improving prevention and control of Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome/other Sexually Transmitted Infections/Tuberculosis (HIV/AIDS/STI/TB) in the Ethiopian Federal Democratic Republic Ministry of Health (MOH). The Catalog of Federal Domestic Assistance number for this program is 93.941.

B. Eligible Applicant

Assistance will be provided only to the MOH. The MOH is the only appropriate and qualified organization to conduct specific set of activities supportive of the CDC GAP technical assistance to Ethiopia. The MOH has been mandated by the Ethiopian Government to provide leadership in the provision of health care to the country of Ethiopia; the MOH is uniquely positioned, in terms of legal authority, ability, and credibility to work in the area of HIV/AIDS/STI/TB prevention and control; the MOH is the only organization capable of conducting and coordinating national HOV/AIDS/STI/TB surveillance; and the MOH is the primary partner of CDC/Ethiopia for HIV/AIDS/STI/TB activities in Ethiopia.

C. Funding

Approximately $100,000 is available in FY 2003 to fund this award. It is expected that the award will begin on or before September 15, 2003, and will be made for a 12-month budget period within a project period of up to five years. Funding estimate may change.

D. Where to Obtain Additional Information

For general comments or questions about this announcement, contact:

Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2700.

For technical questions about this program, contact:

Tadesse Wuhib, Country Director, CDC–Ethiopia, P.O. Box 1014, Entoto Road, Addis Ababa, Telephone: (Office) 251–1–66–95–51; (Cell) 251–9–228543, e-mail address: *wuhibt@etcdc.com.*

Dated: August 14, 2003.

Sandra R. Manning,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 03–21266 Filed 8–19–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Objective Work Plan and Project Abstract.

OMB No.: 0980–0204.

Description: The information collected by the Objective Work Plan is needed to properly administer and monitor the Administration for Native Americans (ANA) Program's competitive areas—Social and Economic Development Strategies (SEDS), ANA Environmental Regulatory Enhancement, Native Language Preservation, and ANA Mitigation of Environmental Impacts to Indian Lands Due to Department of Defense Activities, by providing information in an application for a grant award. This data is used by legislatively-mandated Native American review panels, and ANA, as the basis for recommendations for the decisions to award competitive ANA grants. The project Abstract provides crucial information in a concise format that is used by the independent review panel, ANA staff and the Commissioner during all phases of the review process.

Respondents: Tribal Govt. Native non-profits, Tribal Colleges & Universities.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OWP	650	1	28	18,200
Project Abstract	650	1	1	650

Estimated Total Annual Burden Hours: 18,850.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *rsargis@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF, E-mail address: *lauren_wittenberg@omb.eop.gov.*

Dated: August 14, 2003.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 03–21288 Filed 8–19–03; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0187]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Postmarket Surveillance of Medical Devices

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 September 19, 2003.

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: 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.

Postmarket Surveillance of Medical Devices—21 CFR Part 822 (OMB Control Number 0910–0449)—Extension

Section 522(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360l(a)) authorizes FDA to require manufacturers to conduct postmarket surveillance (PS) of any device that meets the criteria set forth in the statute.

The PS regulation in part 822 (21 CFR part 822) establishes procedures that FDA uses to approve and disapprove PS plans. The regulation provides specific, clear, and flexible instructions to manufacturers so they know what information is required in a PS plan submission. FDA reviews submissions in accordance with §§ 822.15 through 822.18 (which describe the grounds for approving or disapproving a PS plan). If this information is not collected, FDA cannot ensure that the PS will result in the collection of useful data that can reveal unforeseen adverse events or other information necessary to protect the public health.

Respondents to this collection of information are those manufacturers who require PS of their products. As previously stated, the collection of data and information under these regulations is conducted on a very infrequent basis and only as necessary.

