Proposed Amendment to Laser Product Performance Standard
0910- NEW
RIN 0910-AF87
PROPOSED RULE SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Sections 532 through 542 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360ii through 360ss) direct the Secretary of the Department of Health and Human Services (the Secretary) to establish and carry out an electronic product radiation control program to protect the public from unnecessary radiation from electronic products. Section 532 authorizes the Secretary to procure (by negotiation or otherwise) electronic products for research and testing purposes and to sell or otherwise dispose of such products. Section 534(g) directs the Secretary to review and evaluate industry testing programs on a continuing basis; and sections 535(e) and (f) direct the Secretary to immediately notify manufacturers of, and assure correction of, radiation defects or noncompliance with performance standards. The authority for records and reports is contained in sections in 537(b) through (c) of the FD&C Act. The program includes the development, issuance, and administration of performance standards to control the emission of electronic product radiation from electronic products.

The regulations issued under these authorities are listed in the Code of Federal Regulations (CFR), Title 21, Chapter I, Subchapter J. Specifically, 21 CFR parts 1002 through 1010 specify information to be provided to FDA, to users, and/or to be maintained in the event of an investigation of a safety concern or a product recall. Subchapter A regulations, 21 CFR 5.10(a)(3), 5.25(b), 5.35(a)(4), and 5.600 through 5.606 delegate administrative authorities to FDA's Center for Devices and Radiological Health (CDRH).

The propose rule proposes to amend FDA's performance standard for laser products to better harmonize with international standards.

The agency is proposing to amend its regulation of laser products by proposing new § 1040.11(e) that requires manufacturers of laser products to obtain a exemption notification letter from the Department of Defense (DOD) prior to the sale of laser products manufactured for the DOD under an exemption from the laser performance standard. The exemption was granted to the DOD by the FDA. DOD procuring agencies apply the exemption to laser products manufactured solely for the DOD for combat, combat training or for reasons of classified national security. The exemption letter must be obtained by the manufacturer from the DOD prior to entering into commerce with the laser product. The exemption notification letter must be retained by the manufacturer as proof that the DOD authorized the laser product to be manufactured for the DOD per the

requirements of the exemption. The reason for this proposal is that DOD requested that this requirement be codified and the agency believes this rule would provide readily available proof of DOD exemption in the event that an imported product is detained or when a manufacturer claims the product was manufactured for the DOD under the DOD exemption.

The agency is proposing a new § 1040.11(a)(3)(iii) to amend its regulation of laser products that are registered for sale as components. Component registration allows conditional relief from applicability of the laser performance standard under 1040.10 and 1040.11. However, registration is conditional in that the sale of the component must be controlled by the selling manufacturer, either by allowing sales to occur directly to other laser product manufacturers under 1040.10(a)(1) or allowing sales of component replacement parts directly by the selling manufacturer or indirectly for the selling manufacturer under 1040.10(a)(2).

A new § 1040.11(a)(3)(iii) is proposed that requires the selling manufacturer of a registered laser component or replacement part to maintain a record that identifies the purchasers as 1) laser product manufacturers who will certify or register their own laser product containing the component or 2) as resellers (dealers or distributors) of the component replacement part.

This record (documentation) is needed to establish the business intent of the purchaser to either 1) use the component in a product it is manufacturing or 2) purchase the component as a replacement part for distribution to purchasers who will use the part as a replacement in a laser product that is certified under 1040.10 and 1040.11 Records do not need to identify purchasers who acquire the product from the manufacturer for purposes other than resale and as a component replacement part for a certified laser product.

Currently, there is no regulatory requirement for the manufacturer of a component or replacement laser part to make the conditions of sale under 1040.10(a)(1) or 1040.10(a)(2) readily apparent to the FDA. FDA seeks to put responsibility on manufacturers to show documentation to FDA that components have been sold to purchasers who are legitimately entitled to purchase laser products as components.

2. Purpose and Use of the Information Collection

New § 1040.11(e), would allow FDA or a DOD procuring agency to verify that a manufacturer went through the process of obtaining a DOD exemption from the laser product performance standard. This proof is necessary because laser products that are imported by the DOD from a laser manufacturer may be detained by FDA or Customs on the basis that the products have not been reported to FDA as compliant with the laser performance standard. In addition, the FDA has no means to readily confirm that laser products advertised for sale to DOD by manufacturers are approved by DOD for sale to DOD agencies under the DOD exemption. Possession of an exemption letter from the

DOD by a manufacturer serves to prove that the manufacturer went through the administrative process setup by the DOD to apply the exemption.

For § 1040.11(a)(3)(iii), the manufacturer would collect documentation sufficient to support the validity of a claim by the manufacturer that the purchaser is a manufacturer or supplier (dealer / distributor) and a bona fide business entity engaged in laser product commerce. Examples of documentation that identifies the purchaser as a manufacturer may include: a copy of the purchasers' business license, article of incorporation, correspondence on company letterhead, signed agreement with the manufacturer, canceled business check, company brochure, archived copy of company website, or other similar proof. A signed statement from the purchaser is sufficient if it identifies the purchaser as 1) a manufacturer engaged in laser product commerce who will certify a host product that contains the manufacturers component or replacement part or, 2) manufacturer engaged in laser product commerce who will register a host product under 1040.10(a)(1) or (2) that contains the manufacturer's component or replacement part or, 3) a supplier engaged in laser product commerce who will sell the manufacturer's registered laser component or replacement part.

Respondents will be Private Sector businesses.

