



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-0338]

Agency Information Collection Activities; Proposed Collection; Comment Request; Export Notification and Recordkeeping Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with notifications and records required for human drug, biological product, device, animal drug, food, cosmetic, and tobacco product exports.

DATES: Either electronic or written comments on the collection of information must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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-2025-N-0338 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Export Notification and Recordkeeping Requirements." Received comments, those filed in a timely manner (see ADDRESSES), 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, 240-402-7500.

- 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.govinfo.gov/content/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, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Export Notification and Recordkeeping Requirements--21 CFR 1.101

OMB Control Number 0910-0482--Extension

Sections 801 and 802 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381 and 21 U.S.C. 382) charge the Secretary of Health and Human Services, through FDA, with the responsibility of helping to ensure that exports of unapproved new drugs, biologics, devices, animal drugs, food, cosmetics, and tobacco products that are not to be sold in the United States meet the requirements of the country to which the product is to be exported. The respondents to this information collection are exporters who have notified FDA of their

intent to export unapproved products that may not be sold or offered for sale in domestic commerce in the United States as allowed under section 801(e) of the FD&C Act. In general, the notification identifies the product being exported (e.g., name, description, and in some cases, country of destination) and specifies where the notifications were sent. These notifications are sent only for an initial export. Subsequent exports of the same product to the same destination or to certain countries identified in section 802(b) of the FD&C Act would not result in a notification to FDA.

Respondents to the information collection are exporters of products that may not be sold in the United States and are regulated by FDA’s Center for Drug Evaluation and Research (CDER); Center for Biologics Evaluation and Research (CBER); Center for Devices and Radiological Health (CDRH); Center for Veterinary Medicine (CVM); Human Foods Program (HFP); and Center for Tobacco Products (CTP). Respondents to this collection of information maintain records demonstrating their compliance with the requirements in 21 CFR 1.101.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
1.101(d) (CBER)	5	92	460	15	6,900
1.101(d) (CDER)	5	2.4	12	15	180
1.101(d) (CDRH)	16	3.375	54	15	810
Total					7,890

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

Table 2.--Estimated Annual Recordkeeping Burden¹

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
1.101(b), (c), and (e) (CBER)	17	3	51	22	1,122
1.101(b), (c), and (e) (CDER)	121	7.9	960	22	21,120
1.101(b), (c), and (e) (CDRH)	16	3	54	22	1,188
1.101(b), (c), and (e) (CVM)	26	3	78	22	1,716
1.101(b) Office of Global Policy and Strategy	1	65	65	22	1,430
1.101(b) (CTP)	322	3	966	22	21,252
Total					47,828

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

In table 1 we estimate the number of respondents increased for biologics from 4 to 5. The number of respondents increased for drugs from 3 to 5. However, this increase is offset by respondents for devices as the estimated number of exporters decreased from 22 to 16. The number of responses per respondent increased for biologics from 35 to 92 resulting in an increase in burden for biologics reporting from 2,100 to 6,900. Despite decreases in the number of responses per respondent for drugs and devices the increase in biologics reporting resulted in an overall total reporting burden increase from 5,985 to 7,890.

In table 2 we separated each center's recordkeeping to ensure consistency with table 1 and to accurately capture each center's burden estimates. The average No. of Records Per Recordkeeper increased from 4.12 to 14.15 which represents a total recordkeeping burden increase from 39,094 to 47,828.

Based on a review of Agency data the total burden hours have increased by 13,367. In the previous extension request FDA included burden for the Center for Food Safety and Applied Nutrition (now known as HFP). However, upon reevaluation of these burden estimates, HFP offers a "Certificate of Exportability" for conventional foods, food additives, food contact substances, and infant formula products that cannot be legally marketed in the United States but meets the requirements of section 801(e) of the FD&C Act and may be legally exported (<https://www.fda.gov/food/exporting-food-products-united-states/food-export-certificates>). An interested person may apply for this certificate electronically using the Export Certification Application and Tracking System (<https://www.fda.gov/food/food-export-certificates/online-applications-export-certificates-food>). As part of the application, the interested person attests to compliance with section 801(e) of the FD&C Act as provided in 21 CFR 1.101(b). This information collection activity is approved under OMB control number 0910-0793.

Dated: April 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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