DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

AUG 1 3 2009

Niaja Kane
60867-066
FDC Philadelphia
Federal Detention Center
P.O. Box 572
Philadelphia, PA 19106

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2009-N-0281

Dear Ms. Kane:

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 three felonies 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 Conviction

On January 22, 2007, United States District Court for the Eastern District of Pennsylvania entered judgment against you for the following offenses against the United States, namely: trafficking in counterfeit goods in violation of 18 U.S.C. 2320(a) (Count One); holding counterfeit drugs for sale with intent to defraud in violation of 21 U.S.C. 331(i)(3) and 333(a)(2)(Count Two); and attempted possession with intent to distribute a counterfeit controlled substance in violation of 21 U.S.C. 846 (Count Three). You were sentenced to thirty-two months in prison for these offenses as follows: a term of thirty-two months as to Counts One and Three and twelve months as to Count Two, to run concurrently. The underlying facts supporting the felony conviction are as follows:

On or about February 28, 2006, in Philadelphia, in the Eastern District of Pennsylvania, you did, with the intent to defraud and mislead, cause a drug to be a counterfeit drug and held such drug for sale and dispensing. 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 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. With respect to all of these drugs, you intentionally trafficked and attempted to traffic in goods, all of which were counterfeit, and knowingly used on and in connection with such goods counterfeit marks, that is spurious marks identical to and substantially indistinguishable from the shape and imprints found on genuine Viagra® manufactured by Pfizer, genuine Cialis® manufactured by Lilly and genuine Percocet® manufactured for Endo, which 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, the use of which counterfeit marks was likely to cause confusion, to cause mistake and to deceive. In addition, with respect to the tablets purporting to be Percocet®, you 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 mark of Endo, a manufacturer and distributor of controlled substances, which did not, in fact manufacture and distribute such substances, and which substances were thereby falsely purported and represented to be Percocet® 7.5 mg and Percocet® 10 mg tablets, products of Endo.

FDA's Finding

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 your convictions for trafficking in counterfeit goods, holding counterfeit drugs for sale and dispensing with the intent to defraud and mislead and attempting to distribute a counterfeit controlled substance were for conduct related to the regulation of drug products under the Act because the conduct underlying the convictions related to holding of counterfeit drugs for sale or dispensing, which is regulated by FDA.

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 C.F.R. 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 C.F.R. part 12 and 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.

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-0281 and sent to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 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,

Brenda Holman
RADM, United States Public Health Service
Acting Director
Office of Enforcement
Office of Regulatory Affairs