requiring random testing of employees for indications of drug use?

Dated: August 19, 1986.

For the Authority.

Jacqueline R. Bradley,

Executive Director.

[FR Doc. 86-19000 Filed 8-21-86; 8:45 am]

BILLING CODE 6727-01-M

FEDERAL MARITIME COMMISSION

Notice of Agreement(s) Filed

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may impact and obtain a copy of each agreement at the Washington, D.C. Office of the Federal Maritime Commission, 1100 L Street, NW., Room 10325. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, D.C. 20573, within 10 days after the date of the **Federal Register** in which this notice appears. The requirements for comments are found in § 572.603 of Title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 202-010270-017
Title: Gulf-European Freight Association
Parties:
Compagnie Generale Maritime (CGM)
Lykes Bros. Steamship Co., Inc.
Gulf Container Line (GCL), B.V.
Hapag-Lloyd AG
Sea-Land Service, Inc.
Trans-Freight Lines
Nedlloyd Lijnen, B.V.
Synopsis: The proposed amendment would modify the independent action provisions of the agreement to comply with the Commission's regulations.

Agreement No.: 202-010656-013
Title: North Europe-U.S. Gulf Freight Association
Parties:
Atlanticargo (South Atlantic Cargo Shipping NV)
Compagnie Generale Maritime (CGM)
Lykes Bros. Steamship Co., Inc.
Gulf Container Line (GCL), B.V.
Nedlloyd Lijnen, B.V.
Hapag-Lloyd AG
Sea-Land Service, Inc.
Trans Freight Lines
United States Lines, Inc.
Synopsis: The proposed amendment would modify the independent action provisions of the agreement to comply with the Commission's regulations.

Agreement No.: 202-010714-002
Title: Trans-Atlantic American Flag Liner Operators
Parties:
Farrell Lines Incorporated
Sea-Land Service, Inc.
United States Lines, Inc.
Lykes Bros. Steamship Co., Inc.
Synopsis: The proposed amendment would modify the independent action provisions of the agreement to comply with the Commission's regulations.

Agreement No.: 202-010833-001
Title: Eurocorde I
Parties:
North Europe-U.S. Atlantic Conference
U.S. Atlantic-North Europe Conference
Polish Ocean Lines
Synopsis: The proposed amendment would modify the independent action provisions of the agreement to comply with the Commission's regulations.

By Order of the Federal Maritime Commission.

Dated: August 18, 1986.

Joseph C. Polking,

Secretary.

[FR Doc. 86-18946 Filed 8-21-86; 8:45 am]

BILLING CODE 6730-01-M

Agreement(s) Filed

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 1100 L Street, NW., Room 10325. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the **Federal Register** in which this notice appears. The requirements for comments are found in § 572.603 of Title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 202-000150-085
Title: Trans-Pacific Freight Conference of Japan
Parties: American President Lines, Ltd.; Barber Blue Sea Line; Japan Line, Ltd.; Kawasaki Kisen Kaisha, Ltd.; Mitsui O.S.K. Lines, Ltd.; A.P. Moller-Maersk Line; Neptune Orient Lines Limited; Nippon Yusen Kaisha; Orient Overseas Container Line, Inc.; Sea-Land Service, Inc.; Showa Line, Ltd.; United States Lines, Inc.; Yamashita-Shinnihon Steamship Co., Ltd.
Synopsis: The proposed amendment would modify the independent action provisions of the agreement to comply with the Commission's regulations.

Agreement No.: 202-003103-087
Title: Japan-Atlantic and Gulf Freight Conference
Parties: Barber Blue Sea Line; Japan Line, Ltd.; Kawasaki Kisen Kaisha, Ltd.; Mitsui O.S.K. Lines, Ltd.; A.P. Moller-Maersk Line; Neptune Orient Lines Limited; Nippon Yusen Kaisha; Orient Overseas Container Line, Inc.; United States Lines, Inc.; Yamashita-Shinnihon Steamship Co., Ltd.
Synopsis: The proposed amendment would modify the independent action provisions of the agreement to comply with the Commission's regulations.

