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

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 7, 2019

Charles Jeffrey Edwards
Register Number: 33300-379
FMC Fort Worth
3150 Horton Rd.
Fort Worth, TX 76119

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2019-N-4046

Dear Mr. Edwards:

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)(A) of the Act (21 U.S.C. § 335a(l)(1)(A)), of two felony counts under federal law. The factual basis supporting your convictions, as described below, is conduct relating to the regulation of any 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 20, 2018, you were convicted as defined in section 306(l)(1)(A) of the Act (21 U.S.C. § 335a(l)(1)(A)), in the United States District Court for the Middle District of Tennessee, Nashville Division, when the court entered judgment against you, after your plea of guilty, for one count of Mail Fraud in violation of 18 U.S.C. § 1341 and one count of Money Laundering in violation of 18 U.S.C. § 1957. The underlying facts supporting these convictions are as follows:

As contained in Counts 2 and 27 of the Indictment, filed on January 17, 2013, to which you pleaded guilty, from December 2006 through August 2009, you, along with others, through Cumberland Distribution, Inc. (Cumberland), a company you co-owned, were engaged in wholesale distribution of prescription drugs as defined by section 505(e) of the Act (21 U.S.C. 503(e)). Cumberland purchased millions of dollars of prescription drugs from unlicensed drug suppliers who were not authorized to distribute drugs under section 503 of the Act (21 U.S.C. 353). You knew that these unlicensed suppliers often procured drugs from street level drug diverters who had obtained the drugs from persons with legitimate prescriptions. On many occasions, you had drugs shipped to your shell companies, which you used as pass-throughs to create the appearance that your company was purchasing drugs from licensed suppliers when in fact you were purchasing drugs from unlicensed suppliers. Afterwards, you had these drugs shipped to Cumberland's Nashville warehouse where they were re-packaged and shipped to independent pharmacies around the country. You also directed Cumberland employees to create false pedigree documents to make it appear that the diverted drugs were purchased from authorized sellers. The diverted drugs included drugs used to combat HIV/AIDS; antipsychotic medications; anti-depressants; blood pressure medications; diabetes medications, among others. Through the course of your scheme, your company had gross proceeds of approximately $58, 984, 912. You and two others obtained profits of approximately $14, 689, 782.

FDA's Finding

Section 306(a)(2)(B) of the Act (21 U.S.C. § 335a(a)(2)(B)) mandates that the FDA debar an individual from providing services in any capacity to a person that has an approved or pending drug product application if the 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. In enacting the Drug Quality and Security Act (Pub. L. 113-54), Congress amended the Act to give FDA the authority to ensure the security of the American drug supply chain. By unlawfully reselling diverted prescription drugs and falsifying documents to hide the illegal origins of the drugs you resold, you put patients at risk and undermined FDA's regulatory oversight over drug products marketed in the United States. The FDA, therefore, finds that this conduct, which served as a basis for your convictions under 18 U.S.C. 1341 and 1957, relates to the regulation of drugs under the Act.

Section 306(c)(2)(A)(ii) of the Act (21 U.S.C. § 335a(c)(2)(A)(ii)) requires that the debarment of an individual under section 306(a)(2)(B) of the Act be permanent.

Proposed Action and Notice of Opportunity for Hearing

Based on the finding 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. 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(a)(2)(B) of the Act (21 U.S.C. § 335a(a)(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-2019-N-4046 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 C.F.R. § 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 Enforcement and Import Operations, Office of Regulatory Affairs pursuant to FDA Staff Manual Guide 1410.35.

Sincerely,

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