Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations, 45 CFR part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved or will support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it.

Application Submission and Deadline

A. Preapplication Letter of Intent

Although not a prerequisite of application, a non-binding letter of intent-to-apply is requested from potential applicants. The letter should be submitted to the Grants Management Branch, CDC at the address listed in this section. It should be postmarked no later than July 9, 1997. The letter should identify Program Announcement number 708, and the name of principal investigator and specify the priority area to be addressed by the proposed project. The letter of intent does not influence review or funding decisions, but it will enable CDC to plan the review more efficiently and will ensure that each applicant receives timely and relevant information prior to application submission.

B. Application

The original and two copies of the application PHS Form 5161–1 (Revised 7/92, OMB Number 0937–0189) must be submitted to Victoria Sepe, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 321, Atlanta, GA 30305, on or before August 5, 1997.

1. Deadline: Applications will 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 objective review group. (The applicants must request a legibly dated U.S. Postal Service postmark or obtain a receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks will not be acceptable as proof of timely mailing.)

2. Late Applicants: Applications that do not meet the criteria in 1.(a) or 1.(b) above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicants.

Where To Obtain Additional Information

To receive additional written information call (404) 332–4561. You will be asked to leave your name, address, and telephone number and will need to refer to NIOSH Announcement 708. You will receive a complete program description, information on application procedures, and application forms. CDC will not send application kits by facsimile or express mail. Please refer to NIOSH announcement number 708 when requesting information and submitting an application.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Victoria Sepe, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Mailstop E–13, Room 321, 255 East Paces Ferry Road, NE., Atlanta, GA 30305, telephone (404) 842–6804, Internet: vxw1@cdc.gov.

Programmatic technical assistance, including guidelines for SENSOR field-testing target conditions, may be obtained from John P. Sestito, J.D., M.S., Chief, Surveillance Branch, Division of Surveillance, Hazard Evaluation and Field Studies, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, Mailstop R–41, Cincinnati, Ohio 45226, telephone (513) 841–4303, Internet: jps4@cdc.gov.

This and other CDC announcements are available through the CDC homepage on the Internet. The address for the CDC homepage is http://www.cdc.gov.

Potential applicants may obtain a copy of Healthy People 2000 (Full report, Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report, Stock No. 017–001–00473–1) referenced in the Introduction through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Potential applicants may obtain a copy of the SENSOR surveillance guidelines referenced in Sensor Field-Testing of the Evaluation Criteria section from John P. Sestito, NIOSH, at telephone number (513) 841–4303.

Dated: June 11, 1997.

Diane D. Porter,

Acting Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–15886 Filed 6–17–97; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement 756]

Preventing Occupational Latex Allergy in Health Care Workers Notice of Availability of Funds for Fiscal Year 1997

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1997 funds for a cooperative agreement to develop and evaluate the effectiveness of interventions to prevent adverse health effects from latex allergies in health care workers.

CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Occupational Safety and Health. In recognition of the impact of occupational latex allergies, the National Occupational Research Agenda (NORA), published by the National Institute for Occupational Safety and Health (NIOSH) in April 1996 specifically mentions occupational latex allergies under two of the priority areas for research and prevention. (For ordering a copy of NORA, or Healthy People 2000 see the section **WHERE TO OBTAIN ADDITIONAL INFORMATION.**)

Authority

This program is authorized under sections 20(a) and 22(e)(7) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 669(a) and 671(e)(7)).

Smoke-Free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and promote the nonuse of all tobacco products, and Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which

education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Applications may be submitted by public and private, non-profit and for-profit organizations and governments, and their agencies. Thus, universities, colleges, research institutions, hospitals, other public and private organizations, State and local health departments or their bona fide agents, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations, and small, minority-and/or women-owned businesses are eligible to apply.

Note: Public Law 104–65, dated December 19, 1995, prohibits an organization described in section 501(c)(4) of the IRS Code of 1986, that engages in lobbying activities to influence the Federal Government, from receiving Federal funds.

