

DDM

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date 5-6-08

Publication Date 5-7-08

Certifier A. Hawkins

Food and Drug Administration

[Docket No. FDA-2008-N-0063] (formerly Docket No. 2008N-0016)

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: 202-395-6974, or e-mailed to *baguilar@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: Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

oc08107

FDA-2008-N-0063

N

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—(OMB Control Number 0910-0482)—Extension

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(e)). 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(b)), to any of those countries 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 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.

The total burden estimate of 39,120 is based on the number of notifications received by the relevant FDA centers in fiscal year 2007, or the last year the figures were available.

In the **Federal Register** of January 28, 2008 (73 FR 4874), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1.101(d) and (e)	400	3	1,200	15	18,000

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	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
1.101(b) and (c)	320	3	960	22	21,120

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

Dated: 5/1/08
May 1, 2008.

Jeffrey Shuren

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

BILLING CODE 4160-01-S

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

Dawn P. Hawkins