FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

September 25, 2019

Jagen D. Lewicki
(b) (6)

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2019-N-3131

Dear Mr. Lewicki:

This letter is to inform you that the Food and Drug Administration (FDA or the Agency) is proposing to issue an order under section 306(b)(1)(D) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 335a(b)(1)(D)) debarring you for a period of five years from importing or offering for import any drug into the United States. FDA bases this proposal on a finding that you were convicted, as defined in section 306(l)(1)(B) of the Act (21 U.S.C. § 335a(l)(1)(B)), of one felony count under federal law for conspiracy to distribute Human Growth Hormone (HGH) imported from China for a purpose other than the treatment of a disease or other recognized medical condition, the use of which had been authorized by the Secretary of Health and Human Services, and not pursuant to an order of a physician, in violation of 18 U.S.C. § 371 and section 303(e) of the Act (21 U.S.C. § 333(e)). The factual basis supporting this felony conviction, as described below, is conduct relating to the importation into the United States of any drug or controlled substance (21 U.S.C. § 335a(b)(3)(C)). This letter also offers you an opportunity to request a hearing on this proposal and provides you with the relevant information should you wish to acquiesce to this proposed debarment.

Conduct Related to Conviction

On December 20, 2018, you were convicted as defined in section 306(l)(1)(B) of the Act (21 U.S.C. § 335a(l)(1)(B)), in the United States District Court for the Eastern District of Virginia, when the court accepted your plea of guilty for the offense of conspiracy to distribute HGH imported from China for unapproved purposes in violation of 18 U.S.C. § 371 and 21 U.S.C. § 333(e) (section 303(e) of the Act). The underlying facts supporting this conviction are as follows:

As contained in the Stipulation of Facts incorporated into your Plea Agreement, filed on December 20, 2018, from on or about January 2017 to February 2018, you conspired with certain other known and unknown individuals to unlawfully distribute HGH imported from China. Specifically, you submitted periodic orders, and gave money for, HGH to co-conspirators for the purchase of HGH from manufacturers based in China. In addition, you set up various post office boxes at private carriers in the Eastern District of Virginia. The Chinese based manufacturers delivered vials of HGH from China to you at the post office boxes you set up. You received approximately 90 packages from Chinese manufacturers, each containing 200 vials of HGH. You would then sell these vials to individual customers throughout the United States. As stated in the Stipulation of Facts, your actions were in violation of 18 U.S.C. § 371 and 21 U.S.C. § 333(e) (section 303(e) of the Act).

FDA's Finding

Section 306(b)(1)(D) of the Act (21 U.S.C. § 335a(b)(1)(D)) permits FDA to debar a person from importing or offering for import into the United States any drug. An individual who has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance may be subject to debarment, as set forth in section 306(b)(3)(C) of the Act (21 U.S.C. § 335a(b)(3)(C)). FDA finds that the felony count for which you were convicted was for conduct relating to the importation of any drug or controlled substance into the United States because on multiple occasions, you imported HGH from China and conspired to distribute it within the United States, in violation of 18 U.S.C. § 371 and 21 U.S.C. § 333(e) (section 303(e) of the Act).

The maximum period of debarment for each felony under section 306(c)(2)(A)(iii) of the Act (21 U.S.C. § 335a(c)(2)(A)(iii)) is not more than five years. Section 306(c)(3) of the Act (21 U.S.C. § 335a(c)(3)) provides six factors for consideration, where applicable, in determining the appropriateness of and period of permissive debarment for an individual:

1. the nature and seriousness of any offense involved,

2. the nature and extent of management participation in any offense involved, whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense,

3. the nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including the recall or the discontinuation of the distribution of suspect drugs, full cooperation with any investigations (including the extent of disclosure to appropriate authorities of all wrongdoing),the relinquishing of profits on drug approvals fraudulently obtained, and any other actions taken to substantially limit potential or actual adverse effects on the public health,

4. whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future,

5. whether the person to be debarred is able to present adequate evidence that current production of drugs subject to abbreviated drug applications and all pending abbreviated drug applications are free of fraud or material false statements and

6. prior convictions under the Act or under other Acts involving matters within the jurisdiction of the FDA.

The FDA has determined that three of these factors are applicable for consideration:

1. Nature and seriousness of any offense involved.

As described in detail above, you were convicted of conspiracy to distribute HGH imported from China for unapproved purposes in violation of 18 U.S.C. § 371 and 21 U.S.C. § 333(e) (section 303(e) of the Act). Your distribution of HGH was not pursuant to a physician's order or for an FDA approved use. Rather, you imported and distributed HGH for bodybuilding and other unapproved purposes, which placed the American public at risk. HGH has serious, known risks and is carefully regulated in the United States. Among the possible long-term side effects of HGH is an increased risk of cancer. Other dangerous side effects associated with HGH include nerve pain and elevated cholesterol and glucose levels. The Agency finds that your conduct, including the importation of HGH, seriously undermined FDA's new drug approval process and its regulation of drugs. Accordingly, FDA concludes that the nature and seriousness of the offense involved supports the maximum possible period of debarment.

2. **Nature and extent of voluntary steps to mitigate the impact on the public of any offense involved.**

In determining the period of a debarment, FDA must also consider, when applicable, the nature and extent of voluntary steps taken to mitigate the impact on the public of any offense involved, including, among other things, discontinuation of the distribution of suspect drugs, full cooperation with any investigation (including the extent of disclosure to appropriate authorities of all wrongdoing), and any other actions taken to substantially limit potential or actual adverse effects on the public health. We are not aware of any steps you took to discontinue the distribution of the HGH or mitigate the impact on the public of your actions, which supports the conclusion that you displayed a willful disregard for the regulatory processes governing lawful drug importation and distribution as well as new drug approval. Accordingly, FDA will consider this a negative factor. FDA concludes that the failure to take any steps to mitigate the potential impact on the public supports the maximum possible period of debarment.

3. **Prior convictions under the Act or involving matters within the jurisdiction of FDA.**

FDA is unaware of any prior criminal convictions involving matters within the jurisdiction of FDA. The Agency will consider this as a favorable factor.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, FDA concludes that the facts supporting the unfavorable factors outweigh those supporting the favorable factor, and therefore warrant the imposition of a five-year period of debarment. FDA therefore proposes to issue an order under section 306(b)(1)(D) of the Act (21 U.S.C. § 335a(b)(1)(D)) debarring you from importing drugs or offering such articles for import into the United States for a period of five years.

In accordance with section 306 of the Act (21 U.S.C. § 335a) and 21 CFR part 12, you are hereby given an opportunity to request a hearing to show why you should not be debarred.

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 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 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. 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 supports your debarment under section 306(b)(1)(D) of the Act (21 U.S.C. § 335a(b)(1)(D)) 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-2019-N-3131 and sent to the Division of Dockets Management, 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

You also may notify FDA that you acquiesce to this proposed debarment. If you decide to acquiesce, your debarment shall commence upon such notification to FDA in accordance with section 306(c)(2)(B) of the Act (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, Division of Enforcement, Office of Regulatory Affairs pursuant to FDA Staff Manual Guide 1410.35.

Sincerely,

/s/
Scott MacIntire
Director
Division of Enforcement
Office of Enforcement and Import Operations
Office of Regulatory Affairs
U. S. Food and Drug Administration