## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Advisory Committee on Immunization Practices: Teleconference

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

*Name:* Advisory Committee on Immunization Practices (ACIP) Teleconference.

*Time and Date:* 4:15 p.m.–6 p.m. (EST), March 16, 1999.

*Place:* The teleconference call will originate at the Centers for Disease Control and Prevention in Atlanta,Georgia. Please see **SUPPLEMENTARY INFORMATION** for details on accessing the teleconference.

*Status:* Open to the public, teleconference access limited only by availability of telephone ports.

*Purpose:* The Committee is charged with advising the Director, CDC, on the appropriate uses of immunizing agents. In addition, under 42 U.S.C. § 1396s, the Committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines.

*Matters To Be Discussed:* The teleconference agenda will include a discussion on the ACIP 1999 Prevention and Control of Influenza recommendation, and a final decision from the committee members on acceptance of the recommendation for publication in the Morbidity and Mortality Reports and Recommendations.

Agenda items are subject to change as priorities dictate.

*Supplementary Information:* This conference call is scheduled to begin at 4:15 p.m. Eastern Standard Time. To participate in the teleconference, please dial 1/800/713–1971 and enter conference code 497796. You will then be automatically connected to the call.

Due to difficulties in scheduling this meeting, and the necessity to meet publication deadlines, this notice is being published less than 15 days prior to the teleconference.

*Contact Person for More Information:* Gloria A. Kovach, Committee Management Specialist, CDC, 1600 Clifton Road, NE, m/s D50, Atlanta, Georgia 30333. Telephone 404/639–7250.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: March 4, 1999.

**Carolyn J. Russell,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 99–5862 Filed 3–5–99; 4:33 pm]

**BILLING CODE 4163–18–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[Notice of Meeting/Draft Program Announcement 99064]**

### National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention Announcement of Meeting

*Name:* Meeting for Public Comment on Racial and Ethnic Approaches to Community Health Demonstration Projects (REACH).

*Time and Date:* 8:30 a.m.–3:30 p.m., March 16, 1999.

*Place:* Crystal City Marriott, 1700 Jefferson Davis Highway, Arlington, Virginia 22202, (703) 920–3230.

*Status:* Attendees will include invited participants representing private nonprofit organizations, academic institutions, State and local health agencies, community health centers, Indian tribal governments and organizations. The meeting is open to the public and is limited only by space available. The meeting room will accommodate approximately 150 people.

*Purpose:* Attendees will be charged with reviewing major concepts and strategies that pertain to the Centers for Disease Control and Prevention (CDC), National Center for Chronic Disease Prevention and Health Promotion's pending funding announcement for REACH Demonstration Projects. The funding announcement is in response to the ten million dollars appropriated to the CDC by Congress in response to the Health and Human Services Initiative to Eliminate Racial and Ethnic Disparities in Health, which is aimed at eliminating disparities in health outcomes for racial and ethnic communities in six health focus areas by the year 2010.

*Matters to be Discussed:* Agenda items include discussion of directly funding private nonprofit organizations (including community based organizations and foundations); universities, colleges, research institutions, and hospitals; governments and their agencies (including State and local health agencies, and community health centers); and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations; Public input and comments will be sought regarding proposed recipient activities under Phase I/Phase II, evaluation plan, and proposed CDC activities.

Due to administrative delays in the program, this notice was not published fifteen (15) days in advance of the meeting.

Contact Person for More Information: Regina Lee, Office of Minority Health, 5515 Security Lane, Suite 1000, Rockville, MD 20852, Attn: REACH, OFFICE: (301) 443–9924, FAX: (301) 443–8280, EMAIL: rlee@osodhs.dhhs.gov.

### Racial and Ethnic Approaches to Community Health (REACH) Demonstration Projects; Notice of Availability of Funds

### SUMMARY

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1999 funds for a cooperative agreement program for organizations serving racial and ethnic minority populations at increased risk for infant mortality, diabetes, cardiovascular diseases, Human Immunodeficiency Virus (HIV), deficits in breast and cervical cancer screening and management, and deficits in child or adult immunization rates.

The purpose of this notice is to request comments on the proposed program. A more complete description of the goals of this program, the target applicants, availability of funds, program requirements and evaluation criteria follows.

Dates: The public is invited to submit comments by March 24, 1999.

