

that a collection of information entitled "Advisory Opinions" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 29, 1999 (64 FR 73056), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0193. The approval expires on March 31, 2003. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: April 7, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00-9134 Filed 4-12-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-0002]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Application for Exemption From Federal Preemption of State and Local Medical Device Requirements

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 May 15, 2000.

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: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

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.

Application for Exemption From Federal Preemption of State and Local Medical Device Requirements—21 CFR Part 808 (OMB Control No. 0910-0129)—Extension

Section 521(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360k(a)) provides that no State or local government may establish, or continue in effect, any requirement with respect to a medical device that is different from, or in addition to, any Federal requirement applicable to the device under the act. Under section 521(b) of the act, following receipt of a written application from the State or local government involved, FDA may exempt from preemption a requirement that is more stringent than the Federal requirement, or that is necessitated by

compelling local conditions and compliance with the requirement that would not cause the device to be in violation of any portion of any requirement under the act. Exemptions are granted by regulation issued after notice and opportunity for an oral hearing.

The regulations in 21 CFR 808.20 require a State or local government that is seeking an exemption from preemption to submit an application to FDA. The application must include a copy of the State or local requirement, as well as information about its interpretation and application, and a statement as to why the applicant believes that the requirement qualifies for exemption from preemption under the act. FDA will use the information in the application to determine whether the requirement meets the criteria for exemption in the act and whether granting an exemption would be in the interest of the public health.

In addition, 21 CFR 808.25 provides that an interested person may request a hearing on an application by submitting a letter to FDA following the publication by FDA of a proposed response to the application.

In the **Federal Register** of January 18, 2000 (65 FR 2631), the agency requested comments on the proposed collections of information. No significant comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
808.20	3	1	3	100	300
808.25	3	1	3	10	30
Total					330

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

FDA based its estimates of the number of submissions expected in the future contained in table 1 of this document on the number of submissions submitted in

the last 3 years and on the number of inquiries received indicating that applications would be submitted in the next year. FDA based its estimates of the

time required to prepare submissions on discussions with those who have prepared submissions in the last 3 years.

Dated: April 7, 2000.

William K. Hubbard,

*Senior Associate Commissioner for Policy,
Planning, and Legislation.*

[FR Doc. 00-9132 Filed 4-12-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 Cancer Institute Special Emphasis Panel, NCI Transition Career Development Award (K22).

Date: April 26, 2000.

Time: 2 pm to 6 pm.

Agenda: To review and evaluate grant applications.

Place: Fitzpatrick Manhattan Hotel, 687 Lexington Avenue, New York, NY 10022.

Contact Person: Mary Bell, Scientific Review Administrator, Grants Review Branch, National Cancer Institute, National Institutes of Health, 6130 Executive Boulevard, Rockville, MD 20892, 301/496-7978.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.396, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: April 5, 2000.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00-9185 Filed 4-12-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Environmental Health Sciences: Notice of 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 a meeting of the National Advisory Environmental Health Sciences Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Environmental Health Sciences Council, Agenda Available: <http://www.niehs.nih.gov/dert/c-agenda.htm>.

Date: May 15-16, 2000.

Open: May 15, 2000, 8:30 am to 5 pm.

Agenda: Director's Report and discussion of program policies and issues.

Place: Building 31C, Conference Room 6, National Institutes of Health, 3100 Center Drive, Bethesda, MD 20892.

Closed: May 16, 2000, 8:30 am to 2 pm.

Agenda: To review and evaluate grant applications and/or proposals.

Place: Building 31C, Conference Room 6, National Institutes of Health, 3100 Center Drive, Bethesda, MD 20892.

Contact Person: Anne P. Sassaman, Director, Division of Extramural Research and Training, Executive Secretary, National Institutes of Environmental, Health Sciences, NIH/PHS, P.O. Box 12233, Research Triangle Park, NC 27709, 919/541-7723.

(Catalogue of Federal Domestic Assistance Program Nos. 93.113, Biological Response of Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing; 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93-142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances-Basic Research and Education; 93.894, Resources and Manpower Development in the

Environmental Health Sciences, National Institutes of Health, HHS)

Dated: April 5, 2000.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00-9184 Filed 4-12-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Meetings

Pursuant to Public Law 92-463, notice is hereby given of the following meeting of the SAMHSA Special Emphasis Panel I in May 2000.

A summary of the meetings and a roster of the members may be obtained from: Ms. Coral Sweeney, Review Specialist, SAMHSA, Office of Policy and Program Coordination, Division of Extramural Activities, Policy, and Review, 5600 Fishers Lane, Room 17-89, Rockville, Maryland 20857. Telephone: 301-443-2998.

Substantive program information may be obtained from the individual named as Contact for the meeting listed below.

The meetings will include the review, discussion and evaluation of individual grant applications. These discussions could reveal personal information concerning individuals associated with the applications. Accordingly, these meetings are concerned with matters exempt from mandatory disclosure in Title 5 U.S.C. 552b(c) (6) and 5 U.S.C. App. 2, sec. 10(d).

Committee Name: SAMHSA Special Emphasis Panel I (SEP I).

Meeting Dates: May 1-4, 2000.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Closed: May 1-4, 2000, 8:30 a.m.-5 p.m./adjournment.

Panel: Community Action Grants, PA 000-003.

Contact: Michael Kosciński, Room 17-89, Parklawn Building, Telephone: 301-443-6094 and FAX: 301-443-3437.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

Dated: April 3, 2000.

Coral Sweeney,

Review Specialist, Substance Abuse and Mental Health Services Administration.

[FR Doc. 00-9208 Filed 4-12-00; 8:45 am]

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