Dated: May 26, 2002.

Sandra R. Manning,

CGFM, Director, Procurement and Grants Office, Center for Disease Control and Prevention (CDC).

[FR Doc. 02–13780 Filed 5–31–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02169]

Enhanced Surveillance for Newly Vaccine Preventable Diseases; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2002 funds to expand the current New Vaccine Surveillance Network (NVSN) cooperative agreement program to conduct broader-based surveillance and research projects. This program complements existing local, State, and national surveillance efforts and facilitates research on issues related to new vaccine introduction or new vaccine policies and their impact. This program addresses the ''Healthy People 2010'' focus area, Immunization and Infectious Diseases. The purpose of the program is to support a network of sites that provide surveillance and data collection on new vaccine use, the impact of new vaccines, and new vaccine policies through enhanced inpatient and outpatient surveillance, applied epidemiologic research, and investigator-initiated investigations. The two current NVSN sites are affiliated with the University of Rochester, NY, and Vanderbilt University, TN. They are currently in year three of the project.

As new vaccines are licensed and recommended for use, new strategies are needed for surveillance and monitoring. The NVSN currently conducts surveillance and studies in children, but future NVSN activities could extend to the adult population. CDC has identified several areas that are considered programmatic priorities: (1) Population-based collection of clinical and etiological data from children hospitalized for selected current and prospective vaccine preventable diseases such as viral respiratory illnesses caused by influenza, respiratory syncytial virus (RSV), and parainfluenza; (2) collection of similar data from a representative sample of outpatients such that conclusions drawn can be considered population-based; (3) collection of data on illnesses and syndromes among outpatients and inpatients that may be affected by use of new vaccines (e.g., otitis media, lobar pneumonia); and (4) assessment of the impact of new vaccines or policies on clinical practices. CDC also values the flexibility to respond to emerging issues as new vaccines are introduced and new questions arise.

B. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301, 317(k)(1) and 2102(a) of the Public Health Service Act, [42 U.S.C. sections 241, 247b(k), and 300aa–2(a)], as amended. The Catalog of Federal Domestic Assistance number is 93.185.

C. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, faith-based organizations, community-based organizations, other public and private nonprofit organizations, health departments of States or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, federally recognized Indian tribal governments, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau.

Preference will be given to applicants whose geographic areas are not covered by an existing NVSN site.

Note: Title 2 of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award or loan.

D. Availability of Funds

Approximately $500,000 is available in FY 2002 to fund one award. It is expected that the award will begin on or before September 30, 2002, and will be made for a 12-month budget period within a project period of up to five years. Funding estimates may change.

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

Use of Funds

Funds cannot be used for construction or renovation, to purchase or lease vehicles or vans, to purchase a facility to house project staff or carry out project activities, or to supplant existing support.

E. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities shown below under item 1. Recipient Activities, and CDC will be responsible for the activities listed under item 2. CDC Activities.

1. Recipient Activities

a. Establish and operate an NVSN site. To effectively function as part of this network, the site should have the following characteristics and capabilities:

(1) Be established in a defined population, which could include either an entire state or a geographically defined area (or areas) within a state, in order to conduct population-based surveillance. A minimum population base of approximately 500,000 persons may be necessary to accomplish the objectives of certain NVSN activities (e.g., obtaining population-based estimates of influenza and RSV in children less than five years of age).

(2) Have the capacity to simultaneously conduct population-based inpatient surveillance for Acute Respiratory Illness (ARI) among children less than five years old, outpatient ARI surveillance in a representative sample of children, and two other joint projects with one or more of the other NVSN sites. As examples, ongoing projects include: analysis of an existing database to assess vaccine impact among outpatients in the study area, chart reviews from a broad sample of pediatric care providers in the community to assess uptake of Pneumococcal Conjugate Vaccine (PCV) and its clinical impact and impact on vaccination practices (e.g., timeliness in administering other vaccines, number of injections per vaccination visit, etc.).

(3) Have the flexibility to accommodate changes in specific projects and priorities as the public health system's need for information changes or new vaccines are licensed and implemented into the vaccination program. Function effectively as part of a network where projects and protocols are developed collaboratively among investigators at the NVSN sites and CDC.

(4) Have an established relationship with pediatric care providers in both inpatient and outpatient facilities so that surveillance and other studies can be conducted with them during the first year of participation.

b. Develop plans for obtaining additional support to supplement assistance from CDC.

c. Have a relationship with state and local health departments, and other public and private organizations, that have an interest in addressing public health issues relating to new vaccines.

d. Conduct activities addressing section d.(1) through d.(4), below. As an option, propose an additional study addressing section d.(5) that can be implemented as a network-wide project or that can be completed at the recipient's site with or without the participation of other NVSN sites. Specific protocols for activities conducted at more than one surveillance site must be developed collaboratively by investigators at those sites and CDC. Specific protocols for activities conducted at a single site must be approved by CDC.

