diagnosis and treatment of various disorders.

(b) *Classification.* Class I (general controls).

§ 862.2400 Densitometer/scanner (integrating, reflectance, TLC, or radiochromatogram) for clinical use.

(a) *Identification.* A densitometer/scanner (integrating, reflectance, thin-layer chromatography, or radiochromatogram) for clinical use is a device used to measure the concentration of a substance on the surface of a film or other support media by either a photocell measurement of the light transmission through a given area of the medium, or, in the case of the radiochromatogram scanner, by measurement of the distribution of a specific radioactive element on a radiochromatogram.

(b) *Classification.* Class I (general controls).

§ 862.2485 Electrophoresis apparatus for clinical use.

(a) *Identification.* An electrophoresis apparatus for clinical use is a device used to separate molecules or particles, including plasma proteins, lipoproteins, enzymes, and hemoglobins, on the basis of their net charge in specified buffered media. This device is used in conjunction with certain materials to measure a variety of analytes as an aid in the diagnosis and treatment of certain disorders.

(b) *Classification.* Class I (general controls).

§ 862.2500 Enzyme analyzer for clinical use.

(a) *Identification.* An enzyme analyzer for clinical use is a device used to measure enzymes in plasma or serum by nonkinetic or kinetic measurement of enzyme-catalyzed reactions. This device is used in conjunction with certain materials to measure a variety of enzymes as an aid in the diagnosis and treatment of certain enzyme related disorders.

(b) *Classification.* Class I (general controls).

§ 862.2540 Flame emission photometer for clinical use.

(a) *Identification.* A flame emission photometer for clinical use is a device used to measure the concentration of sodium, potassium, lithium, and other metal ions in body fluids. Abnormal variations in the concentration of these substances in the body are indicative of certain disorders (e.g., electrolyte imbalance and heavy metal intoxication) and are, therefore, useful in diagnosis and treatment of those disorders.

(b) *Classification.* Class I (general controls).

§ 862.2560 Fluorometer for clinical use.

(a) *Identification.* A fluorometer for clinical use is a device used to measure by fluorescence certain analytes. Fluorescence is the property of certain substances of radiating, when illuminated, a light of a different wavelength. This device is used in conjunction with certain materials to measure a variety of analytes.

(b) *Classification.* Class I (general controls).

§ 862.2680 Microtitrator for clinical use.

(a) *Identification.* A microtitrator for clinical use is a device used in microanalysis to measure the concentration of a substance by reacting it with a measured "micro" volume of a known standardized solution.

(b) *Classification.* Class I (general controls).

§ 862.2700 Nephelometers for clinical use.

(a) *Identification.* A nephelometer for clinical use is a device used to estimate the concentration of particles in a suspension by measuring their light scattering properties (the deflection of light rays by opaque particles in their path). The device is used in conjunction with certain materials to measure the concentration of a variety of analytes.

(b) *Classification.* Class I (general controls).

§ 862.2720 Plasma oncometer for clinical use.

(a) *Identification.* A plasma oncometer for clinical use is a device used to measure plasma oncotic pressure, which is that portion of the total plasma osmotic pressure contributed by protein and other molecules too large to pass through a specified semipermeable membrane. Because variations in plasma oncotic pressure are indications of certain disorders, measurements of the

variations are useful in the diagnosis and treatment of these disorders.

(b) *Classification.* Class I (general controls).

§ 862.2730 Osmometer for clinical use.

(a) *Identification.* An osmometer for clinical use is a device used to measure the osmotic pressure of body fluids. Osmotic pressure is the pressure required to prevent the passage of a solution with a lesser solute concentration into a solution with greater solute concentration when the two solutions are separated by a semipermeable membrane. The concentration of a solution affects its osmotic pressure, freezing point, and other physiochemical properties. Osmometers determine osmotic pressure by methods such as the measurement of the freezing point. Measurements obtained by this device are used in the diagnosis and treatment of body fluid disorders.

(b) *Classification.* Class I (general controls).

§ 862.2750 Pipetting and diluting system for clinical use.

(a) *Identification.* A pipetting and diluting system for clinical use is a device that provides an accurately measured volume of liquid at a specified temperature that may be used in certain test procedures. This generic type of device system includes serial, manual, automated, and semi-automated dilutors, pipettors, dispensers, and pipetting stations.

(b) *Classification.* Class I (general controls).

§ 862.2800 Refractometer for clinical use.

(a) *Identification.* A refractometer for clinical use is a device used to determine the amount of solute in a solution by measuring the index of refraction (the ratio of the velocity of light in a vacuum to the velocity of light in the solution). The index of refraction is used to measure the concentration of certain analytes (solutes), such as plasma total proteins and urinary total solids. Measurements obtained by this device are used in the diagnosis and treatment of certain conditions.

(b) *Classification.* Class I (general controls).

§ 862.2850 Atomic absorption spectrophotometer for clinical use.

(a) *Identification.* An atomic absorption spectrophotometer for clinical use is a device used to identify and measure elements and metals (e.g., lead and mercury) in human specimens. The metal elements are identified according to the wavelength and intensity of the light that is absorbed when the specimen is converted to the atomic vapor phase. Measurements obtained by this device are used in the diagnosis and treatment of certain conditions.

(b) *Classification.* Class I (general controls).

§ 862.2860 Mass spectrophotometer for clinical use.

(a) *Identification.* A mass spectrophotometer for clinical use is a device used to identify metallic or organic compounds (e.g., lead, mercury, and drugs) in human specimens by ionizing the compound under investigation and separating the resulting ions by means of an electrical and a magnetic field according to their mass.

(b) *Classification.* Class I (general controls).

§ 862.2900 Automated urinalysis system.

(a) *Identification.* An automated urinalysis system is a device used to measure certain of the physical properties and chemical constituents of urine by procedures that duplicate manual urinalysis systems. This device is used in conjunction with certain materials to measure a variety of urinary analytes.

(b) *Classification.* Class I (general controls).

862.2920 Plasma viscometers for clinical use.

(a) *Identification.* A plasma viscometer for clinical use is a device used to measure the viscosity of plasma by determining the time period required for the plasma to flow a measured distance through a calibrated glass tube. Measurements obtained by this device are used to monitor changes in the amount of solids present in plasma in various disorders.

(b) *Classification.* Class I (general controls).

Subpart D—Clinical Toxicology Test Systems

§ 862.3040 Alcohol test system.

(a) *Identification.* A alcohol test system is a device used to measure alcohol (e.g., ethanol, methanol, isopropanol, etc.) in human body fluids (e.g., serum, whole blood, and urine) by methods such as alcohol dehydrogenase (ADH) enzymatic method, gas chromatography, or potassium dichromate method. Measurements obtained by this device are used in the diagnosis and treatment of alcohol intoxication and poisoning.

(b) *Classification.* Class II (performance standards).

§ 862.3050 Breath-alcohol test system.

(a) *Identification.* A breath-alcohol test system is a device used to measure alcohol in the human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.

(b) *Classification.* Class I (general controls).

§ 862.3100 Amphetamine test system.

(a) *Identification.* An amphetamine test system is a device used to measure amphetamine, a central nervous system stimulating drug, in plasma and urine by methods such as gas chromatography, liquid chromatography, thin-layer chromatography, enzyme, immunoassay, or radioimmunoassay. Measurements obtained by this device are used in the diagnosis and treatment of amphetamine overdose and in monitoring levels of amphetamine to ensure appropriate therapy.

(b) *Classification.* Class II (performance standards).

§ 862.3110 Antimony test system.

(a) *Identification.* An antimony test system is a device used to measure antimony, a heavy metal, in urine, blood, vomitus, and stomach contents by methods such as atomic absorption spectroscopy or colorimetry. Measurements obtained by this device are used in the diagnosis and treatment of antimony poisoning.

(b) *Classification.* Class II (performance standards).

§ 862.3120 Arsenic test system.

(a) *Identification.* An arsenic test system is a device used to measure arsenic, a poisonous heavy metal, in urine, vomitus, stomach contents, nails, hair, and blood by methods such as atomic absorption spectrophotometry, ultraviolet spectrophotometry, or colorimetry. Measurements obtained by this device are used in the diagnosis and treatment of arsenic poisoning.

(b) *Classification.* Class II (performance standards).

§ 862.3150 Barbiturate test system.

(a) *Identification.* A barbiturate test system is a device used to measure barbiturates, a class of hypnotic and sedative drugs, in serum, urine, and gastric contents by methods such as thin-layer chromatography, gas chromatography, colorimetry enzyme immunossay, high pressure liquid chromatography, hemagglutination inhibition, or radioimmunoassay. Measurements obtained by this device are used in the diagnosis and treatment of barbiturate overdose and in

monitoring levels of barbiturate to ensure appropriate therapy.

(b) *Classification.* Class II (performance standards).

§ 862.3170 Benzodiazepine test system.

(a) *Identification.* A benzodiazepine test system is a device used to measure any of the benzodiazepine compounds, sedative and hypnotic drugs, in blood, plasma, and urine by methods such as enzyme immunoassay, ultraviolet spectrophotometry, gas chromatography, high pressure liquid chromaography, or thin-layer chromatography. The benzodiazepine compounds include chlordiazepoxide, diazepam, oxazepam, chlorazepate, flurazepam, and nitrazepam. Measurements obtained by this device are used in the diagnosis and treatment of benzodiazepine overdose.

(b) *Classification.* Class II (performance standards).

§ 862.3200 Clinical toxicology calibrator.

(a) *Identification.* A clinical toxicology calibrator is a device that is used as a reference material for equipment set-up and that is used to determine the accuracy of a device by measuring the variation from a standard or by developing a standard curve for a diagnostic assay. A clinical toxicology calibrator can be a mixture of drugs or a specific material for a particular drug (e.g., ethanol, lidocaine, etc).

(b) *Classification.* Class II (performance standards).

§ 862.3220 Carbon monoxide test system.

(a) *Identification.* A carbon monoxide test system is a device used to measure carbon monoxide or carboxyhemoglobin (carbon monoxide bound to the hemoglobin in the blood) in blood by methods such as microdiffusion analysis, spectrophotometric determination, or gas chromatography. Measurements obtained by this device are used in the diagnosis and treatment of or confirmation of carbon monoxide poisoning.

(b) *Classification.* Class II (performance standards).

§ 862.3240 Cholinesterase test system.

(a) *Identification.* A cholinesterase test system is a device used to measure cholinesterase (an enzyme that catalyzes the hydrolysis of acetylcholine to choline) in human specimens by methods such as test paper colorimetry or electrometry. There are two principal types of cholinesterase in human tissues. True cholinesterase is present at nerve endings and in erythrocytes (red blood cells) but is not present in plasma. Pseudo cholinesterase is present in plasma and liver but is not present in erythrocytes. Measurements obtained by this device are used in the diagnosis and treatment of cholinesterase inhibition disorders (e.g., insecticide poisoning and succinylcholine poisoning).

(b) *Classification.* Class II (performance standards).

§ 862.3250 Cocaine and cocaine metabolite test system.

(a) *Identification.* A cocaine and cocaine metabolite test system is a device used to measure cocaine and a cocaine metabolite (benzoylecgonine) in serum, plasma, and urine by methods such as gas chromatography, thin-layer chromatography, enzyme immunoassay, free radical assay, high pressure liquid chromatography, radioimmunoassay, or hemagglutination. Measurements obtained by this device are used in the diagnosis and treatment of cocaine overdose and in monitoring levels of cocaine and its metabolite to ensure appropriate therapy.

(b) *Classification.* Class II (performance standards).

§ 862.3270 Codeine test system.

(a) *Identification.* A codeine test system is a device used to measure codeine, a narcotic pain-relieving drug, in serum and urine by methods such as thin-layer chromatography, enzyme immunoassay, gas chromatography, high pressure liquid chromatography, or hemagglutination inhibition. Measurements obtained by this device are used in the diagnosis and treatment of codeine overdose and in monitoring levels of codeine to ensure appropriate therapy.

(b) *Classification.* Class II (performance standards).

§ 862.3280 Clinical toxicology control material.

(a) *Identification.* A clinical toxicology control material is a device used to provide an estimation of the percision of a device test system and to detect and monitor systematic deviations from accuracy resulting from reagent or instrument defects. This generic type of device includes various control material, such as alcohol, digoxin, digitoxin, theophylline, lidocaine, methotrexate, *N*-acetylprocainamide, procainamide, drug mixtures, and heavy metals.

(b) *Classification.* Class I (general controls).

§ 862.3300 Digitoxin test system.

(a) *Identification.* A digitoxin test system is a device used to measure digitoxin, a cardiovascular drug, in serum and plasma by radioimmunoassay. Measurements obtained by this device are used in the diagnosis and treatment of digitoxin overdose and in monitoring levels of digitoxin to ensure appropriate therapy.

(b) *Classification.* Class II (performance standards).

§ 862.3320 Digoxin test system.

(a) *Identification.* A digoxin test system is a device used to measure digoxin, a cardiovascular drug, in serum and plasma by radioimmunoassay. Measurements obtained by this device are used in the diagnosis and treatment of digoxin overdose and in monitoring levels of digoxin to ensure appropriate therapy.

(b) *Classification.* Class II (performance standards).

§ 862.3350 Diphenylhydantoin test system.

(a) *Identification.* A diphenylhydantoin test system is a device used to measure diphenylhydantoin, an antiepileptic drug, in human specimens by methods such as enzyme immunoassay, radioimmunoassay, gas chromatography, liquid chromotography, and thin-layer chromotography. Measurements obtained by this device are used in the diagnosis and treatment of diphenylhydantoin overdose and in monitoring levels of diphenylhydantoin to ensure appropriate therapy.

(b) *Classification.* Class II (performance standards).

§ 862.3380 Ethosuximide test system.

(a) *Identification.* An ethosuximide test system is a device used to measure ethosuximide, an antiepileptic drug, in human specimens by such methods as thin-layer chromatography, liquid chromatography, gas chromatography, radioimmunoassay, or enzyme immunoassay. Measurements obtained by this device are used in the diagnosis and treatment of ethosuximide overdose and in monitoring levels of ethosuximide to ensure appropriate therapy.

(b) *Classification.* Class II (performance standards).

§ 862.3450 Gentamicin test system.

(a) *Identification.* A gentamicin test system is a device used to measure gentamicin, an antibiotic drug, in human specimens by methods such as hemagglutination inhibition, agar gel diffusion discs, radioimmunoassay gentamicin (125_I) second antibody separation, *Bacillus subtlis* microbiology assay, or enzymatic radiochemical assay. Measurements obtained by this device are used in the diagnosis and treatment of gentamicin overdose and in monitoring levels of

gentamicin to ensure appropriate therapy.

(b) *Classification.* Class II (performance standards).

§ 862.3520 Kanamycin test system.

(a) *Identification.* A kanamycin test system is a device used to measure kanamycin, an antibiotic drug, in plasma and serum by radioimmunoassay. Measurements obtained by this device are used in the diagnosis and treatment of kanamycin overdose and in monitoring levels of kanamycin to ensure appropriate therapy.

(b) *Classification.* Class II (performance standards).

§ 862.3550 Lead test system.

(a) *Identification.* A lead test system is a device used to measure lead, a heavy metal, in blood and urine by methods such as atomic absorption spectroscopy, *delta*-aminolevulinic acid, fluorometric protoporphyrin zinc, or fluorometric protoporphyrin. Measurements obtained by this device are used in the diagnosis and treatment of lead poisoning.

(b) *Classification.* Class II (performance standards).

§ 862.3560 Lithium test system.

(a) *Identification.* A lithium test system is a device used to measure lithium (from the drug lithium carbonate) in serum or plasma by methods such as atomic absorption or flame photometry. Measurements of lithium are used to assure that the proper drug dosage is administered in the treatment of patients with mental disturbances, such as manic-depressive illness (bipolar disorder).

(b) *Classification.* Class II (performance standards).

§ 862.3580 Lysergic acid diethylamide (LSD) test system.

(a) *Identification.* A lysergic acid diethylamide (LSD) test system is a device used to measure lysergic acid diethylamide, a hallucinogenic drug, in serum, urine, and gastric contents by methods such as free radical assay or radioimmunoassay. Measurements obtained by this device are used in the diagnosis and treatment of LSD use.

(b) *Classification.* Class II (performance standards).

§ 862.3600 Mercury test system.

(a) *Identification.* A mercury test system is a device used to measure mercury, a heavy metal, in human specimens by atomic absorption spectroscopy. Measurements obtained by this device are used in the diagnosis and treatment of mercury poisoning.

(b) *Classification.* Class II (performance standards).

§ 862.3610 Methamphetamine test system.

(a) *Identification.* A methamphetamine test system is a device used to measure methamphetamine, a central nervous system stimulating drug, in serum, plasma, and urine by methods such as thin-layer chromatography, gas chromatography, or high-pressure liquid chromatography. Measurements obtained by this device are used in the diagnosis and treatment of methamphetamine overdose.

(b) *Classification.* Class II (performance standards).

§ 862.3620 Methadone test system.

(a) *Identification.* A methadone test system is a device used to measure methadone, an addictive narcotic pain-relieving drug, in serum and urine, by methods such as thin-layer chromatography, liquid chromatography, gas chromatography, enzyme immunoassay, free radical assay, spectrophotometry, hemagglutination inhibition, or radioimmunoassay. Measurements obtained by this device are used in the diagnosis and treatment of methadone overdose and to determine compliance with regulations in methadone maintenance treatment.

(b) *Classification.* Class II (performance standards).

§ 862.3640 Morphine test system.

(a) *Identification.* A morphine test system is a device used to measure morphine, an addictive narcotic pain-relieving drug, and its analogs in serum, urine, and gastric contents by methods such as fluorometry, free radical assay, gas chromatography, hemagglutination inhibition, liquid chromatography, radioimmunoassay, or thin-layer chromatography. Measurements obtained by this device are used in the diagnosis and treatment of morphine overdose.

(b) *Classification.* Class II (performance standards).

§ 862.3650 Opiate test system.

(a) *Identification.* An opiate test system is a device used to measure any of the addictive narcotic pain-relieving opiate drugs in blood, serum, urine, gastric contents, and saliva by methods such as enzyme immunoassay, gas chromatography, thin-layer chromatography, high pressure liquid chromatography, free radical assay, or hemagglutination inhibition. An opiate is any natural or synthetic drug that has morphine-like pharmacological actions. The opiates include drugs such as morphine, morphine glucuronide, heroin, codeine, nalorphine, and meperedine. Measurements obtained by this device are used in monitoring the levels of opiate administration to ensure appropriate therapy and the diagnosis of possible drug dependence.

(b) *Classification.* Class II (performance standards).

§ 862.3660 Phenobarbital test system.

(a) *Identification.* A phenobarbital test system is a device used to measure phenobarbital, an antiepileptic and sedative-hypnotic drug, in human specimens by methods such as radioimmunoassay, enzyme immunoassay, liquid chromatography, or gas chromatography. Measurements obtained by this device are used in the diagnosis and treatment of phenobarbital overdose and in monitoring levels of phenobarbital to ensure appropriate therapy.

(b) *Classification.* Class II (performance standards).

§ 862.3670 Phenothiazine test system.

(a) *Identification.* A phenothiazine test system is a device used to measure any of the drugs of the phenothiazine class in human specimens by methods such as thin-layer chromatography or the ferric chloride/perchloric acid/nitric acid color test. Measurements obtained by this device are used in the diagnosis and treatment of phenothiazine overdose.

(b) *Classification.* Class II (performance standards).

§ 862.3680 Primidone test system.

(a) *Identification.* A primidone test system is a device used to measure primidone, an antiepileptic drug, in human specimens by methods such as thin-layer chomatography, liquid chromatography, gas chromatography, radioimmunoassay, or enzyme immunoassay. Measurements obtained by this device are used in the diagnosis and treatment of primidone overdose and in monitoring levels of primidone to ensure appropriate therapy.

(b) *Classification.* Class II (performance standards).

§ 862.3700 Propoxyphene test system.

(a) *Identification.* A propoxyphene test system is a device used to measure propoxyphene, a pain-relieving drug, in serum, plasma, and urine by methods such as enzyme immonoassay or thin-layer chromatography. Measurements obtained by this device are used in the diagnosis and treatment of propoxyphene overdose or in monitoring levels of propoxyphene to ensure appropriate therapy.

(b) *Classification.* Class II (performance standards).

§ 862.3750 Quinine test system.

(a) *Identification.* A quinine test system is a device used to measure quinine, a fever-reducing and pain-relieving drug used in the treatment of malaria, in serum and urine by methods such as thin-layer chromatography, high-pressure liquid chromatography, spectrophotofluorometry, or gas chromatography. Measurements obtained by this device are used in the diagnosis and treatment of quinine overdose and malaria.

(b) *Classification.* Class II (performance standards).

§ 862.3830 Salicylate test system.

(a) *Identification.* A salicylate test system is a device used to measure salicylates, a class of analgesic, antipyretic and anti-inflammatory drugs that includes aspirin, in human specimens by methods such as the paper strip test or colorimetry. Measurements obtained by this device are used in diagnosis and treatment of salicylate overdose and in monitoring salicylate levels to ensure appropriate therapy.

(b) *Classification.* Class II (performance standards).

§ 862.3850 Sulfonamide test system.

(a) *Identification.* A sulfonamide test system is a device used to measure sulfonamides, any of the antibacterial drugs derived from sulfanilamide, in human specimens by colorimetry. Measurements obtained by this device are used in the diagnosis and treatment of sulfonamide overdose and in monitoring sulfonamide levels to ensure appropriate therapy.

(b) *Classification.* Class II (performance standards).

§ 862.3870 Cannabinoid test system.

(a) *Identification.* A cannabinoid test system is a device used to measure by radioimmunoassay any of the cannabinoids, hallucinogenic compounds endogenous to marihuana, in serum, plasma, saliva, and urine. Cannabinoid compounds include *delta*-9-tetrahydrocannabinol, cannabidiol, cannabinol, and cannabichromene. Measurements obtained by this device are used in the diagnosis and treatment of cannabinoid abuse and in monitoring levels of cannabinoids during clinical investigational use.

(b) *Classification.* Class II (performance standards).

§ 862.3900 Tobramycin Test system.

(a) *Identification.* A tobramycin test system is a device used to measure tobramycin, an aminoglycoside antibiotic drug, in plasma and serum by methods such as radioimmunoassay or *Bacillus subtilis* microbiology assay. Measurements obtained by this device are used in the diagnosis and treatment of tobramycin overdose and in monitoring levels of tobramycin to ensure appropriate therapy.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before April 5, 1982, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments regarding the general provisions are to be identified with the docket number found in brackets in the heading of this document. Comments regarding a particular device are to be identified with the docket number for that device found in the "Panel Recommendations, and FDA's Proposed Classifications" section. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

The Food and Drug Administration has carefully analyzed the economic effects of this proposed rule and has determined that, if promulgated, the rule will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. In accordance with section 3(g)(1) of Executive Order 12291, the impact of this proposed rule has been carefully analyzed, and it has been determined that this proposal does not constitute a major rule as defined in section 1(b) of the Executive Order. Rules proposing classification of devices into class I generally maintain the status quo: These devices are now subject to only the general controls provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j) and, under the proposed rules, would remain subject only to such controls either in their entirety or with certain exemptions. Devices classified into class II would also remain subject only to the general controls provisions of the act unless and until an applicable performance standard were established. Similarly, devices classified into class III remain subject only to the general controls provisions of the act until an additional regulation is promulgated pursuant to section 515(b) of the act (21 U.S.C. 360e(b)) requiring that such devices have in effect approved applications for premarket approval. In accordance with section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)), devices classified by regulation into class III may remain in commercial distribution without an approved premarket approval application for 30 months following the effective date of classification of the device into class III, or for 90 days following the promulgation of a regulation under section 515(b) of the act (21 U.S.C. 360e(b)), whichever occurs later. In sum, device classification rules do not have a significant impact on a substantial number of small entities and are not major rules.

Dated: December 16, 1981.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

[FR Doc. 82-1977 Filed 2-1-82; 8:45 am]

BILLING CODE 4160-01-M

federal register

Tuesday
February 2, 1982

Part III

Department of the Interior

National Park Service

National Register of Historic Places; Annual Listing of Historic Properties

DEPARTMENT OF THE INTERIOR

National Park Service

National Register of Historic Places; Annual Listing of Historic Properties

Pursuant to the National Historic Preservation Act of 1966, as amended (80 Stat. 915, 16 U.S.C. 470 et seq.), the National Park Service, Department of the Interior, has undertaken steps to implement the purposes of that act through: (1) expansion of the National Register of Historic Places, (2) initiating a program of grants-in-aid for historic preservation, and (3) adoption of procedures and criteria for furthering the Nation's historic preservation program.

It is the purpose of this notice, through publication of the information included herein, to apprise the public, as well as governmental agencies, associations, and all other organizations and individuals interested in historic preservation of the properties added to the National Register from Nov. 1, 1980 to Nov. 1, 1981, and of the properties determined eligible for inclusion in the National Register from Nov. 1, 1980 to Nov. 1, 1981.

Carol D. Shull,

Acting Keeper of the National Register.

For a cumulative listing comprising all properties on the National Register, we recommend that users retain the **Federal Register** listings from February 6, 1979 (Vol. 44, No. 26, Part II), March 18, 1980 (Vol. 45, No. 54, Part II), and February 3, 1981 (Vol. 46, No. 22, Part II). Together these listings provide information for all National Register properties and for properties determined eligible for inclusion on the National Register through November, 1981. A limited number of copies of the 1979, 1980 and 1981 Federal Registers Part II are available from the Department of the Interior, National Park Service, National Register of Historic Places, 18th and C Sts., NW., Washington, D.C. 20240.

ALABAMA

BLOUNT COUNTY COVERED BRIDGES THEMATIC RESOURCES. Reference—see individual listings under Blount County.

Blount County

Cleveland vicinity, *Swann Covered Bridge (Blount County Covered Bridges Thematic Resources)* W of Cleveland (8–20–81)
Nectar vicinity, *Nectar Covered Bridge (Blount County Covered Bridges Thematic Resources)* 8 mi. SW of Nectar (8–20–81)
Oneonta vicinity, *Easley Covered Bridge (Blount County Covered Bridges Thematic Resources)* Spans Dub Branch (8–20–81)
Oneonta vicinity, *Horton Mill Covered Bridge (Blount County Covered Bridges Thematic Resources)* 5 mi. (8km) N of Oneonta on Rte. 3 (previously listed in the National Register 12–29–70)

Jefferson County

Birmingham, *Blessed Sacrament Academy (Convent of Perpetual Adoration)*, 1525 Cotton Ave., SW (11–28–80)
Birmingham, *Continental Gin Company*, 4500–5th Ave., S. (11–20–80)
Birmingham, *Forest Park*, Roughly bounded by Highland Golf Course and 38th St. on west; Linwood Rd on east; Overlook and Clairmont on N; Cherry St. on S. (11–21–80)
Birmingham, *Sloss Blast Furnaces*, 1st Ave. (5–29–81) NHL

Madison County

Huntsville, *U.S. Courthouse and Post Office (Downtown Huntsville Multiple Resource Area)* 101 E. Holmes Ave. (Addition) (2–24–81)

Mobile County

Mobile, *Carlen House*, 54 S. Carlen St. (6–12–81)

Montgomery County

Montgomery, *McBryde-Screws-Tyson House*, 433 Mildred St. (11–28–80)
Montgomery, *Scott Street Firehouse*, 418 Scott St. (2–12–81)

Morgan County

Trinity vicinity, *Forest Home*, E of Trinity (11–21–80)

ALASKA

Anchorage Division

Anchorage, *Anchorage City Hall*, 524 W. 4th Ave. (12–2–80)
Anchorage, *Pioneer School House*, 3rd Ave. and Eagle St. (12–3–80)

Barrow-North Slope Division

Barrow, *Point Barrow Refuge Station*, Browersville (12–2–80)

Kodiak Division

Larsen Bay vicinity, *KOD–171 Site (AHRS No. KOD–171)* (8–13–81)
Larsen Bay vicinity, *KOD–233 Site (AHRS No. KOD–233)* (8–13–81)

Seward Division

Seward, *Van Gilder Hotel*, 307 Adams St. (12–2–80)

ARIZONA

Coconino County

Lee's Ferry vicinity, *Navajo Steel Arch Highway Bridge*, SW of Lee's Ferry (8–13–81)

Gila County

San Carlos vicinity, *Coolidge Dam*, SW of San Carlos (10–29–81) (also in Pinal County)

Maricopa County

Gila Bend vicinity, *Gillespie Dam Highway Bridge*, NW of Gila Bend (5–5–81)
Tempe, *Frankenberg House*, 129 E. University Dr. (1–29–81)
Tempe, *Long, Samuel C., House*, 27 E. 6th St. (11–28–80)
Tempe, *1931 Tempe Bridge*, Mill Ave. (8–13–81)

Mohave County

HOOVER DAM. Reference—see Clark County, NV.

Navajo County

Snowflake, *Freeman, John A., House*, Main and Freeman Sts. (11–25–80)

Pinal County

COOLIDGE DAM. Reference—see Gila County.

Yavapai County

Prescott, *Iron Turbine Windmill*, 415 W. Gurley St. (7–9–81)

Yuma County

Dome vicinity, McPhaul Suspension Bridge, W of Dome (8–13–81)

ARKANSAS

Pima County

Tucson, *West University Historic District*, Roughly bounded by Speedway Blvd., 6th St., Park and Stone Aves. (12–10–80)

Pulaski County

Little Rock, *Retan, Albert, House*, 506 N. Elm St. (12–3–80)
Little Rock, *Union Life Building*, 212 Center St. (9–25–81)

Scott County

Waldron, *Forrester, John T., House*, 115 Danville St. (12–8–80)

Sevier County

DeQueen, *Hayes Hardware Store*, 314 DeQueen St. (12–3–80)

Washington County

Fayetteville vicinity, *Kantz House*, E of Fayetteville at 2650 Mission St. (11–14–80)

CALIFORNIA

Alameda County

Alameda, *First Presbyterian Church Sanctuary Building*, 2001 Santa Clara Ave. (11–25–80)
Berkeley, *City Hall*, 2134 Grove St. (9–11–81)
Berkeley, *U.S. Post Office*, 2000 Milvia St. (1–29–81)
Fremont, *Washington Union High School*, 38442 Fremont Blvd. (10–5–81)

Amador County

Jackson, *Kennedy Tailing Wheels*, Jackson Gate Rd. (7–7–81)

Contra Costa County

Walnut Creek vicinity, *Old Borges Ranch*, 1035 Castlerock Rd. (7–7–81)

Humboldt County

Bridgeville vicinity, *Lower Blackburn Grade Bridge*, NW of Bridgeville on CA 36 (6–25–81)

Inyo County

Bishop vicinity, *Laws Narrow Gauge Railroad Historic District*, NE of Bishop (10–1–81)
Death Valley Junction, *Death Valley Junction Historic District*, CA 127 and CA 190 (12–10–80)

Kern County

Bakersfield, *Kern Branch, Beale Memorial Library*, 1400 Baker St. (4–1–81)
Taft, *Fort, The*, Ash and Lincoln Sts. (7–22–81)

Klamath County

Bly, *Bly Ranger Station*, OR 140 (3–11–81)

Los Angeles County

Hollywood, *Hollywood Studio Club*, 1215 Lodi Pl. (11–25–80)
Long Beach, *Pacific Coast Club*, 850 E. Ocean Blvd. (11–20–80)
Long Beach, *Rancho Los Alamitos*, 6400 Bixby Hill Rd. (7–7–81)
Los Angeles, *Los Angeles Pacific Company Ivy Park Substation*, 9015 Venice Blvd. (3–25–81)
Los Angeles, *Los Angeles Union Passenger Terminal*, 800 N. Alameda St. (11–13–80)
Pasadena, *Colorado Street Bridge*, Colorado Blvd. (2–12–81)
Pasadena, *Stoutenburgh House*, 255 S. Marengo Ave. (11–25–80)
Pasadena, *Vista del Arroyo Hotel and Bungalows*, 125 S. Grand Ave. (4–2–81)
Redondo Beach, *Redondo Beach Public Library*, 309 Esplanade St. (3–12–81)

Marin County

Marin City vicinity, *Muir Beach Archeological Site*, W of Marin City (1–26–81)
Marin City vicinity, *Steamship Tennessee Remains*, Golden Gate National Recreation Area (4–15–81)

Mendocino County

Covelo, *Round Valley Flour Mills*, Main and Greely Sts. (11–10–80)
Ukiah, *Sun House*, 431 S. Main St. (9–2–81)

Merced County

Atwater, *Bloss Mansion (George S. Bloss House)* 1020 Cedar Ave. (9–3–81)

Monterey County

Pacific Grove, *Gosby House Inn*, 643 Lighthouse Ave. (12–2–80)

Orange County

Anaheim, *Stanton, Phillip Ackley, House*, 2200 W. Sequoia Ave. (11–21–80)
Orange, *Ainsworth, Lewis, House*, 414 E. Chapman Ave. (3–13–81)
San Clemente, *San Clemente Beach Club*, Avenida Boca De La Playa (4–9–81)

Riverside County

Desert Center vicinity, *North Chuckwalla Mountain Quarry District (CA–Riv–1814)* SE of Desert Center (8–24–81)
Desert Center vicinity, *North Chuckwalla Mountains Petroglyph District Ca-Riv–1383)* SE of Desert Center (9–3–81)

Sacramento County

Folsom, *Folsom Powerhouse*, Folsom Blvd. and Riley St. (5–29–81) NHL
Sacramento, *Brighton School*, 3312 Bradshaw Rd. (4–3–81)
Sacramento, *Wagner, Anton, Duplex*, 701 E St. (11–10–80)

San Bernardino County

Red Mountain vicinity, *Squaw Spring Archeological District* (7–28–81)
Silver Lake vicinity, *Archeological Site CA–SBR–3186*, (2–10–81)

San Diego County

San Diego, *Pythias Lodge Building*, 211 E St. and 870 3rd Ave. (4–8–81)

San Francisco County

San Francisco, *Beach Chalet*, 1000 Great Hwy. (7–22–81)
San Francisco, *Lydia, The (Archeological Site No. 4–SFR–94 H*, King St. and the Embarcadero (7–16–81)

San Joaquin County

Stockton, *Commercial and Savings Bank*, 343 Main St. (11–25–80)
Stockton, *Hotel Stockton*, 133 E. Weber Ave. (4–1–81)

San Mateo County

Half Moon Bay, *Methodist Episcopal Church at Half Moon Bay*, 777 Miramontes St. (11–10–80)

Santa Barbara County

Santa Barbara, *Santa Barbara County Courthouse*, 1100 Anacapa St. (1–23–81)
Santa Barbara vicinity, *Point Conception Light Station*, U.S. Coast Guard Light Station (2–25–81)

Santa Clara County

Palo Alto, *Pettigrew House*, (11–25–80)
Palo Alto, *U.S. Post Office*, 380 Hamilton Ave. (4–5–81)

Santa Cruz County

Santa Cruz vicinity, *Brown, Allan, Site* (6–25–81)

Shasta County

Redding vicinity, *Squaw Creek Archeological Site* (9–3–81)

Sierra County

1872 CALIFORNIA NEVADA STATE BOUNDARY MARKER. Reference—see Washoe County, Nevada.
Nevada City vicinity, *Foote's Crossing Road*, Tahoe National Forest (1–29–81)

Siskiyou County

Weed, *Shasta Inn and Week Lumber Company Boarding House*, 829 and 877 N. Davis St. (11–10–80)

Sonoma County

Sonoma, *Sonoma Grammer School*, 276 E. Napa St. (11–28–80)

Trinity County

Trinity Center vicinity, *Bowerman Barn*, SW of Trinity Center on Guy Covington Dr. (3–20–81)

Tuolumne County

Sonora, *Tuolumne County Courthouse*, 41 W. Yaney Ave. (9–17–81)

Yolo County

Woodland, *Woodland Public Library*, 250 1st St. (9–28–81)

COLORADO

Boulder County

Boulder, *Downtown Boulder Historic District*, CO 19 (12–3–80)

Denver County

Denver, *Paramount Theater*, 519 16th St. (11–21–80)

Jefferson County

Morrison vicinity, *Peterson House (Ticen House)* E of Morrison on Morrison Rd. (9–10–81)

Larimer County

Berthoud, *Bimson Blacksmith Shop*, 224 Mountain St. (7–23–81)

Prowers County

Lamar, *Prowers County Building*, 301 S. Main St. (9–21–81)

Weld County

Erie, *Lincoln School*, 645 Holbrook St. (7–22–81)
Greeley, *Greeley High School and Grade School*, 1015 8th St. (7–23–81)
Keota vicinity, *Keota Stone Circles Archeological District* (7–28–81)

CONNECTICUT

Hartford County

Farmington, *Gridley-Parsons-Staples Homestead*, 1554 Farmington Ave. (7–30–81)
Hartford, *Connecticut State Library and Supreme Court Building*, 231 Capitol Ave. (6–4–81)
Hartford, *Municipal Building*, 550 Main St. (4–27–81)
Hartford, *U.S. Post Office and Federal Building*, 135—149 High St. (10–19–81)
West Hartford, *Webster, Noah, Memorial Library*, 7 N. Main St. (7–30–81)

New Haven County

Meriden, *Curtis Memorial Library*, 175 E. Main St. (4–27–81)
Prospect, *Hotchkiss, David, House*, Waterbury Rd. (5–1–81)
Waterbury, *Benedict-Miller House*, 32 Hillside Ave. (6–12–81)

New London County

Groton, *Smith, Jabez, House*, North Rd. (5–15–81)
New London, *Bulkeley School*, Huntington St. (8–13–81)

Tolland County

Rockville, *Old Rockville High School and East School*, School and Park Sts. (4–27–81)

DELAWARE

Kent County

Felton, *Felton Railroad Station*, E. Railroad Ave. (7–13–81)
Wyoming, *Wyoming Railroad Station*, E. Railroad Ave. (12–4–80)

New Castle County

Odessa vicinity, *Monterey*, N of Odessa on Bayview Rd. (12–5–80)
Wilmington, *Brandywine Park and Kentmere Parkway, Roughly* bounded by Kentmere Pkwy., Augustine Cutoff, Lovering Ave., 18th and Market Sts. (7–23–81)

Sussex County

Georgetown vicinity, *Redden Forest Lodge, Forester's House, and Stable,* Redden State Forest (11–25–80)
Lewes vicinity, *Fisher Homestead,* W of Lewes (12–11–80)

DISTRICT OF COLUMBIA

Washington

MOUNT VERNON MEMORIAL HIGHWAY. Reference—see Alexandria, Virginia (independent city)

FLORIDA

Dade County

Coral Gables, *Venetian Pool,* 2701 De Soto Blvd. (8–20–81)

Franklin County

Apalachicola, *Apalachicola Historic District,* Roughly bounded by Apalachicola River, Apalachicola Bay, 17th and Jefferson Sts. (11–21–80)

Hillsborough County

Plant City, *Plant City High School,* N. Collins St. (2–4–81)

Palm Beach County

Lake Park, *Kelsey City City Hall,* 535 Park Ave. (9–3–81)
Palm Beach, *Mar-A-Lago National Historic Landmark* (12–23–80) (NHL)

St. Johns County

St. Augustine, *St. Augustine Lighthouse and Keeper's Quarters,* Old Beach Rd. (3–19–81)

Volusia County

Oak Hill vicinity, *Ross Hammock Site,* (2–5–81)
Ormond Beach, *Ormond Hotel,* 15 E. Granada Blvd. (11–24–80)

GEORGIA

MARSHALLVILLE AND VICINITY MULTIPLE RESOURCE AREA (Partial Inventory). This area includes: Macon County, Marshallville, *East Main Street Residential District,* E. Main St.; *Marshallville Commerical District,* Main St.; *West Main Street Residential District,* W. Main St.; *Felton, William Hamilton, House,* McCaskill St.; Marshallville vicinity. *Alma Fruit Farm,* GA 49W; *Billy Place,* 430 W. Church St.; *Knob, Wilkes, Plantation;* Massee Lane; *Thronateeska; Willow Lake,* Rt. 1; Peach County, Fort Valley vicinity, *Strother's Farm.* (11–25–80)

Bibb County

Macon, *Vineville Historic District,* GA 247 and U.S. 41 (11–21–80)

Chatham County

Savannah vicinity, *Hill Hall at Savannah State College,* Savannah State College campus (4–23–81)

Cherokee County

Canton, *Cherokee County Courthouse (Georgia County Courthouses Thematic Resources)* (Addition) (5–28–81)

Cobb County

Smyrna, *Ruff's Mill and Concord Covered Bridge,* 10 Concord Rd., SW (11–24–80)

Floyd County

Cave Spring, *CAVE SPRING MULTIPLE RESOURCE AREA.* This area includes: *Cave Spring Commerical Historic District,* Alabama, Rome and Cedartown Rds., Broad and Padlock Sts.; *Cave Spring Residential Historical District,* U.S. 411 and GA 100; *Georgia School for the Deaf Historic District,* Padlock St.; *Rolator Park Historic District,* Off U.S. 411; *Carroll-Harper House,* Cedartown St.; *Carroll, John M., House,* Park St.; *Carroll-Richardson Grist Mill,* Mill St.; *Cave Spring Female Academy,* Rome St.; *Cave Spring High School,* Rome St.; *Cave Spring Railroad Station,* Alabama St.; *Conner, Wesley O., House,* Cedartown St.; *Cowdry, William D., Plantation,* Rome Rd.; *Fannin, Oliver P., House,* Cedartown St.; *Ford, Joseph, House,* Love and Alabama Sts.; *Mann, John T., House,* Rivers St.; *McKinney, Dr. W. T., House,* Cedartown St.; *Rivers Farm,* Rome St.; *Robbins, Samuel W., House,* Rome St.; *Roving House,* Rome St.; *Simmons House,* Cedartown St.; *Simmons, William S. Plantation,* Alabama St.; *Watts George T., House,* Love St.; *Wharton-Trout House,* Rome St. (6–19–80)

Fulton County

Atlanta, *Grady Hospital,* 36 Butler St., SE. (8–13–81)
Atlanta, *WEST PACES FERRY ROAD MULTIPLE RESOURCE AREA.* This area includes: *Peachtree Heights Park,* Pearchtree, Habersham, and Wesley Rds., Andrews Dr., and Peachtree Battle Ave.; *Canton Apartments,* 2846—2840 Peachtree Rd.; *Thornton, Albert E., House,* 105 W. Paces Ferry Rd., NW., and *Trygveson,* 3418 Pinestream Rd., NW. (12–8–80)

Gwinnett County

Norcross, *Norcross Historic District,* Off U.S. 23 (11–21–80)

Heard County

Corinth vicinity, *Ware, John M., Sr., House,* NW of Corinth (11–3–80)
Franklin, *Heard County Jail,* Court Sq. and Shady Lane (1–27–81)

Muscogee County

Columbus, *COLUMBUS MULTIPLE RESOURCE AREA (ADDITIONS).* This area includes: *Church Square* (including The First Baptist Church of Columbus); *Ledger-Enquirer Building,* 17 W. 12th St.; *Carter and Bradley, Cotton Factors and Warehouseman,* 1001–1037 Front Ave.; *W. Jacob Burrus House,* 307 11th St.; *Elisha P. Dismukes House,* 1515 3rd Ave.; *Building at* 1519 3rd Avenue; *Building at* 1531 3rd Avenue; *Henry Lindsay Woodruff House,* 1535 3rd Ave.; *Building at* 1612 3rd Avenue; *Isaac Maund House,* 1608 3rd Ave.; *Columbus Stockade,* 622 10th St.; *Bush-Philips Hardware Co.,* 1025 Broadway; *Power and Baird, Wholesale Dry Goods and Notions,* 1107 Broadway; *Central of Georgia Railroad Terminal,* 700 12th St.; *Wolfson Printing and Paper Co.,* 24 W. 10th St.; *Frank Brothers (printers),* 18 W. 10th St.; *Broad Street Methodist Episcopal Church South,* 1323–1325 Broadway; *Wm. L. Cooke House,* 1523 3rd Ave.; *Building at* 303 11th St. (12–2–80)

Polk County

Cedartown, *Hawkes Children's Library,* N. College St. (11–24–80)

Quitman County

Georgetown, *Quitman County Jail,* Main St. (8–13–81)

Richmond County

Augusta, *Greene Street Historic District,* Greene St. (12–3–80)

Sumter County

Americus vicinity, *Liberty Hall,* SE of Americus on S. Lee St. (11–25–80)

Washington County

Sandersville, *Elder, Thomas Jefferson, High and Industrial School,* 316 Hall St. (5–12–81)

Wilkes County

Rayle vicinity, *Daniel, James and Cunningham, House,* S of Rayle on Bartram Trace Rd. (11–24–80)

HAWAII

FIRE STATIONS OF OAHU THEMATIC RESOURCES. Reference—see individual listings under Honolulu County.

