

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]

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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, verrell@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]

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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