Availability of Funds

Approximately $200,000 is available in FY 1997 to fund one award to develop and evaluate the effectiveness of interventions to prevent adverse respiratory health effects from latex allergies in health care workers.

The amount of funding available may vary and is subject to change. This award is expected to begin on or about September 30, 1997. The award will be made for a 12-month budget period within a project period up to five years. Continuation awards within the project period will be made on the basis of satisfactory progress and availability of funds.

Use of Funds

Restrictions on Lobbying

Applicants should be aware of restrictions on the use of HHS funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. 1352 (which has been in effect since December 23, 1989), recipients (and their subtier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying Congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition, the FY 1997 HHS Appropriations Act, which became effective October 1, 1996, expressly prohibits the use of 1997 appropriated funds for indirect or ''grassroots'' lobbying efforts that are designed to support or defeat legislation pending before State legislatures. This new law, section 503 of Public Law 104–208, provides as follows:

Section 503(a) No part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress, * * * except in presentation to the Congress or any State legislative body itself.

(b) No part of any appropriation contained in this Act shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

Department of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1997, as enacted by the Omnibus Consolidated Appropriations Act, 1997, Division A, Title I, section 101(e), Public Law 104–208 (September 30, 1996).

Background

Surveys have shown that about 10 percent of all health care workers are sensitized to latex. Latex allergy may have serious health and personal consequences. Between 1988 and 1992, the Food and Drug Administration received reports of 1000 systemic allergic reactions to latex, 15 of which were fatal. Many approaches have been recommended for the primary, secondary, and tertiary prevention of adverse health outcomes from latex exposure, including provision of reduced protein or latex antigen gloves, medical screening, respiratory protection programs, and use of alternative glove lubricants (instead of glove powders). Health care facilities and public health agencies need to understand ''what works''; this project will seek applications that formally evaluate the effectiveness of the elements of institution-based comprehensive latex allergy prevention programs, with a particular emphasis on quantitative estimates of latex glove associated exposures.

Purpose

The purpose of this project is to formally evaluate elements of institution-based comprehensive primary, secondary, and tertiary latex allergy prevention strategies, e.g., provision of gloves with reduced and defined levels of latex protein or antigen, provision of latex-free gloves to certain units, health screening, respiratory protection programs, and/or use of alternative glove lubricants instead of glove powders. The existing data on the prevalence of allergic reactions to latex among health care workers suggest that, based on preliminary power calculations, a fairly large population will need to be involved, in the range of five hundred to a thousand workers, including provision for dropouts.

Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under A. (Recipient Activities) and CDC/NIOSH will be responsible for activities under B. (CDC/NIOSH Activities).

A. Recipient Activities

1. Develop and implement the protocol for occupational latex allergy prevention.

2. Ensure appropriate scientific peer review of the protocol and ensure continued review of any and all revisions that are made.

3. Conduct the study according to the revised protocol; implement the proposed prevention strategies and conduct the proposed evaluation component.

4. Report and disseminate research results and relevant health and safety training information to the scientific community, health care providers, relevant professional societies, affected industry and labor representatives, and interested State and Federal agencies.

B. CDC/NIOSH Activities

1. Provide scientific, epidemiologic, and medical collaboration.

2. Provide technical assistance in obtaining, analyzing and reporting of serum specimens for worker latex IgE antibody levels and/or other markers of exposure or response.

3. Provide assistance in the review, analysis and interpretation of the data and cooperate in the preparation and publication of the written reports.

Technical Reporting Requirements

An original and two copies of semi-annual progress reports are required. Timelines for the semi-annual reports will be established at the time of award. Final financial status and performance reports are required no later than 90 days after the end of the project period. All reports are submitted to the Grants Management Branch, Procurement and Grants Office, CDC.

Semi-annual progress report should include:

A. A brief program description.

B. A listing of program goals and objectives accompanied by a comparison of the actual accomplishments related to the goals and objectives established for the period.

C. If established goals and objectives to be accomplished were delayed, describe both the reason for the deviation and anticipated corrective action or deletion of the activity from the project.

