interventions for BMSM. Men will complete a 5-minute eligibility screening interview. The baseline computer-based survey will take 45 minutes. The qualitative interview will take approximately 75 minutes. The number of respondents who will accept HIV testing is estimated to be 200 (accounting for those who did not test at baseline and those who do not consent to test at follow-up). HIV counseling and rapid testing will take 45 minutes. The 3-month follow-up survey will take approximately 30 minutes; the follow-up qualitative interview will take approximately 45 minutes. There is no cost to the respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN TABLE

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
BMSM respondents only	Screening interview	750	1	5/60	63
BMSM and other MSM respondents: Baseline.	ACASI survey interview	300	1	45/60	225
	Qualitative interview	300	1	1.25	375
	HIV testing & counseling	200	1	45/60	150
BMSM and other MSM respondents: 3 month follow-up.	ACASI survey interview	300	1	30/60	150
	Qualitative interview	300	1	45/60	225
	HIV testing & counseling	200	1	45/60	150
	Total Burden Hours				1338

Dated: April 19, 2010.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–9606 Filed 4–23–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0070]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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 May 26, 2010.

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: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0131. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov*.

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.

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)(1), 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 (§ 801.150(a)(2)). The respondents to this collection of information are device manufacturers and contact sterilizers. 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 each year. This estimate varies greatly, from 1 to 100, because some firms provide sterilization services on a part time basis for only one customer while others are large facilities with many customers. The average time required to prepare each written agreement is estimated to be 4 hours. This estimate varies depending on whether the agreement is the initial agreement or an annual renewal, on the format each firm elects to use, and on the length of time required to reach agreement. The estimate applies only to those portions of the written agreement that pertain to the requirements imposed by this regulation. The written agreement generally also includes contractual agreements that are a customary and usual business practice. On the average, the total annual recordkeeping burden is 7,200 hours (90 firms x 20 agreements x 4 hours). The

recordkeeping requirements of § 801.150(a)(2) consist of making copies and maintaining the actual reporting requests which were required under the reporting section of this collection. To fulfill this requirement, FDA estimates it will take about 30 minutes to copy each package, for a total of 900 recordkeeping hours and includes $55,800 operating and maintenance costs.

In the **Federal Register** of February 18, 2010 (75 FR 7276), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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 per 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 associated with this collection of information.

Due to a clerical error, the operating and maintenance costs that appeared in a document published in the **Federal Register** of February 18, 2010, were incorrect. There are actually no operating and maintenance costs associated.

Dated: April 21, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–9555 Filed 4–23–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0194]

Draft Guidance for Industry and Food and Drug Administration Staff; Total Product Life Cycle: Infusion Pump—Premarket Notification [510(k)] Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled "Total Product Life Cycle: Infusion Pump—Premarket Notification [510(k)] Submissions." The recommendations in this guidance are intended to improve the safety and effectiveness of these devices. This draft guidance is not final nor is it in effect at this time. Elsewhere in this issue of the **Federal Register**, FDA is announcing a public meeting regarding external infusion pumps.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by July 26, 2010. Submit written or electronic comments on the collection of information by June 25, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Total Product Life Cycle: Infusion Pump—Premarket Notification [510(k)] Submissions" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. 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.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Alan Stevens, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2561, Silver Spring, MD 20993–0002, 301–796–6294.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has seen an increase in the number and severity of infusion pump recalls. Analyses of medical device reports (MDRs) revealed device problems that appear to be a result of faulty design. Between January 1, 2005, and December 31, 2009, FDA received over 56,000 MDRs associated with the use of infusion pumps. Of these reports, approximately 1 percent were reported as deaths, 32 percent were reported as serious injuries, and 64 percent were reported as malfunctions.

The most frequently reported infusion pump device problems are: Software error messages, human factors (which include but are not limited to use error), broken components, battery failure, alarm failure, over infusion, and under infusion. In some reports, the manufacturer was unable to determine or identify the problem and reported the problem as "unknown." Subsequent root cause analyses revealed that many of these design problems were foreseeable and, therefore, preventable.

After evaluating a broad spectrum of infusion pumps across manufacturers, FDA has concluded there are numerous, systemic problems with device design, manufacturing, and adverse event reporting. The agency believes that the draft guidance provides recommendations that will help mitigate current risks and reduce future risks associated with infusion pumps.

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