Submit comments to: Community Health and Program Services Branch, Attn: Racial and Ethnic Approaches to community Health (REACH), Division of Adult and Community Health, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE, Mailstop K–30, Atlanta, GA 30333, or FAX: (770) 488–5974, E-mail address: ccdinfo@cdc.gov

For Further Information Contact: Letitia Presley-Cantrell, Community Health and Program Services Branch Division of Adult and Community Health, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE, Mailstop K–30, Atlanta, GA 30333, Telephone (770) 488–5426.

### A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1999 funds for a cooperative agreement

program for organizations serving racial and ethnic minority populations at increased risk for infant mortality, diabetes, cardiovascular diseases, HIV, deficits in breast and cervical cancer screening and management services, or deficits in child or adult immunization rates.

The applicant must be the lead organization, or central collaborating organization, for a community coalition of three (3) or more organizations, focusing on minority health concerns. The lead organization will serve as leader, catalyst, facilitator, and coordinator. The lead organization must have direct fiduciary responsibility over the administration and management of the project and will distribute funds to other partners in the coalition as appropriate.

The Racial and Ethnic Approaches to Community Health (REACH) Demonstration Projects are two-phase projects whose purpose is for communities to mobilize and organize their resources in support of effective and sustainable programs which will eliminate the health disparities of racial and ethnic minorities.

The REACH Demonstration Projects are a Department of Health and Human Services initiative in response to the President's Initiative on Race. The REACH Demonstration Projects will test science-based community level interventions which could be effective in eliminating health disparities, with the goal of replicating their successes in other communities.

Phase I is a 12-month planning Phase to organize and prepare infrastructure for Phase II. Cooperative agreements in Phase I will support the planning and development of demonstration programs using a collaborative multi-agency and community participation model. Phase I may also include the collection of data necessary to develop baseline measures for assessing the outcomes of the projects. Upon completion of Phase I, grantees will have utilized appropriate data and developed a Community Action Plan (CAP) designed to reduce the level of disparity within the selected communities in one or more of the six priority areas of complications of diabetes, deficits in breast and cervical cancer screening and management, deficits in child and adult immunizations, cardiovascular diseases, HIV, or infant mortality. The CAP must target a specific racial or ethnic minority community that is African American, American Indian or Alaska Native, Hispanic American, Asian American, or Pacific Islander. Communities or groups which cannot be specified under these categories will not be considered. Only applicants selected for Phase I will be eligible to compete for additional funds to implement and evaluate the demonstration program of Phase II.

Phase II is the implementation of a demonstration project of specified interventions for a specified priority areas(s), for a well defined minority population. Phase Ii also involves appropriate evaluations of interventions and outcomes of the project.

CDC is committed to achieving the health promotion and disease prevention objectives of the Department of Health and Human Services' Initiative to Eliminate Racial and Ethnic Health Disparities, *Healthy People 2000,* and *Healthy People 2010* a nationwide strategy to reduce morbidity and mortality and improve the quality of life. This announcement relates to the *Healthy People 2000* and *Healthy People 2010* priority areas of infant mortality, diabetes, cardiovascular diseases, HIV, cancer screening and prevention, and immunizations specifically pertaining to a racial or ethnic minority community that is African American, American Indian, Alaska Native, Hispanic American, Asian American, or Pacific Islander.

**B. Eligible Applicants**

Applications may be submitted by (a) private nonprofit organizations (including community-based organizations and foundation), (b) universities, colleges, research institutions, and hospitals, (c) governments and their agencies (including State and local health agencies, or their bona fide agents, and community health centers), and (d) federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

*1. Organizational Eligibility Criteria*

Eligible applicants must further be organizations active in community-focused, collaborative efforts which serve to bring together agencies, community groups, academic institutions and other groups to address health or social concerns. These organizations will serve as central collaborating bodies in a community collaboration.

*2. Private and Non-Profit Organizations*

Private and non-profit organizations must have the following characteristics:

a. The applicant organization must be part of a collaborative community health effort that is organized and has appropriate experience as follows:

(i) A governing board composed of more than 50% racial or ethnic minority members at the time of application or prior to Phase II, or

(ii) A significant number of minority individuals in key program positions (including management, administrative, and service provision), who reflect the racial and ethnic demographics, and the characteristics of the population to be served.

In addition, private, nonprofit organizations which are affiliated with a larger organization with a national board, must document that the larger organization has the same board composition listed above.

*3. Lead Organization*

The applicant must be the lead organization, or Center Coordinating Organization, for a community coalition focusing on minority health concerns. The Central Coordinating Organization must have direct fiduciary responsibility over the administration and management of the project. All applicants must include proof of collaborative relationships with a least three (3) other organizations as evidenced by signed Memoranda of agreements (or other official documentation) among the participants. The applicant must be able to show representation by the minority community in the coalition.