D. Other pertinent information, including the status of completeness, timeliness and quality of data.

Application Content

The application must be developed in accordance with the instructions for PHS Form 398 (OMB No. 0925–0001, revised 5/95), information that is contained in this program announcement, and the instructions outlined in the following section headings.

The entire application, including appendices, should not exceed 40 pages and the Proposal Narrative section contained therein should not exceed 25 pages. Pages should be clearly numbered and a complete index to the application and any appendices included. The original and each copy of the application must be submitted unstapled and unbound. All materials must be typewritten, double-spaced, with unreduced type (font size 12 point) on 8½″ by 11″ paper, with at least 1″ margins, headers, and footers, and printed on one side only. Do not include any spiral or bound materials or pamphlets.

The applicant should provide a detailed description of first-year activities and briefly describe future-years objectives and activities.

A. Title Page

The heading should include the title of grant program, project title, organization, name and address, project director's name address and telephone number.

B. Abstract

A one page, singled-spaced, typed abstract must be submitted with the application. The heading should include the title of grant program, project title, organization, name and address, project director and telephone number. This abstract is not in lieu of (but in addition to) the Proposal Narrative, and it should outline the major goals and objectives of the proposal.

C. Proposal Narrative

1. Briefly state the applicant's understanding of the need or problem to be addressed and the purpose of this cooperative agreement. This may be reflected in the protocol, see C.3 below.

2. Describe clearly the objectives, timelines, and steps to be taken in planning and implementing this project, and the respective responsibilities of the applicant for carrying out those steps.

3. Prepare a protocol which covers 500—1000 health care facility employees with potential latex exposure, and includes a review of the literature, a description of the specific intervention to be instituted, description of the type and frequency of health and exposure data collection, the proposed methods of data management and analysis, and an evaluation component.

4. Provide a well designed exposure assessment component as well as a health surveillance component, with: (a) The prevalence of employee allergy-related health outcomes associated with defined levels of glove use and specific glove protein and, if feasible, antigen content; (b) the respiratory, skin, and other symptoms that may be associated with specific glove usage; and (c) markers of exposure or response, e.g., the prevalence of skin prick responses and/or IgE antibodies to latex proteins in the participating workers with exposures to various glove types and lots.

5. Inclusion of women, ethnic, and racial groups: Describe how the CDC policy requirements will be met regarding the inclusion of women, ethnic, and racial groups in the proposed research. (See *Women, Racial and Ethnic Minorities* in the Evaluation Criteria and Other Requirements sections.)

6. Provide letters of support or other documentation of access to potential study sites with the sample characteristics specified. Include documentation that reflects commitment of both management and labor representatives to the proposed study.

7. Human Subjects: State whether or not humans are subjects in this proposal. (See *Human Subjects* in the Evaluation Criteria and Other Requirements sections.)

8. Document the applicant's expertise in the area of occupational health, environmental hygiene, and project management.

9. Provide the name, qualifications, and proposed time allocation of the Project Director who will be responsible for administering the project. Describe staff, experience, facilities, equipment available for performance of this project, and other resources that define the applicant's capacity or potential to accomplish the requirements stated above. List the names (if known), qualifications, and time allocations of the existing professional staff to be assigned to (or recruited for) this project, the support staff available for performance of this project, and the available facilities including space.

D. Budget

Provide a detailed budget which indicates anticipated costs for personnel, equipment, travel, communications, supplies, postage, and the sources of funds to meet these needs. The applicant should be precise about the program purpose of each budget item. For contracts described within the application budget, applicants should name the contractor, if known; describe the services to be performed; and provide an itemized breakdown and justification for the estimated costs of the contract; the kinds of organizations or parties to be selected; the period of performance; and the method of selection. Place the budget narrative pages showing, in detail, how funds in each object class will be spent, directly behind form PHS 398, page 5, Budget for Entire Proposed Period of Support Direct Cost Only. Do not put these pages in the body of the application. CDC may not approve or fund all proposed activities.

