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Dated: January 25, 2001.

John L. Williams,

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

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BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01025]

Public Health Conference Support Cooperative Agreement Program for Human Immunodeficiency Virus (HIV) Prevention; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2001 funds for a cooperative agreement program for Public Health Conference Support for Human Immunodeficiency Virus (HIV) Prevention. This program addresses the "Healthy People 2010" focus area of HIV.

Topics concerned with issues and areas other than HIV prevention should be directed to other public health agencies, or in accordance with the current **Federal Register** notice (see **Federal Register** Notice 01002 [65 FR 43765], published on July 14, 2000).

The purpose of conference support funding is to provide partial support for specific nonfederal conferences in the areas of health promotion and disease prevention information/education programs. Because conference support by CDC creates the appearance of CDC cosponsorship, there will be active participation by CDC in the development and approval of those portions of the agenda supported by CDC funds. CDC funds will not be expended for nonapproved portions of meetings. In addition, CDC will reserve the right to approve or reject the content of the full agenda, press events, promotional materials (including press releases), speaker selection, and site selection.

Contingency awards will be made allowing usage of only 10 percent of the total amount to be awarded until a final full agenda is approved by CDC. This will provide funds to support costs associated with preparation of the agenda. The remainder of funds will be

released only upon approval of the final full agenda. CDC reserves the right to terminate cosponsorship if it does not concur with the final agenda.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations. State and local health departments may apply for funding only under Category 2 (See E. Application Content). Conferences planned for July 1, 2001, through June 30, 2003, are eligible. Foreign organizations are not eligible to apply.

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

Approximately \$200,000 is available in FY 2001 and in FY 2002 to fund approximately 10 to 15 awards each fiscal year. Awards may range from \$10,000 to \$25,000. Organizations will be funded in rank order within each of the three categories. It is expected that the awards will begin on or before 30 days prior to conference dates falling within each funding cycle, and will be funded for a 12-month budget and project period. Funding estimates may vary and are subject to change. Funding estimates for each fiscal year may change based on congressional appropriation and the availability of funds.

Contingency awards will be made allowing usage of only 10 percent of the total amount to be awarded until a final full agenda is approved by CDC. This will provide funds to support costs associated with preparation of the agenda. The remainder of funds will be released only upon CDC approval of the final full agenda. CDC reserves the right to terminate cosponsorship at any time.

Use of Funds

a. CDC funds may be used for direct cost expenditures: salaries, speaker fees (for services rendered), rental of conference related equipment, registration fees, and transportation costs (not to exceed economy class fares) for nonfederal individuals.

b. CDC funds may not be used to purchase equipment, pay honoraria (for conferring distinction) or organizational dues, support entertainment, personal expenses, travel costs or payment of a Federal employee, or per diem and expenses, other than mileage, for local participants.

c. CDC funds may not be used to reimburse indirect costs.

d. CDC funds may not be used to purchase novelty items (e.g., bags, T-shirts, hats, pens) distributed at meetings.

e. CDC will not fund 100 percent of the proposed conference. Part of the cost of the proposed conference must be supported with nonfederal funds.

f. CDC will not fund a conference after it has taken place.

g. CDC funds may be used for only those parts of the conference specifically supported by CDC as documented on the notice of award.

Funding Preferences

Preference for funding may be given to:

a. conferences sponsored by organizations that serve people of color (e.g., African-American and Hispanic women), or highly affected populations or geographic areas;

b. applications consistent with the CDC national goal of assisting in building and maintaining State, local, and community infrastructure and technical capacity to carry out necessary HIV and STD prevention programs; and

c. health departments collaborating with other State agencies, community-based organizations, or colleges and universities;

No preference will be given to organizations that have received funding in past years.

D. Program Requirements

Development of HIV prevention conferences may require substantial CDC collaboration and involvement. Because conference support by CDC creates the appearance of CDC cosponsorship, there will be active participation by CDC in the development and approval of the conference agenda. In addition, CDC will reserve the right to approve or reject the content of the full agenda, press events, promotional materials (including press releases), speaker selection, and site selection.

