

- Receive a second level review by CDC senior staff.

Award Criteria: Criteria that will be used to make award decisions include:

- Scientific merit (as determined by peer review).
- Availability of funds.
- Programmatic priorities.
- A multiple range of study designs, from database studies to prospective cohort studies, will be considered for funding, but priority will be given to projects that include analysis of test confirmed influenza cases.

V.3. Anticipated Announcement and Award Dates

Anticipated Award Date: August 16, 2004.

VI. Award Administration Information

VI.1. Award Notices

Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

VI.2. Administrative and National Policy Requirements

45 CFR Part 74 and Part 92

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>.

The following additional requirements apply to this project:

- AR-1 Human Subjects Requirements.
- AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research.
- AR-3 Animal Subject Requirements.
- AR-7 Executive Order 12372.
- AR-10 Smoke-Free Workplace Requirements.
- AR-11 Healthy People 2010.
- AR-12 Lobbying Restrictions.
- AR-15 Proof of Non-Profit Status.
- AR-22 Research Integrity.
- AR-23 States and Faith-Based Organizations.
- AR-25 Release and Sharing of Data.

Additional information on these requirements can be found on the CDC Web site at the following Internet address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

VI.3. Reporting

You must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, (use form PHS 2590, OMB Number 0925-0001, rev. 5/2001 as posted on the CDC Web site) 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. Budget.
 - e. Additional Requested Information.
 - f. Measures of Effectiveness.
2. Financial status report and annual progress 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.

These reports must be mailed to the Grants Management Specialist listed in the "Agency Contacts" section of this announcement.

VII. Agency Contacts

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

For scientific/research issues, contact: Dr. Mary Lerchen, Acting Director, Office of Extramural Research, CDC, National Center for Infectious Diseases, 1600 Clifton Road, NE., Mailstop: C-19, Atlanta, GA 30333, Telephone: 404-639-0043, E-mail: mll0@cdc.gov.

For questions about peer review, contact: Barbara Stewart, CDC, National Center for Infectious Diseases, 1600 Clifton Road, NE., Mailstop: C-19, Atlanta, GA 30333, Telephone: 404-639-0044, E-mail: bsg2@cdc.gov.

For financial, grants management, or budget assistance, contact: Lynn Walling, Contract Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2612, E-mail: lqw5@cdc.gov.

VIII. Other Information

None.

Dated: April 20, 2004.

William P. Nichols,

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

[FR Doc. 04-9371 Filed 4-23-04; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Diabetes Today Phase II

Announcement Type: New.

Funding Opportunity Number: 04136.

Catalog of Federal Domestic Assistance Number: 93.988.

Key Dates: Application Deadline: June 10, 2004.

I. Funding Opportunity Description

Authority: 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.

Purpose: The purpose of the program is to build on the foundation developed through the initial Pacific Diabetes Today training, focusing on implementing multiple community-based interventions in several Pacific communities, and to evaluate the impact of diabetes prevention and control activities for the Pacific region. This includes assessment of community capacity and infrastructure development and the identification and cataloguing of effective interventions unique for the Pacific Region.

This program addresses the "Healthy People 2010" focus areas of Diabetes, Immunization, Heart Disease and Stroke, Nutrition and Overweight, Physical Activity and Fitness, Vision and Hearing, Chronic Kidney Disease and Public Health Infrastructure.

Activities: Awardee activities for this program are as follows:

- Provide materials, trainers and training sessions, follow-up and technical assistance for conducting education and training on the Pacific Diabetes Today Guidebook.
- Deliver at least one Pacific Diabetes Today training per year using local and/or regional Pacific Diabetes Today trainers.
- Provide resources on an as needed basis to support coalitions including resources necessary for implementing community activities and the community champion responsible for coordination and leading as well as community advisors/experts.
- Expand the focus and reach of community-based interventions with an emphasis on moving into intervention implementation.
- Identify and implement high priority public health intervention strategies that have been determined by a community coalition that such

activities will work in their communities to prevent and control diabetes.

