

U.S. Food and Drug Administration  
Agreement for Shipment of Devices for Sterilization

OMB Control Number 0910-0131

SUPPORTING STATEMENT

**Terms of Clearance:** None.

**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 FD&C Act) (21 U.S.C. 351(c) and 352(a)), nonsterile medical devices that 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 § 801.150(e)(1), manufacturers and sterilizers may sign an agreement containing the following: (1) contact information of the firms involved and the identification of the signature authority of the shipper and receiver, (2) instructions for maintaining accountability of the number of units in each shipment, (3) acknowledgment that the devices that are nonsterile are being shipped for further processing, and (4) 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)).

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.

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

21 CFR 801.150(e)—Nonsterile devices labeled as sterile, agreement and labeling requirements (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)—Nonsterile devices labeled as sterile, record retention (Recordkeeping)

The records must be retained for two years after final shipment or delivery of such devices.

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 FD&C Act.

3. Use of Improved Information Technology and Burden Reduction

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. Because firms are not required to submit written agreements to FDA, we cannot reliably estimate the percentage of respondents that use electronic submissions to fulfill the information collection. However, because of the reduced time needed for electronic fulfillment of the collection, we are assuming that 100% of respondents will use electronic means.

4. Efforts to Identify Duplication and Use of Similar Information

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

The requirements are applied equally to all firms regardless of the firm's size. However, the burden is generally less for small contract sterilizers because they generally have fewer customers and therefore fewer written agreements. The Division of Industry and Consumer Education (DICE) of the Center for Devices and Radiological Health (CDRH) provides technical assistance on request to aid small business in complying with this regulation. DICE also assists in identifying ways manufacturers and contract sterilizers can meet the requirements so that the requirements are neither unfair nor unduly

burdensome. DICE 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. DICE 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

There are no special circumstances for this collection of information.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of April 26, 2019 (84 FR 17837). We received one comment that was not related to the information collection.

9. Explanation of Any Payment or Gift to Respondents

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

10. Assurance of Confidentiality Provided to Respondents

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g. point of contact). The PII submitted via the agreement is name, address, and titles of managers or employees that have signatory responsibility. The agreements are maintained at the plant and are reviewed by FDA during routine inspections.

FDA further determined that although PII is collected the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, the records are not routinely retrieved by name or any other personal identifier from the information collected.

In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected. FDA minimized the PII to be collected to protect the privacy of the individuals.

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 the Freedom of Information Act.

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

12 a. Annualized Hour Burden Estimate

The respondents to this collection of information are device manufacturers and contract sterilizers. FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Recordkeeping Burden

| 21 CFR Section                   | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Average Burden per Recordkeeping | Total Hours |
|----------------------------------|----------------------|---------------------------------|----------------------|----------------------------------|-------------|
| Record retention, 801.150(a) (2) | 100                  | 20                              | 2,000                | .5                               | 1,000       |

Table 2.--Estimated Annual Third-Party Disclosure Burden

| Activity/21 CFR Section                          | No. of Respondents | No. of Disclosures per Respondent | Total Annual Disclosures | Average Burden per Disclosure | Total Hours |
|--|--------------------|-----------------------------------|--------------------------|-------------------------------|-------------|
| Agreement and labeling requirements , 801.150(e) | 100                | 20                                | 2,000                    | 4                             | 8,000       |

FDA’s estimate of the reporting burden is based on data obtained from industry over the past several years. It is estimated that each of the firms subject to this requirement prepares an average of 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. Additionally, contract sterilizers will have an agreement with each medical device manufacturer. 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 usual and customary business practice. The recordkeeping requirements of § 801.150(a)(2) consist of making copies and maintaining the records required under the third-party disclosure section of this collection.

12b. Annualized Cost Burden Estimate

We expect that the agreement and labeling requirements will be satisfied by regulatory affairs professionals. We expect that the recordkeeping requirements will be met by clerical workers.

| Type of Respondent               | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|----------------------------------|--------------------|------------------|------------------------|
| Regulatory Affairs Professional* | 8,000              | \$72.00          | \$576,000              |
| Clerical worker**                | 1,000              | \$16.30          | \$16,300               |
| Total                            |                    |                  | \$235,917              |

\* The estimated wage rate for a Regulatory Affairs Professional is based on The Regulatory Affairs Professional Society (RAPS) average total annual compensation of \$150,422 for a U.S. regulatory affairs professional (<https://www.raps.org/getattachment/Careers/Scope-of-Practice-Survey/2016-Scope-of-Practice-Compensation-Report-for-the-Regulatory-Profession.pdf.aspx?lang=en-US>, p. 11, accessed 10/26/18). The hourly wage rate of \$72 assumes a 40-hour work week and is rounded to the nearest dollar.\*\* The estimated wage rate for a clerical worker is based on the Bureau of Labor and Statistics May 2017 National Occupational Employment and Wage Estimates data for Office Clerks, General (Occupation Code #43-9061), [http://www.bls.gov/oes/current/oes\\_nat.htm#43-0000](http://www.bls.gov/oes/current/oes_nat.htm#43-0000).

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 (50) are reviewed each year. FDA investigators may examine records for 5 customers, on average. Therefore 250 written agreements (50 x 5) are estimated to be examined each year. An estimated average of 15 minutes is required for each review. Therefore, an estimated 62.5 hours are required for review of the written agreements each year.

The hourly rate, \$130 (rounded), is based on the Food and Drug Administration fully loaded FTE cost model (domestic) for the Center for Devices and Radiological Health for FY 2018 (\$270,305), as provided by agency economists, and calculated for a 40-hour work week. The burden to government of this information collection is \$8,125 per year (rounded) which is computed by taking the hourly average FTE cost of \$130 and multiplying it by 62.5 hours.

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects an overall increase of 900 total hours and a corresponding increase of 400 records/disclosures. We attribute this to an increase in the number of agreements that we have seen in inspection data received over the last few years.

There are no program changes to this information collection.

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 will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.