Honolulu County

Haleiwa, *Waialua Fire Station (Fire Stations of Oahu Thematic Resources)* 66—420 Haleiwa Rd. (12–2–80)
Honolulu, *CENTRAL FIRE STATION (FIRE STATIONS OF OAHU THEMATIC RESOURCES),* 104 S. Beretania St. (12–2–80)
Honolulu, *Kaimuki Fire Station (Fire Stations of Oahu Thematic Resources)* 971 Koko Head Ave. (12–2–80)
Honolulu, *Kakaaka Fire Station (Fire Stations of Oahu Thematic Resources)* 620 South St. (12–2–80)
Honolulu, *Kalihi Fire Station (Fire Stations of Oahu Thematic Resources)* 1742 N. King St. (12–2–80)
Honolulu, *Makiki Fire Station (Fire Stations of Oahu Thematic Resources)* 1202 Wilder Ave. (12–2–80)
Honolulu, *Palama Fire Station (Fire Stations of Oahu Thematic Resources)* 879 N. King St. (previously listed in the National Register 4–21–76)

Maui County

Kaho' olawe, *Kaho' olawe Island Archeological District,* Kaho' olawe Island (3–18–81)

IDAHO

EARLY CHURCHES OF EMMETT THEMATIC RESOURCES. Reference—see individual listings under Gem County.

Ada County

Boise, *Lower Main Street Commercial Historic District,* Main St. between 10th and 12th Sts. (11–28–80)
Boise, *Tuttle, Bishop Daniel S., House,* 512 N. 8th St. (12–4–80)

Caribou County

Chesterfield, *Chesterfield Historic District,* (12–4–80)

Cassia County

Albion, *Albion Normal School Campus*, Off ID 77 (11-28-80)
Oakley, *Oakley Historic District*, Main St. and Wilson Ave. (11-28-80)

Custer County

CHALLIS MULTIPLE RESOURCE AREA. This area includes: Challis, *Old Challis Historic District*, Bounded by Valley and Pleasant Aves., 2nd and 3rd Sts.; *Board-and-Batten Commercial Building*, Main Ave.; *Building at 247 Pleasant Avenue; Buster Meat Market*, Main Ave.; *Bux's Place*, 321 Main Ave.; *Challis Cold Storage*, Main Ave.; *Challis High School*, Main Ave.; *Chivers, Bill House*, 3rd St.; *Chivers, Thomas, Cellar*, Challis Creek Rd.; *Chivers, Thomas, House*, Challis Creek Rd.; *Custer County Jail*, Main Ave.; *False-Front Commercial Building*, Main Ave.; *Hosford, Emmett, House*, 3rd St.; *I.O.O.F. Hall*, Main Ave.; *McKendrick House*, 4th St.; *Peck, Bill, House*, 16 Main Ave.; *Penwell House*, North Ave.; *Rowles, Donaldson, House*, North Ave.; *Smith, Henry, House*, 5th St.; *Stone and Log Building*, Pleasant Ave.; *Stone Building*, 3rd St.; *Twin Peaks Sports*, Main Ave.; *Wilkinson, Clyde, House*, 9th St. (12-3-80)
Challis, *Challis Archeological Spring District*, (2-12-81)
Custer, *Custer Historic District* (2-3-81)

Gem County

Emmett, *Catholic Church of the Sacred Heart (Early Churches of Emmett Thematic Resources)* 1st St. (12-3-80)
Emmett, *Emmett Presbyterian Church (Emmett First Southern Baptist Church) (Early Churches of Emmett Thematic Resources)* 2nd St. (12-3-80)
Emmett, *First Baptist Church of Emmett (Early Churches of Emmett Thematic Resources)* 1st St. (12-3-80)
Emmett, *Methodist Episcopal Church (United Methodist Church) (Early Churches of Emmett Thematic Resources)* 1st St. and Washington Ave. (12-3-80)
Emmett, *St. Mary's Episcopal Church (Early Churches of Emmett Thematic Resources)* 1st St. (12-3-80)

Latah County

Moscow, *Fort Russell Neighborhood Historic District*, Roughly bounded by Jefferson, Monroe, 2nd and D Sts. (11-26-80)

Owyhee County

Oreana, *Our Lady, Queen of Heaven Church*, (11-28-80)

Shoshone County

Pritchard vicinity, *Magee Ranger Station*, W of Pritchard (2-18-81)
Wallace, *Wallace Carnegie Library*, City Park (2-3-81)

ILLINOIS

AMERICAN WOMAN'S LEAGUE CHAPTER HOUSES THEMATIC RESOURCES. Reference—see individual listings under Bureau, Henry, Lake, Macoupin, Madison and White Counties.

Bureau County

Princeton, *Princeton Chapter House (American Woman's League Chapter Houses Thematic Resources)* 1007 N. Main St. (11-28-80)

Carroll County

Mount Carroll, *Halderman, Nathaniel, House*, 728 E. Washington St. (11-24-80)
Mount Carroll, *Mount Carroll Historic District*, IL 64 and IL 78 (11-26-80)

Champaign County

Champaign, *Stone Arch Bridge*, Springfield Ave. and 2nd St. (5-14-81)

Coles County

Charleston, *Old Main (Livingston C. Lord Administration Building)* Lincoln Ave. and 7th St. (6-16-81)

Cook County

Chicago, *AVR 661 (Crash Boat)*, Calumet Harbor (11-19-80)
Chicago, *Dunlap Mansion*, 1012 N. Dearborn St. (11-21-80)
Chicago, *Old Stone Gate of Chicago Union Stockyards*, W. Exchange Ave. and S. Peoria St. (5-29-81) NHL
Chicago, *Pulaski Park and Fieldhouse*, 1419 W. Blackhawk St. (8-13-81)
Chicago, *Rosenwald Apartment Building*, 47th St. and Michigan Ave. (8-13-81)
Chicago, *Sheridan Plaza Hotel*, 4601-4613 N. Sheridan Rd. (11-21-80)
Western Springs, *Western Springs Water Tower*, 914 Hillgrove Ave. (6-4-81)

Cumberland County

Toledo, *Cumberland County Courthouse*, Court House Sq. (6-11-81)

DuPage County

Villa Park, *Ardmore Avenue Train Station*, 10 W. Park Ave. (11-21-80)
Wheaton, *Adams Memorial Library*, 102 E. Wesley St. (6-4-81)

Edgar County

Paris, *Edgar County Courthouse*, Main St. (6-4-81)

Greene County

Carrollton, *Hodges House*, 532 N. Main St. (11-3-80)

Henry County

Andover, *Andover Chapter House (American Woman's League Chapter Houses Thematic Resources)* Locust St., NW. (11-28-80)
Annawan, *Annawan Chapter House (American Woman's League Chapter Houses Thematic Resources)* 206 S. Depot St. (11-28-80)

Kane County

Batavia, *White, Louise, School*, Washington Ave. (11-7-80)
Batavia vicinity, *Campana Factory*, N of Batavia (Boundary decrease approved 12-18-80)
Elgin, *First Universalist Church*, 55 Villa St. (11-7-80)
Elgin vicinity, *Memorial Washington Reformed Presbyterian Church*, W of Elgin on W. Highland Ave. Rd. (11-19-80)
Wasco vicinity, *Camptown Town Hall*, W of Wasco at Town Hall Rd. and IL 64 (11-24-80)

Lake County

Highland Park, *Willits, Ward Winfield, House*, 1445 Sheridan Rd. (11-24-80)
Zion, *Zion Chapter House (American Woman's League Chapter Houses Thematic Resources)* 2715 Emmaus Ave. (11-28-80)

Macoupin County

Carlinville, *Carlinville Chapter House (American Woman's League Chapter Houses Thematic Resources)* 111 S. Charles St. (11-28-80)

Madison County

Alton, *Alton Chapter House (American Woman's League Chapter Houses Thematic Resources)* 509 Beacon St. (11-28-80)
Edwardsville, *Edwardsville Chapter House (American Woman's League Chapter Houses Thematic Resources)* 515 W. High St. (11-28-80)
Edwardsville vicinity, *Kuhn Station Site*, SE of Edwardsville (11-25-80)
Granite City vicinity, *Horseshoe Lake Mound and Village Site*, (11-26-80)
Marine, *Marine Chapter House (American Woman's League Chapter Houses Thematic Resources)* Silver St. (11-28-80)

Mercer County

Keithsburg, *United Presbyterian Church*, Main and 8th Sts. (11-7-80)

Morgan County

Jacksonville, *Grierson, Gen. Benjamin Henry, House*, 852 E. State St. (11-20-80)

Ogle County

Oregon, *Ogle County Courthouse*, Courthouse Sq. (9-10-81)

Peoria County

Peoria, *Madison Theatre*, 502 Main St. (11-21-80)

Richland County

Olney, *Elliott Street Historic District*, S. Elliott St. between Chestnut St. and South Ave. (11-26-80)

Sangamon County

Rochester, *Taft Farmstead*, SR 3 (11-20-80)
Rochester vicinity, *Miller, Joseph, House*, Buckhart Rd. (11-24-80)

Union County

Jonesboro vicinity, *St. Paulus Evangelisch Lutherischen Gemeinde*, S of Jonseboro off IL 127 (11-24-80)

Warren County

Monmouth, *Quinby, Ivory, House*, 605 N. 6th St. (11-20-80)

White County

Carmi, *Carmi Chapter House (American Woman's League Chapter Houses Thematic Resources)* 604 W. Main St. (11-28-80)

Will County

Joliet, *Joliet Municipal Airport*, 4000 W. Jefferson St. (12–10–80)
Joliet, *U.S. Post Office*, 150 N. Scott St. (8–20–81)
Lockport vicinity, *Stone Manor*, SE of Lockport (11–26–80)

INDIANA

Allen County

Cedarville vicinity, *Hursh Road Bridge (Bridge No. 38)* W of Cedarville on Hursh Rd. (6–4–81)
Fort Wayne, *Feustel, Robert M., House*, 4101 W. Taylor St. (11–7–80)
Fort Wayne, *Swinney, Thomas W., House*, 1424 W. Jefferson St. (4–27–81)

Cass County

Logansport, *Washington School*, 101 N. Cicott St. (3–2–81)

Dearborn County

Lawrenceburg, *Dearborn County Courthouse*, High and Mary Sts. (4–9–81)

DeKalb County

Spencerville, *Spencerville Covered Bridge*, SR 68 (4–2–81)

Delaware County

Muncie, *Kimbrough, Emily, Historic District*, Bounded by Monroe, East Washington, Hackley, and East Charles Sts. (11–13–80)

Harrison County

Laconia vicinity, *Kintner-Withers House*, S of Laconia on Kintner Bottoms Rd. (11–28–80)

Henry County

New Castle, *Henry County Courthouse*, Courthouse Sq. (4–2–81)

Howard County

Kokomo, *Kokomo City Building*, 221 W. Walnut St. (6–4–81)

Jay County

Portland, *Jay County Courthouse*, U.S. 27 (5–12–81)

Jefferson County

Hanover, *Crowe-Garritt House*, 172 Crowe St. (11–10–80)

Johnson County

Franklin, *Johnson County Courthouse Square*, Court House Sq. (4–16–81)

Lake County

Cedar Lake, *Lassen Hotel*, 7808 W. 138th Pl. (7–7–81)

Lawrence County

Mitchell, *Mitchell Opera House*, 7th and Brooks Sts. (4–2–81)
Williams vicinity, *Williams Bridge*, SW of Williams (11–9–81)

Marion County

Indianapolis, *Majestic Building*, 47 S. Pennsylvania St. (11–20–80)
Indianapolis, *McCormick Cabin Site*, Off U.S. 40 (5–28–81)
Indianapolis, *Somer, Augusta, House*, 29 E. McCarty St. (11–28–80)
Indianapolis, *Whittier, John Greenleaf, School, No. 33*, 1119 N. Sterling St. (5–28–81)

Marshall County

Plymouth, *East LaPorte Street Footbridge*, Spans Yellow River (7–23–81)
Plymouth, *Plymouth Fire Station*, 220 N. Center St. (7–9–81)

Morgan County

Martinsville, *Martinsville High School Gymnasium*, 759 S. Main St. (7–30–81)

Noble County

Albion, *Noble County Courthouse*, Courthouse Sq. (5–12–81)

Perry County

Rome, *Old Perry County Courthouse*, Town Sq. (5–12–81)

Posey County

New Harmony, *Scholle, Mattias, House*, Tavern and Brewery Sts. (3–2–81)

Switzerland County

Vevay vicinity, *Wright, Thomas T., House*, SW of Vevay on IN 56 (12–10–80)

Tippecanoe County

Lafayette, *Downtown Lafayette Historic District*, Roughly bounded by 2nd, Ferry, 6th and South Sts. (11–28–80)
Lafayette, *Mars Theatre*, 11 N. 6th St. (1–26–81)

Vanderburgh County

Evansville, *Washington Avenue Historic District*, Roughly bounded by Madison and Grand Aves., E. Gum and Parett Sts. (11–28–80)

Wabash County

Roann vicinity, Roann Covered Bridge, 4th, N of Roann on SR 700W (8–6–81)

Wayne County

Richmond, *Richmond Gas Company Building*, 100 E. Main St. (6–25–81)
Richmond, *Starr Piano Company Warehouse and Administration Building*, 300 S. 1st St. (6–18–81)

IOWA

COUNTY COURTHOUSES IN IOWA THEMATIC RESOURCES. Reference—see individual listings under Adair, Allamakee, Appanoose, Audubon, Benton, Boone, Calhoun, Chickasaw, Clay, Clayton, Clinton, Crawford, Dallas, Davis, Decatur, Delaware, Dickinson, Dubuque, Fayette, Franklin, Fremont, Greene, Grundy, Hancock, Hardin, Harrison, Henry, Howard, Ida, Iowa, Jackson, Jasper, Jefferson, Johnson, Keokuk, Lee, Louisa, Lucas, Lyon, Madison, Mahaska, Marion, Marshall, Mitchell, Monona, Monroe, Montgomery, Muscatine, O'Brien, Osceola, Page, Plymouth, Pocahontas, Polk, Pottawattamie, Poweshiek, Ringgold, Sac, Shelby, Sioux, Tama, Taylor, Van Buren, Wapello, Washington, Webster, Winnebago, Woodbury, Worth and Wright Counties.

Adair County

Greenfield, *Adair County Courthouse (County Courthouses in Iowa Thematic Resources)* Iowa Ave. and 1st St. (7–2–81)

Allamakee County

Waukon, *Allamakee County Courthouse (County Courthouses in Iowa Thematic Resources)* 107 Allamakee St. (previously listed in the National Register 4–11–77)

Appanoose County

Centerville, *Appanoose County Courthouse (County Courthouses in Iowa Thematic Resources)* Van Buren and N. 12th St. (7–2–81)

Audubon County

Exira, *Audubon County Courthouse (County Courthouses in Iowa Thematic Resources)* Washington and Kilworth Sts. (previously listed in the National Register 7–26–77)

Benton County

Vinton, *Benton County Courthouse (County Courthouses in Iowa Thematic Resources)* E. 4th St. (previously listed in the National Register 10–8–76)

Boone County

Boone, *Boone County Courthouse (County Courthouses in Iowa Thematic Resources)* N. State and W. 2nd Sts. (7–2–81)

Calhoun County

Rockwell City, *Calhoun County Courthouse (County Courthouses in Iowa Thematic Resources)* Court and 4th Sts. (7–2–81)

Chickasaw County

New Hampton, *Chickasaw County Courthouse (County Courthouses in Iowa Thematic Resources)* Prospect St. (7–2–81)

Clay County

Spencer, *Clay County Courthouse (County Courthouses in Iowa Thematic Resources)* W. 4th St. and 3rd Ave. (7–2–81)

Clayton County

Elkader, *Clayton County Courthouse (County Courthouses in Iowa Thematic Resources)* 111 High St. (previously listed in the National Register 10–8–76)

Clinton County

Clinton, *Clinton County Courthouse (County Courthouses in Iowa Thematic Resources)* Between 6th and 7th Aves. (7–2–81)
Delmar, *Delmar Calaboose*, Vane St. (3–19–81)

Crawford County

Denison, *Crawford County Courthouse (County Courthouses in Iowa Thematic Resources)* Broadway (7–2–81)

Dallas County

Adel, *Dallas County Courthouse (County Courthouses in Iowa Thematic Resources)* Town Sq. (previously listed in the National Register 11–26–73)

Davis County

Bloomfield, *Davis County Courthouse (County Courthouses in Iowa Thematic*

Resources) Bloomfield Town Sq. (previously listed in the National Register 5–3–74)

Decatur County

Leon, *Decatur County Courthouse (County Courthouses in Iowa Thematic Resources)* 9th St. (7–2–81)

Delaware County

Manchester, *Delaware County Courthouse (County Courthouses in Iowa Thematic Resources)* Main St. (7–2–81)

Dickinson County

Spirit Lake, *Dickinson County Courthouse (County Courthouses in Iowa Thematic Resources)* Hill Ave. (7–2–81)

Dubuque County

Dubuque, *Dubuque County Courthouse (County Courthouses in Iowa Thematic Resources)* 720 Central Ave. (previously listed in the National Register 6–23–71)

Fayette County

West Union, *Fayette County Courthouse (County Courthouses in Iowa Thematic Resources)* Pine St. (7–2–81)

Franklin County

Hampton, *Franklin County Courthouse (County Courthouses in Iowa Thematic Resources)* Central Ave. and 1st St., NW. (previously listed in the National Register 8–13–75)

Hampton vicinity, *Maysville Schoolhouse,* S of Hampton (6–17–81)

Fremont County

Sidney, *Fremont County Courthouse (County Courthouses in Iowa Thematic Resources)* Clay St. (7–2–81)

Greene County

Jefferson, *Greene County Courthouse (County Courthouses in Iowa Thematic Resources)* E. Lincoln Way and Chestnut Sts. (previously listed in the National Register 12–14–78)

Grundy County

Grundy Center, *Grundy County Courthouse (County Courthouses in Iowa Thematic Resources)* Grundy Ave. (7–2–81)

Hancock County

Garner, *Hancock County Courthouse (County Courthouses in Iowa Thematic Resources)* State St. (7–2–81)

Hardin County

Alden, *Alden Public Library,* 1012 Water St. (3–17–81)

Eldora, *Hardin County Courthouse (County Courthouses in Iowa Thematic Resources)* Edgington Ave. (7–2–81)

Harrison County

Logan, *Harrison County Courthouse (County Courthouses in Iowa Thematic Resources)* 7th St. (7–2–81)

Henry County

Mount Pleasant, *Henry County Courthouse (County Courthouses in Iowa Thematic Resources)* Washington St. (7–2–81)

Howard County

Cresco, *Cresco Opera House,* 115 W. 2nd Ave. (8–27–81)

Cresco, *Howard County Courthouse (County Courthouses in Iowa Thematic Resources)* Elm St. (7–2–81)

Ida County

Ida Grove, *Ida County Courthouse (County Courthouses in Iowa Thematic Resources)* 401 Moorehead St. (previously listed in the National Register 3–15–74)

Iowa County

Marengo, *Iowa County Courthouse (County Courthouses in Iowa Thematic Resources)* Court Ave. (7–2–81)

Jackson County

Bellevue, *Jackson County Courthouse (County Courthouses in Iowa Thematic Resources)* Off IA 62 (7–2–81)

Jasper County

Newton, *Jasper County Courthouse (County Courthouses in Iowa Thematic Resources)* 1st Ave. (7–2–81)

Jefferson County

Fairfield, *Jefferson County Courthouse (County Courthouses in Iowa Thematic Resources)* Court St. (7–2–81)

Johnson County

Iowa City, *Johnson County Courthouse (County Courthouses in Iowa Thematic Resources)* S. Clinton St. (previously listed in the National Register 3–27–74)

Keokuk County

Sigourney, *Keokuk County Courthouse (County Courthouses in Iowa Thematic Resources)* Main St. (7–2–81)

What Cheer, *What Cheer City Hall,* Barnes and Washington Sts. (8–27–81)

Lee County

Fort Madison, *Lee County Courthouse (County Courthouses in Iowa Thematic Resources)* 701 Avenue F (previously listed in the National Register 9–30–76)

Louisa County

Wapello, *Louisa County Courthouse (County Courthouses in Iowa Thematic Resources)* Main St. (7–2–81)

Lucas County

Chariton, *Lucas County Courthouse (County Courthouses in Iowa Thematic Resources)* Courthouse Sq. (7–2–81)

Lyon County

Rock Rapids, *Lyon County Courthouse (County Courthouses in Iowa Thematic Resources)* 3rd and Story Sts. (previously listed in the National Register 10–1–79)

Madison County

Winterset, *Madison County Courthouse (County Courthouses in Iowa Thematic Resources)* City Sq. (previously listed in the National Register 8–13–81)

Mahaska County

Oskaloosa, *Mahaska County Courthouse (County Courthouses in Iowa Thematic Resources)* Market St. and 2nd Ave. (7–2–81)

Marion County

Knoxville, *Marion County Courthouse (County Courthouses in Iowa Thematic Resources)* Main St. (7–2–81)

Marshall County

Marshalltown, *Marshall County Courthouse (County Courthouses in Iowa Thematic Resources)* Courthouse Sq. (previously listed in the National Register 11–21–72)

Mitchell County

Osage, *Mitchell County Courthouse (County Courthouses in Iowa Thematic Resources) 500 State St.* (previously listed in the National Register 8–29–77)

Monona County

Onawa, *Monona County Courthouse (County Courthouses in Iowa Thematic Resources)* Iowa Ave. (7–2–81)

Monroe County

Albia, *Monroe County Courthouse (County Courthouses in Iowa Thematic Resources)* Main St. (7–2–81)

Montgomery County

Red Oak, *Montgomery County Courthouse (County Courthouses in Iowa Thematic Resources)* Coolbaugh and 2nd Sts. (7–2–81)

Muscatine County

Muscatine, *Muscatine County Courthouse (County Courthouses in Iowa Thematic Resources)* 3rd St. (7–2–81)

O'Brien County

Primghar, *O'Brien County Courthouse (County Courthouses in Iowa Thematic Resources)* Fir Ave. (7–2–81)

Osceola County

Sibley, *Osceola County Courthouse (County Courthouses in Iowa Thematic Resources)* 3rd Ave. and 8th St. (7–2–81)

Page County

Clarinda, *Page County Courthouse (County Courthouses in Iowa Thematic Resources)* Main St. (7–2–81)

Plymouth County

LeMars, *Plymouth County Courthouse (County Courthouses in Iowa Thematic Resources) E. 3rd Ave. (7–2–81)*

Pocahontas County

Pocahontas, *Pocahontas County Courthouse (County Courthouses in Iowa Thematic Resources)* Court Sq. (7–2–81)

Polk County

Des Moines, *Polk County Courthouse (County Courthouses in Iowa Thematic Resources)* 6th and Mulberry Sts. (previously listed in the National Register 4–30–79)

Pottawattamie County

Avoca, *Pottawattamie County Sub Courthouse (County Courthouses in Iowa Thematic Resources)* Elm St. (7–2–81)

Poweshiek County

Montezuma, *Poweshiek County Courthouse (County Courthouses in Iowa Thematic Resources)* Town Sq. (7–2–81)

Ringgold County

Mount Ayr, *Ringgold County Courthouse (County Courthouses in Iowa Thematic Resources)* Madison St. (7–2–81)

Sac County

Sac City, *Sac County Courthouse (County Courthouses in Iowa Thematic Resources)* Main St. (7–2–81)

Shelby County

Harlan, *Shelby County Courthouse (County Courthouses in Iowa Thematic Resources)* 7th and Courts Sts. (previously listed in the National Register 11–14–78)

Sioux County

Orange City, *Sioux County Courthouse (County Courthouses in Iowa Thematic Resources)* Off IA 10 (previously listed in the National Register 4–11–77)

Tama County

Toledo, *Tama County Courthouse (County Courthouses in Iowa Thematic Resources)* State St. (7–2–81)
Toledo, *Tama County Jail,* Broadway and State Sts. (8–27–81)

Taylor County

Bedford, *Taylor County Courthouse (County Courthouses in Iowa Thematic Resources)* Court Ave. (7–2–81)

Van Buren County

Keosauqua, *Van Buren County Courthouse (County Courthouses in Iowa Thematic Resources)* 904 4th St. (previously listed in the National Register 11–9–77)

Wapello County

Ottumwa, *Wapello County Courthouse (County Courthouses in Iowa Thematic Resources)* Court St. (7–2–81)

Washington County

Washington, *Washington County Courthouse (County Courthouses in Iowa Thematic Resources)* N. B Ave. (7–2–81)

Webster County

Fort Dodge, *Webster County Courthouse (County Courthouses in Iowa Thematic Resources)* 701 Central Ave. (7–2–81)

Winnebago County

Forest City, *Winnebago County Courthouse (County Courthouses in Iowa Thematic Resources)* J St. (7–2–81)

Woodbury County

Sioux City, *Woodbury County Courthouse (County Courthouses in Iowa Thematic Resources)* 7th and Douglas Sts. (previously listed in the National Register 12–18–73)

Worth County

Northwood, *Worth County Courthouse (County Courthouses in Iowa Thematic Resources)* 921 Central Ave. (7–2–81)
Northwood, *Worth County Courthouse (County Courthouses in Iowa Thematic Resources)* Central Ave. between 10th and 11th Sts. (7–2–81)

Wright County

Clarion, *Wright County Courthouse (County Courthouses in Iowa Thematic Resources)* Central Ave. (7–2–81)

KANSAS

Franklin County

Ottawa, *Ottawa Library,* 5th and Main Sts. (12–1–80)

Geary County

Junction City, *Bartell House,* 6th and Washington Sts. (12–1–80)
Junction City, *Old Junction City High School,* Adams and 6th Sts. (4–24–81)

Gove County

Grainfield, *Grainfield Opera House,* Main and 3rd Sts. (11–28–80)

Johnson County

Olathe, *Pickering, I. O., House,* 507 W. Park St. (12–1–80)

Lyon County

Emporia, *Old Emporia Public Library,* 118 E. 6th St. (11–2–81)

Marshall County

Marysville, *Koester Block Historic District,* Between 9th, 10th, Elm and Broadway Sts. (12–5–80)

Nemaha County

Baileyville vicinity, *St. Mary's Church,* NE of Baileyville (12–5–80)

Riley County

Manhattan, *Anderson Hall,* Kansas State University Campus (11–28–80)
Manhattan, *Platt, Jeremiah, House,* 2005 Claflin Rd. (5–20–81)
Manhattan, *Woman's Club House,* 900 Poyntz Ave. (11–28–80)

Sedgwick County

Wichita, *Orpheum Theater and Office Building,* 200 N. Broadway St. (11–28–80)

Shawnee County

Topeka, *Grand Opera House,* 615 Jackson St. (11–28–80)

Wyandotte County

Kansas City, *Gates, Judge Louis, House,* 4146 Cambridge St. (12–1–80)

KENTUCKY

HISTORIC FIREHOUSES OF LOUISVILLE THEMATIC RESOURCES. Reference—see individual listings under Jefferson County.

Bourbon County

Paris vicinity, *Kennedy, Thomas, House,* SE of Paris on Paris-Winchester Rd. (12–8–80)

Boyle County

Danville vicinity, *Boyle, Judge John, House,* N of Danville on Bellows Mill Rd. (11–25–80)

Calloway County

Murray, *Linn, Will, House,* 103 N. 6th St. (12–4–80)

Campbell County

Newport, *St. Paul's Episcopal Church,* 15 Court Pl. (11–25–80)

Carroll County

Carrollton, *Baker, Paschal Todd, House,* 406 Highland Ave. (11–25–80)

Clark County

Winchester, *CLARK COUNTY MULTIPLE RESOURCE AREA (ADDITIONS).* This area includes: *Clinkenbeard, William, House,* Old Paris Pike; *Martin-Holder-Bush-Hampton Mill,* Lower Howard's Creek; *Pruett, W., House,* Ecton Rd.; *Scobee, Robert, House,* Off SR 60; *Stripp House,* Van Meter Rd.; and *Taylor, F., Mill,* Lower Howard's Creek (11–20–80)

Edmonson County

Brownsville vicinity, *Ford, William, House,* S of Brownsville on U.S. 31W (11–28–80)

Fayette County

Lexington, *Bell Court Neighborhood Historic District,* Roughly bounded by RR tracks, Main St., Boonesboro and Walton Aves. (12–8–80)
Lexington, *Chandler Normal School Building and Webster Hall,* 548 Georgetown St. (12–4–80)
Lexington, *Clark, John, House, (Auvergne),* Tates Creek Pk. (11–25–80)
Lexington, *DeLong Agricultural Implements Warehouse,* Patterson St. (11–25–80)
Lexington, *McCauley, John, House,* 319 Lexington Ave. (12–4–80)
Lexington, *Woodward Heights Neighborhood Historic District,* Roughly bounded by High, Merino, and Pine Sts. (12–1–80)
Lexington vicinity, *Cave Place,* W of Lexington (12–5–80)

Floyd County

Wheelwright, *Wheelwright Commercial District,* Main St. (11–19–80)

Greenup County

Portsmouth vicinity, *Portsmouth Earthworks, Group A (15 Gp 1),* SW of S. Portsmouth (12–4–80)

Henry County

Eminence, *Crutcher House,* Mulberry Pike (12–8–80)

Hopkins County

Nebo vicinity, *Archeological Site 15 HK 79,* SW of Nebo (12–4–80)

Jefferson County

JEFFERSON COUNTY MULTIPLE RESOURCE AREA. This area includes: Anchorage, *Anchorage Historic District,* KY 146; *Anchorage, The,* 804 Evergreen Rd.; *Bayless House,* 1116 Bellewood Rd.; *Coldeway House,* 12005 E. Osage Rd; *Courtney, James, House,* 12006 Hazelwood Rd.; *Hannah House,* 1306 Evergreen Rd.; *Hillcrest,* 11600 Owl Creek Rd.; *Jones Estate,* 1905 Stonegate Rd.; *Marshall, John, Sr., House,* 12106 Osage Rd.; *May, Robert, House,* 11104 Owl Creek Rd.; *Nash-McDonald House,* 1306 Bellewood Rd.; *Nock House,* 1401 Elm Rd.; *Railway Depot,* 1500 Evergreen Rd.; *St. Lukes Church,* 1204

Maple Lane; *Shallcross*, 11804 Ridge Rd.; *Simrall-Warfield House*, 1509 Cold Spring Rd.; *Thompson, James, House*, 1400 Walmut Land; *Webb, John, House*, 12200 Lucas Lane; *Winston's, Dr., House*, 11906 Ridge Rd.; Buechel, *Bannon, Patrick, House*, 4518 Bardstown Rd; *Taggart House*, 5000 Bardstown Rd.; *Stivers, Zodia, House*, 3701 Montclair, Fern Creek, *Bates, Levin, House*, 7300 Bardstown Rd.; *Hite, Abraham, House*, Starlight Lane; *Hite-Chenoweth House*, 4219 Starlight Lane; *Snapp House*, 8300 Bardstown Rd.; Fisherville, *East Cedar Hill Institute*, Clark Station Rd.; *Moore, Simeon, House*, 17317 Taylorsville Rd.; Harrods Creek, *Barber-Barbour House*, 6415 Transylvania Ave.; *Bingham-Hilliand Doll House*, 5001 Avish Lane; *Chrisler House*, 4506 Upper River Rd.; Jeffersontown, *Beech Lawn*, 8000 Six Mile Lane; *Bryan, Floore House*, Taylorsville Rd.; *Funk, Harriet, House*, 9316 Hurstbourne; *Funk, James H., House*, 9000 Taylorsville; *Leatherman House*, 3606 College Dr.; *Stucky House*, 3504 Marlin Dr.; *Tucker, Hazael, House*, 2406 Tucker Station Rd.; *Tway House; Yenowine, George, House*, 1021 Watterson Trail; Louisville, *Cardinal Hill Reservoir*, Cardinal Hill Rd.; Lyndon, *Bellevoir-Ormsby Village*, Whipps Mill Rd.; *Moghera Glass-Ormsby Hall*, 8521 La Grange Rd.; *Williams, Abraham L., L & N Guest House*, Murphy Lane; Middletown *Abell House*, 12210 Old Shelbyville Rd; *Bull, William, House*, 11918 Old Shelbyville Rd; *Frank, Henry, House*, Madison Ave.; *Middletown United Methodist Church*, Madison and Main Sts.; Okolona, *Cooper Memorial Church*, 9900 Preston Hwy.; Prospect, *Trigg, James, House*, Covered Bridge Rd; *Wilhoyte House*, Covered Bridge Rd.; St. Matthews, *Blankenbaker Station*, 21 Poplar Hill Rd.; *Chenoweth House*, 255 Chenoweth Lane; Valley Station, *Aydelott House*, 6814 Bethany Lane; *Lewiston House*, 4902 Ranchland (12–5–80)

Louisville, *Brandeis, Albert S., Elementary School*, 1001 S. 26th St. (12–8–80)

Louisville, *Broadway Temple A.M.E. Zion Church*, 662 S. 13th St. (12–8–80)

Louisville, *Chestnut Street Baptist Church*, 912 W. Chestnut St. (12–3–80)

Louisville, *Crescent Hill Branch Library*, 2762 Frankfort Ave. (3–10–81)

Louisville, *Engelhard House*, 1080 Baxter Ave. (12–5–80)

Louisville, *Fire Department Headquarters (Historic Firehouses of Louisville Thematic Resources)* 1135 W. Jefferson St. (11–7–81)

Louisville, *Firehouse No. 13 (Historic Firehouses of Louisville, Expanded Thematic Resources)* 100 N. 34th St. (3–10–81)

Louisville, *Hook and Ladder Company No. 2 (Historic Firehouses of Louisville Thematic Resources)* 221 S. Hancock St. (11–7–80)

Louisville, *Hook and Ladder Company No. 3 (Historic Firehouses of Louisville Thematic Resources)* Frankfort Ave. and Pope St. (11–7–80)

Louisville, *Hook and Ladder Company No. 4 (Historic Firehouses of Louisville Thematic Resources)* 2301 Jefferson St. (11–7–80)

Louisville, *Hook and Ladder Company No. 5 (Historic Firehouses of Louisville Thematic Resources)* 1824 Garland Ave. (11–7–80)

Louisville, *New Exterprise Tobacco Warehouse*, 925 W. Main St. (12–4–80)

Louisville, *Rose Hill*, 1835 Hampden Ct. (12–3–80)

Louisville, *St. Peter's German Evangelical Church*, 1231 W. Jefferson St. (12–4–80)

Louisville, *Shelby Park Branch Library*, 600 E. Oak St. (12–3–80)

Louisville, *South Central Bell Company Office Building*, 521 W. Chestnut St. (12–3–80)

Louisville, *Steam Engine Company No. 2 (Historic Firehouses of Louisville Thematic Resources)* 617–621 W. Jefferson St. (11–7–80)

Louisville, *Steam Engine Company No. 3 (Historic Firehouses of Louisville Thematic Resources)* 802–804 E. Main St. (11–7–80)

Louisville, *Steam Engine Company No. 4 (Historic Firehouses of Louisville Thematic Resources)* 1024 Logan St. (11–7–80)

Louisville, *Steam Engine Company No. 4 (Historic Firehouses of Louisville Thematic Resources)* 1617 W. Main St. (11–7–80)

Louisville, *Steam Engine Company No. 7 (Historic Firehouses of Louisville Thematic Resources)* 821 S. 6th St. (11–7–80)

Louisville, *Steam Engine Company No. 10 (Historic Firehouses of Louisville Thematic Resources)* 1419 E. Washington (11–7–80)

Louisville, *Steam Engine Company No. 11 (Historic Firehouses of Louisville Thematic Resources)* 1122 Rogers (11–7–80)

Louisville, *Steam Engine Company No. 18 (Historic Firehouses of Louisville Thematic Resources)* 2600 S. 4th St. (11–7–80)

Louisville, *Steam Engine Company No. 20 (Historic Firehouses of Louisville Thematic Resources)* 1330 Bardstown Rd. (11–7–80)

Louisville, *Steam Engine Company No. 20 (Historic Firehouses of Louisville Thematic Resources)* 1735 Bardstown Rd. (11–7–80)

Louisville, *Steam Engine Company No. 21 (Historic Firehouses of Louisville Thematic Resources)* 1761 Frankfort Ave. (11–7–80)

Louisville, *Steam Engine Company No. 22 (Historic Firehouses of Louisville Thematic Resources)* 37th and Broadway (11–7–80)

Lyon County

Eddyville, *Old Eddyville Historic District*, Off KY 730 (4–30–81)

Taylor County

Campbellsville, *Merchant's Hotel*, 102 E. Main St. (11–25–80)

Trigg County

Cadiz vicinity, *Dawson, Thomas, House*, S of Cadiz (12–1–80)

Warren County

WARREN COUNTY MULTIPLE RESOURCE AREA (ADDITIONS). This area includes: Bowling Green, *St. Joseph's District*, Roughly bounded by Gilbert and Potter Sts., Church and Brown's Lock Aves.; *Barren River L and N Railroad Bridge*, spans Barren River; *College Street Bridge*, Spans Barren River; *Curd-Moss House*, Off SR 68; *Davidson, A. C., House; Richardsville Road Bridge*, Spans Barren River; Woodburn vicinity, *Neale, William P., House*, N of Woodburn (11–26–80)

Woodford County

Versailles vicinity, *Lyne, Thomas, House*, S of Versailles on Smith Lane (11–28–80)

LOUISIANA

Allen Parish

Oberlin, *Allen Parish Courthouse*, 5th St. (6–3–81)

Avoyelles Parish

Evergreen, *Bayou Rouge Baptist Church*, Church and College Sts. (12–3–80)