*4. Organizational Experience*

The applicant must document at least 2 years of experience in operating and centrally administering a coordinated public health or related program serving racial or ethnic minority populations. Such programs must have included:

a. The collection of appropriate program data (example of data collected must be appended to the application);

b. the implementation of complex, community level intervention strategies used in successful public health programs in such areas as infant mortality, diabetes, cardiovascular diseases, HIV, deficits in breast and cervical cancer screening and management, or deficits in child or adult immunization rates (examples of programs implemented must be appended to the application).

*5. Tax-Exempt Status*

For those applicants applying as a private, nonprofit organization, proof of tax-exempt status must be provided with the application. Tax-exempt status is determined by the Internal Revenue Service (IRS) Code, Section 501(c)(3). Any of the following is acceptable evidence:

a. A reference to the organization's listing in the IRS's most recent list of

tax-exempt organizations described in section 501(c)(3) of the IRS Code.

b. A copy of a currently valid IRS tax-exemption certificate.

c. A statement from a state taxing body, State Attorney General, or other appropriate state official certifying that the applicant organization has a nonprofit status and that none of the net earnings accrue to any private shareholders or individuals.

d. A certified copy of the organization's certificate of incorporation or similar document if it clearly establishes the nonprofit status of the organization.

**Note:** Public Law 104–65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

**C. Availability of Funds**

In FY 1999, CDC expects to provide up to $9,400,000 for funding approximately 30 Phase I cooperative agreements. It is expected that the awards will begin on or about September 30, 1999 and will be made for a 12-month budget period. Only Phase I recipients which successfully compete for Phase II awards may anticipate and additional four years of funding (for a total project period of five (5) years for Phase I and Phase II). Funding estimates, and continuation of awards, may change based on the availability of funds.

Approximately $30 million may be available to fund approximately 15–20 Phase II cooperative agreements. Criteria for selection of Phase II grantees are:

1. Extent to which Phase I requirements were met.

2. Appropriate definition of the level of health disparity among the target population and the extent of the disparity.

3. Potential for proposed interventions to affect the priority area(s).

4. Extent of inclusion of community participants and partners. Awardee will specifically be evaluated on their ability to recruit and maintain appropriate community and public/private collaborators.

5. The potential for community action plans to assure sustainability of the effort.

6. The potential for the community action plans to leverage additional public and/or private resources to support the overall prevention effort.

7. The appropriateness and thoroughness of the evaluation process to assess the impact and effectiveness of the project intervention in the community. (Standard performance measures to be provided in addendum).

8. The appropriateness and thoroughness of the data collection infrastructure that is planned for and developed for the demonstration project.

Should additional funding become available in the future, a new announcement will be issued and grantees funded under Phase I of this announcement, but not funded for Phase II, will receive preference for funding under the new announcement.

*Use of Funds*

Under this program announcement, funds may not be used for data collection or research until Institutional Review Board (IRB) approval is obtained. Funds may be restricted until appropriate IRB clearances and procedures are in place.

Funds may not be used to support direct patient medical care, or facilities construction in Phase I or Phase II, or to supplant or duplicate existing funding.

Although applicants may contract with other organizations under these cooperative agreements, applicants must perform a substantial portion of the activities (including program management and operations) for which funds are requested.

*Funding Preferences*

Geographic distribution among communities across the United States, diversity in priority areas, and racial/ethnic diversity will be funding considerations. Each applicant may submit only one application, and only one award will be made per geographically-defined community. A community will not be eligible for multiple awards for different priority areas. However, applications addressing related priority areas (e.g. diabetes and cardiovascular diseases, HIV and infant mortality, etc.) will be considered.

**D. Program Requirements**

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

*1. Recipient Activities*

(Phase I)

a. Select intervention strategies which have the most promising potential for reducing the health disparities of the target population. Develop a Community Action Plan reflecting the intervention strategies, and other activities described in Recipient Activities, Phase II.

b. Coordinate and use relevant data and community input to assess the extent of the problem in the selected program priority areas (diabetes, deficits in breast and cervical cancer screening and management, deficits in adult and child immunizations, cardiovascular diseases, HIV or infant mortality).

c. Identify academic partners, foundations, and State and local agencies, from which to strengthen the community's overall ability to eliminate the health disparities of the target population, and to demonstrate the changes in health disparities. Establish community working groups to address critical program issues, and enhance local partnerships to strengthen the overall commitment of the community. Establish linkages with national and state partners (governmental and non-governmental) and other interested organizations.

d. Identify data sources and establish outcome and process evaluation measures to be reviewed at the completion of Phase I. Collaborate with CDC, academic partners or other appropriate organizations, to determine an appropriate evaluation of the program and to identify promising intervention strategies for Phase II.

e. Participate in up to 3 CDC sponsored workshops for technical assistance, planning, evaluation and other essential programmatic issues.

