Assistance; 83.543, Individual and Family Grant (IFG) Program; 83.544, Public Assistance Grants; 83.545, Disaster Housing Program; 83.548, Hazard Mitigation Grant Program.)

Joe M. Allbaugh,

Director.

[FR Doc. 02–804 Filed 1–11–02; 8:45 am]

BILLING CODE 6718–02–P

FEDERAL MARITIME COMMISSION

Notice of Agreement(s) Filed

The Commission hereby gives notice of the filing of the following agreement(s) under the Shipping Act of 1984. Interested parties can review or obtain copies of agreements at the Washington, DC offices of the Commission, 800 North Capitol Street, NW., Room 962. Interested parties may submit comments on an agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days of the date this notice appears in the **Federal Register**.

Agreement No.: 011742–001.

Title: P&O Nedlloyd-Farrell/Hapag-Lloyd/Zim Mediterranean Space Charter Agreement.

Parties: Farrell Lines, Inc. Hapag-Lloyd Container Linie GmbH. P&O Nedlloyd Limited. P&O Nedlloyd B.V. Zim Israel Navigation Co., Ltd.

Synopsis: The proposed agreement modification adds authority for the parties to discuss and agree on the phasing-in and phasing-out of vessels for maintenance and to discuss and agree on criteria to measure adherence to any agreed-upon schedule, as well as any remedial action in the event of non-adherence. The modification also clarifies the parties' authority to use common terminals and adds provisions dealing with force majeure situations, notices, and enforceability. The parties request expedited review.

Dated: January 9, 2000.

By Order of the Federal Maritime Commission.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 02–845 Filed 1–11–02; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the office of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than January 28, 2002.

A. Federal Reserve Bank of Minneapolis (JoAnne F. Lewellen, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. Edward T. Christian, trustee of Edward T. Christian Revocable Trust, Albert Lea, Minnesota; to acquire voting shares of Kiester Investments, Inc., Kiester, Minnesota, and thereby indirectly acquire voting shares of First National Bank of Kiester, Kiester, Minnesota.

Board of Governors of the Federal Reserve System, January 8, 2002.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 02–795 Filed 1–11–02; 8:45 am]

BILLING CODE 6210–02–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0402]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Devices; Third-Party Premarket Submission Review and Quality System Inspections Under United States/European Community Mutual Recognition Agreement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by February 13, 2002.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices; Third-Party Premarket Submission Review and Quality System Inspections Under United States/European Community Mutual Recognition Agreement (OMB Control No. 0910–0378)—Extension

The third-party program under the United States/European (U.S./EC) Community/Mutual Recognition Agreement (MRA) is intended to implement that part of the U.S./EC MRA that covers the exchange of quality system evaluation reports for all medical devices and premarket evaluation reports for selected low-to-moderate risk devices. Under the MRA, firms may apply to become designated as a U.S. Conformity Assessment Body (CAB). Firms who are designated will be qualified to conduct quality system evaluations for all classes of devices and product type examinations and verifications for selected devices based on EC requirements under the voluntary third-party program authorized by MRA. Firms designated as European Union (EU) CABs could conduct quality system evaluations for all classes of devices and premarket 510(k) evaluations for selected devices based on FDA requirements. Under the voluntary third-party program, reports of these evaluations would be submitted by the EU CABs to FDA. The EU CABs would also be required to maintain copies of their evaluation reports.

FDA requests approval of the following collection of information:

Requests for Designation as U.S. CABs—Under this program, U.S. companies were allowed to apply for designation as a U.S. CAB. Such designation enabled the company to perform third-party reviews of U.S. products for export to the EU and third-party audits of quality systems established by manufacturers of medical devices manufactured for export to the EU. Third-party review of U.S. products

for export and third-party audit of quality systems was elective and at the discretion of the manufacturer of the product. At the present time, only eight U.S. CABs are active. The agency is not accepting applications for U.S. CAB designation at this time and in the foreseeable future.

Premarket Reports by EU CABs—Under this program, EU CABs will be able to perform third-party evaluations for certain products manufactured in Europe for export to the United States. Third-party evaluation is elective and at the discretion of the manufacturer of the product.

Quality System Reports by EU CABs—Under this program, EU CABs will be able to perform third-party audits of the quality systems established by EU manufacturers of products manufactured for export to the United States. Third-party audit of quality systems is elective and at the discretion of the manufacturer of the product.

EU CABs must maintain records of their third-party evaluations of quality systems and premarket submissions for certain products manufactured for export to the United States for a period of no less than 3 years.

The program implements that part of the U.S./EC MRA that covers the exchange of quality system evaluation reports for all medical devices and premarket evaluation reports for selected low-to-moderate risk devices.

Respondents to this information collection are businesses or other for-profit organizations.

In the **Federal Register** of October 5, 2001 (66 FR 51050), the agency requested comments on the proposed collection of information. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Item	No. of Respondents	Annual Frequency perResponse	Total Annual Responses	Hours per Response	Total Hours
Premarket Reports by EC CABs	11	5	55	40	2,200
Quality System Reports by EC Cabs	11	15	165	32	5,280
Total					7,480

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Item	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Premarket Reports by EC CABs	11	5	55	10	550
Quality System Reports by EC Cabs	11	15	165	10	1,650
Total					2,200

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The following is an explanation of the burden estimate.

I. Reporting Burden

A. Requests for Designation as U.S. CAB

U.S. firms who have applied and have been accepted for designation as a U.S. CAB will be able to perform third-party evaluations of U.S. products for export to the EU. Likewise, European firms who have applied and been designated as EC CABs, will be able to perform third- party reviews of products to be exported to the United States. The application for nomination as an EU CAB does not represent a paperwork burden subject to the PRA because the designation procedure is an internal process that is required by, and administered by, European authorities. Only the application for designation as a U.S. CAB represents a paperwork burden under the PRA. However, the agency has received 10 applications for designation as U.S. CABs, 8 of whom are still active. The agency is not accepting any applications at this time, and does .not anticipate accepting any applications in the near future. Thus burden for U.S. CAB designation is nonexistent at this time.

B. Premarket Reports

EU CABs are required to submit to FDA reports of their third-party evaluations. Based upon information gathered during the negotiation of the U.S./EC MRA, the agency anticipates that European manufacturers will request third-party review for approximately 55 to 100 medical device products annually. The agency expects that interest and participation in the program will increase with time. The agency further estimates based on dialogue with EC officials, that 11 firms will be designated to act as EC CABs.

C. Quality System Reports

EU CABs are required to submit to FDA reports of their third-party evaluations. Based upon information gathered during the negotiation of the U.S./EC MRA, the agency anticipates that European manufacturers will request third-party audits for approximately 165 medical device products annually. The agency estimates that 11 EU CABs will perform these evaluations.

II. Recordkeeping

FDA requires the reviewers to keep in their records a copy of the report that they submit to FDA for each review. The agency anticipates that 55 premarket reports and 165 quality system reports will be generated and required to be maintained by EU CABs annually. The agency further estimates that each reviewer will require no more than 10 hours (2 hours per recordkeeping per report) for each to maintain such records annually.

Dated: January 7, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–854 Filed 1–11–02; 8:45 am]

BILLING CODE 4160–02–S