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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier A. Corbin

[Docket No. 02N-0215]

Agency Information Collection Activities; Submission for OMB Review;
Comment Request; Export of FDA Regulated Products—Export Certificates

11-17
02-08-02
9-9-02

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Mark L. Pincus, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1471.

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.

Export Certificates for FDA Regulated Products Under Sections 801(e) and 802 of the Federal Food, Drug, and Cosmetic Act—New Collection

FDA is requesting approval from OMB for the collection of information from the public associated with the export of FDA regulated products as indicated in sections 801(e) and 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381(e) and 382), as amended.

In April 1996, a new law entitled “The FDA Export Reform and Enhancement Act of 1996” was enacted. It was designed to ease restrictions on exportation of unapproved products regulated by FDA and to facilitate such exportation by provide foreign governments certificates verifying that the products may be legally exported. Specifically, section 801(e)(4) of the act provides that persons exporting certain FDA-regulated products may request FDA to certify that the products meet the requirements of sections 801(e) or 802 of the act, or other requirements of the act. Section 801(e)(4) of the act requires FDA to issue export certificates within 20 days of receipt of the request and to charge firms up to \$175 for the certificates.

FDA has developed five types of certificates that satisfy the requirements of section 801(e)(4)(B) of the act: (1) “Certificates to foreign governments” are issued for legally marketed products that are in compliance with the requirements of the act; (2) “certificates of exportability” are for the export of products that cannot be marketed legally in the United States, but meet the requirements of sections 801(e) or 802 of the act and may be exported legally; (3) “certificates of a pharmaceutical product” are used for the export of drug products that are legally marketed in the United States. They conform to the format established by the World Health Organization (WHO) and attest to the acceptable current good manufacturing practice status of the manufacturing

facility of the drug product; (4) “nonclinical research use only certificates” for the export of nonclinical research use only product, material, or component that is not intended for human use which may be marketed in and legally exported from the United States under the act; and (5) “certificates of free sale.”

FDA has relied and will continue to rely on information provided by manufacturers for all types of export certificates. Manufacturers are requested to state that they are in compliance with all applicable requirements of the act, at the time that they submit their request to the appropriate center.

FDA will check all information submitted by firms in support of their certificates and any suspected case of fraud will be referred to FDA’s Office of Criminal Investigations for followup. Firms making or submitting false statements on any documents submitted to FDA may be violating the United States Code title 18, chapter 47, section 1001 and be subject to penalties including up to \$250,000 in fines and up to 5 years imprisonment.

In the **Federal Register** of May 30, 2002 (67 FR 37836), the agency requested comments on the proposed collection of information. FDA received four comments, three did not pertain to the information collection requirements and one talked to requirements of the U.S. Department of Agriculture and State agencies.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

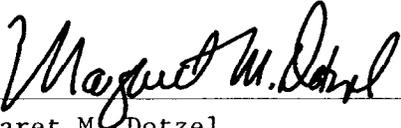
FDA Centers	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Center for Biologics Evaluation and Research	1,479	1	1,479	1	1,479
Center for Drug Evaluation and Research	4,187	1	4,187	1	4,187
Center for Devices and Radiological Health (CDRH)	3,500	1	3,500	2 ²	7,000 ²
Center for Veterinary Medicine	621	1	621	1	621
Total	9,787		9,787		13,287

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

² Based on the CDRH policy of allowing multiple devices to appear on the certificate.

The estimates provided in table 1 are based on each center's latest calendar year counts.

Dated: 9-3-02
September 3, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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