BY CERTIFIED MAIL
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Barry J. Cadden
Register Number: 96522-038
FCI Loretto
772 Saint Joseph St.
Loretto, PA 15940

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2019-N-4248

Dear Mr. Cadden:

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 multiple felonies under Federal law for conduct relating 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 June 27, 2017, 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 District of Massachusetts, when the court entered judgment against you, after a jury verdict, for one count of Racketeering in violation of 18 U.S.C. § 1962(c), one count of Racketeering Conspiracy in violation of 18 USC 1962(d), 52 counts of Mail Fraud in violation of 18 U.S.C. § 1341, and three counts of Introduction of Misbranded Drugs into Interstate Commerce with the Intent to Defraud and Mislead-No Prescriptions in violation of 21 U.S.C. §§ 353(b)(1), 331(a), and 333(a)(2). As contained in Counts 1-2, 4-39, 41-56, 95, and 99-100 of the Indictment, filed on December 16, 2014, you were an owner and director of the New England Compounding Center (NECC), which held itself out as a compounding-only pharmacy, and you served as NECC's president, head pharmacist, and Manager of Record. In addition, you were an owner and director of Medical Sales Management, Inc. (MSM), and served as MSM's Treasurer. MSM provided sales and administrative services to NECC for which MSM was paid a service fee. MSM's sales representatives sold drugs on behalf of NECC to customers throughout the country. In those capacities, you instructed the MSM sales force to falsely represent to customers that NECC was providing the highest quality compounded medications, when in fact you, among other things, failed to properly sterilize drug products consistent with applicable USP standards, failed to test purportedly sterile drugs, authorized the shipping of drugs before test results confirming their sterility were returned, never notified customers of nonsterile results, and compounded drugs with expired ingredients. Additionally, you directed and authorized the shipping and mailing, in interstate commerce, of contaminated methylprednisolone acetate to NECC customers nationwide. You also caused drugs to be introduced and delivered into interstate commerce without the valid prescription of a practitioner licensed by law to administer drugs, which act resulted in the drugs being misbranded.

Further, you defrauded the United States by interfering with and obstructing the lawful governmental functions of the FDA by claiming to be a pharmacy dispensing drugs pursuant to valid, patient-specific prescriptions. In fact, NECC routinely dispensed drugs in bulk without valid, patient-specific prescriptions.

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, Racketeering Conspiracy, Mail Fraud, and Introduction of Misbranded Drugs into Interstate Commerce with the Intent to Defraud and Mislead-No Prescriptions, were for conduct relating to the regulation of drug products under the Act. Specifically, your actions undermined the process for the regulation of drugs because you falsely represented to customers that NECC was providing the highest quality compounded medications, when in fact you, among other things, failed to properly sterilize drug products consistent with applicable USP standards, failed to test purportedly sterile drugs, authorized the shipping of drugs before test results confirming their sterility were returned, never notified customers of nonsterile results, and compounded drugs with expired ingredients. Additionally, you directed and authorized the shipping and mailing, in interstate commerce, of contaminated methylprednisolone acetate to NECC customers nationwide. Your actions compromised the safety of the drugs you manufactured. Further, you also 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 The FDA, therefore, finds that this type of conduct, which served as a basis for your convictions, 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 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.

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-4248 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.

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,

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