commerce of experimental packs of food that deviate from applicable definitions and standards of identity. Section 130.17(c) specifies the information that a firm must submit to FDA to obtain a temporary marketing permit. The information required in a temporary marketing permit application under §130.17(c) enables the agency to monitor the manufacture, labeling, and distribution of experimental packs of food that deviate from applicable definitions of standards of identity. The information so obtained can be used in support of a petition to establish or amend the applicable definition or standard of identity to provide for the variations. Section 130.17(i) specifies the information that a firm must submit to FDA to obtain an extension of a temporary marketing permit.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 130.17(c) | 7 | 1 | 7 | 25 | 175 |
| 130.17(i) | 4 | 2 | 8 | 2 | 16 |
| Total | | | | | 191 |

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

The estimated number of temporary marketing permit applications and hours per response is an average based on the agency's experience with applications received October 1, 1998, through September 30, 2001, and information from firms that have submitted recent requests for temporary marketing permits.

Dated: May 23, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02–13589 Filed 5–29–02; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 02N–0215]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Export of FDA Regulated Products—Export Certificates

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the proposed information collection requirements imposed on firms that intend to export to countries that require an export certificate as a condition of entry for FDA regulated products.

**DATES:** Submit written or electronic comments on the collection of information by July 29, 2002.

**ADDRESSES:** Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Mark L. Pincus, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1471.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Requesting Export Certificates for FDA Regulated Products under U.S.C. Sections 801(e) and 802—New Collection**

FDA is requesting approval from the Office of Management and Budget (OMB) for the collection of information from the public associated with the export of FDA-regulated products as indicated in sections 801(e) and 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381(e) and 382), as amended.

In April 1996, a new law entitled ''The FDA Export Reform and Enhancement Act of 1996'' was enacted. It was designed to ease restrictions on exportation of unapproved products regulated by FDA and to facilitate such exportation by provide foreign governments certificates verifying that the products may be legally exported. Specifically, 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 section 801(e) or

802 of the act, or other requirements of the act. Section 801(e)(4) of the act requires FDA to issue export certificates within 20 days of receipt of the request and to charge firms up to $175 for the certificates.

FDA has developed seven types of certificates that satisfy the requirements of section 801(e)(4)(B) of the act: (1) Certificates to foreign governments are issued for legally marketed products that are in compliance with the requirements of the act; (2) certificates of exportability are for the export of products that cannot be marketed legally in the United States, but meet the requirements of section 801(e) or 802 of the act and may be exported legally; (3) certificates of a pharmaceutical product are used for the export of drug products that are legally marketed in the United States. They conform to the format established by the World Health Organization (WHO) and attest to the acceptable current good manufacturing practice status of the manufacturing facility of the drug product; (4) nonclinical research use only certificates for the export of nonclinical research use only product, material, or component that is not intended for human use which may be marketed in and legally exported from the United States under the act; (5) certificate of free sale; (6) health certificates for food/feed; and (7) specified risk materials of bovine, ovine, and caprine origin certificate.

FDA has relied and will continue to rely on information provided by manufacturers for all types of export certificates. Manufacturers are requested to state that they are in compliance with all applicable requirements of the act at the time that they submit their request to the appropriate center.

FDA will check all information submitted by firms in support of their certificates and any suspected case of fraud will be referred to FDA's Office of Criminal Investigations for followup. Firms making or submitting false statements on any documents submitted to FDA may be violating the United States Code title 18, chapter 47, section 1001 and be subject to 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 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| FDA Centers | No. of Respondents | Annual Frequency Per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| Center for Biologics Evaluation and Research | 1,479 | 1 | 1,479 | 1 | 1,479 |
| Center for Drug Evaluation and Research | 4,542 | 1 | 4,542 | 1 | 4,542 |
| Center for Devices and Radiological Health (CDRH) | 3,500 | 1 | 3,500 | 2[2] | 7,000[2] |
| Center for Veterinary Medicine | 621 | 1 | 621 | 1 | 621 |
| Total | 10,142 | | 10,142 | | 13,642 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information. The above estimates are based on each center's latest calendar year counts.

[2] Based on the CDRH policy of allowing multiple devices to appear on the certificate.

Dated: May 23, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02–13585 Filed 5–29–02; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 02N–0208]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; State Enforcement Notifications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements contained in existing FDA regulations governing State enforcement notifications.

**DATES:** Submit written or electronic comments on the collection of information by July 29, 2002.

**ADDRESSES:** Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Peggy Schlosburg, Office of Information Resources Management (HFA–250),