recognized standards exist and which represent 60 percent of the 510(k)s we receive each year. If the program is successful, FDA will add additional devices, as appropriate.

FDA estimates the burden of this collection as follows:

TABLE 1.—Estimated Annual Reporting Burden[1]

Item	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Requests for designation as U.S. CAB	12	1	12	24	288
Premarket reports by EC CAB's	20	5	100	40	4,000
Quality system reports by EC CAB's	20	5	100	32	3,200
Total					7,488

[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
Records of evaluation of premarket submissions by EC CAB's	20	5	100	10	1,000
Records of evaluation of quality systems	20	5	100	10	1,000
Total					2,000

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

The burdens are explained as follows:

I. Reporting

A. Requests for Designation as U.S. CAB

Under this program, U.S. firms may apply for designation as a U.S. CAB. Such designation will enable that firm to perform third-party evaluations of U.S. products for export to EC. Likewise, European firms may apply to be designated as EC CAB's, which will enable them to perform third-party evaluations of products to be exported to the United States. The application for nomination as an EC CAB does not represent an information collection burden subject to the PRA because the designation procedure is an internal process which 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. The agency anticipates, based on discussions with the National Institute of Science and Technology of the U.S. Department of Commerce and officials of other standards organizations, as well as firms who have expressed interest directly to FDA, that approximately 12 applications for designation as U.S. CAB's will be received.

B. Premarket Reports

Under this program, EC CAB's will be able to perform third-party evaluations for certain products produced in Europe for export to the United States. EC CAB's would be required to submit reports of their evaluations to FDA. Based upon information gathered during the negotiation of U.S./EC MRA, the agency anticipates that European manufacturers will request third-party evaluation for approximately 100 medical device products annually. The agency further estimates, based on dialogue with EC officials, that 20 firms will be designated to act as EC CAB's.

C. Quality System Reports

Under this program, EC CAB's will be able to perform third-party evaluations of the quality systems established by manufacturers of European products produced for export to the United States. EC CAB's would be required to submit reports of their evaluations to FDA. Based upon information gathered during the negotiation of U.S./EC MRA, the agency anticipates that European manufacturers will request third-party evaluations for approximately 100 medical device products annually. The agency estimates that 20 EC CAB's will perform these evaluations.

II. Recordkeeping

As stated previously, firms designated as EC CAB's will be able to perform third-party evaluations of quality systems and premarket submissions for certain products produced for export to the United States. Such evaluation will be conducted consistent with FDA's regulatory requirements, and FDA will require the reviewers to keep, in their records, a copy of the report that they submit to FDA for each evaluation. The agency anticipates that 100 premarket reports and 100 quality system reports will be generated and required to be maintained by EC CAB's annually. Thus, the agency estimates that 100 records of evaluations of quality systems and premarket submissions will be retained by the designated EC CAB's. Based on experience with the Third-Party Review Pilot Program, which was announced in the **Federal Register** of April 3, 1996 (61 FR 14789), the agency anticipates that each recordkeeper will require no more than 2 hours of recordkeeping per review. The agency is estimating five reviews per respondent and a total of 10 hours per recordkeeper.

Dated: December 4, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–33054 Filed 12–11–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–1063]

Announcement of a New Format for Export Certificates

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a new format for export certificates. The new format features the use of several security measures in the paper used to print export certificates to deter falsification of or tampering with FDA-

issued export certificates. The new format may also help authenticate export certificates.

DATES: The agency will begin issuing export certificates using the new format after January 1, 1999.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION: Firms exporting products from the United States are often asked by foreign customers or foreign governments to supply a certification relating to products subject to the Federal Food, Drug, and Cosmetic Act (the act) and other FDA-administered acts. Certification is the process by which a formal or official attestation is made concerning a product's regulatory status or the system by which a commodity is manufactured. Certification does not show that FDA has ''approved'' the product for export; however, some certificates reflect that the product has been approved for marketing in the United States.

FDA currently issues several types of certificates. In brief, the principal certificates are:

1. Certificates to Foreign Government—used for products that may be legally marketed, sold, offered for sale, or distributed in the United States. For food products, these are commonly known as ''certificates of free sale'' or ''certificates of export.''

2. Certificates of Exportability—used for products that meet the requirements for export under section 801(e) or 802 of the act (21 U.S.C. 381(e) or 382)) but may not otherwise be marketed, sold, offered for sale, or distributed in the United States.

3. Certificates of a Pharmaceutical Product—used for pharmaceutical products and conform to the format in the World Health Organization's ''Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.''

FDA's Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Food Safety and Applied Nutrition, and Center for Veterinary Medicine receive and process requests for export certificates for products subject to their respective authorities.

Recently, there has been an increasing demand for export certificates, as well as requests from foreign governments to authenticate certificates and instances where FDA has found counterfeit or falsified certificates. Consequently, to facilitate the issuance and tracking of export certificates, deter unscrupulous persons from making counterfeit or false certificates or otherwise tampering with export certificates, and to help foreign governments identify authentic, FDA-issued export certificates more readily, FDA has adopted a new format for its export certificates. The new format features the use of several security measures in the paper used for export certificates.

FDA will begin using the new format on certificates issued after January 1, 1999. The procedures for requesting and issuing export certificates, as well as the text of the certificates themselves, will remain unchanged.

However, FDA will not use the new format on European Union (EU) Export Health Certificates. These certificates are for fishery products intended for import into the EU and are not considered to be FDA certificates.

FDA is notifying foreign embassies and its counterpart government agencies of the new format and also advising them that otherwise valid export certificates issued before January 1, 1999, remain valid. Consequently, persons whose export certificates were issued before January 1, 1999, but expire after that date, should not need to replace those certificates.

Dated: December 4, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–33052 Filed 12–11–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–1109]

Mercury Compounds in Drugs and Food; Request for Data and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for data and information.

SUMMARY: The Food and Drug Administration (FDA) is announcing a call-for-data to identify food and drug products that contain intentionally introduced mercury compounds, e.g., mercurous chloride, mercuric chloride, phenylmercuric acetate, thimerosal. The agency is seeking both quantitative and qualitative information about the mercury compounds in these food and drug products. This request is part of the implementation of the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit data and information by March 15, 1999. Submit written general comments by March 15, 1999.

ADDRESSES: Submit written general comments on this call-for-data to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit information on human drug products to the Division of Over-the-Counter (OTC) Drug Products (HFD–560), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Submit information on veterinary drug products to the Division of Epidemiology and Surveillance (HFV–210), Center for Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Submit information on food products, including dietary supplements, to the Office of Special Nutritionals (HFS–456), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

FOR FURTHER INFORMATION CONTACT:

For human drug products: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

For veterinary drug products: William C. Keller, Center for Veterinary Medicine (HFV–210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6641.

For food and dietary supplement products: Sharon A. Ross, Center for Food Safety and Applied Nutrition (HFS–456), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5343.

SUPPLEMENTARY INFORMATION:

I. Background

FDAMA (Pub. L. 105–115) was enacted on November 21, 1997. Section 413 of FDAMA, entitled ''Food and Drug Administration Study of Mercury Compounds in Drugs and Food,'' requires FDA to: (1) Compile a list of drugs and foods that contain intentionally introduced mercury compounds, and (2) provide a quantitative and qualitative analysis of the mercury compounds in this list. FDAMA requires the agency to compile the list and provide the analysis within 2 years after the date of its enactment. The statute does not differentiate