Research in Puerto Rico, where dengue is endemic and intermittently epidemic, has shown that levels of awareness about dengue are very high in the population and that the next step should be the translation of this knowledge into practice (behavior change). To achieve this goal a model of community participation to prevent and control dengue should be developed. This model of community participation must be an effectively implemented prevention project.

The objective of the dengue prevention project is to develop and evaluate a community-based participation intervention model that will reduce *Aedes aegypti* infestation in a community in Puerto Rico. To accomplish this two comparable communities in the San Juan, Puerto Rico area will be selected for this study. One community will be a ''control community'' and the second community will be an ''intervened community.'' Entomologic surveys and person-to-person interviews to assess knowledge, attitudes, and practices (KAP) will be conducted during the project in both communities. The entomologic surveys and person-to-person interviews will be conducted 3 times during the project: the beginning of the project, the end of the first year of the project, and 18 months after the beginning of the project.

An additional interview will also be conducted in the intervened community to assess the function and significance of artificial containers that hold water. An ethnographic assessment will be performed to determine the resources and needs of the intervened community. The specific dengue prevention activities that the intervened community will perform will be based on results of the initial entomologic survey, KAP, function and significance of artificial containers, and the ethnographic assessment of the community. There is no cost to respondents.

Respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hours)	Total burden (in hours)
Intervened Community	100	4	45/60	300
Control Community	100	3	45/60	225
Total				525

Dated: November 15, 2002.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 03017]

Systems-Based Diabetes Prevention and Control Programs (DPCPs); Notice of Availability of Funds

A. Authority and Catalog of Federal Domestic Assistance Number (CFDA)

This program is authorized under section 301(a) and 317(k)(2)of the Public Health Service Act, (42 U.S.C. section 241(a) and 247b(k)(2), as amended). The Catalog of Federal Domestic Assistance number is 93.988.

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 Systems-Based Diabetes Prevention and Control Programs (DPCPs). This program addresses the ''Healthy People 2010'' focus areas of Diabetes, Immunization, Access to Quality Health Services, Chronic Kidney Disease, Heart Disease and Stroke, Vision and Hearing, Nutrition and Overweight, Physical Activity and Fitness, and Public Health Infrastructure.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP): Increase the capacity of state diabetes control programs to address the prevention of diabetes and its complications at the community level.

The Program will continue to emphasize prevention of complications and premature mortality among people with diabetes (*i.e.* secondary and tertiary prevention). Further, the Program will continue to incorporate a model of influence by linking new programs and existing programs that support social and environmental policies for the promotion of wellness in both people with diabetes, and those at risk for diabetes. In the future, CDC plans (pending available resources) to turn increasing attention to the identification and dissemination of lifestyle interventions proven to be effective in preventing or delaying Type 2 diabetes among people with impaired fasting glucose or impaired glucose tolerance.

For additional background information please see attachment II of this announcement as posted on the CDC web site at: *www.cdc.gov.*

C. Eligible Applicants

Assistance will be provided only to the health departments of states or their *bona fide* agents, and Territories, including 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. Competition is limited to health departments or their *bona fide* agents because they are uniquely positioned to perform, oversee and coordinate diabetes prevention and control activities in public health settings and as part of a larger public health system. All States and Territories are currently receiving funding for diabetes programs under prior CDC announcements 97064, 98034, and/or 99078.

(**Note:** Throughout this document the use of the term ''State'' or ''statewide'' also refers to the Territories described above.)

For the first year, states currently receiving CDC funds for Comprehensive Programs (funded under program announcements 97064, 98034, and 99078) are entitled to apply for Comprehensive Program funding only.

States currently receiving CDC funds for Core Programs (funded under program announcement 99078) are eligible to apply for either Core or Comprehensive Program funding. Applicants will receive only a Core or Comprehensive award.

Current Core programs applying for Core funding will undergo a technical review of their application and will be funded pending receipt and approval of a technically acceptable application.

Current Comprehensive Programs and Core Programs applying for Comprehensive funding must submit an application which will undergo a competitive review process by an independent objective review panel. As a contingency, currently funded Core programs applying for Comprehensive awards should submit two separate work plans, with budget line items and budget justifications, one for a Core Program and one for a Comprehensive Program.

All applications received from current grant recipients under Program Announcements 97064, 98034, and 99078 will be funded for either a Core or a Comprehensive Program.

After the first year, Tier 2 DPCPs (see explanation of Tier 2 in section ''E. Program Requirements'') will be eligible to compete for Special Projects of National Significance based on availability of funds in years two through four. Eligibility will be limited to high performing Tier 2 DPCPs that demonstrate multi-system integration of public health services and partnerships into a comprehensive, highly functioning, and accountable program. A number of key innovative strategies, implemented by these DPCPs, have been sustained or institutionalized, documented in public health reports or scientific literature and disseminated to other programs as appropriate.

Note: Public Law 104–65 states that an organization described in section 501(c) (4) of the Internal Revenue Code of 1986 which engages in lobbying activities shall not be eligible for the receipt of Federal funds constituting an award, grant, loan or any form.

D. Funding

Availability of Funds

Approximately $23 million is available in FY 2003 to fund 59 awards. It is estimated that approximately $10 million will be available to fund approximately 41 Core awards. It is expected that the average federal contribution to the Core award will be $244,000, ranging from $50,000 to $400,000. Approximately $13 million will be available to fund approximately 18 Comprehensive awards. It is expected that the average federal contribution to the Comprehensive award will be $725,000 ranging from $400,000 to $900,000.

It is expected that the awards will begin on or about March 30, 2003, and will be made for a 12-month budget period within a project period of up to five years. Funding estimates may vary depending on availability of funds.

