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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on providing applications and related submissions in electronic format.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persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance.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 The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.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]

BILLING CODE 4160–01–S

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]

BILLING CODE 4165–15–P

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