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]

BILLING CODE 4160–01–S

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),

Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

State Enforcement Notifications—21 CFR 100.2(d) (OMB Control Number 0910–0275—Extension)

Section 310(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 337(b)) authorizes States to enforce certain sections of the act in their own names, but provides that States must notify FDA before doing so. Section 100.2(d) (21 CFR 100.2 (d)) sets forth the information that a State must provide to FDA in a letter of notification when it intends to take enforcement action under the act against a particular food located in the State. The information required under § 100.2(d) will enable FDA to identify the food against which the State intends to take action and advise the State whether Federal action has been taken against it. With certain narrow exceptions, Federal enforcement action precludes State action under the act.

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
100.2(d)	1	1	1	10	10

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

The reporting burden for § 100.2(d) is insignificant because enforcement notifications are seldom used by States. During the last 3 years, FDA has not received any enforcement notifications. Since the enactment of section 403A(b) of the act (21 U.S.C. 343–1(b)) as part of the Nutrition Labeling and Education Act of 1990, FDA has received only a few enforcement notifications. Although FDA believes that the burden will be insignificant, it believes these information collection provisions should be extended to provide for the potential future need of a State government to submit enforcement notifications informing FDA when it intends to take enforcement action under the act against a particular food located in the State.

Dated: May 23, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–13587 Filed 5–29–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0053]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Devices; State Petitions for Exemption From Preemption

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.

DATES: Submit written comments on the collection of information by July 1, 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.

State Petitions for Exemption From Preemption—21 CFR 100.1(d) (OMB Control Number 0910–0277)—Extension

Under section 403A(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343–1(b)), States may petition FDA for exemption from Federal preemption of State food labeling and standard of identity requirements. Section 100.1(d) (21 CFR 100.1(d)) sets forth the information a State is required to submit in such a petition. The information required under § 100.1(d) enables FDA to determine whether the State food labeling or standard of identity requirement satisfies the criteria of section 403A(b) of the act for