



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 [oir\\_submission@omb.eop.gov](mailto:oir_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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRStaff@fda.hhs.gov](mailto:PRStaff@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 (the FD&C Act) (21 U.S.C. 381) charges the Secretary of Health and Human Services, through FDA, with the responsibility of assuring exports (Exports: Notification and Recordkeeping Requirements--§1.101 (21 CFR 1.101)) which pertain to the exportation of unapproved new drugs, biologics, devices, animal drugs, food, cosmetics, and tobacco products that are not to be sold in the United States.

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 marketed 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 in the case of certain countries identified in section 802(b) of the FD&C Act (21 U.S.C. 382) would not result in a notification to FDA.

The recordkeepers to this information collection are exporters who export human drugs, biologics, devices, animal drugs, foods, cosmetics, and tobacco products that may not be sold in the United States and maintain records demonstrating their compliance with the requirements in section 801(e)(1) of the FD&C Act.

On March 30, 2012, OMB approved "Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products," OMB control number 0910-

0690, which amended, among other sections, §1.101 to incorporate tobacco products. This amendment reflects the Agency's authority over tobacco products under the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31) and added tobacco products to the list of products covered under §1.101(a) and (b).

In the Federal Register of July 3, 2014 (79 FR 38036), 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<sup>1</sup>

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
1.101(d) (Non-Tobacco products)	73	503	36,719	15	550,785

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

Table 2.--Estimated Annual Recordkeeping Burden<sup>1</sup>

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) (Non-Tobacco Products )	320	3	960	22	21,120
1.101(b) (Non-Tobacco Products for Office of International Programs only)	1	189	189	22	4,158
1.101(b) (Tobacco Products Only)	158	3	474	22	10,428
Total					35,706

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

Dated: October 7, 2014.

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Leslie Kux,

Assistant Commissioner for Policy.

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