

Times and Dates: 5:30 p.m.-8:30 p.m., Sunday, July 25, 1993; 8:30 a.m.-4 p.m., Monday, July 26, 1993.

Place: Embassy Suites Hotel-Atlanta Airport, 4700 Southport Road, College Park, Georgia 30349. (Exit 18 Riverdale Road off I-85)

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

Purpose: This committee is charged with advising the Director, CDC, regarding priorities and feasible goals for translation activities and community control programs designed to reduce risk factors, morbidity, and mortality associated with diabetes and its complications. The committee advises regarding policies, strategies, goals and objectives, and priorities; identifies research advances and technologies ready for translation into widespread community practice; recommends public health strategies to be implemented through community interventions; advises on operational research and outcome evaluation methodologies; identifies research issues for further clinical investigation; and advises regarding the coordination of programs with Federal, voluntary, and private resources involved in the provision of services to people with diabetes.

Matters To Be Discussed: The committee will discuss results and translation implications of the Diabetes Control and Complications Trial (DCCT), and will review the relationship of the DCCT results to the goals and objectives for CDC's Division of Diabetes Translation. The committee will further review and provide input on content areas for the upcoming fiscal year 1994 request for applications for state-based diabetes control programs. In addition, the committee will discuss issues related to how the Division of Diabetes Translation can further coordinate diabetes translation and the role of the committee within this coordination process. Division of Diabetes Translation staff will provide updates on diabetes control programs currently operational within the Division.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Fredrick G. Murphy, Program Analyst, Division of Diabetes Translation, National Center for Chronic Disease Prevention and Health Promotion, CDC, 4770 Buford Highway NE., (K-10), Atlanta, Georgia 30341-3724, telephone 404/488-5005.

Dated: July 1, 1993.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control and Prevention (CDC).

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BILLING CODE 4160-10-M

*** Review of Draft Criteria for a Recommended Standard on Occupational Exposure to Respirable Coal Mine Dust: Meeting.**

The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease

Control and Prevention (CDC) announces the following meeting.

Name: Review of Draft Criteria for a Recommended Standard on Occupational Exposure to Respirable Coal Mine Dust.

Times and Dates: 9 a.m.-5 p.m., July 29, 1993; 8 a.m.-2 p.m., July 30, 1993.

Place: Robert A. Taft Laboratories, Auditorium, NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

Status: Open to the public, limited only by the space available. The meeting room accommodates 150 people.

Purpose: The purpose of this meeting is to review and discuss the draft criteria document, "Occupational Exposure to Respirable Coal Mine Dust," with a panel of invited participants selected by NIOSH for their expertise and background in this area. The review will provide NIOSH with individual input and opinion from experts outside the Institute prior to finalizing the criteria document for publication and transmittal to the Department of Labor. The review will emphasize health issues related to occupational exposures to respirable coal mine dust, including coal workers' pneumoconiosis, silicosis, and chronic obstructive pulmonary disease, as well as the related issues of exposure monitoring, medical surveillance, pulmonary function testing, control technology, and respiratory protection in mining. Viewpoints and suggestions from industry, labor, academia, other government agencies, and the public are invited.

Contact Persons for Additional Information: General information may be obtained from Judy Curless, NIOSH, CDC, 4676 Columbia Parkway, Mailstop C-32, Cincinnati, Ohio 45226, telephone 513/533-8314.

Technical information may be obtained from Eileen Kuempel, NIOSH, CDC, 4676 Columbia Parkway, Mailstop C-32, Cincinnati, Ohio 45226, telephone 513/533-8314.

Dated: June 30, 1993.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control and Prevention (CDC).

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Food and Drug Administration

[Docket No. 92N-0421]

Robert A. Fogari; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Deputy Commissioner for Operations of the Food and Drug Administration (FDA) denies Dr. Robert A. Fogari's request for a hearing and issues a final order permanently debarbing Dr. Robert A. Fogari, 58 Twin Brooks Rd., Saddle River, NJ 07458,

under section 306(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 335a(a)). The Deputy Commissioner bases this order on her finding that Dr. Fogari was convicted of Federal felonies under 18 U.S.C. 1001 and 1505 for conduct relating to the development and approval, including the process for development and approval of a drug product; and relating to the regulation of a drug product under the act.

EFFECTIVE DATE: July 8, 1993.

FOR FURTHER INFORMATION CONTACT: Megan L. Foster, Center for Drug Evaluation and Research (HFD-366), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-295-8041.

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.

SUPPLEMENTARY INFORMATION:

I. Background

Dr. Robert A. Fogari, a former clinical investigator who participated in experimental drug studies for nine different drug manufacturers, pled guilty and was sentenced on February 2, 1989, for, in addition to other offenses, two counts of submission of false documents, and one count of obstruction of justice, Federal felony offenses under 18 U.S.C. 1001 and 1505. The basis for these convictions was Dr. Fogari's data falsifications and omissions in the written reports of the drug studies that he conducted.

In a certified letter received by Dr. Robert A. Fogari on January 8, 1993, FDA offered Dr. Fogari an opportunity for a hearing on the agency's proposal to issue an order under section 306(a) of the act debarbing Dr. Fogari from providing services in any capacity to a person that has an approved or pending drug product application. FDA based the proposal to debar on its finding that Dr. Fogari's conduct leading to his convictions under 18 U.S.C. 1001 and 1505 related to the development and approval and the regulation of various drug products.

The certified letter also informed Dr. Fogari that his request for a hearing could not rest upon mere allegations or denials but must present specific facts showing that there was a genuine and substantial issue of fact requiring a hearing. The letter also noted that if it conclusively appeared from the face of the information and factual analyses in his request for a hearing that there was no genuine and substantial issue of fact