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

CRADAs, and can apply for background licenses to the existing patents listed below, subject to any pre-existing licenses already issued for other fields of use.

Please see accompanying announcement for Licensing opportunitites with this technology.

ADDRESSES: 1. CRADA opportunities—Dr. Thomas Stackhouse, National Cancer Institute, Fairview Center, Room 502, Frederick, MD 21701 (phone: 301–846–5465, fax: 301–846–6820).

2. Scientific inquiries—Dr. Larry Keefer, National Cancer Institute, Frederick Cancer and Research Development Center, Building 538, Room 205E, Frederick, MD 21702–1201 (phone: 301–846-1467, fax: 301–846–5946).

EFFECTIVE DATE: Inquiries regarding scientific matters may be forwarded at any time. Confidential CRADA proposals, preferably one page or less, must be submitted to NCI on or before October 10, 1997. Guidelines for preparing full CRADA proposals will be communicated shortly thereafter to all respondents who have been selected.

SUPPLEMENTARY INFORMATION:

Technology Available

DHHS scientists are developing a variety of novel techniques for delivering nitric oxide (NO) to specific organs and cell types for therapeutic benefit. Methods for targeting lung, liver, and other tissues have been introduced to the literature, as have NO-releasing proteins and insoluble polymers. The compounds and drug delivery strategies developed thus far have shown promising antimicrobial, cytostatic, and antimetastatic activities; other activities that have been demonstrated in experimental animals include relief of respiratory distress, protection against toxic liver injury, radiosensitization of hypoxic tumors, and correction of genitourinary tract dysfunction. Publications outlining these developments are available on request, and descriptions of other (unpublished) advances can be obtained from Dr. Stackhouse via a Confidential Disclosure Agreement.

DHHS now seeks collaborative arrangements for the joint evaluation and possible clinical exploitation of these agents. For collaborations with the commercial sector, a Cooperative Research and Development Agreement (CRADA) will be established to provide for equitable distribution of intellectual property rights developed under the CRADA. The successful CRADA awardee will collaboratively characterize compounds supplied by the Government with respect to the potential biomedical application(s) specified in the CRADA. CRADA aims will include rapid publication of research results as well as full and timely exploitation of any commercial opportunities.

NCI's Nitric Oxide Patents

1. Keefer, L. K., *et al.*: Complexes of nitric oxide with polyamines. U.S. Patent 5,155,137, October 13, 1992.

2. Keefer, L. K., *et al.*: Complexes of nitric oxide with polyamines. U.S. Patent 5,250,550, October 5, 1993.

3. Keefer, L. K., *et al.*: Oxygen-substituted derivatives of nucleophile-nitric oxide adducts as nitric oxide donor prodrugs. U.S. Patent 5,366,997, November 22, 1994.

4. Christodoulou, D. D., *et al.*: Mixed ligand metal complexes of nitric oxide nucleophile adducts useful as cardiovascular agents. U.S. Patent 5,389,675, February 14, 1995.

5. Keefer, L. K., *et al.*: Polymer-bound nitric oxide/nucleophile adduct compositions, pharmaceutical compositions and methods of treating biological disorders. U.S. Patent 5,405,919, April 11, 1995.

6. Keefer, L. K., *et al.*: Polymer-bound nitric oxide/nucleophile adduct compositions, pharmaceutical compositions incorporating same and methods of treating biological disorders using same. U.S. Patent 5,525,357, June 11, 1996.

7. Mitchell J. B. *et al.*: Use of nitric oxide releasing compounds as hypoxic cell radiation sensitizers. U.S. Patent Application 08/133,574, filed October 8, 1993

8. Korthuis, R. J., *et al.*: Use of nitric oxide-releasing agents for reducing metastasis risk. U.S. Patent Application 08/344,341, filed November 22, 1994.

