DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94N–0371]

Rami Elsharaiha; Proposal to Debar; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is proposing to issue an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Mr. Rami Elsharaiha from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this proposal on a finding that Mr. Elsharaiha was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. This notice also offers Mr. Elsharaiha an opportunity for a hearing on the proposal. The agency is issuing this notice in the **Federal Register** because all other appropriate means of service of the notice upon Mr. Elsharaiha have proven ineffective.

DATES: Written request for a hearing by February 18, 1999.

ADDRESSES: Submit written requests for a hearing and supporting information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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

SUPPLEMENTARY INFORMATION:

I. Conduct Related to Conviction

On November 22, 1993, Mr. Elsharaiha entered into a plea agreement to plead guilty to one count of making false declarations before a grand jury. Based on this plea, the United States District Court for the District of Maryland entered judgment against Mr. Elsharaiha on March 4, 1994, for one count of making false declarations before a grand jury, a Federal felony offense under 18 U.S.C. 1623.

The underlying facts supporting this felony conviction, and to which Mr. Elsharaiha stipulated in his plea agreement, are as follows:

Mr. Elsharaiha was employed by Quad Pharmaceuticals Co., Inc. (Quad), from June 1986 to September 1991 as an inspector in Quad's quality control laboratory. On January 13, 1993, Mr. Elsharaiha testified before a grand jury empaneled by the United States District Court for the District of Maryland. In his testimony, Mr. Elsharaiha falsely denied that he was aware that anyone had tried to make changes to the raw materials log book while he was an inspector at Quad. Mr. Elsharaiha also falsely denied that he was aware that anyone had poured a substance such as acid onto the pages of the raw material log book in order to expunge information that they did not want seen.

II. FDA's Finding

Section 306(a)(2)(B) of the act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product. Mr. Elsharaiha's felony conviction under 18 U.S.C. 1623 was for illegal conduct relating to the regulation of Quad's drug product. His false statements to the grand jury concerned matters that affect FDA's regulatory decisions about drug products. Under section 306(1)(2) of the act, mandatory debarment applies when an individual is convicted within the 5 years preceding this notice. Section 306(c)(2)(A)(ii) of the act requires that Mr. Elsharaiha's debarment be permanent.

III. Proposed Action and Notice of Opportunity for a Hearing

Based on the findings discussed in section II of this document, FDA proposes to issue an order under section 306(a)(2) of the act permanently debarring Mr. Elsharaiha from providing services in any capacity to a person that has an approved or pending drug product application.

In accordance with section 306 of the act and part 12 (21 CFR part 12), Mr. Elsharaiha is hereby given an opportunity for a hearing to show why he should not be debarred. If Mr. Elsharaiha decides to seek a hearing, he must file on or before February 18, 1999, a written notice of appearance and request for a hearing. The procedures and requirements governing this notice of opportunity for a hearing, a notice of appearance and request for a hearing, information and analyses to justify a hearing, and a grant or denial of a hearing are contained in part 12 and section 306(i) of the act.

Mr. Elsharaiha's failure to file a timely written notice of appearance and request for a hearing constitutes an election by him not to use the opportunity for a hearing concerning his debarment, and a waiver of any contentions concerning this action. If Mr. Elsharaiha does not request a hearing in the manner prescribed by the regulations, the agency will not hold a hearing and will issue the debarment order as proposed in this letter.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the information and factual analyses in the request for a hearing that there is no genuine and substantial issue of fact which precludes the order of debarment, the Commissioner of Food and Drugs will enter summary judgment against Mr. Elsharaiha, making findings and conclusions and denying a hearing.

The facts underlying Mr. Elsharaiha's conviction are not at issue in this proceeding. The only material issue is whether Mr. Elsharaiha was convicted as alleged in this notice and, if so, whether, as a matter of law, this conviction mandates his debarment.

A request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. 94N–0371 and sent to the Dockets Management Branch (address above). All submissions pursuant to this notice of opportunity for a hearing 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.

This notice is issued under section 306 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.99).

Dated: December 23, 1998.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 99–1034 Filed 1–15–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Arthritis Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Arthritis Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 23, 1999, 8 a.m. to 5 p.m.

Location: Holiday Inn, The Kennedy Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: Kathleen R. Reedy or LaNise S. Giles, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12532. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss issues in the design and assessment of clinical trials of drugs, biologics, and devices that are being developed for treatment of systemic lupus erythematosus.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 18, 1999. Oral presentations from the public will be scheduled between approximately 10 a.m. and 10:30 a.m. and 2 p.m. and 2:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 18, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 28, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99–1038 Filed 1–15–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0222]

Agency Information Collection Activities; Announcement of OMB Approval; Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 20, 1998 (63 FR 64556), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0390. The approval expires on May 31, 1999.

Dated: January 9, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–1033 Filed 1–15–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0304]

Agency Information Collection Activities; Announcement of OMB Approval; Application for FDA Approval to Market a New Drug

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Application for FDA Approval to Market a New Drug'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 28, 1998 (63 FR 29229), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0001. The approval expires on November 30, 2001.

Dated: January 9, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–1035 Filed 1–15–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0331]

Agency Information Collection Activities; Announcement of OMB Approval; Medical Devices: Third–Party Review Program under FDAMA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Medical Devices: Third–Party Review Program under FDAMA'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 30, 1998 (63 FR 58397), the agency announced that