

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0292]

Michelle Lynn Torgerson; 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 debaring Michelle Lynn Torgerson, 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. Torgerson was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Ms. Torgerson was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of October 26, 2009, Ms. Torgerson has failed to respond. Ms. Torgerson's failure to respond constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is effective November 13, 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 Federal Food, Drug, and Cosmetic Act (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 4, 2006, the U.S. District Court for the District of Minnesota entered judgment against Michelle L. Torgerson for one count of misbranding a drug, a federal felony offense under sections 301(k), 303(a)(2), and 352(b)(1) (21 U.S.C. 331(k), 333(a)(2), and 353(b)(1)), after accepting her guilty plea

on May 19, 2005. This offense was committed when Michelle L. Torgerson was employed as a nurse by Maxim Health Systems in the State of Minnesota. During that time, Ms. Torgerson conducted unauthorized flu vaccination clinics on the campus of Augsburg College, without the approval of her employer, Maxim Health Systems. Ms. Torgerson also falsely represented that the American Heart Association was sponsoring or otherwise authorizing the clinics. Michelle L. Torgerson acknowledged that, in conducting the unauthorized clinics, she acted with the intent to defraud and mislead the public and that she 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, Ms. Torgerson acknowledged that she dispensed the flu virus vaccine without a written prescription of a practitioner licensed by law to administer the flu virus vaccine. Ms. Torgerson knew that, as a Licensed Practical Nurse, she was not authorized to dispense the flu virus vaccine without a physician's orders. She also acknowledged that she diluted some of the vaccine with saline knowing that this would reduce the flu vaccine's quality and strength.

As a result of this conviction, FDA sent Ms. Torgerson by certified mail on August 7, 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 Michelle L. Torgerson 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 Ms. Torgerson 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. Torgerson failed to respond within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and 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, and under authority delegated to the Acting Director (Staff Manual Guide

1410.35), finds that Michelle L. Torgerson 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, Ms. Torgerson 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 sections 306(c)(1)(B), 306(c)(2)(A)(ii), and 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 Michelle L. Torgerson, in any capacity, during Ms. Torgerson's permanent debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Ms. Torgerson, 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. Torgerson during her period of debarment (section 306(c)(1)(B) of the act).

Any application by Ms. Torgerson for special termination of debarment under section 306(d)(4) of the act should be identified with Docket No. FDA-2009-N-0292 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: October 28, 2009.

Brenda Holman,

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

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