Agreement No.: 202-008190-018
Title: Japan-Puerto Rico and Virgin Islands Freight Conference
Parties: Japan Line, Ltd.; Kawasaki Kisen Kaisha, Ltd.; Mitsui O.S.K. Lines, Ltd.; Nippon Yusen Kaisha; Yamashita-Shinnihon Steamship Co., Ltd.
Synopsis: The proposed amendment would modify the independent action provisions of the agreement to comply with the Commission's regulations.

Agreement No.: 224-010983
Title: Bermuda Terminal Company/ Bermuda Container Line Terminal Service Agreement
Parties: Bermuda Terminal Company Inc. (BTC); Bermuda Container Line Ltd. (BCL)
Synopsis: The proposed agreement would permit BTC to provide terminal services to BCL at Perth Amboy, New Jersey in connection with BCL's transportation service between the Port of New York and Bermuda.

Dated: August 19, 1986.

Joseph C. Polking,

Secretary.

[FR Doc. 86-19012 Filed 8-21-86; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

Antrim Financial Corp., et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank

holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. 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.

Unless otherwise noted, comments regarding each of these applications must be received not later than September 12, 1986.

A. Federal Reserve Bank of Chicago (Franklin D. Dreyer, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *Antrim Financial Corporation,* Mancelona, Michigan; to become a bank holding company by acquiring 100 percent of the voting shares of Antrim County State Bank, Mancelona, Michigan. Comments on this application must be received by September 15, 1986.

2. *Community Financial Corporation,* Harbor Beach, Michigan; to become a bank holding company by acquiring 100 percent of the voting shares of First of America Bank—Huron, Harbor Beach, Michigan. Comments on this application must be received by September 10, 1986.

3. *MH Bancorp, Inc.,* Orland Park, Illinois; to become a bank holding company by acquiring 100 percent of the voting shares of FNB Bancorp, Inc., Chicago Heights, Illinois, and thereby indirectly acquire The First National Bank in Chicago Heights, Chicago Heights, Illinois.

4. *State Financial Services Corporation,* Hales Corners, Wisconsin; to acquire 66.67 percent of the voting shares of Edgewood Bank, Greenfield, Wisconsin

5. *Waterman Bancshares, Inc.,* Waterman, Illinois; to become a bank holding company by acquiring 80 or more of the voting shares of Waterman State Bank, Waterman, Illinois.

B. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. *Commonwealth Bancshares, Inc.,* McLeansboro, Illinois; to become a bank holding company by acquiring at least 80.0 percent of the voting shares of Salem National Bank, Salem, Illinois.

2. *Portland Bankshares, Inc.,* Portland, Arkansas; to become a bank holding company by acquiring at least 80 percent of the voting shares of Portland Bank, Portland, Arkansas.

C. Federal Reserve Bank of Kansas City (Thomas M. Hoenig, Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *Northeastern Oklahoma Bankshares, Inc,* Inola, Oklahoma; to become a bank holding company by acquiring 100 percent of the voting shares of Northeastern Oklahoma Bancorporation, Inc., Inola, Oklahoma, and thereby indirectly acquire Bank of Inola, Inola, Oklahoma.

Board of Governors of the Federal Reserve System, August 18, 1986.

Barbara R. Lowrey,

Associate Secretary of the Board.

[FR Doc. 86-18938 Filed 8-21-86; 8:45 am]

BILLING CODE 6210-01-M

Lakeside Bancshares, Inc.; Application to Engage de Novo in Permissible Nonbanking Activities

The company listed in this notice has filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo,* either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, indentifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than September 12, 1986.

A. Federal Reserve Bank of Atlanta (Robert E. Heck, Vice President) 104 Marietta Street, NW., Atlanta, Georgia 30303:

1. *Lakeside Bancshare, Inc.,* Lake Charles, Louisiana; to engage *de novo* through its subsidiary, Lakeside Life Insurance Company, Inc., Lake Charles, Louisiana, in the sale and underwriting of credit life, accident and health insurance, and other insurances, arising from an extension of credit by a bank or bank holding company pursuant to § 225.25(b)(9) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, August 18, 1986.

