

#### 4. Project Management and Staffing (10 points)

The extent to which applicant identifies professional and support staff who have the knowledge, experience, and authority to carry out recipient activities as evidenced by job descriptions, curricula vitae, organizational charts, etc.

#### 5. Evaluation (10 points)

The quality of the proposed plan for monitoring progress in achieving the purpose and overall goals of this program.

#### 6. Budget (Not Scored)

The extent to which the proposed budget is reasonable, clearly justifiable, and consistent with the intended use of cooperative agreement funds.

#### Executive Order 12372 Review

Applications are subject to Intergovernmental Review of Federal Programs as governed by Executive Order (E.O.) 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 Clara M. Jenkins, 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 314, Atlanta, GA 30305. The due date for State process recommendations is 30 days after the application deadline date for new and competing continuation awards. (A waiver for the 60 day requirement has been requested). The granting agency does not guarantee to "accommodate or explain" for State process recommendations it receives after that date.

#### Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

#### Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.283.

#### Other Requirements

##### *Paperwork Reduction Act*

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

#### Application Submission and Deadline

The original and two copies of the application Form PHS-5161-1 (Revised 7/92, OMB Control Number 0937-0189) must be submitted to Clara M. Jenkins, 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 August 21, 1995.

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. (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

A complete program description and information on application procedures are contained in the application package. Business management technical assistance may be obtained from Gordon R. Clapp, 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) 842-6508.

Programmatic technical assistance may be obtained from Robert W. Pinner, M.D., Special Assistant for Surveillance, Office of the Director, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), Mailstop C-12, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone (404) 639-2603.

Please refer to Announcement Number 539 when requesting information regarding this program.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017-001-00474-0) or Healthy People 2000 (Summary Report, Stock No. 017-001-00473-1) referenced in the INTRODUCTION through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

Potential applicants may obtain a copy of Addressing Emerging Infectious Disease Threats: A Prevention Strategy for the United States through the Centers for Disease Control and Prevention (CDC), National Center for Infectious Diseases, Office of Planning and Health Communication—EP, Mailstop C-14, 1600 Clifton Road, NE., Atlanta, Georgia 30333. Requests may also be sent by facsimile to (404) 639-3039.

Dated: July 17, 1995.

**Joseph R. Carter,**

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

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BILLING CODE 4163-18-P

#### [Announcement Number 543]

#### Cooperative Agreement for State Epidemiology and Laboratory Surveillance and Response

##### Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1995 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.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led 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

PHS 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 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 3,500,000 (based on 1990 census data) are eligible.

#### Availability of Funds

Approximately \$2,000,000 is available in FY 1995 to fund eight to twelve awards. It is expected that the average award will be approximately \$170,000, ranging from \$70,000 to \$250,000. It is expected that the awards will begin on or about September 30, 1995, 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.

#### Purpose

The purpose of this cooperative agreement is to assist State public health agencies in strengthening, maintaining, and enhancing capacity for public health surveillance and response for infectious diseases.

Awards are intended to support the enhancement of existing basic surveillance and response capacity including the development and application of innovative surveillance approaches with a focus on notifiable diseases, foodborne and waterborne diseases, and drug-resistant infections.

#### Program Requirements

In conducting activities to achieve the purpose of this program, the recipient shall be responsible for addressing some or all of the activities under A., below, and CDC shall 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. Implement public health surveillance and response measures for infectious diseases surveillance.

3. Develop and apply innovations in public health surveillance and response for infectious diseases. Examples of such innovations include:

a. Enhance rapid reporting of infectious diseases from clinical laboratories, such as electronic reporting of data already existing in clinical laboratory computer databases;

b. Integrate laboratory-based and clinician-based surveillance information;

c. Develop sentinel approaches for surveillance for certain infectious diseases;

d. Develop relationships with managed care organizations to conduct infectious disease surveillance within their patient populations;

e. Improve use of existing sources of information for infectious diseases surveillance, such as development of a system for surveillance of pneumonia through radiology records, or trends in emergency room visits for diarrhea or pneumonia; and

f. Serve as a regional resource for State health laboratory activities in one or more specific areas, for example, serotyping of *E. coli* or subtyping of legionella from suspected outbreaks.

4. Develop an approach for integrating surveillance information from the State epidemiology and laboratory units to improve early response and disease intervention activities.

5. Develop and implement a plan to ensure that clinical laboratories submit isolates of designated organisms of public health importance to the State laboratory. Plans should be flexible enough to include new infectious

disease problems such as those which occurred with Hantavirus, *E. coli* 0157:H7, and recent multidrug resistant organisms.

6. Develop and implement long- and short-term training for epidemiology and laboratory staff that is consistent with the purpose of this agreement.

7. Monitor and evaluate scientific and operational accomplishments and progress in achieving the purpose of this program.

##### 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.

3. Assist in supporting training activities for the development of epidemiology and laboratory staff in recipient States.

#### Evaluation Criteria

The applications will be reviewed and evaluated according to the following weighted criteria:

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

B. Description of area under surveillance: The extent to which the applicant clearly describes the following information for the State (or appropriate jurisdiction if applicant is a county, city, or other agency): demographic characteristics, population, geographic size, distribution of racial/ethnic minorities, and existing healthcare delivery systems for Medicaid and Medicare patients. (5 points)

C. Description of existing public health infectious disease epidemiology and laboratory capacity. (15 points)

1. 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.

2. 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.

3. The extent to which the applicant:

a. Describes collaboration between its existing epidemiology and laboratory programs in terms of laboratory-based surveillance and health care practitioner surveillance, including the existence of or potential for an integrated surveillance approach;

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 emerging health care delivery system.