9. Saavedra, J. E., *et al.*: Biopolymer-bound nitric oxide-releasing compositions, pharmaceutical compositions incorporating same and methods of treating biological disorders using same. U.S. Patent Application 08/344,157, filed November 22, 1994.

10. Keefer, L. K., *et al.*: Polymer-bound nitric oxide/nucleophile adduct compositions, pharmaceutical compositions incorporating same and methods of treating biological disorders using same. U.S. Patent Application 08/417,913, filed April 6, 1995.

11. Keefer, L. K., *et al.*: Polymer-bound nitric oxide/nucleophile adduct compositions, pharmaceutical compositions incorporating same and methods of treating biological disorders using same. U.S. Patent Application 08/417,917, filed April 6, 1995.

12. Keefer, L. K., *et al.*: Use of nitric oxide-releasing agents to treat impotency. U.S. Patent Application 08/419,044, filed April 10, 1995.

13. Smith, D. J., *et al.*: Polysaccharide-bound nitric oxide/nucleophile adducts. U.S. Patent Application 08/419,424, filed April 10, 1995.

14. Keefer, L. K., *et al.*: Pharmaceutical compositions of secondary amine-nitric oxide adducts. U.S. Patent Application 08/476,601, filed June 6, 1995.

15. Keefer, L. K., *et al.*: N-substituted piperazine NONOates. U.S. Patent Application 08/475,732, filed June 7, 1995.

16. Saavedra, J. E., *et al.*: Selective prevention of organ injury in sepsis and shock using selective release of nitric oxide in vulnerable organs. U.S. Patent Application 08/509,558, filed July 31, 1995.

17. Hrabie, J. A., *et al.*: Method of generating nitric oxide gas using nitric oxide complexes. U.S. Patent Application 08/522,405, filed September 12, 1995.

18. Saavedra, J. E., *et al.*: O^2-aryl substituted diazeniumdiolates. U.S. Patent Application 60/026,816, filed September 27, 1996.

19. Green, S. *et al.*: Encapsulated and non-encapsulated nitric oxide generators used as antimicrobial agents. U.S. Patent Application 08/428,632, filed April 24, 1995.

The role of the National Cancer Institute in this CRADA will include, but not be limited to:

1. Providing intellectual, scientific, and technical expertise and experience to the research project.

2. Providing the Collaborator with samples of the subject compounds for pharmacological evaluation and assist in the development of new compounds, as determined by the research project.

3. Planning research studies and interpreting research results.

4. Publishing research results.

The role of the CRADA Collaborator may include, but not be limited to:

1. Providing significant intellectual, scientific, and technical expertise or experience to the research project.

2. Planning research studies and interpreting research results.

3. Providing technical and/or financial support for ongoing CRADA-related research in the development of the particular application of nitric oxide technology outlined in the agreement.

4. Publishing research results.

Selection criteria for choosing the CRADA Collaborator may include, but not be limited to:

1. The ability to collaborate with NCI on further research and development of

this technology. This ability can be demonstrated through experience and expertise in this or related areas of technology indicating the ability to contribute intellectually to ongoing research and development.

2. The demonstration of adequate resources to perform the research, development and commercialization of this technology (e.g. facilities, personnel and expertise) and accomplish objectives according to an appropriate timetable to be outlined in the CRADA Collaborator's proposal.

3. The willingness to commit best effort and demonstrated resources to the research, development and commercialization of this technology.

4. The demonstration of expertise in the commercial development, production, marketing and sales of products related to this area of technology.

5. The level of financial support the CRADA Collaborator will provide for CRADA-related Government activities.

6. The willingness to cooperate with the National Cancer Institute in the timely publication of research results.

7. The agreement to be bound by the appropriate DHHS regulations relating to human subjects, and all PHS policies relating to the use and care of laboratory animals.

