

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: September 3, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,

and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Special Emphasis Panel, Comparative Medicine.

Date: September 30, 2002.

Time: 7 p.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: Hilton Hotel, 8727 Colesville Road, Silver Spring, MD 20910.

Contact Person: John L. Meyer, PhD, Scientific Review Administrator, Office of Review, National Center for Research Resources, National Institutes of Health, 6705 Rockledge Drive, Msc 7965, One Rockledge Centre, Room 6018, Bethesda, MD 20892-7965, 301-435-0806, meyerj@ncrr.nih.gov.

Dated: August 29, 2002.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333; 93.371, Biomedical Technology; 93.389,

Research Infrastructure, National Institutes of Health, HHS)

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material,