Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (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 granting exemption from Federal preemption.

In the **Federal Register** of January 13, 2005 (70 FR 2412), FDA published a 60-day notice requesting public comment on the information collection provisions. One comment was received. The comment expresses concern that it is unnecessary for FDA to maintain a ''program'' whereby States may petition the FDA to request exemption from preemption because States are not asking for exemptions. The comment asserts that the ''program'' wastes taxpayer dollars and suggests that FDA abolish it.

Under section 403A(b) of the act, States may petition FDA for exemption from Federal preemption of State food labeling and standard-of-identity requirements. FDA's regulations at § 100.1(d), the subject matter of this information collection, set forth the information a State is required to submit in such a petition. Section 100.1(d) implements a statutory information collection requirement. Therefore, FDA cannot abolish the regulations unless the statute is changed.

FDA estimates the burden of the 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
100.1(d)	1	1	1	40	40

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

The reporting burden for § 100.1(d) is insignificant because petitions for exemption from preemption are seldom submitted by States. In the last 3 years, FDA has not received any new petitions; therefore, the agency estimates that one or fewer petitions will be submitted annually. Because § 100.1(d) implements a statutory information collection requirement, only the additional burden attributable to the regulation has been included in the estimate. Although FDA believes that the burden will be insignificant, the agency believes these information collection provisions should be extended to provide for the potential future need of a State or local government to petition for an exemption from preemption under the provisions of section 403(A) of the act.

Dated: April 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–7022 Filed 4–7–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0541]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Exports: Notification and Recordkeeping Requirements

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 May 9, 2005.

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.

Exports: Notification and Recordkeeping Requirements—21 CFR Part 1 (OMB Control Number 0910–0482)—Extension

In the **Federal Register** of December 27, 2004 (69 FR 77255), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

The total burden estimate of 43,214 is based on the number of notifications received by the relevant FDA centers in fiscal year 2004, or the last year the figures were available.

The respondents to this information collection are exporters who have notified FDA of their intent to export unapproved products that may not be sold or marketed in the United States as allowed under section 801(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381). In general, the notification identifies the product being exported (e.g., name, description, and, in some cases, country of destination)

and specifies where the notification should be sent. These notifications are sent only for an initial export; subsequent exports of the same product to the same destination, or in the case of certain countries identified in section 802(b) of the act (21 U.S.C. 382), would not result in a notification to FDA.

The recordkeepers for this information collection are exporters who export human drugs, biologics, devices, animal drugs, foods, and cosmetics that may not be sold in the United States to maintain records demonstrating their compliance with the requirements in section 801(e)(1) of the act.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
1.101(d) and (e)	419	2.8	1,164	17	19,788

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Recordkeeper	Total Hours
1.101(b) and (c)	324	2.8	901	26	23,426

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

Dated: April 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–7023 Filed 4–7–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0124]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body

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 a 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 collection of information associated with the submission of notifications of health claims or nutrient content claims based on authoritative statements of scientific bodies of the U.S. Government.

DATES: Submit written or electronic comments on the collection of information by June 7, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (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 Robbins, Office of Management Programs (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 requirement 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 these topics: (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.

Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body (OMB Control Number 0910–0374)—Extension

Section 403(r)(2)(G) and (r)(3)(C) of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 343(r)(2)(G) and (r)(3)(C)), as amended by the FDA Modernization Act of 1997 (FDAMA), provides that a food producer may market a food product whose label bears a nutrient content claim or a health claim that is based on an authoritative statement of a scientific body of the U.S. Government or the National Academy of Sciences. Under this section of the act, a food producer that intends to use such