3. Use of Improved Information Technology and Burden Reduction

It is likely that many, if not most of the requests for documentation and transmission of documentation for § 1040.11(e) and § 1040.11(a)(3)(iii) will occur via email and scanned documents as attachments to email.

FDA estimates that 80% of the respondents will use electronic means to fulfill the agency's requirement or request due the widespread use of email for exchange of information between companies.

4. Efforts to Identify Duplication and Use of Similar Information

No similar information is currently collected by any other agency and, therefore, no similar information is available that can be used or modified for the purpose described.

5. Impact on Small Businesses or Other Small Entities

The percentage of respondents that may be considered small business is estimated to be 93%.

The FDA has established a Division of Small Manufacturers International and Consumer Assistance (DSMICA). DSMICA provides technical and nonfinancial assistance through a comprehensive program, which includes seminars and educational conferences, informational materials and use of a toll-free number which may be used by firms that require information or assistance. Additional Center for Devices and Radiological Health staff are available for consultation on request.

Since small and large businesses correspond regularly with customers as a matter of business practice, the added time recordkeeping burden for maintaining a file of documentation obtained passively from customers (for example; correspondence, cancelled check, purchase agreement) would be zero. Documentation obtained actively (for example; electronic copy of company website or brochure, proof of business license, signed agreement, etc.) could be obtained via computer or fax equipment the small businesses are likely to have in an office.

6. Consequences of Collecting the Information Less Frequently

   For 1040.11(e), we estimate respondents would need to collect information when providing to DoD, which we estimate to be annually.

   For 1040.11(a)(3)(iii), we estimate respondents would respond when they purchase laser components, which we estimate to be quarterly

   Information will not be collected at set time points, but rather when the respondent intends to take some action such as selling a laser product to DoD or when they intend to purchase laser components. Responses must be submitted at this rate in order to ensure that respondents are legitimate entity engaged in providing lasers to DoD or is a legitimate entity engaged in laser product commerce, respectively.

   There are no legal obstacles to reduce the burden.

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

   Respondents are expected to maintain records pursuant to 1040.10(a)(3)(iii) for more than 5 years.

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

   As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), FDA provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the FEDERAL REGISTER of 06/24/2013 (78 FR 37723)."

9. Explanation of Any Payment or Gift to Respondents

   The regulation does not provide any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

    Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information. All records and other information submitted to FDA are releasable under 21 CFR Part 20. FDA can and does routinely protect company proprietary information, but does not have

on-site means of complying with the requirements for material classified in national security interests.

11. Justification for Sensitive Questions

The information collection does not include questions about sexual behavior and attitudes, religious beliefs, or other matters that are commonly considered private or sensitive in nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

There is an estimated total of 16 burden hours.
For § 1040.11(a)(3)(iii) we estimate 14 respondents would generate 4 records per year for a total of 56 records. Since many companies correspond regularly with customers as a matter of business practice, the recordkeeping burden for maintaining a file of documentation obtained passively from customers (correspondence, cancelled check, purchase agreement) would be zero. This task is expected to be performed by clerical staffs, who prepare a letter, email or fax requesting the information from the manufacturer or supplier, and respondent manufacturer or supplier staff, who prepare a response that verifies the purchaser is a bona fide business that will certify or register the component or replacement part as a manufacturer or sell the part as a supplier. The total annual estimated burden imposed by this provision is 10 hours annually.

For § 1040.11(e) we estimate 25 respondents would need to collect information once per year for a total of 25 records. Manufacturers would request information from DOD, and when received, file the information. This process is estimated to take 15 minutes (5 minutes to request the information from DoD and 10 minutes to file it) per record, for a total time per collection of 6 hours (2 cumulative hours of sending the letter to DoD and 4 cumulative hours of filing the letter) for DOD agency procurement staff and manufacturer staff.

Table 1.--Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
1040.11(e)	25	1	25	.08	2

Table 2 Estimated Annual Recordkeeping Burden

21 CFR Part	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
1040.10(a)(3)(iii)	14	4	56	0.17	10

1040.11(e)	25	1	25	0.17	4
Totals					14

12b. Annualized Cost Burden Estimate

For § 1040.11(e), the cost burden was calculated from a clerical staff wage. This task is expected to be performed by clerical staffs, who prepare a letter, email or fax requesting the information from DOD, and DOD agency procurement clerical staff, who prepare a written response that verifies the manufacturer is a manufacturer under an exemption at § 1002.51.

For § 1040.11(a)(3)(iii), documentation obtained actively (electronic copy of company website or brochure, proof of business license, signed agreement, etc.) could be obtained via the internet, mail, fax or email attachment by clerical staffs of the manufacturer and respondent manufacturer or supplier.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Clerical Staff	16	$20.00	$320
Total			$320

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

The operating and maintenance costs associated with this information collection are based upon correspondence costs (postage) for non-email communications for 20% of respondents (8), estimated at $0.50 per correspondence for a total of $4.00.

14. Annualized Cost to the Federal Government

Estimate of the annualized cost to the Federal government is based on a GS-13 level government employee review of these records to determine if, under § 1040.11(e), a manufacturer is manufacturing a laser product under a DOD exemption. A similar cost will occur when a review of record occurs under § 1040.11(a)(3)(iii) during an investigation to determine if laser products are being sold to consumers when they should be sold only to suppliers or manufacturers. This cost is estimated to be 2 – 5% FTE for a GS-13, or approximately $46,000. Therefore, the annual cost to the government is $46,000.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans to publish the collection of information under these regulations for statistical use unless requested by Congress in accordance with section 533 of the FD&C Act.

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

FDA is not requesting an exemption from displaying the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.