DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

AUG 2 4 2009

Michelle Lynn Torgerson
13748 Skyline Drive
Spicer, MN 56288

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2009-N-0292

Dear Ms. Torgerson:

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 this proposal.

Conduct Related to Conviction

On January 4, 2006, the United States District Court for the District of Minnesota entered judgment against you for one felony count of misbranding a drug (dispensing a prescription drug without a physician's prescription), under 21 U.S.C. 331(k), 333(a)(2), and 353(b)(1) after accepting your guilty plea on May 19, 2005. You were sentenced to nine (9) months in prison and ordered to pay restitution in the amount of $4,597.32 for this offense. The underlying facts supporting the finding of a felony conviction as the basis for this Proposal to Debar are as follows.

In or about November and December 2004, you were employed as a nurse by the Maxim Health Systems, a division of Maxim Healthcare Services, Inc. in the State of Minnesota. During that period you conducted unauthorized flu vaccination clinics on the campus of Augsburg College, without the approval of your employer, Maxim Health Systems. You also falsely represented that the American Heart Association was sponsoring or otherwise authorizing your clinics.

As part of your plea agreement, you acknowledged that, in conducting your unauthorized clinics, you acted with the intent to defraud and mislead the public and that you caused a quantity of a prescription drug, namely, the flu virus vaccine Fluzone®, to be misbranded within the meaning of 21 U.S.C. 353(b)(1), while the flu virus vaccine was being held for sale after being shipped in interstate commerce. Specifically, you acknowledged that you dispensed the flu virus vaccine without a written prescription of a practitioner licensed by law to administer the flu virus vaccine. You knew that, as a Licensed Practical Nurse, you yourself were not authorized to dispense the flu virus vaccine without a physician's orders. You also acknowledged that you diluted some of the vaccine with saline knowing that this reduced the flu vaccine's quality and strength.

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. You were convicted of a felony under Federal law for misbranding of a drug (dispensing a prescription drug without a physician's prescription), in violation of 301(k), 303(a)(2), and 503(b)(1) of the Act (21 U.S.C. 331(k), 333(a)(2), and 353(b)(1)). Misbranding a drug relates to the regulation of a drug product under the Act; therefore, FDA finds that you were convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the Act.

Section 306(c)(2)(A)(ii) of the Act (21 U.S.C. 335a(c)(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 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.

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-0292 and sent to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 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 within the Food and Drug Administration.

Sincerely,

Brenda Holman
Acting Director
Office of Enforcement
Office of Regulatory Affairs