Continuation awards within an approved project period will be made on the basis of satisfactory demonstration of accomplishment of proposed activities, performance improvement plans and results, and the availability of funds.

Direct Assistance

You may request Federal personnel as direct assistance, in lieu of a portion of financial assistance.

Use of Funds

Resources available under this program announcement may not be used to: (1) Support direct patient care services, screening services, individual health services, or the treatment of diabetes; (2) duplicate existing efforts the federal system has established for outpatient diabetes education reimbursement for the Medicare population through the Diabetes Education Program Recognition administered by the Centers for Medicaid and Medicare Services (CMS); or (3) supplant existing State or Federal funding including the Preventive Health and Health Service block grant or other sources.

Programs that have adequately addressed the program key components (*see* attachment IV of this announcement as posted on the CDC web site) and are high performing comprehensive (or Tier 2 in years 2–5) programs may dedicate a portion of the resources available under this program announcement to conduct research projects. Funded research projects involving human subjects will be governed by 45 Code of Federal Regulations, part 46.

Applicants are encouraged to identify and leverage opportunities which will enhance their work with other State health department programs that address related chronic diseases or risk factors. This may include cost sharing to support shared staff positions, such as a chronic disease epidemiologist, program evaluator, health communication specialist, etc. Other cost sharing activities that cut across chronic disease programs and are directly related to recipient program activities may also be appropriate.

Recipient Financial Participation

Matching funds are required for this program. Matching funds are required from non-Federal sources in an amount not less than $1 for each $5 of Federal funds awarded to Core programs and; $1 for each $4 for Comprehensive programs. The matching funds may be cash or its equivalent in-kind or donated services, fairly evaluated. The contribution may be made directly or through donations from public or private entities. Match requirements may change for Tier levels in years two through five. Matching funds must be consistent with the work plan activities that are submitted and approved.

Matching funds may not be met through: (1) The payment of treatment services or the donation of treatment, or direct patient diabetes education services; (2) services assisted or subsidized by the Federal Government; or (3) the indirect or overhead of an organization.

Funding Preference

Due to resource limitations, preference in funding Comprehensive Programs will be given to states with:

1. A larger burden of diabetes and related complications.
2. A larger proportion of residents experiencing racial and ethnic disparities in diabetes prevalence and diabetes related complications.
3. Varied geographic representation across the United States.
4. Varied distribution of population density among funded programs.

E. Program Requirements

In conducting activities to achieve the purpose of this program, both Core and Comprehensive DPCPs will be responsible for the activities under 1. Recipient Activities (except where otherwise noted), and CDC will be responsible for the activities under 2. CDC Activities. It is expected that Comprehensive Programs will demonstrate a more intensive level of effort in each category of recipient activities.

1. Recipient Activities

a. Define the burden of diabetes in a manner that informs and influences public health decision making: Maintain a state specific diabetes surveillance system. This should be accomplished through previously established surveillance systems and ensuring that the Behavioral Risk Factor Surveillance System (BRFSS), Diabetes Module (or other appropriate surveillance system for the Territories), is conducted yearly. Yearly administration of the Diabetes Module is a requirement. The surveillance system should support and inform public health decision making. At a minimum, this data should be used to generate performance-based outcome measures specific to recommended foot and eye exams, immunizations, and

annual Hemoglobin A1C (A1C) tests. It should also be used to guide program activities. Systems should monitor trends, disseminate data and information, and support evaluation efforts. Comprehensive Programs are expected to implement special surveillance strategies (*e.g.*, over-sampling, special surveys, sentinel surveillance systems) that address unmet surveillance needs.

b. Establish and maintain a presence for diabetes prevention and control within the State Health Department. Implement the following critical functions of fiscal management, performance management, program assessment, and strategic planning to carry out the program by working through the respective State and Territorial Health Department infrastructure.

(1). *Fiscal Management:* Develop a Fiscal Management system that supports the program. This system should have the following capacity: accurate and timely tracking of expenditures and sources of match support; accurate projection of categorical balances; and the prevention of excessive unobligated balances by having the flexibility to reallocate funds into appropriate budget categories if priorities change or if staffing patterns change. DPCPs need to establish linkages with appropriate state fiscal management staff, and develop a process for regularly assessing program needs and monitoring expenditures.

(2). *Performance Management:* The DPCP should engage health department leadership to develop a performance management system that incorporates capacity improvement processes and strategic accountability measures. For Comprehensive Programs, a written plan of this performance management system should be in place. This should assist health department officials to create accountability processes within state programs. This will enable them to introduce rewards for good performance and consequences for poor performance. The performance management system should also be linked to the evaluation system and the budget process.

(3). *Program Assessment:* DPCPs are expected to conduct reflective, partner-included assessments to identify strengths and needs in the DPCP's public health infrastructure. Efforts to strengthen identified essential public health services, deemed particularly important in achieving the program's goals, should follow the assessments by developing a performance improvement plan based on identified services that need strengthening. DPCPs will assess and continuously improve public health services so that policies and legislation related to issues such as access to quality care and environmental conditions encourage positive health outcomes. Further, DPCPs will support participatory community efforts promoting systems and community-based approaches aimed at increasing years of healthy life and eliminating the disproportionate burden of diabetes borne by particular racial and ethnic populations. The Ten Essential Public Health Services (*see* attachment III of this announcement as posted on the CDC web site) will provide the basis for assessment. More extensive involvement of partners state-wide is expected of Comprehensive Programs. State public health agencies may or may not be the lead agency for several specific essential public health services. In these cases, identifying the role of the state public health agency with a support role by the DPCP, will help in prioritizing the essential public health services most relevant to achieving the goals of the diabetes program. Performance improvement plans will be implemented in year two and beyond. DPCPs will be expected to demonstrate measurable results linked to performance improvement plans annually.

