

better meet its overall room night demand, and allow travelers to find lodging close to where they need to conduct business. After an analysis of this additional data, the maximum lodging amount published in the **Federal Register** at 67 FR 56160, August 30, 2002 and amended at 67 FR 69634, November 18, 2002, and 68 FR 25034, May 9, 2003, is being changed in the following location:

*State of California*

- City of San Diego.

### B. Change in standard procedure

Since per diem rates frequently change, effective April 28, 2003 (68 FR 22314), the Office of Governmentwide Policy (OGP), GSA, will issue/publish the CONUS per diem rates, formerly published in Appendix A to 41 CFR Chapter 301, solely on the internet at <http://www.qsa.gov/perdiem>. This new process will ensure more timely increases or decreases in per diem rates established by GSA for Federal employees on official travel within CONUS. This notice advises agencies of revisions in per diem rates prescribed by OGP for CONUS. Notices published periodically in the **Federal Register**, such as this one, now constitute the only notification of revisions in CONUS per diem rates to agencies.

Dated: May 20, 2003.

**David A. Drabkin,**

*Acting Associate Administrator.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Program Announcement 03032]

#### Addressing Asthma From a Public Health Perspective; Notice of Availability of Funds

*Application Deadline:* July 14, 2003.

#### A. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301 and 317 of the Public Health Service Act [42 U.S.C. section 241 and 247b], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

#### B. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2003

funds for a cooperative agreement program for "Addressing Asthma from a Public Health Perspective." This program addresses the "Healthy People 2010" focus areas Environmental Health, Occupational Safety and Health, and Respiratory Diseases.

The purpose of the program is to provide the impetus to begin development of program capacity to address asthma from a public health perspective in order to bring about: (1) A focus of asthma-related activity within the agency; (2) an increased understanding of asthma-related data and its application to program planning through development of an ongoing surveillance system; (3) an increased recognition within the public health structure of the state or territory of the potential to use a public health approach to reduce the burden of asthma; (4) linkages of the agency to the many agencies and organizations addressing asthma in the population; and (5) participation in intervention program activities. Epidemiological surveillance is "the ongoing systematic collection, analysis, and interpretation of health data essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those who need to know. The final link in the surveillance chain is the application of these data to prevention and control. A surveillance system includes a functional capacity for data collection, analysis, and dissemination linked to public health programs." Refer to Boss, L.; Kreutzer, R.; Luttinger, D.; Leighton, J.; Wilcox, K.; and Redd, S. The Public Health Surveillance of Asthma, *Journal of Asthma*, 38(1), 83-89, 2001.

This program announcement has three parts: (1) Part A: Developing State Capacity to Address Asthma, (2) Part A Enhanced: Enhancing State Capacity to Address Asthma, and (3) Part B: Implementation of State Asthma Plans.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Center for Environmental Health (NCEH): Reduce the burden of asthma.

#### C. Eligible Applicants

Applications may be submitted by:

- Federally recognized Indian tribal governments.
- Indian tribes.
- Indian tribal organizations.
- State public health departments or their bona fide agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands,

American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau).

*Part A: Developing State Capacity to Control Asthma.* Eligible applicants are those entities listed above that do not have a final, approved, comprehensive, asthma plan or a well-developed asthma surveillance system. Grantees currently funded by CDC Announcement #99109, #01106, or #02085 are not eligible to apply because they have already received funds to conduct activities in Part A: Developing State Capacity to Control Asthma. See Attachment II for a list of states funded by these announcements. All attachments referenced in this announcement are posted with the announcement on the CDC Web site, Internet address: <http://www.cdc.gov>, click on "Funding", then click on "Grants and Cooperative Agreements."

*Part A Enhanced: Enhancing State Capacity to Address Asthma.* Eligible applicants are those entities that are currently funded by CDC Announcement #99109, are in the latter stages of finishing the capacity building process, and are preparing to begin implementing interventions. These states are Colorado, Iowa, Maine, New Jersey, New Mexico, Rhode Island, and Vermont.

Applicants for Part A Enhanced: Enhancing State Capacity to Address Asthma must:

1. Submit a copy of the final, approved, comprehensive State Asthma Plan. Approval can be documented with a letter from the Agency's Health or Medical Director and letters from key partners or by appropriate sign-offs on the asthma plan. Plans that are pending final approval may be accepted if the draft plan is accompanied by letters from the Agency's Health or Medical Director and key partners stating their commitment to and approval of the plan, a time frame for final approval, as well as a description of the plan's approval process status.

2. Have an operational surveillance system for asthma. This may be demonstrated through submission of your most recent and comprehensive published surveillance report that describes asthma within the jurisdiction, including, if available, a report on asthma in the Medicaid population.

Applications for Part A Enhanced: Enhancing State Capacity to Address Asthma that fail to submit evidence requested will be considered non-responsive and returned without review.

*Part B: Implementation of State Asthma Plans.* Eligible applicants are those entities that have a final, approved, comprehensive, State Asthma Plan and an operational surveillance system for asthma. The states of California, Illinois, Michigan, Minnesota, New York, and Oregon are not eligible to apply for any parts: Part A: Developing State Capacity to Address Asthma; Part A Enhanced: Enhancing State Capacity to Address Asthma; or Part B: Implementation of State Asthma Plans, because they are currently funded by CDC Program Announcement #01106 (Part B) or #02085 to implement State asthma activities. See Attachment II for a list of states funded by these announcements.

Applicants for Part B: Implementation of State Asthma Plans must:

1. Submit a copy of the final, approved, comprehensive State Asthma Plan. Approval may be documented with a letter from the Agency's Health or Medical Director and letters from key partners or by appropriate sign-offs on the asthma plan. Plans that are pending final approval may be accepted if the draft plan is accompanied by letters from the Agency's Health or Medical Director and key partners stating their commitment to and approval of the plan. Include a description of the plan's approval process status.

2. Have an operational surveillance system for asthma. This may be demonstrated through submission of your most recent, comprehensive published surveillance report that describes asthma within the State, territory, tribe, or jurisdiction, including, if available, a report on asthma in the Medicaid population.

*Applications for Part B:* Implementation of State Asthma Plans that fail to submit evidence requested will be considered non-responsive and returned without review.

Based on eligibility requirements described in Section C Eligible Applicants, an applicant may apply for:

- Part A: Developing State Capacity to Address Asthma,
- \* Part A Enhanced: Enhancing State Capacity to Address Asthma,
- \* Part B: Implementation of State Asthma Plans, or
- Any combination

However, only one award per applicant will be made. Applicants must submit a separate application for each part they are applying for.

**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, grant or loan.

## D. Funding

### *Availability of Funds*

Approximately \$4,450,000 is available in FY 2003 to fund approximately 9–12 awards.

Part A: Developing State Capacity to Address Asthma. Approximately \$600,000 is available to fund approximately one to three awards. It is expected that the average award will be \$200,000.

### *Part A Enhanced: Enhancing State Capacity to Address Asthma*

Approximately \$2,450,000 is available to fund approximately seven awards. It is expected that the average award will be \$350,000.

### *Part B: Implementation of State Asthma Plans.*

Approximately \$1,400,000 is available to fund approximately one to two awards. It is expected that the average award will be \$700,000.

It is expected that awards under this program announcement will begin on or about August 1, 2003 and will be made for a 12-month budget period for the first year that will end on August 31, 2004. The project period for Part A: Developing State Capacity to Address Asthma will be up to three years, Part A Enhanced: Enhancing State Capacity to Address Asthma for up to three years, and Part B: Implementation of State Asthma Plans for 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*

Cooperative agreement funds may be used to support costs directly related to the program activities and consistent with the scope of the cooperative agreement. Funds under this program announcement may not be used to conduct research projects. Surveillance and evaluation activities that are for the purposes of monitoring program performance are not considered research. Funds under this program announcement may not be used for screening or registry activities. Federal funds awarded under this program announcement may not be used to supplant State or local funds.

### *Recipient Financial Participation*

Matching funds are not required for this program.

### **Funding Preferences**

Funding preferences may include (1) geographic distribution, and (2) racial

and ethnic populations with a disproportionate asthma burden.

## E. Program Requirements

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

### *Part A: Developing State Capacity To Address Asthma*

#### 1. Recipient Activities

- a. Implement a new (or enhance an existing) asthma surveillance system in order to gather and interpret data that will quantify the burden of asthma within the State, and upon which to base the development of the State Asthma Plan. Include asthma morbidity, mortality and work-related asthma.

- b. Develop a comprehensive State Asthma Plan.

- c. Develop and implement an evaluation plan that measures the effectiveness of the program as a whole as well as each intervention. Systematically document lessons learned.

- d. Develop and organize collaborative linkages with appropriate agencies and organizations statewide to together (1) systematically describe the asthma problem in the State; (2) identify available resources; and (3) in conjunction with partners, develop a comprehensive State Asthma Plan.