Barbara R. Lowrey,

Associate Secretary of the Board.

[FR Doc. 86-18939 Filed 8-21-86; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Agency Forms Submitted to the Office of Management and Budget for Clearance

Each Friday the Department of Health and Human Services (HHS) publishes a list of information collection packages it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). The following are those packages submitted to OMB since the last list was published on August 15, 1986

Public Health Service

(Call Reports Clearance Officer on 202-245-2100 for copies of packages).

Food and Drug Administration

Subject: Initial Registration of Medical Device Establishment—Extension—(0910-0059).

Respondents: Businesses or other for-profit; Small businesses or organizations.

OMB Desk Officer: Bruce Artim

Health Care Financing Administration

(Call Reports Clearance Officer on 301–594–8650 for copies of package).

Subject: Information Collection Requirements in 42 CFR Part 282—Hospital Conditions of Participation—Revision—(0938–0328)—HCFA–R–48.

Respondents: Businesses or other for-profit; Non-profit institutions; Small businesses or organizations.

Subject: Information Collection Requirements for Sole Community Home Health Agencies at 45 CFR 405.1633(b)(2), (F) and (G) BERC–197–F—NEW—HCFA–R–85.

Respondents: Individuals or households.

Subject: Health Maintenance Organizations/Competitive Medical Plans National Data Reporting Requirements—Revision—(0938–0469) HCFA–906.

Respondents: State or local governments; Businesses or other for-profit; Non-profit institutions.

OMB Desk Officer: Fay S. Iudicello.

Office of the Secretary

(Call Reports Clearance Officer on 202–245–6511 for copies of package).

Subject: 45 CFR Part 95.600 State Requests for HHS Approval of Federal Financial Participation in the Cost of ADP Systems, Equipment and Services—Revision—(0990–0058).

Respondents: State or local governments.

OMB Desk Officer: Fay S. Iudicello.

Office of Human Development Services

(Call Reports Clearance Officer on 202–472–4415 for copies of package).

Subject: Runaway and Homeless Youth Centers—NEW—

Respondents: State or local governments.

OMB Desk Officer: Judy A. McIntosh.

Social Security Administration

(Call Reports Clearance Officer on 301–594–5706 for copies of package).

Subject: Beneficiary Recontact Report—Revision—(0960–0354).

Respondents: Individuals or households.

OMB Desk Officer: Judy A. McIntosh.

Copies of the above information collection clearance packages can be obtained by calling the Reports Clearance Officer on the number shown above.

Written comments and recommendations for the proposed information collections should be sent directly to the appropriate OMB Desk Officer designated above at the following address: OMB Reports Management Branch, New Executive Office Building, Room 3208, Washington, DC 20503. Attn: (name of OMB Desk Officer)

Dated: August 18, 1986.

Wallace O. Keene,

Acting Deputy Assistant Secretary for Management Analysis and Systems.

[FR Doc. 86–18998 Filed 8–21–86; 8:45 am]

BILLING CODE 4150–04–M

Food and Drug Administration

[Docket No. 86F–0333]

Allied Colloids, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Allied Colloids, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of alkyl (C_{12}–C_{20}) methacrylate-methacrylic acid copolymers as a stabilizer in the manufacture of paper and paperboard in contact with food.

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

SUPPLEMENTARY INFORMATION: 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 6B3911) has been filed by Allied Colloids, Inc., 2301 Wilroy Rd., Suffolk, VA 23434, proposing that § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) be amended to provide for the safe use of alkyl (C_{12}–C_{20}) methacrylate-methacrylic acid copolymers as a stabilizer in the manufacture of paper and paperboard in contact with food.

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 significant 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).