Caddo Parish

Shreveport, *Line Avenue School*, 1800 Line Ave. (6–3–81)

Caldwell Parish

Columbia vicinity, *Breston Plantation House*, N of Columbia (11–22–80)

Catahoula Parish

Harrisonburg, *Sargent House*, Catahoula St. (12–3–80)

Claiborne Parish

Homer, *Claiborne Parish Courthouse*, Courthouse Sq. (10–7–81)

East Baton Rouge Parish

Baton Rouge, *Manship House*, 2250 Kleinert Ave. (11–21–80)

Baton Rouge, *McKinley High School*, 1500 East Blvd. (11–16–81)

Baton Rouge, *Mount Hope Plantation House*, 8151 Highland Rd. (12–3–80)

Scotlandville, *Southern University Archives Building*, Southern University campus (6–11–81)

East Feliciana Parish

Jackson, *Jackson Historic District*, Roughly bounded by Institute Dr., LA 314, Horton and Race Sts. (12–4–80)

Jackson vicinity, *Shades, The*, NE of Jackson (11–6–80)

Franklin Parish

Baskin, *Baskin High School Building*, LA 857 (10–7–81)

Lafayette Parish

Lafayette, *Holy Rosary Institute*, 421 Carmel Ave. (12–3–80)

Natchitoches County

Natchitoches, *Natchitoches Historic District (City Hall)*, (boundary increase approved 11–25–80)

Orleans Parish

New Orleans, *Bullitt-Longnecker House*, 3627 Carondelet St. (10–1–81)

Ouachita Parish

Monroe, *Ouachita Parish High School*, 500 S. Grand St. (4–9–81)

Pointee Coupee Parish

New Roads, *Pointe Coupee Parish Courthouse*, Main St. (10–7–81)

Rapides Parish

Alexandria, *Rapides Opera House*, 1125 3rd St. (6–11–81)

Alexandria, *St. Francis Xavier Cathedral*, 626 4th St. (12–3–80)

Cheneyville vicinity, *Walnut Grove*, E of Cheneyville (11–21–80)

Glenmora vicinity, *Britt Place*, E of Glenmora on Lake Cocodrie Rd. (11–21–80)
Pineville, *Fort Randolph*, Off U.S. 165 (6–1–81)
Pineville, *Fort Buhlow*, Off U.S. 165 (6–1–81)

Red River Parish

Coushatta, *Planter's Hotel*, Carroll St. (12–3–80)

St. James Parish

Convent, *Poche', Judge Felix, Plantation House*, River Rd. (12–3–80)

St. Landry Parish

Grand Coteau, *Grand Coteau Historic District*, LA 93 (11–25–80)

St. Mary Parish

Franklin, *St. Mary's Episcopal Church*, 805 1st St. (11–21–80)
Morgan City, *Morgan City City Hall and Courthouse*, Everett and 1st Sts. (4–9–81)

Tensas Parish

St. Joseph, *St. Joseph Historic District*, Roughly bounded by Panola Ave., Front, Hickory, 4th, and Pauline Sts. (12–10–80)

Webster Parish

Minden, *Webster Parish Library Building*, 521 East-West St. (12–10–80)

West Feliciana Parish

St. Francisville vicinity, *Rosale Plantation*, N of St. Francisville off U.S. 61 (12–8–80)

MAINE

Androscoggin County

Auburn, *Munore, Horace, House*, 123 Pleasant St. (11–10–80)

Cumberland County

North Bridgton, *Farnsworth House*, SR 17 (11–14–80)
Portland, *Maine Historical Society*, 485 Congress St. (11–17–80)
Westbrook, *Walker Memorial Library*, 800 Main St. (11–10–80)

Franklin County

Phillips, *Maine Woods Office*, Main St. (11–10–80)
Strong, *Porter-Bell-Brackley Estate*, Lower Main St. (11–10–80)

Hancock County

Blue Hill, *Barncastle*, South St. (11–10–80)
Blue Hill, *Blue Hill Historic District*, ME 15, ME 172, ME 176, and ME 177 (12–8–80)

Kennebec County

Winthrop vicinity, *Lund, Jon, Site*, SE of Winthrop (11–21–80)

Knox County

Rockland, *Rockland Breakwater Lighthouse*, Rockland Harbor (3–20–81)

Lincoln County

Jefferson, *Jackson, Dr. F. W., House*, ME 32 (11–10–80)

Oxford County

Andover, *Andover Public Library*, Church St. (1–27–81)
North Fryeburg vicinity, *Wiley, Benjamin, House*, SE of North Fryeburg on Fish St. (11–10–80)

Penobscot County

Stetson, *Stetson Union Church*, ME 222 (7–15–81)

Somerset County

Embden vicinity, *Hodgdon Site (Maine Archeological Survey No. 69–4)* (4–23–80)
Skowhegan vicinity, *Weston, Samuel, Homestead*, S of Skowhegan on U.S. 201 (11–10–80)

York County

Kennebunkport vicinity, *Maine Trolley Cars*, Seashore Trolley Museum (11–14–80)

MARYLAND

Allegany County

Cumberland, *First Baptist Church*, 212 Bedford St. (11–10–80)
North Branch and vicinity, *Western Maryland Railway Right-of-Way, Milepost 126 to Milepost 160* (also in Washington County, MD and Morgan County, WV) (7–23–81)

Baltimore (independent city)

Wilkens-Robins Building, 308–312 W. Pratt St. (12–3–80)

Carroll County

Eldersburg vicinity, *Brown, Moses, House*, SE of Eldersburg at 7604 Ridge Rd. (12–11–80)
Taneytown, *Rudisel, Ludwick, Tannery House*, 65 Frederick St. (11–10–80)
Union Bridge vicinity, *Hopewell*, Pearre and Clemsonville Rds. (12–8–80) (also in Frederick County)

Frederick County

HOPEWELL. Reference—see Carroll County
New Market vicinity, *Nelson, Henry, House*, N of New Market (12–4–80)

Hartford County

Creswell vicinity, *Fair Meadows*, S of Creswell on Creswell Rd. (11–25–80)

Kent County

Rock Hall vicinity, *Trumpington*, S of Rock Hall on MD 445 (11–10–80)

Montgomery County

Glen Echo, *Carrousel at Glen Echo Park*, MacArthur Blvd. (7–4–80)
Glen Echo, *Chautauqua Tower*, Glen Echo Park (7–4–80)
Rockville, *Bingham-Brewer House*, 307 Great Falls Rd. (11–24–80)

Prince Georges County

Bowie, *Williams Plains*, MD 3 (11–28–80)
Greenbelt, *Greenbelt Historic District*, Off MD 193 (11–25–80)

Queen Anne's County

Centreville, *Captain's Houses*, Corsica St. (11–17–80)

Talbot County

Easton vicinity, *Old Bloomfield*, W of Easton on Bloomfield Rd. (12–3–80)
St. Michaels, *Cannonball House*, Mulberry St. (12–3–80)

Washington County

WESTERN MARYLAND RAILWAY RIGHT-OF-WAY, MILEPOST 126 TO MILEPOST 160. Reference—see Allegany County

MASSACHUSETTS

Barnstable County

Barnstable, *Barnstable County Courthouse*, Main St. (6–11–81)
Bourne, *Briggs, George I., House*, Sandwich Rd. (9–10–81)
West Yarmouth, *Baxter Mill*, MA 28 (8–27–81)

Bristol County

Fairhaven, *Fairhaven High School*, Huttleston Ave. (1–22–81)
Fairhaven, *Fairhaven Town Hall*, Center St. (1–22–81)
Fall River, *Durfee, B.M.C., High School*, 289 Rock St. (6–11–81)

Essex County

Lynn, *Broad Street Historic District*, Marshall's Wharf (12–2–80)
Lynn, *Old Post Office Building*, 360 Washington St. (9–14–81)
Peabody, *Peabody Civic Center Historic District*, Chestnut, Church, Foster, Franklin, and Lowell Sts. (11–25–80)
Rockport, *Granite Keystone Bridge*, Granite St. (8–27–81)

Hampden County

Chicopee, *Polish National Home*, 136–144 Cabot St. (11–14–80)
Holyoke, *Holyoke Canal System*, Front and South St. and CT River (12–3–80)
Springfield, *Gunn and Hubbard Blocks*, 463–477 State St. (12–3–80)
Springfield, *Water Shops Armory*, 1 Allen St. (12–3–80)

Middlesex County

Malden, *Common Burying Ground at Sandy Bank*, Green St. (8–27–81)
Medford, *Salem Street Burying Ground*, Medford Sq. (8–27–81)
Melrose, *Beebe Estate*, 235 W. Foster St. (5–20–81)

Norfolk County

Walpole, *Walpole Town Hall*, Main St. (10–8–81)
Wellesley Hills, *Intermediate Building*, 324 Washington St. (8–27–81)
Weymouth, *Fogg Library*, 1 Columbian St. (6–11–81)
Weymouth, *Jefferson School*, 200 Middle St. (5–12–81)

Plymouth County

Hull, *Point Allerton Lifesaving Station*, Nantasket Ave. (6–11–81)
Norwell vicinity, *Tack Factory, The*, SW of Norwell at 49 Tiffany Rd. (12–3–80)

Suffolk County

Boston, *BOSTON THEATRE MULTIPLE RESOURCE AREA.* This area includes: *Beach-Knapp District*, Roughly bounded by Harrison Ave., Washington, Kneeland and Beach Sts.; *Liberty Tree District*, Roughly bounded by Harrison Ave., Washington, Essex and Beach Sts.; *Piano Row District*, Boston Common, Park Sq., Boylston Pl. and

Tremont St.; *West Street District*, West St.; *Boston Edison Electric Illuminating Company*, 25–39 Boylston St.; *Boston Young Men's Christian Union*, 48 Boylston St.; *Boylston Building*, 2–22 Boylston St.; *Dill Building*, 11–25 Stuart St.; *Hayden Building*, 681–683 Washington St.; *Metropolitan Theatre*, 252–272 Tremont St.; *Shubert, Sam S., Theatre*, 263–265 Tremont St.; Wilbur Theatre, *244–250 Tremont St.; Wirth, Jacob, Buildings*, 31–39 Stuart St. (12–9–80)

Boston, *Fields Corner Municipal Building*, 1 Arcadia St. (11–12–81)

Boston, *Oak Square School*, 35 Nonantum St. (11–10–80)

Boston, *Russia Wharf Buildings*, 518–540 Atlantic Ave., 270 Congress St. and 276–290 Congress St. (12–2–80)

Worcester County

Webster, *Eddy Block*, 119–131 Main St. and 4 Davis St. (12–3–80)

Webster, *Shumway Block*, 112–116 Main St. (12–3–80)

Webster, *Spauling Block*, 141–143 Main St. (12–3–80)

MICHIGAN

Baraga County

Skanee, *Arvon Township Hall* (7–30–81)

Barry County

Hastings, *Barry County Courthouse Complex*, 220 W. State St. (8–3–81)

Berrien County

Niles, *Chapin, Henry A., House*, 508 E. Main St. (7–30–81)

Dickinson County

Iron Mountain, *Chapin Mine Steam Pump Engine*, Kent St. (7–9–81)

Gogebic County

Bessemer, *Gogebic County Courthouse*, Moore St. (5–8–81)

Ironwood, *Ironwood City Hall*, McLeod Ave. and Norfolk St. (11–28–80)

Ironwood, *Memorial Building*, McLeod Ave. and Marquette St. (11–10–80)

Houghton County

Hancock, *Hancock Town Hall and Fire Hall*, 399 Quincy St. (6–1–81)

Lake Linden, *First Congregational Church*, 1st St. and M–26 (11–17–80)

Lake Linden, *Lake Linden Village Hall and Fire Station*, 401 Calumet Ave. (10–26–81)

South Range, *South Range Community Building*, Trimountain Ave. (4–9–81)

Macomb County

Mount Clemens, *Grand Trunk Western Railroad, Mount Clemens Station*, 198 Grand St. (10–26–81)

Marquette County

Ishpeming, *Ishpeming Municipal Building*, 100 E. Division St. (7–9–81)

Monroe County

Erie vicinity, *North Maumee Bay Archeological District* (12–5–80)

Monroe, *Weis Manufacturing Company*, Union and 7th Sts. (10–26–81)

Oakland County

Highland, *Highland United Methodist Church*, 205 W. Livingston Rd. (7–9–81)

Pontiac, *Eastern Michigan Asylum Historic District*, 140 Elizabeth Lake Rd. (3–20–81)

Ontonagon County

Ontonagon, *Ontonagon County Courthouse*, 601 Trap St. (11–14–80)

Saginaw County

Schultz Site (20SA2) Green Point Site (20SA1) Northeastern Saginaw County (12–8–78)

Schoolcraft County

Manistique, *Manistique Pumping Station*, Deer St. (10–26–81)

Shiawassee County

OWOSSO MULTIPLE RESOURCE AREA. This area includes: Owosso, *Mason Street Historic residential District*, Roughly bounded by Laverock Alley, Dewey, Hickory and Exchange Sts.; *Michigan Avenue-Genessee Street Historic Residential District*, Roughly bounded by Michigan Ave.; Shiawassee, Cass and Clinton Sts.; *Oliver Street Historic District*, Oliver St. between 3rd and Oak Sts., Williams and Goodhue Sts.; *West Town Historic Commercial and Industrial District*, Main St.; *Ayres, Nathan, House*, 604 N. Water St.; *Christian-Ellis House*, 600 N. Water St.; *Christian, Leigh, House*, 622 N. Ball St.; *Comstock, Elias, Cabin*, Curwood Castle Dr., and John St.; *Frieseke, Frederick, Birthplace and Boyhood Home*, 654 N. Water St.; *Gould, Amos, House*, 115 W. King St.; *Gould, Daniel, House*, 509 E. Main St.; *Gould, Ebenezer, House*, 603 W. Main St.; *House at 314 W. King St.; Jacobs, Eugene, House*, 220 W. King St.; *McCormick, Colin, House*, 222 E. Exchange St.; *Miner, Selden, House*, 418 W. King St.; *Old Miller Hospital*, 121 Michigan Ave.; *Opdyke, Sylvester, House*, 655 N. Pine St.; *Palmer, Albert, House*, 528–530 River St.; *Pardee, George, House*, 603 N. Ball St.; *Perrigo, George, House*, 213 N. Cedar St.; *Todd, Edwin, House*, 520 N. Adam St.; *Williams, Alfred, House*, 611 N. Ball St.; *Williams, Benjamin, House*, 628 N. Ball St.; *Woodward, Lee, and Sons Building*, 306 S. Elm St.; *Woodward, Woodward, Lyman, Company Workers' Housing*, 601 Clinton St.; *Woodward, Lyman, Furniture and Casket Company Building*, 216–222 Elm St. (11–4–80)

Washtenaw County

Ann Arbor, *Michigan Theater Building*, 521–609 E. Liberty St. (11–28–80)

Ypsilanti, *Ypsilanti Water Works Stand Pipe*, Summit and Cross Sts. (10–26–81)

Wayne County

Detroit, *Detroit Masonic Temple*, 500 Temple Ave. (11–28–80)

Detroit, *Lee Plaza Hotel*, 2240 W. Grand Blvd. (11–5–81)

Garden City, *Ford, Henry, Square House*, 29835 Beechwood Ave. (11–25–80)

Wexford County

Cadillac, *Shay Locomotive*, Cass St. (10–26–81)

MINNESOTA

Beltrami County

Bemidji, *Bemidji Public Library*, 426 Bemidji Ave. (11–25–80)

Crow Wing County

Crosby, *Crosby Railroad Depot*, Off MN 6 (11–25–80)

Hennepin County

Excelsior, *Excelsior Public School*, 261 School Ave. (11–13–80)

Wayzata, *Great Northern Railroad Depot*, 402 E. Lake St. (7–7–81)

Lincoln County

LINCOLN COUNTY MULTIPLE RESOURCE AREA. This area includes: Ivanhoe, *Lincoln County Courthouse and Jail*, Rotherwood St.; Lake Benton, *Lake Benton Opera House*, Benton St. (previously listed in the National Register 3–25–77); *Osbeck, Ernest, House*, 106 S. Fremont St.; Lake Benton vicinity, *Drammen Farmers' Club*, SR 13; Tyler, *Danebod*, Danebod Court (previously listed in the National Register 6–30–75); *Tyler Public School*, Stront St. (12–1–80)

Tyler, *Lincoln County Fairgrounds (Lincoln County Multiple Resource Area) (additions)* Strong and Marsh Sts. (12–2–80)

LeSueur County

LESUEUR COUNTY MULTIPLE RESOURCE AREA. This area includes: Elysian, *Elysian Public School*, 4th and Frank Sts.; *Elysian Water Tower*, Frank St.; Kasota, *Kasota Town Hall*, Hill and Rice Sts.; *Kasota Village Hall*, Cherry and Webster Sts.; Kasota vicinity, *Bridge No. 4846(1)*, N of Kasota on MN 22; Le Center, *LeSueur County Courthouse and Jail*, 88 S. Park Ave. and 130 S. Park Ave. (2–17–81)

Morrison County

Little Falls, *Little Falls Carnegie Library*, 108 3rd St. (11–3–80)

Olmstead County

Rochester, *Chicago Great Western Railroad Company Depot*, 19 2nd St., SE (12–4–80)

Rochester, *Rochester Armory*, 121 N. Broadway (12–2–80)

Rochester, *Whiting, Timothy A., House*, 225 1st Ave., NW (12–4–80)

Ramsey County

St. Paul, *Church of St. Agnes*, 548 Lafond Ave. (11–19–80)

St. Paul, *Rochat-Louise-Sauerwein Block*, 261–277 W. Seventh St. (11–19–80)

St. Paul, *Smith Avenue High Bridge (Bridge No. 5753)* Smith Ave. (8–6–81)

St. Paul, *Triune Masonic Temple*, 1898 Iglehart Ave. (11–13–80)

St. Louis County

Chisholm, *Saints Peter and Paul Ukrainian Catholic Church*, 530 Central Ave. (8–27–80)

Duluth, *Chester Terrace Apartments*, 1210–1232 E. 1st St. (11–19–80)

Eveleth, *Eveleth Recreation Building*, Off U.S. 53 (11–25–80)

Eveleth, *Park Hotel*, 222 Adams Ave. (11–25–80)

Hibbing, *Anderson House*, 1001 E. Howard St. (12–4–80)
Hibbing, *Butler, Emmett, House*, 2530 3rd Ave., W. (12–4–80)
Hibbing, *City Hall*, 21st St., E. and 4th Ave. (2–12–81)
Hibbing, *Mitchell-Tappan House*, 2125 4th Ave., E (12–2–80)
Hibbing, *Sons of Italy Hall*, 704 E. Howard St. (11–25–80)
Parkville, *Johnson, Old Otto, House*, 202 3rd Ave. (11–25–80)
Virginia, *Bailey House*, 816 S. 5th Ave. (12–4–80)

Wabasha County

Lake City, *Lake City City Hall*, 205 W. Center St. (6–16–81)

Wright County

WRIGHT COUNTY MULTIPLE RESOURCE AREA. This area includes: Albertville, *Albertville Roller Mill*, 5790 Main Ave., NE.; Clearwater, *Clearwater Masonic Lodge No. 28 (G.A.R. Hall No. 112)* Oak and Main Sts.; *First Congregational Church of Clearwater*, Bluff and Elm Sts.; *Webster, William W., House*, Spring and Linn Sts.; Cokato, *Bull, Henry C., House*, 195 E. 3rd St.; Cokato vicinity, *Titrud, Olof M., Round Barn*, SR 30; Delano, *Delano Village Hall*, 127 River St.; *Eagle Newspaper and Job Printing Office*, 300 Railroad Ave.; *Weldele House*, 309 River St.; Delano vicinity, *Franklin Township School House No. 48*, U.S. 12; Hanover, *Hanover Bridge*, Spans Crow River; Howard Lake, *Howard Lake City Hall*, 737, 739 and 741 6th St.; Howard Lake vicinity, *Marysville Swedesburg Lutheran Church*, SR 9; *Middleville Township Hall*, SR 6; Maple Lake vicinity, *St. Mark's Episcopal Chapel*, Off MN 24; Monticello, *Nicherson-Taroox House, Shed and Barn*, 514 E. Broadway; *Rand, Rufus, Summer House and Carriage Barn*, Washington St.; *Simpson Methodist Church and Educational Building*, 4th and Linn Sts.; Monticello vicinity, *Hanaford Farm*, Off SR 106; Montrose, *Hawkins, Dr. E. P., Clinic, Hospital and House*, Buffalo St.; Rockford vicinity, *Marsh, Peter J., Octagon Barn*, Off SR 14; St. Michael, *St. Michael's Catholic Church*, Central Ave. and Main St. (12–11–79)

Yellow Medicine County

Canby, *Canby Commercial District*, U.S. 75 and MN 68 (11–25–80)

MISSISSIPPI

MISSISSIPPI POST OFFICES 1931–1941 THEMATIC RESOURCES. Reference—see individual listings under Attala, Bolivar, Chickasaw, Copiah, Forrest, Hancock, Holmes, Humphreys, Lamar, Leake, Lowndes, Marion, Monroe, Montgomery, Neshoba, Newton, Noxubee, Panola, Pearl River, Pike, Pontotoc, Prentiss, Scott, Sunflower, Tallahatchie, Tippah, Union, Walthall, Washington, Wayne, and Winston Counties.

Adams County

Natchez vicinity, *Mount Olive*, NE of Natchez (11–28–80)
Natchez vicinity, *Saragossa*, S of Natchez on Saragossa Rd. (11–24–80)

Bolivar County

Cleveland, *U.S. Post Office (Mississippi Post Offices 1931–1941 Thematic Reources)* 301 S. Sharpe Avenue (4–7–81)
Rosedale, *Grace Episcopal Church*, 203 Main St. (12–11–80)

Hancock County

Bay St. Louis, *BAY ST. LOUIS MULTIPLE RESOURCE AREA*. This area includes: Bay St. Louis, *Beach Boulevard Historic District*, Roughly bounded by Beach Blvd., Necaise Ave., Seminary Dr., 2nd and 3rd Sts.: *Main Street Historic District*, Main St., *Sycamore Street Historic District*, Sycamore St.; *Washington Street Historic District*, Washington St.; *Building at 242 St. Charles Street* (11–25–80)

Hinds County

Jackson, *Fountainhead*, 306 Glen Way (11–28–80)

Jefferson County

Fayette vicinity, *Laurietta*, S of Fayette off MS 33 (11–24–80)

Lamar County

Lumberton, *U.S. Post Office (Mississippi Post Offices 1931–1941 Thematic Resources)* 104 Heber Ladner Dr. (4–7–81)

Leflore County

Greenwood, *Marclare*, River Rd. (11–25–80)

Marion County

Columbia, *U.S. Post Office (Mississippi Post Offices 1931–1941 Thematic Resources)* 815 Main Street (4–7–81)

Monroe County

Aberdeen vicinity, *Crawford Site (22–Mo–902)*, (11–28–80)

Montgomery County

Winona, *U.S. Post Office (Mississippi Post Offices 1931–1941 Thematic Resources)* 306 Summit St. (4–7–81)

Noxubee County

Macon, *Goodwin-Harrison House*, 213 N. Jefferson St. (11–28–80)

Oktibbeha County

Starkville, *Lampkin-Owens House*, 117 N. Montgomery St. (11–24–80)

MISSOURI

Carter County

Van Buren vicinity, *Big Spring Historic District*, E of Van Buren on MO 103 (3–17–81)

Daviess County

Gallatin, *Daviess County Courthouse*, Public Sq. (11–14–80)

Dunklin County

Kennett, *Kennett City Hall and Masonic Lodge*, 122 College St. (9–17–81)

Greene County

Republic, *Anderson, Elijah Teague, House*, 406 N. Pine St. (11–14–80)
Springfield, *Bentley House*, 603 E. Calhoun St. (11–14–80)
Springfield, *Old Calabosse*, 409 W. McDaniel St. (11–14–80)

Jackson County

Kansas City, *Benton, Thomas Hart, House and Studio*, 3616 Belleview St. (11–21–80)
Kansas City, *Hyde Park Historic District*, Roughly bounded by Armour and Harrison Blvds., 39th St. and Gillham Rd. (11–21–80)
Kansas City, *Kansas City Masonic Temple*, 903 Harrison St., (11–14–80)
Kansas City, *Long, R. A., House (Coninthian Hall)* 3218 Gladstone Blvd. (11–14–80)

Jefferson County

Imperial vicinity, *Kimmswick Bone Bed*, NW of Imperial (11–5–80)

Lafayette County

Lexington, *Wentworth Military Academy*, Washington Ave. and 18th St. (11–24–80)

Montgomery County

High Hill, *High Hill School*, Off U.S. 40 (11–14–80)

Nodaway County

Maryville, *Burns, Caleb, House*, 422 W 2nd St. (11–17–80)

Osage County

Bonnot's Mill, *Dauphine Hotel*, Off MO A (11–14–80)

Perry County

Perryville, *Doerr-Brown House*, 17 E. St. Joseph St. (11–14–80)

Pulaski County

Waynesville, *Old Stagecoach Stop*, Linn St., Courthouse Sq. (11–24–80)

Ralls County

Rensselaer vincinity, *St. Peter's Catholic Church*, SW of Rensselaer on SR 2 (11–14–80)

Ray County

Richmond vicinity, *New Hope Primitive Baptist Church*, SW of Richmond on Old Orrick Rd. (11–14–80)

St. Charles County

St. Charles, *African Church*, 554 Madison St. (11–21–80)
St. Charles, *Old City Hall*, 101 S. Main St. (11–14–80)

St. Louis (independent city)

Old Laclede Gas and Light Company Building, 1017 Olive St. (11–26–80)
West Cabanne Place Historic District, W. Cabanne Pl. (11–21–80)

Shannon County

Eminence vicinity, *Chilton-Williams Farm Complex*, E of Eminence of MO 106 (9–2–81)
Eminence vicinity, *Rhinehart Ranch*, NW of Eminence (11–14–80)

Stone County

Galena, *Stone County Courthouse*, Public Sq. (11–14–80)

MONTANA

ONE ROOM SCHOOLHOUSES OF GALLATIN COUNTY THEMATIC RESOURCES. Reference—see individual listings under Gallatin County.

Beaverhead County

Lima vicinity, *Sheep Creek Wickiup Cave* (9–23–81)

Bighorn County

Decker vicinity, *Lee Homestead*, NE of Decker (7–8–81)

Broadwater County

Townsend vicinity, *McCormick's Livery and Feed Stable Sign*, W of Townsend (7–8–81)

Chouteau County

Fort Benton, *Baker, I. G., House*, 1604 Front St. (11–20–80)
Fort Benton, *Fort Benton Engine House*, Front and 15th Sts. (11–20–80)

Flathead County

Olney vicinity, *Stillwater Ranger Station Historic District*, U.S. 93 (7–8–81)

Gallatin County

Belgrade vicinity, *Pass Creek School (One Room Schoolhouses of Gallatin County Thematic Resources)* NE of Belgrade (7–21–81)
Belgrade vicinity, *Reese Creek School (One Room Schoolhouses of Gallatin County Thematic Resources)* NE of Belgrade (7–21–81)
Belgrade vicinity, *Sedan School (One Room Schoolhouses of Gallatin County Thematic Resources)* NE of Belgrade (7–21–81)
Belgrade vicinity, *Springhill School (One Room Schoolhouses of Gallatin County Thematic Resources)* NE of Belgrade (7–21–81)
Bozeman, *Barnett, R. T., and Company Building*, 13 E. Main St. (12–1–80)
Bozeman vicinity, *Lower Bridger School (One Room Schoolhouses of Gallatin County Thematic Resources)* E of Bozeman (7–21–81)
Bozeman vicinity, *Malmborg School (One Room Schoolhouses of Gallatin County Thematic Resources)* E of Bozeman (7–21–81)
Bozeman vicinity, *Pine Butte School (One Room Schoolhouses of Gallatin County Thematic Resources)* W of Bozeman (7–21–81)
Bozeman vicinity, *Rea School (One Room Schoolhouses of Gallatin County Thematic Resources)* W of Bozeman (7–21–81)
Gallatin Gateway vicinity, *Anderson School (One Room Schoolhouses of Gallatin County Thematic Resources)* E of Gallatin Gateway (7–21–81)
Gallatin Gateway vicinity, *Cottonwood School (One Room Schoolhouses of Gallatin County Thematic Resources)* SE of Gallatin Gateway (7–21–81)
Gallatin Gateway vicinity, *Spanish Creek School (One Room Schoolhouses of Gallatin County Thematic Resources)* NW of Gallatin Gateway (7–21–81)
Manhattan vicinity, *Dry Creek School (One Room Schoolhouses of Gallatin County Thematic Resources)* E of Manhattan (7–21–81)
Triden, *Trident School (One Room Schoolhouses of Gallatin County Thematic Resources)* (7–21–81)

Lewis and Clark County

Helena, *Montana State Capitol Building*, Capitol Complex (2–17–81)

Powell County

Avon vicinity, *Fitzpartick Ranch Historic District*, NW of Avon (7–8–81)

Ravalli County

Corvallis, *Brooks Hotel*, Off East Side Hwy. (11–10–80)

Silver Bow County

Butte, *Silver Bow County Poor Farm Hospital*, 3040 Continental Dr. (7–16–81)

NEBRASKA

WILLA CATHER THEMATIC RESOURCES. Reference—see individual listings under Webster County.

Antelope County

Neligh, *Antelope County Courthouse*, 501–511 Main St. (12–3–80)
Neligh, *Gates College Gymnasium (Antelope County Jail) (APO4–2)* 509 L St. (4–20–81)
Neligh, *St. Peter's Episcopal Church*, 411 L St. (12–3–80)

Buffalo County

Kearney, *Hanson-Downing House*, 723 W. 22nd St. (12–10–80)
Kearney, *U.S. Post Office*, 2401 Central Ave. (9–17–81)

Colfax County

Schuyler, *Colfax County Courthouse*, Off NE 15 (9–3–81)
Schuyler, *Schuyler City Hall*, 1020 A St. (9–3–81)

Dodge County

Fremont, *McDonald, J. D., House*, 310 E. Military Ave. (12–10–80)
North Bend, *North Bend Carnegie Library*, 140 E. 8th St. (9–3–81)

Douglas County

Omaha, *Brandeis-Millard House*, 500 S. 38th St. (11–28–80)
Omaha, *Drake Court Apartments and the Dartmore Apartments Historic District*, Jones St. (11–10–80)
Omaha, *St. Matthias' Episcopal Church*, 1423 S. 10th St. (11–23–80)
Waterloo, *Robinson, J. C., House*, 102 E. Lincoln Ave. (11–28–80)

Lancaster County

Lincoln, *State Arsenal*, 17th and Court Sts. (9–17–81)

Scotts Bluff County

Scottsbluff, *Scottsbluff Carnegie Library*, 106 E. 18th St. (9–3–81)

Seward County

Bee, *States Ballroom* (10–14–81)

Webster County

Bladen vicinity, *Pavelka Farmstead (Willa Cather Thematic Resources)* SE of Bladen (previously listed in the National Register 4–13–79)
Red Cloud, *Burlington Depot (Willa Cather Thematic Resources)* Seward St. (3–5–81)
Red Cloud, *Cather House (Willa Cather Thematic Resources)* 245 Cedar St. (previously listed in the National Register 4–16–69)
Red Cloud, *Farmer's and Merchant's Bank Building (Willa Cather Thematic Resources)* 338 N. Webster St. (3–5–81)
Red Cloud, *St. Juliana Falconieri Catholic Church (Willa Cather Thematic Resources)* 425 W. 3rd St. (3–5–81)
Red Cloud, *Webster County Courthouse (Willa Cather Thematic Resources)* 225 W. 6th St. (3–5–81)

NEVADA

NEWLANDS RECLAMATION (TRUCKEE-CARSON PROJECT) THEMATIC RESOURCES. Reference—see individual listings under Churchill County.
Carson City (independent city)
Bank Saloon, 418 S. Carson St. (12–10–80)
Glenbrook, The, 600 N. Carson St. (5–1–81)

Churchill County

Fallon vicinity, *Carson River Diversion Dam (Newlands Reclamation (Truckee-Carson Project) Thematic Resources)* Carson River (3–25–81)
Fallon vicinity, *Lahontan Dam and Power Station (Newlands Reclamation (Truckee-Carson Project) Thematic Resources)* SW of Fallon (3–25–81)
Fallon vicinity, *Sand Springs Station*, SE of Fallon (11–21–80)

Clark County

Las Vegas, *Tule Springs Ranch*, 9200 Tule Springs Rd. (9–23–81)
Las Vegas vicinity, *Hoover Dam*, E of Las Vegas on U.S. 93 (4–8–81) (also in Mohave County, AZ)

Douglas County

Minden vicinity, *Home Ranch*, W of Minden (12–5–80)

Pershing County

Lovelock vicinity, *Marzen House*, S of Lovelock (8–27–81)

Washoe County

Gerlach, *Gerlach Water Tower*, Main St. (10–29–81)
Reno, *Virginia Street Bridge*, Spans Truckee River (12–10–80)
Verdi vicinity, *1872 California-Nevada State Boundary Marker* (8–27–81) (also in Sierra County, California)

NEW HAMPSHIRE

Belknap County

SANBORNTON SQUARE HISTORIC DISTRICT. Reference—see Merrimack County.
Tilton, *House by the Side of the Road*, 61 School St. (11–26–80)

Carrol County

Madison, *Madison School, District No. 1*, NH 113 (12–11–80)

Cheshire County

Ashuelot, *Ashuelot Covered Bridge*, NH 119 and Bolton Rd. (2–20–81)
Richmond, *Richmond School House No. 6*, NH 119 (11–25–80)

Coos County

Groveton vicinity, *Stark Covered Bridge*, E of Groveton at NH 10 and Northside Rd. (12–1–80)

Grafton County

Dorchester, *Dorchester Community Church*, Off NH 118 (11–25–80)
Lettleton, *Lane, Edward H., House*, 16 Cottage St. (12–8–80)
Lisbon, *Lisbon Inn*, Main St. (12–1–80)

Hillsborough County

Hancock vicinity, *Hancock-Greenfield Bridge*, Forest Rd. (5–5–81)
Mount Vernon vicinity, *Lamson Farm*, Lamson Rd. (2–24–81)
Nashua, *Stark, George, House*, 22 Concord St. (11–25–80)
Peterborough, *All Saints' Church*, 51 Concord St. (12–1–80)
Wilton vicinity, *County Farm Bridge*, NW of Wilton on Old County Farm Rd. (5–14–81)

Merrimack County

Boscawen, *Boscawen Academy and Much-I-Do-Hose House*, King St. (12–8–80)
Boscawen, *Boscawen Public Library*, King St. (5–28–81)
Bradford, *Bradford Town Hall*, W. Main St. (11–13–80)
Concord, *Pierce, Franklin, House*, 52 S. Main St. (10–15–79)
Concord, *Upham-Walker House*, 18 Park St. (5–15–80)
Concord, *White Farm*, 144 Clinton St. (5–15–81)
Henniker, *Henniker Town Hall*, Depot Hill Rd. (2–24–81)
Pittsfield, *Pittsfield Center Historic District*, NH 28 and NH 107 (12–12–80)
Sanbornton vicinity, *Sanbornton Square Historic District*, Sanbornton Sq. (12–8–80) (also in Belknap County)

Rockingham County

Exeter, *Exeter Waterfront Commercial Historic District*, Chestnut Hill Ave., Water, Franklin, Pleasant, High and Chestnuts Sts. (12–3–80)
Exeter, *Tenney, Samuel, House*, 65 High St. (11–25–80)
Kingston, *Nichols Memorial Library*, Main St. (1–28–81)
Newmarket, *Newmarket Industrial and Commercial Historic District*, NH 108 (12–1–80)
Plaistow, *Plaistow Carhouse (Trolley Barn)*, 27 Elm St. (12–10–80)
Rye, *Isles of Shoals*, Appledore Island and environs (12–10–80)
Rye, *Parsons Homestead*, 520 Washington Rd. (12–5–80)

Strafford County

Dover, *Hale, William, House*, 5 Hale St. (11–18–80)
Dover, *Strafford County Farm*, County Farm Rd. (2–25–81)
Milton, *Milton Town House*, NH 16 and Town House Rd. (11–26–80)
New Durham, *New Durham Meetinghouse and Pound*, Old Bay Rd. (12–8–80)
New Durham, *New Durham Town Hall*, Main St. and Ridge Rd. (11–13–80)
New Durham vicinity, *Free Will Baptist Church*, Ridge Top Rd. (11–13–80)

Sullivan County

Grantham vicinity, *Protectworth Tavern*, NH 4A (11–25–80)
Newport vicinity, *Little Red School House 1835 District No. 7*, S of Newport on NH 10 (12–1–80)

NEW JERSEY

Atlantic County

Atlantic City, *World War I Memorial*, O'Donnell Pkwy., S. Albany and Ventnor Aves. (8–28–81)

Bergen County

River Edge, *Steuben Estate Complex*, New Bridge Rd., Main St. and Hackensack River (12–18–70)

Camden County

Runnemede vicinity, *St. John's Episcopal Church and Burying Ground*, Chews Landing Rd. and Old Black Horse Pk. (11–22–80)

Cape May County

Ocean View vicinity, *Calvary Baptist Church*, SW of Ocean View at Seaville Rd. and NJ 9 (11–25–80)

Cumberland County

Millville, *Millville's First Bank Building*, 2nd and E. Main Sts. (11–20–80)

Essex County

Bloomfield, *Oakes Estate*, 240 Belleville Ave. (8–6–81)
Newark, *Newark Metropolitan Airport Buildings*, U.S. 22/1/9 and Port Rd. (12–12–80)
Newark, *St. Joseph's Roman Catholic Church Rectory and School*, W. Market St. (12–8–80)
Newark and Belleville, *Branch Brook Park*, Roughly bounded by Belleville Park, Washington and Clifton Aves., 6th and Orange Sts. (1–12–81)
Orange, *Orange Free Public Library*, 348 Main St. (9–28–81)

Hudson County

STATUE OF LIBERTY NATIONAL MONUMENT, ELLIS ISLAND AND LIBERTY ISLAND. Reference—see New York, NY.

Hunterdon County

High Bridge, *High Bridge Reformed Church*, Church St. and SR 513 (11–21–80)

Mercer County

Trenton, *Berkeley Square Historic District*, Roughly bounded by W. State St., Parkside, Riverside, and Overbrook Aves. (11–20–80)

Middlesex County

Perth Amboy, *Perth Amboy City Hall and Surveyor General's Office*, 260 High St. (1–21–81)

Monmouth County

Red Bank, *Shrewsbury Township Hall*, 51 Monmouth St. (12–8–80)

Morris County

Dover, *Baker Building*, 16 W. Blackwell St. (7–1–81)

Passaic County

Clifton, *U.S. Animal Quarantine Station*, Clifton Ave. (10–9–81)
Paterson, *Thompson, Daniel, and Ryle, John, Houses*, 8 and 9 Mill St. (7–30–81)

Sussex County

Wallpark Center vicinity, *Old Mine Road Historic District*, NJ 521, Delaware, Old Mine, and River Rds. (see also listing in Warren County) (12–3–80) HABS.

Union County

Plainfield, *Crescent Area Historic District*, Roughly bounded by Park, Prospect, and Carnegie Aves., 7th and Richmond Sts. (12–12–80)
Westfield, *Westfield Fire Headquarters*, 405 North Ave., W. (12–08–80)

Warren County

Wallpark Center vicinity, *Old Mine Road Historic District*, NJ 521, Delaware, Old Mine, and River Rds. (see also listing in Sussex County) (12–3–80) HABS.

NEW MEXICO

Bernalillo County

Alameda, *Tafoya, Domingo, House*, 10021 Edith Blvd., NE. (11–17–80)
Albuquerque, *ALBUQUERQUE DOWNTOWN NEIGHBORHOODS MULTIPLE RESOURCE AREA.* This area includes: *Eighth Street-Forrester District*, Roughly bounded by Mountain Rd., Lomas Blvd., Forrester and 7th Sts.; *Fourth Ward District*, Roughly bounded by Central Ave., Lomas Blvd., 8th and 15th Sts.; *Carnes, Chester, House*, 701 13th St., NW.; *Gurule, Delfinia, House*, 306 16th St., NW.; *Harwood School*, 1114 7th St., NW.; *Hayden, A. W., House*, 609 Marble St., NW.; *LeFeber, Charles, House*, 313 5th St.; *Lopez, Hilario, House*, 208 16th St., NW; *Mann, Henry, House*, 723 14th St., NW. (12–1–80)
Albuquerque, *Chaves, Rumaldo, House*, 10023 Edith Blvd., NE (11–24–80)
Albuquerque, *Davis House*, 704 Parkland Circle, SE. (11–17–80)
Albuquerque, *Federal Building*, 421 Gold Ave., SW (11–22–80)
Albuquerque, *Gladding, James N., House*, 643 Cedar St., NE. (11–17–80)
Albuquerque, *Lembke House*, 312 Laguna St., SW (11–25–80)
Albuquerque, *Monte Vista School*, 3211 Monte Vista Blvd., NE. (8–12–81)
Albuquerque, *New Mexico-Arizona Wool Warehouse*, 520 1st St., NW. (7–23–81)
Albuquerque, *Old Post Office*, 123 4th St. (11–17–80)
Albuquerque, *Pearce, John, House*, 718 Central Ave., SW (11–22–80)
Albuquerque, *Skinner Building, 722–724 Central Ave., SW and 103 8th St., SW (11–22–80)*
Albuquerque, *Springer Building*, 121 Tijeras Ave., NE. (11–18–80)

Grant County

Mimbres vicinity, *Mattocks Site*, (12–9–80)

Luna County

Deming vicinity, *Upton Site*, (12–9–80)

Otero County

Sacramento vicinity, *Circle Cross Ranch Headquarters*, SW of Sacramento (11–17–80)

Valencia County

Belen, *Belen Hotel*, 200 Becker Ave. (11–12–80)

NEW YORK

STONE HOUSES OF BROWNVILLE THEMATIC RESOURCES. Reference—individual listings under Jefferson County.