- e. Establish a strong agency commitment within the State Health Department to support the asthma program.

- f. Participate in CDC convened meetings and periodic conference calls for grantees to share experiences, data, and materials.

### *Part A Enhanced: Enhancing State Capacity To Address Asthma*

#### 1. Recipient Activities

- a. Enhance the existing asthma surveillance system to include asthma hospitalizations. Conduct analysis and interpretation of surveillance data and disseminate these data through reports to local, State, and Federal partners and agencies.

- b. If not already completed, obtain final approval for a comprehensive State Asthma Plan. This activity should be completed within three months of the year one budget period.

- c. Implement a subset of interventions described in the State Asthma Plan.

- d. Develop and implement an evaluation plan that measures the effectiveness of your program as a whole as well as each intervention.

Systematically document lessons learned.

e. Maintain existing or expand (as appropriate) statewide coalition and partnership activities; including a workgroup to address work-related asthma if one does not exist. Include as members of this workgroup representatives from State governmental agencies (e.g. state department of labor), Federal agencies, public health agencies, and professional care organizations conducting or interested in occupational health activities.

f. Maintain a strong agency commitment within the State Health Department to support continued efforts of the asthma program.

g. Participate in CDC convened meetings and periodic conference calls for grantees to share experiences, data, and materials.

#### *Part B: Implementation of State Asthma Plans*

##### 1. Recipient Activities

a. Expand existing surveillance efforts for, but not limited to, asthma prevalence, severity, management, mortality, hospitalizations, emergency care, costs of asthma and other indicators in order to monitor the effectiveness of the intervention activities. Include surveillance of work-related asthma.

b. Conduct analysis and interpretation of surveillance data and disseminate these data through appropriate surveillance reports to local, state, and federal partners and agencies.

c. Develop and implement an evaluation plan that measures the effectiveness of your program as a whole and each intervention. Systematically document lessons learned.

d. Maintain existing statewide coalition and partnership activities to oversee implementation and evaluation of the State Asthma Plan. Expand partnership activities as appropriate.

e. Implement defined aspects of the final, approved, comprehensive State Asthma Plan. Maintain existing asthma-related activities currently underway in the health agency and expand as appropriate. Assure institutionalization of asthma intervention activities.

f. Maintain a strong agency commitment within the State Health Department to support continued efforts of the asthma program.

g. Participate in CDC convened meetings and periodic conference calls for grantees to share experiences, data, and materials.

2. CDC Activities for Part A: Developing State Capacity to Address Asthma, Part A Enhanced: Enhancing State Capacity to Address Asthma, and Part B: Implementation of State Asthma Plans

a. Participate with recipients in further development and enhancement of existing surveillance activities, including data collection methods and data analysis.

b. Collaborate with recipients on data analysis and interpretation of individual state surveillance data and release of surveillance reports.

c. Provide technical and scientific assistance and consultation on program development, implementation of the State Asthma Plan, intervention activities and operational issues.

d. Serve as a facilitator for communication between states to share expertise regarding various topics, including the expansion and development of partnerships, implementation of State Asthma Plans, and surveillance activities.

e. Facilitate working group conference calls with recipients.

f. Collaborate on the development of an appropriate evaluation plan that measures the effectiveness of the program as a whole and each intervention.

g. Convene meetings and periodic conference calls for grantees to share experiences, data, and materials.

#### **F. Content**

##### *Letter of Intent (LOI)*

A LOI is optional for this program. The Program Announcement title and number must appear in the LOI. The narrative should be no more than one page, double-spaced, printed on one side, with one-inch margins, and unreduced 12-point font. Your letter will be used to ascertain the level of interest in this announcement and to assist in determining the size and composition of the independent review panel. It should include the following information:

1. Name and address of organization.
2. Name, address, telephone number, fax number, and e-mail address of the organization's primary contact for writing and submitting the application.
3. A clear description of which part of the program announcement (Part A: Developing State Capacity To Address Asthma, Part A Enhanced: Enhancing State Capacity to Address Asthma, Part B: Implementation of State Asthma Plans, or any combination) you are applying for.

##### *Applications*

The Program Announcement title and number must appear in the application.

Use the information in the Program Requirements, Other Requirements, Evaluation Criteria, and this section to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 30 pages for Part A: Developing State Capacity to Address Asthma, 35 pages for Part A Enhanced: Enhancing State Capacity to Address Asthma, or 40 pages for Part B: Implementation of State Asthma Plans, double-spaced, printed on one side, with one-inch margins, and unreduced 12-point font. The application must be submitted unstapled and unbound. Appendices are limited to a maximum of 100 pages and must be submitted unstapled and unbound.

#### Part A: Developing State Capacity To Address Asthma

Include each of the following sections:

##### 1. Description of the Problem

Describe what is known about the asthma burden in the State, territory, tribe, or jurisdiction and efforts to begin to systematically address the problem. Identify existing initiatives, capacity, and infrastructure of the agency within which asthma programs will occur. Describe the barriers that need to be addressed to develop a comprehensive asthma program in the State.

##### 2. Workplan

Provide specific goals, objectives, and activities that describe what the agency intends to accomplish by the end of the three-year project period. These goals, objectives and activities should be measurable, realistic, related to Recipient Activities, and reflect activities in year one, two, and three of the project. Include a project time-line that indicates when the proposed goals, objectives, and activities will be met. Document how progress made toward meeting the objectives will be evaluated. Provide measures for evaluating process, impact, and outcome for each goal and objective. Refer to "Framework for Program Evaluation in Public Health," *Morbidity and Mortality Weekly Report*, September 17, 1999/48(RR-11); 1-40 at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4811a1.htm> or other evaluation resources on the CDC website at <http://www.cdc.gov/eval/index/>.

In addition, describe how lessons learned will be systematically gathered, documented, and included as an integral part of the program evaluation process.

### 3. Surveillance Plan

Describe the current operational asthma surveillance system within the health agency (if one exists). Provide a surveillance plan containing the following information: (a) A description of data currently available to the program; (b) additional data the agency will obtain and methods for obtaining it; (c) plans for identifying specific populations at-risk for poorly controlled asthma (e.g. gender, age groups, racial/ethnic groups, socio-economic groups, and/or geographic areas); (d) how the agency will use data to develop (or enhance) an ongoing surveillance system; and (e) how the surveillance data will be used to support policy, program development, implementation, and evaluation activities. At a minimum, the surveillance system should include measures to track asthma morbidity, asthma mortality, and work-related asthma. For more information about work-related asthma, refer to:

“Surveillance of Work-Related Asthma in Selected U.S. States Using Surveillance Guidelines for State Health Departments—California, Massachusetts, Michigan and New Jersey, 1993–1995,” *Morbidity and Mortality Weekly Report*, June 25, 1999/48 (SS03); 1–20 at <http://www.cdc.gov/mmwr/preview/mmwrhtml/ss4803a1.htm>.

Workgroup Report “The Role of States in a Nationwide Comprehensive Surveillance System for Work-related Diseases, Injuries and Hazards” at <http://www.cste.org/occupationalhealth.htm>.

“Minimum and Comprehensive State-Based Activities in Occupational Safety and Health,” June 1995—DHHS (NIOSH) Publication No. 95–107 at <http://www.cdc.gov/niosh/95-107.html>.

Applicants funded by this announcement will be expected to use the Behavioral Risk Factor Surveillance System (BRFSS) supplemental asthma module within the first year of the project.

Describe a strategy to conduct analysis, interpret surveillance data, and disseminate data through published reports to local, state, and federal partners and agencies.

Present a detailed plan for evaluating whether the asthma surveillance system is useful for monitoring trends over time. Refer to “Updated Guidelines for Evaluating Surveillance Systems, Recommendations from the Guidelines Working Group,” *Morbidity and Mortality Weekly Report*, July 27, 2001/ (50)RR–13; 1–35 or <http://www.cdc.gov/mmwr/preview/mmwrhtml/r5013a1.htm>

### 4. State Asthma Plan

Describe the process by which a comprehensive State Asthma Plan will be developed. The plan must address all persons with asthma in the State regardless of age, race/ethnicity, gender or geographic area. Include key environments in which persons with asthma spend significant time (e.g. home, school, and workplace). If a specific population in the State is not affected by asthma, clearly identify and describe this population.

Include information about the agencies and organizations that will participate in developing the State Asthma Plan. Describe each partner’s roles and responsibilities. Explain how the collaborative relationships will be used after the plan is in place and the agency is ready to implement interventions.

Describe how data collected in the asthma surveillance system will be used to identify priority areas and guide the development of program goals and objectives. Explain how the State Asthma Plan will evolve and change based on surveillance data, evaluation of interventions, and other outside factors that affect the overall climate in the State.