(4). *Strategic Planning:* Develop or update a State Diabetes Strategic Plan for diabetes prevention and control with the goal of advancing the prevention and control of diabetes and its complications, improving access to and the quality of diabetes services and care, and eliminating disparities between population groups. The DPCP and its partners should be involved in the development and implementation of the State Diabetes Strategic Plan. The State Diabetes Strategic Plan should also inform and guide the activities of the DPCP and its partners. As they become available, the results of the Assessment should guide the periodic update and improvement of the State Diabetes Strategic Plan. For Comprehensive Programs, the plan should be comprehensive in nature and reflective of the strategies and activities of the diabetes health system in the state.

c. *Program Design Enhancement:* Expand the current DPCP program model of influence. DPCPs should serve as a catalyst for change positively impacting people with diabetes, their families, and their communities. The DPCP should engage the State Diabetes Health System (SDHS) which includes the DPCP, the state health agencies and other health partners that contribute to diabetes services and programs at the state level, in this effort. Activities include the current population-based approaches for secondary and tertiary prevention for people with diabetes. All activities described must be relevant, complementary to, and consistent with ongoing national efforts such as the National Diabetes Education Program (NDEP), and with national priorities for eliminating racial and ethnic health disparities for diabetes. Core Program activities aligned with the ten essential public health services can include small scale pilots in selected geographic areas or statewide interventions. Comprehensive Programs are expected to have a wider scope of activities in all areas of influence. Comprehensive Programs must also develop public health activities that reach the entire State or implement an existing multifaceted intensive program in a limited geographical area within a defined target population. Allowable program activities that emerge from evolving science will be addressed in future guidance documents which will accompany each request for continuing application.

d. *Establish and Maintain Effective Partnerships:* Create a culture of shared responsibility with the SDHS and other nontraditional partners. The DPCP and partners should collectively plan, implement, and evaluate goals and objectives and align resources to priorities. The DPCP should engage the SDHS to measure the quality and effectiveness of collective efforts and the DPCP's ability to establish and maintain effective partnerships. The goal should be inclusiveness rather than exclusiveness to achieve synergistic results. Within the State Health Department, the DPCP should collaborate and coordinate with partners such as nutrition, physical activity, tobacco, cardiovascular health, maternal and child health, health promotion, PHHS block grant, State Minority Health Program, Office of Women's Health, Office On Aging, public information officer, as well as data partners such as vital statistics and the State's BRFSS. Comprehensive Programs must demonstrate a more extensive partnership base and more significant level of engagement with those partners.

e. *Evaluation:* Conduct ongoing monitoring and evaluation of diabetes prevention and control activities and strategies, including process and impact evaluation. State evaluation efforts should complement and be consistent with national program evaluation goals. Comprehensive Programs are expected to submit an evaluation methodology designed to demonstrate more in-depth, purposeful evaluation of program activities.

f. *Management Information System (MIS):* The MIS will be used for post

award administration, program monitoring, technical assistance, and programmatic decision making. Programs are expected to ensure that information is entered into the MIS in a timely manner. Office of Management and Budget (OMB) clearance for the data collection initiated under this cooperative agreement has been approved. (OMB No. 0920–0479. Expiration date 7/31/2003.)

g. *Protection of Human Subjects:* Ensure that program activities follow all applicable federal regulations concerning the protection of human subjects and the confidentiality of personally identifiable data.

Year One

DPCPs will be awarded as either Core or Comprehensive Programs for the first year.

1. Core programs are expected to establish and maintain a presence in the health department for diabetes prevention and control; define the burden of diabetes in the state and communicate it in a manner that informs and influences public health decision making; establish and maintain effective partnerships; develop a State Diabetes Strategic Plan; and engage in small scale pilots in accordance with program guidance.

2. Comprehensive programs are expected to meet all of the requirements of a Core program and implement statewide interventions or implement multifaceted intensive strategies in geographically defined targeted populations to reduce or eliminate the burden of diabetes.

Years Two Through Five

In subsequent years (years two through five), DPCPs will be placed in one of two Tier levels based on their performance as documented in the interim progress reports, and on the availability of funds. The award strategy is designed to support documented performance results from quality intervention and performance improvement plans. Awards will also be based on budget justification, alignment with CDC strategies, and the ability of a state to continuously execute performance improvement and intervention plans.

Tier 1

This Tier level is intended to support capacity-building programs by establishing a performance management system; a state team with multiple skill sets; an epidemiology-based State Diabetes Strategic Plan to achieve program goals; highly functioning, accountable partnerships; and program strategies and activities to reduce documented burden of diabetes. In this Tier, culturally relevant small-scale interventions at community and/or systems levels, with specific priority audiences in particular communities or geographic areas, are expected.

The performance expectations of this Tier include

1. Meeting minimum requirements outlined in the DPCP Key Components document (*see* attachment IV of this announcement as posted on the CDC web site).

2. Developing a performance improvement plan reflecting priority areas identified in the diabetes public health assessment which is based on the ten essential public health services.

3. Developing a work plan that meets program criteria (logic-modeled) with budget justification.

4. Providing evidence of results based on proximal performance measures which are anticipated to lead to the achievement of the CDC, Division of Diabetes Translation's (DDT's) National Objectives.

Tier 2

DPCPs in this Tier level have a broader-based program capacity supported by the elements of Tier 1, but with increasingly integrated and highly functional partnerships and measurable effects. Programs in this Tier systematically implement priority strategies and interventions in priority communities throughout the state, consistent with their State Diabetes Strategic Plan. They must have evidence of improvement in the diabetes public health infrastructure. Program impacts and results must be evident and measurable through the DPCP performance management system. They have also demonstrated national leadership, sharing lessons learned among local, state, and national partners.