Albany County

Albany, *Knickerbocker and Arnink Garages*, 72—74 (11–28–80)

Cayuga County

Aurora, *Aurora Village-Wells College Historic District*, NY 90 (11–19–80)

Chenango County

Oxford, *Burr, Theodore, House*, Fort Hill Sq. (9–11–81)

Dutchess County

Hyde Park, *Hyde Park Railroad Station*, River Rd. (9–11–81)

Erie County

Buffalo, *Dorsheimer, William, House*, 434 Delaware Ave. (11–21–80)
Buffalo, *Lafayette High School*, 370 Lafayette Ave. (12–3–80)

Franklin County

Paul Smiths, *Smith's, Paul, Hotel Store*, Paul Smith's College Campus (12–3–80)

Fulton County

Johnstown, *Fulton County Jail (Tryon County Jail)* Perry and Montgomery Sts. (10–19–81)

Greene County

Athens, *VILLAGE OF ATHENS MULTIPLE RESOURCE AREA.* This area includes: *Athens Lower Village Historic District*, Roughly bounded by Hudson River, NY 385, Vernon and Market Sts.; *Brick Row Historic District*, Off NY 385; *Stranahan-DelVecchio House*, N. Washington St.; *Van Loon, Albertus, House*, N. Washington St.; *Zion Lutheran Church*, N. Washington St. (11–28–80)

Jefferson County

Brownville, *Archer, William, House (Stone Houses of Brownville Thematic Resources)* 112 Washington St. (11–19–80)
Brownville, *Brown, Gen. Jacob, Mansion (Stone Houses of Brownville Thematic Resources)* Brown Blvd. (11–19–80)
Brownville, *Brownville Hotel (Stone Houses of Brownville Thematic Resources)* Brown Blvd. and W. Main St. (11–19–80)
Brownville, *Vogt House (Stone Houses of Brownville Thematic Resources)* 110 Main St. (11–19–80)
Brownville, *Walrath, Arthur, House (Stone Houses of Brownville Thematic Resources)* 114 Corner Pike (11–19–80)

Kings County

Brooklyn, *Park Slope Historic District*, Roughly bounded by Prospect Park West, Berkeley Pl., 15th St., 6th, 7th and Flatbush Aves., (11–21–80)
New York, *Parachute Jump*, Coney Island (9–2–80)

Livingston County

North Bloomfield, *North Bloomfield School*, 7840 Martin Rd. (5–28–81)

Madison County

Oneida, *Cottage Lawn*, 435 Main St. (11–6–80)

Monroe County

Riga, *Riga Academy*, 3 Riga-Mumford Rd. (11–21–80)

New York County

Liberty Island, *Statue of Liberty National Monument, Ellis Island and Liberty Island* (10–15–66) (also in Hudson County, NJ)
New York, *Houses at 83 and 85 Sullivan Street*, 83–85 Sullivan St. (11–17–80)
New York, *New York Public Library, Hamilton Grange Branch*, 503 and 505 W. 145th St. (7–23–81)
New York, *Stuyvesant Square Historic District*, Roughly bounded by Nathan D. Perleman Pl., 3rd Ave., E. 18th and E. 15th Sts. (11–21–80)

Omondaga County

Syracuse, *Central Technical High School*, 700–745 S. Warren St. (4–9–81)

Orange County

Goshen, *Church Park Historic District*, Park Pl., Main and Webster Sts. (11–17–80)
Montgomery, *MONTGOMERY VILLAGE MULTIPLE RESOURCE AREA.* This area includes: *Bridge Street Historic District; Union Street-Academy Hill Historic District; Crabtree-Patchett House*, 232 Ward St.; *Miller, Johannes, House*, 272 Union St.; *Montgomery Worsted Mills*, Factory St. (11–21–80)
Newburgh, *New York State Armony*, Broadway and Johnson St. (6–18–81)

Otsego County

Cooperstown, *Cooperstown Historic District*, NY 28, NY 80 and Main St. (11–18–80)
Oneonta, *Stonehouse Farm*, E of Oneonta on NY 7 (11–19–80)
Oneonta vicinity, *Fortin Site*, (11–28–80)

Queens County

Rockaway Point vicinity, *Riis, Jacob, Park Historic District*, Rockaway Beach Blvd. (6–17–81)

Rensselarer County

Hoosick Falls, *Hoosick Falls Historic District*, Roughly bounded by RR tracks, Church, Main and Elm Sts. (12–3–80)

Richmond County

Staten Island, *St. Paul's Memorial Church and Rectory*, 225 St. Paul's Ave. (11–21–80)

Schenectady County

Schenectady, *General Electric Realty Plot*, Roughly bounded by Oxford Pl., Union Ave., Nott St., Lenox and Lowell Rds. (11–18–80)

Schoharie County

Fulton, *Shafer Site*, (11–28–80)

Seneca County

Covert, *Covert Historic District*, NY 96 (11–21–80)

Steuben County

Rheims, *Pleasant Valley Wine Company*, SR 88 (11–18–80)

Suffolk County

Bay Shore vicinity, *Fire Island Light Station*, Robert Moses Causeway (9–11–81)
Huntington, *Fort Golgotha and the Old Burial Hill Cemetery*, Main St. and Nassau Rd. (3–2–81)
Mastic Beach, *Floyd, William, House (Old Mastic)* 20 Washington Ave. (10–15–80)

Tioga County

Owego, *Owego Central Historic District*, North Ave., Park, Main, Lake, Court, and Fronts Sts. (12–3–80)

Ulster County

Cragsmoor vicinity, *Chetolah (George Inness, Jr., Estate)*, S of Cragsmoor on Vista Maria Rd. (10–21–80)

Westchester County

Katonah, *Jay, John, Homestead*, Jay St. (5–29–81) NHL
Peeksill vicinity, *Van Cortlandt Upper Manor House*, Oregon Rd. (4–2–81)
Scarsdale, *Wayside Cottage*, 1039 Post Rd. (5–1–81)
Yorktown Heights, *Yorktown Heights Railroad Station*, Commerce St. (3–19–81)

Wyoming County

North Java, *Arcade and Attica Railroad* (11–17–80)

NORTH CAROLINA

Beaufort County

Belhaven, *Belhaven City Hall*, Main St. (1–27–81)

Bertie County

Windsor vicinity, *King House*, NW of Windsor off NC 308 (8–26–71)

Brunswick County

Southport, *Southport Historic District*, Roughly bounded by Cape Fear River, Rhett, Bay, Short and Brown Sts. (11–25–80)

Chatham County

Pittsboro vicinity, *Hadley House and Grist Mill*, NW of Pittsboro on SR 2165 (11–25–80)

Cumberland County

Fayetteville, *Confederate Breastworks*, Raleigh Rd. and U.S. 401 (10–7–81)

Currituck County

Poplar Branch vicinity, *Baum Site (31CK9)*, N of Poplar Branch (12–8–80)

Davidson County

Lexington vicinity, *Sowers, Philip, House*, SR 1162 (11–25–80)
Thomasville vicinity, *Brummell's Inn*, N of Thomasville (11–25–80)
Thomasville, *Thomasville Railroad Passenger Depot*, W. Main St. (7–9–81)

Forsyth County

Winston-Salem, *Reynolda Historic District,* Reynolda Rd. (11–28–80)

Halifax County

Scotland Neck vicinity, *Trinity Church,* N of Scotland Neck on U.S. 258 (11–25–80)
Scotland Neck, *Woodstock,* N of Scotland Neck on U.S. 258 (11–25–80)

Haywood County

Canton vicinity, *Patton Farm,* SW of Canton (11–10–80)

Hertford County

Ashoskie vicinity, *Mulberry Grove,* SW of Ashoskie (11–25–80)

Iredell County

IREDELL COUNTY MULTIPLE RESOURCE AREA. This area includes: Mooresville, *Mooresville Historic District,* NC 115 and NC 152; Statesville, *Academy Hill Historic District,* Western Ave., Bell, Mulberry, Wise and Armfield Sts.; *East Broad Street-Davie Avenue Historic District,* Davie Ave., Broad and Elm Sts.; *Mitchell College Historic District,* NC 90 and U.S. 70; *Statesville Commercial Historic District,* Rougly bounded by Front, Meeting, Broad and Tradd Sts.; Harmony vicinity, *Damascus Baptist Church Arbor,* Off SR 1158 and SR 1582; *Gaither House,* NC 901; *Holland-Summers House,* Off SR 1904; *Morrison-Campbell House,* Off SR 2125; *Snow Creek Methodist Church and Burying Ground,* Off SR 1904; Mooresville, *Brawley, Espy Watts, House,* 601 William St.; *South Broad Street Row,* 251—311 S. Broad St.; Mooresville vicinity, *Cornelius House,* SR 1378 and SR 1302; Mount Mourne vicinity, *Centre Presbyterian Church, Session House and Cemeteries,* SR 1245; *Coddle Creek Associate Reformed Presbyterian Church, Session House and Cemetery,* SR 1146; *Houston, George, House,* NC 115; *Wood Lawn,* SR 1138; Statesville, *Center Street A.M.E. Zion Church,* S. Center St.; *Key Memorial Chapel,* 150 E. Sharpe St.; *McElwee Houses,* 122, 126, 134 and 140 Water St.; *Morrison-Mott House,* 332 N. Center St.; *Sharpe, Col. Silas Alexander, House,* 402 S. Center St.; *Eccles, Henry, House,* SR 2145 and SR 2180; *King-Flowers-Keaton House,* NC 115 and SR 1905; *McClelland-Davis House,* SR 1551; *Turner, Henry, House and Caldwell-Turner Mill Site,* SR 2145; Troutman vicinity, *Davidson House,* SR 1337; (11–24–80)
IREDELL COUNTY MULTIPLE RESOURCE (additions). This area includes: Houstonville vicinity, *Daltonia (John H. Dalton House)* SR 2115; *Welch-Nicholson House and Mill Site;* Statesville vicinity, *Bethesda Presbyterian Church, Session House and Cemetery,* SR 2359; *Ebenezer Academy, Bethany Presbyterian Church and Cemetery,* U.S. 21; and Union Grove vicinity, *Campbell, Perciphull, House,* SR 1832 (12–8–80)

Macon County

Franklin, *Nequasee (Nikwasi),* (11–26–80)

Nash County

Rocky Mount, *Machaven,* 306, S. Grace St. (11–25–80)

New Hanover County

Wilmington, *USS North Carolina (battleship)* Cape Fear River (7–23–81)

Northhampton County

Murfreesboro vicinity, *Princeton Site,* (11–25–80)

Pitt County

Greenville, *Humber, Robert Lee, House,* 117 W. 5th St. (7–9–81)
Greenville, *Jones-Lee House,* 805 E. Evans St. (11–25–80)

Robeson County

Lumberton, *Carolina Threatre,* 319 N. Chestnut St. (7–9–81)

Scotland County

Johns vicinity, *McRae-McQueen House,* SW of Johns on U.S. 501

Transylvania County

Brevard, *Silvermont,* E. Main St. (7–9–81)

NORTH DAKOTA

BUECHNER AND ORTH COURTHOUSES IN NORTH DAKOTA THEMATIC RESOURCES. Reference—see individual listings under Kickey, Divide, Foster, Grand Forks, LaMoure, McHenry, McIntosh, Pembina, Pierce, Richland, Sargent, and Traill Counties. (11–25–80)

Bowman County

Rhame vicinity, *Fort Dilts,* (11–10–80)

Cass County

Fargo, *Dibley House,* 331 8th Ave., S (11–25–80)

Dickey County

Ellendale, *Dickey County Courthouse (Buechner and Orth Courthouses in North Dakota Thematic Resources)* Off U.S. 281 (11–25–80)

Divide County

Crosby, *Divide County Courthouse (Buechner and Orth Courthouses in North Dakota Thematic Resources)* (11–25–80)

Foster County

Carrington, *Foster County Courthouse (Buechner and Orth Courthouses in North Dakota Thematic Resources)* (11–25–80)

Grand Forks County

Grand Forks, *Grand Forks County Courthouse (Buechner and Orth Courthouses in North Dakota Thematic Resources)* (11–25–80)

Hettinger County

Regent, *Hill, Dr. S. W., Drug Store,* Off ND 21 (11–10–80)

LaMoure County

LaMoure, *LaMoure County Courthouse, (Buechner and Orth Courthouses in North Dakota Thematic Resources)* (11–25–80)

McHenry County

Towner, *McHenry County Courthouse, (Buechner and Orth Courthouses in North Dakota Thematic Resources)* (11–25–80)

McIntosh County

Ashley, *McIntosh County Courthouse, (Buechner and Orth Courthouses in North Dakota Thematic Resources)* (11–25–80)

McKenzie County

Grassy Butte, *Grassy Butte Post Office,* Off U.S. 85 (11–26–80)

Pembina County

Cavalier, *Pembina County Courthouse, (Buechner and Orth Courthouses in North Dakota Thematic Resources)* Off ND 5 (11–25–80)

Pierce County

Rugby, *Pierce County Courthouse (Buechner and Orth Courthouses in North Dakota Thematic Resources)* (11–25–80)

Richland County

Wahpeton, *Richland County Courthouse (Buechner and Orth Courthouses in North Dakota Thematic Resources)* Off ND 13 (11–25–80)

Sargent County

Forman, *Sargent County Courthouse, (Buechner and Orth Courthouses in North Dakota Thematic Resources)* Off ND 32 (11–25–80)

Traill County

Hillsboro, *Traill County Courthouse (Buechner and Orth Courthouses in North Dakota Thematic Resources)* Off U.S. 81 (11–25–80)

Ward County

Minot, *Minot Carnegie Library,* 105 2nd Ave., SE (11–10–80)

NORTHERN MARIANA ISLANDS

Mariana Islands District

Garapan Village, Saipan, *Japanese Hospital,* Rte. 3 (12–19–74)
Navy Hill, Saipan, *Japanese Lighthouse,* Navy Hill at Garapan (12–19–74)
Rota, *Commissioner's Office* (4–17–81)
Rota, *Japanese Hospital,* W side of Sasanhaya Bay (4–16–81)
Rota, *Nanyo Kohatsu Kabushiki Kaisha Sugar Mill* (4–16–81)
Rota, *Rectory* (4–16–81)
Rota Island, *Rota Latte Stone Quarry* (12–23–74)
Saipan, *Banzai Cliff,* Banadero (9–30–76)
Saipan, *Isley Field Historic District,* Saipan International Airport (6–26–81)
Saipan, *Suicide Cliff,* Banadero (9–30–76)
Saipan, *Waherak Maihar,* Public Works Headquarters Compound (1–31–78)
Tinian Island, *House of Taga* (12–19–74)
Tinian, *Japanese Structure* (4–16–81)
Tinian, *Nanyo Kohatsu Kabushiki Kaisha Administration Building* (4–16–81)
Tinian, *Nanyo Kohatsu Kabushiki Kaisha Ice Storage Building* (4–17–81)
Tinian, *Nanyo Kohatsu Kabushiki Kaisha Laboratory* (4–16–81)

OHIO

EASTLAKE HOUSES OF ASHLEY THEMATIC RESOURCES. Reference—see individual listings under Delaware County.

BELL, C. S., THEMATIC RESOURCES. Reference—see individual listings under Highland County.

PATROL STATIONS IN CINCINNATI, OHIO THEMATIC RESOURCES. Reference—see individual listings under Hamilton County.

Ashtabula County

Jefferson, *Jefferson Town Hall*, 27 E. Jefferson St. (6–18–81)

Athens County

Chauncey, *Clester, Joseph, House*, SE of Chauncey on SR 111 (11–26–80)

Athens, *Herrold, Thomas Jefferson, House and Store*, 234 W. Washington St. (11–21–80)

Brown County

Wilmington, *Pisgah Christian Church*, NW of Bipley on Pisgah Rd. (11–21–80)

Butler County

Hamilton, *Butler County Courthouse*, 2nd and High Sts. (6–22–81)

Clermont County

Milford, *Promont (Gov. John M. Pattison House)*, 906 Goshen Pk. (11–21–80)

Clinton County

Wilmington, *Main Building*, Sugartree St. (11–21–80)

Wilmington, *Smith Place*, N. South St. (11–25–80)

Coshocton County

Coshocton vicinity, *Milligan, Cuthbert, House*, N of Coshocton (11–25–80)

Cuyahoga County

Berea, *Berea Union Depot*, 30 Depot St. (11–21–80)

Cleveland, *St. Paul's Episcopal Church*, 4120 Euclid Ave. (11–25–80)

Cleveland, *Warazawa Neighborhood District*, E. 65th St. and Forman Ave. (11–28–80)

North Olmsted, *First Universalist Church of Olmsted*, 5050 Porter Rd. (11–25–80)

North Olmsted, *North Olmsted Town Hall*, 5186 Dover Center Rd. (11–25–80)

Parma, *Stearns, Lyman, Farm*, 6975 Ridge Rd. (10–1–81)

Strongsville, *Strong, John Stoughton, House*, 18910 Westwood St. (11–24–80)

Darke County

Greenville, *Carnegie Library and Henry St. Clair Memorial Hall*, 520 Sycamore St. and W. 4th St. (11–26–80)

Versailles, *Versailles Town Hall and Wayne Township House*, 4 W. Main St. (2–18–81)

Delaware County

Ashley, *Building at 500 East High Street (Eastlake Houses of Ashley Thematic Resources)* (11–25–80)

Ashley, *Building at 505 East High Street (Eastlake Houses of Ashley Thematic Resources)* (11–25–80)

Ashley, *Building at 101 North Franklin Street (Eastlake Houses of Ashley Thematic Resources)* (11–25–80)

Ashley, *Building at 223 West High Street (Eastlake Houses of Ashley Thematic Resources)* (11–25–80)

Fairfield County

Amanda, *Barr House*, 350 W. Main St. (11–26–80)

Rushville, *Rushville Historic District*, Bremen Ave., Main and Market Sts. (11–24–80)

Franklin County

Central College Multiple Resource Area. This area includes: Westerville vicinity, *Central College Presbyterian Church*, Sunbury Rd.; *Fairchild Building.*

Sunbury Rd.; *Presbyterian Parsonage*, 6972 Sunbury Rd.; *Washburn, Rev. Ebenezer, House*, 7121 Sunbury Rd. (11–25–80)

Columbus, *Broad Street United Methodist Church*, 501 E. Broad St. (11–26–80)

Columbus, *German Village*, Roughly bounded by Livingston Ave., Pearl and Blackberry Alley, Nursery Lane, and Lathrop St. (boundary increase approved 11–28–80)

Columbus, *Ohio National Bank*, 167 S. High St. (11–26–80)

Columbus, *Welsh Presbyterian Church*, 315 E. Long St. (11–24–80)

Gallia County

Patriot vicinity, *Davis Mill*, NE of Patriot on Cora Mill Rd. (11–28–80)

Greene County

Fairborn, *Mercer Log House*, 41 N. 1st St. (10–16–81)

Hamilton County

Cincinnati, *Aklemeyer Commercial Buildings*, 19—23 W. Court St. (12–9–80)

Cincinnati, *Ida Street Viaduct*, Ida St. (11–28–80)

Cincinnati, *Mount Adams Public School*, 1125 St. Gregory St. (11–24–80)

Cincinnati, *Ninth Street Historic District*, 9th St. between Vine and Plum Sts. (11–25–80)

Cincinnati, *Police Station No. 6 (Police Stations in Cincinnati, Ohio Thematic Resources)* Delta Ave. and Columbia Pkwy. (5–18–81)

Cincinnati, *Police Station No. 7 (Patrol Stations in Cincinnati, Ohio Thematic Resources)* 355 McMillan St. (5–18–81)

Cincinnati, *Police Station No. 2 (Patrol Stations in Cincinnati, Ohio Thematic Resources)* 314 Broadway (previously listed in Lytle Park Historic District 3–26–76)

Cincinnati, *Police Station No. 3 (Patrol Stations in Cincinnati, Ohio Thematic Resources)* 3201 Warsaw Ave. (5–18–81)

Cincinnati, *Police Station No. 5 (Patrol Stations in Cincinnati, Ohio Thematic Resources)* 1024—1026 York St. (previously listed as part of Samuel Hannaford and Sons Thematic Resources 3–3–80)

Montgomery, *Wilder-Swaim House*, 7650 Cooper Rd. (5–20–81)

Highland County

Hillsboro, *Bell, C.S. Foundry and Showroom (Bell, C.S., Thematic Resources)* 154–158 W. Main St. (11–25–80)

Hillsboro, *Bell, Mansion (Bell, C.S., Thematic Resources)* 225 Oak St. (11–25–80)

Hillsboro, *Bell's First Home (Bell, C.S., Thematic Resources)* 222 Beech St. (11–25–80)

Hillsboro, *Bell's Opera House (Bell, C.S., Thematic Resources)* 109–119 S. High St. (11–25–80)

Henry County

Napoleon, *Henry County Sheriff's Residence and Jail*, 123 E. Washington St. (6–24–81)

Jackson County

Wellston, *Clutts House*, 16 E. Broadway St. (11–26–80)

Jefferson County

Adena vicinity, *Hamilton-Ickes House*, N of Adena on SR 10 (11–26–80)

Smithfield, *Smithfield School*, High St. (10–16–81)

Wintersville vicinity, *Bantam Ridge School*, Bantam Ridge Rd. (10–1–81)

Knox County

Mount Vernon vicinity, *Thompson, Enoch, House*, SW of Mount Vernon on OH 661 (11–25–80)

Lake County

Mentor, *Oliver, John G., House*, 7645 Little Mountain Rd. (10–1–81)

Licking County

GRANVILLE MULTIPLE RESOURCE AREA (Partial Inventory). This area includes: Granville, *Granville Historic District*, OH 37; *Bancroft, A. A., House*, N. Pearl St. and Washington Dr.; *Carpenter, Wallace W., House (The Castle)* 323 Summit St.; *Dustin Cabin*, 597 N. Pearl St.; *Rogers House*, 304 N. Pearl St.; *Rose, Capt. Levi, House*, 631 N. Pearl St. (11–28–80)

Johnstown, *Monroe Township Hall-Opera House*, 1 S. Main St. (7–6–81)

Newark, *Rhoads, Peter F., House*, 74 Granville St. (11–28–80)

Lucas County

Toledo, *Ashland Avenue Baptist Church*, Ashland Ave. at Woodruff (11–26–80)

Medina County

Medina, *Munson, Judge Albert, House*, 231 E. Washington St. (11–26–80)

Meigs County

Pomeroy, *Pomeroy Historic District*, 2nd St. and Main St. (Boundary increase approved 11–22–80)

Mercer County

Celina, *Otis Hospital*, 441 E. Market St. (11–25–80)

Celina, *Godfrey, Sen. Thomas J., House*, 602 W. Market St. (11–26–80)

Miami County

Covington, *Covington Historic Government Building*, Spring and Pearl Sts. (6–22–81)

Monroe County

Graysville vicinity, *Ring, Walter, House and Mill Site*, SE of Graysville on SR 575 (11–28–80)

Montgomery County

Dayton, *Dayton Stove and Cornice Works*, 24—28 N. Patterson Blvd. (11–26–80)

Dayton, *Lafee Building*, 22 E. 3rd St. (11–25–80)

Trotwood, *Trotwood Railroad Station and Depot*, 2 W. Main St. (1–26–81)

Muskingum County

Zanesville, *Brendel, Charles, House,* 427 Wayne Ave. (11–25–80)
Zanesville, *Clossman Hardware Store,* 621—623 Main St. (11–25–80)
Zanesville, *Grant School,* Off U.S. 22 (11–25–80)
Zanesville, *Ohio Power Company,* 604 Main St. (11–25–80)
Zanesville, *Wiles, Perry, Grocery Company,* 32 N. 3rd St. (11–25–80)

Perry County

New Lexington, *Perry County Courthouse and Jail,* Main and Brown Sts. (10–8–81)
Somerset, *Sheridan House,* S. Columbus St. (11–28–80)

Pickaway County

Circleville, *Memorial Hall,* 165 E. Main St. (11–21–80)

Ross County

Chillicothe, *Seip House,* 345 Allen Ave. (5–12–81)

Stark County

Alliance vicinity, *Maudru House,* SW of Alliance (11–25–80)
Canton, *Renkert, Harry S., House,* 1414 Market Ave. (6–18–81)

Tuscarawas County

Strasburg, *Garver Brothers Store,* 134 N. Wooster Ave. (11–26–80)

Van Wert County

Van Wert, *Marsh, George H., Homestead and the Marsh Foundation School,* Ridge Rd. (11–28–80)
Willshire, *Willshire School,* Green St. (11–25–80)

Wood County

Bowling Green, *Main Street Historic District,* Main and Wooster Sts. (11–28–80)
North Baltimore, *North Baltimore Town Hall,* 207 N. Main St. (10–29–81)

OKLAHOMA

LATIMER COUNTY THEMATIC RESOURCES RELATING TO COAL MINING. Reference—see individual listings under Latimer County.

Canadian County

Yukon vicinity, *Czech Hall,* S of Yukon (11–25–80)

Choctaw County

Hugo, *Hugo Historic District,* U.S. 70 and U.S. 271 (11–12–80)

Comanche County

Cache vicinity, *Arrastra Site* (5–11–81)
Cache vicinity, *Boulder Cabin,* NW of Cache (5–11–81)
Cache vicinity, *Buffalo Lodge,* NW of Cache (5–11–81)
Cache vicinity, *Ferguson House,* NW of Cache (5–11–81)
Cache vicinity, *Ingram House,* NE of Cache (5–11–81)
Indiahoma, *First State Bank of Indiahoma,* Main St. (11–6–80)
Lawton vicinity, Gore Pit District (Cm–131, 324, & 325) SE of Lawton (11–21–80)

Creek County

Drumright, *Santa Fe Depot,* Broadway and Harley Sts. (4–2–81)
Drumright vicinity, *Tidal School,* S of Drumright off OK 16 (4–2–81)
Drumright, *Washington School,* 214 W. Federal St. (1–28–81)

Haskell County

Stigler vicinity, *Tamaha Jail and Ferry Landing,* NE of Stigler (11–14–80)

Hughes County

Holdenville, *Holdenville City Hall,* 102 Creek St. (9–11–81)

Johnston County

Tishomingo, *Poe, Bessie, Hall,* Murray State College campus (9–11–81)

Latimer County

Wilburton, *Great Western Coal and Coke Company Building (Latimer County Thematic Resources Relating to Coal Mining)* 701 E. Main St. (11–6–80)
Wilburton, *Great Western Coal and Coke Company Mine No. 3 (Latimer County Thematic Resources Relating to Coal Mining)* Off U.S. 270 (11–6–80)
Wilburton, *Mitchell Hall (Latimer County Thematic Resources Relating to Coal Mining)* Eastern Oklahoma State College campus (11–6–80)
Wilburton, *Sacred Heart Catholic Church and Rectory (Latimer County Thematic Resources Relating to Coal Mining)* 102 Center Point Rd. (11–6–80)
Yanush vicinity, *Cupco Church,* S of Yanush off OK 2 (11–6–80)

LeFlore County

Cowlington vicinity, *Overstreet House,* NE of Cowlington off U.S. 59 (11–25–80)
Panama vicinity, *Skullyville County Jail,* W of Panama (11–6–80)

McCurtain County

Broken Bow vicinity, *Tiner School,* E of Btoken Bow (11–21–80)

Oklahoma County

Oklahoma City, *Edgemere Park Historic District,* Roughly bounded by Robinson and Walker and NW 30 and NW 36 (11–12–80)
Oklahoma City, *Tradesman's National Bank Building,* 101 N. Broadway St. (11–5–80)

Okmulgee County

Henryetta vicinity, *Wilson School,* NW of Henryetta (1–28–81)

Osage County

Hominy, *Drummond, Fred, House,* 305 N. Price Ave. (4–16–81)

Payne County

Stillwater, *Berry, James E., House,* 502 S. Duck St. (11–21–80)
Stillwater, *Citizens Bank Building,* 107 E. 9th St. (2–24–81)

Pittsburg County

Canadian, *Canadian Jail and Livery Stable,* Off OK 113 (11–6–80)
Krebs, *St. Joseph's Catholic Church,* Off OK 31 (11–12–80)
McAlester, *McAlester Scottish Rite Temple,* 2nd St. and Adams Ave.
McAlester, *Mass Grave of the Mexican Miners,* Mount Calvary Cemetery (11–14–80)

Seminole County

Wewoka, *Seminole Whipping Tree,* Wewoka Ave. (5–22–81)

Washington County

Bartlesville, *Old Washington County Courthouse,* 400 Frank Phillips Blvd. (1–26–81)

OREGON

Clackamas County

Damascus, *Damascus School,* 14711 SE Anderson Rd. (12–3–80)
Government Camp vicinity, *Clackamas Lake Ranger Station Historic District,* S of Government Camp on Skyline Rd. (4–22–81)

Clatsop County

Astoria, *Flavel, Capt. George, House and Carriage House,* 441 8th St. (11–28–80)

Columbia County

Scappoose, *Watts, James Grant, House,* 206 SE 1st St. (11–28–80)
Scappoose vicinity, *Portland and Southwestern Railroad Tunnel* (8–17–81)

Curry County

Sixes vicinity, *Hughes, Patrick, House,* Cape Blanco State Park (11–28–80)

Douglas County

Roseburg, *Parrott, Mose, House,* 1772 SE. Jackson St. (11–6–80)

Grant County

Prairie City, *Sumpter Valley Railway Passenger Station,* Main and Bridge Sts. (5–5–81)

Hood River County

Parkdale vicinity, *Cloud Cap-Tilly Jane Recreation Area Historic District,* S of Parkdale (3–22–81)

Jackson County

Ashland, *Eddings-Provost House,* 364 Vista St. (11–6–80)
Central Point, *Central Point Public School,* 450 S. 4th St. (12–3–80)
Medford, *BPOE Lodge No. 1168,* 202 N. Central Ave. (11–28–80)
Medford, *Medford Carnegie Library,* 413 W. Main St. (7–30–81)

Klamath County

Klamath Falls vicinity, *Crater Lake Lodge,* Crater Lake National Park (5–5–81)

Lane County

Eugene, *Hayse Blacksmith Shop (Brogdon's Hay, Feed and Seed Store)* 357 Van Buren St. (11–7–80)

Linn County

Shedd, *Porter-Brasfield House,* 31838 Fayetteville Dr. (11–25–80)

Marion County

Jefferson, *Jefferson Methodist Church and Parsonage*, 310 and 342 N. Second St. (11–6–80)
Mount Angel, *Windischar's General Blacksmith Shop*, 110 Sheridan St. (11–7–80)
Salem, *Gilbert, Andrew T., House*, 116 Marion St., NE (11–6–80)
Salem, *Wilson-Durbin House*, 434 Water St. (11–7–80)
Silverton vicinity, *McCallister-Gash Farmhouse*, SW of Silverton at 9626 Kaufman Rd. (11–6–80)

Multnomah County

Bridal Veil vicinity, *Multnomah Falls Lodge and Footpath*, NE of Bridal Veil on Old Columbia River Hwy. (4–22–81)
Corbett vicinity, *Graf, Andreas, House*, SE of Corbett (11–13–80)

Polk County

Dallas, *Dallas Tannery*, 505 SW. Levens St. (11–6–80)

Umatilla County

Pendleton, *Bowman Hotel*, 17 SW. Frazer Ave. (11–6–80)
Umatilla vicinity, *Umatilla (35 UM 1)*, N of Umatilla (1–30–81)

Union County

Union, *Townley, W. J., House*, 782 N. 5th St. (11–6–80)

Wasco County

The Dalles, *Thompson, John L., House*, 209 W. 3rd St. (11–6–80)

PENNSYLVANIA

BERKS COUNTY COVERED BRIDGES THEMATIC RESOURCES. Reference—see individual listings under Berks County.
COVERED BRIDGES OF CHESTER COUNTY THEMATIC RESOURCES. Reference—see individual listings under Chester County.
COVERED BRIDGES OF THE DELAWARE RIVER WATERSHED THEMATIC RESOURCES. Reference—see individual listings under Bucks, Carbon, Lehigh, Luzerne, Northampton, Philadelphia and Schuykill Counties.
COVERED BRIDGES OF LANCASTER COUNTY THEMATIC RESOURCES. Reference—see individual listings under Lancaster County.
COVERED BRIDGES OF SOMERSET COUNTY THEMATIC RESOURCES. Reference—see individual listings under Somerset County.
FOUR PUBLIC SQUARES OF PHILADELPHIA THEMATIC RESOURCES. Reference—see individual listings under Philadelphia County.

Allegheny County

Carnegie, *Carnegie, Andrew, Free Library*, 300 Beechwood Ave. (10–8–81)
Emsworth vicinity, *Reed Hall*, W of Emsworth on Huntington Rd. (11–28–80)
Pittsburgh, *Allegheny Cemetery*, Roughly bounded by N. Mathilda and Butler Sts., and Penn, Stanton, and Mossfield Aves. (12–10–80)

Armstrong County

Kittanning, *Armstrong County Courthouse and Jail*, Market and Jefferson Sts. (11–1–81)

Bedford County

New Enterprise, *New Enterprise Public School*, Off PA 869 (10–8–81)

Berks County

Kutztown vicinity, *Dreibelbis Station Bridge (Berks County Covered Bridges Thematic Resources)* (2–23–81)
Kutztown vicinity, *Kutz's Mill Bridge (Berks County Covered Bridges Thematic Resources)* (2–23–81)
Oley vicinity, *Greisemer's Mill Bridge (Berks County Covered Bridges Thematic Resources)* (2–23–81)
Oley vicinity, *Pleasantville Bridge (Berks County Covered Bridges Thematic Resources)* (2–23–81)
Reading vicinity, *Wertz's Covered Bridge (Berks County Covered Bridges Thematic Resources)* NW of Reading spanning Tulpehocken Creek (previously listed in the National Register 11–17–78)

Bucks County

Cornwells Heights, *Little Jerusalem (BenSalem) A.M.E. Church*, 1200 Bridwater Rd. (12–3–80)
Durham, *Knecht's Mill Covered Bridge (Covered Bridges of the Delaware River Watershed Thematic Resources)* (12–1–80)
Edgewood, *Village of Edgewood Historic District*, Yardley, Langhorne, Edgewood and Stony Hill Rds. (11–28–80)
Erwinna, *Erwinna Covered Bridge (Covered Bridges of the Delaware River Watershed Thematic Resources)* (12–1–80)
New Britain, *Pine Valley Covered Bridge (Covered Bridges of the Delaware River Watershed Thematic Resources)* (12–1–80)
New Hope vicinity, *Van Sant Covered Bridge (Covered Bridges of the Delaware River Watershed Thematic Resources)* (12–1–80)
Newtown vicinity, *Twining Ford Covered Bridge (Covered Bridges of the Delaware River Watershed Thematic Resources)* (12–1–80)
Perkasie, *Mood's Covered Bridge (Covered Bridges of the Delaware River Watershed Thematic Resources)* (12–1–80)
Perkasie, *South Perkasie Covered Bridge (Covered Bridges of the Delaware River Watershed Thematic Resources)* (12–1–80)
Pipersville vicinity, *Loux Covered Bridge (Covered Bridges of the Delaware River Watershed Thematic Resources)* (12–1–80)
Point Pleasant vicinity, *Cabin Run Covered Bridge (Covered Bridges of the Delaware River Watershed Thematic Resources)* (12–1–80)
Point Pleasant vicinity, *Frankenfield Covered Bridge (Covered Bridges of the Delaware River Watershed Thematic Resources)* (12–1–80)
Richardtown vicinity, *Sheard's Mill Covered Bridge (Covered Bridges of the Delaware River Watershed Thematic Resources)* (12–1–80)
Springtown vicinity, *Haupt's Mill Covered Bridge (Covered Bridges of the Delaware River Watershed Thematic Resources)* (12–1–80)
Uhlerstown, *Uhlerstown Covered Bridge (Covered Bridges of the Delaware River Watershed Thematic Resources)* (12–1–80)
Wycombe, *Lacey, Gen. John, Homestead*, Forest Grove Rd. (12–2–80)

Carbon County

Little Gap, *Little Gap Covered Bridge (Covered Bridges of the Delaware River Watershed Thematic Resources)* (12–1–80)

Centre County

Pine Grove Mills vicinity, *Ayres, Bucher Farm*, SW of Pine Grove Mills on Whitehall Rd. (12–1–80)
State College, *Farmers' High School (Pennsylvania State College)* College Ave. and Atherton St. (9–11–81)

Chester County

MERCER'S MILL COVERED BRIDGE (COVERED BRIDGES OF LANCASTER COUNTY THEMATIC RESOURCES) Reference—see Lancaster County.
PINE GROVE COVERED BRIDGE (COVERED BRIDGES OF LANCASTER COUNTY THEMATIC RESOURCES) Reference—see Lancaster County.
Downingtown vicinity, *Gibson's Covered Bridge (Covered Bridges of Chester County Thematic Resources)* SE of Downingtown (12–10–80)
Honey Brook vicinity, *Sandy Hill Tavern*, SE of Honey Brook on PA 340 (12–10–80)
Downingtown vicinity, *Larkin Covered Bridge (Covered Bridges of Chester County Thematic Resources)* N of Downingtown (12–10–80)
Downington vicinity, *Lionville Historic District*, NE of Downington (12–1–80)
Malvern vicinity, *Bartram's Covered Bridge (Covered Bridges of Chester County Thematic Resources)* (also in Delaware County) (12–10–80)
Marshallton vicinity, *Hannum, Col. John House*, NE of Marshallton at 898 Frank Rd. (12–10–80)
Modena vicinity, *Speakman No. 1 (Covered Bridges of Chester County Thematic Resources)* SW of Modena (12–10–80)
Modena vicinity, *Speakman No. 2, Mary Ann Pyle Bridge (Covered Bridges of Chester County Thematic Resources)* S of Modena (12–10–80)
New London vicinity, *Stevens, Linton, Covered Bridge (Covered Bridges of Chester County Thematic Resources)* SW of New London (12–10–80)
West Chester, *West Chester State College Quadrangle Historic District*, Bounded by S. High and S. Church Sts., College and Rosedale Aves. (10–8–81)
West Grove vicinity, *Glen Hope Covered Bridge (Covered Bridges of Chester County Thematic Resources)* SW of West Grove (12–10–80)
West Grove vicinity, *Rudolph and Arthur Covered Bridge (Covered Bridges of Chester County Thematic Resources)* SW of West Grove (12–10–80)

Dauphin County

Halifax vicinity, *Clemson Island Prehistoric District* (9–17–81)
Harrisburg, *Camp Curtin Fire Station*, 2504 N. 6th St. (8–11–81)

Harrisburg, *Seel, William, Building,* 319 Market St. (12–3–80)

Delaware County

BARTRAM'S COVERED BRIDGE (COVERED BRIDGES OF CHESTER COUNTY THEMATIC RESOURCES) Reference—see Chester County.

