

guidance needs to be revised at a later date.

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended—Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Casper E. Uldriks, Center for Devices and Radiological Health (HFZ-300), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240-276-0106.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

MDUFMA (Public Law 107-250) amended section 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352) to require a device, or an attachment to the device, 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. This labeling provision applied to all devices and all device manufacturers, including reproducers.

On August 1, 2005, MDUFSA (Public Law 109-43) amended section 502(u) of the act by limiting the provision to reprocessed single-use devices (SUDs) and the manufacturers who reprocess them. Therefore, section 502(u) of the act, as amended by MDUFSA, no longer sets forth requirements for original equipment manufacturers, unless they also reprocess SUDs. Under the amended provision, if an original device or an attachment to it does not prominently and conspicuously bear the name of the manufacturer of the original

device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, the manufacturer who reprocesses the SUD may identify itself using a detachable label on the packaging of the device.

Section 2(c)(2) of MDUFSA requires that FDA issue guidance not later than 180 days after the date of its enactment to identify the circumstances under which the identifying mark of a manufacturer of an original device is not "prominent and conspicuous," as used in section 502(u) of the act. When finalized, this guidance document will satisfy this MDUFSA requirement. As stated previously, FDA requests that interested person submit their comments on the draft guidance within 30 days of its publication. FDA will consider these comments to determine whether to revise the guidance before issuing it in final form.

**II. Significance of Guidance**

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized will represent the agency's current thinking on "Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended—Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

**III. Electronic Access**

To receive "Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended—Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices" by fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1217) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. The Center for Devices and Radiological Health (CDRH) maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a

regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

**IV. Paperwork Reduction Act of 1995**

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). In the **Federal Register** of September 29, 2005 (70 FR 56910), FDA published a 60-day notice soliciting comments on the information collection provisions contained in this guidance.

**V. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this draft guidance. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 3, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Indian Health Service**

**Proposed Information Collection: Final Rule To Implement Title V of the Tribal Self-Governance Amendments of 2000; Request for Public Comment: 30-Day Notice**

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Request for Public Comment: 30-day Proposed Information Collection: Final Rule to Implement Title V of the Tribal Self-Governance Amendments of 2000.

**SUMMARY:** The Indian Health Service (IHS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. As required by section 3507(a)(1)(D) of the Act, the proposed information collection has been submitted to the Office of Management and Budget (OMB) for review and approval. The IHS received no comments in response to the 60-day **Federal Register** notice (70 FR 44663) published on August 3, 2005. The purpose of this notice is to allow an

additional 30 days for public comment to be submitted directly to OMB.

*Proposed Collection: Title:* 0917-0026, "Final Rule to Implement Title V of the Tribal Self-Governance Amendments of 2000". *Type of Information Collection Request:* Extension, without revision, of currently approved information collection, 0917-0026, "Final Rule to Implement Title V of the Tribal Self-Governance Amendments of 2000". *Form Number:* None. *Forms:* None. *Need and Use of Information Collection:* The "Tribal Self-Governance Amendments of 2000", Public Law 106-206 (the act), repeals Title III of the Indian Self-Determination Act, Public Law 93-638, as amended, (ISDA) and enacts Title V that established a permanent Self-Governance program within DHHS. Thus Indian and Alaska Native Tribes are now able to compact for the operation, control, and redesign of various IHS activities on a permanent basis. The final rule has been negotiated among representatives of Self-Governance and non-Self-Governance Tribes and the DHHS. The final rule included provision governing how DHHS/IHS carries out its responsibility to Indian Tribes under the Act and how Indian Tribes carry out their responsibilities under the Act. As required by section 517(b) of the Act,

the Department has developed this final rule with active Tribal participation of Indian Tribes, inter-Tribal consortia, Tribal organizations and individual Tribal members, using the guidance of the Negotiated Rulemaking Act, 5 U.S.C. 561 *et seq.* Health status reporting requirements will be negotiated on an individual Tribal basis and included in individual compacts of funding agreements. Response to the data collection continues to be voluntary; however, submission of the data is essential to participation in the Tribal Self-Governance process. Self-Governance Tribes have the option of participating in the Tribal Self-Governance process. Self-Governance Tribes have the option of participating in a voluntary national uniform data collection effort with the IHS. The department is seeking continued OMB approval of the collection of information identified in the following sections of the regulations: Subpart C-Selection of Tribes for Participation in Self-Governance, Subpart D and E-Compact and Funding Agreement, Subpart N-Construction Projects, and Subpart P-Appeals. *Affected Public:* Individual Tribes. *Type of Respondents:* Tribal Representatives.

The table below provides the estimated burden hours for this information collection:

TABLE.—ESTIMATED ANNUAL BURDEN HOURS

| CFR section   | Estimated number of respondents | Responses per respondent | Average burden hour per response | Total annual burden hours |
|---|---------------------------------|--------------------------|----------------------------------|---------------------------|
| Subpart C—Eligibility criteria .....                                    | 50                              | 1                        | 10.0                             | 500                       |
| Subpart D—Self-governance compact and Subpart E—Funding agreement ..... | 50                              | 1                        | 34.0                             | 1,700                     |
| Subpart N—Construction .....  | 30                              | 1                        | 40                               | 1,200                     |
| Subpart P—Appeals .....   | 8                               | 1                        | 40                               | 320                       |
| <b>Total Annual Burden</b> .....  |                                 |                          |                                  | <b>3,720</b>              |

There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

*Request for Comments:* Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function; (b) whether the agency processes the information collected in a useful and timely function; (c) the accuracy of public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information); (d) whether the methodology and assumptions used to determine the estimate are logical; (e) ways to enhance the quality, utility, and

clarity of the information being collected; and (f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*Direct Comments to OMB:* Send your written comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time, directly to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Allison Eydt, Desk Officer for IHS.

