The FY 2005 Native Language Program Announcement expands the Category I—Program Area of Interest and the necessary assessment data to be collected. ANA recommends each applicant consider the Program Area of Interest in the development of a project. The Program Area of Interest under Category I is ''A project for data collection and compilation that surveys the current language status through a ''formal'' method (*e.g.*, work performed by a linguist and/or a language survey conducted by community members) or an ''informal'' method (*e.g.*, a community consensus of the language status based on elders, Tribal scholars and/or other community members) with the development of long-range language preservation goals and uses elders in the development of these goals. This assessment data should capture, at a minimum, the following data: number of speakers; age of speakers; gender of speakers; level(s) of fluency; number of first language speakers (native language as the first language acquired); number of second language speakers (native language as the second language acquired); where native language is used (*e.g.*, home, court system, religious ceremonies, church, media, school, governance or cultural activities); source of data (formal and/or informal); and rate of language loss or gain. (Legal authority: Section 803(a) and (d) and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b–3.)

Dated: December 17, 2004.

Quanah Crossland Stamps,

Commissioner, Administration for Native Americans

[FR Doc. 04–28216 Filed 12–23–04; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0497]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on Pharmacogenomics Data Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry on Pharmacogenomics Data Submissions'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 11, 2004 (69 FR 48876), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0557. The approval expires on December 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: December 17, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–28134 Filed 12–23–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0166]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Infant Feeding Practices Study II

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Infant Feeding Practices Study II'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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 the **Federal Register** of October 1, 2004 (69 FR 58915), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0558. The approval expires on December 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: December 17, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–28136 Filed 12–23–04; 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; Proposed Collection; Comment Request; Exports: Notification and Recordkeeping Requirements

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 notification and recordkeeping requirements for persons exporting human drugs, biological products, devices, animal drugs, food, and cosmetics that may not be marketed or sold in the United States.

DATES: Submit written or electronic comments on the collection of information by February 25, 2005.

ADDRESSES: Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit written comments 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: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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 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.

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

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 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), to any of those countries would not result in a notification to FDA.

The recordkeepers to 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.

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
1.101(d) through (e)	419	2.8	1164	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 of Recordkeeping	Total Annual Records	Hours per Record-keeper	Total Hours
1.101(b) through (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: December 17, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–28137 Filed 12–23–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0535]

Agency Information Collection Activities; Proposed Collection; Comment Request; MedWatch: Food and Drug Administration Medical Products Reporting Program

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 revisions to Form FDA 3500 and Form FDA 3500A, (also known as MedWatch reporting forms). These forms are currently used to report to the agency about adverse events, product problems and medication/device use errors that occur with FDA regulated products, including drugs, biologicals, medical devices, special nutritional products, and cosmetics.

DATES: Submit written or electronic comments on the collection of information by February 25, 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 20857. All comments should be identified with the docket number found in brackets in the heading of this document. Copies of Form FDA 3500 and Form FDA 3500A are available for public examination on