

labeling) in electronic format based on the International Conference on Harmonisation Electronic Common Technical Document specification.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on providing applications and related submissions in electronic format. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

This notice contains no new collections of information. The information requested for human drug and biological products is already covered by the collection of information on postmarketing safety reporting regulations (21 CFR parts 312, 314, and 601) submitted to the Office of Management and Budget (OMB) for review and clearance. This notice announces the availability of a guidance that provides applicants with an alternative mechanism for submitting applications and related submissions to the agency.

IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/guidance/index.htm> or at <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: August 21, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03-22183 Filed 8-28-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on the National Health Service Corps; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), notice is hereby given of the following meeting:

Name: National Advisory Council on the National Health Service Corps.

Dates and Times: September 18, 2003, 5 p.m.–7 p.m.; September 19, 2003, 8:30 a.m.–5 p.m.; September 20, 2003, 9 a.m.–5:30 p.m.; and September 21, 2003, 8 a.m.–10:30 a.m.

Place: Embassy Suites Hotel Raleigh/Crabtree, 4700 Creedmoor Road, Raleigh, NC 27612, 919-881-0000.

Status: The meeting will be open to the public.

Agenda: The agenda will focus on the implementation of the National Health Service Corps program within the state of North Carolina. Meeting will further cover the continuing needs of health professional shortage areas within the state. Agenda items and times are subject to change as priorities dictate.

FOR FURTHER INFORMATION CONTACT: Tira Robinson, Division of National Health Service Corps, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 8A-55, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 594-4140.

Dated: August 21, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03-22073 Filed 8-28-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request: Pretesting of NCI Office of Communications Messages

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on April 3, 2003, page 16295 and allowed 60 days for public comment. No public comments

were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: Pretesting of NCI Office of Communications Messages.

Type of Information Collection Request: Extension (OMB # 0925-0046, expires 8/31/03).

Need and Use of Information Collection: In order to carry out NCI's legislative mandate to educate and disseminate information about cancer prevention, detection, diagnosis, and treatment to a wide variety of audiences and organizations (e.g., cancer patients, their families, the general public, health providers, the media, voluntary groups, scientific and medical organizations), the NCI Office of Communications (OC) needs to pretest its communications strategies, concepts, and messages while they are under development. The primary purpose of this pretesting, or formative evaluation, is to ensure that the messages, communication materials, and information services created by OC have the greatest capacity of being received, understood, and accepted by their target audiences. By utilizing appropriate qualitative and quantitative methodologies, OC is able to (1) understand characteristics of the intended target audience—their attitudes, beliefs and behaviors—and use this information in the development of effective communication tools and strategies; (2) produce or refine messages that have the greatest potential to influence target audience attitudes and behavior in a positive manner; and (3) expend limited program resource dollars wisely and effectively.

Frequency of Response: On occasion.

Affected Public: Individuals or households; Businesses or other for profit; Not-for-profit institutions; Federal Government; State, local or tribal Government.

Type of Respondents: Adult cancer patients; members of the public; health care professionals; organizational representatives.

The annual reporting burden is as follows:

Estimated Number of Respondents: 13,780;

Estimated Number of Responses per Respondent: 1;

Average Burden Hours Per Response: .1458; and

Estimated Total Annual Burden Hours Requested: 2,010. There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ellen Eisner, Communications Research Manager, OC Director's Office, NCI, NIH, Building 31, Room 10A03, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number (301) 435-7783 or e-mail your request, including your address to: EisnerE@occ.nci.nih.gov.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: August 21, 2003.

Reesa Nichols,

Project Clearance Liaison, NCI.

[FR Doc. 03-22085 Filed 8-28-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; 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 Institute of Environmental Health Sciences Special Emphasis Panel, Review of PO1 Applications.

Date: September 30, 2003.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Homewood Suites by Hilton-RDU Airport, 4603 Central Park Dr., Durham, NC 27703.

Contact Person: Leroy Worth, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, P.O. Box 12233, MD EC-30/Room 3171, Research Triangle Park, NC 27709, 919/541-0670, worth@niehs.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 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; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: August 22, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03-22083 Filed 8-28-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; 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, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel, Concept Review—"The Synthesis and Testing of Nonsteroidal and Nonhormonal Male Contraceptive Agents".

Date: September 17, 2003.

Time: 12 p.m. to 2 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Hameed Khan, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, National Institutes of Health, 6100 Executive Blvd., Room 5E01, Bethesda, MD 20892, (301) 435-6902, khanh@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: August 20, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03-22084 Filed 8-28-03; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Departmental Advisory Committee on Commercial Operations of the Bureau of Customs and Border Protection ("COAC")

AGENCY: Department of Homeland Security.