(1) Conduct year-round enhanced surveillance according to NVSN protocol, for selected current and prospective vaccine preventable diseases by performing the following activities in all surveillance area hospitals that admit children less than five years old: Provide staff to screen admissions year-round and enroll children with ARIs; collect information on demographics, insurance coverage, medical history, risk factors, hospital course, admission and discharge diagnoses, and laboratory results from parents and medical records; collect nasal and throat swabs from all enrolled children; perform viral culture and Polymerase Chain Reaction (PCR) testing for influenza, RSV, and parainfluenza on all collected samples (PCR primers will be supplied by CDC); conduct quality assurance checks of the data in accordance with NVSN procedures; and enter data and send it to CDC using the NVSN web-based data collection system. Have the flexibility to extend surveillance to other vaccine preventable diseases (e.g., pertussis) which may require the conduct of other laboratory tests.

(2) Conduct surveillance similar to that described in section d.(1) among a representative sample of children less than five years old seen at outpatient practices in the surveillance area such that results can be considered population-based. Only PCR will be used to test specimens from outpatients.

(3) Study the impact of incorporating new vaccines on provider policies, practices, and utilization. Collect data from a network of pediatric outpatient care providers to document the impact of new vaccines recommended for routine use among children, potentially including combination vaccines.

(4) Investigate the impact of new vaccines on disease burden and health care utilization through analysis of local databases. Have established access, or propose developing one or more data sources that are representative of children in the surveillance area. Possible sources of data include insurance databases, managed care organization data, Medicaid databases, or other sources that would include vaccination and disease burden data.

(5) Develop and conduct other applied epidemiologic and/or health services research projects related to new vaccine introduction. Examples of completed or current projects include: ARI inpatient surveillance of about 1,000 patients recruited during the first 18 surveillance months; complementary outpatient surveillance of ARIs; analyses of Medicaid and private insurance databases to assess the impact of PCV on the burden of pneumococcal disease-related outcomes; survey of provider attitudes and practices regarding PCV; conduct a feasibility study of implementing a recommendation for universal influenza vaccination of young children 6–35 months old (focus groups, national provider survey, time and motion study in seven practices, and a database analysis).

e. Routinely evaluate progress in achieving the purpose of this program.

f. Analyze and interpret data from NVSN projects, and publish and disseminate findings in collaboration with CDC.

2. CDC Activities

a. Provide CDC investigator(s) to monitor the NVSN cooperative agreement as project officer(s). At least one CDC investigator will be assigned to each NVSN project.

b. Provide consultation, scientific, and technical assistance in designing and conducting individual NVSN projects.

c. Assist in the development of research protocols for Institutional Review Boards (IRB) review by all cooperating institutions participating in the research projects. For each protocol, the CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

d. As needed and arranged with investigators, perform laboratory evaluation of specimens or isolates (e.g., molecular epidemiologic studies, evaluation of diagnostic tools) obtained in NVSN projects; provide PCR primers and quality control specimens; and integrate results with data from other NVSN sites.

e. Manage, maintain, and update the secure, encrypted CDC web-based system which is used by the NVSN for data entry of ARI surveillance data at the sites, transfer of data from sites to CDC, merging of data from NVSN sites, and creation of data sets and data summaries which are accessible by each site. Each NVSN site will be able to download only its own site's raw data through the web-based system.

f. Analyze and interpret data from NVSN projects, and publish and disseminate findings in collaboration with NVSN site investigators.

F. Content

Applications

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Applications will be evaluated based on the criteria listed in this program announcement, so it is important to follow them in preparing your program plan. The narrative (excluding budget, appendices, and required forms) should be no more than 30 single-spaced pages, printed on one side, with one-inch margins, and 12 point font. Only the following information should be presented in appendices: Letters of support, documentation of bona fide agent status, curricula vitae of key project personnel, and budget. Letter of support should clearly indicate collaborators' willingness to be participants in the NVSN activities. All other materials or information that should be included in the narrative will not be accepted if placed in the appendices.

Applicants should propose at least one project from the activities provided in Program Requirements. Each specific project proposal should be clearly identified in a distinct portion of the Operational Plan and should not exceed four pages. Descriptions should include objectives, methods, analytic approach, and illustrative sample size calculations recognizing that data from two or more sites may be aggregated for analysis. Although the specific activities described address distinct issues and needs, they may be implemented in an integrated manner such that staff members work on more than one activity, and supplies and equipment are shared, etc. The specific project proposal(s) will be reviewed as a potential project that could be conducted under the award, but the NVSN may choose not to conduct the project depending on other NVSN competing interests, needs, and resources.

