DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ashley Brandon Foyle
848 N. Rainbow Blvd. #44
Las Vegas, NV 89107

10-31-2012

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2012-N-0867

Dear Mr. Foyle:

This letter is to inform you that the Food and Drug Administration (FDA or the Agency) is proposing to issue an order debarring you for a period of five years 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 misdemeanor 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), and that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs. This letter also offers you an opportunity to request a hearing on this proposal.

Conduct Related to Conviction

On May 5, 2010, you entered into a plea agreement where you pleaded guilty to a one-count information charging you with a misdemeanor offense of introducing and delivering for introduction into interstate commerce of a misbranded drug. On July 7, 2011, judgment was entered against you in the United States District Court for the District of Nevada for a misdemeanor violation of sections 301(a), 502(o), 303(a)(1) of the FD&C Act (21 U.S.C. §§ 331(a), 352(o), 333(a)(1)). The underlying facts supporting this conviction, which you admitted to in your plea agreement, are as follows.

On July 23, 2008, at JFK International Mail Facility, agents from Custom and Border Protection found two express mail packages, each with a return address of Muhi Trading Corporation, Bahadur Manzil. A border search was conducted on both packages, which revealed 1,000 capsules labeled as the prescription drug omeprazole in each package. The pills were in blister packs on which was written "Omega Biotech LTD." You and your co-defendant David Freeman were the importers of record for the packages. At all relevant times, neither Muhi Trading Corporation nor Omega Biotech LTD were registered to manufacture, prepare, propagate, compound or process drugs.

On January 20, 2009, an agent with the Office of Criminal Investigations at FDA (OCI) conducted an undercover purchase of omeprazole through a website you and your co-defendant used to sell your misbranded drugs. You and Mr. Freeman repackaged omeprazole on or about that same date in your apartment and mailed it to the undercover agent. Laboratory testing of the tablets you sent to the OCI agent confirmed that the tablets contained omeprazole. On February 24, 2009, OCI agents

searched your residence pursuant to a warrant and found unapproved drugs. During the interview that followed, you acknowledged that you brought the unapproved omeprazole drugs into the United States for resale and that you repackaged them before selling them to U.S. customers.

The omeprazole pills that you imported, repackaged, and sold had not been approved by or registered with FDA. At no time was your apartment registered as a location where drugs could be manufactured, prepared, propagated, compounded or processed.

These acts violated sections 301(a), 502(o), 303(a)(1) of the FD&C Act (21 U.S.C. §§ 331(a), 352(o), 333(a)(1).

FDA's Finding

Section 306(b)(2)(B)(i)(I) of the Act (21 U.S.C. § 335a(b)(2)(B)(i)(I)) permits FDA to debar an individual if FDA finds that the individual has been convicted of a misdemeanor under federal law for conduct relating to development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of drug products under the FD&C Act, and if FDA finds that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs. You pleaded guilty to introducing and delivering for introduction into interstate commerce of a misbranded drug in violation of sections 502(o), 301(a), 303(a)(1) of the FD&C Act (21 U.S.C. §§ 352(o), 331(a), 333(a)(1)). FDA therefore finds that your federal misdemeanor conviction for this violation relates to the regulation of drug products under the FD&C Act. FDA also finds that this your conduct, the introduction into interstate commerce of an unapproved and misbranded drug product, served as a basis for your conviction, and that it undermined the process for the regulation of drugs because the introduction of a misbranded drug into interstate commerce is a violation of the FD&C Act.

The maximum period of debarment under section 306(b)(2)(B)(i)(I) of the Act is five years (21 U.S.C. § 335a(c)(2)(A)(iii)). Section 306(c)(3) of the Act (21 U.S.C. § 335a(c)(3)) provides six factors for consideration in determining the appropriateness and the period of a permissive debarment. The factors applicable here include: (1) the nature and seriousness of the offense involved; (2) the nature and extent of management participation in any offense involved; (3) the nature and extent of voluntary steps taken to mitigate the impact on the public of any offense involved; and (4) prior convictions involving matters within the jurisdiction of FDA.