Erie County

Fairview, *Sturgeon House,* 102 S. Garwood St. (12–10–80)

Fayette County

Connellsville, *Carnegie Free Library,* S. Pittsburgh St. (10–8–81)

Franklin County

Mercersburg, *Church Hill Farm,* NE of Mercersburg at 8941 Kings Lane (12–2–80)
Waynesboro, *Borough Hall of the Borough of Waynesboro,* 57 E. Main St. (12–2–80)

Fulton County

Burnt Cabins, *Burnt Cabins Gristmill Property,* Allen's Valley Rd. (11–28–80)

Indiana County

Indiana, *Graff's Market,* 27 N. 6th St. (12–4–80)

Lackawanna County

Scranton, *Municipal Building and Central Fire Station, 340* N. Washington Ave. and 518 Mulberry St. (9–11–81)

Lancaster County

Brownstone vicinity, *Zook's Mill Covered Bridge (Covered Bridges of Lancaster County Thematic Resources)* W of Brownstone (12–11–80)
Christiana vicinity, *Mercer's Mill Covered Bridge (Covered Bridges of Lancaster County Thematic Resources)* NE of Christiana (also in Chester County) (12–11–80)
Churchtown vicinity, *Pool Forge Covered Bridge (Covered Bridges of Lancaster County Thematic Resources)* NW of Churchtown (12–11–80)
Churchtown vicinity, *Weaver's Mill Covered Bridge (Covered Bridges of Lancaster County Thematic Resources)* SW of Churchtown (12–11–80)
Columbia vicinity, *Forry's Mill Covered Bridge (Covered Bridges of Lancaster County Thematic Resources)* NE of Columbia (12–11–80)
Columbia vicinity, *Seigrist's Mill Covered Bridge (Covered Bridges of Lancaster County Thematic Resources)* NE of Columbia (12–10–80)
Denver vicinity, *Butcher's Mill Covered Bridge (Covered Bridges of Lancaster County Thematic Resources)* S of Denver (12–11–80)
Ephrata vicinity, *Bitzer's Mill Covered Bridge (Covered Bridges of Lancaster County Thematic Resources)* SE of Ephrata (12–11–80)
Ephrata vicinity, *Keller's Covered Bridge (Covered Bridges of Lancaster County Thematic Resources)* SW of Ephrata (12–10–80)
Intercourse vicinity, *Leaman Place Covered Bridge (Covered Bridges of Lancaster County Thematic Resources)* S of Intercourse (12–11–80)
Kirkwood vicinity, *Jackson's Mill Covered Bridge (Covered Bridges of Lancaster County Thematic Resources)* N of Kirkwood (12–10–80)
Kirkwood vicinity, *Pine Grove Covered Bridge (Covered Bridges of Lancaster County Thematic Resources)* (Also in Chester County) (12–11–80)
Kirkwood vicinity, *White Rock Forge Covered Bridge (Covered Bridges of Lancaster County Thematic Resources)* S of Kirkwood (12–10–80)
Lancaster, *Landis Mill Covered Bridge (Covered Bridges of Lancaster County Thematic Resources)* (12–10–80)
Lancaster, *U.S. Post Office,* 50 W. Chestnut St. (7–23–81)
Lancaster vicinity, *Pinetown Covered Bridge (Covered Bridges of Lancaster County Thematic Resources)* E of Lancaster (12–11–80)
Lititz vicinity, *Buck Hill Farm Covered Bridge (Covered Bridges of Lancaster County Thematic Resources)* S of Lititz (12–10–80)
Manheim, *Shearer's Covered Bridge (Covered Bridges of Lancaster County Thematic Resources)* (12–10–80)
Manheim vicinity, *Kaufman's Distillery Covered Bridge (Covered Bridges of Lancaster County Thematic Resources)* SW of Manheim (12–11–80)
Manheim vicinity, *Mount Hope Estate,* NW of Manheim on PA 72 (12–1–80)
Manheim vicinity, *Risser's Mill Covered Bridge (Covered Bridges of Lancaster County Thematic Resources)* SW of Manheim (12–10–81)
Manheim vicinity, *Shank's Mill Covered Bridge (Covered Bridges of Lancster County Thematic Resources)* S. of Manheim (12–10–80)
Pequea vicinity, *Colemanville Covered Bridge (Covered Bridges of Lancaster County Thematic Resources)* NE of Pequea (12–11–80)
Refton vicinity, *Lime Valley Covered Bridge (Covered Bridges of Lancaster County Thematic Resources)* N of Refton (12–10–80)
Rothsville vicinity, *Erb's Covered Bridge (Covered Bridges of Lancaster County Thematic Resources)* N of Rothsville (12–10–80)
Soundersbury vicinity, *Herr's Mill Covered Bridge (Covered Bridges of Lancaster County Thematic Resources)* SW of Soundersburg (12–10–80)
Strasburg vicinity, *Neff's Mill Covered Bridge (Covered Bridges of Lancaster County Thematic Resources)* W of Strasburg (12–11–80)
Terre Hill vicinity, *Red Run Covered Bridge (Covered Bridges of Lancaster County Thematic Resources)* NW of Terre Hill (12–11–80)
Washington vicinity, *Murry Site,* S of Washington (12–10–80)
Willow Street vicinity, *Baumgardner's Mill Covered Bridge (Covered Bridges of Lancaster County Thematic Resources)* SW of Willow Street (12–11–80)

Lebanon County

Lebanon, *Gloninger Estate,* 2511 W. Oak St. (12–10–80)

Lehigh County

Allentown, *Bogert Covered Bridge (Covered Bridges of the Delaware River Watershed Thematic Resources)* (12–1–80)
Allentown, *Haines Mill,* Walnut St. and Main Blvd. (9–11–81)
Allentown, *Lehigh County Prison,* 4th and Linden Sts. (9–11–81)
Allentown, *Old Lehigh County Courthouse,* 5th and Hamilton Sts. (9–11–81)
Allentown vicinity, *Schlicher Covered Bridge (Covered Bridges of the Delaware River Watershed Thematic Resources)* (12–1–80)
Alburtis, *Lock Ridge Furnance Complex,* Franklin and Church Sts. (9–11–81)
Orefield vicinity, *Geiger Covered Bridge (Covered Bridges of the Delaware River Watershed Thematic Resources)* (12–1–80)
Orefield vicinity, *Manasses Guth Covered Bridge (Covered Bridges of the Delaware River Watershed Thematic Resources)* (12–1–80)
Orefield vicinity, *Rex Covered Bridge (Covered Bridges of the Delaware River Watershed Thematic Resources)* (12–1–80)
Orefield vicinity, *Wehr Covered Bridge (Covered Bridges of the Delaware River Watershed Thematic Resources)* (12–1–80)
Slatington, *Fireman's Drinking Fountain,* Main St. (11–9–81)

Luzerne County

Huntington Mills vicinity, *Bittenbender Covered Bridge (Covered Bridges of the Delaware River Watershed Thematic Resources)* (12–1–80)
Wilkes-Barre, *Comerford Theater,* 71 Public Sq. (12–3–80)

Lycoming County

Muncy, *Muncy Historic District,* Roughly bounded by Ridell Lane, Sherman, Washington and Mechanic Sts. (7–3–80)

Montgomery County

Bryn Mawr vicinity, *Mill Creek Historic District,* E of Bryn Mawr (12–10–80)
Gladwyne, *Gladwyne Historic District (Merion Square Historic District)* PA 23 (12–10–80)
Norristown vicinity, *Barley Sheaf Inn.* N of Norristown at 420 W. Germantown Pk. (12–10–80)
Norristown vicinity, *Morris, Anthony, House,* N of Norristown on Stump Hall Rd. (12–3–80)

Northampton County

Bethlehem, *1762 Waterworks,* Monocacy Creek (5–29–81) NHL
Easton, *Easton House,* 167–169 Northampton St. (12–3–80)
Kreiderville, *Kreiderville Covered Bridge (Covered Bridges of the Delaware River Watershed Thematic Resources)* (12–1–80)
Nazareth, *Nazareth Hall Tract,* Zizendorf Sq. (11–28–80)

Northumberland County

Northumberland, *Priestley, Dr. Joseph, House (Cross Keys Inn)* 100 King St. (9–11–81)
Turbotville vicinity, *Kirk, William, House,* W of Turbotville (12–2–80)

Philadelphia County

Philadelphia, *Franklin Hose Company No. 28,* 730—732 S. Broad St. (12–3–80)
Philadelphia, *Franklin Square (Four Public Squares of Philadelphia Thematic Resources)* Race and 6th Sts. (9–14–81)
Philadelphia, *Leidy, Dr. Joseph, House,* 1319 Locust St. (12–4–80)
Philadelphia, *Logan Square (Four Public Squares of Philadelphia Thematic Resources)* 18th and Race Sts. (9–14–81)
Philadelphia, *Princeton Club,* 1221—1223 Locust St. (12–4–80)
Philadelphia, *Rittenhouse Square (Four Public Squares of Philadelphia Thematic Resources)* Rittenhouse Sq. and 18th St. (9–14–81)
Philadelphia, *Thomas Mill Covered Bridge (Covered Bridges of the Delaware River Watershed Thematic Resources) (12–1–80)*
Philadelphia, *Union Methodist Episcopal Church (Jones Tabernacle A.M.E. Church and Parish House)* 2019 W. Diamond St. (10–15–80)
Philadelphia, *Walnut-Chancellor Historic District,* 21st., Walnut and Chancellor Sts. (12–1–80)
Philadelphia, *Washington Square (Four Public Squares of Philadelphia Thematic Resources)* Locust and 6th Sts. (9–14–81)
Philadelphia, *Young Men's Christian Association,* 115 N. 15th St. (12–2–80)

Schuylkill County

Rock vicinity, *Rock Covered Bridge (Covered Bridges of the Delaware River Watershed Thematic Resources)* (previously listed in the National Register 1–3–78 as Schuylkill County Bridge No. 113)
Rock vicinity, *Zimmerman Covered Bridge (Covered Bridges of the Delaware River Watershed Thematic Resources)* (previously listed in the National Register 1–3–78 as Schuylkill County Bridge No. 114)

Somerset County

Berlin vicinity, *Beechdale Bridge (Covered Bridges of Somerset County Thematic Resources)* SW of Berlin (12–10–80)
Davidsville vicinity, *Packsaddle Bridge (Covered Bridges of Somerset County Thematic Resources)* (12–10–80)
New Baltimore, *New Baltimore Bridge (Covered Bridges of Somerset County Thematic Resources)* (12–10–80)
Shanksville vicinity, *Glessner Bridge (Covered Bridges of Somerset County Thematic Resources)* NW of Shanksville (12–10–80)
Somerset vicinity, *Barronvale Bridge (Covered Bridges of Somerset County Thematic Resources)* W of Somerset (12–11–80)
Somerset vicinity, *King's Bridge (Covered Bridges of Somerset County Thematic Resources)* W of Somerset (12–11–80)
Somerset vicinity, *Walter's Mill Bridge (Covered Bridges of Somerset County Thematic Resources)* N of Somerset (12–10–80)
Stoystown vicinity, *Trostletown Bridge (Covered Bridges of Somerset County Thematic Resources)* SE of Stoystown (12–11–80)
Tire Hill vicinity, *Shaffer's Bridge (Covered Bridges of Somerset County Thematic Resources)* W of Tire Hill (12–10–80)
Ursina vicinity, *Lower Humbert Bridge (Covered Bridges of Somerset County Thematic Resources)* N of Ursina (12–10–80)

PUERTO RICO

LIGHTHOUSE SYSTEM OF PUERTO RICO THEMATIC RESOURCES. Reference—see individual listings under Arecibo vicinity, Cabo Rojo, Guanica vicinity, Guayama vicinity, Ponce vicinity, San Juan, San Juan vicinity, Culebrita Island, Mona Island, and Vieques Island.
Arecibo vicinity, *Fargo de Arecibo (Lighthouse System of Puerto Rico Thematic Resources)* (previously listed in the National Register 11–23–77)
Arecibo vicinity, *Faro de Punta Borinquen (Lighthouse System of Puerto Rico Thematic Resources)* (10–22–81)
Arecibo vicinity, *Faro de Punta Higuero (Lighthouse System of Puerto Rico Thematic Resources)* (10–22–81)
Cabo Rojo, *Faro de los Morrillos de Cabo Rojo (Lighthouse System of Puerto Rico Thematic Resources)* (10–22–81)
Guanica vicinity, *Faro de Guanica (Lighthouse System of Puerto Rico Thematic Resources)* (previously listed in the National Register 3–28–77)
Guayama vicinity, *Faro de Punta de las Figuras (Lighthouse System of Puerto Rico Thematic Resources)* (10–22–81)
Guayama vicinity, *Faro de Punta de la Tuna (Lighthouse System of Puerto Rico Thematic Resources)* (10–22–81)
Ponce, *Castillo de Serralles,* Cerro El Vigia, (11–3–80)
Ponce vicinity, *Faro de la Isla de Caja de Muertos (Lighthouse System of Puerto Rico Thematic Resources)* (10–22–81)
Ponce vicinity, *Faro del Puerto de Ponce (Lighthouse System of Puerto Rico Thematic Resources)* (10–22–81)
San Juan, *Faro de Morro (Lighthouse System of Puerto Rico Thematic Resources* (10–22–81)
San Juan, *Superintendent of Lighthouses' Dwellings (Lighthouse System of Puerto Rico Thematic Resources)* (10–22–81)
San Juan vicinity, *Faro de las Cabezas de San Juan (Lighthouse System of Puerto Rico Thematic Resources)* (10–22–81)

Culebrita Island

Culebra vicinity, *Faro Isla de Culebritas (Lighthouse System of Puerto Rico Thematic Resources)* (10–22–81)

Mona Island

Faro de la Isla de la Mona (Lighthouse System of Puerto Rico Thematic Resources) (10–22–81)

Vieques Island

Esperanza vicinity, *Faro de Punta Mulas (Lighthouse System of Puerto Rico Thematic Resources)* (previously listed in the National Register 11–17–77)

RHODE ISLAND

Kent County

Coventry, *Waterman, William, House,* RI 102 (11–14–80)

Providence County

East Providence, *EAST PROVIDENCE MULTIPLE RESOURCE AREA.* This area includes: *Rumford Chemical Works and Mill House Historic District,* N. Broadway, Newman and Greenwood Aves.; *Rumford Historic District,* Pleasant St., Greenwood and Pawtucket Aves.; *Bicknell-Armington Lightning Splitter House,* 3591 Pawtucket Ave., *Boston and Providence Railroad Bridge,* Spans Ten Mile River, *Bridgham Farm* 120, 148, 150, and 160 Pleasant St.; *Carpenter, Lakeside, and Springvale Cemeteries,* Newman and Pawtucket Aves.; *Daggett, Nathaniel, House,* 74 Roger Williams Ave.; *Dennis, James, House,* 3120 Pawtucket Ave.; *District 6 Schoolhouse,* 347 Willett Ave.; *Little Neck Cemetery,* Off RI 103; *Newman Cemetery,* Newman and Pawtucket Aves.; *Newman Congregational Chuch,* 100 Newman Ave.; *Oddfellow's Hall,* 63–67 Warren Ave.; *Squantum Association,* 947 Veterans Memorial Pkwy.; *St. Mary's Episcopal Church,* 83 Warren Ave.; *Whitcomb Farm.* 36 Willett Ave. (11–28–80)

Washington County

Exeter vicinity, *Fisherville Historic and Archeological District,* SW of Exeter on William Reynolds Rd. (12–5–80)
Exeter vicinity, *Hallville Historic and Archeological District,* SW of Exeter on Hallville Rd. (12–5–80)
Exeter vicinity, *Parris Brook Historic and Archeological District,* Mount Tom Rd. (12–5–80)
Exeter vicinity, *Queen's Fort,* NE of Exeter on Stony Lane (11–26–80)
Exeter vicinity, *Sodom Mill Historic and Archeological District,* Sodom Trail (11–24–80)
Wyoming vicinity, *Hillsdale Historic and Archeological District,* E of Wyoming on Hillsdale Rd. (11–24–80)

SOUTH CAROLINA

COLUMBIA MULTIPLE RESOURCE AREA (ADDITIONS) Reference—see Lexington and Richland Counties.
COURTHOUSES IN SOUTH CAROLINA DESIGNED BY WILLIAM AUGUSTUS EDWARDS THEMATIC RESOURCES. Reference—see individual listings under Abbeville, Calhoun, Dillon, Jasper, Lee and York Counties.
PACOLET SOAPSTONE QUARRIES THEMATIC RESOURCES. Reference—see individual listings under Cherokee and Spartanburg Counties.

Abbeville County

Abbeville, *Abbeville County Courthouse (Courthouse in South Carolina Designed by William Augustus Edwards Thematic Resources)* (previously listed in Abbeville Historic District 9–14–72)

Anderson County

Belton, *Chamberlain-Kay House,* 205 River St. (11–25–80)

Berkeley County

Cordesville vicinity, *Richmond Plantation,* SE of Cordesville (11–24–80)

Calhoun County

St. Matthews, *Banks, Col. J. A., House,* 104 Dantzler St. (11–24–80)
St. Matthews, *Calhoun County Courthouse (Courthouses in South Carolina Designed by William Augustus Edwards Thematic Resources)* S. Railroad Ave. (10–30–81)
St. Matthews vicinity, *Houser, David, House,* W of St. Matthews on U.S. 176 (11–25–80)

Charleston County

Charleston, *Cigar Factory,* Block bounded by East Bay, Columbus, Blake and Drake Sts. (11–25–80)
Charleston vicinity, *Barnwell House, (Prospect Hill Plantation),* S of Charleston (11–25–80)
McClellanville vicinity, *Cape Romain Lighthouses,* SE of McClellanville on Lighthouse Island (11–12–81)
McClellanville vicinity, *Wedge, The,* NE of McClellanville (11–25–80)

Cherokee County

Gaffney vicinity, *Archeological Site 38CK1 (Pacolet Soapstone Quarries Thematic Resources)* (12–10–80)
Gaffney vicinity, *Archeological Site 38CK44 (Pacolet Soapstone Quarries Thematic resources)* (also in Spartanburg County) (12–10–80)
Gaffney vicinity, *Archeological Site 38CK45 (Pacolet Soapstone Quarries Thematic Resources)* (12–10–80)

Chester County

Great Falls, *Great Falls Depot,* Republic St. (11–25–80)
Great Falls, *Republic Theater,* 806 Dearborn St. (11–26–80)

Colleton County

Walterboro, *Hickory Valley Historic District,* Roughly bounded by Ireland Creek, Jeffries Blvd., Wichman, Verdier and Ivanhoe Sts. (11–21–80)
Walterboro, *Walterboro Historic District,* Roughly bounded by Jeffries Blvd., Sanders, Black, Church, Valley and Lemacks Sts. (11–10–80)

Dillon County

Dillon, *Dillon County Courthouse (Courthouses in South Carolina Designed by William Augustus Edwards Thematic Resources)* 1303 W. Main St. (10–30–81)

Fairfield County

RIDGEWAY MULTIPLE RESOURCE AREA. This area includes: Ridgeway, Ridgeway Historic District, U.S. 21 and SC 34; *Ruff's Chapel, U.S. 21 and SC 34; Wilson, Monroe, House,* Railroad Ave. and SR S20–20. (11–25–80)

Florence County

Florence vicinity, *Stockade, The,* E of Florence on National Cemetery Rd. (11–28–80)

Georgetown County

Murrells Inlet, *Murrells Inlet Historic District,* Off U.S. 17 (11–25–80)

Greenville County

Greenville, *Old Textile Hall,* 322 W. Washington St. (11–25–80)

Jasper County

Ridgeland, *Jasper County Courthouse (Courthouses in South Carolina Designed by William Augustus Edwards Thematic Resources)* Russell St. (10–30–81)

Kershaw County

Camden vicinity, *Mulberry Plantation,* S of Camden on U.S. 521 (11–25–80)

Lee County

Bishopville, *Lee County Courthouse (Courthouses in South Carolina Designed by William Augustus Edwards Thematic Resources)* 123 Main St. (10–30–81)

Lexington County

West Columbia, *Gervais Street Bridge (Columbia Multiple Resource Area (Additions))* Spans Congaree River (See also listing in Richland County) (11–25–80)
West Columbia, *Mount Hebron Temperance Hall,* 3041 Leaphart Rd. (11–24–80)

McCormick County

Mount Carmel vicinity, *Calhoun Mill,* NE of Mount Carmel (11–24–80)

Newberry County

Newberry, *NEWBURY MULTIPLE RESOURCE AREA.* This area includes: *Boundary Street-Newberry Cotton Mills Historic District,* Roughly bounded by Drayton, Boundary, Charles, Terrant and Crosson Sts.; *Caldwell Street Historic District,* Caldwell St.; *College Street Historic District,* College St.; *Harrington Street Historic District,* Harrington St.; *Main Street Historic District,* Roughly bounded by Harper, Summer, Douglas, Johnstone, Holman, and McMorris Sts.; *Newberry Historic District* (previously listed in the National Register 12–31–74) *(boundary increase)* Roughly bounded by Friend, McKibben, Harrington, Lindsay and Coates Sts.; *Vincent Street Historic District,* Vincent and Crosson Sts.; *West Boundary Street Historic District,* Boundary and Jessica Sts.; *Burton House; Cousins House,* Nance St.; *Higgins, Francis B., House,* 1520 Boundary St.; *Mower, George, House,* 1526 Boundary St.; *Reighley, Ike, House,* 2304 Main St.; *Stewart House,* 1001 Wilson St.; *Summer Brother Stores,* 900 Main St.; *Timberhouse,* 1427 Ebenezer Rd.; *Wells Japanese Garden,* Lindsay St.; *Wells, Osborne, House,* 1101 Fair St. (11–26–80)

Oconee County

Walhalla, *St. John's Lutheran Church,* 301 W. Main St. (11–24–80)

Orangeburg County

Eutawville vicinity, *St. Julien Plantation,* SC 6 (11–28–80)

Richland County

Columbia, *Columbia Multiple Resource Area (Additions).* This area includes: *Building at 1722–1724 Main Street; Canal Dime Savings Bank,* 1530 Main St.; *First National Bank,* 1208 Washington St.; *Palmetto Building,* 1400 Main St.; (See also listing in Lexington County) (11–25–80)

Spartanburg County

ARCHEOLOGICAL SITE 38CK44 (PACOLET SOAPSTONE QUARRIES THEMATIC RESOURCES). Reference—see Cherokee County.
Pacolet vicinity, *Archeological Site 38SP11 (Pacolet Soapstone Quarries Thematic Resources)* (12–10–80)
Pacolet vicinity, *Archeological Site 38SP12 (Pacolet Soapstone Quarries Thematic Resources)* (12–10–80)
Pacolet vicinity, *Archeological Site 38SP13 (Pacolet Soapstone Quarries Thematic Resources)* (12–10–80)
Pacolet vicinity, *Archeological Site 38SP17 (Pacolet Soapstone Quarries Thematic Resources)* (12–10–80)
Pacolet vicinity, *Archeological Site 38SP18 (Pacolet Soapstone Quarries Thematic Resources)* (12–10–80)
Pacolet vicinity, *Archeological Site 38SP19 (Pacolet Soapstone Quarries Thematic Resources)* (12–10–80)
Pacolet vicinity, *Archeological Site 38SP20 (Pacolet Soapstone Quarries Thematic Resources)* (12–10–80)
Pacolet vicinity, *Archeological Site 38SP21 (Pacolet Soapstone Quarries Thematic Resources)* (12–10–80)
Pacolet vicinity, *Archeological Site 38SP23 (Pacolet Soapstone Quarries Thematic Resources)* (12–10–80)
Pacolet vicinity, *Archeological Site 38SP52 (Pacolet Soapstone Quarries Thematic Resources)* (12–10–80)
Pacolet vicinity, *Archeological Site 38SP53 (Pacolet Soapstone Quarries Thematic Resources)* (12–10–80)
Pacolet vicinity, *Archeological Site 38SP54 (Pacolet Soapstone Quarries Thematic Resources)* (12–10–80)
Pacolet vicinity, *Archeological Site 38SP57 (Pacolet Soapstone Quarries Thematic Resources)* (12–10–80)

York County

Clover vicinity, *Bethel Presbyterian Church,* SC 557 (12–10–80)
Rock Hill, *Withers Building,* Oakland Ave. (8–20–81)
York, *York County Courthouse (Courthouses in South Carolina Designed by William Augustus Edwards Thematic Resources)* (previously listed in York Historic District 10–18–79)

SOUTH DAKOTA

Bon Homme County

Springfield, *Main Hall,* University of South Dakota campus (2–3–81)

Grant County

Milbank, *Hollands Grist Mill,* U.S. 12 (2–24–81)

Hughes County

Pierre, *Farr House,* 106 E. Wynoka St. (12–4–80)

Lyman County

Oacoma, *Lower Brule Agency House,* 1st St. and Lichtenstien Ave. (11–21–80)

Minnehaha County

Hartford, *Mundt, John, Building,* 103 N. Main Ave. (2-17-81)
Sioux Falls, *South Dakota School for the Deaf,* 1800 E. 10th St. (6-14-81)

Pennington County

Keystone, *Keystone School,* 3rd St. (2-22-81)
Rapid City, *Rapid City Carnegie Library,* 604 Kansas City St. (2-17-81)

Spink County

Redfield, *Chicago and Northwestern Depot,* U.S. 212 (11-21-80)

TENNESSEE

Bradley County

Cleveland, *Craigmiles Hall,* 170 Ocoee St., NE. (11-25-80)
Cleveland, *Tipton-Fillauer House,* 62 Broad St., NW. (12-8-80)

Davidson County

Nashville, *Ewing, Alexander, House,* 5101 Buena Vista Pk. (11-25-80)
Nashville, *Frost Building (Sunday School Board of the Southern Baptist Convention)* 161 8th Ave., N. (11-25-80)
Nashville, *Rutledge Hill Historic District,* Roughly bounded by Middleton, 2nd, Lea and Hermitage Aves. (7-8-80)
Nashville, *Turner-Cole House,* 2122 W. End Ave. (11-25-80)

Franklin County

Winchester, *Trinity Episcopal Church,* 213 1st Ave., NW (11-25-80)

Gibson County

Humboldt, *Senter-Rooks House,* 2227 Main St. (7-9-80)

Grainger County

Blaine vicinity, *Poplar Hill,* NE of Blaine (7-8-80)
Rutledge vicinity, *Cocke, William, House,* NE of Rutledge (7-3-80)

Greene County

Tusculum, *Tusculum College Historic District,* U.S. 11 and TN 107 (11-25-80)

Grundy County

Monteagle, *DuBose Memorial Church Training School,* Fairmont and College Sts. (11-25-80)

Hamilton County

Chattanooga, *Faxon-Thomas Mansion,* 10 Bluff View Ave. (11-25-80)
Chattanooga, *Thomas, Benjamin F., House,* 938 McCallie Ave. (12-3-80)
Chattanooga, vicinity, *Cummings, Judge Will, House,* W. of Chattanooga at 4025 Cummings Rd. (7-3-80)

Henry County

Paris, *Grove, E. W. Henry County High School,* Grove Blvd. (11-25-80)

Knox County

Knoxville, *Johnson, Andrew, Hotel,* 912 S. Gay St. (7-9-80)
Knoxville, *Williams, Col. John, House,* 2325 Dandridge Ave. (12-3-80)

Madison County

Jackson, *East Main Street Historic District,* Irregular pattern along E. Main St. (7-3-80)
Jackson vicinity, *Deberry-Hurt House,* SW of Jackson (7-8-80)

Montgomery County

Clarksville, *Oak Top,* 107 Madison Ter. (7-8-80)
Clarksville vicinity, *Ringgold Mill Complex,* NW of Clarksville on Mill Rd. (7-8-80)

Overton County

Livingston, *Overton County Courthouse,* Court Sq. (11-13-80)

Sevier County

Sevierville, *Andes, Riley H., House,* Douglas Dam Rd. (7-8-80)

Shelby County

Memphis, *Annesdale,* 1325 Lamar Ave. (11-25-80)
Memphis, *Lenox School,* 519 S. Edgewood Ave. (7-30-81)
Memphis, *Libertyland Grand Carousel,* Libertyland Theme Park (7-3-80)
Memphis, *Memphis Trust Building,* 12 S. Main St. (11-25-80)
Memphis, *Stephens-Cochran House,* 784 Poplar Ave. (7-9-80)
Memphis, *U.S. Marine Hospital Executive Building and Laundry-Kitchen,* 360 and 374 W. California Ave. (7-2-80)

Trousdale County

Hartsville, *Hartsville Depot,* Broadway (7-3-80)

Washington County

Johnson City vicinity, *Bashor Mill,* NE of Johnson City (7-8-80)

Williamson County

Franklin, *Wyatt Hall,* U.S. 31 (7-2-80)

Wilson County

Lebanon vicinity, *Campbell, Dr. John Owen, House,* W of Lebanon on U.S. 70 (12-8-80)

TEXAS

Austin County

Bellville, *Austin County Jail,* 36 S. Bell St. (11-12-80)

Bexar County

San Antonio, *City of San Antonio Municipal Auditorium,* 100 Auditorium Circle (9-14-81)
San Antonio, *San Antonio Water Works Pump Station No. 2,* Brackenridge Park (8-21-81)

Chambers County

Anahuac, *Fort Anahuac (41 CH 226)* TX 564 (7-1-81)

Dallas County

Dallas, *Number 4 Hook and Ladder Company,* Cedar Springs Rd. and Reagan St. (5-4-81)

Eastland County

Cisco, *Mobley Hotel,* 4th St. and Conrad Hilton Ave. (5-13-81)

El Paso County

El Paso, *El Paso High School,* 1600 N. Virginia St. (11-17-80)

Harris County

Houston, *Courtlandt Place Historic District,* 2—25 Courtlandt Pl. (12-3-80)
Houston, *Harris County Courthouse of 1910,* 301 Fannin St. (5-13-81)
Houston, *Milroy, John, House,* 1102 Heights Blvd. (11-12-80)

Hays County

Kyle vicinity, *Kyle, Claiborne, Log House,* SW of Kyle (5-28-81)

Hill County

Hillsboro, *Hill County Jail,* N. Waco St. (5-28-81)

Jefferson County

Port Arthur, *Gates Memorial Library,* 317 Stilwell Blvd. (5-4-81)

Medina County

Castroville vicinity, *de Montel, Charles, House,* NW of Castroville (11-25-80)

Runnels County

Ballinger, *Van Pelt House,* 209 10th St. (12-3-80)

Rusk County

Henderson, *Poe-Jones-Richardson House,* 300 Tipps St. (11-25-80)

Tarrant County

Fort Worth, *Burnett, Burk, Building,* 500—502 Main St. (11-12-80)

Travis County

Austin vicinity, *Walnut Creek Archeological District,* N of Austin (9-24-81)

Victoria County

Victoria, *Tonkawa Bank Site,* Riverside Park (2-13-81)

Webb County

Laredo, *Webb County Courthouse,* 1000 Houston St. (5-4-81)

Wichita County

Wichita Falls, *Weeks House,* 2112 Kell Blvd. (12-3-80)

TRUST TERRITORIES OF THE PACIFIC ISLANDS

Ponape District

Kolonia, *Catholic Belltower,* Catholic Mission (11-25-80)

UTAH

Beaver County

Beaver, *Muir, David, House,* 295 N. 300 West St. (11-25-80)

Cache County

Clarkston vicinity, *Harris, Martin, Gravesite,* N of Clarkston (11-28-80)
Smithfield, *Smithfield Public Library,* 25 N. Main St. (2-17-81)
Wellsville, *Wellsville Tabernacle,* 75 S. 100 East St. (11-26-80)

Emery County

Castle Dale, *Christensen, Paul C., House,* Off UT 10 (12-2-80)

Garfield County

Panguitch vicinity, *Pole Hollow Archeological Site* (7-16-81)

Grand County

Moab, *Moab L. D. S. Church,* Off U.S. 160 (11-28-80)

Juab County

Callao vicinity, *Fish Springs Caves Archeological District* (5-11-81)

Salt Lake County

Salt Lake City, *Liberty Park,* Roughly bounded by 5th E., 7th E., 9th S. and 13th S. (12-11-80)
Salt Lake City, *Utah State Fair Grounds,* 10th W. and N. Temple Sts. (1-27-81)
Salt Lake vicinity, *Wasatch Mountain Club Lodge,* SE of Salt Lake City (11-10-80)

San Juan County

Blanding vicinity, *Butler Wash Archeological District* (7-11-81)
Blanding vicinity, *Patterson, Nancy, Site, (11-21-80)*
Bluff vicinity, *Sand Island Petroglyph Site* (7-11-81)

Summit County

Park City, *Park City Community Church,* 402 Park Ave. (11-25-80)
Park City, *St. Luke's Episcopal Church,* 523 Park Ave. (11-28-80)

Utah County

Mapleton, *Bird, Roswell Darius, Sr., House,* 115 S. Main St. (11-28-80)

Washington County

St. George, *Woodward School,* 100 West and Tabernacle Sts. (11-23-80)
Washington, *Washington School,* Main and Telegraph Sts. (11-23-80)

Wayne County

Hanksville vicinity, *Bull Creek Archeological District* (4-30-81)

VERMONT

Caledonia County

Lyndonville, *Darling Inn,* Depot St. (11-24-80)

Franklin County

St. Albans, *L'Ecole Saintes-Anges,* 247 Lake St. (11-28-80)

Lamoille County

Jeffersonville, *Cambridge Meetinghouse,* Church St. (2-6-81)
Johnson, *Johnson Railroad Depot,* Railroad St. (11-28-80)

Rutland County

Fair Haven, *Fair Haven Green Historic District,* Park Pl., Adams and Main Sts. (11-24-80)

VIRGIN ISLANDS

St. Croix Island

Christiansted vicinity, *Estate La Reine,* 20 Kings Quarter and 19 Queens Quarter (11-24-80)

St. John Island

VIRGIN ISLANDS NATIONAL PARK MULTIPLE RESOURCE AREA. This area includes: Brown Bay, *Brown Bay Plantation Historic District;* Brown Bay vicinity, *Liever Marches Bay Historic District;* Cinnamon Bay, *Rustenberg Plantation South Historic District;* Dennis Bay, *Dennis Bay Historic District;* East End vicinity, *More Hill Historic District;* Hurricane Hole vicinity, *Hermitage Plantation Historic District;* Leinster Bay, *Annaberg Historic District;* Reef Bay, *Reef Bay Great House Historic District; Reef Bay Sugar Factory Historic District;* Reef Bay vicinity, *Jossie Gut Historic District; L'Esperance Historic District;* Cruz Bay, *Lind Point Fort;* Cruz Bay vicinity, *Cathrineberg-Jockumsdahl-Herman Farm,* E of Cruz Bay (previously listed in the National Register 3-30-78); *Cinnamon Bay Plantation,* NE of Cruz Bay on Cinnamon Bay (previously listed in the National Register 7-11-78); *Lameshur Plantation,* E of Cruz Bay on Little Lameshur Bay (previously listed in the National Register 6-23-78); *Mary Point Estate,* NE of Cruz Bay (previously listed in the National Register 5-22-78); and Trunk Bay, *Trunk Bay Sugar Factory* (7-23-81)

VIRGINIA

Albemarle County

Covesville vicinity, *Edgemont,* SE of Covesville on VA 712 (11-28-80)

Alexandria (independent city)

Mount Vernon Memorial Highway, Washington St. and George Washington Memorial Pkwy. (5-18-81) (also in District of Columbia, Arlington and Fairfax Counties VA)
Protestant Episcopal Theological Seminary, 3737 Seminary Rd. (11-17-80)

Appomattox County

Pamplin, *Pamplin Pipe Factory,* (11-25-80)

Arlington County

MOUNT VERNON MEMORIAL HIGHWAY. Reference—see Alexandria (independent city).
Arlington vicinity, *Colonial Village,* Roughly bounded by Wilson and Key Blvds., Lee Hwy., N. 18th, Troy and Rhodes Sts. (12-9-80)
Bristol (independent city)
Bristol Railroad Station, State and Washington Sts. (11-28-80)

Campbell County

Rustburg, *Campbell County Courthouse,* U.S. 501 (10-29-81)

Charles City County

Charles City vicinity, *Upper Weyanoke,* S of Charles City on VA 619 (12-9-80)

Colonial Heights (independent city)

Fort Clifton Site, Conduit Rd. (2-3-81)

Cumberland County

Cumberland vicinity, *Thornton, Charles Irving, Tombstone,* W of Cumberland on Oak Hill Rd. (11-25-80)

Fairfax County

MOUNT VERNON MEMORIAL HIGHWAY. Reference—see Alexandria (independent city)

Gloucester County

Gloucester vicinity, *Warner Hall,* VA 629 (11-25-80)

Nelson County

Shipman vicinity, *Soldier's Joy,* SE of Shipman on VA 626 (11-28-80)

Norfolk (independent city)

Old Norfolk City Hall, 235 E. Plume St. (10-29-81)

Northampton County

Cape Charles vicinity, *Stratton Manor,* SE of Cape Charles off VA 642 (11-28-80)

Petersburg (independent city)

Washington Street Methodist Church, 14—24 E. Washington St. (11-24-80)

Pittsylvania County

Chatham, *Pittsylvania County Courthouse,* U.S. 29 (10-29-81)

Prince William County

Manassas Park vicinity, *Conner House,* Conner Dr. (10-6-81)

Richmond (independent city)

Almshouse, The, 210 Hospital St. (10-29-81)

Salem (independent city)

Academy Street School, Academy St. (10-1-81)

Smyth County

Marion vicinity, *Thomas, Abijah, House,* SW of Marion on VA 657 (11-28-80)
Seven Mile Ford vicinity, *Aspenvale Cemetery,* Off U.S. 11 (12-5-80)

Wise County

Wise, *Wise County Courthouse,* VA 640 (3-2-81)

WASHINGTON

Ferry County

Curlew, *Curlew School,* Off WA 4A (11-28-80)

Kittitas County

Cle Elum, *Cle Elum-Roslyn Beneficial Association Hospital,* 505 Power St. (12-3-80)

Okanogan County

Tonasket vicinity, *Bonaparte Mountain Cabin,* E of Tonasket in Okanogan National Forest (4-20-81)

Skagit County

Anacortes, *Causland Park,* 8th St. and M Ave. (5-7-81)

Snohomish County

Sultan vicinity, *Horseshoe Bend Placer Claim,* N of Sultan (5-7-81)

Thurston County

Olympia, *Lord, C. J., Mansion,* 211 W. 21st Ave. (5-7-81)

Olympia, *Thurston County Courthouse*, Capitol Way (7-23-81)

Walla Walla County

Dixie, *Dixie High School*, Off U.S. 410 (7-23-81)

Whatcom County

Bellingham, *Black, Alfred L., House*, 158 S. Forest St. (12-4-80)
Bellingham, *Citizen's Dock*, 1201 Roeder Ave. (5-14-81)

WEST VIRGINIA

BERKELEY COUNTY MULTIPLE RESOURCE AREA. This area includes: *Baltimore and Ohio Railroad and Related Industries Historic District; Boomtown Historic District; Boydville Historic District; Bunker Hill Historic District; Darkesville Historic District; Downtown Martinsburg Historic District; East Martinsburg Historic District; Greenhill Cemetery Historic District; Harlan Spring Historic District; Hedgesville Historic District; Jones Mill Run Historic District; Mill Creek Historic District; Ridge Road Historic District; South Water Street Historic District; Swan Pond Manor Historic District; Tuscarora Creek Historic District; Watkins Ferry Toll House; Martinsburg Aspen Hall*, Boyd Ave.; Gerrardstown, *Campbellton;* Bunker Hill vicinity, *Drinker, John, House*, Sam Mason Rd.; Bunker Hill, *Edgewood;* Martinsburg, *Faraway Farm;* Hedgesville, *French, Teter Myers, House;* Falling Waters, *Harmony Cemetery;* Marlow vicinity, *Maidstone Manor Farm;* Martinsburg, *Mount Zion Baptist Church, Opequon Lane; Martinsburg, Myers House; Martinsburg Redbud Hollow;* Bunker Hill, *Ridgeway Farm;* Falling Waters, *White Bush.*
Power Plant and Dam No. 4; Power Plant and Dam No. 5; Hedges-Robinson-Myers House; Brick Kilns (Continental Clay Brick Plant) (12-10-80)
HATFIELD CEMETERIES IN SOUTHWESTERN WEST VIRGINIA THEMATIC RESOURCES. Reference—see individual listings in Logan and Mingo Counties.
WEST VIRGINIA COVERED BRIDGES THEMATIC RESOURCES. Reference—see individual listings under Barbour, Cabell, Greenbrier, Harrison, Jackson, Lewis, Marion, Monroe, Monongalia, Pocahontas, and Wetzel Counties.

