DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0301]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Customer/Partner Service Surveys

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 January 22, 2002.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (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.

Customer/Partner Service Surveys (OMB Control No. 0910–0360)—Extension

Under section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393), FDA is authorized to conduct research and public information programs about regulated products and responsibilities of the agency. Executive Order 12862, entitled ''Setting Customer Service Standards,'' directs Federal agencies that ''provide significant services directly to the public'' to ''survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services.'' FDA is seeking OMB clearance to conduct a series of surveys to implement Executive Order 12862. Participation in the surveys is voluntary. This request covers customer/partner service surveys of regulated entities, such as: Food processors; cosmetic, drug, biologic and medical device manufacturers; consumers; and health professionals. The request also covers ''partner'' (State and local governments) customer service surveys. FDA will use the information from these surveys to identify strengths and weaknesses in service to customers/partners and to make improvements. The surveys will measure timeliness, appropriateness and accuracy of information, courtesy, and problem resolution in the context of individual programs. FDA projects 25 customer/partner service surveys per year, with a sample of between 50 and 6,000 customers each, requiring an average of 18 minutes for review/completion per survey. Some of these surveys will be repeats of earlier surveys, for purposes of monitoring customer/ partner service and developing long-term data.

In the **Federal Register** of July 25, 2001 (66 FR 38711), 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]

Type of Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Mail/telephone/fax/web-based	20,000	1	20,000	.30	6,000

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

Dated: December 13, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–31335 Filed 12–19–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0514]

Medical Devices; Guidance on Labeling of Reprocessed Single Use Devices; Request for Comments and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing an opportunity for interested persons to submit comments and suggestions on the contents of a guidance document that FDA is considering drafting on the labeling of reprocessed single use devices (SUDs) with respect to the name of the original equipment manufacturer (OEM) and the remanufacturer (i.e., reprocessor). FDA is publishing this notice in order to gather informed comment before drafting the guidance.

DATES: Submit written or electronic comments or suggestions by March 20, 2002.

ADDRESSES: Submit written comments and information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Larry Spears, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4692.

SUPPLEMENTARY INFORMATION:

I. Background

In a citizen petition, dated March 22, 2001, the Association of Disposable Device Manufacturers (ADDM) requested that FDA: (1) Require reprocessors of SUDs (hereinafter referred to as reprocessed devices) to remove the OEM trademark from the devices and any references to the OEM in the label of devices; (2) take actions to identify and enforce this requirement; and (3) refuse to approve premarket submissions unless the applicant represents that the device will meet this requirement.

On September 17, 2001, FDA issued a response to this petition. FDA denied the petition because FDA believed that misleading implications from representations concerning the OEM may be remedied by the disclosure of

additional facts about the remanufacturer. Specifically, FDA stated:

FDA, however, does believe that representations concerning the OEM may be misleading unless the reprocessor of a single use device provides additional information that would indicate that the reprocessor is the manufacturer responsible for product problems. As you note in your petition, hospitals and other user facilities must alert FDA or the manufacturer whenever there is information that ''reasonably suggests that a device has or may have caused or contributed to the death ... [or] serious injury to a patient ...'' 21 CFR 803.30(a). Moreover, the user or FDA may need to know the identity of the manufacturer, not only for the purposes of reporting adverse events to FDA, but to assure that the responsible manufacturer or FDA can investigate the problem to determine if additional steps should be taken, including distribution of safety information to the users, or product recalls. Accordingly, FDA believes that when a reprocessed product's labeling makes representations that suggest the OEM should be notified of product problems, additional information that provides the correct identity of the reprocessor as the remanufacturer who is responsible for adverse event reporting, recalls, or other corrective actions, is ''material'' information within the meaning of section 201(n) of the Act because such information is necessary to enable FDA's postmarket reporting procedures under section 519 of the Act to function effectively.

In the response to the petition, FDA also said that it would publish a guidance document that will recommend more specific language and direction to regulated industry on this matter. Before it develops this guidance document, FDA is inviting interested persons to submit comments and suggestions on the contents of such a guidance.

The ADDM petition and FDA's response are available from the Dockets Management Branch (address above). Please reference Docket No. 01P–0148.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments or suggestions regarding this issue by March 20, 2002. Two copies of any comments are to be submitted, except that individuals may submit one 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 28, 2001.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 01–31334 Filed 12–19–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Submission of Information Collection to the Office of Management Budget for Review Under the Paperwork Reduction Act

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of renewal of a current approved information collection.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this notice announces that the Bureau of Indian Affairs is submitting an information collection request to the Office of Management and Budget for clearance and extension. The information collection request for the Indian Child Welfare Act Annual Report is cleared under OMB Control Number 1076–0131 through December 31, 2001.

DATES: Submit comments on or before January 22, 2002.

ADDRESSES: Written comments should be sent directly to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Desk Officer for the Department of Interior, Room 10102, 725 17th Street NW, Washington, DC 20503.

Send a copy of your comments to Larry Blair, Bureau of Indian Affairs, Branch of Tribal Government, Division of Social Services, 1849 C Street NW (MS–4660–MIB), Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Interested persons may obtain copies of the information collection requests without charge by contacting Mr. Larry Blair, (202) 208–2479 (this is not a toll free number). Facsimile number (202) 208–2648.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Department has issued regulations prescribing procedures by which an Indian tribe may receive funding to provide ICWA services. Funding is authorized by the Indian Child Welfare Act, Public Law 95–608, 92 Stat. 3069, 25 U.S.C. 1918.

A **Federal Register** notice soliciting comments from interested parties to renew this information collection was published on October 2, 2001 (66 FR 50201). No comments were received. Upon review of ICWA program information previously collected, we realized that a change was needed to more accurately reflect the public burden. Therefore, we are submitting this information collection for revision and renewal. 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.

II. Request for Comments

The Department invites comments on:

(1) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility;

(2) The accuracy of the Bureau's estimate of the burden of the information collection, 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 information collection on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other collection techniques or forms of information technology.

III. Data

Title of the Information Collection: ICWA of 1978.

OMB: 1076–0131; Expiration date: December 31, 2001.

Type of Review: Revision and renewal of a current approved information collection.

Summary of Collection of Information: The collection of information will ensure that the provisions of Public Law 95–608 are met.

Affected Entities: Federally recognized tribes who receive grant funding to provide ICWA services.

Frequency of Response: Quarterly.

Estimated Number of Annual Responses: One annual and four quarterly reports (the fourth quarter report is also the annual report).

Estimated Time Per Response: One-half hour for each of 4 reports from 536 grantees.

Estimated Total Annual Burden Hours: 1,072 hours.

This notice is published in accordance with the authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 209 Departmental Manual 8.1.

Dated: December 11, 2001.

Neal A. McCaleb,

Assistant Secretary—Indian Affairs.

[FR Doc. 01–31336 Filed 12–19–01; 8:45 am]

BILLING CODE 4310–02–P