

Dated: November 9, 2009.

Brenda Holman,

Acting Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. E9-28083 Filed 11-20-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0288]

Anthony W. Albanese: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) (the agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Anthony W. Albanese from providing services in any capacity to a person that has an approved or pending drug product application. We base this order on a finding that Mr. Albanese was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Mr. Albanese was given notice of the proposed permanent debarment and an opportunity to request a hearing within the time frame prescribed by regulation. As of October 30, 2009, Mr. Albanese has failed to respond. Mr. Albanese's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective November 23, 2009.

ADDRESSES: Submit applications for special termination of debarment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Office of Regulatory Affairs (HFC-230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-632-6844.

SUPPLEMENTARY INFORMATION:

I. Background

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.

On November 5, 2004, the U.S. District Court for the District of Rhode

Island entered judgment against Mr. Albanese for one count of conspiracy to sell drug samples in violation of 18 U.S.C. 371; one count of unlawful sale of drug samples in violation of 21 U.S.C. 331(t), 333(b)(1), and 353(c)(1); one count of health care fraud in violation of 18 U.S.C. 1347(a) and 2; and one count of money laundering in violation of 18 U.S.C. 1956(a)(1)(A)(i) and 2.

FDA's finding that debarment is appropriate is based on the felony conviction related to the sale of drug samples. The factual basis for this conviction is as follows: From July 3, 2000, and continuing until on or about August 16, 2002, Mr. Albanese knowingly sold and offered to sell prescription drug samples that had been provided by pharmaceutical companies to Dr. Wallace E. Gonsalves, Jr. Mr. Albanese paid cash and goods in kind to Dr. Gonsalves for drug samples, removed the sample drugs from their packaging, and placed them for sale at his pharmacy as prescription drugs.

As a result of his conviction, FDA sent Mr. Albanese by certified mail on September 1, 2009, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B) of the act that Mr. Albanese was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. The proposal also offered Mr. Albanese an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Albanese failed to respond within the time frame prescribed by regulation and has therefore waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Acting Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(a)(2)(B) of the act, and under authority delegated to the Acting Director (Staff Manual Guide 1410.35), finds that Mr. Albanese has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act.

As a result of the foregoing finding, Mr. Albanese is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under

section 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**) (see section 306(c)(1)(B) and (c)(2)(A)(ii), and section 201(dd) of the act (21 U.S.C. 321(dd)). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Mr. Albanese, in any capacity, during Mr. Albanese's debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Albanese, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Albanese during his debarment (section 306(c)(1)(B) of the act).

Any application by Mr. Albanese for special termination of debarment under section 306(d)(4) of the act should be identified with Docket No. FDA-2009-N-0288 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. 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.

Dated: November 10, 2009.

Brenda Holman,

Acting Director, Office of Enforcement, Office of Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Diseases Transmitted through the Food Supply

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of annual update of list of infectious and communicable diseases that are transmitted through handling the food supply and the methods by which such diseases are transmitted.

SUMMARY: Section 103 (d) of the Americans with Disabilities Act of 1990,