SUPPORTING STATEMENT
FOR
Agreement for Shipment of Devices for Sterilization
21 CFR 801.150(e)
OMB No. 0910-0131

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Abstract

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)) (Attachment A), nonsterile medical devices which are labeled as sterile but are in interstate transit to a facility to be sterilized are normally considered by the Food and Drug Administration (FDA) to be adulterated and misbranded. FDA regulations established 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 actual sterilization at another establishment, a practice that facilitates the processing of devices and is economically necessary for some firms. Under this section of the law (21 CFR 801.150(e)) (Attachment B), manufacturers and sterilizers may sign an agreement containing instructions for maintaining accountability of the number of units in each shipment; acknowledgment that the devices are nonsterile and are being shipped for further processing; and specifications for the product's sterilization processing. http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=5f867b9e64427fa94a91a527b37fdd0d&tpl=/ecfrbrowse/Title21/21cfr801_main_02.tpl

This agreement allows the manufacturer to ship adulterated or misbranded products to be sterilized without initiating regulatory action and provides FDA with a means to protect consumers from use of nonsterile products. The agreement must include: (a) instructions for maintaining accountability of the number of units in each shipment, (b) acknowledgment that the devices are nonsterile, being shipped for further processing, and (c) specifications for sterilization processing.

These agreements must be retained for two years, as FDA may review them up to two years after final shipment or delivery of devices.

The FDA is requesting approval from the Office of Management and Budget (OMB) for the following information collections:

21 CFR 801.150(e) Reporting

This section lists the information to be contained in the written agreement and labeling requirements for the shipment of nonsterile devices labeled as sterile.

21 CFR 801.150(a)(2) Recordkeeping

This section says that records must be retained for two years.

This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information Collection

It is common industry practice to manufacture and/or assemble, package and fully label a product as sterile (when it is not sterile) at one establishment and to ship it to another establishment or contract sterilizer for sterilization. A written agreement allows the manufacturer to ship misbranded products without FDA initiating regulatory action and provides FDA with a means to protect consumers from use of nonsterile products. FDA normally reviews agreements during routine plant inspections, and firms are not required to submit the written agreements to FDA. To discontinue this procedure would place an economic hardship on the industry and an additional burden on FDA to police product in interstate commerce for failure to comply with adulteration and misbranding provisions of the act.

The respondents to this collection of information are device manufacturers and contract sterilizers. They are private sector businesses.

3. Use of Improved Information Technology and Burden Reduction

FDA does not have a say in how this process is to be accomplished, but the written agreements do not require a significant amount of paperwork. Electronic data transmission and facsimile transfer devices may be used to reduce paperwork burden in updating sterilization procedures and other pertinent information. Use of computers has also greatly reduced the time needed to compile, submit, and maintain the required documents. Firms are not required to submit written agreements to FDA. The percent of electronic submissions between medical devices manufacturers and contract sterilizers cannot be estimated with any degree of accuracy.

4. Efforts to Identify Duplication and Use of Similar Information

The FDA is the only agency authorized to regulate mislabeled, adulterated, or misbranded medical device products. The written agreement is prepared and agreed to by both the device manufacturer and the contract sterilizer. There is, therefore, no duplication of efforts. There is no similar information already available that could be used for the agreement between a manufacturer and contract sterilizer. Each agreement is unique because sterilization processes vary according to the product to be sterilized and factors such as the lot, batch size, etc.

There is no other similar information collected that can be used to ensure that mislabeled, misbranded, or adulterated medical products are sterilized prior to being placed in the marketplace.

5. Impact on Small Businesses or Other Small Entities

All respondents to this information collection are businesses. The requirements are applied equally to all firms regardless of the firm's size. However, the burden is generally less for the small contract sterilizers because they generally have fewer customers and therefore fewer written agreements. The Division of Small Manufacturers, International, and Consumers Assistance (DSMICA) of the Center for Devices and Radiological Health (CDRH) provides technical assistance on request to aid small business in complying with this regulation. DSMICA also assists in identifying ways manufacturers and contract sterilizers can meet the requirements so that the requirements are neither unfair nor unduly burdensome. DSMICA maintains a toll-free "800" number and a website for the convenience of businesses. Details of a sterilization contract and a sample contract are provided in written manuals on the GMP regulation and on sterilization processing. DSMICA reports that the process of preparing the written agreement has become routine so that very few questions regarding the written agreement have been received in the past several years.

