DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

July 13, 2018

Poornanand Palaparty, MD
(b) (6)

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2018-N-1988

Dear Dr. Palaparty:

This letter is to inform you that the Food and Drug Administration (FDA or Agency) is proposing to issue an order debarring you for a period of three years 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 of a misdemeanor under Federal law for causing the introduction or delivery for introduction into interstate commerce of prescription drugs that were misbranded under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The type of conduct that served as the basis for your misdemeanor conviction relates to the regulation of drugs. This letter also offers you an opportunity to request a hearing on this proposal, and provides you with the relevant information should you acquiesce to this proposed debarment.

Conduct Related to Conviction

On September 5, 2013, you entered a plea of guilty to one count of misbranding, a misdemeanor offense, in violation of section 301(a) of the FD&C Act (21 U.S.C. §331(a)), and on November 12, 2013 judgment was entered against you in the United States District Court for the Northern District of Ohio. The underlying facts supporting this conviction are as follows.

Between July 4, 2004, and February 26, 2009, you were a physician (oncologist) in Ohio. During this time, you purchased and received oncology drugs, including Kytril, Gemzar, Oxaliplatin, Irinotecan, Camptosar, Zometa, Gemcitabine, Campto, Zoledronic Acid, and Carboplatin, from an online distributor located in Canada. These new drugs originated outside the United States and were not approved by FDA for introduction or delivery for introduction into interstate commerce in the United States. Thus, you caused the introduction or delivery for introduction into interstate commerce of prescription drugs that were misbranded for lacking adequate directions for use in their labeling.

FDA's Finding

Section 306(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. § 335a(b)(2)(B)(i)(I)) permits FDA to debar an individual if FDA finds that the individual has been convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the Act, and if FDA finds that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs. You caused the introduction or delivery for introduction into interstate commerce of misbranded drugs in violation of the Act by purchasing and receiving unapproved in the United States. FDA finds that the conduct that served as the basis for your conviction undermines the regulation of drug products under the FD&C Act because it obstructed FDA in its function to comprehensively regulate the manufacture, importation, and sale of prescription drugs in interstate commerce in the United States. Accordingly, the Agency finds that you are subject to debarment under section 306(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. § 335a(b)(2)(B)(i)(I)).

The maximum period of debarment under section 306(c)(2)(A)(iii) of the FD&C Act is five years. (21 U.S.C. § 335a(c)(2)(A)(iii)). Section 306(c)(3) of the FD&C Act (21 U.S.C. § 335a(c)(3)) provides six factors for consideration in determining the appropriateness and the period of a permissive debarment. The factors applicable here include: (1) the nature and seriousness of the offense involved; (2) the nature and extent of management participation in this offense; (3) the nature and extent of voluntary steps taken to mitigate the impact on the public of any offense involved; and (4) prior convictions involving matters within the jurisdiction of FDA.

1. Nature and seriousness of the offense.

As noted above, you were convicted of one misdemeanor count of causing the introduction or delivery for introduction into interstate commerce of misbranded drugs in violation of the FD&C Act by purchasing and receiving new drugs that were not approved by FDA for sale in the United States. You purchased and received numerous units of unapproved oncology drugs, such as Kytril, Gemzar, Oxaliplatin, Irinotecan, Camptosar, Zometa, Gemcitabine, Campto, Zoledronic Acid, and Carboplatin, from a foreign drug distributor between July 4, 2004, and February 26, 2009. You continued purchasing these misbranded drugs despite being notified by FDA on multiple occasions between 2004 and 2007 that foreign drug shipments destined for your office had been detained and appeared to be unlawfully marketed unapproved new drugs. You admitted to ordering these drugs from Canada because there was a "significant difference" in cost and to not passing any cost savings to your patients.

FDA finds that your conduct created a risk of injury to consumers by exposing patients to unapproved new drugs. Furthermore, your conduct undermined the Agency's drug approval process and the Agency's oversight of the manufacture, importation, and sale of drug products in interstate commerce in the United States. Accordingly, FDA considers the nature and seriousness of your conduct as an unfavorable factor.

2. The nature and extent of management participation in any offense involved, whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense.

In determining the appropriate period of debarment, FDA also considers the nature and extent of your management participation in the offense, and whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense. You admitted to ordering the misbranded drugs for use in your practice, and admitted to administering the misbranded drugs to your patients. You additionally admitted that even though you purchased the misbranded drugs at a cheaper cost, you did not pass on the cost savings to your patients. You were a licensed physician and as such held a position of authority in your medical practice where you directed your employees to place orders from the foreign drug distributor and where your conduct served as an example for your employees. Therefore, your pattern of misconduct is considered more serious than if you were an employee. Accordingly, the Agency will consider this as an unfavorable factor.

3. The nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including the recall or the discontinuation of the distribution of suspect drugs, full cooperation with any investigations (including the extent of disclosure to appropriate authorities of all wrongdoing), the relinquishing of profits on drug approvals fraudulently obtained, and any other actions taken to substantially limit potential or actual adverse effects on the public health.

FDA also considers the nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including among other things, full cooperation with any investigations (including extent of disclosure to appropriate authorities of all wrongdoing) and any other actions taken to substantially limit potential or actual adverse effects on the public health. FDA acknowledges that you took certain steps to mitigate the impact of the criminal activity of which you were a part. For instance, you accepted responsibility and cooperated fully with the United States after FDA agents visited your office. Furthermore, you ceased the purchase and use of unapproved new drugs from the foreign distributor after FDA agents visited your office. The Agency will consider this a favorable factor.

4. Prior convictions under this Act or under other Acts involving matters within the jurisdiction of the Food and Drug Administration.

FDA is unaware of any prior convictions. The Agency will consider this as a favorable factor.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, FDA has concluded that the unfavorable factors cumulatively outweigh the favorable factors and that debarment is appropriate. Accordingly, FDA proposes to issue an order under section 306(b)(2)(B) of the Act (21 U.S.C. 335a(b)(2)(B)) debarring you for a period of three years from providing services in any capacity to a person having an approved or pending drug product application. You were convicted of causing the introduction or delivery for introduction into interstate commerce of misbranded drugs, a misdemeanor offense under the FD&C Act.

As explained above, this offense relates to the regulation of drug products under the Act. Furthermore, the conduct that served as the basis for this conviction undermines the process for the regulation of drugs. Based on the factors discussed above, FDA proposes a three-year debarment period.

In accordance with section 306 of the Act and 21 CFR part 12, you are hereby given an opportunity to request a hearing to show why you should not be debarred as proposed in this letter. 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 FD&C 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. 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-2018-N-1988 and sent to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 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 the Secretary that you acquiesce to this proposed debarment. If you decide to acquiesce, your debarment shall commence upon such notification to the Secretary in accordance with section 306(c)(2)(B) of the FD&C Act (21 U.S.C. § 335a(c)(2)(B)).

This notice is issued under section 306 of the FD&C Act (21 U.S.C. § 335a) and under authority delegated to the Director, Office of Enforcement within the Food and Drug Administration.

Sincerely,

/s/
Armando Zamora
Acting Director
Office of Enforcement & Import Operations