DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

0586 '03 FEB 13 P1:27

January 31, 2003

Peter C. Baker
Director, Investigations Branch
Philadelphia District Office
Food and Drug Administration
900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Re: Edmund J. Striefsky (Docket No. 00N-1427)

Dear Mr. Baker:

Thanks for the help. As discussed in recent e-mails, enclosed is the letter to be handed to Edmund J. Striefsky. The address and phone number we have is:

502 Williamsburg Rd
Lansdale, PA 19446
215-362-1253

Following delivery, I'll need a very brief letter, signed, from the person making the delivery, stating that he/she personally handed the letter titled "PROPOSAL TO DEBAR NOTICE OF OPPORTUNITY FOR HEARING Docket No. 00N-1427" to Striefsky, noting date, time, and place. The letter can be sent to me at the address below.

If you encounter any problems, or have any questions, please do not hesitate to contact me at 301-594-2041. Thanks again for your assistance.

Sincerely yours,

Dave Read
Director, Division of Regulatory Policy I (HFD-7)
Center for Drug Evaluation and Research
Food and Drug Administration
1451 Rockville Pike
Rockville, MD 20852

Enclosure

00N-1427

LET 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 31 2003

HAND DELIVERY

Edmund J. Striefsky
502 Williamsburg Road
Landsdale, PA 19446

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. 00N-1427

Dear Mr. Striefsky:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order permanently debarring 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 also offers you an opportunity to request a hearing on your proposed debarment.

Conduct Related to Conviction

On October 28, 1998, you entered into a plea agreement with the United States Attorney, District of Maryland, in which you pleaded guilty to one count of distribution into interstate commerce of an adulterated drug product, a Federal felony offense under section 501(a)(2)(B) of the Act (21 U.S.C. 351(a)(2)(B)). The United States District Court, District of Maryland, accepted this plea on October 28, 1998. On January 28, 1999, the United States District Court, District of Maryland, judged you guilty of this offense and sentenced you. The underlying facts supporting this felony conviction are as follows:

On or about December 2, 1985, you were hired by Mutual Pharmaceutical Co., Inc. ("Mutual") in its quality control laboratory and you were subsequently made Mutual's Vice President of the Quality Unit. In that capacity you were responsible for, among other things, maintaining the overall quality of Mutual's products. From approximately 1987 until 1992, Mutual experienced problems manufacturing several of its generic drug products according to the formulas approved under the abbreviated new drug applications (ANDAs) for such products, and according to good manufacturing practice (GMP) requirements contained in the Act and Agency regulations. As a result of these problems, certain drugs manufactured by Mutual during this time were adulterated within the meaning of the Act and should not have

been distributed. However, adulterated drugs were apparently distributed on several occasions by Mutual during this period, and these distributions were facilitated by the fraudulent and misleading actions of you and other Mutual employees. Your conviction was based upon one specific instance occurring on or about October 7, 1991, in which an adulterated drug product, Acetazolamide 250 mg. tablets, batch number 18234, was shipped from Philadelphia, Pennsylvania to Baltimore, Maryland. You not only knew that the drug was adulterated when it was distributed in interstate commerce, but caused the preparation and maintenance of false batch production records that failed to show that the batch in question had been reprocessed and that the batch number had been changed.

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 under the Act. Your felony conviction for introducing adulterated drugs into interstate commerce is related to the regulation of a drug product under the Act because it is the purpose of the Act generally and the specific section of the Act that you were found guilty of violating to regulate drug products by ensuring that adulterated drug products are not distributed and used by consumers. Additionally, the fraudulent and misleading conduct underlying your conviction is directly related to the regulation of a drug product under the Act because it permitted a drug that was adulterated to be distributed in interstate commerce.

Under section 306(l)(2) of the act (21 U.S.C. 335a(l)(2)), debarment under section 306(a)(2)(B) of the Act must be initiated by FDA within 5 years of the conviction on which the debarment is based. Additionally, section 306(c)(2)(A)(ii) of the Act (21 U.S.C. 335a(c)(2)(A)(ii)) requires that a debarment issued under section 306(a)(2) of the Act (21 U.S.C. 335a(a)(2)) be permanent.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, FDA proposes to issue an order under section 306(a)(2) of the Act (21 U.S.C. 335(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 section 306 of the Act (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 section 306(i) of the act (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.

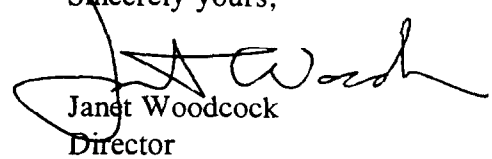
A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the information and factual analyses in your request for a hearing that there is no genuine and substantial issue of fact which 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. 00N-1427 and sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. You must file four copies of all submissions pursuant to this notice of opportunity for hearing. 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 the Federal Food, Drug, and Cosmetic Act (sec. 306 (21 U.S.C. 335a)) and under authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.99).

Sincerely yours,



Janet Woodcock
Director
Center for Drug Evaluation and Research