Dated: November 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0452]

Agency Information Collection Activities; Proposed Collection; Comment Request; Agreement for Shipment of Devices for Sterilization

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements relating to shipment of nonsterile devices that are to be sterilized elsewhere or are shipped to other establishments for further processing, labeling, or repacking.

DATES: Submit written or electronic comments on the collection of information by January 16, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, 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 collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Agreement for Shipment of Devices for Sterilization—21 CFR 801.150(e) (OMB Control Number 0910–0131)—Extension

Under sections 501(c) and 502(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351(c) and 352(a)), nonsterile devices that are labeled as sterile but are in interstate transit to a facility to be sterilized are adulterated and misbranded. FDA regulations in § 801.150(e) (21 CFR 801.150(e)) establish a control mechanism by which firms may manufacture and label medical devices as sterile at one establishment and ship the devices in interstate commerce for sterilization at another establishment, a practice that facilitates the processing of devices and is economically necessary for some firms. Under § 801.150(e), manufacturers and sterilizers may sign an agreement containing the following: (1) Instructions for maintaining accountability of the number of units in each shipment; (2) acknowledgment that the devices that are nonsterile are being shipped for further processing; and (3) specifications for sterilization processing.

This agreement allows the manufacturer to ship misbranded products to be sterilized without initiating regulatory action and provides FDA with a means to protect consumers from use of nonsterile products. During routine plant inspections, FDA normally reviews agreements that must be kept for 2 years after final shipment or delivery of devices.

The respondents to this collection of information are device manufacturers and contact sterilizers.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
801.150(e)	90	20	1,800	4	7,200

[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 of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
801.150(a)(2)	90	20	1,800	0.5	900

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

FDA's estimate of the reporting burden is based on actual data obtained from industry over the past several years where there are approximately 90 firms subject to this requirement. It is estimated that each of these firms on the average prepares 20 written agreements per year. The recordkeeping requirements of 21 CFR 801.150(a)(2) consist of making copies and maintaining the actual reporting requests which are required under the reporting section of this collection.

Dated: November 9, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0327]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Medical Device User Fee and Modernization Act Small Business Qualification Certification (Form FDA 3602)

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 December 15, 2006.

ADDRESSES: 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: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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.

Medical Device User Fee and Modernization Act Small Business Qualification Certification (Form FDA 3602)—(OMB Control Number 0910–0508)—Extension

The Medical Device User Fee and Modernization Act (MDUFMA) small business qualification certification form (Form FDA 3602), amends the Federal Food, Drug, and Cosmetic Act to provide for user fees for certain medical device applications. FDA published a **Federal Register** notice on August 2, 2006 (71 FR 43784), announcing fees for fiscal year (FY) 2007. To avoid harming small businesses, MDUFMA provides for reduced or waived fees for applicants who qualify as a ''small business.'' This means there are two levels of fees, a standard fee, and a reduced or waived small business fee.

For FY 2006, you can qualify for a small business fee discount under MDUFMA if you reported gross receipts or sales of no more than $100 million on your Federal income tax return for the most recent tax year. If you have any affiliates, partners, or parent firms, you must add their gross receipts or sales to yours and the total must be no more than $100 million. If your gross receipts or sales are no more than $30 million (including all of your affiliates, partners, and parent firms), you will also qualify for a waiver of the fee for your first (ever) premarket application (PMA, product development protocol (PDP), biologics license application (BLA), or premarket report). An applicant must pay the full standard fee unless it provides evidence demonstrating to FDA that it meets the ''small business'' criteria. The evidence required by MDUFMA is a copy of the most recent Federal income tax return of the applicant, and any affiliate, partner, or parent firm. FDA will review these materials and decide whether an applicant is a ''small business'' within the meaning of MDUFMA.

Form FDA 3602 is available in the guidance document entitled ''Guidance for Industry and FDA: FY 2006 MDUFMA Small Business Qualification Worksheet and Certification.'' This guidance describes the criteria FDA will use to decide whether an entity qualifies as a MDUFMA small business and will help prospective applicants understand what they need to do to meet the small business criteria for FY 2006 and subsequent fiscal years.

In the **Federal Register** of August 29, 2006 (71 FR 51196), FDA published a 60-day notice soliciting comments on the information collection provisions. In response to that notice, no comments were received.

Description of Respondents: Respondents will be businesses or other for-profit organizations.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3602	2,000	1	2,000	1	2,000
Total					2,000

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