

Program (EA) and the Job Opportunities and Basic Skills Training Program (JOBS) under Title IV-A of the Social Security Act. OFA develops, recommends and issues policies, procedures and interpretations to provide direction to these programs. It develops and implements standards and policies for regulating integrated quality control activities of the Department and the operating Divisions. The Office provides technical assistance to states and assesses their performance in administering these programs, reviews state planning for administrative and operational improvements, and recommends actions to improve effectiveness. It directs reviews, provides consultations and conducts necessary negotiations to achieve adherence to federal law and regulations in state plans for public assistance program administration.

b. KH.20 Functions. Delete paragraph E in its entirety, and replace it with the following:

E. Division of JOBS Program provides direction and technical guidance in the nationwide administration of the Job Opportunities and Basic Skills Training (JOBS) Program under Title IV-A of the Social Security Act. The Division proposes and implements national policy for JOBS and title IV-A; develops regulations to implement new legislation; and prepares policy interpretations as necessary. The Division develops and implements strategies to assist States, Indian tribes, and Alaska Native organizations in establishing, expanding, and/or improving their JOBS programs. It provides oversight of technical assistance contracts, identification of successful practices, and information exchange through conferences, technology transfers, publications and resource networks. The Division monitors state compliance with federal laws and regulations, and promotes cross-program policy initiatives to support ACF objectives.

Dated: January 4, 1995.

Donna E. Shalala,
Secretary.

[FR Doc. 95-660 Filed 1-10-95; 8:45 am]

BILLING CODE 4184-01-M

Centers for Disease Control and Prevention

Fernald Dosimetry Reconstruction Project Workshop: Public Meeting

The National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC), and the Radiological

Assessments Corporation (RAC) announce the following meeting.

Name: Fernald Dosimetry Reconstruction Project Workshop.

Time and date: 7 p.m.-9 p.m., January 18, 1995.

Place: Sheraton Springdale Hotel, 11911 Sheraton Lane, Springdale, Ohio 45246.

Status: Open to the public for observation and comment, limited only by space available. The meeting room accommodates approximately 75-100 people.

Purpose: Under the Memorandum of Understanding with the Department of Energy (DOE), the Department of Health and Human Services has been given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production and use. The purpose of the workshop is: (1) to discuss the review by the National Academy of Sciences on the RAC Task 4 Methodology Report; and (2) to describe how the comments received on the draft Task 2 and 3 Source Term Report have been addressed in the final report. In addition, CDC and the Agency for Toxic Substances and Disease Registry will discuss options for further involving communities in their work.

Agenda items are subject to change as priorities dictate.

Contact person for more information: Steven A. Adams, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, (F-35), Atlanta, Georgia 30341-3724, telephone 404/488-7040.

Dated: January 4, 1995.

William H. Gimson,

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

[FR Doc. 95-631 Filed 1-10-95; 8:45 am]

BILLING CODE 4163-18-M

Current Status of the Vessel Sanitation Program and Experience to Date with Program Operations; Public Meeting

The National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Current Status of the Vessel Sanitation Program (VSP) and Experience to Date with Program Operations—Public meeting between CDC and the cruise ship industry, private sanitation consultants, and other interested parties.

Time and Date: 9 a.m.-4 p.m., Wednesday, January 25, 1995.

Place: Doral Inn, 541 Lexington Avenue at East 49th Street, New York, New York 10022, telephone 212/755-1200.

Status: Open to the public for participation, comment, and observation, limited only by space available.

Purpose: To discuss current status of the VSP and experience to date with program operations.

Matters to be discussed: During the past 8 years, as part of the revised VSP, CDC has conducted a series of public meetings with members of the cruise ship industry, private sanitation consultants, and other interested parties. This meeting is a continuation of that series of public meetings. Some of the topics to be discussed at this meeting include CDC's interim recommendations to minimize transmission of Legionnaires' disease from whirlpool spas aboard cruise ships, the VSP budget and fees, shipbuilding construction guidelines for cruise vessels destined to call on U.S. ports, the CDC consumer advisory for consumption of raw or undercooked food, and vessel construction inspections.

For a period of 15 days following the meeting, through February 9, 1995, the official record of the meeting will remain open so that additional material or comments may be submitted to be made part of the record of the meeting.

Contact person for more information: Thomas E. O'Toole, Deputy Chief, Special Programs Group (F29), NCEH, CDC, 4770 Buford Highway, NE, Atlanta, Georgia 30341-3724, telephone 404/488-7073.

Dated: January 4, 1995.

William H. Gimson,

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

[FR Doc. 95-632 Filed 1-10-95; 8:45 am]

BILLING CODE 4163-18-M

Food and Drug Administration

[Docket No. 94N-0285]

Andrew Morris; 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 debaring Mr. Andrew Morris, 5731 Laurel Hill Dr., Indianapolis, IN 46226, 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 Mr. Morris was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product; and relating to the regulation of a drug product under the act. Mr. Morris has notified FDA that he acquiesces to debarment and, therefore, has waived his opportunity for a hearing concerning this action.

