Dated: January 27, 2010.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0420]

Brian Ullom: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Brian Ullom 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 Mr. Ullom was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Mr. Ullom was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of December 2, 2009, Mr. Ullom failed to respond. Mr. Ullom's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective February 2, 2010.

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 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 August 17, 2009, the U.S. District Court for the Western District of Kentucky entered judgment against Brian Ullom for one count of participation in a scheme to defraud health care benefit programs by billing patients and patients' 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; and one count of knowingly selling, purchasing and trading prescription drug samples with the intent to defraud, in violation of sections 301(t) and 503(c)(1) of the act (21 U.S.C. 331(t) and 353(c)(1)).

FDA's finding that debarment is appropriate is based on the felony conviction related to the sale of drug samples. The factual basis for this conviction is as follows: Beginning in or about 2002 and continuing until on or about October 12, 2006, Mr. Ullom, with the intent to defraud, knowingly sold, purchased, and traded prescription drug samples. During that time period, Mr. Ullom obtained prescription drug samples by purchasing the drug samples from others, including a local physician and a pharmaceutical sales representative. After obtaining the samples, he removed the drugs from their original sample packaging and sold them to the public through his pharmacy. At the time of sale, he knew the drugs were samples, and he resold them with the intent to defraud and mislead the purchaser by selling the sample drugs as drugs properly obtained and dispensed.

As a result of this conviction, FDA sent Mr. Ullom by certified mail on October 27, 2009, a notice proposing to permanently debar him 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 Brian Ullom was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. In accordance with section 306(i) of the act and part 12 (21 CFR part 12), the proposal also offered Mr. Ullom an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Accordingly, Mr. Ullom had to request a hearing by December 2, 2009. As of December 2, 2009, Mr. Ullom had not responded to the notice. Mr. Ullom thus failed to respond within the timeframe prescribed by regulation and as a result has waived both his opportunity for a hearing and waived any contentions concerning his debarment (21 U.S.C. 335(a)(i); 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, under authority delegated to the Acting Director (Staff Manual Guide 1410.35), finds that Brian Ullom 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, Mr. Ullom 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), (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 Brian Ullom, in any capacity, during Mr. Ullom's debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Ullom, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he 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 Mr. Ullom during his period of debarment (section 306(c)(1)(B) of the act).

Any application by Mr. Ullom for special termination of debarment under section 306(d)(4) of the act should be identified with Docket No. FDA–2009–N–0420 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: January 8, 2010.

Brenda Holman,

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

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