Other Requirements

Paperwork Reduction Act

Projects that involve the collection of information from 10 or more individuals and funded by cooperative agreements will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations (45 CFR Part 46) regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing evidence of this assurance in accordance with the appropriate guidelines and forms provided in the application kit.

Women, Racial and Ethnic Minorities

It is the policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian, Alaskan Native, Asian, Pacific Islander, Black and Hispanic. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the Federal Register, Vol. 60, No. 179, pages 47947-47951, dated Friday, September 15, 1995.

Application Submission and Deadline

The original and two copies of the completed application PHS Form 5161-1 (revised 7/92, OMB Number 0937-0189) must be submitted to Sharron P. Orum, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mailstop E-18, Room 300, Atlanta, Georgia 30305, on or before May 30, 1997.

1. Deadline

Applications shall be considered as meeting the deadline if they are either:

a. Received on or before the deadline date, or
b. Sent on or before the deadline date and received in time for submission to the objective review group. (Applications must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks will not be acceptable as proof of timely mailings.)

2. Late Applications

Applications which do not meet the criteria in either 1.a. or 1.b. above are considered late applications. Late applications will not be considered and will be returned to the applicant.

Where To Obtain Additional Information

A complete program description, information on application procedures, an application package, and business management technical assistance may be obtained from Locke Thompson, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mailstop E-18, Room 300, Atlanta, GA 30305, telephone (404) 842-6595 or through the Internet or CDC WONDER electronic mail at: lxt1@cdc.gov. Programmatic technical assistance may be obtained from Matthew J. Kuehnert, M.D. or Marsha A. Jones, Hospital Infections Program, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), Mailstop E-69, Atlanta, GA 30333, telephone (404) 639-6413 or through the Internet or CDC WONDER electronic mail at: mgk6@cdc.gov. You may obtain this announcement from one of two Internet sites: CDC’s homepage at: http://www.cdc.gov or the Government Printing Office homepage (including free on-line access to the Federal Register) at: http://www.access.gpo.gov.

Please refer to Announcement Number 733 when requesting information and submitting an application.


Joseph R. Carter,
Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).
[FR Doc. 97-10829 Filed 4-25-97; 8:45 am]
BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 720]

Epidemiology and Laboratory Capacity for Infectious Diseases

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1997 funds for a cooperative agreement program to ensure adequate capacity of local, State, and national efforts to conduct epidemiology and laboratory surveillance and response for infectious diseases.

CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Immunization and Infectious Diseases. (For ordering a copy of Healthy People 2000, see the section WHERE TO OBTAIN ADDITIONAL INFORMATION.)

Authority

This program is authorized under sections 301(a) [42 U.S.C. 241(a)] and 317 [42 U.S.C. 247b] of the Public Health Service Act, as amended. Applicable program regulations are found in 42 CFR Part 51b, Project Grants for Preventive Health Services and 42 CFR Part 52, Grants for Research Projects.

Smoke-Free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products, and Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.
Eligible Applicants

Eligible applicants are limited to the official public health agencies of States or their bona fide agents. This includes the District of Columbia, American Samoa, the Commonwealth of Puerto Rico, the Virgin Islands, the Federated States of Micronesia, Guam, the Northern Mariana Islands, the Republic of the Marshall Islands, the Republic of Palau, and federally recognized Indian tribal governments. In addition, official public health agencies of county or city governments with jurisdictional populations greater than 2,500,000 (based on 1990 census data) are eligible to apply.

This announcement is an expansion of the State Epidemiology and Laboratory Surveillance and Response Program that was implemented in FY 1995 and FY 1996 with awards to 15 State and local public health agencies under Program Announcement 543. The intention of this announcement is to add new recipients to the 15 that are currently funded. Thus, the 15 recipients under Program Announcement 543 are ineligible to apply for funds provided through this announcement. The 15 State or local public health agencies currently funded are: Washington, Maine, Massachusetts, New York City, New York, New Jersey, West Virginia, Pennsylvania, Florida, Georgia, Louisiana, Kansas, Colorado, Hawaii, and County of Los Angeles.

Availability of Funds

Approximately $1,800,000 is available in FY 1997 to fund five to ten awards. It is expected that the average annual award amount (for both direct and indirect costs) will be approximately $200,000, ranging from $70,000 to $250,000. It is expected that the awards will begin on or about September 1, 1997, and will be made for a 12-month budget period within a project period of up to five years. Funding estimates may vary and are subject to change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress and availability of funds.

Although a requirement for matching funds is not a condition for receiving an award under this cooperative agreement program, applicants must document the non-Federal human and fiscal resources that will be available to conduct proposed activities. Federal funds cannot be used to replace or supplant existing State and local support. See APPLICATION CONTENT AND EVALUATION CRITERIA (section G: Budget) for additional information.