Barbour County

Carrollton, *Carrolton Covered Bridge (West Virginia Covered Bridges Thematic Resources)* SR 36 (6-4-81)
Philippi, *Philippi Covered Bridge (West Virginia Covered Bridges Thematic Resources)* Main St. over Tygart Valley River (previously listed in the National Register 9-14-72)

Boone County

Madison, *Boone County Courthouse*, State St. (4-9-81)

Cabell County

Huntington, *Memorial Arch*, Memorial Park (4-16-81)
Huntington, *Ninth Street West Historic District*, 9th St., Madison and Jefferson Aves. (11-28-80)
Milton, *Mud River Covered Bridge (West Virginia Covered Bridges Thematic Resources)* Off U.S. 60 on SR 25 over Mud River (previously listed in the National Register 6-10-75)

Greenbrier County

Lewisburg vicinity, *Herns Mill Covered Bridge (West Virginia Covered Bridges Thematic Resources)* W of Lewisburg (6-4-81)
Lewisburg vicinity, *Hokes Mill Covered Bridge (West Virginia Covered Bridges Thematic Resources)* NW of Lewisburg (6-4-81)
White Sulphur Springs vicinity, *Mountain Home*, SW of White Sulphur Springs on U.S. 60 (11-28-80)

Hampshire County

Romney vicinity, *Sycamore Dale*, W of Romney off SR 8 (12-2-80)

Harrison County

Bridgeport vicinity, *Simpson Creek Covered Bridge (West Virginia Covered Bridges Thematic Resources)* (6-4-81)
Salem, *Salem Historic District*, WV 23 (12-2-80)
Wolf Summit vicinity, *Fletcher Covered Bridge (West Virginia Covered Bridges Thematic Resources)* NW of Wolf Summit (6-4-81)

Jackson County

Sandyville vicinity, *Sarvis Fork Covered Bridge (West Virginia Covered Bridges Thematic Resources)* (6-4-81)
Staats Mill, *Staats Mill Covered Bridge (West Virginia Covered Bridges Thematic Resources)* SR 40 (previously listed in the National Register 5-29-79)

Kanawha County

Charleston, *Kearse Theater*, 161, 165, 167 Summers St. (11-28-80)
Charleston, *Wood, Col. Henry Hewitt, House*, 6560 Roosevelt Ave., SE (11-28-80)

Lewis County

Walkersville vicinity, *Walkersville Covered Bridge (West Virginia Covered Bridges Thematic Resources)* S of Walkersville (6-4-81)

Lincoln County

Alum Creek vicinity, *Holley Hills Estate*, S of Alum Creek on Coal River Rd. (12-1-80)

Logan County

Sarah Ann vicinity, *Hatfield Cemetery (Hatfield Cemeteries in Southwestern West Virginia Thematic Resources)* S of Sarah Ann on U.S. 119 (11-28-80)

Marion County

Barrackville, *Barrackville Covered Bridge (West Virginia Covered Bridges Thematic Resources)* SR 21 (previously listed in the National Register 3-30-73)

Mercer County

Princeton, *Mercer County Courthouse*, Courthouse Sq. (11-28-80)

Mingo County

New Town vicinity, *Hatfield Cemetery (Hatfield Cemeteries in Southwestern West Virginia Thematic Resources)* S of New Town on SR 6 (11-28-80)

Monongalia County

Laurel Point vicinity, *Dents Run Covered Bridge (West Virginia Covered Bridges Thematic Resources)* N of Laurel Point (6-4-81)

Monroe County

Salt Sulphur Springs vicinity, *Indian Creek Covered Bridge (West Virignia Covered Bridges Thematic Resources)* 1.5 mi. S of Salt Sulphur Springs on U.S. 219 (previously listed in the National Register 4-1-75)
Lillydale vicinity, *Laurel Creek Covered Bridge (West Virginia Covered Bridges Thematic Resources)* SR 23/4 (6-4-81)

Morgan County

WESTERN MARYLAND RAILWAY RIGHT-OF-WAY, MILEPOST 126 TO MILEPOST 160. Reference—see Allegany County, MD
Berkeley Springs, *Suit, Samuel Taylor, Cottage*, WV 9 (11-28-80)

Ohio County

Wheeling, *Elm Grove Stone Arch Bridge*, U.S. 40 (8-21-81)

Pocahontas County

Cass, *Cass Historic District*, SR 1 and SR 7 (11-28-80)
Hillsboro vicinity, *Locust Creek Covered Bridge (West Virginia Covered Bridges Thematic Resources)* SR 31 (6-4-81)

Randolph County

Elkins, *Randolph County Courthouse and Jail*, Randolph Ave. and High St. (11-28-80)

Summers County

Hinton, *Summers County Courthouse*, Ballangee St. and 1st Ave. (3-2-81)

Wetzel County

Hundred vicinity, *Fish Creek Covered Bridge (West Virginia Covered Bridges Thematic Resources)* SR 13 (6-4-81)

WISCONSIN

Adams County

Friendship vicinity, *Roche-a-Cri Petroglyphs* (5-11-81)

Ashland County

Glidden vicinity, *Marion Park Pavilion*, Marion Park (6-4-81)

Bayfield County

Bayfield, *Bayfield Historic District*, WI J and WI 13 (11-25-80)
Bayfield vicinity, *Pureair Sanatorium*, S of Bayfield (8-20-81)
Salmo vicinity, *Bayfield Fish Hatchery*, WI 13 (7-22-81)

Brown County

Green Bay, *Kellogg Public Library and Neville Public Museum*, 125 S. Jefferson St. (6-9-81)

Dane County

Belleville, *Library Park*, Bounded by Vine, Main, Park and Pearl Sts. (1–26–81)
Dane vicinity, *Dunroven House*, 7801 Dunroven Rd. (11–28–80)
Madison, *Bernard-Hoover Boathouse*, 622 E. Gorham St. (7–30–81)
Madison, *Braley, Judge Arthur B., House*, 422 N. Henry St. (11–28–80)
Madison, *Clarke, Bascom B., House*, 1150 Spaight St. (11–28–80)
Madison, *Dean, Nathaniel W., House*, 4718 Monona Dr. (11–7–80)
Madison, *Kayser, Adolph H., House*, 802 E. Gorham St. (11–28–80)
Madison vicinity, *Drohman Cabin*, 6701 E. Broadway (9–28–81)

Dodge County

Beaver Dam, *Dodge County Historical Museum*, 127 S. Spring St. (7–7–81)
Beaver Dam, *St. Mark's Episcopal Church*, 130 E. Maple St. (11–28–80)
Horicon, *Van Brunt, Daniel C., House*, 139 W. Lake St. (9–14–81)

Douglas County

Lake Nebagamon, *Lake Nebagamon Auditorium*, 1st St. (9–14–81)
Superior, *Pattison, Martin, House*, 906 E. 2nd St. (2–12–81)

Florence County

Florence vicinity, *Fern School*, SW of Florence on WI 101 (3–20–81)

Grant County

Potosi, *Potosi Brewery*, Main St. (11–19–80)

Kewaunee County

Casco vicinity, *Massart Farmstead*, N of Casco on SR C (11–19–80)

La Crosse County

La Crosse, *U.S. Fish Control Laboratory*, Riverside Park (9–17–81)
La Crosse vicinity, *Smith Valley School*, 4130 Smith Valley Rd. (7–30–81)
West Salem, *West Salem Village Hall*, 103 S. Leonard St. (9–14–81)

Lafayette County

Argyle, *Star Theatre*, 200 S. North St. (11–7–80)

Manitowoc County

Manitowoc, *Manitowoc County Courthouse*, 8th and Washington Sts. (4–16–81)

Marathon County

Wausau vicinity, *Single, Benjamin, House*, W of Wausau at 4708 Stettin Dr. (11–24–80)

Marinette County

Amberg, *Amberg Town Hall*, Grant St. (3–20–81)

Milwaukee County

Glendale, *Elderwood*, 6789 N. Elm Tree Rd. (12–4–80)
Milwaukee, *Forest Home Cemetery and Chapel*, 2405 Forest Home Ave. (11–3–80)
Milwaukee, *Milwaukee Fire Department High Pressure Pumping Station*, 2011 S. 1st St. (7–7–81)

Monroe County

Kendall, *Kendalls Depot*, N. Railroad St. (8–12–81)
Sparta, *Sparta Free Library*, Court and Main Sts. (9–3–81)

Oconto County

Oconto, *St. Peter's and St. Joseph's Catholic Churches*, 516 Brazeau Ave. and 705 Park Ave. (11–10–80)

Oneida County

Rhinelander, *Oneida County Courthouse*, S. Oneida Ave. (3–20–81)

Outagamie County

Hortonville, *Hortonville Community Hall*, 312 W. Main St. (1–23–81)

Price County

Fifield vicinity, *Round Lake Logging Dam*, NE of Fifield (9–17–81)

Polk County

St. Croix Falls vicinity, *Dalles Bluff Site (47PK67)*, S of St. Croix Falls (9–5–81)

Racine County

Racine, *Badger Building*, 610 Main St. (12–3–80)
Racine, *Kaiser's*, 218 6th St. (11–25–80)
Racine, *Racine Public Library*, 701 S. Main St. (3–20–81)

Rock County

Janesville, *Janesville Public Library*, 64 S. Main St. (7–1–81)

Sauk County

Baraboo, *Baraboo Public Library*, 230 4th Ave. (9–14–81)
Baraboo, *Tuttle, A. G., Estate*, N. Elizabeth St. (11–6–80)
Lake Delton vicinity, *Peterson, Seth, Cottage*, Dell Ave. (11–9–81)
Prairie du Sac, *Tripp Memorial Library and Hall*, 565 Water St. (9–14–81)

Sheboygan County

Kohler, *Riverbend*, Lower Falls Rd. (12–4–80)
Plymouth, *Huson, Henry H., House and Water Tower*, 405 Collins St. (11–28–80)
Sheboygan, *Third Ward School*, 1208 S. 8th St. (9–3–81)
Sheboygan vicinity, *Kletzien Mound Group (47–Sb–61) (Black River Group No. 2)*, S. 9th St. (7–23–81)

Walworth County

Lake Geneva vicinity, *Meyerhofer Cobblestone House*, E of Lake Geneva on Townline Rd. (12–8–80)

Waukesha County

Brookfield vicinity, *Gredler-Gramins House*, 20190 Davidson Rd. (11–24–80)
Delafield, *Delafield Fish Hatchery*, Main St. (5–13–81)
Eagle vicinity, *Ward District No. 3 Schoolhouse*, WI 67 and Betts Rd. (7–7–81)
Genesee Depot, *Genesee Town Hall*, Genesee St. (6–25–81)
Mukwonago, *Andrews, Sewall, House*, 103 Main St. (7–7–81)

WYOMING

Albany County

Laramie, *East Side School*, Off U.S. 30 (3–17–81)

Converse County

Douglas, *Christ Episcopal Church and Rectory*, 4th and Center Sts. (11–17–80)

Laramie County

Cheyenne, *Capitol North Historic District*, Roughly bounded by E. 29th, and E. 25th St., Warren and Pioneer Aves. (12–10–80)

Park County

Cody vicinity, *Mummy Cave*, W of Cody (2–18–81)

Sheridan County

Big Horn, *Odd Fellows Hall*, Jackson St. (12–9–80)
Sheridan vicinity, *Fort Mackenzie*, N of Sheridan on WY 337 (6–18–81)

Uinta County

Evanston, *St. Paul's Episcopal Church*, 10th and Sage Sts. (11–17–80)

Weston County

Newcastle vicinity, *Cambria Casino*, N of Newcastle (11–18–80)

FOREIGN COUNTRIES

Morocco

Tangier, *American Legation Building*, 8 Zankat America (1–8–81)

* * * * *

The following properties were omitted from the listing in the **Federal Register**, Part II, February 3, 1981.

CALIFORNIA

San Francisco County

San Francisco, *Rincon Annex*, 101–199 Mission St. (11–16–79)

COLORADO

Chaffee County

Nathrop vicinity, *St. Elmo Historic District*, Pitkin, 1st, Main and Poplar Sts. (9–17–79)

Denver County

Denver, *U.S. Customhouse*, 721 19th St. (10–16–79)

El Paso County

Manitou Springs, *Barker House*, 819 Manitou (10–11–79)
Manitou Springs, *First Congregational Church*, 101 Pawnee Ave. (10–16–79)

La Plata County

Durango, *Newman Block*, 801–813 Main Ave. (10–15–79)

Montezuma County

Pleasant View vicinity, *Lancaster, James A., Site (5MT4803)* (4–14–80)

GEORGIA

Floyd County

Cave Spring, *CAVE SPRING MULTIPLE RESOURCE AREA*. This area includes:

Cave Spring Commercial Historic District, Alabama, Rome and Cedartown Rds., Broad and Padlock Sts.; *Cave Spring Residential Historic District,* U.S. 411 and GA 100; *Georgia School for the Deaf Historic District,* Padlock St.; *Rolator Park Historic District,* Off U.S. 411; *Carroll-Harper House,* Cedartown St.; *Carroll, John M., House,* Park St.; *Carroll-Richardson Grist Mill,* Mill St.; *Cave Spring Female Academy,* Rome St.; *Cave Spring High School,* Rome St.; *Cave Spring Railroad Station,* Alabama St.; *Conner, Wesley O., House,* Cedartown St.; *Cowdry, William D., Plantation,* Rome Rd.; *Fannin, Oliver P., House,* Cedartown St.; *Ford, Joseph, House,* Love and Alabama Sts.; *Mann, John T., House,* Rivers St.; *McKinney, Dr. W. T., House,* Cedartown St.; *Rivers Farm,* Rome St.; *Robbins, Samuel W., House,* Rome St.; *Roving House,* Rome St.; *Simmons House,* Cedartown St.; *Simmons, William S., Plantation,* Alabama St.; *Watts, George T., House,* Love St.; *Wharton-Trout House,* Rome St. (6–19–80)

NEW MEXICO

Valencia County

Belen, *Chaves, Felipe, House,* 325 Lala St. (7–4–80)

WASHINGTON

King County

Seattle, *Ferry, Pierre P., House,* 1531 10th Avenue E. (4–18–79)

Stevens County

Colville, *Keller House,* 700 N. Wynne St. (4–18–79)

Colville, *McCauley, H. M., House,* 285 Oak St. (4–18–79)

* * * * *

The following is a list of corrections to properties listed on the National Register. Additional corrections may appear in subsequent updates of the **Federal Register.**

ARIZONA

Coconino County

Winslow vicinity, *Nuvakwewtaqa* (8–2–77) (previously listed as Chavez Pass Pueblo Site)

CALIFORNIA

Alameda County

Oakland, *Greek Orthodox Church of the Assumption,* 9th and Castro Sts. (5–22–78) (previously listed at 920 Brush St.)

GEORGIA

Fulton County

Atlanta, *Brookwood Hills Historic District,* Off U.S. 19 and GA 9 (12–21–79) (previously listed 12–21–80)

Jeff Davis County

Hazelhurst, *Jeff Davis County Courthouse (Georgia County Courthouse Thematic Resources)* Courthouse Square (9–18–80) (previously listed in Hazelhurst)

IDAHO

Valley County

McCall, *Rice Meetinghouse* (4–9–80) (previously listed as Rice Illinois Meetinghouse)

KENTUCKY

Nicholas County

Carlisle, *Carlisle, Louisville and Nashville Passenger Depot,* Market and Locust Sts. (5–18–79) (previously listed as Louisville and Nashville Passenger Depot)

MARYLAND

Baltimore (independent city)

Lightship Chesapeake, Baltimore's Inner Harbor (8–11–80) (previously listed in the District of Columbia)

NEW JERSEY

Bergen County

Fort Lee and vicinity, *Palisades Interstate Park,* West bank of the Hudson River (10–15–66) (also in Rockland County, NY) NHL (previously listed in Orange County, NY)

RHODE ISLAND

Washington County

Saunderstown, Y.W.C.A. Site, NW of Saunderstown on Gilbert Stuart Rd. (11–20–80) (previously listed as Y.M.C.A.)

TENNESSEE

Hamilton County

Chattanooga, *Etheridge Automobile Showroom and Tirestore,* 329 Market St. (4–2–73) (previously listed as Newton Chevrolet Building)

VIRGINIA

Fairfax (independent city)

Fairfax County Courthouse and Jail, 4000 Chain Bridge Rd. (5–3–74) (previously listed as Fairfax County Courthouse)

* * * * *

The following properties have been demolished and/or removed from the "National Register of Historic Places." This action does not necessarily modify the applicability, if any, of provisions of section 2124 of the Tax Reform Act of 1976, as amended.

ARIZONA

Gila County

Globe, *Old Dominion Library,* Murphy St. (demolished)

CALIFORNIA

Mariposa County

Yosemite Village, *Degnan House and Bakery,* Southside Dr., Yosemite National Park (removed)

DELAWARE

Sussex County

Cool Spring vicinity, *Fisher House,* SE of Cool Spring, Broadkill Hundred (removed)

ILLINOIS

Cook County

Brookfield, *Grossdale Station,* Prairie and Burlington Aves. (removed)

Chicago, *Sacred Heart Mission Church,* 11652 S. Church St. (removed)

DuPage County

Winfield, *Besch House,* O S 070 Church St. (removed)

Rock Island County

Rock Island, *Industrial Home No. 94,* 2100 3rd. Ave. (demolished)

INDIANA

Dubois County

Jasper, *Gramelspacher-Gutzweiler House,* 7th and Main Sts. (removed)

IOWA

Dallas County

Perry, *Perry Volunteer Fire Department Engine House,* 1208 1st St. (demolished)

MASSACHUSETTS

Worcester County

Worcester, *Bannister, Emory, House (Worcester Multiple Resource Area)* 3 Harvard St. (3–5–80) (demolished)

MICHIGAN

Monroe County

Monroe, *Fix House,* Sterling State Park (3–16–72) (demolished)

NEW YORK

Erie County

Buffalo, *Niagara Frontier Transit Buildings,* 855 Main St. (5–14–80) (demolished)

Westchester County

Ossining *Rohr, George, Saloon and Boardinghouse,* 1—3 Highland Ave. (12–1–78) (demolished)

PENNSYLVANIA

Pike County

Bushkill, *Bushkill Gristmill,* U.S. 209 (8–3–79) (demolished)

SOUTH CAROLINA

Spartanburg County

Moore vicinity, *Fredonia,* E of Moore off U.S. 221 (10–9–74) (demolished)

TENNESSEE

Madison County

Jackson, *Jones, Casey, Home and Railroad Museum,* 211 W. Chester St. (removed)

TEXAS

Collin County

McKinney, *McKinney, Collin, Cabin,* Finch Park (9–18–78) (demolished)

WEST VIRGINIA

Wood County

Parkersburg, *Parkersburg City Hall*, 5th and Market Sts. (12–11–79) (demolished)

* * * * *

The following properties have been determined to be eligible for inclusion in the "National Register." Determinations of eligibility are usually made at the request of the concerned Federal Agency under the authorities in section 2(b) and 1(3) of Executive Order 11593, and the National Historic Preservation Act of 1966, as amended, as implemented by the Advisory Council on Historic Preservation, 36 CFR Part 800. This listing is not complete. Pursuant to the authorities discussed herein, an Agency Official shall refer any questionable actions to the Keeper, National Register of Historic Places, National Park Service, U.S. Department of the Interior, Washington, D.C. 20240, for an opinion respecting a property's eligibility for inclusion in the "National Register."

Historical properties which are determined to be eligible for inclusion in the National Register of Historic Places are entitled to protection pursuant to section 106 of the National Historic Preservation Act of 1966, as amended, and the procedures of the Advisory Council on Historic Preservation, 36 CFR, Part 800. Agencies are advised that in accord with the procedures of the Advisory Council on Historic Preservation, before an agency of the Federal Government may undertake any project which may have an effect on such a property, the Advisory Council on Historic Preservation shall be given an opportunity to comment on the proposal.

ALABAMA

Mobile County

Cochrane Bridge over the Mobile River

Montgomery County

Veteran's Administration Medical Center

Tuscaloosa County

Tuscaloosa, *Veterans Administration Medical Center*

ALASKA

Ketchikan Division

Coffman Cove Site (49 PET 067) Prince of Wales Island

Kodiak Division

Archeological Site 49–KOD–190

North Slope Borough

Barrow, *Utkiavik (Old Barrow)*

ARIZONA

Gila County

Archeological Site AZ:0:15:44 (63.3)
Archeological Site AZ:0:15:45 (63.3)
Archeological Site AZ:0:15:49 (63.3)
Archeological Site AZ:0:15:58 (63.3)
Archeological Site AZ:0:15:75 (63.3)
Archeological Site AZ:0:15:76 (63.3)
Archeological Site AZ:0:15:78 (63.3)
Archeological Site AZ:0:15:81 (63.3)
Archeological Site AZ:0:15:82 (63.3)
Archeological Site AZ:0:15:83 (63.3)
Archeological Site AZ:0:15:84 (63.3)
Archeological Site AZ:0:15:85
Archeological Site AZ:0:15:86
Archeological Site AZ:0:15:87 (63.3)
Archeological Site AZ:0:15:88 (63.3)
Archeological Site U:3:43 (63.3)
Archeological Site U:3:9 (63.3)
Pine, *Pine Elementary School District No. 12* (63.3)
Rye, *Archeological Site U:3:44* (63.3)
Rye, *Archeological Site U:3:49* (63.3)
Rye, *Archeological Site U:3:54* (63.3)
Rye, *Archeological Site U:3:56* (63.3)
Rye, *Archeological Site U:3:57* (63.3)
Rye, *Archeological Site U:3:58* (63.3)
Rye, *Archeological Site U:3:61* (63.3)
Rye, *Archeological Site U:3:66* (63.3)

Maricopa County

General Motors Phoenix Laboratory Building (63.3)
Phoenix, *Archeological Site AZ T:12:38 (ASM)* (63.3)
Phoenix, *Chelsea Place Historic District* (63.3)
Phoenix, *Former Pay 'N' Takit Store* (63.3)
Phoenix, *Grace Lutheran Church* (63.3)
Phoenix, *Kenilworth Historic District* (63.3)
Phoenix, *Las Colinas Archeological Site (AZ T:12810)*, Boundary Increase
Phoenix, *McClintock House* (63.3)
Phoenix, *Original Phoenix Townsite, Blocks 1 and 2*
Phoenix, *Phoenix LDS Second Ward Church* (63.3)
Phoenix, *Publix Market* (63.3)
Phoenix, *Thayer House* (63.3)

Mohave County

Mohave Hope Cabin
Mohave Hope Mine and Mining Camp

Navajo County

Archeological Site AZ–D–10–22
Archeological Site NA 14,495 (63.3)
Archeological Site NA 14,605 (63.3)
Archeological Site NA 14,614 (63.3)
Archeological Site NA 14,615 (63.3)
Archeological Site NA 14,617 (63.3)
Black Mesa Multiple Resource Area

Pima County

Barrel Canyon Archeological District
Upper Davidson Canyon Archeological District
Nolic, *Archeological Site AA:13:19*
Tucson, *Drexel Village Site AA:16:49*
Tucson, *Irvington Village Site AA:16:46*
Tucson, *Midvale Historic Site A AA:16:61*
Tucson, *Midvale Historic Site B AA:16:62*
Tucson, *Southern Pacific Railroad Oil House No. 3*
Tucson, *Veteran's Administration Medical Center*

Yavapai County

Prescott, *Veteran's Administration Medical Center*

Yuma County

Palo Verde-Devers Multiple Resource Area
Palo Verde-Devers Transmission Line Corridor-Segment 1
Palo Verde Transmission Line Corridor-Segment 8 (also in Maricopa County)

ARKANSAS

Chicot County

Powell Canal Site

Garland County

Lake Ouachita, *Avery Site (3GA113)*

Pulaski County

Little Rock, *U.S. Post Office and Courthouse*, 600 W. Capitol Ave.

Washington County

Veteran's Administration Medical Center

CALIFORNIA

Helkau District

Alameda County

Castro Valley, Archeological Site CA–Ala–60
Fremont, *Harvey, Sylvester P., Home and 1854 Cabin*, 3590 Grand Lake Dr.
Fremont, *Shinn Home*, 1269 Peralta Blvd.
Newark, *Patterson, G. W., House (Ardenwood)*

Calaveras County

Romaggi House

Contra Costa County

Black Diamond Historic District (63.3)
Hercules, *Cco-248*
Richmond, *Ellis Landing Shellmound*
Richmond, *Richmond Shipyard No. 3*
Richmond, *Stege Mounds Archeological District* (63.3)

Del Norte County

Hiouchi, *Myrtle Creek Ditch*

Glenn County

Archeological Site CA LAK 1112, Mendocino National Forest
Archeological Site CA MEN 1612, Mendocino National Forest

Lake County

Archeological Site CA–LAK–802, Mendocino National Forest (63.3)
Archeological Site CA–LAK–1133, Mendocino National Forest

Los Angeles County

Propulsion System for the Ferryboat Sierra Nevada, Terminal Island
Long Beach, *Bradley Building* (63.3)
Los Angeles, *Goodyear Tire and Rubber Plant*, 6701 S. Central Ave.
Los Angeles, *Veteran's Administration Medical Center*
Pasadena, *Bungalow Courts*
Pasadena, *Dowling-Rodriguez House*, 570 N. Raymond Ave.
Pasadena, *Evanston Inn*, 385–395 Marengo
Pasadena, *Merrill-Grider House* 1285 N. Summit Ave.
Pasadena, *Prospect Boulevard Bridge*
Pasadena, *Prospect Park Historic District*, Prospect Blvd.
Pasadena, *South Marengo Historic District*

Pasadena, *Tract 1032 Historic District*
Pomona, *Fox Theatre* (63.3)

Madera County

Buchanan Dam Archeological District (also in Mariposa County)

Marin County

Sausalito, *Point Bonita Light Station*

Mendocino County

Archeological Site CA-MEN-208
Archeological Site CA-MEN-268
Archeological Site CA-MEN-320/643
Archeological Site CA-MEN-321
Archeological Site CA-MEN-323
Archeological Site CA-MEN-325
Archeological Site CA-MEN-329
Archeological Site CA-MEN-330
Archeological Site CA-MEN-1643/H
Archeological Site CA-MEN-1705/H
Pilil Site (Snow Rock) 05-08-53-258
Cleone vicinity, *Kennedy, John, House*

Mono County

Archeological Site CA-MNO-529

Nevada County

Archeological Site FS-05-17-57-73
Archeological Site FS-05-17-57-74
Archeological Site FS-05-17-57-232
Archeological Site FS-05-17-57-280
Archeological Site FS-05-17-57-281
Archeological Site FS-05-17-57-282
Excelsior Ditch Co. Nev. 207
Grass Valley vicinity, *Archeological Site CA-NEV-407*

Orange County

Building at 114 Pacific Coast Highway (63.3)
Downtown Santa Ana Historic District

Placer County

Archeological Site FS-05-17-57-69
Archeological Site FS-05-17-57-209

Plumas County

Archeological Site CA-Plu-115

San Bernardino County

Archeological Site CA-SBr-189
Archeological Site SBr-112
Archeological Site SBr-4285
Archeological Site SBR-4440 (Fort Irwin) (63.3)
Archeological Site SBR-4441 (Fort Irwin) (63.3)
Archeological Site SBR-4442 (Fort Irwin) (63.3)
Archeological Site SBR-4443 (Fort Irwin) (63.3)
Archeological Site SBR-4444 (Fort Irwin) (63.3)
Archeological Site SBR-4445 (Fort Irwin) (63.3)
Archeological Site SBR-4562 (Fort Irwin) (63.3)
Archeological Site SBR-4563 (Fort Irwin) (63.3)
Crowder Canyon Archeological District Boundary Extension
Fort Irwin, *Archeological Site SBr-4170* (63.3)
Fort Irwin, *Archeological Site SBr-4213* (63.3)
Fort Irwin, *Archeological Site SBr-4214* (63.3)
Fort Irwin, *Archeological Site SBr-4215*

San Diego County

Archeological Site CA-SDi-799
Archeological Site SDi-5133
Archeological Site SDi-5130
Archeological Site CA-SDi-7311
Archeological Site W-1837
Archeological Site W-1838
Archeological Site W-1839
San Diego, *Armed Forces Y.M.C.A. Building*, Centre City
San Diego, *Frost Lumber Corner Building*, Centre City
San Diego, *Golden West Hotel*, Centre City
San Diego, *Hotel San Diego*, Centre City
San Diego, *Plaza de Pantoja*, Centre City
San Diego, *Police Headquarters Complex*, Centre City
San Diego, *San Diego Gas and Electric Substation B*, Centre City
San Diego, *Senator Hotel*, Centre City
San Diego, *Soap Factory Complex*, Centre City
San Diego, *Tower Bowling Alley*, Centre City

San Francisco County

Hills Brothers Building
San Francisco, *Bayshore Mound (CA-SFr-7)* (63.3)
San Francisco, *Oriental Warehouse*
San Francisco, *Veteran's Administration Medical Center*

San Joaquin County

Stockton, *California Water Services Company Station No. 1 Complex*

San Mateo County

Daly City, *Schoolhouse Station (Colma Railroad Station)*, 11 Washington St.

Santa Barbara County

Arroyo Hondo Bridge
Arroyo Quemado Bridge
Vandenberg Air Force Base, *Archeological Site CA-SBa-534*
Vandenberg Air Force Base, *Archeological Site CA-SBa-662*
Vandenberg Air Force Base, *Archeological Site CA-SBa-678*
Vandenberg Air Force Base, *Archeological Site CA-SBa-680*

Santa Clara County

Realty Building, 19 N. 2nd St.
San Jose, *Building at 295 East San Fernando Street*
San Jose, *Commercial Building*, 28 N. 1st St.
San Jose, *Fox Theater*, 345 S. 1st. St.
San Jose, *King Conservatory of Music*, 261 N. Second St.
San Jose, *Moir Building*, 233 N. 1st St.
San Jose, *Montgomery Hotel*, 211 S. 1st St.
San Jose, *Nathan Flats and House*, 31—33, 35—37 and 45 E. Julian St.
San Jose, *Sainte Claire Building*, 311 S. 1st St.
San Jose, *San Jose Historic District*, 1st, 2nd and 3rd Sts.
San Jose, *Tognazzi Building*, 261—265 N. 1st St.
San Jose, *Twohy Building*, 210 S. 1st St.

Shasta County

Archeological Site 05-14-56-284, Shasta-Trinity National Forest
Anderson vicinity, *Battle Creek Bridge*, Grover Rd.
LaMoine, *LaMoine Lumber and Trading Company Railroad (Logging System Historic District)* (also in Trinity County)

Siskiyou County

Archeological Site CA-Sis-361
Scott River Bridge
Shelley Bridge

Solano County

Fairfield, *Goosen Mansion*
Suisun City, *House at 407 California Street*
Suisun City, *House at 821-823 Main Street*
Suisun City, *House at 216 Morgan Street*
Suisun City, *House at 400 Morgan Street*
Suisun City, *House at 406 Morgan Street*
Suisun City, *House at 221 Solano Street*
Suisun City, *Jones, K.I., House*, 308 California St.
Suisun City, *Suisun City Fire Department*

Tehema County

Archeological Site CA-TEH-962

Trinity County

Archeological Site CA-Tri-205
Archeological Site CA-Tri-438
Eagle Ranch 05-14-54-43, Shasta-Trinity National Forest

Tuolumne County

Rambling Archeological Site (CA-TUO-1285)
Skunk Creek Archeological Site (CA-TUO-1284)

COLORADO

Globeville German Congregational Church, E. 44th Ave. and Lincoln St.

Adams County

Larson Property 5AM77, 7381 Washington St., North

Arapahoe County

Littleton, *Willowcroft*, 3600 W. Bowles Ave.

Bent County

Fort Lyon, *Veteran's Administration Medical Center*

Denver County

Denver City Park (63.3)
Denver, *Building at 23 Acoma Street*
Denver, *Building at 100 Broadway*
Denver, *Buildings at 2—10 Broadway*
Denver, *Buildings at 68—74 Broadway*
Denver, *Buildings at 76—96 Broadway*
Denver, *Buildings at 101—111 Broadway*
Denver, *Buildings at 108—114 Broadway*
Denver, *Buildings at 21—39 South Broadway*
Denver, *Buildings at 38—42 South Broadway*
Denver, *Buildings at 76—86 South Broadway*
Denver, *Buildings at 94—98 South Broadway*
Denver, *Building at 2526 Welton*
Denver, *Building at 2745 Welton*
Denver, *Building at 2812 Welton*
Denver, *Building at 2824 Welton*
Denver, *Building at 2831 Welton*
Denver, *Building at 32 West Ellsworth Avenue*
Denver, *Building at 48 West Ellsworth Avenue*
Denver, *Building at 50 West Ellsworth Avenue*
Denver, *Building at 58 West Ellsworth Avenue*
Denver, *Building at 62 West Ellsworth Avenue*

Denver, *Building at 68 West Ellsworth Avenue*
Denver, *Building at 105 West Ellsworth Avenue*
Denver, *Building at 106 West Ellsworth Avenue*
Denver, *Buildings at 36—42 West Ellsworth Avenue*
Denver, *Building at 35 West Irvington Place*
Denver, *Building at 39 West Irvington Place*
Denver, *Building at 43 West Irvington Place*
Denver, *Building at 51 West Irvington Place*
Denver, *Building at 59 West Irvington Place*
Denver, *Building at 101 West Irvington Place*
Denver, *Building at 102 West Irvington Place*
Denver, *Elyria Elementary School*
Denver, *Fort Logan National Cemetery*, 3698 Sheridan Blvd.
Denver, *Glenarm Recreation Center*, 2800 Glenarm St.

Douglas County

Cheese Ranch Historic District
Highlands Headquarters Ranch Historic District

Eagle County

Archeological Site 5EA306

El Paso County

Woodman Hall (63.3)
Colorado Springs, *Garfield School* (63.3)
Colorado Springs, *Myron Stratton House* (63.3)

Garfield County

Archeological Site 5GF126, Battlement Mesa
Archeological Site 5GF128, Battlement Mesa
Archeological Site 5GF133, Battlement Mesa
Archeological Site 5GF134, Battlement Mesa
Archeological Site 5GF135, Battlement Mesa
Archeological Site 5GF519
McGuirk-Nordstrom House (Site 5GF786)
Spencer House (Site 5GF594)

Grand County

Archeological Site 5GA–122
Archeological Site 5GA–128
Archeological Site 5GA–151
Archeological Site 5GA–153
Archeological Site 5GA–572
Archeological Site 5GA–680

Lake County

Archeological Site 5LK385
Archeological Site 5LK386
Malta vicinity, *Denver and Rio Grande Western Railroad*

Larimer County

Bear Lake Comfort Station, Rocky Mountain National Park (63.3)
Bear Lake Ranger Station, Rocky Mountain National Park (63.3)

Las Animas County

Trinidad Foundry 5LA2160

Mineral County

Creede vicinity, *Sevenmile Bridge (5ML27)* SW of Creede

Otero County

La Junta, *Building at 15 Wickham*
La Junta, *Sciumbato, George, Grocery*, 706 W. 2nd St.

Weld County

Greeley, *Bolker Subdivision*
Greeley, *Building at 1421 Eighth Street*
Greeley, *Building at 1443 Fifth Street*
Greeley, *Building at 1539 Fifth Street*
Greeley, *Building at 1801 Fifth Street*
Greeley, *Building at 1823 Fifth Street*
Greeley, *Building at 1824 Fifth Street*
Greeley, *Building at 605 Fourteenth Avenue*
Greeley, *Building at 617 Fourteenth Avenue*
Greeley, *Building at 1112 Sixth Street*
Greeley, *Fifth Street Neighborhood Area*

CONNECTICUT

Fairfield County

Bridgeport, *St. John's Nepomucene School*
Danbury, *Old Danbury Jail*, 80 Main St. (63.3)
Stamford, *Building at 10–12 Linden Place* (63.3)
Stamford, *Railroad Company Trolley Barn*
Stamford, *Stamford Railroad Station*
Stamford, *Trolley Office Building*

Hartford County

Harwinton, *Valley View Farms Incorporated Cook Farm and Wind Mill*, South Rd.
Harwinton, *Valley View Farms Incorporated Red Salt Box House*
Harwinton, *Valley View Farms Incorporated Shanley House*, Plymouth Rd.

New Haven County

Southwest Ledge Lighthouse, New Haven Harbor
New Haven, *Schubert Theater*
North Haven, *Bishop and State Street Historic District*

New London County

New London Ledge Lighthouse
East Lyme, *Niantic River Highway Bridge*
Griswold, *Prehistoric Archeological Site P58–001* (63.3)
Mystic, *Mystic Bridge Union Switch and Signal Company "Style B" Electric Interlocking Machine and Model Board*, Mystic Bridge
Waterford, *Niantic River Highway Bridge*

Windham County

Williamantic, *Building at 877 Main Street*

DELAWARE

Reedy Island Range Rear Lighthouse, Taylor's Bridge

New Castle County

Wilmington, *Wilmington Boulevard Historic District Amendment*

DISTRICT OF COLUMBIA

Washington

Mitchell Park Archeological Site (63.3)
Anacostia, *Jenkins Archeological Site*

FLORIDA

Duval County

Jacksonville, *Cogswell, A. R., Building*, 433 W. Bay St.
Jacksonville, *First Baptist Church*, W. Church St.
Jacksonville, *Old Stanton High School*, 521 W. Ashley St.
Jacksonville, *Seminole Club*, N. Hogan St.
Jacksonville, *U.S. Fidelity and Guaranty Company*, 424 N. Hogan St.
Jacksonville, *Wolf, Levy, Building*, N. Hogan St.
New Berlin, *St. John's River Power Park Archeological District*

Escambia County

Pensacola, *Barrancas National Cemetery*

Hardee County

Aboriginal Site No. 1

Manatee County

Bradenton, *Carruthers Mound (8–Ma–119)*, *(63.3)*

Monroe County

Key West, *Key West Naval Station Historic District*

Pinellas County

Veteran's Administration Medical Center-Bay Pines

GEORGIA

Atkinson County

Willacoochee, *Gaskins, Dr. J. A., House*, GA 82 (63.3)
Willacoochee, *West Willachoochee Historic District* (63.3)
Willacoochee, *Willacoochee Masonic Lodge* (63.3)

Baldwin County

Milledgeville vicinity, *Vinson-Ashfield House*, E of Milledgeville

Berrien County

Alapaha, *Kendrick-Gaskins House*, GA 82 (63.3)
Alapaha, *Paulk House, George St.* (63.3)

Chatham County

Savannah, *C.S.S. Georgia*
Tybee Island, *Fort Screven Historic District*

Clarke County

Athens, *Miller Hall*, Ogelthorpe Ave. and Buck Rd.

Cobb County

Marietta, *Brumby-Arnoldus House*, 472 Powder Springs St.
Smyrna, *Carmichael, J. H., House*, 501 Log Cabin Rd. (63.3)

Dade County

Trenton, *Archeological Site ES–1611–1* (63.3)

DeKalb County

Fort Creek Mountain Site (9DA18) Soapstone Ridge
Atlanta, *Southern G. F. Building*, 263 Decatur St., SE
Decatur, *U.S. Honor Farm Complex*, 3074 Panthersville Rd. (63.3)

Dougherty County

Albany, *South Central Albany Multiple Resource Area*

Elbert County

Archeological Site EB 418

Fannin County

Weaver Site 9Gi(DOT)21 (also in Gilmer County)

Floyd County

Archeological Site ES–949–7
Archeological Site ES–949–9
Archeological Site ES–949–16 (Fourche-Hardy Farm)

Fulton County

Pallas Apartments, 1559 Peachtree St.
Atlanta, *Academy of Medicine*, 825 W. Peachtree St.
Atlanta, *Biltmore Hotel*, 817 W. Peachtree St.
Atlanta, *Knox Apartments No. 1*, 1543 Peachtree St.
Atlanta, *Knox Apartments No. 2*, 1576 W. Peachtree St.
Atlanta, *Knox Apartments No. 3*, 1586 W. Peachtree St.
Roswell, *Smith House*, 935 Alpharetta St.

Glynn County

Gascoigne Bluff Site (63.3)

Gordon County

Calhoun vicinity, *Haynes, Cleo, House and Frame Structure*

Grady County

Pine Park Community Center, GA 38 (63.3)

Henry County

Stockbridge, *Turner House*, SR 42 (63.3)

Laurens County

Dublin, *Wrightsville and Tennille Railroad*, S. Jefferson St.

Lincoln County

Lincolnton, *Rees Building* (63.3)

Madison County

State Route 72 Highway Bridge, SR 72 over Broad River

McIntosh County

Archeological Site 9Mc141, Harris Neck National Wildlife Refuge (63.3)

Monroe County

Forsyth, *Berner House* (63.3)
Forsyth, *Old Main Post Office*

Muscogee County

Fourteenth Street Bridge

New County

Newton Factory Community Archeological District

Oconee County

Watkinsville, *Archeological Sites 90c20 and 90c23*
Watkinsville, *Archeological Sites 90c21 and 90c22*
Pickens County

Archeological Site Kc9Pi1

Richmond County

Augusta, *Butler Creek Archeological District*
Augusta, *Veteran's Administration Medical Center*

Stewart County

Richland, *Saville House*

Terrell County

Parrott, *Whaley, John C., Homeplace*

Thomas County

Ochlocknee, *Zeigler Building*
Thomasville, *Chinquapin Plantation*, Old Cassidy Road (63.3)

Tift County

Tifton, *Tifton Bridge*
Tifton, *Tifton Cotton Mill Complex*, SR 82

Toombs County

Lyons, *Twenty Columns*, Liberty and Johnson Sts. (63.3)
Vidalia vicinity, *Moses-Coleman House*, E of Vidalia (63.3)

Towns County

Kelly Bridge, SR 87 over Hiawassee River

Troup County

La Grange, *Broad Street Historic District*

Twiggs County

Jeffersonville Historic District

Walker County

Hixon, William, House, Boundary Amendment

Ware County

Waycross, *Moody-Adams House*, 843 Reynolds St. (63.3)
Waycross, *New Waycross Historic District* (63.3)
Waycross, *Saint Ambrose Mission*, 1013 Reynolds St. (63.3)

Washington County

Sandersville, *Carter, William W., House*

White County

Cleveland, *Mauney Homestead*

Whitfield County

Dalton, *Dug Gap Breastworks UGS 9–WD–8*

HAWAII

Honolulu County

Honolulu, *Palm Circle Historic District*
Oahu, *Waimanalo Ditch System*

IDAHO

Ada County

Lee Street Historic District

Benewha County

St. Maries vicinity, *Saint Joe Baldy Site (10 BW 2)*

Bonner County

Coolin, *Vinther and Nelson Cabin*

Shoshone County

Mullan, *Rock Creek Flume*
Wallace, *Albi's Bar and Hotel (Camia Building)* 6th and Pine Sts.
Wallace, *Arnold, Deloros, Building*
Wallace, *d'Alene, Coeur, Hardware Company*
Wallace, *d'Alene, Coeur, Iron Works*
Wallace, *Hale Building*, 7th and Bank Sts.
Wallace, *Hecla Mining Company*, Cedar and 7th Sts.
Wallace, *Martin, P. L., Building*
Wallace, *Runge Furniture Company Building*, 7th and Bank Sts.
Wallace, *Union Pacific Depot*
Wallace, *Wallace City Hall*
Wallace, *Wallace Public Library*, River and 5th St.