The performance expectations of this Tier include:

1. Demonstrating quality activities linked to the Ten Essential Public Health Services with activities in each of the four indicators.

2. Demonstrating results in the implementation of improvement plans.

3. Meeting the expectations of Tier 1.

4. Developing a work plan that meets Tier 2 criteria (logic-modeled) with budget justification based on Tier 2 funding levels.

5. Demonstrating readiness in terms of capacity to take on a larger scope of program activities (staffing, management support, technological resources, partnerships, *etc.*).

6. Providing evidence of results based on proximal performance measures which are anticipated to lead to the achievement of the CDC, DDT's National Objectives.

Special Projects of National Significance

High performing Tier 2 programs will be eligible to request additional funding to support projects of national significance. Tier 2 DPCPs who are awarded funds to carry out these Special Projects have demonstrated multi-system integration of public health services and partnerships into a comprehensive, highly functioning, and accountable program. A number of key innovative strategies, implemented by these DPCPs, have been sustained or institutionalized, documented in public health reports or scientific literature and disseminated to other programs as appropriate. It is anticipated that Special Projects will be funded for a specified period of time and may include one or more of the following: (1) Spreading successful population-based interventions accomplished in earlier phases of the program to reach populations still unserved; (2) Conducting projects which provide national leadership in sharing and promoting processes and results. Helping CDC to influence national policies based on emerging needs and discovery of effective practices and policies; and (3) Developing and conducting research projects of national significance, which appropriately contribute to the emerging diabetes public health science base.

The performance expectations of the Special Projects will be specific to the nature of the Project, with the expectation that the Tier 2 programs that are conducting the Special Projects will:

1. Demonstrate quality activities linked to the Ten Essential Public Health Services with activities in each of the four indicators.

2. Demonstrate results in the implementation of improvement plans.

3. Meet the expectations of Tier 2.

4. Develop a work plan that meets criteria for Tier 2 programs and Special Projects with appropriate budget justification based on the nature of the Project.

5. Demonstrate readiness in terms of capacity to take on a larger scope of program activities required to implement Special Projects (staffing, management support, technological resources, partnerships, *etc.*).

6. Provide evidence of results based on proximal performance measures which are anticipated to lead to the

accomplishment of the CDC, DDT's National Objectives.

2. CDC Activities.

a. Provide ongoing guidance, training, consultation, and technical assistance in all aspects of diabetes prevention and control, as described under Recipient Activities.

b. Provide up-to-date information that describes proven interventions and current research in appropriate areas of diabetes prevention and control.

c. Provide resources, tools, and technical assistance to improve and enhance program evaluation efforts.

d. Provide resources and technical assistance to improve monitoring and surveillance systems. Provide technical assistance in the coordination of surveillance and other data systems to measure and characterize the burden of diabetes.

e. Collaborate with the DPCPs and other appropriate partners to develop and disseminate programmatic guidance and other resources for specific interventions, health communication campaigns, and other national initiatives.

f. Facilitate the adoption and adaptation of effective practices through workshops, trainings, conferences, and electronic and verbal communication among recipients of cooperative agreement awards under this program announcement, and other diabetes prevention and control partners.

g. Support the development and maintenance of a system for DPCP input into planning and sharing of information.

h. Assist in and support the development and maintenance of partnerships and networks with Federal and non-Federal, public and private sector organizations to help implement diabetes prevention and control programs, thereby maintaining a national infrastructure to complement the infrastructure in the states and territories and their local jurisdictions.

i. Facilitate effective communication and integration between NDEP and state DPCPs. This includes, but is not limited to, NDEP training, media, and other program products and tools.

j. Provide up-to-date information on the responsible conduct of research and technical assistance for program activities involving human subjects.

F. Content

The Program Announcement title and number must appear in the application. Use the information in the Program Requirements, Recipient Activities, Evaluation Criteria, and Other Requirements sections 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 applications (excluding forms and attachments) should be no more than 50 pages, double-spaced, printed on one side, with one-inch margins, and unreduced 12 point font. Necessary supporting information (tables, organizational charts, position descriptions, *etc.*) may be provided as attachments. A signed original and two copies of the application must be mailed to the CDC Grants Office.

Applicants are strongly encouraged to utilize the MIS. The format of DDT's MIS complements the application content specified in this announcement. Therefore, to avoid duplication of effort, the application content may be entered into the DDT MIS. Hard copies will be generated from the MIS for formal submission to the CDC Procurement and Grants Office with the required signed forms. OMB clearance for the data collection initiated under this cooperative agreement has been approved. (OMB No. 0920–0479. Expiration date 7/31/2003.)

Applicants for comprehensive level funding must demonstrate optimal core capacity as evidenced by the following: Established surveillance systems; sound infrastructure and management (including fiscal management, performance management, program assessment, and strategic planning); proven experience with results in the implementation of well designed small-scale pilot projects; effective partnerships; and sound monitoring and evaluation of diabetes prevention and control activities including process and impact evaluation. In addition, Comprehensive Program applications must include a plan to develop public health activities that reach the entire State, or to implement an existing multifaceted intensive program in a limited geographical area within a defined target population.

Both Core and Comprehensive Program applicants should respond to items one through seven below. However, applicants should note that in some areas different information is requested of applicants. Current Core grantees applying for a Comprehensive award should provide two separate applications, one Core application and one Comprehensive application, and address the comprehensive component by describing their planned or proposed comprehensive activities.

