DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

AUG 17 2009

Kevin Xu
66582-179
CI Big Spring
Correctional Institution
2001 Rickabaugh Drive
Big Spring, TX 79720

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2009-N-0286

Dear Mr. Xu:

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 five felonies under Federal law for conduct relating to the regulation of a drug product. This letter also offers you an opportunity to request a hearing on the proposal.

Conduct Related to Conviction

On January 20, 2009, judgment was entered against you in the United States District Court for the Southern District of Texas on five felony convictions under Federal law relating to the regulation of a drug product. Counts One through Five consisted of the following: participating in a conspiracy to traffic and attempt to traffic in counterfeit goods, to cause the introduction and delivery from introduction of misbranded prescription drugs into interstate commerce, and to cause the counterfeiting of trademarks, in violation of 18 U.S.C. 371 (Count One); misbranding of the labeling on the blister strips of Tamiflu capsules with the intent to defraud and mislead, in violation of 21 U.S.C. 331(a) and 333(a)(2) (Count Two); misbranding of the labeling on the blister strips of Zyprexa pills with the intent to defraud and mislead, in violation of 21 U.S.C. 331(a) and 333(a)(2) (Count Three) ; misbranding of the labeling on the blister strips of Plavix pills with the intent to defraud and mislead, in violation of 21 U.S.C. 331(a) and 333(a)(2) (Count Four); and trafficking and attempting to traffic in counterfeit Zyprexa in violation of 18 U.S.C. 2320(a) and (2) (Count Five). The underlying facts supporting the finding of a felony conviction as the basis for this Proposal to Debar are as follows.

Beginning in or about July, 2006 and continuing thereafter to on or about July, 2007, in the Houston Division of the Southern District of Texas and elsewhere, you did knowingly, intentionally, and willfully combine, conspire and confederate and agree with other persons to commit certain offenses against the United States, namely:

a. To traffic and attempt to traffic in counterfeit goods in violation of 18 U.S.C. 2320(a);
b. To violate the Federal Food, Drug, and Cosmetic Act, namely, with the intent to defraud and mislead, cause the introduction and delivery for introduction of prescription drugs into interstate commerce that are misbranded, in violation of 21, U.S.C. 331(a) and 333(a)(2); and
c. To violate the Federal Food, Drug and Cosmetic Act, namely, with the intent to defraud and mislead, cause the counterfeiting of trademarks Viagra and Cialis in violation of 21, U.S.C. 331(i) and 333(a)(2).

You conspired with others to export pharmaceutical drug products that bore the trademarks Zyprexa, Tamiflu, Casodex, Plavix and Aricept without the authorization of manufacturer of these drugs, and then to resell these products to the public.

On or about December 8, 2007, you used an internet email address to send an email listing the tracking numbers connected to the sale of counterfeit pharmaceuticals. On or about April 9, 2007, you caused coconspirators residing in the Republic of China to place in interstate commerce for shipment to the United States various blister strips containing counterfeit Tamiflu, Casodex, Zyprexa, and Plavix in violation of 18 U.S.C. 371.

On or about December 8, 2006, with the intent to defraud or mislead, you caused the introduction and delivery for introduction into interstate commerce of drugs that were misbranded in violation of 21 U.S.C. 331(a) and 333(a)(2), namely a shipment containing blister strips of Tamiflu capsules that were labeled in a manner to falsely represent that these blister strips contained genuine Tamiflu.

On or about January 3, 2007, with the intent to defraud or mislead, you caused the introduction and delivery for introduction into interstate commerce of drugs that were misbranded in violation of 21 U.S.C. 331(a) and 333(a)(2), namely a shipment containing blister strips of Zyprexa pills that were labeled in a manner to falsely represent that these blister strips contained genuine Zyprexa.

On or about February 20, 2007, with the intent to defraud or mislead, you caused the introduction and delivery for introduction into interstate commerce of drugs that were misbranded in violation of 21 U.S.C. 331(a) and 333(a)(2), namely a shipment containing blister strips of Plavix pills that were labeled in a manner to falsely represent that these blister strips contained genuine Plavix.

On or about December 8, 2006, in the Southern District of Texas, you intentionally trafficked in goods, namely pharmaceutical drugs, and knowingly used a counterfeit mark, the Zyprexa trademark, on and in connection with such goods. The Zyprexa trademark is used to identify a pharmaceutical product marketed by Eli Lilly. The use of this counterfeit mark was likely to cause confusion, mistake and deception regarding said mark.

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 a drug product under the Federal Food, Drug, and Cosmetic Act. FDA finds that any one of your felony convictions on Count One through Five as referenced herein, is sufficient to support debarment for conduct relating to the regulation of a drug product under the Act.

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 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 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.

Kevin Xu
Docket No. FDA-2009-N-0286

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-0286 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 Federal Food, Drug, and Cosmetic 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
Acting Director
Office of Enforcement
Office of Regulatory Affairs