ILLINOIS

Cook County

Berwyn, *Berwyn Train Depot*, Oak Park and Windsor Aves.
Chicago, *Chicago Art Institute*, Michigan Ave.
Chicago, *Commercial Building*, 130 W. Lake
Chicago, *Fire Station*, 209 N. Dearborn
Chicago, *Humboldt Park Fieldhouse*
Chicago, *Pulaski Park Fieldhouse*
Chicago, *Selwyn-Harris Theaters*, 170–186 N. Dearborn St.
Chicago, *Woods Theater*, 50 W. Randolph
Oak Park, *Cicero Gas Company Building*, 115 N. Oak Park Ave.

La Salle County

Utica, *Archeological Site 11–LS–1*

Madison County

Alton vicinity, *Archeological Site GT–5*

Marion County

Archeological Site 11–Mr–11 (63.3)

Menard County

Petersburg, *Eberhard, Leopold, Home*

Peoria County

Mossville, *Rench Archeological District*

Vermillion County

Danville, *Danville Branch of the National Home for Disable Volunteer Soliders*

Winnebago County

Rockford, *Haight Village Historic District*

INDIANA

Abington County

Cambridge City, *Building at 100 W. Main Street* (63.3)

Grant County

Marion, *Veteran's Administration Medical Center*

Jefferson County

Deputy, *McNeil Stone Fort Archeological Site (12 Je 4)* Dixenford Rd.

Marion County

Indianapolis, *Garfield, James A., School*, 209 E. Raymond St.
Indianapolis, *Garfield Park*
Indianapolis, *Raymond Street Houses*, 37, 39, 47, 53, 55 and 59 Raymond St.
Indianapolis, *Veteran's Administration Medical Center*, Cold Spring Rd.

Martin County

Martin County Bridge No. 21 over Indian Creek

Vanderburgh County

Skora Building, 2nd and Sycamore Sts.
Evansville, *Evansville Municipal Market*

IOWA

Des Moines County

Skunk River Bridge (also in Lee County)

Dubuque County
Dubuque, *Eagle Point Bridge*

Jackson County
Bridge over Bear Creek

Johnson County
Sutliff Bridge (63.3)

Lee County
Keokuk, *Keokuk National Cemetery*

Marion County
Knoxville, *Veteran's Administration Medical Center*

Polk County
Des Moines, *Veteran's Administration Medical Center* (63.3)

Scott County
Davenport, *Bergfeld, Fritz, Block*, 321—323 W. 2nd St.
Davenport, *Buildings at 305—307 West Second Street*
Davenport, *Buildings at 325—327 West Second Street*
Davenport, *Central Fire Station*, 331 Scott St.
Davenport, *City Hall*, 226 W. 4th St.
Davenport, *Iowa Soldiers' Orphans' Home*, 2800 Eastern Ave.
Davenport, *Lend-A-Hand Club Building*, 105 S. Main St.
Davenport, *Schmidt, George M., Block*, 301—303 W. 2nd St.

Webster County
Lehigh vicinity, *Archeological Site 13WB164*
Lehigh vicinity, *Archeological Site 13WB217*
Lehigh vicinity, *Archeological Site 13WB244*
Lehigh vicinity, *Archeological Site 13WB252*
Lehigh vicinity, *Archeological Site 13WB256*
Lehigh vicinity, *Archeological Site 13WB264*

KANSAS

Jefferson County
Half Mount Truss Bridge
Meriden, *Meriden Rock Creek Bridge*

Johnson County
Archeological Site 14J0505
Archeological Site 14J0507
Archeological Site 14J0514
Archeological Site 14J0515
Archeological Site 14J0521

Leavenworth County
Leavenworth, *Veteran's Administration Medical Center* (63.3)

Sedgwick County
Wichita, *U.S. Post Office and Courthouse*
Wichita, *Veteran's Administration Medical Center* (63.3)

KENTUCKY

Bourbon County
Millersburg Historic District

Bracken County
Archeological Site 15 Bk 12

Clark County
Carnegie Library (Olmstead Memorial Library) Kentucky Wesleyan Administration Building

Daviess County
Owensboro, *Brothers Lodge No. 132 I.O.O.F.*, 200 W. 3rd St.
Owensboro, *First Presbyterian Church*, 114 W. 3rd St.
Owensboro, *Reno Building*, 103 W. 3rd St.
Owensboro, *Wiles Brothers Clothiers*, 2nd and Allen Streets

Fayette County
Lexington, *Veteran's Administration Medical Center* (63.3)

Grant County
Starnes Bridge over Eagle Creek (63.3)

Greenup County
Archeological Site 15 GP 14

Jefferson County
Louisville, *Schaftlein Archeological Site* (15JF317)

Kenton County
Covington, *Mosler Safe Building*
Covington, *Telephone Company Building*

McCreary County
Archeological Site B081
Archeological Site B105
Archeological Site ON06B
Archeological Site (Pete King House), Shoopman

Spencer County
Archeological Site 15SP26
Archeological Site 15SP340
Archeological Site 15SP412

LOUISIANA

DeSoto Parish
Gloster, *Craven, Glen, House*

Jefferson Parish
Bayou des Coquilles Site, Jean Lafitte National Historical Park

Rapides Parish
Alexandria, *Veteran's Administration Medical Center*

Red River Parish
Old Methodist Parsonage
St. Mary's Parish
Avoca Island Pumping Plant Number 1

MARYLAND

Allegany County
Eckhart Branch Bridge
Cumberland, *Canada Historic District*
Cumberland, *Dumbhundred Historic District*

Baltimore (independent city)
Baltimore Music Hall (Lyric Theater) 124 W. Mount Royal Ave.
Baltimore Retail District Multiple Resource Area, Roughly bounded by Franklin, Cathedral, Liberty, Greene and Baltimore Sts.
Franklin Square Historic District

Baltimore County
Mt. Royal Terrace Historic District, (63.3)
Mt. Vernon Historic District, (63.3)
Seton Hill Historic District, (63.3)
Union Square Historic District (63.3)
Baltimore, *Bartlett-Hayward Plant (Roundhouse Square)*, 200 Scott St. (63.3)
Baltimore, *Brown's Arcade*, 322—328 N. Charles St. (63.3)
Baltimore, *Butchers Hill-East Baltimore Historic District*, (63.3)
Baltimore, *Clifton School*
Baltimore, *Rieman's Block (Lexington Green)*, 617—631 W. Lexington St. (63.3)
Baltimore, *St. John's School (Martin DePorres Center)*, 908—914 Valley St. (63.3)
Bel Air, *Emmorton School*, 104 W. Wheel Road

Dorchester County
Horn Point Archeological Site

Frederick County
Hagerstown, *Linden Grove*

Garrett County
Crellin, *Crellin Historic District* (63.3)

Hartford County
Havre de Grace, *Havre de Grace Historic District*

Montgomery County
Takoma Park Historic District Boundary Extension (63.3)
Germantown, *Waters, Horace, House*

Prince Georges County
Hyattsville, *Alexandria Junction Tower*

Washington County
Salisbury Mill Sprechers Mill
Hagerstown vicinity, *Kershner, Kathryn, House*
Sharpsburg, *Grove, Jacob, House*, 100 W. Main St.

Wicomico County
Main Street Commercial District, Main, Little Water and Water Sts.
Main Street Residential District, Main St.
Sharptown Bridge
Sharptown, *Fletcher, Harry C., House*, 402 School St.
Sharptown, *Mt. Vernon Methodist Protestant Church*, Railway and Church Sts.
Sharptown, *Robinson House*, 301 Water St.
Sharptown, *Twilley, G. C., House*, Water St.
Sharptown, *Walker House*, Water St.
Sharptown, *Watson House*, Railway and Vine Sts.

Worcester County
Snow Hill, *Snow Hill Historic District* (63.3)

MASSACHUSETTS

Archeological Site 19BN374, Cape Cod National Seashore

Berkshire County
Washington Mountain Brook Historic Archeological District
Adams, *Berkshire Mill No. 1*

Bristol County
Fall River, *Borden, A. J., Building*, 91–111 S. Main St.
New Bedford, *Dawson Block (Eagles Home)* 1851 Purchase St.
Norton, *Crane, G. B., Site*
Norton, *White Crow Archeological Site*

Essex County

Danvers, *Danvers Town Hall*
East Lynn, *East Lynn Oddfellow's Hall*, 289 Essex St.
Newburyport, *James Steam Mills* (63.3)
North Andover, *Parker-Chickering House*
Salem, *Power Block*, 134–146 Washington St.
Salem, *Y.M.C.A.*

Franklin County

Northfield, *Schell Bridge*

Hampden County

Springfield, *Federal Square Armory Complex*

Hampshire County

Northampton, *Veteran's Administration Medical Center*

Middlesex County

Framingham, *Building at 46 Park Street*
Framingham, *Buildings at 1–5 Central Street*
Framingham, *Hollis Street Fire Station*
Framingham, *Saxonville Firehouse*, Watson Pl.

Norfolk County

Quincy, *Greenleaf Building*, 1415 Hancock St.

Plymouth County

Bridge on Edward Foster Road over Scituate Harbor, Tidal Creek
Hull, *Graves Light*
Scituate, *Minots Ledge Light (Lovers Light)*

Suffolk County

Boston, *Edglewood Diner*, 1883 Dorchester Ave.
Boston, *U.S. Post Office—Chelsea*
Boston, *U.S. Post Office—Winthrop Branch* 240 Winthrop St.
Chelsea, *Panonia Building*
Roxbury, *Baker, Sarah J., School*, 33 Perrin St.

Worcester County

Oxford, *Building at 5 Charlton Street*
Oxford, *Building at 7 Charlton Street*

MICHIGAN

Berrien County

Archeological Sites 20BE132 and 20BE306 (Wymer Site and the Rock Hearth Site) (63.3)
Edison Site 20BE122 (63.3)
King Site 20BE354

Calhoun County

Battle Creek, *Veteran's Administration Medical Center*

Dickinson County

Sturgeon Falls Hydro Generation Plant

Eaton County

Eaton Rapids, *West Knight Street Bridge (63.3)*

Fond du Lac County

Bragg School Building (63.3)

Isabella County

Mount Pleasant, *Creamery, The*, 320 W. Broadway (63.3)

Jackson County

Ament Mills (Norvell Mill) 305 Mill Rd.
Norvell Dam and Bridge, Mill Rd.

Monroe County

Weis Manufacturing Company (63.3)

Saginaw County

Archeological Site 20SA581 (63.3)
Archeological Site 20SA582 (63.3)
Dehmel Road Bridge, Spans Cass River
Saginaw, *Bancroft Hotel*, 107 S. Washington St.
Saginaw, *Eddy Building*, Genessee and Washington Sts.

St. Joseph County

Stover Site 20BE307 (63.3)
US–12 Mottville Bridge over the St. Joseph River (63.3)

Wayne County

Allen Park, *Allen Park Veteran's Administration Hospital*
Detroit, *Bohn Aluminum*, E. Grand Blvd.
Detroit, *Chene Street Commercial District* Roughly bounded by Chene St., Canfield Ave. and Grand Blvd.
Detroit, *Detroit Steel Products Company*, E. Grand Blvd.
Detroit, *Dom Polski Hall*, 2279 Forest Ave.
Detroit, *Guarantee Trust and Loan Company (Dennison Bookkeeping)*, 2126 E. Grand Blvd.
Detroit, *Hupp Motor Car Company*, Milwaukee and Mt. Elliott Aves.
Detroit, *Immaculate Conception Church*, 3414 Trombly Ave.
Detroit, *Majeske School*, 2139 Trombly Ave.
Detroit, *Malawa Funeral Home (Brown Brothers Funeral Home)* 4110 St. Aubin Ave.
Detroit, *Maxwell Motor Company (Fisher Body Company)*, E. Grand Blvd. and Milwaukee Ave.
Detroit, *Parke School*, 3010 E. Milwaukee
Detroit, *St. Elizabeth's Church and Schools*, 3138 E. Canfield Ave.
Detroit, *St. Hyacinth Roman Catholic Church and School*, 3151 Farnsworth
Detroit, *St. Michael's Greek Catholic Church (Temple of Faith Missionary Baptist Church)*, 2384 E. Grand Blvd.
Detroit, *St. Stanislaus Church and Parish House*, 2818 Dubois Ave.

MINNESOTA

Goodhue County

Red Wing Pottery Dump Site
Red Wing, *Archeological Site 21GD148*

Hennepin County

Fort Snelling National Cemetery

Ramsey County

St. Paul, *Armstrong House*, 233–235 W. Fifth St. (63.3)
St. Paul, *Banholzer, William, House*, 680 Stewart Ave. (63.3)
St. Paul, *Chicago Great Western Railway Co. Aerial Lift Bridge* (63.3)
St. Paul, *How Residence*, 455 Grand Ave.
St. Paul, *Myrick, Nathan, House*, 103–105 Wilken St. (63.3)
St. Paul, *Robert Street Bridge*
St. Paul, *Wabasha Street Bridge* (63.3)

Stearns County

Cold Spring vicinity, *Wocken Archeological Site* St. Cloud, *Veteran's Medical Center*

MISSISSIPPI

Itawasba County

Archeological Site 221t621, Tombigbee River Multiple Resource District
Archeological Site 221t624, Tombigbee River Multiple Resource District

Perry County

Old Augusta, *Leaf River Site 22Pe543*

Tishomingo County

Archeological Site 22 TS 1098, Bay Springs Lock and Dam Construction Area
Iuka, *Brinkley House*, Eastport St.

Yalobusha County

Coffeeville, *Coffeeville Hotel*

Yazoo County

Yazoo City, *Hancock Site 22-Yz-509*
Yazoo City, *Line, P., House (Kinkead Site) (22-Yz-592)*
Yazoo City, *Milner Site 22-Yz-515*
Yazoo City, *O'Neil Creek 22-Yz-624*
Yazoo City, *Rugby Site 22-Yz-513*

MISSOURI

Kansas City, *18th and Vine Street Historic District*

Barry County

Archeological Site 23BY540 (63.3)

Benton County

Archeological Site 23BE 1054

Boone County

Archeological Site 23BO950
Columbia vicinity, *Archeological Site 23BO406*
Columbia vicinity, *Archeological Site 23BO990*
Columbia vicinity, *Archeological Site 23BO991*

Carroll County

Carrollton, *One West Washington Avenue*

Cole County

Jefferson City, *Hagen House*

Dunklin County

Archeological Site 23DU227
Archeological Site 23DU232
Archeological Site 23DU234
Archeological Site 23DU241

Franklin County

Archeological Site 23FR263, Meramec State Park (63.3)
Archeological Site 23FR266, Meramec State Park (63.3)

Greene County

Springfield, *Dollison-Walnut Historic District*
Springfield, *Early East Springfield Archeological District* (63.3)
Springfield, *Gibson Chapel Presbyterian Church*, 536 E. Tampa St. (63.3)
Springfield, *Hampton Wedge Historic District*
Springfield, *Pythian Home*, 451 Pythian St.

Springfield, *Shockley-Firestone Building*, 816 St. Louis St.

Hickory County

Archeological Site 23HI466
Archeological Site 23HI496
Archeological Site 23HI501

Jackson County

Archeological Site 23JA243, Blue River Pkwy. (63.3)

Jefferson County

DeSoto, *United States Post Office*, 17 Boyd St.

Lincoln County

Old Monroe Archeological District (also in St. Charles County)
Elsberry, *Archeological Site 23LN97*
Elsberry, *Archeological Site 23LN103*

Marlon County

Hannibal, *Robinson Funeral Home*

Montgomery County

Archeological Site 23MT290

St. Louis County

Wainwright-Real Estate Row Historic District
Normandy, *St. Vincent's Hospital*, 7301 St. Charles Rock Road
St. Louis, *Arcade Building and Wright Buildings*, 804–814 Olive St. and 803–815 Pine St.
St. Louis, *De Baliviere Bus Garage Complex*, 97 DeBaliviere
St. Louis, *North Broadway Bus Garage*, 812 E. Taylor St.
St. Louis, *Railway Exchange Building*, 6th and Olive Sts.
St. Louis, *South Broadway Bus Garage*, 4041 S. Broadway
St. Louis, *Stix, Beer, and Fuller Building*, 6th and Washington Sts.
St. Louis, *Western Union Building*, 900–910 Chestnut

Scott County

Morley vicinity, *Archeological Site 23ST174*

Warren County

Archeological Site 23WN63

MONTANA

Archeological Site 24PH1162
Fort Peck, Upper Missouri River

Beaverhead County

Tash Ranch (D.L. Ranch)

Big Horn County

Lodge Grass vicinity, *Owl Creek Site*
Broadwater County
Townsend, *Historic Resources of Dry Creek Area* (also in Meagher County)

Carbon County

Red Lodge, *Red Lodge Commercial Historic District*

Cascade County

Great Falls, *Liberty Theater Building*, 301 Centeral Ave. (63.3)

Dawson County

South Bank Site 24DW140

Gallatin County

Bozeman, *Huffine House, Bozeman West Project F 50–2(4)79*
Bozeman, *Rea School, Bozeman West Project F 50–2(4)79*

Garfield County

Archeological Site 24GF248
Archeological Site 24GF250

Jefferson County

Boulder, *Hubbard Bridge (Boulder River Bridge)*
Butte, *Elk Park Ice Pond (24JF439)*

Lewis and Clark County

Ft. Harrison, *Veteran's Administration Medical Center*
Helena, *Montana National Guard Headquarters*, 1100 Last Change Gulch
Helena, *Montana Powder and Equipment Company*, 12 E. Lawrence St. (63.3)
Helena, *St. Helena School*, 529 N. Warren St.
Lincoln, *Lincoln Gulch Townsite (24LC467)*

Missoula County

Palace Hotel, 123–141 W. Broadway
Huson, *White Tail Archeological Site (23M048)*
Missoula, *East Side Historic District*
Missoula, *Missoula Hotel*, 141–147 W. Main St.

Musselshell County

Klein Mine Site (63.3)

Powder River County

Ashland, *41 Archeological Sites*

Prairie County

Fallon, *Archeological Site 24PE153*

Ravalli County

Victor, *Bitterroot River Bridge*

Rosebud County

Three Strike Site 24RB373
Colstrip vicinity, *Ellison's Rock Site 24RB1020 (1019)*

Treasure County

McKean Spirit Site 24TE37

Wibaux County

Wibaux, *Chappel Block*, 105, 109 Wibaux St.

NEVADA

Carson City County

Stewart Indian School (63.3)

Clark County

Overton Beach Archeological District

Elko County

Archeological Site 26EK2304
Archeological Site 26EK2305

Mineral County

Borealis Archeological District

NEW HAMPSHIRE

Hillsborough County

Manchester, *Bridge Street Corporation Housing*
Manchester, *Commercial Building District*, Bridge and Elm Sts.

Rockingham County

Portsmouth, *Deer Street Archeological District*
Portsmouth, *Deer Tavern Site*
Portsmouth, *Hart-Shortridge Site*

Sullivan County

Claremont, *Hubbard House*
Claremont, *Washington-Winter Street Historic District*
Claremont, *Webster House*
Concord, *French-Thompson House*
Concord, *Industrial District*

NEW JERSEY

Laflin Rand-Dupont Powder Works

Atlantic County

Atlantic City, *Fire Station No. 8*
Atlantic City, *Fire Station No. 9*

Bergen County

Ackerman, Thomas, Sawmill Site
Edgewater, *Building at 309 River Road*
Hennion, Thomas, House Site
Hopper, Levi, House, 335 Campgar Rd.
Stivers, William, House

Burlington County

Archeological Site 28–Bu–121
Archeological Site 28–Bu–123
Archeological Site 28–Bu–124
Bridgeboro Historical District
Fortnum Motors
Sabino Site

Essex County

Caldwell, *Old Caldwell Firehouse*
Newark, *Lefcourt Building*, 744 Broad St.
Newark, *Lincoln Park Historic District Addendum*, 1078½, 1080 and 1080½ Broad St.

Hudson County

Southern Hoboken Historic District
The Olean-Bayonne Standard Oil Pipeline
Jersey City, *Bergen Station Post Office*, 750–766 Grand St.
Jersey City, *Buildings at 273–273½ Tenth Street*
Jersey City, *Greenville Yard Piers*

Hunterdon County

Dart Mill Historic District
Sergeantsville Historic District
Lambertville, *Lilley Mansion*

Middlesex County

Blackwell, J. A., House
Wellnut Hill Archeological Site (28–Mi–90)
Wicoff Farm

Monmouth County

Asbury Park, *Steinbach Building*
Long Branch, *Congregation Brothers of Israel Synagogue*
Long Branch, *Doll House at 87 Second Avenue*
Long Branch, *Summer House at 87 Second Avenue*

Morris County

Archeological Site 28–Mr–195
Archeological Site 28–Mr–197
Archeological Site 28–Mr–198
Bank Barn, 231 Mountain Ave.

Bow, Paul de, House, 150 Mountain Ave.
Cook-Stephens House Site
Former Morris Canal House
Jacobus Historic District
Pre-historic Site 28–Mr–199
Upper Longwood Forge Historic District
Vreeland-Van Duyne House, 50 Jacksonville Rd.
Franklin Lakes, *Pulis, Albert, House,* 322 Pulis Ave.
Kinnelon, *Van Ness House,* 66 Brook Valley Rd.
Montville, *Van Duyne House,* 292 Main Rd.
Morristown, *Turnkey Elderly Housing* (63.3)
Pompton Plains, *Bow, Paul Barney de, House,* 150 Mountain Ave.
Towaco, *Jacobus, Daniel, House,* 88 Old Lane
Towaco, *Vreeland, John H., Outkitchen,* 52 Jacksonville Rd.

Passaic County

Dundee Canal

Somerset County

Lyons, *Veteran's Administration Medical Center* (63.3)

Union County

Caldwell Parsonage (63.3)
Rahway, *Rahway River Park*

Warren County

Scotts Mountain Rural Historic District

NEW MEXICO

Fort Bliss Multiple Resource Area

Bernalillo County

Archeological Site NM:0:3:1:11
Archeological Site NM:1:15:3:6

Chaves County

Archeological Site LA 27573

Dona Ana County

Archeological Site OCA:FA1
Archeological Site OCA:FA:2
Archeological Site OCA:FA5
Archeological Site OCA:FA:6
Archeological Site OCA:FA8
Archeological Site OCA:FA9
Archeological Site OCA:FA:10
Archeological Site OCA:FA:11
Archeological Site OCA:FA:12
Archeological Site OCA:FA:13
Archeological Site OCA:FA:15
Archeological Site OCA:FA:16
Archeological Site OCA:FA:18
Archeological Site OCA:FA:20
Archeological Site OCA:FA:21
Archeological Site OCA:FA:22
Archeological Site OCA:FA:23
Archeological Site OCA:FA:24
Las Cruces, *Archeological Site NMSU 848* (63.3)

McKinley County

Jones Ranch Road Project, Archeological Site V2:97
Jones Ranch Road Project, Archeological Site V2:98
Jones Ranch Road Project, Archeological Site V2:99
Jones Ranch Road Project, Archeological Site V2:101
Jones Ranch Road Project, Archeological Site V2:102
Jones Ranch Road Project, Archeological Site V2:103
Jones Ranch Road Project, Archeological Site V2:104
Jones Ranch Road Project, Archeological Site V2:105
Jones Ranch Road Project, Archeological Site V2:106
Jones Ranch Road Project, Archeological Site V2:107
Jones Ranch Road Sites, Archeological Site V2:108

Otero County

Fairchild Site, Dog Canyon White Sands National Monument
San Juan County
Archeological Site LA 20239

NEW YORK

Portchester, *Putnam-Mellor Engine and Hose Company*

Albany County

Albany, *South End Historic District—Plum Street Extension*

Bronx County

New York, *P.S. 15 Little Red Schoolhouse,* 4010 Dyre Ave.
New York, *P.S. 17 City Island Community Center,* 190 Fordham
South Bronx, *Morris High School Historic District*

Broome County

Binghamton, *Parlor City Historic District* (63.3)

Columbia County

Hudson, *Hudson Historic District* (63.3)

Erie County

Buffalo, *Buffalo Plank Road (UB 1682)*

Kings County

Brooklyn, *Brooklyn Army Terminal*

New York County

New York, *City Center Dance Theater,* W. 55th St.

Onondaga County

Syracuse, *Main Post Office,* 101 N. Clinton St.

Ontario County County

Canandaigua, *Veterans' Administration Medical Center*

Oswego County

Oswego, *Oswego West Side Archeological District*

Queens County

Fort Totten
Brooklyn, *Cypress Hills National Cemetery* (also in Kings County)
Jamaica, *Grace Episcopal Church* (63.3)

Rochester County

Rochester, *Commercial Historic District,* South Ave.

Rockland County

Clarkstown, *Upper Nyack Firehouse,* 330 N. Broadway
Grand View on Hudson, *Grand View Village Hall,* 118 River Rd.
Haverstraw, *Haverstraw King's Daughters Public Library* (63.3)

Saratoga County

Snake Hill Site, *Saratoga Lake* (63.3)

Suffolk County

The Church Site
Brookhaven, *Smith Estate*
Northport, *Veteran's Administration Medical Center,* Middleville Rd.
Southold, *Southold Library,* Main Rd. (63.3)

Thompkins County

Ithaca, *St. James AME Zion Church*

Westchester County

Ossining, *Building at 49–51 State Street*
Tarrytown, *Foster Memorial AME Zion Church* (63.3)
Tarrytown, *Pierson School*

NORTH CAROLINA

Caswell County

Womack's Mill (County Line Creek Watershed) (also in Rockingham County)

Cherokee County

Archeological Site 31 Ce 22

Cumberland County

Shaw-Gillis House
Fayetteville, *Poe, Edgar Allen, House,* 206 Bradford Ave.

Durham County

Durham, *Old North Durham Historic District*

Forsyth County

Cherry-Marshall Historic District
Winston-Salem, *Bahnson-Smith House,* 203 E. Cemetery St.
Winston-Salem, *House at 129 South Poplar,* 129 S. Poplar Street
Winston-Salem, *Leinbach, Edward, House,* 235 S. Church Street
Winston-Salem, *Pfohl, D. J., House,* 113 Cemetery St.
Winston-Salem, *Salem Town Hall and Fire Station,* 301 Liberty St.
Winston-Salem, *Shore-Nissen House,* 1281 4th St.
Winston-Salem, *Union Station (Davis Garage),* 300 Claremont Ave.
Winston-Salem, *Winston-Salem Southbound Freight Terminal,* S. Liberty St.

Gaston County

Mount Holly, *Davenport House,* 1505 N. Main St.
Mount Holly, *Nantz House,* 714 N. Main St.

Graham County

Archeological Site 31 GH 78 (A, B, C)
Archeological Site 31 GH 80
Archeological Site 31 GH 82
Archeological Site 31 GH 86
Archeological Site 31 GH 88
Archeological Site 31 GH 91

Guilford County

Old Greensborough Historic District Boundary Extension, Elm, S. Davie, E. Washington, W. Washington and S. Green Sts.

Hoke County

McNeill House

Madison County

California Creek Missionary Baptist Church

Martin County

Smithwick-Green-Clark House, U.S. 17
Woolard-Perry House

Pitt County

Bethel vicinity, *Brown, Henry Williamston, House*
Bethel vicinity, *Brown, Herbert P., House*
Bethel vicinity, *Moore House*

Northampton County

Jackson, *Bank of Northampton Building*

Washington County

Plymouth, *Plymouth Depot*, 612 Washington St.

NORTH DAKOTA

McKenzie County

Arnegard, *Cinnamon Creek Ridge Archeological District*

Mercer County

Zap, *Archeological Site 32ME218* (63.3)

OHIO

Allen County

Lima, *Holland Block Annex*, 112—116 E. High St.

Athens County

Athens, *West Hills Historic District*
Glouster, *Hisylvania No. 2 2 Mine Entrances and Tipple*

Belmont County

Cravet Site No. 1 (33-BL-17) (63.3)

Cuyahoga County

Strongsville, *Strongsville Activity Center*

Hamilton County

Cincinnati, *Avondale Community Center*
Cincinnati, *Block 23 (Ben's Department Store)* Bounded by Central Ave., 7th, 8th, and former John Sts.
Cincinnati, *Boldface Playground Shelter*
Cincinnati, *Building at 1032 Foracker Avenue*
Cincinnati, *Buildings at 1307—1309 Pendleton Street*
Cincinnati, *Building at 1422 Apjones Street*
Cincinnati, *Building at 2843 Melrose Avenue*
Cincinnati, *Building at 3022 Park*
Cincinnati, *Buildings at 4008, 4010 and 4012 Gulow Street*
Cincinnati, *Building at 4217 Mad Anthony Street*
Cincinnati, *Building at 4224 Williams Place*
Cincinnati, *Building at 4267 Williams Place*
Cincinnati, *Carmel United Presbyterian Church*, 3549 Reading Rd.
Cincinnati, *Court Street Historic District*
Cincinnati, *St. Leo's Church Complex*, Baltimore St. and St. Leo Pl.
Cincinnati, *Streetscape 959—1031 E. McMillan Street*
Cincinnati, *The Nelson Building*, 2501—2507 Kemper Lane

Hocking County

Logan, *Hocking County Courthouse*, E. Main St. (63.3)

Knox County

Lehmon Road Bridge, SR 259 (63.3)

Meigs County

Old Pomeroy High School, OH 33 (63.3)

Montgomery County

Dayton, *Roosevelt High School*

Portage County

Ravenna, *Etna House Hotel*, 219 W. Main St. (63.3)

Ross County

Chillicothe Veteran's Administration Medical Center,

Scioto County

Portsmouth, *Fowler Building*, 700 Second St. (63.3)
Portsmouth, *Fowler Property #1*, 716 Second St. (63.3)
Portsmouth, *Fowler Property #2*, 712 Second St. (63.3)

Summit County

Akron, *Mustill, Frederick, House*, 234 Ferndale St.
Akron, *Mustill Store*, 248 Ferndale St.
Akron, *Ohio Canal Lock No. 15*
Akron, *Ohio Canal Locks No. 10—14* (Staircase of Locks)

OKLAHOMA

Creek County

Sapulpa, *Main Post Office*

Muskogee County

Fort Gibson, *Fort Gibson National Cemetery*

OREGON

Baker County

Court House Ranch Rock Cairn Site 35 WA 109, Wallowa-Whitman National Forest

Benton County

Corvallis, *Arnold Family House*, 806 SW. 5th St.
Corvallis, *Benton Plaza Hotel*

Clackamas County

Estacada, *Hades Creek Site (35CL51)*
Milwaukie, *State Highway Division Office and Police Headquarters Building* (63.3)

Curry County

Gold Beach Ranger Station

Deschutes County

Bend, *Old Main Post Office*, 745 N. Wall St.

Douglas County

Hilltop Site 35 DO 183)
Kirkendall Creek Site (35 DO 186)
Mott Bridge, Umpqua National Forest
Mule Shank II Prehistoric Site, Umpqua National Forest (63.3)
Standley Site (35 DO 182)

Jackson County

Ashland, *Lithia Park Historic District*
Community Kitchen Shelter, McKee Bridge Picnic Ground
Mortared Rock Bar-b-que, McKee Bridge Picnic Ground
Mortared Rock Retaining Wall, McKee Bridge Picnic Ground

Jefferson County

Madras, *Archeological Site 35JE100*

Lane County

Eugene, *East Blair Historic District*
Veneta, *Sailor Barn*, 22968 OR 126 (63.3)
Veneta vicinity, *Country Fair Site 35 LA 440*
Veneta vicinity, *Long Tom Site 35 LA 439*

Marion County

Salem Pioneer Cemetery

Multnomah County

Portland, Portland Fire Station No. 24, 5340 N. Interstate Ave.

Tillamook County

Dolph Toll Road, Siuslaw National Forest also in Yamhill County (63.3)

Union County

Archeological Site 35 UN75, Pilcher Creek Reservoir (63.3)
Archeological Site 35 UN145, Pilcher Creek Reservoir (63.3)
Archeological Site 35 UN147, Pilcher Creek Reservoir (63.3)
Archeological Site 35 UN148, Pilcher Creek Reservoir (63.3)

Wallowa County

Tamarach Gulch Archeological Site, Wallowa-Whitman National Forest

PENNSYLVANIA

Allegheny County

Monroeville, *McGinley House*, McGinley Rd.
Pittsburgh, *Immaculate Heart of Mary Church*
Pittsburgh, *Veteran's Administration Medical Center*

Bedford County

Bedford Historic District

Berks County

Reading, *Park Line Historic District*
Reading, *Penn's Common Historic District*

Center County

Houserville Quarry Site (Houserville Archeological District)

Chester County

Coatsville, *Veteran's Administration Medical Center*

Dauphin County

Harrisburg, *Bergner Building*, 226–230 Market St. (63.3)
Harrisburg, *Blackstone Building*, 112 Market St. (63.3)
Harrisburg, *Colonial Theater (Lochiel, Herr, & Wilson Hotels)*, 229 Market St. (63.3)
Harrisburg, *Dauphin Deposit Bank*, 213 Market St. (63.3)
Harrisburg, *Durbin Building* (63.3)
Harrisburg, *First Church of God*, 15–17 N. 4th St. (63.3)
Harrisburg, *Fox Ridge Historic District*

Harrisburg, *Goldsmith Building*, 8 N. Market Sq. (63.3)
Harrisburg, *Kogan Building*, 120 Market St. (63.3)
Harrisburg, *Kunkle Building (Feller Building)*, 301 Market St. (63.3)
Harrisburg, *Market Square Presbyterian Church*, 20 S. 2nd St.
Harrisburg, *Menaker, Mortimer H., Building*, 17–19 S. Second Street
Harrisburg, *Old City Hall*, 423 Walnut St. (63.3)
Harrisburg, *Pomeroy's Annex*, 326 Market St. (63.3)
Harrisburg, *Senate Hotel*, 122 Market St. (63.3)
Harrisburg, *Telegram Building*, 227 Walnut St. (63.3)
Harrisburg, *Warner Hotel*, 17–21 N. 2nd St. (63.3)
Harrisburg, *Zion Lutheran Church*, 9–17 S. 4th St. (63.3)

Delaware County

Media, *Delaware County Institute of Science*, 11 Veterans Sq.

Lebanon County

Lebanon *Veteran's Administration Medical Center*

Philadelphia County

Philadelphia, *Benjamin Franklin Hotel*, 822–840 Chestnut St.
Philadelphia, *Building at 1227 Locust Street*
Philadelphia, *Building at 1229 Locust Street*
Philadelphia, *Buildings at Philadelphia Naval Shipyard*
Philadelphia, *Philadelphia National Cemetery*
Philadelphia, *Uptown Theater*, 2240–2248 N. Broad St.

Tioga County

Nelson, *Beechers Island United Presbyterian Church*

Washington County

Charleroi Historic District
The LeMoyne Crematory (63.3)

York County

York Haven Road Bridge

PUERTO RICO

Humacao, *Los Corrales 1 (12VPr2–46)* Vieques
Humacao, *Veridales 1 (12VPr2–33)* Vieques
Ponce, *El Bronce (PO–13–1)*
Ponce, *Hacienda Tribes Mechanical Water-Wheel*

RHODE ISLAND

Kent County

East Greenwich, *Booth Property Site*

Newport County

Jamestown, *Former Harbor Entrance Control Post*, Beavertail Point
Jamestown, *Jamestown Bridge Site (RI 711)* Seaside Dr.

Providence County

North Smithfield, *Mowry, William, House*, Farnum Pike
North Smithfield, *Todd Farm*, 670 Farnum Pike

Washington County

Narragansett, *Kinney-Anthony Farm*
North Kingstown, *RI 667*
North Kingstown, *RI 669 Bestwick Site*
North Kingstown, *RI 670 Scrabbletown Brook Site*
North Kingstown, *Scrabbletown Historical* and *Archeological District*

SOTH CAROLINA

Berkeley County

Archeological Site 38BK202 (also in Charleston County)

Chesterfield County

Archeological Site 38CT30 (63.3)
Archeological Site 38CT38 (63.3)
Archeological Site 38CT40 (63.3)
Archeological Site 38CT44 (63.3)
Archeological Site 38CT57 (63.3)
Archeological Site 38CT58 (63.3)

Dorchester County

Archeological Site 38DR23

Oconee County

Russell House, Sumter National Forest

Richland County

Columbia, *Veteran's Administration Medical Center*

SOUTH DAKOTA

Brown County

Aberdeen, *Chicago Northwestern Passenger Depot* (63.3)

Hughes County

Archeological Site 39HU173

Minnehaha County

Shriver-Johnson Building
Sioux Falls, *Veteran's Administration Medical Center*

Tripp County

Winner, *Main Post Office*, 402 Monroe St.

TENNESSEE

Anderson County

Clinton, *Clinton Railroad Depot*, Market St.
Norris, *Massengill Bridge*

Bedford County

Rural Vernacular Buildings, Along the Duck River (also in Maury and Marshall Counties)

Bradley County

Cleveland, *Main Post Office*, 155 Broad St.

Cannon County

Woodbury, *Brevard House*

Fentress County

Leatherwood, *Archeological Site H002*

Hamilton County

Chattanooga, *Union Station Rail Yard Archeological Site* (63.3)

Jefferson County

Chestnut Hill vicinity, *Hill-Hance House*, U.S. 411

Knox County

Knoxville, *1875 Building*, 607—09 Gay Street
Knoxville, *Fouche Block*, 601—05 Gay St.
Knoxville, *Millers Warehouse*, 913 Clinch Ave.

Maury County

Bryant-Pennington House (Michael Lancaster Cabin) Bryant Lane
Branch's Mill Archeological Site, Howard Bridge
Columbia Reservoir Multiple Resource District Cannon Bend Archeological District
Columbia Reservoir Multiple Resource District Cheek Bend Archeological District
Davis Ford Road Archeological District, Vaughn Bend
Duck River Valley Railroad Archeological District, Blue Springs Rd.
Fountain Mill Archeological Site, SR 50
Greater Sowell House, Sowell Bend
Harris-Harmon House, Harris Lane
Harris Plantation Archeological Site, Harris Lane
Hight House, SR 50 and Deep Ford Rd.
Holland Cabin Site, Holland Bend
Shelton House and Office, SR 50
Wilhoite Mill Archeological Site, SR 31A

Marshall County

Caney Spring Historic District
Hardison Mill Archeological District, U.S. 41 (also in Maury County)
Joyce's Mill Archeological Site, Duck River off River Rd.
Lillard's Mill Archeological District, McClean Bend
Lillard's Mill Historic District

Morgan County

Rugby Colony Historic District Boundary Amendment

Robertson County

Springfield, *Izor, Richard Hamilton, House*, Lawrence Rd.
Springfield, *Stark, John B., House*, Lawrence Rd.

Scott County

Archeological Site 40St6, Big South Fork National River and Recreation Area
Archeological Site BS15, No Business Creek
Archeological Site BS26, Parch Corn Creek
Archeological Site BS40, Station Camp Creek
Archeological Site BS40e (Corn Crib), Station Camp Creek
Archeological Site BS401 (Blacksmith Shop), Station Camp Creek
Archeological Site BS41 (Main Lodge, Parch Corn Creek Hunting Reserve), Station Camp Creek
Archeological Site BS50
Archeological Site BS50A
Archeological Site BS51 (Old John Litton Place)
Archeological Site H007, Bandy Creek
Archeological Site H007A (Corn Crib) Bandy Creek
Archeological Site H008 (George Blevins Cabin)
Archeological Site H018 (Al Blevins House Site
Leatherwood, *H003 Barn*

Shelby County

Memphis, *Memphis Street Railway Company Office and Street Car Complex*

Trousdale County

Hartsville vicinity, *Duncan Archeological Site 40 TR 27*

Washington County

Johnson City, *Hammer-Taylor House*, U.S. 19W

Williamson County

Brentwood, *WSM Radio Transmission Complex*, Rt. 7 Concord Rd.

TEXAS

Fort Bliss Multiple Resource Area

Bell County

Sarah's Site 41BL240 (63.3)

Culberson County

Van Horn, *Three-Mile-Sulfur Archeological District*

Dallas County

Dallas, *Main Post Office*, 400 N. Ervay
Dallas, *Veteran's Administration Medical Center*

Dewitt County

Guadalupe River Bridge

El Paso County

Archeological Site 41EP289
Archeological Site 41EP321

Harris County

Houston National Cemetery

Montgomery County

Archeological Site 41MO73 (63.3)

Potter County

Amarillo, *Amarillo Medical Complex, Veteran's Administration Medical Center*

Taylor County

Elm Creek Watershed, (also in Runnels County)

TRUST TERRITORY OF THE PACIFIC ISLANDS

Balabat Village Pebaey and Malal Site
Wiya Bird Cave

UTAH

San Juan County

Archeological Site UT V–13–16
Archeological Site UT V–13–17
Archeological Site UT V–13–18
Archeological Site UT V–13–19
Archeological Site UT V–13–20
Archeological Site UT V–13–21
Archeological Site UT V–13–22
Archeological Site UT V–13–24
Archeological Site UT V–13–27
Archeological Site UT V–13–28
Blanding, *Grand Gulch Archeological District*
Blanding vicinity, *Recapture Dam Archeological District*, 3 mi. N of Blanding

Utah County

Payson, *Nebo Stake Tabernacle*, 182 N. Main St.
Provo, *Building at 209 North 400 West Street*
Provo, *Building at 466 West Center*
Provo, *Roberts, William D., House*, 212 N. 500 West St.
Provo, *St. Francis of Assisi Church*, 172 N. 5th West St.
Provo, *Taylor Brothers Warehouse*, 60 N. 300 West St.
Provo, *Taylor, George, Jr., House*, 187 N. 400 West St.