### 5. Collaboration Plan

Describe experiences with collaborative relationships around asthma or with other chronic or environmentally-related or occupationally-related disease requiring extensive collaborative relationships both within and outside the agency. Specifically define the approach to be used to establish or further develop these relationships.

Document partnerships with the clinical community; local health agencies; physician organizations; community health centers; local, State, or regional asthma or respiratory health organizations (such as the American Lung Association); local education authorities; and groups or organizations that serve minority or other populations experiencing a disproportionate burden of asthma. If one or more of these partners will not be included, the applicant should explain why.

Describe how the collaboration will (1) establish leadership, (2) develop consensus regarding goals, (3) identify roles and responsibilities of members, (4) develop procedures and patterns of communications, and (5) sustain the participation of members over time.

Provide letters of commitment from each specific organization, including a statement of how they intend to collaborate, as well as their expertise,

and capacity to carry out assigned responsibilities.

Grant funds may be used to leverage asthma program development in the State, territory, tribe or jurisdiction along with resources from other agencies and organizations.

Present a plan to determine the effectiveness of collaborations.

### 6. Management and Staffing Plan

Demonstrate the applicant’s organizational commitment to the asthma program by describing how the agency as a whole will focus its efforts on asthma. Provide a plan to maintain a strong commitment within the State Health Department to support continued efforts of the asthma program.

Describe the organizational location of the proposed staff, their relation to the State’s asthma contact (the position in the agency currently responsible for contact with CDC on asthma issues), and the support within the organizational structure for the activities defined for the project staff. Attach an organizational chart for the unit where asthma activities will be located and, at a minimum, the next two levels above it.

Describe the qualifications and roles of trained public health professionals to serve as a full-time asthma coordinator for the agency to manage the planning process and conduct other programmatic activities; a full-time epidemiologist to develop and implement surveillance activities for the asthma project; and a supervisor who will assure support for the project staff. Other program positions may also be proposed. Attach position descriptions, qualifications, and curricula vitae for all staff positions.

For each position, describe the primary roles and responsibilities for the project staff over the three-year grant period. Also, include the specific staff activities that will contribute to meeting each objective.

Provide a plan to expedite filling of the staff position(s) and assure that they have been or will be approved by the applicant’s personnel system. Include a letter of support from the agency guaranteeing hiring of personnel and support for the asthma program. Also, describe positions in the asthma program that are currently filled, but will not be funded by resources under this cooperative agreement.

Document assurance of the ability of key project staff to participate in conferences or grantee meetings convened by CDC and willingness to share innovations, information, data, and materials.

## 7. Budget

Include a detailed first-year budget and narrative justifications as well as annual budget projections for years two and three. The applicant should describe the program purpose for each budget item. For each contract contained within the budget, provide (1) the name the contractor(s); (2) method of selection; (3) period of performance; (4) description of activities; and (5) an itemized budget with narrative justifications. If this information is not available when the application is submitted, and the contract(s) is approved by the CDC, then the funds for the contract(s) will be restricted for expenditure on the award.

The budget should include travel funds for project staff to attend a yearly conference or grantee meeting convened by CDC. In addition, the applicant should include costs for one person to travel to Atlanta, GA, to attend the 6th National Environmental Health Conference on December 3–5, 2003. Review the CDC/NCEH web site for additional information concerning this conference: <http://www.cdc.gov/nceh/default.htm>.

List other funds, outside this cooperative agreement, that will be used to support this program.

### Part A Enhanced: Enhancing State Capacity To Address Asthma

#### 1. Description of the Problem

Describe what is known about the asthma burden in the State, territory, tribe or jurisdiction and efforts to systematically address the problem. Include a description of populations at increased risk of poorly controlled asthma (e.g. gender, age groups, racial/ethnic groups, socio-economic groups, and geographic areas).

Identify existing initiatives, capacity, and infrastructure of the agency within which the asthma programs will occur.

Describe how barriers, identified when developing the State Asthma Plan, were addressed.

#### 2. Workplan

Provide specific goals, objectives, and activities that describe what the agency intends to accomplish by the end of the three-year project period. These goals, objectives and activities should be measurable, realistic, related to Recipient Activities, and reflect activities in year one, two, and three of the project. Include a project time-line that indicates when the proposed goals, objectives, and activities will be met.

Document how progress made toward meeting the objectives will be evaluated. Provide measures for evaluating

process, impact, and outcome for each goal and objective. Refer to "Framework for Program Evaluation in Public Health," *MMWR*, September 17, 1999/48 RR-11; 1–40 at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4811a1.htm> or other evaluation resources on the CDC website at <http://www.cdc.gov/eval/index/>.

In addition, describe how lessons learned will be systematically gathered, documented, and included as an integral part of the evaluation process.

#### 3. Surveillance Plan

Describe the current operational asthma surveillance system within the health agency. Submit copies of the most recent and comprehensive published surveillance report that describes asthma within the State, territory, tribe or jurisdiction, including if available, a report of asthma in the Medicaid population and for enrollees of the State Children's Health Insurance Program (CHIP).

Provide a surveillance plan containing the following information: (a) A description of data currently available to the program; (b) additional data the agency will obtain and methods for obtaining it; (c) plans for identifying specific populations at risk for poorly controlled asthma (e.g. gender, age groups, racial/ethnic groups, socio-economic groups, or geographic areas); (d) how the agency will use data to develop or enhance an ongoing surveillance system; and (e) how the surveillance data will be used to support policy, program development, implementation, and evaluation activities.

At a minimum, the surveillance system should include measures to track asthma morbidity, asthma mortality, work-related asthma, and asthma hospitalizations. For more information about work-related asthma, refer to the following references:

"Surveillance of Work-Related Asthma in Selected U.S. States Using Surveillance Guidelines for State Health Departments—California, Massachusetts, Michigan and New Jersey, 1993–1995," *Morbidity and Mortality Weekly Report*, June 25, 1999/48 (SS03); 1–20 at <http://www.cdc.gov/mmwr/preview/mmwrhtml/ss4803a1.htm>.

Workgroup Report "The Role of States in a Nationwide Comprehensive Surveillance System for Work-related Diseases, Injuries and Hazards" at <http://www.cste.org/occupationalhealth.htm>.

"Minimum and Comprehensive State-Based Activities in Occupational Safety and Health," June 1995—DHHS

(NIOSH) Publication No. 95–107 at <http://www.cdc.gov/niosh/95-107.html>.

Applicants funded by this announcement will be expected to use the Behavioral Risk Factor Surveillance System (BRFSS) supplemental asthma module within the first year of the project.

Describe the methods that will be used to conduct analysis, interpret surveillance data, and a strategy for disseminating data through published reports to local, State, and Federal partners and agencies.

Present a detailed plan to determine whether the asthma surveillance system is useful for monitoring asthma trends over time, determining the effectiveness of interventions, and modifying the State Asthma Plans. Refer to "Updated Guidelines for Evaluating Surveillance Systems," *Morbidity and Mortality Weekly Report*, July 27, 2001/(50)RR13; 1–35 at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5013a1.htm>.

#### 4. State Asthma Plan

Submit a copy of the final, approved, comprehensive State Asthma Plan. Approval may be documented with a letter from the agency's Health or Medical Director and letters from key partners or by appropriate sign-offs on the plan. State Asthma Plans that are pending final approval may be accepted if the draft plan is accompanied by letters from the agency's Health or Medical Director and key partners stating their commitment to and approval of the plan, a time frame for final approval, as well as a description of the approval process status. The letters should assure that the State Asthma Plan would be completed within the first three months of the year one budget period.

Describe the process by which the comprehensive State Asthma Plan was developed and how it addresses all persons with asthma in the State regardless of age, race/ethnicity, gender, or geographic area and includes key environments in which persons with asthma spend significant time (e.g. home, school, workplace). If a specific population in the State is not affected by asthma, clearly identify and describe this population.

Include information about the agencies and organizations that are participating in the planning process and describe their roles and responsibilities.

Explain how the collaborative relationships will be used after the plan is in place and the agency is ready to implement interventions.

Describe how data collected in the asthma surveillance system is used to

identify priority areas and guide the development of program goals and objectives. If a State Asthma Plan already exists, describe the subset of interventions to be implemented with these grant funds. Note that a statewide approach is encouraged. If focusing on one part of the state's population, explain and justify the rationale for this approach.

Proposed activities to meet the plan's objectives may include, but are not limited to, efforts to (1) expand surveillance for asthma; (2) improve provider compliance with the National Asthma Education and Prevention Program's (NAEPP) "Guidelines for the Diagnosis and Management of Asthma," (Clinical Practice Guidelines, Guidelines for the Diagnosis and Management of Asthma. National Institutes of Health (NIH), National Heart, Lung and Blood Institute. NIH publication No. 97-4051, April 1997); (3) improve the skills of patients and families affected by asthma to manage the disease; (4) review legislation and policies impacting people with asthma; (5) identify environmental factors that contribute to asthma prevalence and morbidity, and reduce or eliminate exposure to these factors; and (6) communicate between those implementing and those affected by planned activities.

