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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94 N-0424]

Mohammad Uddin; 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. Mohammad Uddin 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. Uddin 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. Uddin 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. Uddin have proven ineffective.

DATES: Written request for a hearing by *(insert date 30 days after date of publication in the Federal Register)*.

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 19, 1993, Mr. Uddin entered into a plea agreement to plead guilty to one count of obstruction of an agency proceeding. Based on this plea, the United States District Court for the District of Maryland entered judgment against Mr. Uddin on June 17, 1994, for one count of obstruction of an agency proceeding, a Federal felony offense under 18 U.S.C. 1505.

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

Mr. Uddin was Assistant Vice President of Research and Development at Halsey Drug Co., Inc. (Halsey), during the period August 1987 through March 10, 1993. During an FDA inspection of Halsey on October 22, 1990, to determine Halsey's compliance with the act, Mr. Uddin was interviewed by FDA investigators. Although Mr. Uddin knew that Halsey had made three research and development (R&D) batches of sulfamethoxazole/trimethoprim (generic Bactrim), during the interview he told the investigators that these batches had not been made. He also told the investigators that he had made filing batches of generic Bactrim in both single and double strength dosage forms, when, in fact, he had not made the single strength batch. Mr. Uddin's false statements to FDA investigators obstructed FDA's inspection and audit of Halsey.

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. Uddin's felony conviction under 18 U.S.C. 1505 was for illegal conduct relating to the regulation of Halsey's drug product. His false statements to FDA investigators 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. Uddin's debarment be permanent.

III. Proposed Action and Notice of Opportunity for a Hearing

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

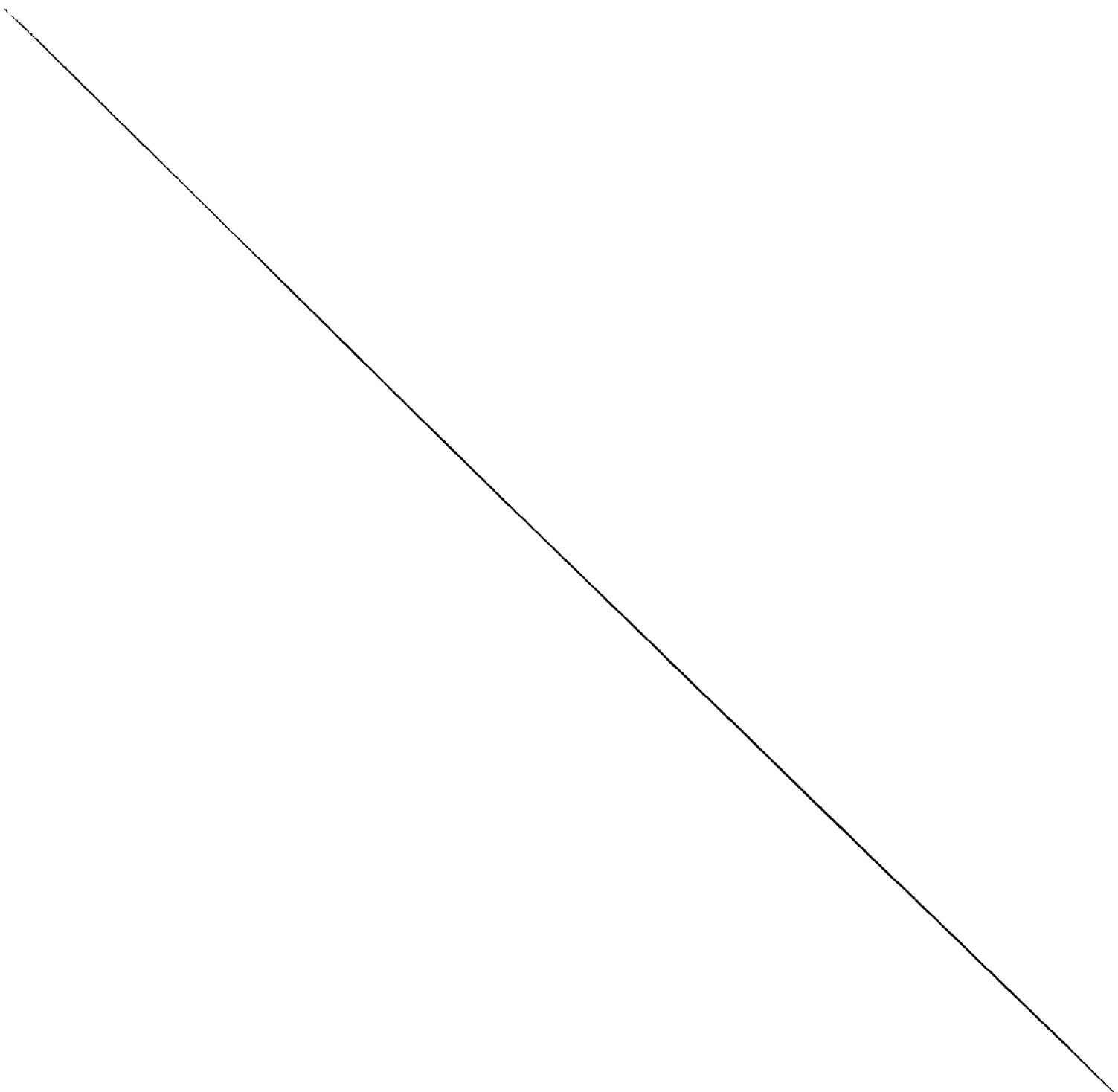
In accordance with section 306 of the act and part 12 (21 CFR part 12), Mr. Uddin is hereby given an opportunity for a hearing to show why he should not be debarred. If Mr. Uddin decides to seek a hearing, he must file on or before (*insert date 30 days after date of publication in the Federal Register*), 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. Uddin'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. Uddin 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. Uddin, making findings and conclusions and denying a hearing.

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

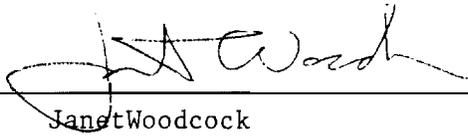
A request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. 94 N-0424 and sent to the Dockets Management Branch (address above). All submissions pursuant to this notice of opportunity for a hearing are to be filed in four copies. 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.



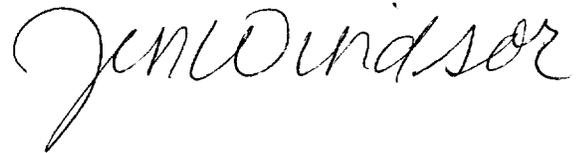
This notice is issued under section 306 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.99).

Dated: December 23, 1998

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



Janet Woodcock
Director
Center for Drug Evaluation
and Research



JW [FR Dec. 9⁹ 8:45 am Filed 9⁹ 8:45 am]

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