(Phase II)

a. Implement the community action plan addressing the selected priority area(s) for the target population. Initiate actions to assure the interventions are provided appropriately and in a timely manner.

b. Collect appropriate data to monitor and evaluate the program including process and outcome measures.

c. Collaborate with academic or other appropriate institutions in the analysis and interpretation of the data.

d. Maintain linkages and collaborations with local partners, and develop new linkages with state and national partners.

e. Establish mechanisms with foundations, and other public and/or private groups to maintain financial support for the program at the conclusion of federal support.

f. Participate in conferences and workshops to inform and educate others regarding the experiences and lessons learned from the project, and collaborate with appropriate partners to publish the results of the project to the public health community.

*2. CDC Activities*

a. Provide consultation and technical assistance in the planning and evaluation of program activities.

b. Provide up-to-date scientific information on the basic epidemiology of the priority area(s), recommendations on promising intervention strategies, and other pertinent data and information needs for the specified priority area(s) including prevention measures and program strategies.

c. Assist in the analysis of data and evaluation of program progress.

d. Assist recipients in collaborating with State and local health departments, community planning groups, foundations and other funding institutions, and other potential partners.

e. Foster the transfer of successful prevention interventions and programs models through convening meetings of grantees, workshops, conference, and communications with project officers.

**E. Application Content**

Each applicant may submit only one application. Applicants should use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Applications will be evaluated on the criteria listed, so it is important to follow them in laying out the program plan. In developing this plan, applicants must describe a community-based program within at least one of the six following priority areas: (1) Infant mortality, (2) diabetes, (3) cardiovascular diseases, (4) HIV, (5) deficits in breast and cervical cancer screening and management, or (6) deficits in child and adult immunizations, that specifically focus on a racial or ethnic minority community that is African American, American Indian, Alaska Native, Hispanic American, Asian American, or Pacific Islander.

The narrative should be no more than 30 double-spaced pages, printed on one side, with one inch margins, and 12 point font. The thirty pages does not include budget, appended pages, or items placed in appended pages (resumes, agency descriptions, etc.). The narrative should include:

*1. Introduction*

A brief summary of which ethnic or racial group the applicant will target, the population size of both the ethnic or racial group and total population of the catchment area of the applicant and its partners, the geographic boundaries in which the applicant will operate (append a legible map to the application) and the priority area(s) chosen for the proposal.

*2. Community, Need, and Priority Area(s)*

A description of the specific community's health problem and need for the priority area(s) for which the applicant will address. Any data in support of the priority area(s) and which defines the degree of disparity in terms of mortality or morbidity (or other measures appropriate to the priority areas(s)). All sources of data and information must be referenced.

*3. Organizational Summary*

A brief organizational summary including mission statement, history of incorporation, and experience in community-based work. Relevant supporting documents (including resumes and job descriptions of participating staff) should be appended to the application, but should not be included in this summary.

A brief history of the organization's experience in operating and centrally administering a coordinated public health or related program serving racial or ethnic minority populations (including program data collection and interventions for one or more of six (6) priority areas). Other collaborative ventures should be included with a description of the both the nature and extent of the collaborations. Signed Memoranda of Agreement (or other official documentation) of the relevant collaboration should be appended to the document, but not included in this section of the narrative. Tribal resolution(s) or letter(s) of support from tribal chair(s) or president(s) should be appended to this section of the document for those applicants applying as a federally recognized tribe.

*4. History and Experience in Working With Ethnic/Racial Groups*

Succinctly describe past working efforts in minority communities. Applicants should also explain their current relationship with the target population. Any other related experience in which the applicant was involved but not the lead organization, but which is specific to the target population should also be included. Letters of support, awards, newspaper articles, evaluation reports, and other forms of recognition which validate statements and past efforts should be appended to the application.

*5. Community Action Plan*

A description of plans for developing and organizing the planning effort, to including who is or should partner in the effort, how community participation will be obtained, how the applicant anticipates enhancing the sustainability of the effort including improving linkages with collaborators and other organizations to leverage more resources (such as foundations, health departments, and other potentially influential and beneficial groups), how the applicant will collect data and information to track progress towards project goals of decreasing disparities. Letters of support from agencies, institutions, and other potential collaborators as well as any examples of previous planning documents should be appended to the application.

