DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

AUG 07 2009

Mr. Wallace E. Gonsalves Jr.
Register #05319-070
FCI Schuylkill
Federal Correction Institution
P.O. Box 759
Minersville, PA 17954

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2009-N-0287

Dear Mr. Gonsalves:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order 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 of a felony under Federal law for conduct relating to the regulation of a drug product under the Federal Food, Drug, and Cosmetic Act (the Act). This letter also offers you an opportunity to request a hearing on the proposal.

Conduct Related to Convictions

This proposal to debar is based on felony convictions obtained in two separate proceedings.

On September 15, 2004, the United States District Court for the District of Rhode Island entered judgment against you for two counts of product tampering in violation of 18 U.S.C. 1365(a) and two counts of drug adulteration in violation of 21 U.S.C. 331(k) and 333(a)(2).

Further, on September 14, 2004, the United States District Court for the District of Rhode Island accepted your plea of guilty, made pursuant to a plea agreement, and entered judgment against you for one count of conspiracy to sell drug samples in violation of 18 U.S.C. 371 and 21 U.S.C. 333(a)(2) and 353(c)(1), one count of unlawful sale of

drug samples in violation of 21 U.S.C. 331(t), 333(b)(1), and 353(c)(1), and one count of health care fraud in violation of 18 U.S.C. 1347(a) and 2.

The underlying facts supporting the felony convictions relevant to this Proposal to Debar are as follows.

While you were licensed by the state of Rhode Island as a physician, you practiced medicine at your local medical office located at 1596 Broad Street, Providence Rhode Island. From at least March of 2000 until on or about August 26, 2002, you tampered with a quantity of Measles, Mumps, and Rubella (MMR) and Varicella Virus (varicella) vaccine. During that same time period, you caused that vaccine to become adulterated by diluting the vaccine as well as failing to properly store and maintain that vaccine. Further, on numerous occasions, pharmaceutical sales representatives visited your office to provide you with drug samples. Sections 331(t), 353(c)(1), and 353(d) of Title 21, United States Code, prohibit the sale, purchase or trading of a drug sample. From at latest July 3, 2000 and continuing until at least on or about August 16, 2002, you knowingly sold and offered to sell drug samples to Anthony W. Albanese.

FDA's Finding

Conviction 1 (Adulteration of a Drug)

From at latest March of 2000 until on or about August 26, 2002, with the intent to defraud and mislead, you caused a quantity of MMR vaccine to be adulterated while the vaccine was being held for sale and administration to patients after being shipped in interstate commerce, by reducing the quality and strength of the vaccine by failing to properly store and maintain the vaccine, which caused the vaccine to be adulterated within the meaning of 21 U.S.C. 351(a)(2)(b), and diluted the vaccine which caused the vaccine to be adulterated within the meaning of 21 U.S.C. 351(d), in violation of 21 U.S.C. 331(k) and 333(a)(2). This offense carries a term of imprisonment of three years, thus constituting a felony.

Conviction 2 (Adulteration of a Drug)

From at latest March of 2000 until on or about August 26, 2002, with the intent to defraud and mislead, you caused a quantity of varicella vaccine to be adulterated while the vaccine was being held for sale and administration to patients after being shipped in interstate commerce, by reducing the quality and strength of the vaccine by failing to properly store and maintain the vaccine, which caused the vaccine to be adulterated within the meaning of 21 U.S.C. 351(a)(2)(b), and diluted the vaccine which caused the vaccine to be adulterated within the meaning of 21 U.S.C. 351(d), in violation of 21 U.S.C. 331(k) and 333(a)(2). This offense carries a term of imprisonment of three years, thus constituting a felony.

Conviction 3 (Sale of Drug Samples)

From at latest July 3, 2000 and continuing until at least on or about August 16, 2002, you sold quantities of drug samples of Avandia (4 mg strength) to Anthony Albanese for cash or other consideration. This conduct was a violation of sections 301(t), 303(b)(1), and 503(c)(1) of the Act, 21 U.S.C. 331(t), 333(b)(1), and 353(c)(1). This offense caries a maximum term of imprisonment of ten years, thus constituting a felony conviction.

Section 306(a)(2)(B) of the Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual if 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. FDA finds that any one of your felony convictions for adulteration of a drug and sale of drug samples, is sufficient to support debarment for conduct relating to the regulation of a drug product under the Act.

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 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, the Agency 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 mandates 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-2009-N-0287 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.

This notice is issued under section 306 of the Act (21 U.S.C. 335a) and under authority delegated to the Director, Office of Enforcement, Office of Regulatory Affairs (FDA Staff Manual Guide 1410.35).

Sincerely,

Alyson L. Saben
Acting Director
Office of Enforcement
Office of Regulatory Affairs