1. Background and Need:

a. Provide an estimate of the burden of diabetes and its complications, and its geographic and demographic distribution within the State. Reference the data sources that support these estimates. Describe the challenges to diminishing the morbidity and mortality from diabetes in your State.

b. Include a description of the populations that are at high risk for diabetes in your State. If possible, describe the social, ecological, or economic conditions that contribute to the disproportionate burden of diabetes in the population, as well as knowledge, attitudes, and beliefs that impact the health practices of the population. If available, attach references for any studies or sources from which this information was obtained.

c. Provide an analysis of the barriers to addressing the burden of diabetes in the State.

2. Program Accomplishments and Proven Capacity:

a. Describe efforts to develop and incorporate diabetes surveillance systems, including BRFSS, in monitoring and tracking diabetes-related health status in the State. Include information on how data is used in diabetes program planning and decision making.

b. Describe unique or significant advances toward achieving program objectives and the CDC, DDT's National Objectives.

c. Provide findings, conclusions, or status of pilot projects and/or statewide activities. Where appropriate, provide success stories of program activities or other methods of determining success.

d. Provide examples of successful efforts to influence the widespread application of accepted standards, policies, and protocols. Describe the methodology for determining the success of these efforts.

e. Describe specific program activities and accomplishments in addressing the needs of underserved populations, or populations at high risk for diabetes in the State.

f. Describe how the DPCP engages partners, including their diabetes advisory groups or coalitions, other Chronic Disease Programs, and non-traditional partners, in program planning, implementation, coordinating efforts and evaluation in support of the DPCP work plan objectives.

g. Describe how the DPCP has managed its fiscal and human resources in the past five years (including history of unobligated balances, how match requirements have been met, turnover in key staff positions, professional development of DPCP staff, supportive leadership, *etc.*).

h. Provide letters of support that reflect the involvement of diverse (traditional and non-traditional) organizations in planning the response

to this program announcement. Include specific roles and responsibilities of the partner providing the letter in the State Diabetes Strategic Plan or activity/intervention that is pertinent.

i. If available, provide a state diabetes strategic plan, diabetes advisory group or coalition by-laws, action plans, and any other substantive work products from these partnerships that demonstrate quality and effectiveness.

3. Program Work Plan:

Provide a clear work plan that addresses the items listed below. Some objectives may reflect the process by which the program or activity is developed, while others will reflect the actual public health impact, output or outcome that results.

Each DPCP should state their measurable and time-phased objectives for the project period that will help achieve the goal(s) of the program. A ''logic model'' or causal relationship should be evident among the long term objectives, process objectives, and activities.

a. Provide measurable and time-phased long term objectives for the five-year project period that should mirror the following CDC, DDT's National Objectives:

(1). By 2008, DPCPs should have demonstrated success in achieving an increase in persons with diabetes who receive recommended foot exams, eye exams, flu and pneumococcal immunizations, and A1C tests.

(2). By 2008, DPCPs should have demonstrated progress in establishing linkages for the promotion of wellness and physical activity for persons with diabetes.

(3). By 2008, all DPCPs should have demonstrated progress in eliminating health disparities for high risk populations with respect to diabetes prevention and control.

(4). Each DPCP should establish measurement procedures and surveillance systems, including baseline and target measurements of the percent of persons with diabetes receiving recommended foot exams, eye exams, flu and pneumococcal immunizations and recommended A1C tests, as a means of assessing program success. b. Provide measurable, specific and time-phased one year budget period objectives that will help achieve the stated time-phased long term objectives. c. Describe in detail a plan for systems-based activities, and methods for achieving each of the proposed one year budget period objectives.

4. Evaluation Plan:

Describe how progress, the achievement of program objectives and the effectiveness of program activities will be monitored and evaluated. Describe how data will be collected, analyzed, and used to improve the program. Specify the person(s) responsible for designing and implementing evaluation activities, collecting and analyzing data, and reporting findings. DPCPs should incorporate the six steps of the ''CDC Framework for Program Evaluation'' when creating the DPCP evaluation plan. The six connected steps assist in the planning and evaluation of a variety of interventions. The CDC Evaluation Framework steps are:

Step 1: Engage stakeholders: Include individuals and organizations that are involved in program operations, served or affected by the program, and the primary users of evaluation.

Step 2: Describe the program: Descriptions should be sufficiently detailed to ensure understanding of program objectives and strategies. Include a logic model that links program objectives and activities to eventual outcomes/effects.

Step 3: Focus the evaluation design: Specify the questions to be answered through the evaluation activities proposed. These questions should guide the evaluation process and be directly linked to the objectives stated above. Specify the methods for quantitative and qualitative data collection, such as the use of questionnaires, surveys, other data collection instruments, interviews, and focus groups, *etc.* (Assure that appropriate Human Subjects Research procedures and OMB requirements have been followed and documented.)

Step 4: Gather credible evidence: Specify the information (data) that will be collected to answer the evaluation questions stated above. Specify the sources of information (data) to be collected. Since this evaluation is designed to measure change as a result of the intervention, specify the baseline against which the change is being measured.

Step 5: Justify conclusions: Specify the process to be used to analyze, synthesize, and report the data.

Step 6: Ensure use and share lessons learned: Explain how the data resulting from the evaluation will be used to improve or expand the program. Discuss how the results of the evaluation will be reported and who will receive the results.

More information about the six steps can be found at: *http://www.cdc.gov/eval/framework.htm.*

Note: Include samples of data collection tools in the attachments, if available.

In addition, the evaluation plan should document and describe program successes, unmet needs, barriers, and problems encountered in planning, implementing, or in coordinating activities.