Wasatch County

Strawberry Valley Archeological District

Washington County

Zion Lodge Historic District

VERMONT

Caledonia County

Hardwick, *Bridgman-Monticello House*

Rockingham County

Bellows Falls, *Rockingham Hotel*

Washington County

Waterbury vicinity, *Bolton Falls Dam*, Winooski River

Windsor County

White River Junction, *Veteran's Administration Medical Center*

VIRGINIA

Bristol County

U.S. Post Office

Danville County

Danville, *Danville National Cemetery*

Hampton (independent city)

Hampton National Cemetery
Veteran's Administration Medical Center

Henrico County

Richmond, *Richmond National Cemetery*
Sandston, *Seven Pines National Cemetery*

Norfolk County

Norfolk, *U.S. Post Office*, 600 Granby St.

Roanoke County

Salem, *Veteran's Administration Medical Center*

Rockingham County

Cromer House (63.3)

Staunton County

Staunton National Cemetery

Winchester County

Winchester National Cemetery

WASHINGTON

Benton County

Day, John, Lock and Dam Project Area Port of Benton
Prosser Steel Bridge (63.3)

Chelan County

West Monitor Bridge (63.3)

Clark County

Vancouver, *Fort Vancouver-Kanaka Village*

Ferry County

Archeological Site 45–SP–FE–1 (63.3)
Archeological Site 45–SP–FE–2 (63.3)
Archeological Site 45–SP–FE–13 (63.3)
Archeological Site 45–SP–FE–18 (63.3)
Archeological Site 45–SP–FE–25 (63.3)
Archeological Site 45–SP–FE–33 (63.3)

Kittitas County

Yakima, *Wa Pai Xie Archeological District*

Pierce County

McNeil Island Archeological District

Skamania County

North Booneville, *Archeological Site SA–11*

Spokane County

Washington Street Bridge (63.3)

Stevens County

Orient Bridge (63.3)

Whitman County

F Street Bridge (63.3)

WEST VIRGINIA

Jefferson County

Charles Town, *Belvedere (Belvedere Farms)*
Charles Town, *Beverly*
Charles Town, *Jones House*
Charles Town, *Little Elmington (Hillside)*
Charles Town, *Old Cave Farm (Beyeler House)*
Charles Town, *Springland* (63.3)
Charles Town, *Vinton (Vinton Farms)*

Lewis County

Bruffey Farm, Skin Creek
Butcher-Bush Farm, Little Skin Creek
Crawford, *Crawford Historic District*, SR 48
Crawford, *Davisson-Blair Mansion*, Crane Camp Run
Roanoke, *Bond Barn*, U.S. 19
Roanoke, *Bush, Michael, House Site*, SR 23/3
Roanoke, *Conrad, Mary, Park*, WV 19 and WV 23
Roanoke, *Rhodes Farm*, West Fork River
Roanoke, *Roanoke Historic District*, SR 19 and SR 23
Roanoke, *Rohrbough House*, Crooked Run
Roanoke, *Smith House*, SR 23/3
Roanoke, *Whitesel-Kerns Farm*, Dunkin Run
Vandalia, *Peterson Farm*, Skin Creek
Vandalia, *Ramsey-West Farm*, Pen Run
Walkersville, *Davisson Summer House*, Blackwater Run and West Fork River
Walkersville, *Walkersville Historic District*, SR 44 and SR 19
Weston, *Cutright Farmsteads*, West Fork River
Weston, *Stalnaker Farm*, Glady Fork of Skin Creek

Lincoln County

Waldport, *Alsea Bay Bridge*

Mingo County

Williamson vicinity, *Cotiga Mound*, 6 mi. NW of Williamson

Monongalia County

Belldina's Bottom Archeological Site
Fort Martin School
Gingrich House
Van Voorhis Farm Archeological Site
Morgantown vicinity, *Fort Martin Archeological Site*
Upshur County

Post Mill Bridge No. 1
Post Mill Bridge No. 2

Wood County

Parkersburg, *Tavenner House*, 2401 Camden Ave.

WISCONSIN

Chippewa County

Chippewa Falls, *Main Post Office*, 315 N. Bridge St.

Forest County

Butternut Lake Site (47–Fr–122) Nicolet National Forest
Flanner-Steger Camp No. 5, Nicolet National Forest

Grant County

Patch Grove, *Paul, Alexander, Store*

La Crosse County

La Crosse, *26 Properties*

Monroe County

Tomah, *Veteran's Administration Medical Center*

Sawyer County

Chippewa River Bridge

Trempealeau County

Independence, *City Hall*

Waupaca County

Waupaca House (Readfield Country Store)

Winnebago County

Oshkosh, *North Main Street Historic District*, 15, 21, 23, 25, and 27 N. Main St.
Oshkosh, *Sawyer, Edgar P., House*, 1331 Algoma Blvd. (63.3)

WYOMING

Converse County

Antelope Creek Archeological District
Red Butte Stone Circle Site 48C026
Lost Springs Vicinity, *Culvert at Chicago and North Western Transportation Company Milepost* 514.23
Lost Springs Vicinity, *Culvert at Chicago and North Western Transportation Company Milepost 516.45*

Lincoln County

Archeological Site 48LN717

Niobrara County

Old Woman Creek Hills Archeological Site (48NO119) (63.3)
Spanish Diggings (also in Platte County)
Lusk, *Chicago and Northwestern Railroad Water Tower*

Sweetwater County

Archeological Site 48SW1455
Bairoil, *Bairoil "Tipi Ring" Site (48SW2369)* (63.3)
Point of Rocks Stage Station vicinity, *Overland Trail*

Teton County

Fishing Bridge Historic District, Yellowstone National Park (63.3)

* * * * *

The following is a list of corrections to the list of properties determined eligible in the **Federal Register**, Part II, February 3, 1981. Additional corrections may appear in subsequent updates.

COLORADO

Arapahoe County

Littleton, *Littleton Atchison, Topeka and Santa Fe Depot* (63.3) (previously listed as Littleton, Atchison, Topeka and Santa Fe Depot)

Denver County

Denver, *West High School* (63.3) (previously listed as Wesh High School)

Garfield County

Denver and Rio Grande Railroad (63.3) (previously listed as Denver and Grande Railroad)

[FR Doc. 82–2365 Filed 2–1–82; 8:45 am]
BILLING CODE 4310–70–M

federal register

Tuesday
February 2, 1982

Part IV

Department of Health and Human Services

Food and Drug Administration

Chemical Compounds in Food-Producing Animals; Availability of Criteria for Guideline

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 77N-0026]

Chemical Compounds in Food-Producing Animals; Availability of New Threshold Assessment Criteria for Guideline

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces the availability of new threshold assessment criteria for the guideline proposed in the agency's "Chemical Compounds in Food-Producing Animals, Criteria and Procedures for Evaluating Assays for Carcinogenic Residues." The threshold assessment criteria have been revised after an evaluation of the comments on the March 20, 1979, sensitivity of the method (SOM) proposal.

DATES: Comments by April 5, 1983; the guideline is effective February 2, 1982.

ADDRESS: Written comments and requests for single copies of the guideline to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joseph A. Settepani, Bureau of Veterinary Medicine (HFV-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4500.

SUPPLEMENTARY INFORMATION:

General Information

The Federal Food, Drug, and Cosmetic Act (the act), to ensure consumer protection, requires that sponsors of compounds to be given to food-producing animals provide adequate data from rigorous scientific testing so that FDA can determine the product's safety prior to approving its use. In FDA's evaluation of the compounds' safety, the agency must by law be able to determine whether a compound is or may be carcinogen and whether its use may leave carcinogenic residues in edible animal tissue. If a compound has that potential, it is subject, as part of the general food safety evaluation required of all compounds, to special data colletion requirements regarding carcinogenicity. The data collection provisions for carcinogenicity are designed to determine whether a compound is a carcinogen and, if so, under what conditions the compound may be safely used.

In the **Federal Register** of March 20, 1979 (44 FR 17070), FDA proposed regulations that would establish criteria by which data regarding carcinogenicity would be collected. Accompanying the proposed regulations was a threshold assessment guideline that suggested a means for determining whether a particular compound raised sufficient concern of potential carcinogenicity that the compound should be subject to carcinogenicity testing. The proposed regulations are still under consideration by FDA and have not been made final. In the meantime, FDA has been using the proposed procedures as a guideline in considering the approvability of particular compounds on a case-by-case basis.

Although FDA is continuing to evaluate the proposed procedures in their entirety, it has become apparent that the threshold assessment guideline currently being applied on a case-by-case basis should be immediately revised. FDA believes that the initially proposed threshold assessment guideline required some compounds to be subject unnecessarily to lengthy data collection requirements for carcinogenicity. For this reason, the agency has prepared a more discriminating decisionmaking guideline.

This revised guideline, discussed below, eliminates a number of problems that characterized the earlier guideline. Whereas significantly fewer compounds are expected to be subject to the expensive carcinogenicity data collection requirements, the agency has not compromised public health concerns in the revised approach. FDA believes that the previously proposed guideline unduly placed emphasis on residue levels in the edible tissue of food-producing animals and on the extent of use of the sponsored compound, factors which are not indicators per se of carcinogenic potential. In addition, the proposed threshold assessment used an arbitrary scoring system which assigned fixed numerical values to the biological activity and use of the sponsored compound. This improperly implied a precision that is simply unattainable in this area. Accordingly, the agency has revised the guideline to contain a decision-free approach in deciding whether a sponsored compound should be evaluated as a carcinogen. This system emphasizes structure-activity relationships, the biological activity of the compound, and the possible mutagenicity activity of the compound, factors which are better indicators of carcinogenic potential than extent of use and residue levels in tissue.

In addition, the amount of data for a threshold assessment for many compounds will be less than that previously required, again a cost-effective measure. Therefore, increased costs to the animal drug industry have been restrained while still affording adequate protection of the public health.

Since the agency needs to conduct a threshold assessment to ascertain the need for carcinogenicity testing, FDA believes that it should announce the availability of the guidelines for public comment. The agency further believes that industry access to and familiarity with these guidelines allows industry to predict, accurately and regularly, the agency's responses, requirements, and positions. Similarly, familiarity with the rationale and bases for the guidelines will enable sponsors to attempt to formulate equally acceptable alternative means for determining whether a particular compound should be tested for carcinogenicity.

Background

The proposed regulations referred to above would establish minimum criteria and a multi-step procedure for establishing conditions of use for carcinogenic animal drugs to prevent the occurrence of cancer-causing residues in edible products of food-producing animals to which drugs, food additives, or color additives have been administered. The first step in the procedure is not governed by reference to a proposed regulation but rather by the application of the threshold assessment guideline.

When a sponsor starts the process of obtaining approval for use of a compound, it provides the agency information on matters such as safety, proposed patterns of use, and intended therapeutic or other effects of the compound. A sponsor will often provide preliminary physiological, metabolic, or toxicological data derived from its own studies and from the scientific literature. At this point, the agency must determine, based on the available data, whether a sponsored compound will be subject to evaluation as a carcinogen. The threshold assessment is the means by which the agency makes this determination. The threshold assessment as discussed in the proposed regulations constitutes a guideline and intentionally was not codified in order to facilitate changes whenever scientific advances or circumstances dictate a more appropriate manner of making this determination.

The March 20, 1979, threshold assessment was based on the concept that the probability that the use of a

sponsored compound will yield edible tissue presenting a risk of cancer to man from residues could be evaluated by the product of the following three factors:

1. Extent of *use;*
2. Level of *residue* of toxicological concern; and
3. Potential *toxicological significance* of the residue.

The threshold assessment instituted a scoring system using the above three factors that would enable the agency to discriminate between those compounds that would be regulated solely according to the general food safety requirements of the act and those compounds that would in addition be subject to evaluation as a carcinogen.

This system did not adequately discriminate between the compounds likely and not likely to present a risk of cancer. Accordingly, the agency is making available a new threshold assessment guideline and is requesting comments.

A. General Principles of the New Threshold Assessment

The new threshold assessment is based on the same three factors utilized in the March 20, 1979, **Federal Register** proposal: Potential carcinogenic (toxicological) significance, extent of use, and the level of residue of carcinogenic concern. The numerical scoring system, however, has been replaced by a "decision-tree approach" based on the toxicity and use factors. A residue score is used only if the toxicity and use factors do not provide a basis for determining whether the proposed sensitivity of the method (SOM) regulations apply. If new information changes the status of any factor, a decision may be changed by the subsequent application of the threshold assessment.

In the new system a compound is assigned to one of two (Low (L) or High (H)), instead of one of three, use categories. Compounds previously classified as Medium use, and subjected to a 10 parts per billion "cap" on allowable residues, have been assigned to the Low use category under the new procedure. The numerical scoring system has been eliminated. The toxicity factor has been changed. A compound is assigned to one of four (A through D), instead of one of three, toxicity categories. Compounds with the lowest carcinogenic potential will be placed in category A; those with the highest carcinogenic potential will be placed in category D. The assignment is based on structure, data from short-term genetic toxicity tests, subchronic or chronic feeding studies, and any other available relevant information to assess carcinogenic potential. This information will allow an initial assessment of the probability that the compound will act as a chemical carcinogen. If a compound is dismissed from testing for carcinogenicity on this basis, but the subsequent testing required under the general food safety requirements indicates a carcinogenic potential (such as effects in the required reproduction study suggesting that the compound may be a hormonal carcinogen), the compound may be reassigned to a toxicity category that may require testing for carcinogenicity.

Under the former threshold assessment, a sponsor under some circumstances could receive a more favorable score by not submitting any data at all. Under that scheme the submission or presence of either structure-activity relationship data, short-term genetic toxicity data, or other biological, physiological, and pharmacological data that raised a suspicion that residues of the sponsored compound were carcinogenic, resulted in the assignment of a maximum score. The absence of data resulted in the assignment of a less severe score. The current threshold assessment resolves this anomaly and provides that the absence of any biological information regarding the potential carcinogenicity of a compound results in the assignment of the compound to category D or C based solely on structure-activity relationships. The new threshold assessment resolves yet another anomaly under the former scheme by providing the sponsor the opportunity to receive a more favorable toxicity category assignment. For example, if the sponsor of a compound that has been initially assigned to category D on the basis of the structure of the compound subsequently submits a battery of short-term genetic toxicity tests and subchronic feeding studies that do not raise suspicion of carcinogenic potential, the category D assignment will be revised to category B. If adequate chronic feeding studies have been conducted in two rodent species and demonstrate that the compound is not carcinogenic, the category D assignment will be revised to category A.

The residue factor retains numerical scoring (parts per billion level of the total residue at the time treated animals are normally expected to be marketed) but tissue correction factors are used to adjust the numerical values. A score based on the residue factor may be reduced if the sponsor can identify a portion of the residue and establish that the portion is not of carcinogenic concern.

B. Comments Received

1. General

Many comments were received on the threshold assessment as proposed on March 20, 1979. Numerous comments addressed the nature of and need for a threshold assessment. Comments maintained that the threshold assessment should be a managerial tool to determine the testing path that a product must follow to secure approval. Comments argued that the threshold assessment should identify three categories of compounds:

a. Those compounds that need testing for carcinogenicity;

b. Those compounds that do not need testing for carcinogenicity;

c. Those that might need testing for carcinogenicity;

The agency recognizes the merit of these comments and has modified the threshold assesment. The new threshold assessment identifies those compounds for which testing for carcinogenicity is required and assigns them to category C or D. Those compounds for which testing for carcinogenicity is not required or has been completed with no finding of carcinogenicity are assigned to category A. Finally, those compounds for which testing for carcinogenicity may be required are assigned to category B. (See discussion in Section A.)

One comment objected to using the threshold assessment as a means of exempting a drug from the requirement of chronic testing for carcinogenicity. The comment argued that the SOM should require, as a principle, chronic toxicity testing for drugs used in food-producing animals. The comment added, "If FDA is to exempt a sponsor of a drug for food-producing animals, from chronic toxicity testing, it should do so by a waiver that requires more than structure-activity relationships and the results of short-term genetic tests." However, no elaboration of the additional data requirements alluded to in the comment was provided.

The agency does not agree that chronic testing for carcinogenicity should be required for all compounds. The agency recognizes that all compounds are not equally likely to be carcinogenic. A purpose of the threshold assessment is to identify compounds that do not appear to have carcinogenic potential. More than structure-activity relationships and short-term genetic toxicity tests is considered in the decision not to require chronic testing. For example, the agency considers the proposed use of the compound, feeding studies in experimental animals

conducted under the general food safety requirements, and the residue level remaining in the edible tissue.

Comments stated that if previously conducted long-term feeding studies indicate a lack of carcinogenic potential, the compound should be exempt from the SOM regulations.

The agency agrees and has revised the threshold assessment to clarify this aspect. If adequate chronic bioassays for carcinogenicity have been conducted in two test species and demonstrate that the sponsored compound and its residues are not carcinogenic, the compound will be assigned to toxicity category A and will be evaluated under the general food safety provisions of the act. The chronic bioassays should include metabolic information from test and target species that demonstrates that the patterns of metabolism are sufficiently similiar to suggest adequate autoexposure in the test animals (i.e., that the test animals will be exposed to a spectrum of metabolites similar to that produced by the target species). There may also be cases where chronic toxicity testing of a compound has been performed, but the data do not meet current agency standards for demonstrating that the compound is not carcinogenic. These data, depending on their quality and relevance of the study to assess carcinogenicity, may be of equal or greater value than the evidence in the other areas considered in the threshold assessment. In such a case, the compound will be assigned to an appropriate category after consideration of all the evidence.

One comment stated that the threshold assessment was not necessary because the present investigational use regulations (21 CFR 511.1) are being used to determine whether the SOM regulations apply.

The agency does not agree. The present investigational use regulations do not detail what information is needed and how the information will be used to determine whether the compound should be evaluated as a carcinogen. The purpose of the threshold assessment guideline is to make available to sponsors the criteria for determining whether the SOM testing procedures will be required.

One comment argued that the March 20, 1979, threshold assessment was being applied, without revision, to investigational use drugs and that this application was inappropriate. Comments also contended that unless the threshold assessment is revised the agency should authorize provisional marketing for compounds while the SOM testing requirements are being completed.

As discussed above, the agency has revised the threshold assessment and believes that the revisions correct deficiencies. The former threshold assessment is not now used. The new guideline supersedes that of March 20, 1979, and will be effective February 2, 1982. The Federal Food, Drug, and Cosmetic Act does not authorize the agency to allow provisional marketing of unapproved products.

Another comment stated that residues in tissues below the 0.2 part per billion level should not be subject to the SOM procedure even if the compound is a suspect carcinogen.

The agency disagrees with this assertion, because it ignores the variation in the potency of carcinogens.

Comments recommended that the threshold assessment use a "decision-tree approach."

The agency agrees, and a "decision-tree approach" as noted above has been adopted in the new threshold assessment.

A comment argued that the threshold assessment as originally proposed was too arbitrary and that a precise numerical score could not be derived from the three imprecise factors used.

The agency agrees, in part. Numerical scores for the use and toxicological significance factors are no longer employed. The total residue factor is a quantitative measurement of the residue in the tissue and, accordingly, the numerical score for the total residue factor has been retained, although its application has been limited.

2. The Use Factor

Several comments were received regarding the use factor. One comment requested that the use factor be corrected to take into account the probability that edible tissue of a treated animal will be consumed. The comment argued that the correction would entail multiplying the use factor by a species consumption factor, which in turn would be based on the relative weight of food derived from each animal species consumed in the average human diet (e.g., 1.0 for beef, 0.7 for swine, 0.5 for poultry).

The threshold assessment no longer assigns a number to the use factor and the suggested procedure cannot be adopted. The agency does agree that some allowance should be made for the less frequent human consumption of organ tissue from various species. These corrections will be applied to the residue factor.

Comments requested that the use factor be corrected to take into account the time of treatment in the animal's life span. Various numerical factors were suggested.

The agency does not agree that correction of the use factor in the manner suggested in the comments is appropriate because this factor is intended as a measure of the potential frequency of human exposure. The residue factor already provides the appropriate correction. The residue depletion study provides data to assure that the residue had depleted to a safe level regardless of when in the animal's life span the compound is administered. In the absence of data the agency cannot be assured that the residues have depleted when the animal is marketed as food even if the drug is given early in the animal's life.

A further comment requested that the use factor be corrected to take into account the relative frequency of the disease for which the drug is indicated.

The agency disagrees. Making a correction for the frequency of disease is impractical due to variations in disease patterns.

3. Residue of Toxicological Concern

One comment suggested that the residue of toxicological concern be corrected to take into account the frequency with which a tissue will be consumed. This would be accomplished by multiplying the residue present by a tissue correction factor.

The agency agrees, and the new threshold assessment incorporates the suggested procedure.

Another comment requested that the level of residue of toxicological concern be corrected to take into account the bioavailability of residues. The comment maintained that only that portion of the residue that can be absorbed is of toxicological concern.

The agency does not fully agree with this comment. Residues that are not bioavailable cannot be assumed to be safe because the cells of the human gastrointestinal tract will be exposed to these residues, and effects on these cells cannot be ignored. Additionally, the agency is not able to conclude that a low bioavailability of a residue presents a trivial carcinogenic risk without information on the structure and carcinogenic potential of the residue. Bioavailability studies, as currently conceived, by themselves do not address these issues. However, as noted earlier, if the sponsor can produce data demonstrating that the carcinogenic concern for any part(s) of the residue is unwarranted, that portion may be discounted from the total residue.

One comment recommended that the wording "at the preslaughter withdrawal

time proposed in the labeling" be used instead of "at the earliest time the animals are expected to be marketable as food." The comment also stated that the slaughter times used in normal husbandry practice should be used, not chance happenings such as the occasional marketing of a suckling pig.

The agency intended that "the earliest time the animals are expected to be marketable as food" will be based on the slaughter time used in normal husbandry practices and reasonably certain to be followed in practice. If the sponsor provides a withdrawal period in the proposed labeling that is consistent with these principles, the residue level at that withdrawal period will be used in the threshold assessment. The wording in the guideline has been modified accordingly.

A comment stated that a high level of residues alone could force a compound into the SOM data collection process.

The agency agrees that this was possible under the old threshold assessment. The revised threshold assessment emphasizes toxicity and use and limits the applicability of the residue level.

Comments also stated that it was improper to assign the maximum score for potential toxicological significance when there were adverse data in only one of three areas considered in the factor. Comments also maintained that this practice in the presence of contrary information from other sources was overly conservative.

The agency has revised this aspect of the threshold assessment. In the present version each toxicological consideration (structure-activity relationship, genetic toxicity and other toxicity studies) may modify the carcinogenic significance factor. Data from each source may either increase or lessen the carcinogenic significance factor. Obviously, data collected from the genetic toxicity tests or subchronic toxicity studies that raise a concern regarding the carcinogenic potential of a sponsored compound will not be dismissed in the absence of data collected from adequate chronic feeding studies demonstrating the lack of such a potential.

A comment pointed out that structure-activity relationships have limited value in identifying carcinogens. The comment maintained that the list referred to in the proposal was not supported by any documentation and should be reviewed by an independent panel of experts. A related comment stated that direct scientific information obtained on a compound should outweigh considerations posed by hypothesis or conjecture in determining potential toxicological significance. For example, it was argued that results from subchronic feeding studies should be given more significance than structure-activity relationships.

The agency is aware that structure-activity relationships do not definitively identify carcinogens. Structure-activity relationships, however, may raise concern that a compound has carcinogenic potential. The list of structures was intentionally general to ensure that compounds with some carcinogenic potential would not be missed. Because of the uncertainties in selecting potential carcinogens on the basis of molecular structure, the guide will be used as a screening tool by an internal committee of agency scientists. This group will consider all of the relevant structural and biological information available on a specific compound before a final decision is made to assign the compound initially to toxicity category C or D based on its structure.

The structure guide made available with the new threshold assessment guideline has been revised to eliminate structures for which correlation between structure and carcinogenic potential is not supported. The agency has provided documentation in support of the structures on the revised list and requests comments. In the future, the agency plans to sponsor a workshop to refine the structure guide and would invite scientists from government, private industry, and the academic community.

Comments said that if mutagenicity tests are negative, other positive findings should be ignored in the threshold assessment.

The agency does not agree. The agency must consider any evidence that raises suspicion that a compound has carcinogenic potential. Because the correlation between mutagenicity tests and cancer bioassays is not always reliable, the agency cannot ignore adverse data from the feeding studies or structure-activity relationships.

One comment argued that the relative potency of the compound in mutagenicity tests should be considered in reducing the concern for potential carcinogenicity.

The agency here again does not agree. Correlations between mutagenic potency and carcinogenic potency have not been demonstrated to an extent sufficient to provide an adequate basis for regulatory decisions.

One comment requested clarification on what additional information would be considered in the assessment of potential toxicological significance.

The new threshold assessment mentions specific types of information that the agency will consider as raising concern that a compound has carcinogenic potential. Consideration of information, however will not be limited to the examples provided in the new threshold assessment. The agency must use any scientific information available that will help resolve or clarify whether a substance has carcinogenic potential.

One comment expressed the opinion that the occurrence of hyperplasia in subchronic feeding studies is not a good indicator of carcinogenicity. The comment maintained that hyperplasia can be a common reparative response related to various spontaneous and toxic drug related effects.

The agency does not equate the occurrence of hyperplasia in subchronic feeding studies with proof positive of carcinogenicity. However, hyperplasia does raise concern that a compound has carcinogenic potential because hyperplasia in some instances has been shown to be associated with cancer (Refs. 1,2,3). A finding of abnormal cell proliferation requires the submission of data from tests more definitive than subchronic tests in order to remove carcinogenic concern.

Comments suggested that specific classes of compounds (for example, prescription drugs, drugs administered to animals during a period when they are not food animals, antibiotics produced by fermentation processes, drugs used in minor species of food-producing animals, and drugs that are poorly absorbed after oral or topical administration) should be exempted from the threshold assessment and the SOM regulations.

The agency does not fully agree that the products cited as examples in the comment warrant exemption from the threshold assessment and the SOM regulations. FDA does not currently believe that it is appropriate for these purposes to differentiate among classes of products administered to food-producing animals in the manner suggested by the comments. When a product presents a low potential for human risk of cancer based on either the proposed conditions of use, the potential or demonstrated toxicity, or the residue level remaining in the edible tissue at the prescribed withdrawal time, however, the threshold assessment reduces the likelihood that the SOM data collection process will be required. Antibiotic biomass products, however, are unique because of their complex composition. These products do not lend themselves to evaluation under the present threshold assessment. These products are being evaluated for safety

under an alternative procedure to be published by the agency.

A comment supported the position that the binding of residues to cellular nucleophiles and the alteration of nucleic acids may raise a suspicion of a direct acting carcinogen. Another comment, however, disagreed because, if true, sulfate and glucuronide conjugates and other metabolites that are normally considered detoxification products would have to be deemed suspect carcinogens.

With regard to cellular nucleophiles, the agency means those macromolecules (such as some proteins or nucleic acid) that are capable of covalently binding to a sponsored compound or a metabolite. The agency will not out of hand dismiss sulfate and glucuronide conjugates or other metabolic products from carcinogenic concern unless data demonstrate that it is appropriate to do so. If the sponsor can produce data demonstrating that the carcinogenic concern for a metabolite is unwarranted, that portion of the total residue may be discounted from the total residue in the threshold assessment.

A comment disagreed with the statement that any compound that has the ability to disturb normal hormonal balance will be of carcinogenic concern. The comment proposed that evidence of alteration of tumor incidence simply through an alteration of the hormonal balance in the test animals, when such a demonstration can be well documented, should remove concern that the compound is a direct acting carcinogen. While the comment agreed that any compound that increases tumors in the human population is of concern regardless of the mechanism of tumor induction, the comment stated that a different approach should be taken in setting a tolerance for those substances that act indirectly and proposed that the procedure outlined in the SOM proposal should be restricted to direct acting carcinogens.

The agency does not mean to include automatically within the scope of the SOM procedure all hormones and compounds that alter normal hormonal balance. The threshold assessment has been revised to clarify this aspect. The agency will be concerned about persistent increases in potentially carcinogenic hormones in the edible tissues of the target animal when the sponsored compound is used according to the proposed conditions of use. The agency will be concerned about the increase in the potentially carcinogenic hormone, whether the increase occurs through direct use of the hormone or indirectly through use of another compound that causes alterations in cellular regulatory mechanisms. In these situations, it is the final result—the increase in a potentially carcinogenic compound—that is of concern to the agency. At the present time, the agency will not alter the guidelines to limit their application to direct acting carcinogens. The agency certainly encourages research to determine the mechanism of action of direct and indirect acting carcinogens. When that type of information becomes available, the agency will consider the information and make any appropriate revisions in the SOM procedure.

There may be cases in which hormonal balance is altered when the sponsored compound is administered, but the hormone increased is not a demonstrated or suspect carcinogen. This type of response will raise concern as to the extent that a persistent alteration in normal hormonal balance in test animals indicates altered functional capacity in the hormone-producing organ and could indicate a preneoplastic condition. If data demonstrate a preneoplastic condition, the compound will be assigned to toxicity category D.

C. Economic Considerations

Executive Order 12291 and the Regulatory Flexibility Act require economic impact analyses of proposed regulations likely to have significant economic consequences overall, for particular sectors, or for small entities. As explained elsewhere in this notice, the threshold assessment is not a rule, but rather a guideline. Moreover, the comments received on the initial threshold assessment (44 FR 17071) do not reveal signifiant concern about the economic aspects of the threshold assessment itself. Therefore, the agency concludes that an analysis of economic impact is not required in this case.

FDA recognizes, however, that the application of this guideline may cause the agency to conclude that some sponsored compounds warrant additional testing for carcinogenicity. In such cases, the sponsored compound would be subject to SOM testing requirements unless the sponsor demonstrates the product's safety by some equally appropriate means. The agency's March 1979 draft regulatory analysis of the SOM proposal concluded that the prescribed SOM studies of exogenous compounds could cost sponsors up to several million dollars for each target animal/route of administration. Because the costs of SOM procedures to new animal drug sponsors could be significant, and because the threshold assessment guideline will have the effect of triggering the SOM requirements in these cases, some explanation of the agency's intentions with respect to regulatory analysis and regulatory flexibility analysis of these closely related initiatives is in order.

FDA believes that the SOM procedure itself, as a practical matter, contains virtually all the potential for economic impact represented by the combined threshold assessment/SOM initiative. The threshold assessment guideline is simply the agency's screening procedure for identifying animal drugs presenting possible carcinogenic risk to humans. The agency notes that the revised guideline relies principally on data from tests usually conducted by sponsors of animal drug products intended for use in food-producing animals. FDA now uses the results of short-term toxicity tests, and followup bioassays when indicated, to implement the general food safety provisions of the act. In the future, the results of these studies will be combined with the mutagenicity battery results, to serve as the basic screening data of the threshold assessment. Therefore, within the constraints of scientific and public health acceptability, the revised guideline reflects the agency's desire to contain incremental costs, which in this case are limited to from $7,600 to $10,000 per product for the mutagenicity battery.

Issuing the guideline at this time, therefore, will have no significant economic consequences that will not be examined in the regulatory analyses of the final decisions concerning SOM requirements and related implementation. On the other hand, the availability of this guideline should help remove uncertainties as to the carcinogenicity screening process, facilitate the testing programs and product development decisions of sponsors, and accelerate the approval process for new animal drugs for which carcinogenicity is not an issue.

Conclusion

The SOM procedure is being used on a case-by-case basis to provide a comprehensive, systematic data collection procedure for evaluating the carcinogenic potential of chemical compounds intended for use in food-producing animals and to ensure that edible tissues derived from such animals are free from unacceptable levels of cancer-causing residues. The threshold assessment guideline serves as the decisionmaking tool by which the agency determines whether a compound will be evaluated under the SOM procedure as well as under the general food safety requirements of the Federal Food, Drug, and Cosmetic Act that

address aspects of toxicity other than carcinogenicity. In light of comments on the proposed SOM regulations received at the public hearing held on June 21 and 22, 1979, as well as the comments received as of September 4, 1979, and in light of the agency's own dissatisfaction with the threshold assessment as originally structured, it became apparent that in order to provide a better decisionmaking tool the quideline had to be revised. The revisions have been based on the comments as well as on the agency's expertise. The underlying premise of the threshold assessment remains that if the use of the compound is likely to yield edible animal tissue presenting a risk of cancer to man, that compound should be evaluated under the proposed SOM procedure to determine if the compound is a carcinogen. The converse of that premise, however, is also true. If the probability is remote that a compound will yield edible animal tissue presenting a risk of cancer to man, the sponsor should not be subject to the requirements put forth in the SOM procedure.

The agency plans to hold a workshop to discuss the general provisions of the revised guidelines. The workship will be held after the agency has had adequate time to review the written comments. The exact time and place of the workshop will be announced in the **Federal Register.**

References

The following material is on file with the Dockets Management Branch, FDA, and may be seen in that office between 9 a.m. and 4 p.m., Monday through Friday.

1. Ward, J. M., "Unique Toxic Lesions Induced by Chemical Carcinogens in Rodents: Indications of a Short-Term Bioassay for Carcinogenesis Testing of Environmental Chemicals," *Medical Hypotheses,* 6:421–425, 1980.

2. Shinozuka, H., B. Lombardi, S. Sell, and R. M. Iammarino, "Early Histological and Functional Alterations of Ethionine Liver Carcinogenesis in Rats Fed a Choline-Deficient Diet," *Cancer Research,* 38:1092–1098, 1978.

3. Hayden, D. W., G. G. Wade, and A. H. Handler, "The Goitrogenic Effect of 4,4¹-Oxydianiline in Rats and Mice," *Veterinary Pathology,* 15:649–662.

The agency invites comments on the new guideline. The guideline may be modified by comments received. No modification or set of modifications will be acceptable if its effect would be that the threshold assessment would fail to identify those compounds which present a risk of cancer to man.

Interested persons may on or before April 5, 1982, submit written comments on the guideline to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857. Comments should be in two copies (except that individuals may submit single copies of comments), identified with the docket number found in brackets in the heading of this document. The guideline and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 17, 1981.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

Dated: January 12, 1982.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 82–2560 Filed 2–1–82; 8:45 am]

BILLING CODE 4160–01–M

Reader Aids

Federal Register

Vol. 47, No. 22

Tuesday, February 2, 1982

INFORMATION AND ASSISTANCE

PUBLICATIONS

Code of Federal Regulations

CFR Unit	202-523-3419 523-3517
General information, index, and finding aids	523-5227
Incorporation by reference	523-4534
Printing schedules and pricing information	523-3419

Federal Register

Corrections	523-5237
Daily Issue Unit	523-5237
General information, index, and finding aids	523-5227
Privacy Act	523-5237
Public Inspection Desk	523-5215
Scheduling of documents	523-3187

Laws

Indexes	523-5282
Law numbers and dates	523-5282 523-5266
Slip law orders (GPO)	275-3030

Presidential Documents

Executive orders and proclamations	523-5233
Public Papers of the President	523-5235
Weekly Compilation of Presidential Documents	523-5235
United States Government Manual	523-5230

SERVICES

Agency services	523-4534
Automation	523-3408
Dial-a-Reg	
Chicago, Ill.	312-663-0884
Los Angeles, Calif.	213-688-6694
Washington, D.C.	202-523-5022
Library	523-4986
Magnetic tapes of FR issues and CFR volumes (GPO)	275-2867
Public Inspection Desk	523-5215
Special Projects	523-4534
Subscription orders (GPO)	783-3238
Subscription problems (GPO)	275-3054
TTY for the deaf	523-5229

FEDERAL REGISTER PAGES AND DATES, FEBRUARY

CFR PARTS AFFECTED DURING FEBRUARY

At the end of each month, the Office of the Federal Register publishes separately a list of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
4893 4673

7 CFR

301 4675
987 4489

Proposed Rules:
319 4693

9 CFR

Proposed Rules:
201 4668
203 4668

10 CFR

2 4490
9 4676
50 4497
516 4493

12 CFR

545 4498

13 CFR

101 4676

14 CFR

39 4498-4501
71 4502
73 ..... 4503, 4504

Proposed Rules:
Ch. I 4523
39 4523
71 ..... 4527, 4528
73 4529

15 CFR

Proposed Rules:
371 4677
806 4530

16 CFR

Proposed Rules:
13 4532

18 CFR

271 4504

Proposed Rules:
271 4535
273 4535
274 4535

19 CFR

Proposed Rules:
4 4535

21 CFR

81 4677
522 4678
546 4678

Proposed Rules:
862 4802

22 CFR

Proposed Rules:
203 4535

23 CFR

Proposed Rules:
230 4536

24 CFR

207 4507

26 CFR

1 4508
5e 4680
7 4681

Proposed Rules:
1 4694

28 CFR

0 4513

30 CFR

916 4513

Proposed Rules:
906 4694

32 CFR

1602 4640
1605 4640
1609 4640
1618 4640
1621 4640
1624 4640
1627 4640
1630 4640
1633 4640
1636 4640
1642 4640
1645 4640
1648 4640
1651 4640
1653 4640

33 CFR

100 4515
117 ..... 4516, 4517
165 4515

40 CFR

Proposed Rules:
35 4704
52 4704
122 4706
260 4706
264 4706

AGENCY PUBLICATION ON ASSIGNED DAYS OF THE WEEK

The following agencies have agreed to publish all documents on two assigned days of the week (Monday/Thursday or Tuesday/Friday).

This is a voluntary program. (See OFR NOTICE 41 FR 32914, August 6, 1976.)

Monday	Tuesday	Wednesday	Thursday	Friday
DOT/SECRETARY	USDA/ASCS		DOT/SECRETARY	USDA/ASCS
DOT/COAST GUARD	USDA/FNS		DOT/COAST GUARD	USDA/FNS
DOT/FAA	USDA/REA		DOT/FAA	USDA/REA
DOT/FHWA	USDA/SCS		DOT/FHWA	USDA/SCS
DOT/FRA	MSPB/OPM		DOT/FRA	MSPB/OPM
DOT/MA	LABOR		DOT/MA	LABOR
DOT/NHTSA	HHS/FDA		DOT/NHTSA	HHS/FDA
DOT/RSPA			DOT/RSPA	
DOT/SLSDC			DOT/SLSDC	
DOT/UMTA			DOT/UMTA	

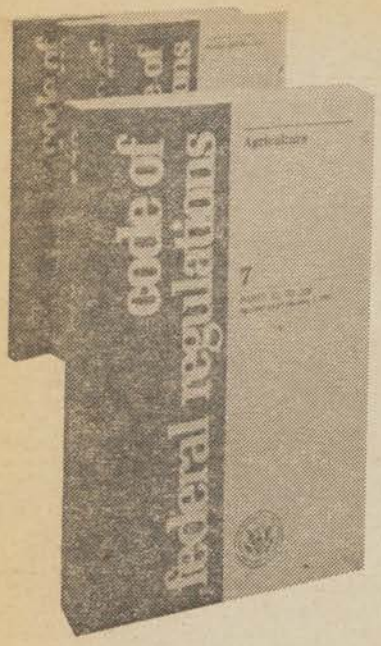
Documents normally scheduled for publication on a day that will be a Federal holiday will be published the next work day following the holiday. Comments on this program are still invited.

Comments should be submitted to the Day-of-the-Week Program Coordinator, Office of the Federal Register, National Archives and Records Service, General Services Administration, Washington, D.C. 20408.

List of Public Laws

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws.**

Last Listing January 6, 1982



Just Released

Code of Federal Regulations

Revised as of July 1, 1981

Quantity	Volume	Price	Amount
_____	Title 32—National Defense (Parts 800 to 999)	$8.00	$_____
_____	Title 41—Public Contracts and Property Management (Chapter 18 (Parts 1 to 52, Vol. II))	9.50	_____
		Total Order	$_____

A Cumulative checklist of CFR issuances for 1981 appears in the back of the first issue of the Federal Register each month in the Reader Aids section. In addition, a checklist of current CFR volumes, comprising a complete CFR set, appears each month in the LSA (List of CFR Sections Affected).

Please do not detach

Order Form

Mail to: Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402

Enclosed find $_____. Make check or money order payable to Superintendent of Documents. (Please do not send cash or stamps). Include an additional 25% for foreign mailing.

Charge to my Deposit Account No.

☐☐☐☐☐☐☐–☐

Order No._____

VISA

MasterCard

Credit Card Orders Only

Total charges $_____ Fill in the boxes below.

Credit Card No. ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Expiration Date Month/Year ☐☐☐☐

Please send me the **Code of Federal Regulations** publications I have selected above.

Name—First, Last

Street address

Company name or additional address line

City State ZIP Code

(or Country)

PLEASE PRINT OR TYPE

For Office Use Only.

	Quantity	Charges
Enclosed		
To be mailed		
Subscriptions		
Postage		
Foreign handling		
MMOB		
OPNR		
UPNS		
Discount		
Refund		