facilitate any communication which may be necessary between the parties to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the State at the hearing. The presiding officer may be reached at (410) 786–2055.

Sincerely,

Thomas A. Scully

Section 1116 of the Social Security Act (42 U.S.C. section 1316); 42 CFR Section 430.18)

(Catalog of Federal Domestic Assistance Program No. 13.714, Medicaid Assistance Program)

Dated: August 25, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 03–22245 Filed 8–28–03; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Community Services

Grant to the Rural Community Assistance Program

AGENCY: Office of Community Services, Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Award announcement.

CFDA: The Catalog of Federal Domestic Assistance (CFDA) number for this program is 93.570. The title is Rural Community Development Activities Program (RF Program).

Amount of Award: $500,000.

SUMMARY: Notice is hereby given that a noncompetitive grant award is being made to the Rural Community Assistance Program, Inc. to provide training and technical assistance to small communities struggling to deal with the safety and security of small and very small community water and wastewater treatment systems. This award addresses Congressional concern that many small and very small community water and wastewater treatment systems might be most vulnerable to terrorist attack, yet the least prepared to deal with the issues.

The application is not within the scope of any existing or expected to be issued program announcement for the Fiscal Year 2003—Rural Community Development Activities Program (RF) as authorized under the Community Services Block Grant Act of 1998, as amended; sections 680(a)(3)(B) of the Community Opportunities Accountability, and Training and Educational Services (COATES) Act (Pub. L. 105–285). This application is expected to provide valuable on-site training and technical assistance to small and very small communities struggling to deal with the safety and security of small community water and wastewater treatment systems. This announcement is inviting application for a 12-month budget period and a 24 month project period.

The funds are not being competed due to the Senate appropriation language in FY 2003 that directs the Office of Community Services to support a Rural Community Assistance Program Small Community Infrastructure Safety and Training and Technical project. Congress intends the funds to go to an organization that is capable of conducting a project that is national in scope that provides State, regional and national infrastructure safety training workshops and on-site technical assistance targeted to small and very small community water and wastewater treatment systems.

FOR FURTHER INFORMATION CONTACT: Administration for Children and Families, Office of Community Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Veronica Terrell—(202) 401–5295, *vterrell@acf.hhs.gov.*

Dated: August 22, 2003.

Clarence H. Carter,

Director, Office of Community Services.

[FR Doc. 03–22099 Filed 8–28–03; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0367]

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Applications and Related Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions.'' This is one in a series of guidance documents on providing regulatory submissions to FDA in electronic format. This guidance discusses issues related to the electronic submission of new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics licensing applications (BLAs), investigational new drug applications (INDs), master files, advertising material, and promotional labeling. The submission of these documents in electronic format should improve the agency's efficiency in processing, archiving, and reviewing them.

DATES: Submit written or electronic comments on the draft guidance by October 28, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Randy Levin, Center for Drug Evaluation and Research (HFD–001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301/594–5411, e-mail: *levinr@cder.fda.gov*, or

R. Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5349.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions.'' This draft document provides guidance to industry regarding submission of marketing applications (NDAs, ANDAs, BLAs), INDs, and related submissions (master files, advertising, and promotional

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