5. Program Infrastructure and Management Plan: Describe how the program will be effectively managed including:

a. Staffing: Minimal key staffing for the program should include a full-time DPCP coordinator, a designated evaluation lead, and a designated epidemiology/surveillance lead.

b. Staffing Responsibilities: Responsibilities of key staff should include: a DPCP coordinator responsible for the overall program operation and coordination; a designated evaluation lead responsible for ensuring that the program and its projects are evaluated regularly for process and impact measures and that results are appropriately disseminated; and a designated epidemiology/surveillance lead who will ensure the integrity of surveillance systems and other DPCP epidemiological activities and facilitate intra and inter health department exchange of epidemiological information. In addition, the DPCP should designate a staff member to facilitate and oversee a process for integrating other program components such as NDEP messages and tools into program planning and implementation activities.

c. Management Plan and Organization Operations: Provide a copy of the organizational chart that indicates the placement of the proposed program. A description of clear and direct lines of authority within the program staff and to the next two higher levels of supervisory authority should be provided. Fiscal controls and their relationship to program staff and management should be included. Discuss strategies for ensuring timely and appropriate communication among staff on the status of program implementation and related issues. The DPCP should receive guidance and support from the State Chronic Disease Director or the equivalent. The priority DPCP goals and objectives should be part of, or incorporated in, the overall State Health Department strategic plan.

d. Qualifications: Describe the qualifications of the designated or proposed staff. Provide abbreviated (one-to-two page) resumes and brief job descriptions for designated staff, and brief job descriptions for the proposed staff.

e. Responsibility: Identify key staff positions responsible for the implementation of each program activity, especially the required full

time coordinator, the evaluation lead and the epidemiology/surveillance lead.

f. Contingency plans: Describe plans for ongoing management and operation of the project if there are unexpected vacancies, hiring restrictions, or difficulty recruiting in key positions.

6. Financial Participation: Matching funds are required from non-Federal sources in the amount of not less than $1 for each $5 of Federal funds awarded to Core Programs under this program announcement. Comprehensive Programs are required to match $1 for each $4 of Federal funds awarded under this announcement. Match requirements may change in years two through five. The applicant should identify and describe:

a. Sources of allowable matching funds for the program and the estimated amounts from each.

b. Procedures for documenting and tracking the receipt and value of noncash matching funds.

7. Budget and Narrative Justification:

a. Financial Assistance

Provide a detailed line-item budget and narrative justification for all operating expenses consistent with and clearly related to the proposed objectives and planned activities. Be precise about the program purpose of each budget item and itemize calculations when appropriate.

Applicants are required to attend the DDT Annual Conference and the DPCP Project Directors' Meeting and should budget appropriately. DPCPs are also encouraged to attend and participate in non-conference training such as Diabetes Today and the Diabetes Collaborative, as appropriate. Other travel which may be of relevance to the DPCP goals and activities include the annual meetings of the following organizations: National Diabetes Education Program Partnership Network, ASTCDD (Chronic Disease Conference), American Diabetes Association (ADA), American Association for Diabetes Educators (AADE), National Association of Community Health Centers (NACHC), American Association of Health Plans (AAHP) and American Public Health Association (APHA). Travel budget should support other recipient activities as considered necessary.

b. Direct Assistance

To request a Federal assignee, applicants must provide the following information:

1). Number of assignees requested

2). Description of the position and proposed duties

3). Ability or inability to hire locally with financial assistance

4). Justification for request

5). Organizational chart and name of intended point of contact to assignee

6). Opportunities for training, education, and work experiences for assignees

7). Description of assignees' access to computer equipment for communication with CDC (*e.g.*, personal computer at home, personal computer at workstation, shared computer at workstation on site, shared computer at a central office).

G. Application Submission and Deadline

Application Forms

Submit the signed original and two copies of CDC Form 0.1246(E). 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–TIM) at: 770–488–2700. Application forms can be mailed to you.

Submission Date, Time, and Address

Applications must be received by 4 p.m. Eastern Time January 9, 2003. Submit the application to: Technical Information Management—PA#03017, CDC Procurement and Grants Office, 2920 Brandywine Road, Room 3000, Atlanta, Georgia 30341–4146.

CDC Acknowledgment of Application Receipt

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

Deadline

Applications shall be considered as meeting the deadline if they are received before 4 p.m. Eastern Time on the deadline date. Applicants sending applications 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.

Applications which do not meet the above criteria will not be eligible for competition and will be discarded. Applicants will be notified of their failure to meet the submission requirements.

H. Evaluation Criteria

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

An Objective Review Panel appointed by CDC will evaluate the scientific and technical merit of Comprehensive Program applications and their responsiveness to the information requested in the ''Application Content'' sections above. Core Program applications will receive a technical review for acceptability. Each application will be reviewed and evaluated against the following criteria:

Core Program Evaluation Criteria (100 Points Total)

1. Program Work Plan (75 points Total)

The extent to which the work plan addresses the following information:

a. Long Term and Process Objectives (10 points)

Measurable, specific, time-phased five-year project period long term objectives, and measurable, time-phased one-year budget period process objectives that will help achieve the goals and objectives of the program. The applicant used the State's latest data as baseline.

b. Program Work Plan Methodology (25 points)

The Program Work plan provides a detailed description of system-based activities and methods for achieving each of the proposed one year budget period objectives that appears reasonable and likely to be successful.

c. Evaluation Plan (20 points)

The plan for evaluating progress, the effectiveness of activities and attainment of each of the proposed objectives, to include a clear description of the evaluation methodology and frequency of reporting, appears adequate. The six steps of the CDC Framework for Program Evaluations are used as a framework for the plan. (*See* section E. 4. Evaluation Plan under Application Content section). Logic

models that link program objectives and activities to eventual outcomes/effects should be included.

