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

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 FDA to be adulterated and misbranded. FDA regulations 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 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.

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 Food and Drug Administration (FDA) is requesting approval from the Office of Management and Budget (OMB) for the retention of records in written agreements for shipment of devices for sterilization.

21 CFR 801.150(e) Recordkeeping

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

2. Purpose and Use of the Information

It is common industry practice to manufacture and/or assemble, package and fully label 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 recordkeeping 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 FD & C Act.

3. Use of Information Technology and Burden Reduction

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. Utilization of computers and word processors has also greatly reduced the time needed to compile, submit and maintain the required documents.

There are no technical or legal obstacles to collection of this information.

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, 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 Business or Other Small Entities

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 Assistance (DSMA) of the Center for Devices and Radiological Health (CDRH) provides technical assistance on request to aid small business in complying with this regulation. DSMA also assists in identifying ways manufacturers and contract sterilizers can meet the requirements so that the requirements are neither unfair nor unduly burdensome. DSMA maintains an "800" number and a AFacts-On-Demand" Fax back service 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. DSMA 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

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.

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 Agency

Notice has been published in the Federal Register on June 12, 2000 (65 FR 36816)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) (see Attachment C). No significant comments were received.

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

Gary Cranston, President
Professional Contract Sterilization, Inc.
Taunton, Massachusetts
April 28, 2000

Arthur Harris, General Manager
Chicago Sterilization Services
Chicago, Illinois
April 28, 2000

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 Respondent

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 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. Estimate of Hour Burden Including Annualized Hourly Costs

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

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

Estimated Annual Recordkeeping Burden					
CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
801.150(e)	90	20	1800	4	7200

There are no Capital or Operating and Maintenance costs associated with this collection of information.

There are approximately 90 firms subject to this recordkeeping 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 is 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 7200 hours (90 firms x 20 agreements x 4 hours).

No dollar burden has been estimated for the recordkeeping requirement in Sec. 801.150(a)(2) because these records are maintained as a usual and customary part of normal business activities. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

FDA's estimate of the burden is based on actual data obtained from industry during the past 3 years where there are approximately 90 firms subject to this requirement.

Even though these records are maintained as a usual and customary part of normal business activities, a dollar burden is estimated as follows. The Regulatory Affairs Professional Society (RAPS), in their 1995 salary survey, estimate the average salary for regulatory affairs professionals to be $74,900, or $36 per hour. The total estimated burden cost to industry for recordkeeping relating to this information collection, would have been $259,200, which is the total number of hours expended (7200) multiplied by the RAPS

average wage rate of $36 per hour.

13. Estimate of the Other Total Annual Cost Burden to Respondent of Recordkeepers

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

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 employee is projected to cost FDA/CDRH $89,705, which consists of the employee's salary and any overhead which accompany that employee. Therefore, the average hourly wage rate (including overhead) for an FDA/CDRH employee would be $43.

The burden to government for this information collection is $2,419 per year which is computed by taking the hourly average FTE cost of $43 and multiplying it by 56.25 hours.

15. Explanation of Program Changes of Adjustment

There have been no program changes for this collection of information 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 recordkeeping 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 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. Collection of Information Employing Statistical Methods

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

List of Attachments to Supporting Statement:

Attachment A - Sections 501(c) and 502(a) of the Federal Food Drug and Cosmetic Act
Attachment B - 21 CFR 801.150 (e)
Attachment C - Federal Register Notice Soliciting Comments on "Agreement for Shipment of Devices for Sterilization"