- Work with communities to examine their diabetes and chronic disease burden, and current resources. Assist in developing a comprehensive diabetes control and prevention plan.

(Communities may address nutrition, physical activity and health communication as well as interventions that include multifaceted strategies to change social and physical environments.)

- Identify and leverage opportunities and collaborate with at least two jurisdictional/state organizations and key partners, one of whom must be a Diabetes Prevention and Control Program, to build institutional supports that will ultimately provide a permanent Pacific Diabetes Today training home.

- Build an alliance of partnerships and coalitions committed to collectively planning, implementing and evaluating effective strategies for prevention and control of diabetes and associated risk factors in Pacific Islanders and Hawaiians. Partners may include, but are not limited to: Diabetes Prevention and Control Programs; local, jurisdiction/state education institutions, e.g., community colleges and universities; key community organizations, e.g., women's groups; health care and professional organizations, e.g., Pacific Islands Health Officers Association (PIHOA), Pacific Basin Medical Association (PBMA); and community and faith-based leaders.

- Establish and maintain a local jurisdiction/state Pacific Diabetes Today Advisory Council. Assist in organizing and facilitating meetings, approaches to sharing experiences and lessons learned.

- Coordinate community Diabetes and chronic disease prevention and control plans and objectives with jurisdiction/state public health plans. Ensure that community objectives, activities and interventions are consistent with, and supportive of jurisdiction/state public health plans for the prevention and control of diabetes.

- Ensure timely communication and exchange of information by sharing of experiences, strategies and results with Pacific Basin and Hawaiian communities and CDC through the use of the Internet; workshops, site visits to and between communities and jurisdictions; and other activities.

- Establish and maintain Diabetes Today staff/program champion designated only to working with Diabetes Today programs to provide

oversight to communities in planning, developing, implementing and evaluating interventions and monitoring progress. The staff/champion will provide resources to community programs and make available the expertise to assist and enhance the work of communities.

- Collaborate with the Diabetes Today National Training Center in identifying community interventions and best practices for consideration of their appropriateness in the Pacific region and Hawaii and develop a 2 and one-half day course that will facilitate understanding of key elements of selected interventions that hold promise for Pacific communities.

- Conduct on-going monitoring and evaluation of diabetes prevention and control activities and strategies.

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

CDC Activities for this program are as follows:

- Provide ongoing guidance, consultation and technical assistance in all aspects of diabetes prevention and control.

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

- Collaborate with the Awardees and other appropriate partners, including but not limited to, the Diabetes Today National Training Center in identifying community interventions and best practices to replicate in the Pacific region and Hawaii.

- Assist in and support the development and maintenance of partnerships and networks to help support the implementation of community-based interventions and best practices.

- Facilitate effective communication and integration between NDEP, jurisdiction/State Diabetes Prevention and Control Programs (DPCP's) and Pacific communities. This includes, but is not limited to, NDEP training, media and other program products and tools.

II. Award Information

Type of Award: Cooperative Agreement.

CDC involvement in this program is listed in the Activities Section above.

Fiscal Year Funds: FY 2004.

Approximate Total Funding: \$425,000.

Approximate Number of Awards: 8–10 awards.

Approximately Average Award: \$35,000.

Floor of Award Range: None.

Ceiling of Award Range: None.

Anticipated Award Date: August 30, 2004.

Budget Period Length: 12 months.

Project Period Length: 5 Years.

Throughout the project period, CDC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal Government.

III. Eligibility Information

III.1. Eligible Applicants

Applications may be submitted by public or private nonprofit organizations and by governments and their agencies, such as:

- Public nonprofit organizations.
- Private nonprofit organizations.
- Universities.
- Colleges.
- Hospitals.
- Community-based organizations.
- Faith-based organizations.
- State and local governments or their

Bona Fide Agents, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, Hawaii, and the Republic of Palau.