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

1. Recipient Activities

a. Manage all activities related to conference content (e.g., objectives, topics, participants, session design, workshops, special exhibits, speakers, fees, agenda composition, printing). Many of these items may be developed in concert with CDC personnel assigned to support the conference.

b. Provide draft copies of the agenda and proposed related activities to the CDC Project Officer for review and comment. Submit a copy of the final agenda and proposed related activities to the CDC Grants Management Office for acceptance/approval.

c. Determine and manage all promotional activities (e.g., title, logo, announcements, mailers, press). CDC must review and approve the use of any materials with reference to CDC involvement or support.

d. Manage all registration processes with participants, invites, and registrants (e.g., travel, reservations, correspondence, conference materials and hand-outs, badges, registration procedures).

e. Plan, negotiate, and manage conference site arrangements, including all audio-visual needs.

f. Develop and conduct education and training programs on HIV prevention.

g. If the proposed conference is or includes a satellite broadcast:

(1) Provide individual, on-camera rehearsals for all presenters;

(2) Provide at least one full dress rehearsal involving the moderator, all presenters, equipment, visuals, and practice telephone calls at least one day before the actual broadcast and as close to the actual broadcast time as possible;

(3) Provide full scripting and Teleprompter use for the moderator and all presenters; and

(4) Select a professional moderator.

h. Collaborate with CDC staff in reporting and disseminating results, recommendations, relevant HIV prevention, education and training information to appropriate Federal, State, and local agencies, health-care providers, HIV/AIDS prevention and service organizations, and the general public.

2. CDC Activities

a. Provide technical assistance through telephone calls, correspondence, and site visits in the areas of program agenda development, implementation, and priority setting related to the cooperative agreement.

b. Provide scientific collaboration for appropriate aspects of the program, including selection of speakers, pertinent scientific information on risk

factors for HIV infection, preventive measures, and program strategies for the prevention of HIV infection.

c. Review draft agendas; the Grants Management Officer will issue approval or disapproval of the final agenda and proposed related activities prior to release of restricted funds.

d. Assist in the reporting and dissemination of research results and relevant HIV prevention education and training information to appropriate Federal, State, and local agencies, health-care providers, the scientific community, and HIV/AIDS prevention and service organizations, and the general public.

E. Application Content

Organizations should submit separate applications in any of the three following categories:

Category 1—Sharing Lessons Learned From HIV Prevention Program, Behavioral Interventions, or Service Delivery and Networking With Other Organizations and Agencies: Regional, national, or international conferences for individuals or organizations responsible for implementing HIV prevention programs or providing relevant services. The focus will be on information exchange, including lessons learned from program or service delivery, and sharing information about successful or unsuccessful program experiences. Conferences may also provide opportunity for staff of different organizations and agencies, involved in HIV prevention programs and services, to meet and develop joint plans or activities or other collaborations and working relationships.

Category 2—Technical Support for HIV Prevention Program Services for a Defined Population or Geographic Area: Local, statewide, or regional conferences supported by local or State health departments, providing information or training on HIV prevention interventions believed or proven to be effective for a defined population within a specific locality including a State, or multi-state area. The focus will be on technology transfer, guidelines for program implementation, lessons learned from program or service delivery experience, successful program delivery models, and development of professional skills. State and local health departments may apply only under Category 2; and

Category 3—Technology Transfer Training: Regional, national, or international conferences for researchers to impart information or guidelines on how to implement theoretically based or empirically demonstrated behavioral science research.

The main goal is to train health and other professionals in new, innovative, and enhanced behavioral interventions. Universities and colleges may apply under Category 3.

Topics of Special Interest

Prevention of HIV infection related to:

a. Populations in special settings (e.g., correctional institutions, shelters for runaway youth);

b. Under served geographic areas, especially rural populations;

c. People of color (especially African-American and Hispanic women of color);

d. Support of comprehensive primary and secondary prevention programs for persons living with HIV;

Letter Of Intent (LOI)

Interested applicants must submit Letters of Intent (LOIs) to CDC. They will be used to select potential applicants. Upon review of the LOIs, CDC will extend written invitations to prospective applicants to submit applications. CDC will accept applications by invitation only. Availability of funds may limit the number of applicants, regardless of merit, that receive an invitation to submit an application. CDC will notify prospective applicants within 30 days following receipt of the LOI.

Applicants must submit an original and two copies of a two-page typewritten LOI that briefly describes:

a. The application category (1, 2, or 3).

b. The title of the proposed conference.

c. The location of the proposed conference.

d. Proposed conference dates.

e. The purpose of the proposed conference.

f. The intended audience of the proposed conference (number and description).

g. Target population(s) (e.g., youth, women, men who have sex with men [MSM], injecting drug users [IDU] and persons living with HIV).

h. The estimated total cost of the proposed conference.

i. The percentage of the total cost (which must be less than 100 percent) being requested from CDC.

j. The relationship of the conference to CDC TOPICS of special interest above.