EFFECTIVE DATE: May 16, 1994.

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: Tamar S. Nordenberg, Center for Drug Evaluation and Research (HFD-366), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-2041.

SUPPLEMENTARY INFORMATION:

I. Background

Mr. Andrew Morris, a former employee at Quad Pharmaceuticals, Inc. (Quad), first as a bench chemist and later as a manager in Quad's research and development department, pled guilty and was sentenced on May 13, 1994, for making a false statement to a U.S. Government agency, a Federal felony under 18 U.S.C. 1001, and for obstructing an agency proceeding, a Federal felony under 18 U.S.C. 1505. The basis for this conviction was as follows:

A. False Statement to a Federal Agency

Mr. Morris, while working as a bench chemist at Quad, made a false representation in a certificate of analysis regarding the potency of a particular lot of the drug azathioprine sodium, which was submitted to FDA in support of an abbreviated new drug application (ANDA) for the drug.

B. Obstruction of an Agency Proceeding

During an FDA audit of Quad's research and development department, Mr. Morris gathered and destroyed certain nonsterile samples of colistimethate sodium. These samples had previously been represented to FDA as sterile in batch production records. These records were prepared under Mr. Morris' supervision and were included in the ANDA for the drug product.

Mr. Morris is subject to debarment based on a finding, under section 306(a)(2) of the act (21 U.S.C. 335a(a)(2)), that he was convicted of felonies under Federal law for conduct relating to the development, approval, and regulation of a drug product. Mr. Morris' false statements in documents used to support the ANDA's for the two Quad drug products relate to the development or approval of a drug product because FDA relies on the safety and efficacy data and information in the ANDA's in making its decisions whether to approve drug products. Mr. Morris' false statements and destruction of drug samples relate to the regulation of drug products because FDA's regulatory decisions about Quad drug

products may have been affected by the conduct.

In a letter received by FDA on May 16, 1994, Mr. Morris notified FDA of his acquiescence to debarment, as provided for in section 306(c)(2)(B) of the act. A person subject to debarment is entitled to an opportunity for an agency hearing on disputed issues of material fact under section 306(i) of the act, but by acquiescing to debarment, Mr. Morris waived his opportunity for a hearing and any contentions concerning his debarment.

II. Findings and Order

Therefore, the Interim Deputy Commissioner for Operations, under section 306(a) of the act, and under authority delegated to her (21 CFR 5.20), finds that Mr. Andrew Morris has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product (21 U.S.C. 335a(a)(2)(A)); and relating to the regulation of a drug product (21 U.S.C. 335a(a)(2)(B)).

As a result of the foregoing findings and based on his notification of acquiescence, Mr. Andrew Morris is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 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 May 16, 1994, the date of notification of acquiescence (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii) and 21 U.S.C. 321(ee)). Any person with an approved or pending drug product application who knowingly uses the services of Mr. Morris, in any capacity, during his period of debarment, will be subject to civil money penalties. If Mr. Morris, 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. In addition, FDA will not accept or review any ANDA's submitted by or with the assistance of Mr. Morris during his period of debarment.

Any application by Mr. Morris for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 94N-0285 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: January 4, 1995.

Linda A. Suydam,

Interim Deputy Commissioner for Operations.
[FR Doc. 95-695 Filed 1-10-95; 8:45 am]

BILLING CODE 4160-01-F

National Institute on Deafness and Other Communication Disorders; National Institutes of Health

Notice of Meetings of the National Deafness and Other Communication Disorders Advisory Council and its Planning Subcommittee

Pursuant to Public Law 92-463, notice is hereby given of the meetings of the National Deafness and Other Communication Disorders Advisory Council and its Planning Subcommittee on January 25-27, 1995, at the National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland. The meeting of the full Council will be held in Conference Room 10, Building 31C, and the meeting of the subcommittee will be in Conference Room 7, Building 31C.

The meeting of the Planning Subcommittee will be open to the public on January 25 from 2 pm until 3 pm for the discussion of policy issues. The meeting of the full Council will be open to the public on January 26 from 8:30 am until recess for a report from the Institute Director and discussion of extramural policies and procedures at the National Institutes of Health and the National Institute on Deafness and Other Communication Disorders and on January 27 from 8:30 am to approximately 9:30 am for a report on extramural programs of the Division of Human Communication. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in sec. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and section 10(d) or Public Law 92-463, the meeting of the Planning Subcommittee on January 25 will be closed to the public from 3 pm to adjournment. The meeting of the full Council will be closed to the public on January 27 from approximately 9:30 am until adjournment. The closed portions of the meetings will be for the review, discussion, and evaluation of individual grant applications. The applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Further information concerning the Council and Subcommittee meetings