

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).

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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(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.

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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