Also include the name of the organization, primary contact person's name, mailing address, telephone number, and if available, fax number and e-mail address. Current recipients of CDC HIV funding must provide the award number and title of the funded programs. No attachments, booklets, or

other documents accompanying the LOI will be considered. The two-page limitation (inclusive of letterhead and signatures), must be observed or the letter of intent will be returned without review.

CDC will review the LOIs based on the following criteria:

a. Documented need for the proposed conference;

b. Potential contribution to the prevention of HIV/AIDS;

c. National HIV prevention priorities based on emerging trends in the epidemic:

(1) Prevention of HIV transmission through behavior change.

(2) Providing comprehensive prevention services to persons living with HIV.

(3) Building capacity and enhancing HIV prevention programs for populations at higher risk for infection (e.g., MSM, IDU, and their sex and needle-sharing partners), especially in communities of color.

d. The proposed conference's relationship to the CDC determined topics of special interest;

e. Timing of the conference that will allow for CDC input; and

f. Availability of funds.

Completing Applications

Use the information in sections D. Program Requirements, G. Evaluation Criteria, and H. Other Requirements to develop your application content. (Do not use the instructions in PHS 5161 package to complete your narrative.) Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan.

The narrative should be no more than 12 double-spaced pages, printed on one side, with one-inch margins, and 12-point font. Please write your narrative in English only and do not use jargon and abbreviations. Pages must be clearly numbered, and a complete index to the application and its appendices must be included. The original and two required copies of the application must be submitted Unstapled and Unbound. Materials which should be part of the basic plan should not be in the appendices.

Include the following information:

a. A project summary cover sheet that includes:

(1) Application category (1, 2, or 3).

(2) Name of organization.

(3) Name of conference.

(4) Location of conference.

(5) Date(s) of conference.

(6) Target population(s) (e.g., youth, women, MSM, IDU).

(7) Intended audience and number.

(8) Dollar amount requested.

(9) Total conference budget.

b. Biographical sketches and job descriptions of the individuals responsible for planning and coordinating the conference.

c. A Budget Narrative separately identifying and justifying line items to which the requested Federal funds would be applied.

d. A draft agenda for the proposed conference.

e. Award number and title of funded programs for current recipients of CDC HIV funding. Applicants must not have submitted the same proposal for review for funding to other parts of CDC.

F. Submission and Deadlines

If your conference dates fall between July 1 and December 31, 2001, you can apply under Cycle I.

If your conference dates fall between January 1 and June 30, 2002, you can apply under Cycle II.

If your conference dates fall between July 1 and December 31, 2002, you can apply under Cycle III.

If your conference dates fall between January 1 and June 30, 2003, you can apply under Cycle IV.

Letter of Intent Due Dates:

Cycle I: February 16, 2001: For conferences July 1–December 31, 2001.

Cycle II: July 13, 2001: For conferences January 1–June 30, 2002.

Cycle III: January 18, 2002: For conferences July 1–December 31, 2002.

Cycle IV: July 19, 2002: For conferences January 1–June 30, 2003.

On or before the above dates. Submit the original and two signed copies of the LOI to: Edna Green, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 01025, Centers for Disease Control and Prevention, 2920 Brandywine Road, M/S K-75, Room 3000, Atlanta, GA 30341-4146.

If your LOI does not arrive in time for submission to the review group, it will not be considered in the current competition unless you can provide proof that you mailed it on or before the deadline (e.g., receipt from U.S. Postal Service or a commercial carrier; private metered postmarks are not acceptable).

Application

Submit the original and two copies of PHS 5161 (OMB Number 0937-0189). Forms are available at the following Internet address: <http://forms.psc.gov/forms/phs/ps5161-1.pdf> or in the application kit.

Note: Please use the criteria listed in section G of this announcement as the format for the narrative of your application.

Application Due Dates and Earliest Possible Award Dates

Cycle I: March 30, 2001—June 1, 2001

Cycle II: September 14, 2001—

November 2, 2001

Cycle III: March 15, 2002—May 15, 2002

Cycle III: September 13, 2002—

November 1, 2002

On or before the above dates, submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

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 date and received in time for submission to the independent review group.