Since enhanced surveillance will be done in collaboration with the other NVSN sites, most projects will need to be designed so that data can be integrated with data from the other sites. The ARI surveillance data from hospitals and outpatient clinics must be merged with data from other sites. Some local databases of vaccination or disease burden (e.g., registries or insurance company data) may be proprietary; however, for joint NVSN projects, the data can be analyzed locally and presented in joint publications.

This would require that variables be available and defined in a way that is compatible with data from other sites. Sites are expected to make every effort to ensure that data can be integrated with those of other NVSN sites.

In describing the impact of incorporation of new vaccines on provider policies, practices, and utilization (Recipient activities, d.(3)), applicants may include, but are not limited to, a description of the number of vaccine and injections offered at visits during the first two years of life; vaccine-specific coverage rates of all recommended vaccines at specified ages, both before and after incorporating new vaccines; the number of visits used to complete administration of all recommended vaccine by ages one and two; and revenues and costs associated with incorporating new vaccines in practice.

Budget Instructions:

For each line-item (as identified on the Form 424a of the application), show both Federal and non-Federal (e.g., State or other funding) shares of total cost for the NVSN. For each staff member listed under the Personnel line item, indicate their specific responsibilities relative to each of the proposed projects. Include provisions for the principal investigator and one NVSN participant to travel to two meetings at CDC in Atlanta during the first year of participation, and one meeting at CDC in Atlanta during subsequent years of participation.

G. Submission and Deadline

Application

Submit the original and two copies of PHS 5161–1. Forms are available in the application kit and at the following Internet address: *www.cdc.gov/od/pgo/forminfo.htm.* On or before July 15, 2002, submit the application to: Technical Information Management-PA02169, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Rd, Room 3000, Atlanta, GA 30341–4146.

Deadline: Applications shall be considered as meeting the deadline if they are received on or before the deadline date.

H. Evaluation Criteria

Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals as stated in section ''A. Purpose'' of this announcement. Measures must be objective and quantitative and must measure the intended outcome. These measures of effectiveness shall be submitted with the application and shall be an element of evaluation.

Each application will be evaluated against the following criteria by an independent review group appointed by CDC:

1. Surveillance and Research Plan (30 points)

The application will be evaluated based on: (a) Methodology for conducting population-based surveillance among inpatients at all surveillance area hospitals; (b) methodology for conducting population-based surveillance among outpatients at a representative sample of outpatient practices; and (c) quality of the proposed additional research projects, as requested in the Application Content section above, regarding objectives, methodology/design, feasibility, and collaboration and participation of partner organizations and CDC. The applicant also must state the degree to which they have met CDC policy requirements regarding representation of women, ethnic, and racial groups in the proposed research, including: (1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation; (2) the proposed justification when representation is limited or absent; (3) a statement as to whether the design of the study is adequate to measure differences when warranted; (4) a statement as to whether plans for recruitment and outreach for study participants include the process of establishing partnerships with community ties and recognition of mutual benefits.

2. Personnel Qualifications and Management Plan (30 points)

The extent to which the applicant can demonstrate qualifications for establishing an NVSN site and managing projects will be evaluated: (a) The extent to which the applicant's plan for establishing and operating the NVSN site clearly describes the organizational structure and procedures and identifies all participating persons and groups including identifying key professional staff and their roles and responsibilities; (b) past experience of key professional staff in conducting work similar to that proposed in this announcement (provide curriculum vitae of each in appendix); (c) identifying key professional personnel from other collaborating organizations, agencies, etc. outside of the applicant's agency who will participate in NVSN activities (provide curriculum vitae for each in an appendix), with roles described; (d) description of support staff and services to be assigned to the NVSN; (e) description of approach to flexible staffing to accommodate the changing requirements of NVSN projects that may occur due to changing public health needs and new vaccines or vaccine policies.

3. Description of Existing Relationships With Pediatric Vaccination Providers in the Surveillance Area and Ability to Obtain Their Participation for Surveillance and Research Activities (20 points)

The extent to which the applicant demonstrates: (a) Past experience working with pediatric inpatient facilities and outpatient care providers in conducting epidemiologic and health services research of vaccines or other health care practices or interventions; (b) the ability to develop and maintain strong cooperative relationships broadly with both public and private vaccine providers at the NVSN site, including public health agencies, academic centers, managed care organizations, and community organizations; and (c) support from non-applicant participating agencies, institutions, organizations, laboratories, consultants, etc. indicated in applicant's operational plan. Applicant should provide (in an appendix) letters of support which clearly indicate collaborators' willingness to contribute to NVSN activities. Do not include letters of support from CDC personnel.