Use of Funds

Restrictions on Lobbying

Applicants should be aware of restrictions on the use of HHS funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352 (which has been in effect since December 23, 1989), recipients (and their subter contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying Congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition, the FY 1997 HHS Appropriations Act, which became effective October 1, 1996, expressly prohibits the use of 1997 appropriated funds for indirect or “grass roots” lobbying efforts that are designed to support or defeat legislation pending before State legislatures. This new law, Section 503 of Pub. L. No. 104–208, provides as follows:

Sec. 503(a) No part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress, * * * except in presentation to the Congress or any State legislative body itself.

(b) No part of any appropriation contained in this Act shall be used to pay the salary or expenses of any grant or contract recipient, or acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.


Background

Once expected to be eliminated as a public health problem, infectious diseases remain the leading cause of death worldwide. In the United States and elsewhere, infectious diseases increasingly threaten public health and contribute significantly to the escalating costs of health care. Despite the continued threat of infectious diseases and the emergence of new, re-emergent and drug-resistant diseases, the public health infrastructure of the United States is often inadequately prepared to support the surveillance necessary for early detection and response to public health threats from infectious diseases. These deficiencies were made clear in a series of National Academy of Science, Institute of Medicine, reports published between 1987 and 1992. Emerging Infections, Microbial Threats to Health in the United States, published in 1992, provided specific recommendations to address these deficiencies and emphasized a critical leadership role for both CDC and State health departments in a national effort to detect and control infectious disease threats.

In partnership with other Federal agencies, State and local health departments, academic institutions, and others, CDC has developed a plan for revitalizing the nation’s ability to identify, contain, and prevent illness from emerging infectious diseases. The plan, Addressing Emerging Infectious Disease Threats; A Prevention Strategy for the United States, identifies objectives in four major areas: surveillance, applied research; prevention and control; and infrastructure. The plan proposes three major domestic surveillance activities:

1. Strengthening the local and State public health infrastructures for infectious disease surveillance and response;
2. Establishing provider-based sentinel surveillance networks; and,
3. Establishing population-based emerging infections programs to conduct surveillance and applied epidemiologic, laboratory, and prevention research. This announcement addresses the first objective—strengthening the local and State public health infrastructure for infectious disease surveillance.

Concern about the quality of surveillance data and its ability to support good public health decision-making has led to a reevaluation of public health surveillance by the Council of State and Territorial Epidemiologists (CSTE) and the CDC. CSTE and CDC are working to improve public health surveillance by such approaches as utilization of laboratories as sources of surveillance information and development of sentinel surveillance methodology to complement the traditional “notifiable diseases” approach. These goals are consistent with directions outlined by CDC’s new Health Information Surveillance Systems (HISS) Board.
Purpose

The purpose of this cooperative agreement is to assist State and eligible local public health agencies in strengthening and enhancing basic capacity for public health surveillance and response for infectious diseases. Awardees are intended to support the development or enhancement of existing basic surveillance and response capacity with a focus on notifiable diseases; food-, water- and vector-borne diseases; vaccine-preventable diseases; and drug-resistant infections. In this regard, strengthening collaboration between laboratory and epidemiology practice is seen as a crucial component. Additional epidemiologic or laboratory components addressing infectious diseases problems of particular State or local importance may also be supported.

Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for describing activities A.1 through A.3 below (including A.4 if that is a described program activity for that State or eligible official public health agency of county or city government), and CDC will be responsible for conducting activities under B., below:

A. Recipient Activities

1. Develop public health capacity for surveillance and response for infectious diseases, including flexible surveillance and response capability to meet the challenges of new and emerging infectious diseases.
2. Strengthen the collection and use of surveillance information from clinical, epidemiologic, and laboratory sources to improve early response and disease intervention activities.
3. Monitor and evaluate scientific and operational accomplishments and progress in achieving the purpose of this program. Prepare reports and publications to disseminate scientific and programmatic findings.
4. Develop and implement long- and short-term training for epidemiology and laboratory staff that is consistent with the purpose of this announcement.

B. CDC Activities

1. Provide consultation and assistance in establishing enhanced reporting from laboratories and health care practitioners and in developing response capability.
2. Assist in monitoring and evaluating scientific and operational accomplishments and progress in achieving the purpose of this program.

Technical Reporting Requirements

Narrative progress reports are required semiannually. The first semiannual report is required with each year’s non-competing continuation application and should cover program activities from date of the previous report (or date of award for reporting in the first year of the project). The second semiannual report is due with the Financial Status Report (FSR) 90 days after the end of each budget period and should cover activities from the date of previous report. All progress reports should address the following: (1) Status of each recipient activity; (2) Impact of recipient activities in addressing gaps in surveillance and response capacity; and (3) Progress toward overall objectives as related to the PURPOSE and Recipient Activities sections of this announcement. An original and two copies of all reports are required.

