

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

[Docket No. 2004N-0541]

### **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.

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**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:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**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 Part 1 (OMB Control Number 0910-0482)—Extension**

In the **Federal Register** of December 27, 2004 (69 FR 77255), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

The total burden estimate of 43,214 is based on the number of notifications received by the relevant FDA centers in fiscal year 2004, or the last year the figures were available.

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 Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381). In general, the notification identifies the product being exported (e.g., name, description, and, in some cases, country of destination) and specifies where the notification should be 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 act (21 U.S.C. 382), would not result in a notification to FDA.

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

### 3

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
1.101(d) and (e)	419	2.8	1,164	17	19,788

<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	Annual Frequency per Record	Total Annual Records	Hours per Recordkeeper	Total Hours
1.101(b) and (c)	324	2.8	901	26	23,426

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

Dated: April 1, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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