*6. Evaluation Plan*

A description of the evaluation and monitoring process that the applicant will use to track and measure progress in Phase I. The evaluation plan should include time-specific objectives which account for the major activities of the community action plan, the means of tracking and measuring the collaborative work with coalition partners, and any other relevant process measures. Timeliness, objectives, and other supporting documentation should be included in the appendix for this section.

*7. Budget*

Provide a line-item budget with a detailed, narrative justification that is consistent with the purpose and objectives of this cooperative agreement.

**F. Submission and Deadline**

*Letter of Intent (LOI)*

Organizations intending to apply must submit a non-binding letter of intent to the address below. Your letter of intent should include the following information:

1. Identify the project by name and announcement number (99064).

2. Identify the geographic location, health priority area(s), and racial/ethnic group which the application will address.

3. Certification that you meet the applicable eligibility requirements contained in Section B., ''Eligible Applicants.''

This letter is a prerequisite for application under this announcement, but will not influence the review or funding decision process. This process will enable CDC to plan more efficiently for the processing and review of the applications.

The letter of intent must be submitted and received at the address below on or before [14 days after the date of the publication of the final R.A. in the **Federal Register**].

Send the letter to: Adrienne Brown, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99064, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, Georgia 30341–4146.

*Application*

Submit the original and five copies of PHS–398 (OMB Number 0925–0001) (adhere to the instructions on the Errata Instruction Sheet for PHS 398). Forms are in the application kit. Submit the application on or before [DATE TO BE DETERMINED], to the business management contact listed in Section J., ''Where to Obtain Additional Information.''

Deadline: Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline with a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

*Late Applications*

Applications which do not meet the criteria in (a) or (b) above are considered late applications, will not be considered, and will be returned to the applicant.

**G. Evaluation Criteria (100 points)**

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

*1. Background on Community and Priority Area(s): (25 Points)*

The extent to which the applicant clearly defines the racial/ethnic group, community, and priority area(s) to be addressed. The extent to which the applicant uses data and other supporting evidence to document the disparities within the group, and the appropriateness of the target population sizes (see addendum—to be developed) for the priority area(s) selected. The degree of the disparity between the target population and the general population based on local data wherever available, or from state or national level data which directly supports the basis for the health disparity in the priority area(s) selected.

*2. Organizational Summary: (20 Points)*

Extent to which the applicant describes existing facilities and staff (including resumes and job descriptions) appropriate for the proposed activities. The extent to which the applicant describes the history, nature, and extent of their community activities with supporting documentation. The adequacy of proposed staffing and collaborations with partners, particularly to meet the design and evaluation needs of the project. Also describe the degree to which you have met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research.

*3. History and Experience in Working on Public Health Programs With Ethnic/Racial Groups: (25 Points)*

Extent to which the applicant documents their experience and successes in operating and centrally administering a coordinated public health or related program serving the target population for the selected priority area(s) (including appended letters of support). Extent of experience in other public health programs, and public health research or related data collection.

*A. Community Action Plan (CAP): (20 Points)*

Extent to which the applicant demonstrates a thorough and reasonable plan for the development of their CAP, including the assurance of community participation in the CAP.

*5. Evaluation Plan: (10 Points)*

Extent to which the applicant presents a reasonable and thorough evaluation plan for Phase I. Appropriateness of evaluation methods, goals, objectives, and timeliness to the development of the community action plan and the overall planning effort, and identification of data and information sources needed to track progress toward the project's objectives.

*6. Budget (Not Scored)*

Extent to which a line-item budget is presented, justified, and is consistent with the purposes and objectives of the cooperative agreement.

**H. Other Requirements**

*Technical Reporting Requirements*

Provide CDC with original plus two copies of:

1. Progress reports semiannually;

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

3. Final financial and performance reports, no more than 90 days after the end of the project period. Send all reports to the business management contact listed in Section J., ''Where to Obtain Additional Information.''

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

AR–1 Human Subjects Requirements

AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR–7 Executive Order 12372 Review

AR–8 Public Health System Reporting Requirements

AR–9 Paperwork Reduction Act Requirements

AR–10 Smoke-Free Workplace Requirements

AR–11 Healthy People 2000

AR–12 Lobbying Restrictions

AR–14 Accounting System Requirements

AR–15 Proof of Non-Profit Status

**I. Authority and Catalog of Federal Domestic Assitance (CFDA) Number**

This program is authorized under sections 301, 317(k)(2), and 1706 (e) of the Public Health Service Act, [42 U.S.C. section 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.206.

