



Food and Drug Administration
Rockville MD 20857

CERTIFIED MAIL
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DEC 9 2002

Recd. 12/29/02

Baldev Raj Bhutani
663 Circle Lane
Lake Forest, IL 60045

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. 02N-0291

Dear Mr. Bhutani:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order permanently debarbing you 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 you were convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the Federal Food, Drug, and Cosmetic Act (the Act). This letter offers you an opportunity for a hearing on the proposal.

Conduct Related to Conviction

On February 12, 1996, you were found guilty of one count of conspiracy, a Federal felony offense under 18 U.S.C. 371, and six other counts, also Federal felonies, related to violations under 21 U.S.C. 331(a), 331(e), 331(k), and 333(a)(2). A new trial was ordered by the United States District Court for the Northern District of Illinois-Eastern Division on December 17, 1997. On April 28, 1999, the United States Court of Appeals for the Seventh Circuit reversed the District Court's ruling that you were entitled to a new trial and reinstated your conviction. On October 12, 1999, you pled guilty to one count of wire fraud, a Federal felony under 18 U.S.C. 1343. On February 15, 2000, you were adjudged guilty of all of these offenses and sentenced by the United States District Court for the District of Illinois-Eastern Division. The United States Court of Appeals for the Seventh Circuit affirmed the District Court's denial of a motion for a new trial on September 12, 2001. The underlying facts supporting this felony conviction are as follows:

From its establishment as a corporation, you were President and Treasurer of Alra Laboratories, Inc. As Alra's president, you were responsible for all of the corporation's research, product development, manufacturing, and distribution activities. You determined which drug products to develop, oversaw manufacturing, and directed marketing. You were also responsible for nearly all communications and dealings with the FDA. In your capacity as President and Treasurer, you knowingly and willfully made false, fictitious, and fraudulent representations in matters within the jurisdiction of FDA.

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Specifically, you were found guilty of:

- Conspiracy (in violation of 18 U.S.C. 371) to commit the following offenses against the United States: manufacturing and introducing adulterated and misbranded generic drug products into interstate commerce (in violation of 21 U.S.C. 331(a)); failing to establish and maintain records as required under the Act (in violation of 21 U.S.C. 331(e)); making false statements to the FDA (in violation of 18 U.S.C. 1001); obstructing the administration of law in proceedings pending before the FDA (in violation of 18 U.S.C. 1505); and obstructing proceedings before a Federal grand jury (in violation of 18 U.S.C. 1503).
- Adulterating the drug product Lactulose Syrup, USP, lot 52-230-P, in violation of 21 U.S.C. 331(k), by including decomposed Lactulose raw material in the finished drug product, and by deviating from the approved manufacturing procedures by adding an undocumented substance, sodium hydroxide, to this drug product in an unapproved manner.
- Failing to establish and maintain records as required under the Federal Food, Drug, and Cosmetic Act (in violation of 21 U.S.C. 331(e)), specifically failing to establish and maintain accurate drug manufacturing batch production records for the drug product Lactulose Syrup, USP, lot 52-230-P, in that you failed to document the unauthorized addition of sodium hydroxide more than 2 years after the original manufacture of this lot.
- Introducing into interstate commerce, in violation of 21 U.S.C. 331(a), the drug product Lactulose Syrup, USP, lot 52-230-P, which was (1) not manufactured in accordance with good manufacturing practices regulations, and (2) contained an undocumented substance, sodium hydroxide.
- Adulterating the drug product Lactulose Syrup, USP, lot 92-558-P, by violating good manufacturing practices regulations and by preparing and holding the drug product under unsanitary conditions whereby it may have been contaminated with filth (21 U.S.C. 331(k)). More specifically, you received the drug product's active raw material, lactulose concentrate, in punctured drums and then directed Alra employees to inject hot glue into the punctures to plug the leaks, and to wrap self-adhesive duct tape over the punctures, and thereafter use this contaminated raw material in the manufacture of a finished drug product.
- Introducing into interstate commerce the drug product Lactulose, lot 92-558-P, which was adulterated in that it was not manufactured in accordance with good manufacturing practices regulations, and it was prepared and held under unsanitary

conditions whereby it may have been contaminated with filth, in violation of 21 U.S.C. 331(a). Alra then used this contaminated raw material in the manufacture of a finished drug product and shipped it in interstate commerce to customers.

- Adulterating the drug product K+10 by violating good manufacturing practices regulations under 21 U.S.C. 331(k), by contaminating this drug product with metal shavings from a stainless steel pipe, and by preparing and holding the drug product under unsanitary conditions whereby it may have been contaminated with filth and rendered injurious to health. Specifically, you directed employees to make tablets from the drug product when you knew the granulation powder contained metal fragments from a stainless steel pipe.

FDA's Finding

Under 21 U.S.C. 335a(a)(2)(B), debarment of an individual is required 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. Your felony convictions under 21 U.S.C. 331(a), 331(e), 331(k), and 333(a)(2) make your debarment mandatory under 21 U.S.C. 335a(a)(2). As required under 21 U.S.C. 335a(c)(2)(A)(ii), your debarment is permanent.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, FDA proposes to issue an order under 21 U.S.C. 335a(a)(2) permanently debarring you from providing services in any capacity to a person that has an approved or pending drug product application.

In accordance with 21 U.S.C. 335a and 21 CFR part 12, you are hereby given an opportunity for a hearing to show why you should not be debarred.

If you decide to seek a hearing, you must file: (1) on or before 30 days from the date of receipt of this letter, a written notice of appearance and request for hearing, and (2) on or before 60 days from the date of receipt of this letter, the information on which you rely to justify a hearing. The procedures and requirements governing this notice of opportunity for 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 21 CFR part 12 and 21 U.S.C. 335a(i).

Your failure to file a timely written notice of appearance and request for hearing constitutes an election by you not to use the opportunity for a hearing concerning your debarment, and a waiver of any contentions concerning this action. If you do 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.

Baldev Raj Bhutani
Docket No. 02N-0291

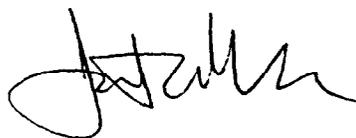
A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the information and factual analyses in your request for a hearing that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

You should understand that the facts underlying your conviction are not at issue in this proceeding. The only material issue is whether you were convicted as alleged in this notice and, if so, whether, as a matter of law, this conviction mandates your debarment.

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. 02N-0291 and sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. You must file four copies of all submissions under this notice of opportunity for hearing. The public availability of information in this submissions is governed by 21 CFR 10.20(j). Publicly available submission may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under 21 U.S.C 335a and under authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.34).

Sincerely yours,



Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research