Dated: November 12, 2009.

Howard K. Koh,

Assistant Secretary for Health.

[FR Doc. E9–28080 Filed 11–20–09; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0281]

Niaja Kane: 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 Niaja Kane 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 Ms. Kane was convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the act. Ms. Kane was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of September 20, 2009, Ms. Kane failed to respond. Ms. Kane's failure to respond constitutes a waiver of her 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 otherwise relating to the regulation of any drug product under the act.

On January 22, 2007, the U.S. District Court for the Eastern District of Pennsylvania accepted Niaja Kane's guilty plea and entered judgment against her for trafficking in counterfeit goods in violation of 18 U.S.C. 2320(a), holding counterfeit drugs for sale with intent to defraud in violation of 21 U.S.C. 331(i)(3) and 333(a)(2), and attempted possession with intent to distribute a counterfeit controlled substance in violation of 21 U.S.C. 846. The actions underlying these convictions were associated with Ms. Kane's order of counterfeit Percocet®, Viagra®, and Cialis® on or about February 28, 2006. These drugs included approximately 2,040 tablets purporting to be Viagra®, 1,200 tablets purporting to be Cialis®, 2,333 tablets purporting to be Percocet® 7.5 milligrams (mg), and 6,573 tablets purporting to be Percocet® 10 mg. All of these drugs, without authorization, bore the trademark, trade name and identifying marks, imprints and other characteristics of the products they purported to be, thereby falsely purporting to be manufactured, processed, packed, or distributed by the legitimate holders of such trademarks. Ms. Kane intentionally trafficked and attempted to traffic in goods, all of which were counterfeit. She knowingly used on and in connection with such goods counterfeit marks, that is spurious marks identical to and substantially indistinguishable from shape and imprints found on the genuine products whose marks were in use and were registered for those products by those companies on the principal register of the United States Patent and Trademark Office. Ms. Kane also, with intent to defraud and mislead, willfully caused a drug to be a counterfeit drug and held for sale or dispensing the drugs referenced previously. With respect to the tablets purporting to be Percocet®, Ms. Kane knowingly and intentionally attempted to possess with intent to distribute or dispense a mixture and substance containing oxycodone, a Schedule II controlled substance contained in Percocet®, all of which without authorization bore the identifying marks of the manufacturer and distributor of the controlled substance, which did not manufacture or distribute such substances.

As a result of these convictions, FDA sent Ms. Kane by certified mail on August 13, 2009, a notice proposing to permanently debar her 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 Niaja Kane was convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the act. The proposal also offered Ms. Kane an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Kane failed to respond within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her 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, under authority delegated to the Acting Director (Staff Manual Guide 1410.35), finds that Niaja Kane has been convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the act.

As a result of the foregoing finding, Ms. Kane is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 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 Niaja Kane, in any capacity, during Ms. Kane's debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Ms. Kane, during her period of debarment, provides services in any capacity to a person with an approved or pending drug product application, she 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 Ms. Kane during her period of debarment (section 306(c)(1)(B) of the act).

Any application by Ms. Kane for special termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 2009–N–0281 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 9, 2009.

Brenda Holman,

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

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

BILLING CODE 4160–01–S

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.

[FR Doc. E9–28084 Filed 11–20–09; 8:45 am]

BILLING CODE 4160–01–S

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,