**J. Where To Obtain Additional Information**

To receive additional written information and to request an application kit, call 1–888–GRANTS4 (1–888–472–6874). You will be asked to leave your name and address and will be instructed to identify the Program Announcement Number 99064.

If you have questions after reviewing the contents of all the documents, business management technical assitance may be obtained from: Adrienne Brown, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99064, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room, 3000, Atlanta, GA 30341–4146, Telephone: (770) 488–2755, E-mail: asm1@cdc.gov

For program technical assistance, contact: Letitia Presley-Cantrell, Centers for Disease Control and Prevention (CDC), 4770 Buford Hwy, NE, Mailstop K–30, Atlanta, Georgia 30341, Telephone (770) 488–5426, ccdinfo@cdc.gov

Also see the CDC home page on the Internet: http://www.cdc.gov

Dated: March 4, 1999.

**John L. Williams,**

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

[FR Doc. 99–5866 Filed 3–9–99; 8:45 am]

**BILLING CODE 4163–18–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 98N–0747]**

### Agency Information Collection Activities; Announcement of OMB Approval; Customer/Partner Satisfaction Surveys

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Customer/Partner Satisfaction Surveys'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of December 24, 1998 (63 FR 71294), 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 0910–0360. The approval expires on March 31, 2002. A copy of the supporting statement for this information collection is available on the Internet at ''http://www.fda.gov/ohrms/dockets''.

Dated: March 4, 1999.

**William K. Hubbard,**

*Acting Deputy Commissioner for Policy.*

[FR Doc. 99–5903 Filed 3–9–99; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 98N–0482]**

### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Adverse Experience Reporting for Licensed Biological Products, and General Records

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

**DATES:** Submit written comments on the collection of information by April 9, 1999.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

**SUPPLEMENTARY INFORMATION:** In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Adverse Experience Reporting for Licensed Biological Products—21 CFR 600.80, 600.81, and 600.90; and General Records—21 CFR 600.12 (OMB Control Number 0910–0308)—Extension**

Under the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 201 *et seq.*) and the Public Health Service Act (42 U.S.C. 262 and 264), FDA is required to ensure the marketing of only those biological products that are shown to be safe and effective. Under the authority of section 301(e) of the act (21 U.S.C. 331(e)), FDA issued regulations for adverse experience reports related to the use of licensed biological products. FDA issued the adverse experience reporting requirements to enable FDA to take actions necessary for the protection of the public health in response to reports of adverse experiences related to licensed biological products. The adverse experience reporting system flags potentially serious safety problems with licensed biological products, focusing especially on newly licensed products. Although premarket testing discloses a general safety profile of a new drug's comparatively common adverse effects, the larger and more diverse patient populations exposed to the licensed biological product provides the opportunity to collect information on rare, latent, and long-term effects. Reports are obtained from a variety of sources, including patients, physicians, foreign regulatory agencies, and clinical investigators. Information derived from the adverse experience reporting system contributes directly to increased public health protection because such information enables FDA to recommend important changes to the product's labeling (such as adding a new warning), to initiate removal of a biological product from the market when necessary, and to assure the manufacturer has taken adequate corrective action, if necessary.

Manufacturers of biological products for human use must also keep records of each step in the manufacture and distribution of products including any recalls of the product. The recordkeeping requirements serve preventative and remedial purposes. These requirements establish accountability and traceability in the manufacture and distribution of products, and enable FDA to perform meaningful inspections.

Section 600.12 (21 CFR 600.12) requires that all records of each step in the manufacture and distribution of a product be made and retained for no less than 5 years after the records of manufacture have been completed or 6 months after the latest expiration date for the individual product, whichever represents a later date. In addition, records of sterilization of equipment and supplies, animal necropsy records, and records in cases of divided manufacturing of a product are required to be maintained. Section 600.12(b)(2) requires complete records to be maintained pertaining to the recall from distribution of any product.

Section 600.80(c)(1) (21 CFR 600.80(c)(1)) requires the licensed manufacturer to report each adverse experience that is both serious and unexpected, regardless of source, as soon as possible but in any case within 15 working days of initial receipt of the information. Section 600.80(e) requires licensed manufacturers to submit a 15-day alert report obtained from a postmarketing clinical study only if there is a reasonable possibility that the