This document is scheduled to be published in the
Federal Register on 05/21/2019 and available online at
https://federalregister.gov/d/2019-10537, and on **govinfo.gov**

4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0801]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Exports: Notification and Recordkeeping Requirements

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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 0910-0482. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, 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.

Exports: Notification and Recordkeeping Requirements--21 CFR 1.101

OMB Control Number 0910-0482--Extension

Section 801 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381) charges 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 which 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 (21 U.S.C. 382(b)) would not result in a notification to FDA.

The recordkeepers for this information collection are exporters of products that may not be sold in the United States who are regulated by the following FDA Centers: 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); Center for Food Safety and Applied Nutrition (CFSAN); 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.

In the *Federal Register* of February 15, 2019 (84 FR 4473), 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	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	180	900	15	13,500
1.101(d) (CDRH)	160	1	160	15	2,400
Total					22,800

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

Table 2.-- Estimated Annual Recordkeeping Burden[1]

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
1.101 (b), (c), (e) (CBER, CDER, CDRH, CFSAN, and CVM)	320	3	960	22	21,120
1.101(b) Office of International Programs only	1	189	189	22	4,158
1.101(b) (currently regulated Tobacco Products)	322	3	966	22	21,252
Total					46,530

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

We have adjusted our burden estimate, which has resulted in an overall decrease of 129,543 hours to the currently approved burden. The reporting burden estimate for CDRH has been adjusted to correct an error and corresponding miscalculation in the previous burden estimate and has been updated based on recent internal data. This adjustment contributed to the overall burden estimate reduction by eliminating 8,030 responses and 120,450 hours from the reporting burden estimate. CBER's estimated reporting burden for the information collection in table 1 reflects a decrease of 7,575 hours and a corresponding decrease of total annual responses (193 to 92). We attribute this adjustment to a normal variation in the number of submissions we received over the last few years. CTP's current number of respondents and recordkeeping burden

hours in table 2 are expected to decrease by 23 respondents and 1,518 hours. This is based on summary derived from the monthly operational reports that manufacturers and importers of tobacco products are required to file with the Alcohol and Tobacco Tax and Trade Bureau.

Dated: May 16, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-10537 Filed: 5/20/2019 8:45 am; Publication Date: 5/21/2019]