A Bona Fide Agent is an agency/organization identified by the jurisdiction/state as eligible to submit an application under the jurisdiction/state eligibility in lieu of a jurisdiction/state application. If you are applying as a bona fide agent of a State or local government, you must provide a letter from the State or local government as documentation of your status. Place this documentation behind the first page of your application form.

III.2. Cost Sharing or Matching

Matching funds are not required for this program.

III.3. Other

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.

IV. Application and Submission Information

IV.1. Address To Request Application Package

To apply for this funding opportunity use application form PHS 5161. Forms are available on the CDC Web site, at the following Internet address: www.cdc.gov/od/pgof/forminfo.htm.

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

IV.2. Content and Form of Submission Application

You must submit a project narrative with your application forms. Your narrative must be submitted in the following format:

- Maximum number of pages: 30. If your narrative exceeds the page limit, only the first pages, which are within the page limit, will be reviewed.
- Double-spaced.
- Font size: 12 point un-reduced.
- Paper size: 8.5 by 11 inches.
- Page margin size: one-inch margins.
- Printed only on one side of page.
- Held together only by rubber bands or metal clips; not bound in any other way.

Your narrative should address activities to be conducted over the entire project period, and must include the following items in the order listed:

1. Official Transmittal Letter—Letter of transmittal from the mayor, community-based or governmental official identifying the lead agency (Diabetes Prevention and Control Program, State Health Department or bona fide agent) and citing the amount requested. Include a description of the lead agency, including fiduciary and programmatic capabilities, as related to this announcement.

2. Table of Contents—Table of Contents with page numbers for each section.

3. Executive Summary—Executive Summary briefly describing the overall project, partnerships, intervention strategies and long and short-term outcomes.

4. Plan—Provide a clear work plan that includes specific, measurable, achievable, realistic and time-phased and realistic long and short term objectives based on the needs of the community and gaps in community-based diabetes prevention and control activities. Include a description of the target populations. The plan should identify likely approaches, strategies and interventions to be used over the five-year period. The plan should address first year objectives and activities in depth and their relationship to attaining short-term outcomes. The plan should also include efforts to ensure long-term sustainability of project efforts and outcomes.

5. Staff/Program Champion—Description of the proposed staff/ champion, the qualifications and responsibilities of each and the percent of time committed to Diabetes Today Phase II.

6. Local Diabetes Today Advisory Council—Description of the community members and the specific role/ contribution of each member. Include a list of key partners. Decisionmaking processes and methods of accountability of the members should be described.

7. Evaluation and Monitoring—Describe how progress and achievement of program objectives and program activities will be monitored and evaluated. Describe how data will be collected, analyzed and used to improve the program. Specify the person responsible for implementing monitoring and evaluation activities and reporting findings.

8. Budget and Budget Justification/ Narrative—Provide a detailed line-item budget and narrative justification for all expenses related to the proposed objectives and planned activities for the first year. Clearly indicate the purpose of each budget item and estimated budget amounts to be sub-contracted to the local community-based organizations or other key partners. The budget and the narrative justification will not be counted in the stated page limit.

Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit. This additional information includes:

- Resumes or description of expertise in working with communities.
- Letters of Support—Provide letters of support and/or Memoranda of Understanding (as appropriate) from key partners that support their roles and responsibilities.
- Community Descriptions

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access www.dunandbradstreet.com or call 1-866-705-5711.

For more information, see the CDC Web site at: <http://www.cdc.gov/od/pgofunding/pubcomm.htm>.

If your application form does not have a DUNS number field, please write your DUNS number at the top of the first page of your application, and/or include

your DUNS number in your application cover letter.

Additional requirements that may require you to submit additional documentation with your application are listed in section “VI.2. Administrative and National Policy Requirements.”

IV.3. Submission Dates and Times

Application Deadline Date: June 10, 2004.

Explanation of Deadlines:

Applications must be received in the CDC Procurement and Grants Office by 4 p.m. eastern time on the deadline date. If you send your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If CDC receives your application 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, you will be given the opportunity to submit documentation of the carriers guarantee. If the documentation verifies a carrier problem, CDC will consider the application as having been received by the deadline.