8. The willingness to accept the legal provisions and language of the CRADA with only minor modifications, if any. These provisions govern the equitable distribution of patent rights to CRADA inventions. Generally, the rights of ownership are retained by the organization that is the employer of the inventor, with (1) the grant of a license for research and other Government purposes to the Government when the CRADA Collaborator's employee is the sole inventor, or (2) the grant of an option to elect an exclusive or nonexclusive license to the CRADA Collaborator when the Government employee is the sole inventor.

Dated: July 21, 1997.

Kathleen Sybert,

Acting Director, Office of Technology Development, National Cancer Institute, National Institutes of Health.

[FR Doc. 97–21148 Filed 8–8–97; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions referenced below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for U.S. companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the issued U.S. patents and the U.S. patent applications referenced below may be obtained by contacting Carol Lavrich, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057 ext. 287; fax: 301/402–0220; e-mail: CL21R@NIH.GOV. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: The National Institutes of Health is seeking licensees and/or CRADA collaborators for the further development, evaluation, and commercialization of nitric oxide (NO) compounds and subsequent drug delivery strategies for the treatment of a variety of medical disorders. Published elsewhere in this issue of the **Federal Register** is a notice describing the CRADA opportunities available from the National Cancer Institute for these NO technologies. A complete listing of these technologies may be found in the CRADA notice; abstracts for some of them appear below.

Complexes of Nitric Oxide With Polyamines

LK Keefer, JA Hrabie (NCI)
Serial No. 07/585,793 filed 20 Sep 90; U.S. Patent 5,155,137 issued 13 Oct 92

Novel complexes of nitric oxide and polyamines are potentially useful in treating a variety of clinical disorders. These nitric oxide/polyamine complexes release nitric oxide under physiological conditions in a sustained and controllable fashion and possess long-lived pharmacological effects.

Related cases: Serial No. 07/906,479 filed 30 Jun 92 (DIV), which issued as U.S. Patent 5,250,550 on 05 Oct 93; Serial No. 08/522,405 filed 02 Feb 96 (CIP of 07/906,479)

Oxygen Substituted Derivatives of Nucleophile-Nitric Oxide Adducts as Nitric Oxide Donor Products

LK Keefer, TM Dunams, JE Saavedra (NCI)
Serial No. 07/950,637 filed 23 Sep 92; U.S. Patent 5,366,997 issued 22 Nov 94

A novel class of compounds that release nitric oxide (NO) *in vivo* offers to improve the treatment of many clinical disorders. This new class of compounds is stable to acidic conditions of the stomach and in the blood stream but releases nitric oxide at sites of metabolic activation. Thus, they provide organ-selective NO release and can be advantageously administered orally.

Polymer-Bound Nitric Oxide/ Nucleophile Adduct Compositions, Pharmaceutical Compositions Incorporating Same, and Methods of Treating Biological Disorders

LK Keefer, JA Hrabie (NCI)
Serial No. 07/935,565 filed 24 Aug 92; U.S. Patent 5,405,919 issued 11 Apr 95

A polymeric composition capable of releasing nitric oxide including a polymer and a nitric oxide-releasing N_2O_2-functional group bound to the polymer; pharmaceutical compositions including the polymeric composition; and methods for treating biological disorders in which dosage with nitric oxide is beneficial. The compositions can be used as and/or incorporated into implants, injectables, condoms, prosthesis coatings, patches, and the like for use in a wide variety of medical applications.

Nitric Oxide-Releasing Compounds for the Sensitization of Hypoxic Cells in Radiation Therapy

JB Mitchell, MC Krishna, D Wink, JE Liebmann, A Russo (NCI)
Serial No. 08/319,888 filed 07 Oct 94; U.S. Patent 5,650,442 issued 22 Jul 97

A novel method has been developed for sensitizing oxygen-poor, or hypoxic, tumor cells, which will increase the effectiveness of radiation treatment. It has long been known that ionizing radiation is more effective in killing cancer cells if the cells are in an oxygen-rich environment; however, the farther tumor cells are away from the blood