Dated: December 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–24040 Filed 12–14–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0389]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reprocessed Single-Use Device Labeling

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 January 17, 2006..

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 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.

Reprocessed Single-Use Device Labeling (21 U.S.C. 352(u))

Section 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352), among other things, establishes requirements that the label or labeling of a medical device must meet so that it is not misbranded and subject to regulatory action. The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250) amended section 502 of the act to add section 502(u) to require devices (both new and reprocessed) to bear prominently and conspicuously the name of the manufacturer, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying the manufacturer. Section 2(c) of The Medical Device User Fee Stabilization Act of 2005 (MDUFSA) (Public Law 109–43) amends section 502(u) of the act by limiting the provision to reprocessed single-use devices (SUDs) and the manufacturers who reprocess them. Under the amended provision, if the original SUD or an attachment to it prominently and conspicuously bears the name of the manufacturer, then the reprocessor of the SUD is required to identify itself by name, abbreviation, or symbol, in a prominent and conspicuous manner on the device or attachment to the device. If the original SUD does not prominently and conspicuously bear the name of the manufacturer, the manufacturer who reprocesses the SUD for reuse may identify itself using a detachable label that is intended to be affixed to the patient record. MDUFSA was enacted on August 1, 2005, and becomes self-implementing on August 1, 2006.

The requirements of section 502(u) of the act impose a minimal burden on industry. This section of the act only requires the manufacturer, packer, or distributor of a device to include their name and address on the labeling of a device. This information is readily available to the establishment and easily supplied. From its registration and premarket submission database, FDA estimates that there are 3 establishments that distribute approximately 300 reprocessed SUDs. Each response is anticipated to take 0.1 hours resulting in a total burden to industry of 30 hours.

In the **Federal Register** of September 29, 2005 (70 FR 56910), 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 of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the Act	No. of Respondents	Annual Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
502(u)	3	100	300	0.1	30

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

Dated: December 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–24041 Filed 12–14–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0442]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Food and Drug Administration Recall Regulations (Guidelines)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''FDA Recall Regulations (Guidelines)'' 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 24, 2005 (70 FR 49654), 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 0910–0249. The approval expires on October 31, 2008. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets.*

Dated: December 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–24042 Filed 12–14–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committees; Filing of Annual Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that, as required by the Federal Advisory Committee Act, the agency has filed with the Library of Congress the annual reports of those FDA advisory committees that held closed meetings during fiscal year 2005.

ADDRESSES: Copies are available from the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 301–827–6860.

FOR FURTHER INFORMATION CONTACT: Theresa L. Green, Advisory Committee Oversight and Management Staff (HF–4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1220.

SUPPLEMENTARY INFORMATION: Under section 13 of the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR 14.60(c), FDA has filed with the Library of Congress the annual reports for the following FDA advisory committees that held closed meetings during the period October 1, 2004, through September 30, 2005.

Center for Biologics Evaluation and Research:

Blood Products Advisory Committee

Cellular, Tissue and Gene Therapies Advisory Committee (formerly the Biological Response Modifiers Advisory Committee)

Vaccines and Related Biological Products Advisory Committee

Center for Devices and Radiological Health:

Medical Devices Advisory Committee (consisting of reports for the Dental Products Panel; Ear, Nose, and Throat Devices Panel; Neurology Devices Panel; and Orthopaedic and Rehabilitation Devices Panel)

Annual reports are available for public inspections between 9 a.m. and 4 p.m., Monday through Friday, at the following locations:

1. The Library of Congress, Madison Bldg., Newspaper and Current Periodical Reading Room, 101 Independence Ave. SE., rm. 133, Washington, DC; and

2. The Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Dated: December 2, 2005.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. 05–24039 Filed 12–14–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

[Funding Opportunity Number: HHS–2006–IHS–TSGP–0002; CFDA Number: 93.210]

Tribal Self-Governance Program; Negotiation Cooperative Agreement; New Funding Cycle for Fiscal Year 2006

Key Dates: Applications Due—January 20, 2006; Objective Review Committee to Evaluate Applications—March 8–9, 2006; Anticipated Project Start Date—April 1, 2006.

I. Funding Opportunity Description

The purpose of the program is to award cooperative agreements that provide negotiation resources to Tribes interested in participating in the Tribal Self-Governance Program (TSGP) as authorized by Title V, Tribal Self-Governance Amendments of 2000 of the Indian Self-Determination and Education Assistance Act of Public Law (Pub. L.) 93–638, as amended. The TSGP is designed to promote self-determination by allowing Tribes to assume more control of Indian Health Service (IHS) programs and services through compacts negotiated with the IHS. The Negotiation Cooperative Agreement provides Tribes with funds to help cover the expenses involved in preparing for and negotiating with the IHS and assists eligible Indian Tribes to prepare for Compacts and Funding Agreements (FAs) with an effective date of October 1, 2006, or January 1, 2007.

The Negotiation Cooperative Agreement provides resources to assist Indian Tribes to conduct negotiation activities that include but are not limited to:

- Analysis of the complex IHS budget to determine what programs, services, functions, and activities (PSFAs) will be negotiated.
- Development of the terms and conditions that will be set forth in a Compact and Funding Agreement (FA).
- Consultant costs such as Attorney or Financial Advisors.
- Communication Costs.
- Identification of Tribal shares that will be included in the FA.

The award of a Negotiation Cooperative Agreement is not required as a prerequisite to enter the TSGP. Indian Tribes that have completed comparable health planning activities in previous years using tribal resources but have not received a Tribal self-governance planning award are also eligible to apply. Applicants must provide a statement that the planning phase has been conducted to the satisfaction of the Indian Tribe and must include: (a) Legal and budgetary research; and (b) internal Tribal government planning and organizational preparation relating to the administration of health programs.

II. Award Information

Type of Award: Cooperative Agreement.

Estimated Funds Available: The total amount identified for Fiscal Year (FY) 2006 is $240,000 for approximately twelve (12) Tribes to enter the TSGP negotiation process for compacts beginning in Fiscal Year (FY) 2007 or Calendar Year (CY) 2007. Awards under this announcement are subject to the availability of funds.

Anticipated Number of Awards: The estimated number of awards to be funded is approximately 12.

Project Period: 12 months.

Award Amount: $20,000 per year.

Programmatic Involvement: IHS TSGP funds will be awarded as cooperative agreements and will have substantial programmatic involvement to establish a process through which Tribes can effectively approach the IHS to identify programs and associated funding which could be incorporated into programs.

The IHS roles and responsibilities will include:

- Identification of IHS staff that will consult with applicants on methods used by the IHS to manage and deliver health care.
- Provide applicants with a list of laws and regulations that provide authority for the various IHS programs.