

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 debarbing 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,

Public Law 101–336, requires the Secretary to publish a list of infectious and communicable diseases that are transmitted through handling the food supply and to review and update the list annually. The Centers for Disease Control and Prevention (CDC) published a final list on August 16, 1991 (56 FR 40897) and updates on September 8, 1992 (57 FR 40917); January 13, 1994 (59 FR 1949); August 15, 1996 (61 FR 42426); September 22, 1997 (62 FR 49518–9); September 15, 1998 (63 FR 49359), September 21, 1999 (64 FR 51127); September 27, 2000 (65 FR 58088), September 10, 2001 (66 FR 47030), and September 27, 2002 (67 FR 61109), September 26, 2006 (71 FR 56152), and November 17, 2008 (73 FR 67871). The final list has been reviewed in light of new information and has been revised as set forth below.

DATES: *Effective Date:* November 23, 2009.

FOR FURTHER INFORMATION CONTACT: Dr. Art Liang, National Center for Zoonotic, Vector-Borne, and Enteric Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop G–24, Atlanta, Georgia 30333.

Telephone: (404) 639–2213.

SUPPLEMENTARY INFORMATION: Section 103 (d) of the Americans with Disabilities Act of 1990, 42 U.S.C. 12113 (d), requires the Secretary of Health and Human Services to:

1. Review all infectious and communicable diseases which may be transmitted through handling the food supply;
2. Publish a list of infectious and communicable diseases which are transmitted through handling the food supply;
3. Publish the methods by which such diseases are transmitted; and,
4. Widely disseminate such information regarding the list of diseases and their modes of transmissibility to the general public.

Additionally, the list is to be updated annually.

Since the last publication of the list on September 26, 2006 (67 FR 61109), no information has been added.

I. Pathogens Often Transmitted by Food Contaminated by Infected Persons Who Handle Food, and Modes of Transmission of Such Pathogens

Some pathogens are frequently transmitted by food contaminated by infected persons. The presence of any one of the following signs or symptoms in persons who handle food may indicate infection by a pathogen that could be transmitted to others through

handling the food supply: diarrhea, vomiting, open skin sores, boils, fever, dark urine, or jaundice. The failure of food-handlers to wash hands (in situations such as after using the toilet, handling raw meat, cleaning spills, or carrying garbage, for example), wear clean gloves, or use clean utensils is responsible for the foodborne transmission of these pathogens. Non-foodborne routes of transmission, such as from one person to another, are also major contributors in the spread of these pathogens. Pathogens that can cause diseases after an infected person handles food are the following:

Noroviruses, Hepatitis A virus, *Salmonella Typhi*,* *Sapoviruses*, *Shigella* species, *Staphylococcus aureus*, *Streptococcus pyogenes*.

II. Pathogens Occasionally Transmitted by Food Contaminated by Infected Persons Who Handle Food, but Usually Transmitted by Contamination at the Source or in Food Processing or by Non-Foodborne Routes

Other pathogens are occasionally transmitted by infected persons who handle food, but usually cause disease when food is intrinsically contaminated or cross-contaminated during processing or preparation. Bacterial pathogens in this category often require a period of temperature abuse to permit their multiplication to an infectious dose before they will cause disease in consumers. Preventing food contact by persons who have an acute diarrheal illness will decrease the risk of transmitting the following pathogens:

Campylobacter jejuni, *Cryptosporidium* species, *Entamoeba histolytica*, Enterohemorrhagic *Escherichia coli*, Enterotoxigenic *Escherichia coli*, *Giardia intestinalis*, Nontyphoidal *Salmonella*, *Taenia solium*, *Vibrio cholerae*, *Yersinia enterocolitica*.

References

1. *World Health Organization*. Health surveillance and management procedures for food-handling personnel: report of a WHO consultation. World Health Organization technical report series; 785. Geneva: World Health Organization, 1989.
2. *Frank JF, Barnhart HM*. Food and dairy sanitation. In: Last JM, ed. Maxcy-Rosenau public health and preventive medicine, 12th edition. New York: Appleton-Century-Crofts, 1986:765–806.
3. *Bennett JV, Holmberg SD, Rogers MF, Solomon SL*. Infectious and parasitic diseases. In: Amler RW, Dull HB, eds. Closing the gap: the burden of unnecessary illness. New York: Oxford

* 1. Kauffmann-White scheme for designation of *Salmonella* serotypes

- University Press, 1987:102–114.
4. *Centers for Disease Control and Prevention*. Locally acquired neurocysticercosis—North Carolina, Massachusetts, and South Carolina, 1989–1991. *MMWR* 1992; 41:1–4.
5. *Centers for Disease Control and Prevention*. Foodborne Outbreak of Cryptosporidiosis—Spokane, Washington, 1997. *MMWR* 1998; 47:27.
6. *Noel JS, Humphrey CD, Rodriguez EM, et al.*, Parkville virus: A novel genetic variant of human calicivirus in the sapporo virus clade, associated with an outbreak of gastroenteritis in adults. *J. Med. Virol.* 52:173–178, 1997.
7. *Centers for Disease Control and Prevention*. Surveillance for foodborne disease outbreaks—United States, 2006. *MMWR Morbidity and Mortality Weekly Report* 2009; 58:609–615.
8. *Widdowson MA, Sulka A, Bulens SN, Beard RS, Chaves SS, Hammond R, Salehi EDP, Swanson E, Totaro J, Woron R, Mead PS, Bresee JS, Monroe SS, Glass RI*. Norovirus and Foodborne Disease, United States, 1991–2000. *Emerging Infectious Diseases* 2005; 11:95–102.

Dated: November 16, 2009.

Tanja Popovic,

Chief Science Officer, Centers for Disease Control and Prevention (CDC).

[FR Doc. E9–28093 Filed 11–20–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

FY 2010 Special Diabetes Program for Indians Community-Directed Grant Program

Announcement Type: New/
Competing Continuation.
Funding Opportunity Number: HHS–2010–IHS–SDPI–0002.
Catalog of Federal Domestic Assistance Number: 93.237.

Key Dates

Application Deadline: December 13, 2009.

Review Date: January 6–8, 2010.

Earliest Anticipated Start Date: January 18, 2010.

Other information: This announcement will be open throughout Fiscal Year (FY) 2010 based on existing budget cycles. Refer to application instructions for additional details. This current announcement targets grantees that currently operate under a budget cycle that begins on January 1.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting grant applications for the FY 2010 Special Diabetes Program for