An original and two copies of the FSR are required no later than 90 days after the end of each budget period.

The final performance report and FSR are due no later than 90 days after the end of the project period. All reports are submitted to the Grants Management Officer, CDC. (See section on APPLICATION SUBMISSION AND DEADLINE for address.)

Notification of Intent to Apply

In order to assist CDC in planning and executing the evaluation of applications submitted under this program announcement, all parties intending to submit an application are requested to inform CDC of their intention to do so not later than 10 working days prior to the application due date. Notification can be provided by facsimile, postal mail, or E-mail to Greg Jones, M.P.A., Funding Resources Specialist, Office of Administrative Services, National Center for Infectious Diseases, 1600 Clifton Road, NE., Mailstop C–19, Atlanta, Georgia 30323, facsimile: (404) 639–4195, E-mail address: gj1@cdc.gov.

Application Content and Evaluation Criteria

The application should be presented in a manner that demonstrates the applicant’s ability to address the proposed activities in a collaborative manner with CDC based upon information contained in this announcement and the instructions outlined below.

All pages must be clearly numbered and a complete index to the application and its appendices must be included. To facilitate photocopying, do not bind, staple, or paper clip any pages of any copy of the application, including appendices. Do not include any bound documents in the appendices. Do not include cardboard, plastic, or other page separators between sections. The entire application must be typewritten, single spaced, and in unredacted type on 8½” by 11” white paper, with at least 1” margins, including headers and footers, and printed on one side only.

Provide a brief abstract (no more than two pages) of the application. The application narrative should be limited to 12 pages (excluding abstract and appendices) and must contain the following sections in the order presented. The narrative must stand by itself; it should not refer the reader to the appendices for any details essential to understanding the application. For each section the criteria by which the applications will be reviewed and evaluated are listed:

A. Understanding the objectives of the State Epidemiology and Laboratory Capacity Building Program: Evaluation criteria: (10 points).
   - The extent to which the applicant demonstrates a clear understanding of the background and objectives of this program.

B. Description of the population under surveillance, either the State or other appropriate jurisdiction (if an applicant is a county, city, or other agency): Evaluation criteria: (5 points).
   - The extent to which the applicant clearly describes the population size, demographic characteristics, racial/ethnic makeup, and public health delivery systems for Medicaid and Medicare patients.

C. Description of existing public health infectious disease epidemiology and laboratory capacity: Evaluation criteria: (15 points).
   - The extent to which the applicant describes the scope of its existing surveillance and response activities in infectious diseases with respect to epidemiology and laboratory activities. Extent to which the applicant includes descriptions of reporting requirements, spectrum of laboratory specimen testing performed, degree of automation of laboratory and epidemiologic information management, and public health response capacity.
   - The extent to which the applicant describes existing staffing, management, material and equipment investment, training, space, and financial support of laboratory and epidemiologic capacity for public health surveillance and response for infectious diseases.
   - The extent to which the applicant demonstrates current collaboration between its epidemiology and laboratory programs in laboratory-based
surveillance and health care practitioner surveillance, including the existence of, or potential for, integrated uses of surveillance data;

b. Describes current or previous collaborative relationships with clinical laboratories, local health agencies, academic medicine groups, and health care practitioners, including HMOs or managed care providers;

c. Demonstrates the potential of these relationships for enhanced surveillance and public health response activities; and

d. Demonstrates an understanding of the interaction between public health, managed care, and the health care delivery system.

D. Identification of areas of need in public health surveillance and response for infectious diseases: Evaluation criteria: (20 points).

The extent to which the applicant:

1. Identifies State and local needs in epidemiology and laboratory capacity for public health surveillance and response for infectious diseases.

2. Describes steps to be taken to facilitate and strengthen collaboration between epidemiology and laboratory practice, utilizing recent developments in laboratory and computer technologies (e.g., molecular characterization of pathogens, electronic reporting, and computer networks with database systems that facilitate sharing of information).

3. Identifies specific important diseases or conditions (e.g., notifiable diseases, foodborne and waterborne diseases, vaccine-preventable diseases and drug-resistant infections) which will be addressed.

E. Operational Plan (Note: Provide a detailed description of first year activities only and briefly describe future year activities): Evaluation criteria: (40 points).

The extent to which the applicant presents a plan for addressing the identified needs which:

1. Clearly describes the proposed organizational and operating structure/ procedures, staffing plan, participating agencies, organizations, institutions, and key individuals;

2. Outlines a clear plan of activities that will be undertaken to address the identified needs in capacity;

3. Outlines a clear plan of activities that will be undertaken to address the specific diseases for conditions to be addressed;

4. Provides current letters of support from participating agencies, institutions, and organizations indicating their willingness to participate in major surveillance and public health response initiatives; and

5. Is consistent with, and adequate to achieve, the needs identified and the purpose and objectives of this program.

F. Plan for monitoring and evaluation: Evaluation criteria: (10 points).

The extent to which the applicant describes a detailed plan both for how they will monitor the implementation of the project and how they will evaluate the impact of the project.

