DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Matthew Schroeder/66594-097
FCI Morgantown
Federal Correction Institution
P.O. Box 1000
Morgantown, WV 26507

09-24-2014

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2013-N-0961

Dear Mr. Schroeder:

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 FD&C Act). This letter also offers you an opportunity to request a hearing on this proposal.

Conduct Related to Conviction

On August 2, 2012, you entered into a guilty plea to one felony count of aiding and abetting in the fraudulent dispensing of phenazepam while misbranded and without a prescription. On October 11, 2012, judgment was entered against you in the United States District Court for the Northern District of Georgia for a felony violation of sections 301(k), 503(b)(1), 303(a)(2) of the FD&C Act (21 U.S.C. §§331(k), 353(b)(1) & 333(a)(2)) and 18 U.S.C. § 2. The underlying facts supporting this conviction are as follows.

Through your company Novel Research Supply and the eBay ID "finemineralsfossilssio2," you sold phenazepam and methylenedioxypyrovalerone, which are unapproved drugs. Neither of these drugs has legitimate medicinal applications and both are used by drug users for recreational purposes as street drug alternatives. In August 2010, (b) (6) purchased phenazepam on eBay from "finemineralsfossilssio2." Later that month, (b) (6) died after having ingested phenazepam by injection. Three other individuals who also ingested phenazepam were hospitalized.

In this way, on or about August 20, 2010, in the Northern District of Georgia and elsewhere, you aided and abetted with the intent to defraud and mislead, dispensed and caused to be dispensed the prescription drug phenazepam without a prescription, which is an act that resulted in that drug being misbranded while held for sale after shipment in interstate commerce. All in violation of 21 U.S.C. §§331(k), 353(b)(1), and 333(a)(2) and 18 U.S.C. §2.

FDA's Findings

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 drug products under the Act. As described above, you aided and abetted the misbranding of a drug, intending to defraud or mislead, in violation of the Act. Specifically, you dispensed and caused to be dispensed a prescription drug without a prescription, which is an act that resulted in that drug being misbranded.

FDA, finds that the conduct underlying this felony conviction, relates to the regulation of a drug product because the misbranding of drugs undermines the drug approval process and FDA's regulatory oversight over prescription drug products marketed in the United States.

Section 306(c)(2)(A)(ii) of the Act (21 U.S.C. § 335a(c)(2)(A)(ii)) requires that your debarment 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)(B) of the Act (21 U.S.C. § 335a(a)(2)(B)) permanently debarring you from providing services in any capacity to a person having an approved or pending drug product application.

In accordance with section 306 of the Act and 21 CFR part 12, you are hereby given an opportunity to request a hearing to show why you should not be debarred as proposed in this letter.

If you decide to seek a hearing, you must file the following: (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, FDA will not hold a hearing and will issue a final 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. You should understand that the facts underlying your conviction are not at issue in this proceeding. A hearing will be denied if the data and information you submit, even if accurate, are insufficient to justify the factual determination urged. 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 deny your request for a hearing and enter a final order of debarment.

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. FDA-2013-N-0961 and sent to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

You also may notify the Secretary that you acquiesce to this proposed debarment. If you decide to acquiesce, your debarment shall commence upon such notification to the Secretary in accordance with section 306(c)(2)(B) (21 U.S.C. § 335a(c)(2)(B)).

This notice is issued under section 306 of the Act (21 U.S.C. § 335a) and under authority delegated to the Director, Office of Enforcement & Import Operations within the Food and Drug Administration.

Sincerely,

Douglas Stearn
Director,
Office of Enforcement & Import Operations

cc:
Douglas Stearn
Armando Zamora
Thomas South
Michael Verdi
OC OCC Drug Team Assigment
Eva Temkin
John Jenkins
Julie Finegan
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