DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Brian Ullom
Register # 10291-033
FCI Ashland
Satellite Camp
P.O. Box 6000
Ashland, KY 41105

OCT 27 2009

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2009-N-0420

Dear Mr. Ullom:

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 a felony 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 or about August 17, 2009, judgment was entered against you in the United States District Court for the Western District of Kentucky on two felony convictions. Count One consists of participation in a scheme to defraud health care benefit programs by billing patients and patient's health care benefit programs, including Medicare and Medicaid, for prescription drug samples and for prescriptions that were never filled, in violation of 18 U.S.C. 1347. Count Two consists of knowingly selling, purchasing and trading prescription drug samples with the intent to defraud, in violation of 21 U.S.C. 331(t) and 353(c) (1). The underlying facts supporting these felony convictions are as follows.

Beginning in or about 2002 and continuing until on or about October 12, 2006, in the Western District of Kentucky, you did with the intent to defraud, knowingly sell, purchase and trade prescription drug samples, in violation of 21 U.S.C. 331(t) and 353(c)(1). During that time period, you obtained prescription drug samples by purchasing the drug samples from others,

including a local physician and a pharmaceutical sales representative. After obtaining those samples, you, aided by others, removed the drugs from their original sample packaging and sold the drug samples to the public through your pharmacy, Rueben's Pharmacy. At the time of sale, you knew that the drugs were drug samples and you resold the drugs with the intent to defraud and mislead the purchaser by selling the sample drugs as drugs properly obtained and dispensed. At or about the time of each sale, you, along with others, billed the patient and the patient's insurance provider, including Medicare and Medicaid, for the drug samples. In doing so, you, along with others, executed a scheme to defraud Medicare and Medicaid in connection with the delivery of and payment for prescription drugs.

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 your felony conviction for knowingly selling, purchasing, and trading prescription drug samples is sufficient to support debarment for conduct relating to the regulation of a drug product under the Act because the sale, purchase, and trading of prescription drug samples is prohibited by the Act.

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 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.

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-0420 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