Dated: August 14, 1986.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86–18943 Filed 8–21–86; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 86F–0328]

Borg-Warner Chemicals, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Borg-Warner Chemicals, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the expanded safe use of phosphorous acid, cyclic neopentanetetrayl bis(2,4-di-*tert*-butyl-phenyl) ester as an antioxidant for olefin polymers in contact with food.

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

SUPPLEMENTARY INFORMATION: 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 6B3944) has been filed by Borg-Warner Chemicals, Inc., Washington, WV 26181, proposing that § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) be amended to provide for the expanded safe use of phosphorous acid, cyclic neopentanetetrayl bis(2,4-di-*tert*-butyl-phenyl) ester as an antioxidant for olefin polymers in contact with food.

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 significant 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), as published in the **Federal Register** of April 26, 1985 (50 FR 16636).

Dated: August 14, 1986.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86–18941 Filed 8–21–86; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 86M–0329]

Medtronic, Inc.; Premarket Approval of STERx Tip™ Pacing Lead, Models 5025 and 5525

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by

Medtronic, Inc., Minneapolis, MN for premarket approval, under the Medical Device Amendments of 1976, of the STERx Tip™ Pacing Lead, Models 5025 and 5525. After reviewing the recommendation of the Circulatory System Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant of the approval of the application.

DATE: Petitions for administrative review by September 22, 1986.

ADDRESS: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Tara Ryan, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7559.

SUPPLEMENTARY INFORMATION: On December 17, 1985, Medtronic, Inc., Minneapolis, MN 55432, submitted to FDA an application for premarket approval of the STERx Tip™ Pacing Lead, Models 5025 and 5525. Model 5025 ventricular and Model 5525 atrial leads may be used where permanent ventricular or atrial or dual chamber pacing systems are indicated.

On May 23, 1986, the Circulatory System Devices Panel, an FDA advisory committee, reviewed and recommended approval of the application. On July 29, 1986, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at CDRH—contact Tara Ryan (HFZ–450), address above.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under Part 12 (21 CFR Part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register.** If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before September 22, 1986, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h), 90 Stat. 554–555, 571 (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: August 13, 1986.

John C. Villforth,

Director, Center for Devices and Radiological Health.

[FR Doc. 86–18944 Filed 8–21–86; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 86M–0330]

Medtronic, Inc.; Premarket Approval of the STERx TIP ™ Pacing Lead, Models 4003 and 4503

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Medtronic, Inc., Minneapolis, MN, for premarket approval, under the Medical Device Amendments of 1976, of the STERx TIP ™ Pacing Lead, Models 4003 and 4503. After reviewing the recommendation of the Circulatory System Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant of the approval of the application.

DATE: Petitions for administrative review by September 22, 1986.

ADDRESS: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Tara Ryan, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7559.

SUPPLEMENTARY INFORMATION: On March 19, 1986, Medtronic, Inc., Minneapolis, MN 55432, submitted to CDRH an application for premarket approval of the STERx TIP ™ Pacing Lead, Models 4003 and 4503. The Model 4003 ventricular and Model 4503 atrial leads have application where permanent ventricular or atrial or dual chamber pacing systems are indicated.

On May 23, 1986, the Circulatory System Devices Panel, an FDA advisory committee, reviewed and recommended approval of the application. On July 29, 1986, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at CDRH—contact Tara Ryan (HFZ–450), address above.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under Part 12 (21 CFR Part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory

committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register.** If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before September 22, 1986, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h), 90 Stat. 554–555, 571 (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: August 13, 1986.

John C. Villforth,

Director, Center for Devices and Radiological Health.

[FR Doc. 86-18945 Filed 8-21-86; 8:45 am]

BILLING CODE 4160-01-M

Public Health Service

AIDS Vaccine Development: Private Sector/Government Collaborative Efforts

AGENCY: Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: This notice establishes a framework for collaborative efforts between the Public Health Service (PHS) and the private sector for the development, testing, production and distribution of a vaccine for the prevention of Acquired Immune Deficiency Syndrome (AIDS).