4. Description of the Population Base and the Vaccine Providers in the NVSN Site (10 points)

The extent to which the applicant provides a: (a) Clear definition of the geographic area and population base in which the NVSN site will operate; (b) description of the demographics of the proposed population base including a description of various special populations as they relate to the proposed activities of the NVSN site; and (c) description of vaccination providers within the NVSN site and

availability of or participation in a vaccination registry.

5. Understanding the Objectives of the NVSN (5 points)

The extent to which the applicant demonstrates: (a) A clear understanding of the background and objectives of this cooperative agreement program; (b) a clear understanding of the requirements, responsibilities, problems, constraints, and complexities that may be encountered in establishing and operating the NVSN site; (c) a clear understanding of the roles and responsibilities of participation in the NVSN network.; and (d) knowledge and understanding of current research and activities performed in this area, past studies, and existing literature.

6. Evaluation (5 points)

The quality of the plan for monitoring and evaluating the quality of vaccine coverage data, quality and timeliness of laboratory data, completeness of case ascertainment, population representativeness of surveillance data, and the scientific and operational accomplishments of the NVSN site and individual NVSN projects, including plans to monitor and evaluate progress in achieving the goals of the cooperative agreement program.

7. Budget (not scored)

The application will be evaluated on the extent to which the line-item budget is detailed, clearly justified, consistent with the purpose and objectives of the program, and reflects both Federal and non-Federal (e.g., State funding) shares of total cost for the NVSN site.

If requesting funds for any contracts, provide the following information for each proposed contract: name of proposed contractor, breakdown and justification for estimated costs, description and scope of activities to be performed by contractor, period of performance, and method of contractor selection (e.g., sole-source or competitive solicitation).

8. Human Subjects (not scored)

The application should adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects. (not scored; however, an application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable).

I. Other Requirements

Technical Reporting Requirements

Applicants should submit an original plus two copies of:

1. Annual progress reports. The results of the Measures of Effectiveness shall be a data requirement to be submitted with or incorporated into progress report.

2. Financial status report, no more than 90 days after the end of the budget period.

3. Final financial report and performance report, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I of the announcement.

AR–1 Human Subjects Requirements
AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–8 Public Health System Reporting Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions
AR–14 Accounting System Requirements
AR–15 Proof of Non-Profit Status
AR–22 Research Integrity

J. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC home page Internet address—*http://www.cdc.gov.* Click on ''Funding'' then ''Grants and Cooperative Agreements.''

For business management assistance contact: Peaches Brown, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta GA 20241–4146, Telephone number: 770–488–2738, E-mail address: *prb0@cdc.gov.*

For program technical assistance, contact:

Ben Schwartz, M.D., Epidemiology and Surveillance Division, National Immunization Program, Centers for Disease Control and Prevention, 1600 Clifton Road, MS E–61, Atlanta GA 30333, Phone: 404–639–8254, E-mail: *bxs1@cdc.gov.*

Marika K. Iwane, Ph.D., M.P.H., Epidemiology and Surveillance Division, National Immunization Program, Centers for Disease Control and Prevention, 1600 Clifton Road, MS E–61, Atlanta GA 30333, Phone: 404–639–8257, E-mail: *miwane@cdc.gov.*

Dated: May 26, 2002.

Sandra R. Manning,

CGFM, Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 02–13779 Filed 5–31–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Prospective Grant of Exclusive License: Systems and Methods for Aerosol Delivery of Agents

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This is a notice in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i) that the Centers for Disease Control and Prevention (CDC), Technology Transfer Office, Department of Health and Human Services (DHHS), is contemplating the grant of a worldwide exclusive license to practice the inventions embodied in the patent application referred to below to D. J. Schweihs of Nashville, Tennessee. The patent rights in these inventions have been assigned to the government of the United States of America. The patent application to be licensed is:

Title: Systems and Methods for Aerosol Delivery of Agents. U.S. Patent Application Serial No. 60/276,539.

Filing Date: 03/15/01.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7.

This invention comprises an aerosol vaccination system designed for the administration of measles vaccine. The device is a hand held, battery powered ultrasonic nebulizer which delivers vaccine to the respiratory tract via disposable nasal prongs. The prototype vaccine is measles; however, this device may be adapted for any vaccine suitable for respiratory administration.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments, and other materials relating to the contemplated license should be directed to Andrew Watkins, Director, Technology Transfer Office, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, Mailstop K–79, Atlanta, GA 30341, telephone: (770)