d. Program Infrastructure and Management Plan (20 points)

DPCP staffing pattern adequately supports the work plan proposed to include the number and type of staff and their qualifications and experience. The Management Plan describes a methodology for effective management, to include a sound management structure, *i.e.* a full time DPCP coordinator and designated evaluation and epidemiology/surveillance leads; clear and direct lines of authority, supervisory and fiscal controls; contingency plans for ongoing management in case of unexpected staff disruption shall be included. Include a copy of the organizational chart that indicates the placement of the DPCP, resumes for designated staff, and job descriptions for the proposed staff. Strategies for ensuring timely and appropriate communication among staff on the status of program implementation and related issues are included in the plan. Describe how the DPCP and its partners will collaborate to collectively complete a diabetes specific assessment based on the ten essential public health services. The results of the assessment will assist in identifying specific areas of strength and areas for improvement in developing an optimal public health diabetes program in subsequent years.

2. Accomplishments and Proven Capacity of the Core Program (15 points)

Core program accomplishments and activities that make it appear likely that the applicant will successfully carry out proposed activities, to include:

a. Existing state-based diabetes surveillance system, including annual administration of the Diabetes Module of the BRFSS.

b. Advances toward achieving the CDC, DDT's National Objectives (provide data as evidence of progress).

c. Findings, conclusions, or status of pilot projects in health systems, health communications, and community interventions.

d. Examples of successful efforts to influence the widespread application of accepted standards, policies, and protocols, which support diabetes prevention and control.

e. Accomplishments of any diabetes advisory groups or coalitions in providing guidance to the DPCP in program planning, implementation, coordinating efforts and evaluation (may include a copy of the by-laws).

f. Activities and accomplishments in addressing the needs of underserved populations and/or populations with a disparate burden of diabetes and its related complications are included.

g. DPCP's management of its fiscal and human resources in the past five years (including history of unobligated balances, how match requirements have been met, turnover in key staff positions, professional development of DPCP staff, supportive leadership, *etc.*) are addressed.

3. Background and Need (10 points)

The extent to which the DPCP demonstrates the need for support. Narrative should include:

a. Estimated prevalence of diabetes and its complications, and its geographic and demographic distribution within the State.

b. Description of the high risk populations, including racial/ethnic minorities, the elderly, and the indigent/disenfranchised population. Description of the characteristics of the targeted population relative to the social, ecological, or economic conditions that contribute to the disproportionate burden of diabetes in the population, as well as their knowledge, attitudes, beliefs, and health practices relative to diabetes.

c. Analysis of the findings of (b) above in relation to known or anticipated barriers to diabetes education, self management, preventive community services and health care.

4. Budget and Justification (Reviewed but Not Scored)

The extent to which the line item budget justification is reasonable and consistent with the purpose and program goal(s) and objectives of the cooperative agreement. This includes both requests for financial assistance and how the DPCP proposes to meet the match requirement.

5. If any resources available under this program announcement will be used to conduct research projects involving human subjects, the application must adequately address Title 45 CFR Part 46. (Reviewed but Not Scored, however an application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.)

6. The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes: (1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation; (2) The proposed justification when representation is limited or absent; (3) A statement as to whether the design of the study is adequate to measure differences when warranted; and (4) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits. (Reviewed but Not Scored)

Comprehensive Program Evaluation Criteria (100 points total)

1. Program Work Plan (60 points total)

The Program Work plan provides a detailed description of system-based activities and methods for achieving each of the proposed objectives that appears reasonable and likely to be successful.

a. Long Term and Process Objectives (10 points) Measurable, specific, time-phased five-year project period long term objectives, and measurable, specific, time-phased one year budget period process objectives, that will help achieve the time-phased long term objectives of the program, are provided. The DPCP used the state's latest data as baseline.

b. Program Work Plan Methodology (20 points) The Work Plan provides a detailed description of systems-based activities and methods for achieving each of the proposed one year budget period objectives that appears reasonable and likely to be successful. Existing comprehensive activities are described, including plans for maintaining or modifying them. New Comprehensive program activities are adequately described and justified.

c. Evaluation Plan (15 points) The plan for evaluating progress, the effectiveness of activities and attainment of each of the proposed objectives, to include a clear description of the evaluation methodology and frequency of reporting, appears adequate. The plan should incorporate the six steps of the CDC Framework for Program Evaluation. (*See* section E. 4. Evaluation Plan under Application Content section). Logic models that link program objectives and activities to eventual outcomes/effects should be included.

d. Program Infrastructure and Management Plan (15 points)

DPCP staffing pattern adequately supports the work plan proposed to include the number and type of staff and their qualifications and experience. The Management Plan describes a methodology for effective management,

to include a sound management structure, *i.e.* a full time DPCP coordinator and designated evaluation and epidemiology/surveillance leads; clear and direct lines of authority, supervisory and fiscal controls; contingency plans for ongoing management in case of unexpected staff disruption shall be included. A copy of the organizational chart that indicates the placement of the DPCP, resumes for designated staff and job descriptions for the proposed staff. Strategies for ensuring timely and appropriate communication among staff on the status of program implementation and related issues are included in the plan. The management plan should demonstrate how the DPCP will address increased program responsibility and fiscal and human resources. Describe how the DPCP and its partners will collaborate to collectively complete a diabetes specific assessment based on the ten essential public health services. The results of the assessment will assist in identifying specific areas of strength and areas for improvement in developing an optimal public health diabetes program in subsequent years.

