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 provided in the application kit.

Animal Subjects

If the proposed project involves research on animal subjects, the applicant must comply with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions. An applicant organization proposing to use vertebrate animals in CDC-supported activities must file an Animal Welfare Assurance with the Office for Protection from Research Risks at the National Institutes of Health.

Women and Racial and Ethnic Minorities

It is the policy of the CDC to ensure that women and racial and ethnic groups will be included in CDC 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 and racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is not feasible, this situation must be explained as part of the application. In conducting the review of applications for scientific merit, review groups will evaluate proposed plans for inclusion of minorities and both sexes as part of the scientific assessment and assigned score. 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, Friday, September 15, 1995, pages 47947–47951.

Application Submission and Deadlines

1. 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 Officer (whose address is reflected in section 2., ''Applications''). It should be postmarked no later than September 11, 1997. The letter should identify the announcement number, 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.

2. Applications

Applicants should use Form PHS–398 (OMB Number 0925–0001) and adhere to the ERRATA Instruction Sheet for Form PHS–398 contained in the Grant Application Kit. Please submit an original and five copies on or before November 11, 1997 to: Ron Van Duyne, Grants Management Officer, ATTN: Joanne Wojcik, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, MS E–13, Atlanta, GA 30305.

3. Deadlines

a. Applications shall be considered as meeting a deadline if they are either:

(1) Received at the above address on or before the deadline date, or

(2) Sent on or before the deadline date to the above address, and received in time for the review process. Applicants should 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 shall not be accepted as proof of timely mailings.

b. Applications which do not meet the criteria above are considered late applications and will be returned to the applicant.

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 announcement 807. You will receive a complete program description, information on application procedures, and application.

If you have questions after reviewing the contents of all the documents, business management information may be obtained from Joanne Wojcik, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., MS E–13, Atlanta, GA 30305, telephone (404) 842–6535; fax: (404) 842–6513; Internet: jcw6@cdc.gov.

Programmatic technical assistance may be obtained from Roy M. Fleming, Sc.D., Associate Director for Grants, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Building 1, Room 3053, MS D–30, Atlanta, GA 30333, telephone: 404–639–3343; fax: 404–639–4616; Internet: rmf2@cdc.gov.

Please refer to announcement number 807 when requesting information and submitting an application.

This and other CDC Announcements can be found on the CDC home page (http://www.cdc.gov) under the Funding section.

CDC will not send application kits by facsimile or express mail.

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.

Dated: August 5, 1997.

Diane D. Porter,

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

[FR Doc. 97–21102 Filed 8–8–97; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Clinical Laboratory Improvement Advisory Committee (CLIAC) Meeting

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

Name: Clinical Laboratory Improvement Advisory Committee.

Times and Dates: 8:30 a.m.–4:30 p.m., September 11, 1997. 8:30 a.m.–4:30 p.m., September 12, 1997.

Place: CDC, Auditorium A, Building 2, 1600 Clifton Road, NE, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available.

Purpose: This committee is charged with providing scientific and technical advice and guidance to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the need for, and the nature of, revisions to the standards under which clinical laboratories are regulated; the impact of proposed revisions to the standards; and the

modification of the standards to accommodate the technological advances.

Matters To Be Discussed: Agenda items include Genetics Testing; Proficiency Testing (PT) Implementation; Data measuring the effectiveness of CLIA in improving laboratory performance.

Agenda items are subject to change.

Contact Person: John Ridderhof, Dr.P.H., Division of Laboratory Systems, Public Health Practice Program Office, CDC, 4770 Buford Highway, NE, MS G25, Atlanta, Georgia 30341–3724, telephone 770/488–4674.

Dated: August 5, 1997.

Carolyn J. Russell,

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

[FR Doc. 97–21100 Filed 8–8–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94N–0193]

Robert E. Sacher; Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Dr. Robert E. Sacher, 117 Deer Path Lane, Weston, MA 02193, from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Dr. Sacher was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Dr. Sacher has failed to request a hearing and, therefore, has waived his opportunity for a hearing concerning this action.

EFFECTIVE DATE: August 11, 1997.

ADDRESSES: Application for termination of debarment to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Leanne Cusumano, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

On June 1, 1992, the U.S. district court for the District of Massachusetts entered judgment against Dr. Robert E. Sacher for one count of corruptly influencing, obstructing, and impeding the due administration of justice in an administrative proceeding of FDA, a Federal felony under 18 U.S.C. 1505.

As a result of this conviction, FDA served Dr. Sacher by certified mail on November 25, 1994, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application, and offered him an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(a)(2)(B) of the act (21 U.S.C. 335a(a)(2)(B)), that Dr. Sacher was convicted of a felony under Federal law for conduct relating to the regulation of a drug product. Dr. Sacher did not request a hearing. His failure to request a hearing constitutes a waiver of his opportunity for a hearing and a waiver of any contentions concerning his debarment.

II. Findings and Order

Therefore, the Director of the Center for Drug Evaluation and Research, under section 306(a) of the act, and under authority delegated to her (21 CFR 5.99(b)), finds that Dr. Robert E. Sacher has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product.

As a result of the foregoing finding, Dr. Robert E. Sacher is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 507, 512, or 802 of the act (21 U.S.C. 355, 357, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective August 11, 1997 (sections 306a(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) of the act (21 U.S.C. 321(d))). Any person with an approved or pending drug product application who knowingly uses the services of Dr. Sacher, in any capacity, during his period of debarment, will be subject to civil money penalties (section 307(a)(6) of the act). If Dr. Sacher, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications or abbreviated antibiotic drug applications from Dr. Sacher during his period of debarment.

Any application by Dr. Sacher for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 94N–0193 and sent to the Dockets Management Branch (address above). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 18, 1997.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 97–21085 Filed 8–8–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of CRADA Opportunities

National Cancer Institute: Nitric Oxide Technology: Opportunities for Cooperative Research and Development Agreements (CRADAs) for the development of medicinal agents useful for treating a variety of disorders arising from localized physiologic deficiencies of the multifaceted bioregulatory molecule, nitric oxide. The NCI is looking for multiple CRADA Collaborators to develop independently different aspects of their nitric oxide technology.

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice for CRADA opportunities.

SUMMARY: Pursuant to the Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. § 3710, and Executive Order 12591 of April 10, 1987, as amended by the National Technology Transfer and Advancement Act of 1995), the National Cancer Institute (NCI) of the National Institutes of Health (NIH) of the Public Health Service (PHS) of the Department of Health and Human Services (DHHS) seeks Cooperative Research and Development Agreements (CRADAs) with pharmaceutical or biotechnology companies to develop applications of nitric oxide technology. Any CRADA for the biomedical use of this technology will be considered. The CRADAs would have an expected duration of one (1) to five (5) years. The goals of the CRADAs include the rapid publication of research results and timely commercialization of products, diagnostics and treatments that result from the research. The CRADA Collaborators will have an option to negotiate the terms of an exclusive or nonexclusive commercialization license to subject inventions arising under the