in addressing the emergence of antimicrobial resistance.

DATES: Comments must be submitted in writing on or before August 4, 2000.

FOR FURTHER INFORMATION CONTACT: Requests for copies of the Draft Public Health Action Plan to Combat Antimicrobial Resistance should be made to the Office of Health Communication, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Mailstop C–14, 1600 Clifton Road, Atlanta, GA 30333; fax: 404–639–5489; or e-mail: *ncid@cdc.gov*; or Internet URL: *http://www.cdc.gov.drugresistance/actionplan/*.

ADDRESSES: Comments on the Draft Public Health Action Plan to Combat Antimicrobial Resistance should be submitted to the Office of Health Communication, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Mailstop C–14, 1600 Clifton Road, Atlanta, GA 30333; fax: 404–639–5489; e-mail: *aractionplan@cdc.gov*; or Internet URL: *http://www.cdc.gov.drugresistance/actionplan/*.

SUPPLEMENTARY INFORMATION: Antimicrobial resistance is an emerging public health threat that has been identified as an important priority by the Institute of Medicine and other expert bodies and is the subject of several proposed Healthy People 2010 goals relative to Infectious Diseases. In late 1998, CDC, FDA, and NIH recognized the need for better coordination and stimulation of the Federal response to this threat. In addition, in December of 1998, Senators William Frist and Edward Kennedy held a roundtable discussion on antimicrobial resistance, and a hearing was held in February 1999. Shortly thereafter, an Interagency Task Force on Antimicrobial Resistance was created to develop a Public Health Action Plan to Combat Antimicrobial Resistance. The Task Force is co-chaired by CDC, FDA, and NIH, and includes the Health Care Financing Administration, the Health Resources and Services Administration, Agency for Healthcare Research and Quality, the Department of Agriculture, the Department of Defense, the Department of Veterans Affairs, and the Environmental Protection Agency.

The Draft Public Health Action Plan to Combat Antimicrobial Resistance, Part I focuses on domestic issues. Since AR transcends national borders and requires a global approach to its prevention and control, Part II of the plan, to be developed subsequently, will identify actions that more specifically address international issues. The Plan includes a summary and a list of issues, goals, and 87 action items addressing four focus areas: Surveillance, Prevention and Control, Research, and Product Development. For each action item, ''coordinator'' and ''collaborator'' agencies/departments and timelines are specified. The Interagency Task Force will monitor, and if necessary, update the Plan, during the coming years.

Jeffrey P. Koplan,

Director, Centers for Disease Control and Prevention (CDC).

Ruth Kirschstein,

Acting Director, National Institutes of Health (NIH).

Jane E. Henney,

Commissioner, Food and Drug Administration (FDA).

[FR Doc. 00–15847 Filed 6–21–00; 8:45 am]

BILLING CODE 4160–18–P 4140–01–P 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00055]

Surveillance for Invasive Fungal Infections in Transplant Recipients; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds for a cooperative agreement program for surveillance for invasive fungal infections among transplant recipients. CDC is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2010,'' a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the focus area of Immunization and Infectious Disease. For the conference copy of ''Healthy People 2010,'' visit the internet site: <http://www.health.gov/healthypeople>.

The purpose of the program is to conduct active, prospective surveillance to estimate the incidence and describe the epidemiology of opportunistic invasive fungal infections (OI's) in bone marrow/stem cell and solid organ transplant recipients, and to establish through this surveillance, a network of bone marrow/stem cell and solid organ transplant centers.

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, State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations.

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 2000 to fund one award. It is expected that the award will begin on or about September 30, 2000, and will be made for a 12-month budget period within a project period of up to 3 years. The funding estimate may change.

A continuation award within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

D. Program Requirements

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. Develop and implement a plan to network transplant medical centers to conduct surveillance for invasive fungal infections. This network should consist of multiple centers with large numbers of transplants performed per year (a minimum of 100 to 200 bone marrow/stem cell per center a year and a minimum of 200 solid organ transplants per year) to have adequate estimates of the incidence of various invasive fungal OIs (a total transplant population of at least 5000 per year (*i.e.* 10 to 20 centers)).

b. Design a network that will consider centers of various sizes and affiliations and includes centers from various U.S. regions to ensure representativeness.

c. Develop a work plan to manage surveillance activities at the different transplant centers.

d. Design a strategy for the participating medical centers to report every case of invasive fungal OI's that occurs in any of their transplant recipients, even if not hospitalized.

e. Design a data collection form for reporting each individual incident case of invasive fungal OI in a transplant recipient.

f. Develop a standardized protocol for surveillance for invasive fungal infections in stem cell/bone marrow and solid organ transplant recipients.

g. Analyze findings and publish as necessary.