This announcement is the definitive guide on application format, content, and deadlines. It supersedes information provided in the application instructions. If your application does not meet the deadline above, it will not be eligible for review and will be discarded. You will be notified that you did not meet the submission requirements.

CDC will not notify you upon receipt of your application. If you have a question about the receipt of your application, first contact your courier. If you still have a question, contact the PGO-TIM staff at (770) 488-2700. Before calling, please wait two to three days after the application deadline. This will allow time for applications to be processed and logged.

IV.4. Intergovernmental Review of Applications

Your application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order (EO) 12372. This order sets up a system for State and local governmental review of proposed Federal assistance applications. You should contact your State single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your State's process. Click on the following link to get the

current SPOC list: <http://www.whitehouse.gov/omb/grants/spoc.html>.

IV.5. Funding Restrictions

Restrictions, which must be taken into account while writing your budget, are as follows:

- Resources available under this program announcement are to be used for capacity building and intervention development. They may not be used to: (1) Support direct patient care services, screening services, individual health services, or the treatment of diabetes, or (2) supplant existing Jurisdictional/State or Federal funding including the Preventive Health and Health Service Block Grant or other sources.

- If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement should be less than 12 months of age.

IV.6. Other Submission Requirements

Application Submission Address: Submit the original and two hard copies of your application by mail or express delivery service to: Technical Information Management-PA# 04136, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

Applications may not be submitted electronically at this time.

V. Application Review Information

V.1. Criteria

You are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the "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.

Your application will be evaluated against the following criteria:

1. Work Plan for Intervention Strategies (45 Points)

- Provide a detailed description describing activities and methods for achieving each of the proposed objectives that appear reasonable and likely to be successful.
- Provide a description of long-term objectives, process (one year) objectives, activities and specific methods to assist local communities in Diabetes Today Activities.

- Identify likely approaches, strategies and interventions to be used over the five-year period to address diabetes prevention and control.

- List Objectives that are specific, measurable, achievable, relevant and time-bound. Five-year objectives and the first year budget period process objectives and activities to be used, timelines, possible barriers, organizations/partners and responsible person should be addressed. Provides a detailed description of experience, expertise and capacity to assist local communities in implementing diabetes prevention and control activities.

- Describes plans to coordinate activities with jurisdiction/state programs to prevent and control diabetes.

2. Training, Resources, Follow-Up and Technical Assistance (20 Points)

- Provide a detailed description of education, training, trainers and provision of resources, follow-up and technical assistance activities and methods that appear reasonable and likely to be successful.

3. Program Leadership, Collaboration and Structure (15 Points)

- Identify a lead/fiduciary agency that will ensure accountability for achieving objectives and for expenditures in relationship to performance of all partners. May be a Diabetes Prevention and Control Program or Community-based Organization.

- Describe the proposed structure including decision making processes, monitoring, problem solving and providing support to community-based activities.

- Provide letters of support or memorandum of agreement that describe specific collaborative activities. Provides evidence that staff/champion have relevant qualifications and experience to facilitate community-based interventions.

4. Advisory Council (10 Points)

- Describe local Advisory council in terms of expertise, community representation, collaborative experiences, and agency representation.

- Describe how local jurisdiction/state Diabetes Today Advisory Council is used to plan, implement and evaluate community-based interventions.

- Describe how money, facilities, expertise and shared decision making will be conducted in collaboration with partners.

5. Plans for Monitoring and Evaluation (10 Points)

- Describe the evaluation progress and how evaluation will be used to achieve long-term and process objectives and the effectiveness of activities.

- Clearly describe the evaluation methodology and frequency of reporting.

- Provide a description of how data will be collected and analyzed.

- Specify the person(s) responsible for collecting and analyzing data and reporting findings.

6. Budget and Justification (Reviewed but Not Scored)

- Provide a budget and budget justification that is reasonable and consistent with the purpose and program goal of the cooperative agreement.