DATE: To facilitate consideration, plans for collaborative efforts should be submitted by October 21, 1986, but plans submitted after that date will also be considered.

Address for submission and contact for further information: Dr. Lowell T. Harmison, Science Advisor, PHS, Room 13–95, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443–2650.

SUPPLEMENTARY INFORMATION: The PHS and its involved component agencies, the Alcohol, Drug Abuse and Mental Health Administration (ADAMHA), the Centers for Disease Control (CDC), the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) are engaged in ongoing research toward the development of an AIDS vaccine and have developed the capacity necessary for the support of those efforts. The PHS is now at an important stage in the development of an AIDS vaccine. We would like to couple our own efforts with those of industry, universities, and other parts of the private sector to facilitate the prompt development, testing, production and distribution of an AIDS vaccine. Therefore, the PHS is establishing a more formal framework for its collaborative efforts with the private sector. This framework is intended to ensure that all entities have an equal opportunity to seek collaborative agreements with the PHS and that proposals for such agreements are considered in an orderly fashion.

Collaborative agreements will be negotiated on a case-by-case basis in accordance with the considerations set forth in this notice. Under these collaborative research and development agreements, the PHS may provide: (1) *Patent licensing (both exclusive and nonexclusive),* (2) *research results,* (3) *scientific knowledge,* (4) *laboratory facilities,* (5) *animal models and animal testing,* (6) *assistance in the formulation of clinical protocols and clinical trials,* and (7) *other assistance, as appropriate,* to private entities that are seeking to develop, produce and market an immunological approach (vaccine) for the prevention of AIDS. The PHS does not provide financial assistance through the collaborative agreement mechanism and thus this notice does not establish an assistance program or a request for proposals. The framework established by this notice is limited to comprehensive efforts to develop, test and produce an AIDS vaccine as described below.

Vaccine Approaches

A broad base of research exists upon which to build an AIDS vaccine development and testing program—a program consisting of steps leading from vaccine conceptualization through prototype development and animal and clinical testing to FDA approval, production and availability. To implement this program, the PHS welcomes collaborative plans for pursuing vaccine development that include virus subunits, genetically engineered subunit antigens, synthetic peptides, infectious recombinant viruses, anti-idiotype antibodies, attenuated HTLV–III/LAV, killed HTLV–III/LAV and other potentially immunogenic molecular configurations. These approaches have been grouped as follows to assist in preparing your plans:

(a) *Development of Synthetic Vaccine.* Define optimum pathogen growth, identify essential immunogen and prepare immunogen from: (1) purified viral antigen extracted from whole virus, virus particles or mammalian cells expressing virus proteins (this approach will provide preliminary information on the immunogenicity of natural antigens); (2) antigen produced by recombinant DNA technology (this strategy is based on identification of an antigen and its subsequent synthesis in a microbiological system); (3) antigen produced by chemical synthesis (similar to (2) but based on chemically synthesized antigen); and (4) anti-idiotype antibodies produced by monoclonal antibody techniques. If necessary, identify adjuvants to enhance immunogenicity in animals and humans. Demonstrate immunogenicity protection in animals with standardized challenge goals.

(b) *Development of a Live, Genetically Modified Viral Vector or Attenuated Vaccine.* These approaches would involve one or more of the following steps: (1) growth in acceptable cells, tissues or other cultures of a virus in which has been inserted a gene coding for HTLV–III/LAV antigen which would be expressed in a vaccinated host and would subsequently elicit protective antibodies against HTLV–III/LAV; (2) a demonstration of satisfactory infectivity and antigenicity; (3) a demonstration of genetic stability (lack of reversion); (4) a demonstration of immunogenicity in animals; and (5) a demonstration of protection in animals.

(c) *Other Approaches.* Identification and development of other immunization approaches (for example, passive immunization) that would be medically useful and safe.

Although the PHS encourages the pursuit of a broad range of approaches, it recognizes that there is no assurance of success for any of these approaches.