6. Consequences of Collecting the Information Less Frequently

The information collection occurs annually. If the information collection were conducted less frequently, the FDA would not be able to assure that devices labeled as sterile have been sterilized. This could endanger public health by allowing diversion of nonsterile devices into the marketplace.

The written agreement also establishes a control mechanism by which manufacturers and contract sterilizers can assure that nonsterile devices labeled as sterile are not incorrectly released into the market without being sterilized. If written agreements were not available to FDA for review, a resource intensive burden would be placed on the agency to assure consumers were protected from misbranded nonsterile products labeled as sterile being shipped in interstate commerce.

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The collection of information under this regulation is consistent with 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

Notice has been published in the Federal Register on February 18, 2010 (75 FR 7276), soliciting comments on this information collection prior to its submission to the Office of Management and Budget (OMB) as required by 5 CFR 1320.8(d) No comments related to the information collection were received. http://edocket.access.gpo.gov/2010/pdf/2010-3027.pdf

The following individuals were consulted to provide information about the burden estimate:

Gary Cranston, President
Professional Contract Sterilization, Inc.
Taunton, Massachusetts

Clark W. Houghtling, Corporate Account Manager and
Senior Ethylene Oxide (EO) Technical Specialist
STERIS Isomedix Services
Queensbury, NY

Rebecca Rickey, Vice President Quality Assurance
Sterigenics International
Fort Worth, TX

In addition, FDA continually meets with respondents affected by this collection through its medical device inspection program, Federal Register comments to this collection, and other meetings and correspondence received.

9. Explanation of Any Payment of Gift to Respondents

There is no payment or gift provided to respondents of this information collection.

10. Assurance of Confidentiality Provided to Respondents

Data relating to this information collection is subject to release under 21 CFR Part 20, “Public Information," in determining whether documents may be disclosed under Freedom of Information.

11. Justification for Sensitive Questions

The information required does not include questions about sexual behavior, attitude, religious beliefs, or any other matters which are commonly considered private or sensitive in nature.

12. Estimates of Annualized Burden Hours and Costs

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

12a. Annualized Hour Burden Estimate

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

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 Record-keepers	Annual Frequency of Record-keeping	Total Annual Records	Hours per Record	Total Hours
801.150(a)(2)	90	20	1,800	30/60	900

1There 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 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 four 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 21 CFR 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.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Regulatory Affairs Specialist	7,200	$75.00	$540,000.00
Clerical (for the copying, etc)	900	20.00	$18,000.00
Total			$558,000.00

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

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

14. Annualized Cost to the Federal Government

Costs for the Federal government are minimal because the review of written agreements is conducted during routine scheduled inspections conducted every two years under the medical device Quality System regulations. Therefore, written agreements for one-half of the regulated firms (45) are reviewed each year. FDA investigators may examine records for 5 customers, on average. Therefore 225 written agreements (45 x 5) are estimated to be examined each year. An estimated average of 15 minutes is required for each review. Therefore, an estimated 56.25 hours are required for review of the written agreements each year.

An average full time equivalent (FTE) employee is projected to cost FDA/CDRH $120,000, which consists of the employee's salary and any overhead which accompanies that employee. Therefore, the average hourly wage rate (including overhead) for an FDA/CDRH employee would be $69, which is the salary of $120,000 divided by 1,750 working hours.

The burden to government for this information collection is $3,881 per year which is computed by taking the hourly average FTE cost of $69 and multiplying it by 56.25 hours.

15. Explanation for Program Changes or Adjustments

The estimated burden to industry for this collection has not changed since it was last approved by OMB.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans to publish this collection of information for statistical use.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is seeking approval to not display the expiration date for OMB approval of the information collection, because the format has not been developed by the government. Each individual firm develops its own format in the creation of sterilization agreements, and a requirement to display the OMB expiration date would be imposing additional requirements and burden on the public. The Federal Register notice will inform the public of the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

Currently, CDRH is not requesting an exemption to Certification for the Paperwork Reduction Act Submissions.

B. Statistical Methods

There are no statistical methods being employed in this collection of information.