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by NCCDPHP staff. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

An Objective Review Panel appointed by CDC will evaluate the scientific and technical merit of Program applications and their responsiveness to the information requested in the Application "Content" section above.

An objective review panel will evaluate complete and responsive applications according to the criteria listed in "V.1. Criteria" section above. In addition, the following factors may affect the funding decision:

- Geographic diversity.
- Preference to organizations in certain geographic areas.
- Due to resource limitations, funding preference will be given to jurisdictions/State Health Departments and Community-Based Organizations that were funded for Phase I of Diabetes Today.

V.3. Anticipated Announcement and Award Dates

August 30, 2004.

VI. Award Administration Information

VI.1. Award Notices

Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the

recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

VI.2. Administrative and National Policy Requirements

45 CFR Part 74 and Part 92

For more information on the Code of Federal Regulations, see the National Archives and Records administration at the following Internet address: www.access.gpo.gov/nara/cfr-table-search.html.

The following additional requirements apply to this project:

- AR-7 Executive Order 12372.
- AR-10 Smoke-Free Workplace Requirements.
- AR-11 Healthy People 2010.
- AR-12 Lobbying Restrictions.

Additional information on these requirements can be found on the CDC Web site at the following Internet address: <http://www.cdc.gov/od/pgofunding/ARs.htm>.

VI.3. Reporting Requirements

You must provide CDC with a signed original and two copies of the following reports:

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 for the subsequent year, and must contain the following elements:

a. Current Budget Period Activities Objectives—(1) A description of accomplishments and progress in achieving objectives within the planned budget during the first six months of the current budget period, (2) reasons for not achieving established objectives and what will be done to meet unmet objectives, (3) Current budget period financial progress, (4) new budget period proposed program activities and objectives, (5) Detailed line-item budget and justification, (6) If contracts are proposed, provide the name of the contractor(s), method of selection, period of performance, scope of work, and itemized budget and budget justification/narrative.

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.

VII. Agency Contacts

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

For program technical assistance, contact: Ron Stoddard, Project Officer, Program Development Branch, Division of Diabetes Translation, Centers for Disease Control and Prevention, 4770 Buford Highway, MS K-10, Atlanta, Georgia 30341-3717, Telephone: (770) 488-5013, E-mail: rrs1@cdc.gov.

For budget assistance in the states, contact: Tiffney Esslinger, Contract Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: (770) 488-2686, E-mail: tde2@cdc.gov.

For budget assistance in the territories, contact: Vincent Falzone, Contract Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: (770) 488-2763, E-mail: vcf6@cdc.gov.

Dated: April 20, 2004.

William P. Nichols,

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

[FR Doc. 04-9372 Filed 4-23-04; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0176]

Preparation for the International Conference on Harmonization Meetings in Washington, DC; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled "Preparation for ICH meetings in Washington, DC" to provide information and receive comments on the International Conference on Harmonization (ICH) as well as the upcoming meetings in Washington, DC. The topics to be discussed are the topics for discussion at the forthcoming ICH Steering Committee Meeting. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Experts Working Groups meetings in Washington, DC, June 7-10, 2004, at which discussion of the topics

underway and the future of ICH will continue.

Date and Time: The meeting will be held on May 17, 2004, from 1:30 to 4:30 p.m.

Location: The meeting will be held at 5600 Fishers Lane, 3d floor, Potomac Conference Room, Rockville, MD 20857. For security reasons, all attendees are asked to arrive no later than 1:30 p.m., as you will be escorted from the front entrance of 5600 Fishers Lane to the Potomac Conference Room.

Contact Person: Sema Hashemi, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3050, FAX: 301-480-0716, e-mail: Sema.Hashemi@fda.hhs.gov.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to make oral presentations, to the contact person by May 7, 2004.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

If you need special accommodations due to a disability, please contact Sema Hashemi at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The ICH was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization among the following three regions: The European Union,