Send requests for more information on the proposed collection or to obtain a copy of the data collection instrument(s) and instructions to: Mrs. Christina Rouleau, IHS Reports Clearance Officer, 801 Thompson Avenue, TMP Suite 450, Rockville, MD 20852-1601, call non-toll free (301) 443-5938, send via facsimile to (301) 443-2316, or send your e-mail requests, comments, and return address to: [crouleau@hqe.ihs.gov](mailto:crouleau@hqe.ihs.gov).

*For Further Information* directly pertaining to the proposed data collection instrument and/or the process, please contact Tena Larney, Reyes Building, 801 Thompson Avenue, Suite 200, Rockville, MD 20852-1627, Telephone (301) 443-7821.

*Comment Due Date:* You comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: October 4, 2005.

**Robert G. McSwain,**  
Deputy Director, Indian Health Service.  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Indian Health Service**

**Proposed Collection: Indian Health Service Loan Repayment Program; Request for Public Comment: 30-Day Notice**

**AGENCY:** Indian Health Service, HHS.  
**ACTION:** Request for Public Comment: 30-day Proposed Information Collection: Indian Health Service Loan Repayment Program.

**SUMMARY:** In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed information collection projects, the

Indian Health Service (IHS) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection list below. This proposed information collection project was published in the August 3, 2005, **Federal Register** (70 FR 44662) and allowed 60 days for public comment. No public comment was received in response to the notice. The purpose of this notice is to allow 30 days for public comment to be submitted to OMB.

*Proposed Collection: Title:* 0917-0014, "Indian Health Service Loan Repayment Program". *Type of Information Collection Request:* Extension of a currently approved collection which expires December 31, 2005. *Form Number:* No reporting forms required. *Need and Use of Information Collection:* The IHS Loan Payment Program (LRP) identifies health professionals with pre-existing financial obligations for education expenses that meet program criteria and who are qualified and willing to serve at, often remote, IHS health care facilities. Under the program, eligible health professionals sign a contract under which the IHS agrees to repay part or all of their indebtedness for professional

training education. In exchange, the health professionals agree to serve for a specified period of time in IHS health care facilities. Eligible health professionals that wish to apply must submit an application to participate in the program. The application requests personal, demographic and educational training information, including information on the educational loans of the individual for which repayment is being requested (i.e., date, amount, account number, purpose of each loan, interest rate, the current balance, etc). The data collected is needed and used to evaluate applicant eligibility; rank and prioritize applicants by specialty; assign applicants to IHS health care facilities; determine payment amounts and schedules for paying the lending institutions; and to provide data and statistics for program management review and analysis. *Affected Public:* Individual and households. *Type of Respondents:* Individuals. Table 1 below provides the following: Types of data collection instruments, estimated number of respondents, number of responses per respondent, annual number of responses, average burden hour per response, and total annual burden hour.

TABLE 1.—ESTIMATED BURDEN HOURS

| Data collection instrument   | Estimated number of respondents | Responses per respondent | Average burden hour per response* | Total annual burden hours |
|------------------------------|---------------------------------|--------------------------|-----------------------------------|---------------------------|
| Section I .....              | 425                             | 1                        | 0.25 (15 min) ....                | 106.25                    |
| Section II .....             | 425                             | 1                        | 0.25 (30 min) ....                | 212.5                     |
| Section III .....            | 425                             | 4                        | 0.25 (15 min) ....                | 425                       |
| Contract .....               | 425                             | 1                        | 0.334 (20 min) ..                 | 141.95                    |
| Affidavit .....              | 425                             | 1                        | 0.167 (10 min) ..                 | 70.97                     |
| Lender's Certification ..... | 1,700                           | 1                        | .025 (15 min) .....               | 425                       |

\*For ease of understanding, burden hours are also provided in actual minutes.

There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

*Request for Comments:* Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function; (b) whether the IHS processes the information collected in a useful and timely fashion; (c) the accuracy of the public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information); (d) whether the methodology and assumptions used to determine the estimate are logical; (e) ways to enhance the quality, utility, and clarity of the information being collected; and (f) ways to minimize the public burden through the use of

automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*Direct Comments to OMB:* Send your written comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time, to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for IHS.

To request more information on the proposed collection or to obtain a copy of the data collection instrument(s) and/or instruction(s), contact: Mrs. Christina Rouleau, IHS Reports Clearance Officer, 801 Thompson Avenue, TMP Suite 450,

Rockville, MD 20852-1601, or call non-toll free (301) 443-5938 or send via facsimile to (301) 443-2316, or send your E-mail requests, comments, and return address to: [crouleau@hqe.ihs.gov](mailto:crouleau@hqe.ihs.gov).

*Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received on or before November 10, 2005.

Dated: September 4, 2005.

**Robert G. McSwain,**  
Deputy Director, Indian Health Service.  
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