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

February 5, 2020

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Euton M. Laing, M.D.
1527 NJ-27 #100
Somerset, NJ 08873

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2019-N-5439

Dear Mr. Laing:

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 count of conspiracy to distribute, with intent to defraud and mislead, misbranded drugs dispensed by Meds 2 Go, Inc in violation of sections 301(a) & 503(b)(1) of the Act (21 U.S.C. § 331(a) & 353(b)(1)) and 18 U.S.C. §§ 2 and 371, and a second count of conspiracy to distribute, with intent to defraud and mislead, misbranded drugs dispensed by Aracoma Dug Company in violation of sections 301(a) & 503(b)(1) of the Act (21 U.S.C. § 331(a) & 353(b)(1)) and 18 U.S.C. §§ 2 and 371. In accordance with section 303(a)(2) of the Act (21 U.S.C. § 333(a)(2)), these constitute a felonies. The conduct that served as the basis of your conviction under the federal laws described above relates to the regulation of any drug product under the Act. 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 August 22, 2019, you were convicted in the United States District Court for the Western District of Kentucky, Louisville Division, when the court entered judgment against you after your plea of guilty, for one count of conspiracy to distribute, with intent to defraud and mislead, misbranded drugs dispensed by Meds 2 Go, Inc in violation of sections 301(a) & 503(b)(1) of the Act (21 U.S.C. § 331(a) & 353(b)(1)) and 18 U.S.C. §§ 2 and 371, and a second count of conspiracy to distribute, with intent to defraud and mislead, misbranded drugs dispensed by Aracoma Dug Company in violation of sections 301(a) & 503(b)(1) of the Act (21 U.S.C. § 331(a) & 353(b)(1)) and 18 U.S.C. §§ 2 and 371. As described in the Plea Agreement in your case, filed on July 17, 2018, from 2010 through at least 2011, you conspired with others to provide prescription drugs to Rx Limited Internet customers which were misbranded within the meaning of the Act, because the drugs were prescribed without a valid prescription in violation of sections 301(a) and 503(b)(1) of the Act (21 U.S.C. § 331(a) & 353(b)(1)). The prescriptions were not valid because they were issued outside of the scope of professional practice. Specifically, the prescriptions were issued based on limited medical questionnaires and without face-to-face encounters. The misbranded prescription drugs were then dispensed by Aracoma Dug Company and Meds 2 Go, Inc. The misbranded prescription drugs were sent to customers in various locations.

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 if the 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. The FDA finds that the felonies for which you were convicted, conspiracy to violate the Act by distributing misbranded drugs and conspiracy to distribute misbranded drugs, were for conduct relating to the regulation of drug products under the Act. Specifically, in violation of section 301(a) of the FD&C Act (21 U.S.C. § 331(a)), you caused drugs to be introduced and delivered into interstate commerce without the valid prescription of a practitioner licensed by law to administer drugs, which resulted in the drugs being misbranded under section 503(b)(1) of the Act (21 U.S.C. §

353(b)(1)). Under section 503(b)(1) of the Act (21 U.S.C. § 353(b)(1)), a drug must be dispensed by a valid prescription when because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or when it is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug. FDA, therefore, finds that the type of conduct, which served as a basis for your conviction, relates to the regulation of drugs.

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(i) 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 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.

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)).

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-5439 and sent to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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.

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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