Explain how the State Asthma Plan will evolve and change based on analysis of surveillance data, evaluation of interventions, and other outside factors that affect the overall climate in the State.

#### 5. Collaboration Plan

Describe experiences with collaborative relationships around asthma or with other chronic or environmentally-related or occupationally-related disease requiring extensive collaborative relationships both within and outside the agency. Specifically define the approach to be used to establish or further develop these relationships.

Document partnerships with the clinical community; local health agencies; physician organizations; community health centers; local, State, or regional asthma or respiratory health organizations (e.g. American Lung Association); local education authorities, and groups or organizations that serve minority or other populations experiencing a disproportionate burden of asthma. If one or more of these partners is not listed, the applicant should explain why.

Describe how the collaboration (1) established leadership, (2) developed consensus regarding goals, (3) identified

roles and responsibilities, (4) developed procedures and patterns for communication, (5) and sustained the participation of members over time.

Provide letters of commitment from each specific organization, including a statement of how they are or intend to collaborate, as well as their expertise, and capacity to carry out assigned responsibilities.

Describe how the partners who developed the State Asthma Plan will continue to work together to implement and monitor the intervention strategies and modify the plan over time. Expand partnership activities as appropriate.

Grant funds may be used to leverage asthma program development in the State, territory, tribe or jurisdiction along with resources from other collaborative agencies and organizations.

#### 6. Implementation Plan

Provide specific, realistic, measurable, and time-phased objectives for each of the interventions to be implemented over the three-year project period using resources of this announcement. If objectives and interventions from the plan are addressed using other resources, explain how they are related. While the overall State Asthma Plan must address all populations, interventions should be prioritized based on surveillance data, focusing on high priority and disparate populations first.

Interventions that change systems and individuals to provide improved disease management or education are preferred. This discussion might include the guidelines that the applicant will use for work-related asthma (e.g., adapted from generic Minimum and Comprehensive State-Based Activities in Occupational Safety Health, June 1995—DHHS (NIOSH) Publication No. 95-107) at <http://www.cdc.gov/niosh/95-107.html>; or from the Workgroup Report "The Role of States in a Nationwide Comprehensive Surveillance System for Work-related Diseases, Injuries and Hazards" (refer to <http://www.cste.org/occupationalhealth.htm>). Include an assessment of existing and needed resources to implement these strategies.

Describe how the State Asthma Plan implementation activities were developed and how members of the statewide partnership group determined that these particular objectives and strategies would be addressed first. Demonstrate the extent to which the intervention plan is supported in the community by the inclusion of letters of support from key members of the community. Describe how the partners who developed the asthma plan will

continue to work together to implement and monitor the intervention strategies and modify the plan over time. Expand partnership activities as appropriate.

Demonstrate the scientific basis for proposed interventions. If proposed interventions include case management programs, assure that patients enrolled are those with moderate to severe persistent asthma and are receiving care consistent with the National Asthma Education and Prevention Program (NAEPP) Guidelines for the Diagnosis and Management of Asthma. Refer to "Guidelines for the Diagnosis and Management of Asthma," (Clinical Practice Guidelines, Guidelines for the Diagnosis and Management of Asthma. National Institutes of Health (NIH), National Heart, Lung and Blood Institute. NIH publication No.97-4051, April 1997) or link to <http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.htm>.

Provide the methodology and specific measures for monitoring progress in meeting all objectives related to implementation of activities in the asthma plan.

Describe how process, impact, and outcome objectives will be evaluated. (Refer to "Framework for Program Evaluation in Public Health," *Morbidity and Mortality Weekly Report*, September 17, 1999/48 RR-11; 1-40 at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4811a1.htm> or other evaluation resources on the CDC Web site at <http://www.cdc.gov/eval/index>).

#### 7. Management and Staffing

Demonstrate the applicant's organizational commitment to the asthma program by describing how the agency as a whole will focus its efforts on asthma. Provide a plan to maintain a strong agency commitment within the State Health Department to support continued efforts of the asthma program.

Describe the organizational location of the proposed staff, their relation to the State's asthma contact (the position in the agency currently responsible for contact with CDC on asthma issues), and the support within the organizational structure for the activities defined for the project staff. Attach an organizational chart for the unit where asthma activities will be located and, at a minimum, the next two levels above it.

Describe the qualifications and roles of trained public health professionals to serve as a full-time asthma coordinator for the agency to manage the planning process and conduct other programmatic activities; a full-time epidemiologist to develop and implement surveillance activities for the

asthma project; and a supervisor who will assure support for the project staff. Other program positions may also be proposed. Attach position descriptions, qualifications and curricula vitae for all staff positions.

For each position, describe the primary roles and responsibilities for the project staff over the three-year grant period. Also, include the specific staff activities that will contribute to meeting each objective.

Provide a plan to expedite filling of the staff position(s) and assure that they have been or will be approved by the applicant's personnel system. Include a letter of support from the agency guaranteeing hiring of personnel and support for the asthma program. Also, describe positions in the asthma program that are currently filled, but will not be funded by resources under this cooperative agreement.

Document assurance of the ability of key project staff to participate in the conferences or grantee meetings convened by CDC and willingness to share innovations, information, data, and materials.

#### 8. Budget

Include a detailed first-year budget, narrative justifications, as well as annual budget projections for years two and three. The applicant should describe the program purpose for each budget item. For each contract contained within the budget, provide (1) the name the contractor(s); (2) method of selection; (3) period of performance; (4) description of activities; and (5) an itemized budget with narrative justifications. If this information is not available when the application is submitted, and CDC approves the contract(s), then the funds for the contract(s) will be restricted for expenditure on the award.

The budget should include travel funds for project staff to attend a yearly conference or grantee meeting convened by CDC. In addition, the applicant should include costs for one person to travel to Atlanta, GA, to attend the 6th National Environmental Health Conference on December 3–5, 2003. Review the CDC/NCEH web site for additional information concerning this conference: <http://www.cdc.gov/nceh/default.htm>.

If applicable, list other funds outside of this cooperative agreement that will be used to support this program.

#### Part B: Implementation of State Asthma Plans

Include each of the following sections:

#### 1. Description of Problem

Describe what is known of the asthma problem in the State, territory, tribe, or jurisdiction and efforts to systematically address the problem. Include a description of populations at increased risk of poorly controlled asthma (e.g. gender, age groups, racial/ethnic groups, socio-economic groups, or geographic areas).

Describe existing asthma initiatives, capacity, and infrastructure of the agency within which the asthma programs occur.

#### 2. Workplan

Provide specific goals, objectives and activities that describe what the agency intends to accomplish by the end of the five-year project period. These goals, objectives and activities should be measurable, realistic, related to the Recipient Activities, and reflect plans in year one through five of the project. Include a project time-line that indicates when the proposed goals, objectives, and activities will be met.

Document how progress made toward meeting the objectives will be evaluated. Provide measures for evaluating process, impact, and outcome for each goal and objective. Refer to "Framework for Program Evaluation in Public Health," *MMWR*, September 17, 1999/48 RR-11; 1–40 at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4811a1.htm> or other evaluation resources on the CDC website at <http://www.cdc.gov/eval/index/>.

In addition, describe how lessons learned will be systematically gathered, documented, and included as an integral part of the evaluation process.

#### 3. Surveillance Plan

Describe the current operational asthma surveillance system within the health agency. Submit copies of the most recent, comprehensive published surveillance report that describes asthma within the State, territory, tribe, or jurisdiction, including if available, a report of asthma in the Medicaid population and for enrollees of the State Children's Health Insurance Program (CHIP).

Provide a surveillance plan containing the following information: (a) A description of data currently available to the program; (b) additional data the agency will obtain and methods for obtaining it; (c) plans for identifying specific populations at risk for poorly controlled asthma (e.g. gender, age groups, racial/ethnic groups, socio-economic groups, or geographic areas); (d) how the agency will use data to develop or enhance an ongoing

surveillance system; and (e) how the surveillance data will be used to support policy, program development, implementation, and evaluation activities.

Describe all asthma indicators to be assessed over time including, but not limited to, prevalence, severity, management, mortality, hospitalization, emergency care, and costs of asthma. Refer to Boss, L.; Kreutzer, R.; Luttinger, D.; Leighton, J.; Wilcox, K.; and Redd, S. "The Public Health Surveillance of Asthma," *Journal of Asthma*, 38(1), 83–89, 2001.

Discuss the use of the Behavioral Risk Factor Surveillance System (BRFSS) asthma module(s) and the frequency of its use.