G. Provide a detailed budget with a line-item justification and any other information to demonstrate that the request for assistance is consistent with the purpose and objectives of this cooperative agreement program.

Although matching funds is not a condition for receiving an award under this program, include in the budget, a separate line-item accounting of non-Federal contributions (funding, personnel, and other resources) that will be directly allocated to the proposed activities. Identify any non-applicant sources of these contributions.

Evaluation criteria: (Not Scored).

The extent to which the proposed budget is reasonable, clearly justifiable, and consistent with the intended use of cooperative agreement funds. The extent to which the applicant provides detailed information on non-Federal contributions.

Executive Order 12372 Review

Applications are subject to Intergovernmental Review of Federal Programs as governed by Executive Order 12372. E.O. 12372 sets up a system for State and local government review of proposed Federal assistance applications. Applicants (other than federally recognized Indian tribal governments) should contact their State Single Point of Contact (SPOC) as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC for each affected State. A current list of SPOCs is included in the application kit. Indian tribes are strongly encouraged to request tribal government review of the proposed application. If SPOCs or tribal governments have any process recommendations on applications submitted to CDC, they should forward them to Sharron P. Orum, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mailstop E–18, Atlanta, Georgia 30305, on or before Monday, June 16, 1997. No applications or additional materials will be accepted after the deadline.

1. Deadline

Applications will be considered as meeting the deadline if they are either:

a. Received on or before the deadline date; or

b. Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

2. Late Applications

Applications which do not meet the criteria in 1.a. or 1.b. above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Where To Obtain Additional Information

To receive additional written information call (404) 332–4561. You
will be asked to leave your name, address, and telephone number and will need to refer to Announcement 720. You will receive a complete program description, information on application procedures, and application forms.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Oppie M. Byrd, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mailstop E–18, Atlanta, Georgia 30305, telephone: (404) 842–6546, facsimile: (404) 842–6513, E-mail: oxb3@cdc.gov.

Programmatic technical assistance may be obtained from Pat McConnon, M.P.H., National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), Mailstop C–12, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone: (404) 639–2175, E-mail: pjm2@cdc.gov.

Please refer to Announcement 720 when requesting information regarding this program.


Joseph R. Carter, Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Savannah River Site Health Effects Subcommittee.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention (CDC), announce the following meeting.

Name: Citizens Advisory Committee on Public Health Service Activities and Research at DOE Sites: Savannah River Site Health Effects Subcommittee (SRS).

Times and Dates: 8:30 a.m.–5 p.m., May 15, 1997, 8:30 a.m.–12 noon, May 16, 1997.

Place: Holiday Inn Select, 130 Clairmont Avenue, Decatur, Georgia 30030.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Background: Under a Memorandum of Understanding (MOU) signed in December 1990 with DOE, the Department of Health and Human Services (HHS) was given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production use. HHS has delegated program responsibility to CDC.

In addition, an MOU was signed in October 1990 and renewed in November 1992 between ATSDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR’s public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or “Superfund”). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List, and sites that are the subject of petitions from the public, and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

Purpose: This subcommittee is charged with providing advice and recommendations to the Director, CDC, and the Administrator, ATSDR, regarding community, American Indian Tribes, and labor concerns pertaining to CDC’s and ATSDR’s public health activities and research at this DOE site. Activities shall focus on providing a forum for community, American Indian Tribal, and labor interaction and serve as a vehicle for community concern to be expressed as advice and recommendations to CDC and ATSDR.

Matters to be Discussed: Agenda items include: presentations from the National Center for Environmental Health (NCEH) regarding current activities and the National Institute for Occupational Safety and Health and ATSDR will provide updates on the progress of current studies. Agenda items are subject to change as priorities dictate.

Contact Persons for More Information: Paul G. Renard or Nadine Dickerson, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, (F–35), Atlanta, Georgia 30341–3324, telephone 770/488–7040, FAX 770/488–7044.


Carolyn J. Russell, Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

Food and Drug Administration

[Docket No. 97N–0143]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

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 (the PRA).

DATES: Submit written comments on the collection of information by May 28, 1997.

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: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507) FDA has submitted the following proposed collection of information to OMB for review and clearance.

Citizen Petition—21 CFR Part 10.30—(OMB Control Number 0910–0183—Reinstatement)

The Administrative Procedure Act (5 U.S.C. 553(e)) provides that every agency shall accord any interested person the right to petition for issuance, amendment, or repeal of a rule. Section 10.30 (21 CFR 10.30) provides that any person may submit to the agency a citizen petition requesting the Commissioner of Food and Drugs to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.