2. Program Accomplishments and Proven Capacity To Serve as a Comprehensive Program (35 points)

Program accomplishments and activities that make it appear likely that the applicant will successfully carry out proposed comprehensive activities to include:

a. Advanced and enhanced state-based diabetes surveillance system, minimally including annual administration of the diabetes module of the BRFSS.

b. Status and impact of statewide and other comprehensive program activities in health systems, health communications, and community interventions that have advanced the program toward achieving improvements in the CDC, DDT's National Objectives. Data should be provided to support program impact and as evidence of progress.

c. Description of evaluation activities and examples of efforts to disseminate program activities and lessons learned to the broader diabetes community.

d. Evidence of internal and external policy changes resulting from comprehensive program efforts, including accomplishments of any diabetes advisory groups or coalitions (may include a copy of the by-laws).

e. Examples of successful efforts to influence the widespread application of accepted standards, policies, and protocols which support diabetes prevention and control.

f. Accomplishments in addressing the needs of underserved populations and/or reducing health disparities in populations with a disparate burden of diabetes and its related complications.

g. DPCP's management of its fiscal and human resources in the past five years (including history of unobligated balances, how match requirements have been met, turnover in key staff positions, professional development of DPCP staff, supportive leadership, *etc.*) are addressed.

3. Background and Need (5 points)

The extent to which the DPCP demonstrates the need for support. Narrative should include:

a. Estimated prevalence of diabetes and its complications, and its geographic and demographic distribution within the State.

b. Description of the high risk populations, including racial/ethnic minorities, the elderly, and the indigent/disenfranchised population. Description of the characteristics of the targeted population relative to the social, ecological, or economic conditions that contribute to the disproportionate burden of diabetes in the population, as well as their knowledge, attitudes, beliefs, and health practices relative to diabetes.

c. Analysis of the findings of b. above in relation to known, or anticipated, barriers to diabetes education, self management, preventive community services and health care.

4. Budget and Justification (reviewed but not scored)

The extent to which the line-item budget justification is reasonable and consistent with the purpose and program goals and objectives of the cooperative agreement. This includes both requests for financial assistance and how the DPCP proposes to meet the match requirement.

5. If any resources available under this program announcement will be used to conduct research projects involving human subjects, the application must adequately address title 45 CFR part 46. (Reviewed but Not Scored, however, an application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.)

6. The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes: (1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation; (2) The proposed justification when representation is limited or absent; (3) A statement as to whether the design of the study is adequate to measure differences when warranted; and (4) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits. (Reviewed but Not Scored)

I. Other Requirements

Technical Reporting Requirements

Provide CDC with a signed original and two copies of:

1. Interim progress reports, no less than 90 days before the end of the budget periods. The format of the Division of Diabetes Translation's (DDT) Management Information System (MIS) is aligned with the interim progress report content. Therefore, to avoid duplication of effort, the interim progress report content may be entered into the DDT MIS and hard copies generated from MIS for formal submission to the CDC Procurement and Grants Office. The content of the interim progress report must be entered into the DDT MIS, by the grantee, within one month of the due date of the interim progress report. The interim progress report will serve as your non-competing continuation application, and must contain the following broad elements (subject to change as the program evolves): progress and performance for the first eight months of the current budget period objectives/activities, the proposed objectives/activities for the new year's budget period related to Surveillance, Work Plan, Program Coordination, Program Infrastructure, and Financial information (including a detailed line-item budget and justification). Progress in implementing improvement plans starting in year two, must be reported as part of the required interim progress reports.

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

3. Final financial and performance reports no more than 90 days after the end of the five year project period.

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

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

AR–1 Human Subjects Requirements
AR–2 Requirement for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–7 Executive Order 12372 Review
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions

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, Room 3000, Atlanta, GA 30341–4146. Telephone (770) 488–2700.

For business management and budget assistance in the States, contact: Angela Webb, Grants Management Specialist, Acquisition and Assistance Branch B, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146. Telephone (770) 488–2784. Email address: *AQW6@cdc.gov.*

For business management and budget assistance in the Territories, contact: Terri Brown, Grants Management Specialist, International & Territories Acquisition and Assistance Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, Georgia 30341–4146. Telephone (770) 488–2638. Email address: *aie9@cdc.gov.*

For program technical assistance, contact: Patricia L. Mitchell, MPH, Health Comm. Section Chief, Program Development Branch, DDT, NCCDPHP, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, MS K10, Atlanta, GA 30341–3717. Telephone (770) 488–5634. Email address: *plm3@cdc.gov.*

Dated: November 12, 2002.

Edward Schultz,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 02–29837 Filed 11–22–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–5556]

Agency Information Collection Activities; Announcement of OMB Approval; Food Contact Substances Notification System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Food Contact Substances Notification System'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 21, 2002 (67 FR 35724), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0495. The approval expires on November 30, 2005. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets.*

Dated: November 14, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–29807 Filed 11–22–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 13, 14, and 15, 2003, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, FAX 301–827–6776, e-mail: *somersk@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12536. Please call the Information Line for up-to-date information on this meeting.

Agenda: On January 13, 2003, the committee will discuss the safety and efficacy of biologic licensing application BL 103979, FABRAZYME (agalsidase beta, Genzyme Corp.) for the treatment of Fabry's disease. On January 14, 2003, the committee will discuss the safety and efficacy of biologic licensing application BL 103977, REPLAGAL (agalsidase alfa, Transkaryotic Therapies, Inc.) for the treatment of Fabry's disease. On January 15, 2003, the committee will discuss the safety and efficacy of biologic licensing application BL 125058, ALDURAZYME (laronidase, BioMarin Pharmaceutical, Inc.) for the treatment of mucopolysaccharidosis.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 6, 2003. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 6, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.