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

February 3, 2020

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Paul J. Elmer
Register Number: 15826-028
Terre Haute FCI
4200 Bureau Road North
Terre Haute, IN 47808

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2019-N-5923

Dear Mr. Elmer:

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 multiple felonies under federal law. The factual basis supporting your convictions, as described below, is for 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 September 23, 2019, 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 Southern District of Indiana, when the court entered judgment against you, after a jury verdict, for one count of Conspiracy in violation of 18 U.S.C. § 371, three counts of Introduction of Adulterated Drugs into Interstate Commerce in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 351, and six counts of Adulterating Drugs While Holding for Sale After Shipment in Interstate Commerce in violation of 21 U.S.C. §§ 331(k), 333(a)(1), and 351.[1] The underlying facts supporting these convictions are as follows.

As contained in Counts 1 and 3-11 of the Indictment, filed on February 7, 2019, you were the President and owner of Pharmakon Pharmaceuticals, Inc. (Pharmakon). Pharmakon compounded sterile drugs for public, private, and military hospitals and medical centers located throughout the United States. In that capacity you conspired to defraud the United States by interfering with and obstructing, through deceitful and dishonest means, the lawful functions of the FDA and to commit an offense against the United States by corruptly influencing, obstructing, and impeding, and endeavoring to influence, obstruct, and impede, the due and proper

[1] For the three counts of Introduction of Adulterated Drugs into Interstate Commerce, the judgment gives §331(a) as the relevant statutory subsection, while the indictment gives §§ 333(a)(1) and 351, in addition to § 331(a). For the six counts of Adulterating Drugs While Holding for Sale After Shipment in Interstate Commerce, the indictment gives §§ 331(k), 333(a)(1), and 351 as the relevant statutory subsections. The judgment gives §331(a) as the relevant statutory subsection, which is a clerical error. The correct subsection for these counts is § 331(k), as set forth in the indictment.

administration of the law under which a pending proceeding was being had before an agency of the United States, specifically FDA inspections of Pharmakon. Among other things, you and your co-conspirators provided or directed others to provide false statements, during three inspections and in related correspondence, to the FDA regarding the practices at Pharmakon. In addition, on three separate occasions you introduced and delivered for introduction into interstate commerce, and caused to be introduced and delivered for introduction into interstate commerce, adulterated drugs which were adulterated because the drugs were purported to be and represented as drugs which were recognized in an official compendium and the strength of such drugs differed from the standard set forth in such compendium: Fentanyl, Promethazine, and Morphine sulfate. On six other occasions you caused drugs, that were being held for sale after the shipment of a drug component in interstate commerce, to become adulterated because the drugs were purported to be and represented as drugs which were recognized in an official compendium and the strength of such drugs differed from the standard set forth in such compendium: Midazolam, Fentanyl citrate, Phenylephrine, and Morphine sulfate.

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 any 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. Your conduct in distributing under- and over-potent drugs and in lying to and misleading FDA about this undermined FDA's regulatory oversight over drugs marketed in the United States. The FDA, therefore, finds that this conduct, which served as a basis for your convictions for Conspiracy, Introduction of Adulterated Drugs into Interstate Commerce, and Adulterating Drugs While Holding for Sale After Shipment in Interstate Commerce, 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 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 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 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.

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-5923 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.

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