Evaluation Criteria

The application will be reviewed and evaluated according to the following criteria:

A. Understanding of the Problem (20%)

(1) Applicant's understanding of the general objectives of the proposed cooperative agreement, (2) Evidence of ability to understand the problem and to conceive/design and evaluate effective interventions, and (3) Information about the occurrence of occupational latex allergies and any steps taken to prevent it in the proposed study population.

B. Program Personnel (25%)

(1) Applicant's technical experience (e.g., in the areas of occupational health, allergy, industrial hygiene, project management), (2) The qualifications (e.g., in the areas of industrial engineering, occupational safety and health) and time allocation of the professional staff to be assigned to this project, and (3) The applicant's ability to describe the approach to be used in carrying out the responsibilities of the applicant in this project.

C. Study Design (30%)

Steps proposed in planning and implementing this project and the respective responsibilities of the applicant for carrying out those steps. The degree to which efficient and innovative approaches are proposed to address the problem; the adequacy of the applicant's evidence of access to appropriate study populations; and 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.

D. Goals, Objectives, Methods and Evaluation (15%)

The extent to which the proposed goals and objectives are clearly stated, time-phased, measurable and include process and outcome evaluation. The extent to which the methods are sufficiently detailed to allow assessment of whether the objectives can be achieved for the budget period. The extent to which a qualified plan is proposed that will help achieve the goals stated in the proposal.

E. Facilities and Resources (10%)

The adequacy of the applicant's facilities, equipment, and other resources available for performance of this project.

F. Human Subjects (Not Scored)

Whether or not exempt from the Department of Health and Human Services (DHHS) regulations, are procedures adequate for the protection of human subjects? Recommendations on the adequacy of protections include: (1) Protections appear adequate, and there are no comments to make or concerns to raise, (2) protections appear adequate, but there are comments regarding the protocol, (3) protections appear inadequate and the Objective Review Group has concerns related to human subjects; or (4) disapproval of the application is recommended because the research risks are sufficiently serious and protection against the risks are inadequate as to make the entire application unacceptable.

G. Budget Justification (Not Scored)

The budget will be evaluated to the extent that it is reasonable, clearly justified, and consistent with the intended use of funds.

Executive Order 12372 Review

This program is not subject to the Executive Order 12372 review.

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number for this project is 93.283.

Other Requirements

Paperwork Reduction Act

Projects that involve the collection of information from ten or more individuals and funded by this cooperative agreement will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the DHHS Regulations, 45 CFR part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved or will support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it.

Women, Racial and Ethnic Minorities

It is the policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian, Alaskan Native, Asian, Pacific Islander, Black and Hispanic. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the **Federal Register**, Vol. 60, No. 179, pages 47947–47951, and dated Friday, September 15, 1995.

Application Submission and Deadline

A. Preapplication Letter of Intent

Although not a prerequisite of application, a non-binding letter of intent-to-apply is requested from potential applicants. The letter should be submitted to the Grants Management Branch, CDC at the address listed in this section. It should be postmarked no later than July 10, 1997. The letter should identify Program Announcement number 756 and name of principal investigator. The letter of intent does not influence review or funding decisions, but it will enable CDC to plan the review more efficiently and will ensure that each applicant receives timely and relevant information prior to application submission.

B. Application

The original and two copies of the application PHS Form 398 (Revised 5/95, OMB Number 0925–0001) must be submitted to Victoria Sepe, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Mailstop E–13, 255 East Paces Ferry Road, NE., Room 321, Atlanta, GA 30305, on or before July 28, 1997.

1. Deadline: Applications will 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 objective review group. (The applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks will not be acceptable as proof of timely mailing.)

2. Late Applicants: Applications that do not meet the criteria in 1.(a) or 1.(b) above are considered late applications. Late applications will not be considered and will be returned to the applicants.

Where To Obtain Additional Information

To receive additional written information call 1–404–332–4561. You

will be asked to leave your name, address, and telephone number and will need to refer to NIOSH Announcement 756. You will receive a complete program description, information on application procedures, and application forms. CDC will not send application kits by facsimile or express mail. Please refer to NIOSH Announcement Number 756 when requesting information and submitting an application.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Victoria Sepe, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Mailstop E–13, Room 321, 255 East Paces Ferry Road, NE., Atlanta, GA 30305, telephone (404) 842–6804, Internet: vxw1@cdc.gov.

