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

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

September 27, 2019

Gerald Tighe
(b) (6)

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2019-N-3591

Dear Mr. Tighe:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order under section 306(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 335a(a)(2)(B)) 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, as defined in section 306(l)(1) of the Act (21 U.S.C. § 335a(l)(1)), of one felony count under Federal law for conspiracy to commit wire fraud in violation of 18 U.S.C. § 371. Furthermore, the conduct that served as the basis for your felony conviction relates to the regulation of a drug product under the Act (21 U.S.C. § 335a(a)(2)(B)). 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 July 14, 2017, you entered a plea of guilty to one count of conspiracy to commit wire fraud, a felony offense, in violation of 18 U.S.C. § 371, and on December 19, 2017, judgment was entered against you in the United States District Court for the Eastern District of New York. The underlying facts supporting this conviction under section 306(l)(1) of the Act (21 U.S.C. § 335a(l)(1)) are as follows.

You were the founder, sole owner, and president of Med Prep Consulting, Inc. (Med Prep), a medical drug repackager located and incorporated in New Jersey in 1994. Med Prep manufactured, repackaged, processed, packed, labeled, held, compounded, and distributed various drug products, including pain management medications, anesthesia and operating room drugs, and oncology and dialysis drugs. As president of Med Prep, you were its highest-ranking corporate official, and you were responsible for and oversaw all aspects of its business, including its manufacturing and quality operations.

Between approximately January 2007 and April 2013, you knowingly and intentionally conspired with other individuals to devise a scheme and artifice to defraud healthcare providers and to obtain money and property from them by means of materially false and fraudulent pretenses, representations, and promises, and for the purpose of executing such scheme and artifice, and attempting to do so, to transmit and cause to be transmitted, by means of wire communication in interstate commerce, writings, signs, signals, pictures, and sounds. Specifically, during this time period, you conspired with others to introduce and introduced, or caused the introduction of, adulterated and misbranded drugs into interstate commerce, all with the intent to defraud and mislead healthcare providers. The adulterated drugs you introduced or caused to be introduced into interstate commerce were adulterated because they were prepared, packed, and held under insanitary conditions and because the drugs consisted in whole or in part of a filthy, putrid, and decomposed substance. The misbranded drugs you introduced or caused to be introduced in interstate commerce were misbranded because the drugs were dangerous to health when used as labeled and because the labeling on the drugs regarding use by dates and the strength of the ingredients were false and misleading. You assured healthcare providers that they were receiving drug products from Med Prep that were produced in full compliance with the law, were compounded and packaged in compliance with Chapter 797 of the United States Pharmacopeia (USP 797) and would be safe for patients. You also told healthcare providers that the beyond use dates that you assigned to sterile drug products were supported by sterility testing that satisfied the requirements of USP 797. These representations were made in, among other places, quarterly reports

that were sent by e-mail to healthcare providers and on Med Prep's website. You did not inform healthcare providers of failures to comply with USP 797 and basic sterility practices, and breaches of aseptic technique in Med Prep's cleanroom, which occurred repeatedly at Med Prep's facility.

By engaging in this conduct, you violated Federal and State law applicable to drug preparation and created serious risks for patients who were being treated for cancer and other illnesses. You misrepresented the quality of Med Prep's drug processing and repackaging operation in order to increase market share, and you engaged in substandard practices in order to save money and increase your profits. Relying on these misrepresentations and omissions, healthcare providers paid Med Prep approximately $34,970,881 for its services between approximately 2007 and 2012.

FDA's Finding

Section 306(a)(2)(B) of the Act (21 U.S.C. § 335a(a)(2)(B)) mandates that FDA debar 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. As described above, your conduct included making false and fraudulent representations concerning the adulterated and misbranded drugs that you introduced or caused to be introduced into interstate commerce. FDA finds that this type of conduct, which served as a basis for your felony conviction under Federal law, relates to the regulation of drug products under the Act.

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 (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 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 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-2019-N-3591 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 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 Strategic Planning and Operational Policy
Office of Partnerships and Operational Policy
Office of Regulatory Affairs
U. S. Food and Drug Administration

bcc:
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