D. Identification of areas of need and potential areas for innovation in public health surveillance and response for infectious diseases:

1. The extent to which the applicant identifies and describes needs in capacity (epidemiology and laboratory) for public health surveillance and response for infectious diseases. (25 points)

2. The extent to which the applicant identifies potential areas for development and application of innovative approaches to surveillance and response for infectious diseases (15 points). Examples include, but are not limited to:

a. Enhancement of rapid reporting of infectious disease from clinical laboratories for diseases in which such laboratories are an important source of surveillance information;

b. Integration of laboratory-based and clinician-based surveillance information;

c. Development of sentinel approaches for surveillance for certain infectious diseases;

d. Development of relationships with managed care organizations to conduct infectious disease surveillance within their patient populations;

e. Exploration of existing sources of data for infectious diseases surveillance (e.g., vital statistics, hospital discharge records, radiology records, insurance claims data, pharmacy records, and data from managed care organizations and HMOs); and

f. Service as a regional resource for State health laboratory activities in one or more specific areas, for example, serotyping of *E. coli* or subtyping of legionella from suspected outbreaks.

E. Operational Plan (25 points):

1. The extent to which the applicant:

a. Presents a plan for building capacity for public health surveillance and response for infectious diseases which clearly describes the proposed organizational and operating structure/procedures, staffing plan, participating agencies, organizations, institutions, and key individuals;

b. Describes plans for using the surveillance data to help implement public health responses; and

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

2. The extent to which the applicant's plan includes development and application of innovative approaches to surveillance and response for infectious diseases (examples of which are listed in paragraph D., above). The extent to which the applicant identifies specific important diseases or conditions (e.g., notifiable diseases, foodborne and waterborne diseases, and drug-resistant infections) which will be addressed. If applicant proposes to serve as a regional resource for State health laboratory activities, the extent to which the applicant specifies: (1) activities (e.g., providing regional testing for Hantavirus, or other infections or diseases) and (2) States that will be served (including letters of support from these States).

3. The extent to which applicant's plan is consistent with, and adequate to achieve, the purpose and objectives of this program.

F. The extent to which the applicant describes a detailed plan for monitoring and evaluation that will show the operational achievements and impact of the project. (5 points)

G. The extent to which the proposed budget is reasonable, clearly justifiable, and consistent with the intended use of cooperative agreement funds. (Not Scored)

#### Executive Order 12372 Review

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Programmatic technical assistance may be obtained from Pat McConnon, 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, Email Address: PJM2@CIDOD1.EM.CDC.GOV.

Please refer to Announcement Number 543 when requesting information regarding this program.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017-001-00474-0) or Healthy People 2000 (Summary Report, Stock No. 017-001-00473-1) referenced in the Introduction through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

Dated: July 17, 1995.

**Joseph R. Carter,**

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

[FR Doc. 95-18023 Filed 7-20-95; 8:45 am]

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**Food and Drug Administration**

[Docket No. 95N-0173]

**Procter & Gamble Pharmaceuticals, Inc., et al.; Withdrawal of Approval of NADA's**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of 16 new animal drug applications (NADA's). Fourteen NADA's are held by Procter & Gamble Pharmaceuticals, Inc., and one each is held by Lemmon Co. and Happy Jack, Inc. The firms notified the agency in writing that the animal drug products were no longer marketed and requested that the approval of the applications be withdrawn. In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the regulations by removing the entries which reflect approval of the NADA's.

**EFFECTIVE DATE:** July 31, 1995.

**FOR FURTHER INFORMATION CONTACT:** Mohammad I. Sharar, Center for Veterinary Medicine (HFV-216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1722.

**SUPPLEMENTARY INFORMATION:** The sponsors of the applications listed in the table in this document have informed FDA that these animal drug products are no longer marketed and have requested that FDA withdraw approval of the applications.

NADA No.	Drug name	Sponsor name and address
10-158	Furamazone, bismuth subsalicylate bolus	Procter & Gamble Pharmaceuticals, Inc., P.O. Box 191, Norwich, NY 13815
10-358	Nitrofurantoin tablets and boluses	do
12-291	Nitrofurantoin oral suspension	do
12-612	Nitrofurazone, nifuroxime, dipiperodon hydrochloride (HCl) ear solution.	do
34-716	Buquinolate	do
35-314	Buquinolate and bacitracin zinc	do
35-315	Buquinolate, bacitracin zinc, and penicillin	do
35-317	Buquinolate and penicillin	do
35-327	Buquinolate, bacitracin methylene disalicylate (bacitracin MD), and penicillin.	do
35-329	Buquinolate and bacitracin MD	do
38-657	Buquinolate and chlortetracycline	do
39-925	Buquinolate and roxarsone combination	do
39-926	Buquinolate and roxarsone	do
41-744	Nitrofurantoin sodium injection	do
95-017	Etorphine HCl injection and diprenorphine HCl injection.	Lemmon Co., Sellersville, PA 18960
115-580	Piperazine adipate powder	Happy Jack, Snow Hill, NC 28580

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADA's 10-158, 10-358, 12-291, 12-612, 34-716, 35-314, 35-315, 35-317, 35-327, 35-329, 38-657,

39-925, 39-926, 41-744, 95-017, 115-580, and all supplements and amendments thereto is hereby withdrawn, effective July 31, 1995..

In a final rule published elsewhere in this issue of the **Federal Register**, FDA is removing 21 CFR 520.1560, 520.1560a, 520.1560b, 520.1801, 520.1801a, 522.1563, 524.1580a, 558.62(c)(2)(v), 558.105,

558.128(c)(5)(iii), 558.325(c)(3)(iv), 558.460(c)(2)(v), and 558.530(d)(3)(vii), and amending 21 CFR 510.600(c), 522.723, and 522.883 to reflect the withdrawal of approval of the above mentioned NADA's.