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.

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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