(Applicants must request 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

Letter of Intent

LOIs will be reviewed by CDC and an invitation to submit a full application will be made based on the following criteria:

1. Documented need for the proposed conference;

2. Potential contribution to the prevention of HIV/AIDS;

3. National HIV prevention priorities based on emerging trends in the epidemic:

a. Prevention of HIV transmission through behavior change.

b. Providing comprehensive prevention services to persons living with HIV.

c. Building capacity and enhancing HIV prevention programs for populations at higher risk for infection (e.g., MSM, IDU, and their sex and needle-sharing partners), especially in communities of color.

4. The proposed conference's relationship to the CDC determined topics of special interest;

5. Timing of the conference that will allow for CDC input; and

6. Availability of funds.

Application Narrative

Each application will be evaluated individually against the following

criteria (TOTALING 100 POINTS) by an independent review group appointed by CDC. Use these headings in preparing your application.

1. Category-Specific Criterion (20 points):

a. If Applying Under Category 1—Sharing Lessons Learned From HIV Prevention Program, Behavioral Interventions, or Service Delivery and Networking With Other Organizations and Agencies: Extent to which the applicant provides evidence that participants and presenters will have the opportunity to interact during the conference, share information on successful and unsuccessful program experiences, and develop collaborative working relationships.

b. If Applying Under Category 2—Technical Support for HIV Prevention Program Services for a Defined Population or Geographic Area: Extent to which the applicant specifically relates the content of the conference to HIV prevention community planning priorities for a defined population, or within a specific geographic area, and the extent to which the Applicant justifies the need for the proposed conference.

c. If Applying Under Category 3—Technology Transfer Training: Extent to which the applicant demonstrates the scientific soundness of the technology to be transferred, as evidenced by its inclusion in HIV prevention research publications, peer reviewed journals, or scientific consensus panel review, and the extent of the need for applying the new technology or knowledge by HIV prevention programs.

The following criteria apply to all applications:

2. Proposed Program and Technical Approach (30 points):

a. The extent to which the proposed conference description demonstrates a relationship to HIV prevention and education, responds to a specific public health need, influences public health practices, and indicates collaboration with other agencies serving the intended audience, including local health and education agencies concerned with HIV prevention.

b. The applicant's description of conference objectives in terms of quality, specificity, and the feasibility of the conference based on the operational plan, and the extent to which evaluation mechanisms for the conference adequately assess increased knowledge, attitudes, and behaviors of the target participants.

c. The relevance and effectiveness of the proposed agenda in addressing the chosen HIV prevention and education topic(s).

d. The degree to which conference activities proposed for CDC funding strictly adhere to the prevention of HIV transmission. For conferences dealing with people living with HIV/AIDS; the degree to which conference activities focus on primary and secondary prevention goals.

3. Applicant Capability and Experience (25 points):

a. The adequacy and commitment of institutional resources to administer the program for the proposed conference.

b. The adequacy of existing and proposed facilities and resources for conducting conference activities.

c. The degree to which the applicant has established and used critical linkages with health and education departments, and community planning groups with the mandate for HIV prevention. Letters of support (limit of five) from such agencies which address related capability and experience should be included. They must explain how the agency will work with the applicant to plan the proposed conference. Letters that do not pertain directly to the proposed conference will not be considered.

4. Qualifications of Program Personnel (25 points):

a. The qualifications, experience, and commitment of the principal staff person, and his or her ability to devote adequate time and effort to provide effective leadership.

b. The competence of associate staff persons, discussion leaders, and speakers to accomplish conference objectives.

c. The degree to which the application demonstrates that all key personnel have education and expertise relative to the conference objectives, are informed about the transmission of HIV, and understand nationwide information and education efforts currently underway that may affect, and be affected by, the proposed conference.

5. Budget Justification and Adequacy of Facilities (not scored): The proposed budget will be evaluated on the basis of its reasonableness, concise and clear justification, consistency with the intended use of cooperative agreement funds, and the extent to which the applicant documents financial support from other sources.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with the original plus two copies of the final financial status report (reporting actual expenses) and performance report, no more than 90 days after the end of the budget/project period. The performance report should include:

1. The cooperative agreement number;
2. Title of the conference;
3. Name of the principal investigator, program director or coordinator;
4. Name of the organization that conducted the conference;
5. A copy of the agenda;
6. A list of individuals who participated in the formally planned sessions of the meeting;
7. A summarization of the meeting results, including a discussion of its achievement of the stated conference objectives; and
8. The Program Review Panel's report that all written materials have been reviewed as required.