1. Nature and seriousness of the offense.

You were found guilty of introducing misbranded drugs into interstate commerce. FDA regulates the approval, manufacture and distribution of drugs in the United States. You and your co-defendant created a scheme to import unapproved prescription drugs from India and subsequently sell them in the United States.

Because the drug products you sold had not been approved by FDA, they posed a health risk to those who took them. In providing these drugs to your customers in the U.S., you displayed a wanton disregard for the public health, as well as the drug regulatory process. FDA finds that your conduct created a risk of injury to your customers, and undermined the integrity of the Agency's regulation of drug products. Accordingly, FDA considers the nature and seriousness of your conduct as an unfavorable factor.

2. Nature and extent of management participation in any offense involved.

In determining the appropriate period of debarment, FDA also shall consider the nature and extent of your management participation in the offense, and whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense. You and your co-defendant were the importers of record for the misbranded drugs you ordered from India and you repackaged and sold them yourselves through a website to customers in the U.S. Thus, the record establishes that you and your co-defendant managed all the management functions of your apparently self-run business practice. Accordingly, FDA considers this an unfavorable factor.

3. The nature and extent of voluntary steps taken to mitigate the impact on the public.

The record does not indicate that you took any steps to mitigate the impact on the public of your actions or that you took any action to limit potential or actual adverse effects of your conduct on the public health. Accordingly, FDA has determined that your failure to take any steps to mitigate the impact of your conduct on the public is an unfavorable factor.

4. Prior convictions under this Act or under other Acts involving matters within the jurisdiction of the Food and Drug Administration.

FDA is unaware of any prior convictions. FDA considers this a favorable factor.

Weighing all factors, the Agency has determined that the facts supporting the unfavorable factors far outweigh those in support of the single favorable factor, and therefore warrant the imposition of a five year permissive debarment in this case. As discussed above, the conduct that formed the basis of your conviction created a risk of injury to your customers from the sale of an unapproved and misbranded drug and demonstrated a disregard for the public's safety and the Agency's regulation of drug products.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, FDA proposes to issue an order under section 306(b)(2)(B) of the Act (21 U.S.C. § 335a(b)(2)(B)) debarring you for a period of five years from providing services in any capacity to a person having an approved or pending drug product application. You were convicted of introducing a misbranded drug into interstate commerce, a federal misdemeanor offense under the FD&C Act. As explained above, this offense relates to the regulation of drug products under the FD&C Act. Furthermore, the conduct that served as the basis for this conviction undermines the process for the regulation of drugs. Based on the factors discussed above, FDA proposes a five-year debarment period.

In accordance with section 306 of the FD&C 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 FD&C 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. 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.

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 permits your debarment under section 306(b)(2)(B) of the FD&C Act (21 U.S.C. § 335a(b)(2)(B)) as proposed in this letter.

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. FDA-2012-N-0867 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) of the FD&C Act (21 U.S.C. § 335a(c)(2)(B)).

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

Sincerely,

Reynaldo R. Rodriquez, Jr.

Reynaldo R. Rodriquez, Jr.
Acting Director,
Office of Enforcement & Import Operations
Office of Regulatory Affairs

cc:

HFC-300/ Jeffrey Ebersole
GCF-1/ Seth Ray
HFD-1/Dr. John Jenkins
HFD-300/Douglas Stearn
HFD-300/Harry Schwirck
Ilisa Berstein
HFD-003/Keith Webber
HFC-2/ Michael Verdi
HFC-22/Matthew Warren

HFD-45/Ball, Leslie
HFD-45/Constance Cullity
HFD-45/Susan K. Cummins
HFD-45/Thomas Moreno
HFD-45/Karena Cooper
HFD-45/David Burrow
HFV-200/Daniel G. McChesney

HFC-230/Debarment File
HFC-230/CF
HFM-100 (CBER)
HFC-200/CF