Dated: January 13, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–844 Filed 1–24–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0190]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Export Certificates for FDA Regulated Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by February 24, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

Export of FDA Regulated Products—Export Certificates—(OMB Control Number 0910–0498)—Extension

In April 1996, a law entitled ''The FDA Export Reform and Enhancement Act of 1996'' amended sections 801(e) and 802 of the act (21 U.S.C. 381(e) and 382). It was designed to ease restrictions on exportation of unapproved pharmaceuticals, biologics, and devices regulated by FDA. Section 801(e)(4) of the act provides that persons exporting certain FDA-regulated products may request that FDA certify that the products meet the requirements of sections 801(e) or 802 or other requirements of the act. This section of the law requires that FDA issue certification within 20 days of receipt of the request and charge firms up to $175 for the certifications.

This section of the act authorizes FDA to issue export certificates for regulated pharmaceuticals, biologics, and devices that are legally marketed in the United States, as well as for pharmaceuticals, biologics, and devices that are not legally marketed, but are acceptable to the importing country as specified in sections 801(e) and 802 of the act. Section 801(e)(4) of the act provides that FDA shall, upon request, issue certificates for human drugs and biologics, animal drugs, and devices that either meet the applicable requirements of the act and may be legally marketed in the United States or may be legally exported under the act although they may not be legally marketed in the United States. The act does not require FDA to issue certificates for food, including animal feeds, food and feed additives, and dietary supplements, or cosmetics. However, because foreign governments may require certificates for these types of products, the agency intends to continue to provide this service as resources permit. FDA issues six types of certificates: (1) Certificate to Foreign Government (FDA 3613), (2) Certificate of Exportability (FDA 3613a), (3) Certificate of a Pharmaceutical Product (FDA 3613b), (4) Non-clinical Research Use Only Certificate (FDA 3613c), Office of Cosmetics and Colors ''Certificate'' (Exports) Application (FDA 3613d), and Food Export Certificate Application (FDA 3613e). Table 1 of this document lists the different certificates and details their uses:

TABLE 1. LIST OF FDA EXPORT CERTIFICATES

Certificate Name	Form FDA	Use	Issuing FDA Center
Certificate to Foreign Government	3613	For the export of products that can be legally marketed in the United States.	Center for Biologic Evaluation and Research (CBER); Center for Devices and Radiological Health (CDRH); Center for Veterinary Medicine (CVM)
Certificate of Exportability	3613a	For the export of products that cannot be legally marketed in the United States but meet the requirements of sections 801(e) or 802 of the act and may be legally exported.	CBER; CDRH; CVM
Certificate of a Pharmaceutical Product	3613b	For use by the importing country when considering whether to license the product in question for sale in that country. Conforms to the format established by the World Health Organization.	CBER; Center for Drug Evaluation and Research; CVM
Non-Clinical Research Use Only Certificate	3613c	For the export of non-clinical research use only product, material, component that is not intended for human use which may be marketed in, and legally exported from the United States under the act.	CBER; CDRH
Office of Cosmetics and Colors ''Certificate'' (Exports) Application	3613d	For the export of products that are identified by the requester as cosmetics.	Center for Food Safety and Applied Nutrition (CFSAN)

TABLE 1. LIST OF FDA EXPORT CERTIFICATES—Continued

Certificate Name	Form FDA	Use	Issuing FDA Center
Food Export Certificate Application	3613e	For food products and dietary supplements that may be legally marketed in the United States.	CFSAN

In the **Federal Register** of June 21, 2005 (70 FR 35678), FDA published a 60-day notice requesting public comment on the information collection provisions involving export certificates. FDA received three comments; however, only one was related to the information collection.

The commenter suggested that extending the ''Certificate to Foreign Government'' 2-year expiration date to 3, 4 or 5 years would reduce their financial burden. The export certificate expiration date is based on the agency inspection schedule. At this time FDA is not considering reevaluating the inspection schedule.

FDA will continue to rely on self-certification by manufacturers for the first three types of certificates listed in Table 1 of this notice. Manufacturers are requested to self-certify that they are in compliance with all applicable requirements of the act, not only at the time that they submit their request to the appropriate center, but also at the time that they submit the certification to the foreign government.

The appropriate FDA centers will review product information submitted by firms in support of their certificate and any suspected case of fraud will be referred to FDA's Office of Criminal Investigations for follow-up. Firms making or submitting to FDA false statements on any documents may constitute violations of 18 U.S.C. 1001, with penalties including up to $250,000 in fines and up to 5 years imprisonment.

FDA estimates the burden of this collection of information as follows:

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Center	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
CBER	1,501	1	1,501	1	1,501
CDER	4,803	1	4,803	1	4,803
CDRH	5,674	1	5,674	2[2]	11,348
CFSAN, Office of Cosmetics and Colors	730	1	730	1	730
CFSAN, Office of Plant and Dairy Foods	181	1	181	1.5	271.5
CFSAN, Office of Nutritional Products, Labeling and Dietary Supplements	660	1	660	1.5	990
CFSAN, Office of Seafood	575	1	575	1.5	862.5
CVM	664	1	664	1	664
Total					21,170

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Based on center policy that allows multiple devices to appear on one certificate.

Dated: January 13, 2006.

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[FR Doc. E6–845 Filed 1–24–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0011]

Global Harmonization Task Force, Study Groups 1, 2, 3, and 4; New Proposed and Final Documents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of several proposed and final documents that have been prepared by Study Groups 1, 2, 3, and 4 of the Global Harmonization Task Force (GHTF). These documents are intended to provide information only and represent a harmonized proposal and recommendation from the GHTF Study Groups that may be used by governments developing and updating their regulatory requirements for medical devices. These documents are intended to provide information only and do not describe current regulatory requirements; elements of these documents may not be consistent with current U.S. regulatory requirements.