With the prior approval of CDC, copies of proceedings or publications resulting from the conference may be substituted for the final performance report, provided they contain the information requested in items 1 through 8 above.

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 in the application kit.

- AR-5HIV Program Review Panel Requirements
- AR-8 Public Health System Reporting Requirements
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-1 Proof of Non-Profit Status
- AR-20 Conference Support

See Attachment II for Background Statement

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under the Public Health Service Act, Section 301(a), 42 U.S.C. 241(a), as amended and Section 317(a), 42 U.S.C. 247b(a), as amended. The Catalog of Federal Domestic Assistance number is 93.941.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address—<http://www.cdc.gov>. Click on "Funding" then "Grants and Cooperative Agreements."

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 Announcement number of interest (Announcement 01025).

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Edna Green, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 01025, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone (404) 488-2743, E-mail address ecg4@cdc.gov.

For program technical assistance, contact: Sheila Isoke, Supervisory Public Health Advisor, Training and Technical Support Systems Branch, Division of HIV/AIDS Prevention—Intervention Research and Support, National Center for HIV, STD and TB Prevention, 1600 Clifton Road, NE., M/ S E40, Atlanta, GA 30333, Telephone: (404) 639-0962, E-mail address: shc1@cdc.gov.

Dated: January 19, 2001.

Sandra R. Manning,

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

[FR Doc. 01-2268 Filed 1-30-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Advisory Committee for Injury Prevention and Control, Centers for Disease Control and Prevention: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92-463) of October 6, 1972, that the charter for the Advisory Committee for Injury Prevention and Control of the Centers for Disease Control and Prevention, Department of Health and Human Services, has been renewed for a 2-year period, through October 31, 2002.

FOR FURTHER INFORMATION CONTACT: Thomas Blakeney, 1600 Clifton Road, NE, M/S K58, Atlanta, Georgia 30333, telephone 770/488-1481.

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: January 25, 2001.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 01-2625 Filed 1-30-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

The National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC) Announces the Following Meeting

Name: Current Status of the Vessel Sanitation Program (VSP) and Experience to Date with Program Operations—Public meeting between CDC and the cruise ship industry, private sanitation consultants, and other interested parties.

Time and Date: 9 a.m.–4 p.m., March 13, 2001.

Place: Auditorium, Port Everglades Administration Building, 1850 Eller Drive, Fort Lauderdale, Florida 33316. Telephone (954) 356-6650; Fax (954) 356-6671.

Status: Open to the public, limited by the space available. The meeting room accommodates approximately 100 people.

Purpose: During the past 15 years, as part of the revised VSP, CDC has conducted a series of public meetings with members of the cruise ship industry, private sanitation consultants, and other interested parties.

This meeting is a continuation of that series of public meetings to discuss current status of the VSP and experience to date with program operations.

Matters To Be Discussed: Agenda items will include a VSP Program Director Update; 2000 Program Review; Update on the implementation of the VSP Program Operations Manual 2000; Revision of the Final Recommended Shipbuilding Construction Guidelines for Cruise Vessels Destined to Call on U.S. Ports; Update on Disease Surveillance and Outbreak Investigations; and VSP Training Seminars.

For a period of 15 days following the meeting, through March 28, 2001, the official record of the meeting will remain open so that additional materials or comments may be submitted to be made part of the record of the meeting. Advanced registration is encouraged. Please provide the following information: Name, title, company name, mailing address, telephone number, facsimile number and E-mail address to Dorothy Johnson, facsimile (770)488-4127 or E-mail: DJJohnson@cdc.gov.

Contact Person for More Information: Dave Forney, Chief, VSP, NCEH, CDC, 4770 Buford Highway, NE, M/S F-16, Atlanta, Georgia 30341-3724, telephone (770)488-7333, E-mail: DForney@cdc.gov.

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: January 25, 2001.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0037]

Draft "Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion." The draft guidance document provides recommendations on manufacturing and quality assurance applicable to pre-storage leukocyte reduction of blood components intended for transfusion. This draft guidance document describes manufacturing procedures and controls that should be in place and would supersede the FDA memorandum issued on May 29, 1996, entitled "Recommendations and Licensure Requirements for Leukocyte-Reduced Blood Products."

DATES: Submit written comments on the draft guidance at any time, however, comments should be submitted by May 1, 2001, to ensure their adequate consideration in preparation of the final guidance document.

ADDRESSES: Submit written requests for single copies of "Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion" to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your