Include surveillance and public health intervention of work-related asthma. Provide the applicant's definition of work-related asthma. (Refer to "Surveillance of Work-Related Asthma in Selected U.S. States Using Surveillance Guidelines for State Health Departments—California, Massachusetts, Michigan and New Jersey, 1993–1995," *Morbidity and Mortality Weekly Report*, June 25, 1999/48 (SS03); 1–20 at <http://www.cdc.gov/mmwr/preview/mmwrhtml/ss4803a1.htm>).

Describe the methods that will be used to conduct analysis, interpret surveillance data, and a strategy for disseminating this data (e.g. published reports) to local, State, and Federal partner and agencies.

Present a detailed plan to determine whether the asthma surveillance system is useful for monitoring asthma trends over time, determining the effectiveness of asthma interventions, and modifying the State Asthma Plan. (Refer to "Updated Guidelines for Evaluating Surveillance Systems," *Morbidity and Mortality Weekly Report*, July 27, 2001/ (50)RR13; 1–35) at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5013a1.htm>.

#### 4. Approved State Asthma Plan

Submit a copy of the final, approved, comprehensive State Asthma Plan. Approval may be documented with a letter from the agency's Health or Medical Director and letters from key partners, or by appropriate sign-offs on the plan. State Asthma Plans that are pending final approval may be accepted if the draft plan is accompanied by letters from the agency's Health or Medical Director and key partners stating their commitment to and approval of the plan. Also include a description of the plan's approval process and a time-line for final approval.

The approved plan (or attachments to the plan) must include:

a. Background information that defines the current condition and describes why asthma should be a public health priority, and an assessment of the asthma burden in the State, territory, tribe, or jurisdiction using population-based data. The plan must address all persons with asthma in the State regardless of age, race/ethnicity, or gender and include key environments in which persons with asthma spend significant time (*e.g.* home, school, or workplace). If a specific population in the State is not affected by asthma, the plan should clearly identify and describe this population.

b. A description of the process by which the plan was developed, a list of partners that participated in the development of the plan, and how they contributed to the process.

c. A description of the established asthma priorities within the State, territory, tribe, or jurisdiction based on the results of surveillance activities. These objectives should be time-phased and organized in accordance with the priorities identified in the State Asthma Plan. Highlight issues unique to your region and note how your priorities may differ or coincide with national asthma control priorities.

d. Proposed activities to meet the plan's objectives including, but not limited to, efforts to (1) expand surveillance for asthma; (2) improve provider compliance with the National Asthma Education and Prevention Program's (NAEPP) "Guidelines for the Diagnosis and Management of Asthma," (Clinical Practice Guidelines, Guidelines for the Diagnosis and Management of Asthma. National Institutes of Health (NIH), National Heart, Lung and Blood Institute. NIH publication No. 97-4051, April 1997); (3) improve the skills of patients and families affected by asthma to manage the disease; (4) review legislation and policies impacting people with asthma; (5) identify environmental factors that contribute to asthma prevalence and morbidity, and reduce or eliminate exposure to these factors; and (6) communicate between those implementing and those affected by planned activities.

#### 5. Collaboration Plan

Describe experiences with collaborative relationships around asthma or with other chronic or environmentally related or occupationally related disease requiring extensive collaborative relationships both within and outside the agency.

Specifically define the approach to be used to establish or further develop these relationships.

Document partnerships with the clinical community; local health agencies; physician organizations; community health centers; local, State, or regional asthma or respiratory health organizations (*e.g.* American Lung Association); local education authorities; and groups or organizations that serve minority or other populations experiencing a disproportionate burden of asthma. If one or more of these partners will not be included, the applicant should explain why.

Describe how the collaboration will (1) establish leadership, (2) develop consensus regarding goals, (3) identify roles and responsibilities of members, (4) develop procedures and patterns of communications, and (5) sustain the participation of members over time.

Provide letters of commitment from each specific organization, including a statement of how they intend to collaborate, as well as their expertise, and capacity to carry out assigned responsibilities.

Describe how partners who developed the State Asthma Plan will continue to work together to implement and monitor intervention strategies and modify the plan over time. Expand partnership activities as appropriate.

Note that grant funds may be used to leverage asthma program development in the State, territory, tribe or jurisdiction along with resources from other agencies and organizations.

Present a plan to determine the effectiveness of collaborations.

#### 6. Implementation Plan

Provide specific, realistic, measurable, and time-phased objectives for each of the interventions to be implemented over the five-year project period using resources of this announcement. If objectives and interventions from the plan are addressed using other resources, explain how they are related. While the overall State Asthma Plan must address all populations, implementation strategies should be prioritized based on surveillance data, focusing on high priority and disparate populations first. Interventions that change systems and individuals to provide improved disease management or education are preferred.

Discuss guidelines the applicant will use for work-related asthma (*e.g.*, adapted from generic Minimum and Comprehensive State-Based Activities in Occupational Safety Health, June 1995—DHHS (NIOSH) Publication No. 95-107) at <http://www.cdc.gov/niosh/95-107.html>; or from the Workgroup Report

"The Role of States in a Nationwide Comprehensive Surveillance System for Work-related Diseases, Injuries and Hazards" at <http://www.cste.org/occupationalhealth.htm>).

Include an assessment of existing and needed resources to implement these strategies.

Describe how the State Asthma Plan implementation activities were developed and how members of the statewide partnership group determined that these particular objectives and strategies would be addressed. Demonstrate the extent to which the intervention plan is supported in the community by including letters of support from key members of the community.

Demonstrate the scientific basis for proposed interventions. If proposed interventions include case management programs, assure that patients enrolled are those with moderate to severe persistent asthma and are receiving care consistent with the National Asthma Education and Prevention Program (NAEPP) Guidelines for the Diagnosis and Management of Asthma. Refer to "Guidelines for the Diagnosis and Management of Asthma," (Clinical Practice Guidelines, Guidelines for the Diagnosis and Management of Asthma. National Institutes of Health (NIH), National Heart, Lung and Blood Institute. NIH publication No. 97-4051, April 1997) at <http://www.nhlbi.nih.gov/guidelines/asthma/asthdln.htm>.

Provide the methodology and specific measures for monitoring progress in meeting all objectives related to implementation of activities in the asthma plan. Discuss how process, impact and outcome objectives will be evaluated. Refer to "Framework for Program Evaluation in Public Health," *Morbidity and Mortality Weekly Report*, September 17, 1999/48 RR-11; 1-40 at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4811a1.htm> or other evaluation resources on the CDC Web site at <http://www.cdc.gov/eval/index>.

#### 7. Management and Staffing Plan

Demonstrate the applicant's organizational commitment to the asthma program by describing how the agency as a whole will focus its efforts on asthma. Explain how the overall asthma program will be institutionalized and sustained upon completion of funding from this cooperative agreement.

Describe the organizational location of proposed staff, their relation to the State's asthma contact (the position in the agency currently responsible for contact with the CDC on asthma issues), and the support within the

organizational structure for the activities defined for the project staff. Attach an organizational chart for the unit where the asthma activities will be located and, at a minimum, the next two levels above it.

Describe the qualifications and roles of trained public health professionals who will serve as a full-time asthma coordinator for the agency to manage programmatic activities; 2 full-time epidemiologists to develop and implement surveillance activities for the asthma project; and a supervisor who will assure support for the project staff. Other program positions may also be proposed. Attach position descriptions, qualifications, and curricula vitae for all staff positions.

Include a description of existing asthma program staff within the health department, the current function of these staff members, their role in developing this project plan, and management structure of the asthma program. Describe asthma surveillance staff and their role within the project activities.

For each position, describe the primary roles and responsibilities for the program staff over the five-year project period. Include specific activities that will contribute to meeting stated program goals/objectives.

Document assurance of ability to access and utilize funds, if awarded, for the purposes of this announcement.

If intervention activities will be implemented through contracts, define the process by which these contracts will be awarded and monitored.

Discuss the role of the statewide partnership group and oversight of intervention activities.

Document assurance of ability of key project staff to participate in the conferences or grantee meetings convened by CDC and willingness to share innovations, information, data, and materials.

## 8. Budget

Include a detailed first-year budget, narrative justifications, as well as annual budget projections for years two through five. The applicant should describe the program purpose for each budget item. For each contract contained within the budget, applicants should provide (1) the name the contractor(s); (2) method of selection; (3) period of performance; (4) description of activities; and (5) an itemized budget with narrative justifications. If this information is not available when the application is submitted, and CDC approves the contract(s), then the funds for the contract(s) will be restricted for expenditure on the award.

The budget should include travel for key project staff to attend a yearly conference or grantee meeting convened by CDC. In addition, the applicant should include costs for one person to travel to Atlanta, GA, to attend the 6th National Environmental Health Conference on December 3–5, 2003. Review the CDC/NCEH web site for additional information concerning this conference: <http://www.cdc.gov/nceh/default.htm>.