Programmatic technical assistance may be obtained from Dr. Lee Petsonk, Division of Respiratory Disease Studies, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC), 1095 Willowdale Road, Mailstop 240, Morgantown, WV 26505, telephone (304) 285–5714, Internet address: elp2@cdc.gov.

This and other CDC announcements are available through the CDC homepage on the Internet. The address for the CDC homepage is: http://www.cdc.gov.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report, Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

National Occupational Research Agenda: Copies of this publication may be obtained from the National Institute for Occupational Safety and Health, Publications Office, 4676 Columbia Parkway, Cincinnati, OH 45226–1998 or telephone 1–800–356–4674, and is available through the NIOSH Home Page: http://www.cdc.gov/niosh/nora.html.

Dated: June 11, 1997.

Diane D. Porter,

Acting Director, National Institute for Occupational Safety and Health Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–15888 Filed 6–17–97; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Citizens Advisory Committee on Public Health Service (PHS) Activities and Research at Department of Energy (DOE) Sites: Idaho National Engineering Laboratory Health Effects Subcommittee: Time Change

Federal Register *CITATION OF PREVIOUS ANNOUNCEMENT:* 62 FR 30870—dated June 5, 1997.

SUMMARY: Notice is given that the meeting time for the Citizens Advisory Committee on PHS Activities and Research at DOE Sites: Idaho National Engineering Laboratory (INEL) Health Effects Subcommittee, of the Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention (CDC) has changed. The meeting dates, place, status, and purpose, announced in the original notice remain unchanged.

Original Times and Dates: 8:30 a.m.–5 p.m., June 26, 1997. 8:30 a.m.–5 p.m., June 27, 1997.

New Times and Dates: 8:30 a.m.–5 p.m., June 26, 1997. 6 p.m.–7 p.m., June 26, 1997. 8:30 a.m.–5 p.m., June 27, 1997.

CONTACT PERSONS FOR MORE INFORMATION: Arthur J. Robinson, Jr., or Nadine Dickerson, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, (F–35), Atlanta, Georgia 30341–3724, telephone 770/488–7040, FAX 770/488–7044.

Dated: June 12, 1997.

Nancy C. Hirsch,

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

[FR Doc. 97–15916 Filed 6–17–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0184]

Gen-Probe®, Inc.; Premarket Approval of Gen-Probe® Amplified Mycobacterium Tuberculosis Direct Test

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Gen-Probe®, Inc., San Diego, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Gen-Probe® Amplified *Mycobacterium tuberculosis* Direct Test (MTD). After reviewing the recommendation of the Microbiology Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter on December 15, 1995, of the approval of the application.

DATES: Petitions for administrative review by July 18, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review, to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Sharon L. Hansen, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–2096.

SUPPLEMENTARY INFORMATION: On July 11, 1994, Gen-Probe®, Inc., San Diego, CA, 92121, submitted to CDRH an application for premarket approval of the Gen-Probe® Amplified MTD. The device is a target-amplified nucleic acid probe test for the in vitro diagnostic detection of *M. tuberculosis* complex rRNA in acid fast bacilli (AFB) smear positive concentrated sediments prepared from sputum (induced or expectorated), bronchial specimens (e.g., bronchoalveolar lavages or bronchial aspirates), or tracheal aspirates. The MTD test is intended for use as an adjunctive test for evaluating AFB smear positive concentrated sediments prepared using NALC–NaOH digestion-decontamination of respiratory specimens from untreated patients suspected of having tuberculosis. Patients who have received no anti-tuberculous therapy, less than 7 days of such therapy, or have not received such therapy in the last 12 months may be evaluated with this test. The MTD test should be performed only in laboratories proficient in the culture and identification of *M. Tuberculosis* (Level II and III, or extent 3 and 4). The MTD should always be performed in conjunction with a mycobacterial culture.

On May 2, 1995, the Microbiology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On December 15, 1995, CDRH approved the