TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of respondents	Annual frequency per recordkeeper	Total annual records	Hours per record	Total hours
807.25(d) [2]—List of Officers, Directors, and Partners	22,338	1	22,338	0.25 (15 minutes)	5,585
807.26 [2]—Labeling and Advertisements Available for Review.	17,032	4	68,128	0.5 (30 minutes)	34,064
Total	.....	.....	.....	.....	39,649

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Recurring burden—Firm is required to keep records.

The following adjustments and program changes resulted in a 5,672-hour decrease to the overall total hour burden estimate for this information collection request.

- We adjusted the number of respondents based on updated registration and listing data.
- In the reporting burden table, we corrected the table footnotes to accurately indicate whether the information collection (IC) is a one-time or reoccurring burden.
- We also adjusted some of the IC descriptions in the table for increased clarity.
- We updated our estimate of Hours per Response for ''807.22(a) Initial Registration and Listing'' (+ 0.5 hours), ''807.22(b)(1) Annual Registration'' (− 0.25 hours), and ''807.22(b)(3) Annual Update of Listing Information'' (− 0.25 hours). Based on our review of the program, we believe these changes to the burden estimate will more accurately reflect the current preparation time for these ICs.

Dated: May 2, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09412 Filed 5–7–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–7011]

Laser Products—Conformance With IEC 60825–1 Ed. 3 and IEC 60601–2–22 Ed. 3.1 (Laser Notice No. 56); Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Laser Products—Conformance with IEC 60825–1 Ed. 3 and IEC 60601–2–22 Ed. 3.1 (Laser Notice No. 56).'' This guidance describes the Agency's approach regarding compliance with FDA's performance standards for laser products. FDA believes that under the circumstances described in this guidance, conformance with certain International Electrotechnical Commission (IEC) standards would provide adequate protection of the public health and safety for laser products similar to performance standards in FDA's regulations. Accordingly, for laser product manufacturers that comply with the comparable clauses in IEC standards specified in the guidance, FDA does not intend to enforce the specified laser performance standards in FDA's regulations.

DATES: The announcement of the guidance is published in the **Federal Register** on May 8, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–7011 for ''Laser Products—Conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 (Laser Notice No. 56).'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit

both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Laser Products—Conformance with IEC 60825–1 Ed. 3 and IEC 60601–2–22 Ed. 3.1 (Laser Notice No. 56)'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Patrick Hintz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4228, Silver Spring, MD 20993–0002, 301–796–6927.

SUPPLEMENTARY INFORMATION:

I. Background

FDA recognizes that the IEC is a global organization that prepares and publishes international standards for electrical, electronic, and related technologies, including laser products. This means that manufacturers distributing products in the United States and other countries might have to ensure conformance of their products with IEC standards as well as comply with FDA regulatory requirements. Complying with FDA regulations and conforming to the identified IEC standards may cause manufacturers to duplicate their efforts.

FDA acknowledges the advantages of a universal set of device-specific criteria and requirements. Moreover, FDA believes that under the circumstances described in this guidance, conformance with certain IEC standards would provide adequate protection of the public health and safety for laser products similar to FDA's performance standards in §§ 1040.10 and 1040.11 (21 CFR 1040.10 and 1040.11). FDA eventually intends to amend its standards for laser products at §§ 1040.10 and 1040.11 to harmonize many of its requirements with those of the IEC because FDA acknowledges the advantages of one set of criteria and requirements worldwide. Until these requirements are harmonized, for laser product manufacturers that comply with the comparable clauses in IEC 60825–1 Ed. 3 and IEC 60601–2–22 Ed. 3.1, FDA does not intend to enforce the comparable requirements in §§ 1040.10 and 1040.11.

On June 24, 2007, FDA's Center for Devices and Radiological Health (CDRH) published a guidance entitled ''Laser Products—Conformance with IEC 60825–1 and IEC 60601–2–22; Guidance for Industry and FDA Staff (Laser Notice No. 50)'' (*https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/laser-products-conformance-iec-60825-1-and-iec-60601-2-22-laser-notice-no-50*). Laser Notice No. 56 will not replace the recommendations provided in that 2007 guidance, and manufacturers can follow either Laser Notice No. 50 or 56.

FDA considered comments received on the draft guidance that appeared in the **Federal Register** of January 19, 2018 (83 FR 2789). FDA revised the guidance as appropriate in response to the comments.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Laser Products—Conformance with IEC 60825–1 Ed. 3 and IEC 60601–2–22 Ed. 3.1 (Laser Notice No. 56).'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Laser Products—Conformance with IEC 60825–1 Ed. 3 and IEC 60601–2–22 Ed. 3.1 (Laser Notice No. 56)'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500024 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR parts	Topic	OMB control No.
1002, 1010, 1040 ...	Reporting and Recordkeeping for Electronic Products—General Requirements	0910–0025

Dated: May 2, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09381 Filed 5–7–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3353]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Antimicrobial Animal Drug Distribution Reports and Recordkeeping

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 June 7, 2019.

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 emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0659. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St, North Bethesda, MD 20852, 301–796–3794, *PRAStaff@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.

Antimicrobial Animal Drug Distribution Reports and Recordkeeping—21 CFR 514.87

OMB Control Number 0910–0659—Extension

Sponsors of approved or conditionally approved applications for new animal drugs containing an antimicrobial active ingredient are required by section 512 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b) to submit to FDA an annual report on the amount of each such ingredient in the drug that is sold or distributed for use in food-producing animals. Sponsors are also required to maintain distribution records for their animal drug products, including separate information for each month of the calendar year, under section 512(l)(3) of the FD&C Act. These provisions were enacted to assist FDA in our continuing analysis of the interactions (including drug resistance), efficacy, and safety of antimicrobials approved for use in both humans and food-producing animals for the purpose of mitigating the public health risk associated with antimicrobial resistance.

Section 514.87 of our regulations (21 CFR 514.87) codifies the reporting requirements established in the FD&C Act. Sponsors submit antimicrobial animal drug sales and distribution reports to the Agency on Form FDA 3744. Each report must specify: (1) The amount of each antimicrobial active ingredient by container size, strength, and dosage form; (2) quantities distributed domestically and quantities exported; and (3) a listing of the target animals, indications, and production classes that are specified on the approved label of the product. The report must cover the period of the preceding calendar year and include separate information for each month of the calendar year. Each report must also provide a species-specific estimate of the percentage of each product that was sold or distributed domestically in the reporting year for use in cattle, swine, chickens, or turkeys for such species that appear on the approved label.

Collection of information on the amount of animal antimicrobials being distributed, including species-specific information, is necessary to support our ongoing efforts to encourage the judicious use of antimicrobials in food-producing animals to help ensure the continued availability of safe and effective antimicrobials for animals and humans. We intend to use these data to supplement existing information, including data collected under the National Animal Health Monitoring System and the National Antimicrobial Resistance Monitoring System programs. Data from multiple sources are needed to provide a comprehensive and science-based picture of antimicrobial drug use and resistance in animal agriculture.

In the **Federal Register** of October 1, 2018 (83 FR 49395), 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	FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
514.87(a) through (e)—Annual Reports for Sponsors With Active Applications—Paper Submission	3744	10	7.5	75	62	4,650
514.87(a) through (e)—Annual Reports for Sponsors With Active Applications—Electronic Submission	3744	10	7.5	75	52	3,900
514.87(a) through (e)—Annual Reports for Sponsors With Inactive Applications—Paper Submission	3744	4	26.5	106	2	212
514.87(a) through (e)—Annual Reports for Sponsors With Inactive Applications—Electronic Submission	3744	3	35	105	2	210
Total						8,972

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