If applicable, list other funds outside this cooperative agreement that will be used to support this program.

## G. Submission and Deadline

### *Letter of Intent (LOI) Submission*

On or before June 27, 2003, submit the LOI to the Grants Management Officer identified in the "Where to Obtain Additional Information" section of this announcement.

### *Application Forms*

Submit the signed original and two copies of PHS 5161–1 (OMB Number 0920–0428). Forms are available at the following Internet address: <http://www.cdc.gov/od/pgo/forminfo.htm>.

If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO-TIMS) at: (770) 488–2700. Application forms can be mailed to you.

### *Submission Date, Time, and Address*

The application must be received by 4 p.m. Eastern Time on July 14, 2003. Submit the application to: Technical Information Management—PA#03032, Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146.

Applications may not be submitted electronically.

### *CDC Acknowledgement of Application Receipt*

A postcard will be mailed by PGO–TIM, notifying you that CDC has received your application.

### *Deadline*

Letters of intent and applications shall be considered as meeting the deadline if they are received before 4 p.m. Eastern Time on the deadline date. Any applicant who sends their application by the United States Postal Service or commercial delivery services must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If an application is received after closing due to (1) carrier error, when the carrier

accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, CDC will upon receipt of proper documentation, consider the application as having been received by the deadline.

Any application that does not meet the above criteria will not be eligible for competition, and will be discarded. The applicant will be notified of their failure to meet the submission requirements.

## H. Evaluation Criteria

### *Application*

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 goal as stated in purpose section of this announcement. Measures must be objective and quantitative and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

An independent review group appointed by CDC will evaluate each application against the following criteria:

### Part A: Developing State Capacity To Address Asthma

#### 1. Workplan (25 points)

The extent to which:

a. The applicant identifies goals, objectives, and activities that are consistent with the Recipient Activities; are specific, measurable and realistic; and reflect activities in year one, two, and three of the project period.

b. Objectives will contribute to accomplishment of the goals.

c. Activities are likely to achieve objectives.

d. The time-line for accomplishing proposed goals, objectives, and activities is reasonable.

e. Measures for monitoring and evaluating the process, impact, and outcome of each goal and objective are specific and appropriate.

f. The plan to systematically gather and document lessons learned is incorporated into the program evaluation process.

#### 2. Management and Staffing Plan (20 points)

The extent to which:

a. The agency demonstrates a high level of commitment and organizational support for the asthma program. Organizational charts show where the asthma program is located.

b. The roles of proposed staff members are defined and appropriate for carrying out stated responsibilities.

c. The staffing plan identifies at least a full-time asthma coordinator, at least a full-time epidemiologist, and a supervisor.

d. Job descriptions, qualifications, and curricula vitae indicate that each proposed staff member has the credentials, knowledge, training, and experience to perform assigned tasks.

e. The plan to expedite filling of the staff position(s), assuring that they will be approved by the applicant's personnel system, is realistic.

f. The applicant plans to attend CDC conferences/meetings and is willing to share innovations, information, data, and materials.

### 3. Surveillance Plan (20 points)

The extent to which the plan:

a. Provides a comprehensive description of data currently available to the program, additional data the agency will obtain, and methods for obtaining it.

b. Identifies populations at risk for poorly controlled asthma, such as specific age groups, ethnic groups, socio-economic groups, or geographic areas.

c. The applicant provides a reasonable approach for how the agency will develop or enhance an ongoing surveillance system and how the data will be used to support policy, program development, implementation, and evaluation.

d. Uses appropriate measures to track asthma morbidity, asthma mortality, and work-related asthma over time.

e. Includes the Behavioral Risk Factor Surveillance System supplemental asthma module within the first year of the project period.

f. Uses appropriate strategies for conducting analysis, interpreting surveillance data, and disseminating data through published reports.

g. Includes reasonable strategies for evaluating whether the asthma surveillance system is useful for monitoring trends over time.

### 4. State Asthma Plan (15 points)

The extent to which:

a. The applicant describes how the comprehensive State Asthma Plan will be developed.

b. The plan addresses all persons with asthma regardless of age, race/ethnicity, gender, or geographic area and includes key environments in which persons with asthma spend significant time (e.g. home, school, workplace).

c. The number and type of agencies and organizations proposed to

participate in developing the State Asthma Plan are appropriate. Partner's roles and responsibilities are fully described and reasonable.

d. Collaborative relationships will be used appropriately when implementing interventions.

e. Data collected in the asthma surveillance system will be used to identify priority areas and guide the development of program goals and objectives.

f. The process of making changes to the State Asthma Plan is reasonable.

### 5. Collaboration Plan (10 points)

The extent to which:

a. The applicant demonstrates prior successful collaborations that address asthma or other chronic or environmentally-related or occupationally-related problems.

b. Collaborating organizations and agencies include a wide variety of appropriate partners in the clinical community; local health agencies; physician organizations; community health centers; local, state or regional asthma or respiratory health organizations (such as the American Lung Association), local education authorities; and groups or organizations that serve populations experiencing a disproportionate burden of asthma. If one or more of these partners are not included, the applicant explains why.

c. Partners will work together to: (1) Establish leadership, (2) develop a consensus regarding goals, (3) identify roles and responsibilities through a negotiated process, (4) develop routine and consistent patterns of communications, and (5) sustain the participation of members over time.

d. Letters of commitment from key organizations demonstrate their willingness, expertise, and capacity to carry out assigned responsibilities.

e. The plan for determining the effectiveness of collaborations is reasonable.

### 6. Description of the Problem (10 points)

The extent to which:

a. The applicant fully describes what is known about the asthma burden in the State, tribe, territory or jurisdiction; identifies populations at increased risk of poorly controlled asthma (regardless of gender, age, race/ethnicity, or geographic area); and explains efforts to systematically address the problem.

b. The applicant identifies existing initiatives, capacity, and infrastructure of the agency within which asthma programs will occur.

c. The applicant identifies barriers that need to be resolved in order to develop comprehensive asthma program in the State.

d. The applicant demonstrates the agency's commitment to addressing asthma by accomplishments to date and understanding of the problem.

### 7. Budget (reviewed, but not scored)

The extent to which:

a. The budget is comprehensive and includes details for year one projections and details for year two and three of the budget period.

b. The budget contains justifications that are consistent with stated goals, objectives, activities, and the intended use of cooperative agreement funds.

c. The budget is reasonable and includes funds for project staff to attend a yearly conference or grantee meeting convened by CDC. In addition, the applicant should include costs for one person to travel to Atlanta, GA, to attend the 6th National Environmental Health Conference on December 3-5, 2003. Review the CDC/NCEH web site for additional information concerning this conference: <http://www.cdc.gov/nceh/default.htm>.

### 8. Performance Goals (reviewed, but not scored)

The extent to which the applicant will reduce the burden of asthma in the State, territory, tribe or jurisdiction.

### Part A Enhanced: Enhancing State Capacity To Address Asthma

#### 1. Workplan (25 points)

The extent to which:

a. The applicant identifies goals, objectives, and activities that are consistent with the Recipient Activities, are specific, measurable and realistic, and reflect activities in year one, two, and three of the project period.

b. Objectives will contribute to accomplishment of the goals.

c. Activities are likely to achieve objectives.

d. The time-line for accomplishing proposed goals, objectives, and activities is reasonable.

e. Measures for monitoring and evaluating the process, impact, and outcome of each goal and objective are specific and appropriate.

f. The plan to systematically gather and document lessons learned is incorporated into the program evaluation process.

#### 2. Management and Staffing Plan (20 points)

The extent to which:

a. The agency demonstrates a high level of commitment and organizational support for the asthma program. Organizational charts show where the asthma program is located.

b. The roles of proposed staff members are defined and appropriate for carrying out stated responsibilities.

c. The staffing plan includes at least a full-time asthma coordinator, at least a full time epidemiologist, and a supervisor.

d. Job descriptions, qualifications, and curricula vitae indicate that each proposed staff member has the credentials, knowledge, training, and experience to perform assigned tasks.

e. The plan to expedite filling of the staff position(s), assuring that they will be approved by the applicant's personnel system, is realistic.

f. The applicant plans to attend CDC conferences and meetings and is willing to share innovations, information, data, and materials.

