Description Information for a Biological In Vitro Diagnostic Product'' published in the **Federal Register** of November 10, 1998 (63 FR 63067).

In the **Federal Register** of July 8, 1997 (62 FR 36558), FDA announced the availability of Form FDA 356h that will be used as a single harmonized application form for all drug and licensed biological products. Manufacturers may voluntarily begin using this form for a biological in vitro diagnostic product. FDA will announce in the future when manufacturers are required to use this form for all products. Use of the new harmonized Form FDA 356h will allow a biologic product manufacturer to submit one biologics license application instead of two separate applications (product license application and establishment license application).

This guidance document represents the agency's current thinking with regard to the content and format of the CMC and establishment description sections of a license application for a biological in vitro diagnostic product. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments are to should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document by using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: March 1, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–5521 Filed 3–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Special Emphasis Panel, Comparative Medicine.

Date: March 25, 1999.

Time: 1:00 pm to 2:00 pm.

Agenda: To review and evaluate grant applications.

Place: Office of Review, National Center for Research Resources, 6705 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Bela J. Gulyas, Director, Office of Review, National Center for Research Resources, National Institutes of Health, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892, 301–435–0811.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333; 93.371, Biomedical Technology; 93.389, Research Infrastructure, National Institutes of Health, HHS).

Dated: March 2, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99–5660 Filed 3–5–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel HIV in the Lungs, Heart and Blood: Role of Chemokines and Their Receptors.

Date: March 30, 1999.

Time: 8:00 am to 3:00 pm.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Georgetown, 2101 Wisconsin Avenue, NW., Washington, DC 20007.

Contact Person: Anne P. Clark, Scientific Review Administrator, NIH, NHLBI, DEA, Review Branch, Rockledge II, 6701 Rockledge Drive, Room 7186, Bethesda, MD 20892–7924, (301) 435–0280.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.9839, Blood Diseases and Resources Research, National Institutes of Health, HHS).

Dated: March 2, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99–5657 Filed 3–5–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the

provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel ZDK1 GRB–1(M2)P.

Date: April 8–9, 1999.

Time: April 8, 1999, 7:30 pm to Adjournment.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Carolyn Miles, Scientific Research Administrator, Review Branch, DEA, NIDDK, Natcher Building, Room 6AS–37, National Institutes of Health, Bethesda, MD 20892, (301) 594–7791.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, ZDK1 GRB–8(M1)P.

Date: April 14–16, 1999.

Time: April 14, 1999, 8:30 am to adjournment.

Agenda: To review and evaluate grant applications.

Place: Crowne Plaza Hotel, 14th & K Streets, NW., Washington, DC 20005.

Contact Person: Roberta J. Haber, Scientific Research Administrator, Review Branch, DEA, NIDDK, Natcher Building, Room 6AS–25N, National Institutes of Health, Bethesda, MD 20892, (301) 594–8898.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: March 2, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99–5658 Filed 3–5–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99018]

Water Intervention Studies To Determine the Fraction of Gastrointestinal Illness Attributable to Drinking Water; Notice of Availability of Funds

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 water intervention studies to determine the amount of gastrointestinal illness attributable to drinking water. This program addresses the ''Healthy People 2000'' priority area(s) of Immunization and Infectious Diseases. The purpose of the program is to provide assistance for conducting two studies: one in a municipality receiving drinking water from a conventionally treated, surface water source and a second in a municipality with a ground water source. Since the amount of waterborne disease in a population can most directly be estimated by determining the rate of gastrointestinal illness in the community and multiplying this by an estimate of the percentage of illness that is attributable to water, these studies will involve measuring both of these parameters in a population.

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 $1,800,000 is available in FY 1999 to fund approximately two awards. It is expected that the average award will be $900,000 ranging from $900,000 to $1,800,000. It is expected that the awards will begin on or about April 15, 1999, and will be made for a 12-month budget period within a project period of up to two years. The funding estimate may change.

Continuation awards 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 shall be responsible for the activities under ''Recipient Activities'' below and CDC shall be responsible for the activities under ''CDC Activities'' below:

Recipient Activities

1. Develop a study design and protocol.

2. Identify a community where residences are served by a single water utility.

3. Conduct a household intervention trial that allows determination of what proportion of illness is attributable to drinking water. For example, studies have been conducted using intervention devices installed in household plumbing to eliminate viable pathogens. Investigators may want to consider conducting a randomized, blinded trial in which control households receive a sham device.

4. Measure disease outcomes among study participants. Examples of such outcomes could include: (a) clinically defined diarrhea, (b) vomiting, (c) laboratory studies of stool from cooperative, ill participants that would be tested broadly for bacterial, parasitic, and viral pathogens, and (d) antibody response to specific pathogens such as Cryptosporidium and caliciviruses in study participants willing to give serum.

5. Collaborate with the water utility, the American Water Works Research Foundation (AAWRF) and its collaborators, and others as appropriate to evaluate the relationship between health outcomes and physical and microbial water quality data.

6. The recipient(s) will develop a Quality Assurance Project Plan (QAPP) and will coordinate the plan with EPA to ensure that the results are of high quality.

7. Determine rates of relevant outcomes in the community in which the intervention study is being conducted. For example, this could be done through ongoing, cross-sectional, random telephone surveys of the population served by the water utility during the study period. Examples of outcomes that could be measured include signs and symptoms of gastrointestinal illness, water consumption patterns, days of work or school missed, etc.

8. Publish the results of the study.

CDC Activities

1. CDC and EPA are available to provide technical assistance in the design and conduct of the research. If needed, this may include:

a. providing technical consultation in the design and conduct of the project, including data collection, evaluation, and analytic approach;

b. facilitating exchange of information among collaborators;

c. performing selected laboratory tests;