In the **Federal Register** of May 15, 2003 (68 FR 26307), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	No. of Responses	Total Annual Responses	Hours per Response	Total Hours
822.9 and 822.10	5	1	5	120	600
822.21	2	1	2	40	80
822.26	1	1	1	8	8
822.27	1	1	1	40	40
822.28	1	1	1	40	40
822.29	1	1	1	120	120
822.30	1	1	1	40	40
822.34	1	1	1	20	20
822.38	23	2	46	80	3,680
Totals					4,628

[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 Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
822.31	23	1	23	20	460
822.32	69	1	69	10	690
Totals					1,150

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

FDA estimates, based on current staffing and resources, only one actual PS action and manufacturers' aversion to the stigma of PS over the past year. One PS action will be issued for generic devices comprising of approximately five manufacturers. Each manufacturer will be required to submit a PS plan (§§ 822.9 and 822.10) and interim and final reports on the progress of the surveillance (§ 822.38). FDA anticipates that, on a case-by-case basis, requests for additional information may be made from a manufacturer. FDA expects that a small number of respondents will propose changes to their PS plans (§ 822.21), request a waiver of a specific requirement of this regulation (§ 822.29), or request exemption from the requirement to conduct PS of their device (§ 822.30). FDA's experience has shown that a few respondents will go out of business (§ 822.26) or cease marketing the device subject to PS (§ 822.28) each year. In addition, manufacturers must certify transfer of records when ownership changes (§ 822.34).

Section 822.25 does not constitute information collections subject to review under the PRA because ''* * * they entail no burden other than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument * * *'' (5 CFR 1320.3(h)(1)).

FDA expects that at least some of the manufacturers will be able to satisfy the PS requirement using information or data they already have. For purposes of calculating burden, however, FDA has assumed that each PS order can only be satisfied by a 3-year clinically-based surveillance plan, using three investigators. These estimates are based on FDA's knowledge and experience with limited implementation of section 522 of the act under the Safe Medical Devices Act of 1990. Therefore, FDA would expect that the recordkeeping requirements would apply to a maximum of 23 manufacturers (6 added each year) and 69 investigators (3 years per surveillance plan). After 3 years,

FDA would expect these numbers to remain level as the surveillance plans conducted under the earliest orders reach completion and new orders are issued.

Dated: August 13, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–21226 Filed 8–19–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0191]

Agency Emergency Processing Under OMB Review; Submission of Validation Data for Reprocessed Single-Use Devices; Correction

AGENCY: Food and Drug Administration; HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of July 23, 2003 (68 FR 43534). The document corrected a notice that appeared in the **Federal Register** of July 8, 2003 (68 FR 40676), that announced that a proposed collection of information had been submitted to the Office of Management and Budget for emergency processing under the Paperwork Reduction Act of 1995. The July 23, 2003, document published with an incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy and Planning (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 03–18692, appearing on page 43534 in the **Federal Register** of July 23, 2003, the following correction is made:

1. On page 43534, in the first column, in the fourth line, ''[Docket No. 2003N–0069]'' is corrected to read ''[Docket No. 2003N–0191]''.

Dated: August 13, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–21227 Filed 8–19–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 18, 2003, from 8 a.m. to 6 p.m.

Location: Gaithersburg Hilton Hotel, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3514, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 19516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 18, 2003, the following committee updates are tentatively scheduled: (1) Announcement of appointment of the new Director, Division of Hematology, Office of Blood Research and Review, Center for Biologics Evaluation and Research; (2) summary of Public Health Service Advisory Committee on Blood Safety and Availability; (3) summary of National Heart, Lung and Blood Institute workshop on pathogen reduction and blood component safety; (4) approval of human immune deficiency virus, type 1 (HIV–1) group ''O'' sensitive assays; (5) revised guidance on Severe Acute Respiratory Syndrome; (6) updated donor travel survey; and (7) labeling and storage: Blood and blood components (proposed regulation). In the morning, the committee will also hear informational presentations on: (1) An overview of counterterrorism exercise; and (2) the current status of West Nile Virus safety. In the afternoon, the committee will hear presentations, discuss and provide recommendations on the topic of supplemental testing for HIV–1 and hepatitis C virus.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 8, 2003. Oral presentations from the public will be scheduled between approximately 10 a.m. and 10:15 a.m., 11:30 a.m. and 12:30 p.m., and 4:15 p.m. and 4:45 p.m. on September 18, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 8, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Linda A. Smallwood or Pearline K. Muckelvene at 301–827–1281 at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 13, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–21229 Filed 8–19–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0347]

Small Entity Compliance Guide on Labeling *Trans* Fatty Acids; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a small entity compliance guide (SECG) for a final rule published in the **Federal Register** of July 11, 2003, entitled ''Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims.'' This SECG, also entitled ''Food Labeling: *Trans* Fatty Acids in Nutrition