### 3. State Asthma Plan (15 points)

The extent to which:

a. The State Asthma Plan is comprehensive and approved by the state health agency. If not already approved, the applicant provides assurance that the State Asthma Plan will be completed within 3 months of the first budget year.

b. The plan addresses all persons with asthma regardless of gender, age, race/ethnicity, or geographic area and includes key environments in which persons with asthma spend significant time (e.g. home, school, workplace).

c. The number and type of agencies and organizations that participated in developing the State Asthma Plan are appropriate. Partner's roles and responsibilities are fully described and reasonable.

d. The applicant describes the collaboration's progress in (1) establishing leadership, (2) developing a consensus regarding goals, (3) identifying roles and responsibilities through a negotiated process, (4) developing routine and consistent patterns of communications, and (5) sustaining the participation of members over time.

e. Collaborative relationships are used after the plan is in place and the agency begins to implement selected interventions.

f. Proposed activities to meet the plan's objectives include, but are not limited to, efforts to (1) expand surveillance for asthma; (2) improve provider compliance with the National Asthma Education and Prevention Program's (NAEPP) "Guidelines for the Diagnosis and Management of Asthma," (Clinical Practice Guidelines, Guidelines for the Diagnosis and Management of Asthma. National Institutes of Health (NIH), National Heart, Lung and Blood Institute. NIH

publication No. 97-4051, April 1997); (3) improve the skills of patients and families affected by asthma to manage the disease; (4) review legislation and policies impacting people with asthma; (5) identify environmental factors that contribute to asthma prevalence and morbidity, and reduce or eliminate exposure to these factors; and (6) communicate between those implementing and those affected by planned activities.

g. Data collected in the asthma surveillance system was (and will be) used to identify priority areas and guide the development of program goals and objectives.

h. The applicant describes how the State Asthma Plan will evolve over time and the process by which changes are made.

### 4. Surveillance Plan (15 points)

The extent to which:

a. The applicant has an operational surveillance system for asthma.

b. Attached surveillance reports are of high quality and fully describe the burden of asthma within State, territory, tribe, or jurisdiction, including, if available a report on asthma in the Medicaid population.

c. The applicant describes data currently available, additional data the agency will obtain, and methods for obtaining it.

d. The applicant clearly identifies populations at risk for poorly controlled asthma such as specific age groups, ethnic/racial groups, socio-economic groups, or geographic areas.

e. The applicant explains how the agency will enhance an ongoing surveillance system and how data will be used to support policy, program development, implementation, and evaluation activities.

f. The plan uses appropriate measures to track asthma morbidity, asthma mortality, work-related asthma, and asthma hospitalizations over time.

g. The applicant plans to use the Behavioral Risk Factor Surveillance System supplemental asthma module within the first year of the project period.

h. The surveillance plan describes appropriate strategies to conduct analysis, interpret surveillance data, and disseminate data through published reports.

i. Includes reasonable strategies for evaluating whether the asthma surveillance system is useful for monitoring trends over time.

### 5. Collaboration Plan (10 points)

The extent to which:

a. The applicant has had previous experience collaborating with other

chronic or environmentally related or occupationally related agencies.

b. Collaborating organizations and agencies include a wide variety of appropriate partners in the clinical community; local health agencies; physician organizations; community health centers; local, state or regional asthma or respiratory health organizations (such as the American Lung Association), local education authorities; and groups or organizations that serve populations experiencing a disproportionate burden of asthma. If one or more of these partners are not included, the applicant explains why.

c. The applicant describes how the collaboration's progress in: (1) Establishing leadership, (2) developing a consensus regarding goals, (3) identifying roles and responsibilities through a negotiated process, (4) developing routine and consistent procedures and patterns of communications, and (5) sustaining the participation of members over time will be documented and monitored.

d. Letters of commitment from key organizations demonstrate their willingness, expertise, and capacity to carry out assigned responsibilities.

e. The applicant fully describes how partners who developed the State Asthma Plan will continue to work together to monitor the intervention strategies over time.

f. The plan for determining the effectiveness of collaborations is reasonable.

### 6. Implementation Plan (10 points)

The extent to which:

a. The applicant presents specific, realistic, measurable and time-phased objectives for each intervention proposed.

b. Interventions focus on high priority and disparate populations. Priorities are based on surveillance data.

c. Interventions will change systems and individuals to provide improved disease management or education.

d. The community supports the intervention plan.

e. The applicant demonstrates a scientific basis for each intervention.

f. The methods and measures for monitoring progress of interventions are appropriate.

### 7. Description of the Problem (5 points)

The extent to which:

a. The applicant provides a comprehensive description of what is known about the asthma burden in the State, tribe, territory or jurisdiction including all ages, race/ethnic groups, and geographic areas.

b. The applicant fully identifies existing initiatives, capacity, and

infrastructure of the agency within which the asthma programs will occur.

c. The barriers identified when developing the State Asthma Plan were addressed.

d. The agency's commitment to addressing asthma is demonstrated by accomplishments to date and understanding of the problem.

#### 8. Budget (reviewed, but not scored)

The extent to which:

a. The budget is comprehensive and includes details for year one and projections for year two and three of the project period.

b. The budget contains justifications that are consistent with stated goals, objectives, activities, and the intended use of cooperative agreement funds.

c. The budget is reasonable and includes funds for project staff to attend a yearly conference or grantee meeting convened by CDC. In addition, the applicant included costs for one person to travel to Atlanta, GA, to attend the 6th National Environmental Health Conference on December 3-5, 2003.

#### 9. Performance Goals (reviewed, but not scored)

The extent to which the applicant will reduce the burden of asthma in the State, tribe, territory, tribe or jurisdiction.

### Part B: Implementation of State Asthma Plan

#### 1. Implementation Plan (25 Points)

The extent to which:

a. Implementation objectives are specific, realistic, measurable and time-phased for each of the interventions.

b. High priority interventions are based on surveillance data and focus on disparate populations first. Strategies that change systems and individuals to provide improved disease management are included.

c. There is a clear link between the State Asthma Plan and the proposed interventions, including an assessment of existing and needed resources to implement these strategies.

d. The intervention plan is supported in the community and this is demonstrated by the inclusion of letters of support from key members of the community.

e. Statewide partners are involved in implementing and monitoring the plan over time.

f. Proposed intervention strategies are appropriate and have a scientific basis. Asthma management activities are consistent with the National Asthma Education and Prevention Program (NAEPP) "Guidelines for the Diagnosis and Management of Asthma."

g. Methods and measures for monitoring intervention activities are specific, reasonable, and likely to assess the effectiveness of activities in reaching program goals and objectives. Process, impact, and outcome objectives are included.

#### 2. Management and Staffing Plan (20 Points)

The extent to which:

a. The applicant demonstrates a high level of commitment and organizational support for the asthma program. Organizational charts demonstrate clear lines of authority and coordination with related programs at the State health department such as tobacco control, environmental health, or maternal and child health. The plan for institutionalizing and sustaining the asthma program beyond the 5-year project period is achievable.

b. Job descriptions and curricula vitae indicate that each proposed staff member has the credentials, knowledge, training and experience to perform assigned tasks.

c. The roles of proposed staff members are defined and appropriate for carrying out stated responsibilities.

d. The staffing plan includes at least a full-time asthma coordinator, at least 2 full-time epidemiologists, and a supervisor. Other staff position(s) are also included.

e. The plan to expedite filling of the staff position(s), assuring that they will be approved by the applicant's personnel system, is realistic.

f. The role of the statewide partnership group is appropriate for the oversight of intervention activities.

g. The applicant documents assurance that key personnel will attend scheduled grantee meetings and CDC-sponsored national asthma conferences, and that the applicant agrees to share innovations, information, data and materials.

#### 3. Workplan (15 Points)

The extent to which:

a. The applicant identifies goals, objectives and activities that are specific, measurable, realistic, related to the Recipient Activities, and reflect plans in year one through five of the project.

b. Objectives will contribute to the accomplishment of the stated goals.

c. Activities are likely to achieve related objectives.

d. Project time-line is realistic and indicates when each goal, objective, and activity will be met.

e. Measures for monitoring and evaluating the process, impact, and outcome of each goal and objective are appropriate and specific.

#### 4. Surveillance System (15 Points)

The extent to which:

a. The applicant has an operational surveillance system for asthma within the health agency.

b. Attached surveillance reports are of high quality and comprehensively describe the asthma burden within the State, territory, tribe, or jurisdiction, including, if available, a report on asthma in the Medicaid population and the State Children's Health Insurance Program (SCHIP).

c. The applicant identifies all data currently available to the program as well as additional data the agency will obtain and methods for obtaining it. Plan includes use of the Behavioral Risk Factor Surveillance System (BRFSS) asthma module(s).

d. The plan identifies populations at risk for poorly controlled asthma such as specific racial/ethnic groups, socio-economic groups, and/or geographic areas.

e. The applicant presents a reasonable approach for how the agency will enhance an ongoing surveillance system and how the data will be used to support policy, program development, implementation, and evaluation activities.

f. The plan describes appropriate measures for asthma prevalence, severity, management, mortality, hospitalization, emergency care, and costs of asthma.

g. The plan includes surveillance and public health interventions for work-related asthma.

h. The approach for conducting analysis, interpreting surveillance data, and disseminating data through published reports is appropriate.

i. The plan for evaluating the asthma surveillance system addresses all program goals and objectives, will be effective in monitoring asthma trends over time, will determine the effectiveness of asthma interventions, and will support modifications to the State Asthma Plan.

