

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 debaring 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 debaring 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Arthritis Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.