2. CDC Activities

a. Provide technical assistance in the development of a data collection form.

b. Provide periodic laboratory confirmation of identified isolates, and pathology confirmation of available diagnostic tissues, as needed and appropriate.

c. Assist with data management and statistical support to analyze the surveillance data, as needed.

d. Assist in the development of a research protocol for Institutional Review Board (IRB) review by all cooperating institutions participating in the research project. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

E. Application Content

Use the information in the Program Requirements, Other Requirements and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 30 double spaced pages printed on one side, with one inch margins and unreduced font.

F. Submission and Deadline

Letter of Intent (LOI)

In order to assist CDC in planning the evaluation of applications submitted under this Program Announcement, all parties intending to submit an application are requested to submit an LOI to inform CDC of their intention to do so. The LOI should include (1) name and address of institution and (2) name, address, and telephone number of contact person. Notification can be provided by facsimile, postal mail, or Email.

On or before July 15, 2000, submit the letter of intent to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Application

Submit the original and two copies of PHS 5161–1 (OMB Number 0937–0189). Forms are available in the application kit.

On or before July 31, 2000, 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

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

1. Background and Need (10 points)

Extent to which applicant demonstrates a clear understanding of the purpose, and objectives of the focus area being addressed. Extent to which applicant demonstrates that the proposed project addresses the purpose.

2. Capacity (45 points)

Extent to which applicant describes adequate resources and facilities (both technical and administrative) for conducting the project. Extent to which applicant documents that professional personnel involved in the project are qualified and have past experience and achievements in research related to that proposed as evidenced by curriculum vitae, publications, etc. If applicable, extent to which applicant includes letters of support from participating non-applicant organizations, individuals, *etc.*, and the extent to which such letters clearly indicate the author's commitment to participate as described in the operational plan.

3. Objectives and Technical Approach (45 points total)

a. Extent to which applicant describes measurable and time-phased objectives of the proposed project which are consistent with the purpose of the focus area being addressed. (10 points)

b. Extent to which applicant presents a detailed operational plan for initiating and conducting the project which clearly and appropriately addresses all recipient activities for the specific programmatic focus area being addressed. Extent to which applicant clearly identifies specific assigned responsibilities of all key professional personnel. Extent to which the plan clearly describes applicant's technical approach/methods for conducting the proposed studies and extent to which the approach/methods are feasible, appropriate, and adequate to accomplish the objectives. Extent to which applicant describes specific study protocols or plans for the development of study protocols that are appropriate for achieving project objectives. Extent to which applicant clearly describes collaboration with CDC and/or others during various phases of the project. (25 points)

c. Extent to which applicant provides a detailed and adequate plan for evaluating progress toward achieving project process and outcome objectives. (5 points)

d. The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes (1) the proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation, (2) the proposed justification when representation is limited or absent, (3) a statement as to whether the design of the study is adequate to measure differences when warranted and (4) a statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits. (5 points)

4. Budget (not scored)

Extent to which the line-item budget is detailed, clearly justified, and consistent with the purpose and objectives of this program.

5. Human Subjects (not scored)

Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects?

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of

1. Semi-annual progress reports;

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

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301(a) and 317(k)(2) of the Public Health Service Act, [42 U.S.C. sections 241(a) and 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

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–GRANTS (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.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Gladys Gissentanna, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, Atlanta, GA 30341–4146. Telephone Number: 770–488–2753; Email Address: gcg4@cdc.gov.

For program technical assistance, contact: Rana A. Hajjeh, M.D., National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Atlanta, GA 30333, Telephone Number: 404–639–4753; E-mail Address: rfh5@cdc.gov.

Dated: June 16, 2000.

Henry S. Cassell, III,

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

[FR Doc. 00–15769 Filed 6–21–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: State Human Services System.

OMB No.: New Collection.

Description: Collect Data from States to Provide Updated Information on what systems software each State has created in the area of State Systems which effect TANF, CW, OCSE and Child Care Projects.

Respondents: 54 States and Territories.

Annual Burden Estimates:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Survey	54	4	1	216

Estimated Total Annual Burden Hours: 216.

In compliance with the requirements of Section 350(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: June, 15, 2000.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 00–15844 Filed 6–21–00; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Temporary Deferment of Activities Relating to Certain Biologics Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Center for Biologics Evaluation and Research (CBER) will be converting its current biologics license application (BLA) data base system into a new data base system. During the period required for this conversion, the agency will temporarily defer certain submissions subject to CBER review and approval, and the review period, if any, on pending submissions will be suspended. FDA plans to temporarily defer action on submissions related to BLA's, product license applications (PLA's), establishment license applications (ELA's), and any related correspondence. FDA is also requesting that sponsors voluntarily refrain from filing the affected submissions during this period. FDA estimates that the deferment period will be about 1 month.

FOR FURTHER INFORMATION CONTACT: Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–2000.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 201 *et seq.*) and section 351 of the Public Health Service Act (42 U.S.C. 262), CBER is responsible for