#### 5. Approved State Asthma Plan (15 Points)

The extent to which:

a. A commitment by the Agency to implement this plan is demonstrated by the inclusion of a letter of support from the Secretary of Health or the Agency's Medical Director. If the State Asthma Plan is not already approved, the applicant provides assurance that it will be completed within 3 months of the first budget year.

b. The State Asthma plan is comprehensive, addressing all persons with asthma regardless of age, race/

ethnicity, gender, or geographic area. It also includes key environments in which persons with asthma spend significant time such as the home, school, and workplace.

c. The Plan defines the current status of asthma, why asthma should be a public health priority, and an assessment of the asthma burden in the State, territory, tribe, or jurisdiction. Applicant also lists asthma priorities and provides evidence that these priorities are directly related to analysis of population-based surveillance data. Objectives are time-phased and organized in accordance with the priorities identified in the State Asthma Plan.

d. The applicant fully describes how the Plan was developed and how partners participated in the process. The number and type of agencies that participated and their contributions in developing the State Asthma Plan are appropriate.

e. Proposed activities to meet the plan's objectives include, but are not limited to, efforts to: (1) Expand surveillance for asthma; (2) improve provider compliance with the National Asthma Education and Prevention Program's (NAEPP) "Guidelines for the Diagnosis and Management of Asthma," (Clinical Practice Guidelines, Guidelines for the Diagnosis and Management of Asthma. National Institutes of Health (NIH), National Heart, Lung and Blood Institute. NIH publication No. 97-4051, April 1997); (3) improve the skills of patients and families affected by asthma to manage the disease; (4) review legislation and policies impacting people with asthma; (5) identify environmental factors that contribute to asthma prevalence and morbidity, and reduce or eliminate exposure to these factors; and (6) communicate between those implementing and those affected by planned activities.

#### 6. Collaboration Plan (5 Points)

The extent to which:

a. The applicant has experience collaborating with partners around asthma or other chronic or environmental related or occupationally related diseases both within and outside the agency.

b. Collaborating organizations and agencies include a wide variety of appropriate partners in the clinical community; local health agencies; physician organizations; community health centers; local, state or regional asthma or respiratory health organizations (such as the American Lung Association), local education authorities; and groups or organizations

that serve populations experiencing a disproportionate burden of asthma. If one or more of these partners are not included, the applicant explains why.

c. The applicant includes a description of the collaboration's progress in: (1) Establishing leadership, (2) developing a consensus regarding goals, (3) identifying roles and responsibilities through a negotiated process, (4) developing routine and consistent patterns of communications, and (5) sustaining the participation of members over time.

d. Letters of commitment from key organizations demonstrate their willingness, expertise, and capacity to carry out assigned responsibilities.

e. The applicant presents a sound plan to determine the effectiveness of collaborations.

#### 7. Description of the Problem (5 Points)

The extent to which:

a. The applicant provides a comprehensive description on what is known about the asthma burden in the State, tribe, territory, or jurisdiction, and a description of populations at increased risk of poorly controlled asthma within the jurisdiction (*e.g.*, ethnic groups, socio-economic groups, and geographic areas).

b. The applicant identifies existing initiatives, capacity, and infrastructure of the agency within which the asthma programs will occur.

c. The agency's commitment to addressing asthma is demonstrated by accomplishments to date and understanding of the problem.

#### 8. Budget (reviewed, but not scored)

The extent to which:

a. The budget is comprehensive and includes details for year one and projections for year two and three of the project period.

b. The budget contains justifications that are consistent with stated goals, objectives, activities, and the intended use of cooperative agreement funds.

c. The budget is reasonable and includes funds for project staff to attend a yearly conference or grantee meeting convened by CDC. In addition, the applicant included costs for one person to travel to Atlanta, GA, to attend the 6th National Environmental Health Conference on December 3-5, 2003.

#### 9. Performance Goals (reviewed, but not scored)

The extent to which the applicant will reduce the burden of asthma in the State, territory, tribe or jurisdiction.

## I. Other Requirements

### Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Detailed Line-Item Budget and Justification.

e. Additional Requested Information.

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

3. Final financial and performance reports, 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.

### Additional Requirements

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I of the program announcement as posted on the CDC web site.

AR-7 Executive Order 12372

AR-9 Paperwork Reduction Act Requirements

AR-10 Smoke-Free Workplace Requirements

AR-11 Healthy People 2010

AR-12 Lobbying Restrictions

AR-21 Small, Minority and Women-owned Business

## J. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC web site, Internet address: <http://www.cdc.gov>. Click on "Funding" then "Grants and Cooperative Agreements".

For general questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone: (770) 488-2700.

For business management and budget assistance, contact: Mildred Garner, Grants Management Officer, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA

30341-4146, Telephone: (770) 488-2745, e-mail address: [mqg4@cdc.gov](mailto:mqg4@cdc.gov).

For business management and budget assistance in the territories, contact: Charlotte Flitcraft, Grants Management Officer, Procurement and Grants Office, Centers for Disease Control and Prevention, 2020 Brandywine Rd., Atlanta, GA 30319, Telephone: (770) 488-2632, e-mail address: [caf5@cdc.gov](mailto:caf5@cdc.gov).

For program technical assistance, contact: Kathie Sunnarborg, MPH, CHES, Public Health Advisor, Air Pollution and Respiratory Health Branch, National Center for Environmental Health, Centers for Disease Control and Prevention, 1600 Clifton Rd., NE, Mailstop E-17, Atlanta, GA 30333, Telephone number: (404) 498-1451, e-mail address: [ksunnarborg@cdc.gov](mailto:ksunnarborg@cdc.gov).

Dated: May 21, 2003.

**Sandra R. Manning,**

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

[FR Doc. 03-13222 Filed 5-27-03; 8:45 am]

BILLING CODE 4163-18-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 02P-0479]

**Determination That Periactin Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined that Periactin (cyproheptadine hydrochloride (HCl)) 4-milligram (mg) tablets were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for cyproheptadine HCl 4-mg tablets.

**FOR FURTHER INFORMATION CONTACT:**

Mary Catchings, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions,

show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products with Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

Periactin 4-mg tablets are the subject of NDA 12-649. On October 17, 1961, Merck & Co., Inc., received approval to market Periactin 4-mg tablets.

On November 5, 2002, CorePharma LLC submitted a citizen petition (Docket No. 02P-0479/CP1) under 21 CFR 10.30 requesting that the agency assign reference listed drug status to a currently marketed cyproheptadine hydrochloride 4-mg tablet drug product. At that time, FDA exercised its discretion under § 314.161(a) to determine if Periactin 4-mg tablets were withdrawn for reasons of safety or effectiveness.

After reviewing agency records, FDA has determined that Periactin 4-mg tablets were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list Periactin 4-mg tablets in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer

to Periactin 4-mg tablets may be approved by the agency.

Dated: May 19, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-13193 Filed 5-27-03; 8:45 am]

BILLING CODE 4160-01-S

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**FDA/Industry Exchange Workshop on FDA Clinical Trials Statutory and Regulatory Requirements; Public Workshop**

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

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA) Philadelphia District, in cooperation with the Society of Clinical Research Associates, (SoCRA) is announcing a workshop on FDA clinical trial statutory and regulatory requirements. Topics for discussion include: Financial incentives and funding, pre-IND (investigational new drug application) meetings and FDA meeting process, medical device aspects of clinical research, informed consent requirements, adverse event reporting, how FDA conducts bio research inspections, ethics in clinical research, FDA and confidence in the conduct of clinical research, and how FDA addresses fraud in clinical research. This 2-day workshop for the clinical research community targets sponsors, monitors, clinical investigators, institutional review boards and those who interact with them for the purpose of conducting FDA regulated clinical research. The workshop will include both industry and FDA perspectives on proper conduct of clinical trials regulated by FDA.

**Date and Time:** The public workshop is scheduled for Wednesday, June 25, 2003, from 8:30 a.m. to 4:45 p.m. and Thursday, June 26, 2003, from 8:45 a.m. to 4:45 p.m.

**Location:** The public workshop will be held at the Pittsburgh Marriott Center City Hotel, 112 Washington Pl., Pittsburgh, PA 15219.

**Contact:** Daniel R. Tammariello, FDA, 7 Parkway Center, Suite 250, Pittsburgh, PA 15220, 412-644-3394, ext. 16, FAX: 412-644-4496, e-mail:

[dtammari@ora.fda.gov](mailto:dtammari@ora.fda.gov) or Marie Falcone, Industry and Small Business Representative, FDA, Room 900 U.S. Customhouse, 200 Chestnut St.,