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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0304]

Susan F. Knott; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying a request for a hearing submitted by Susan F. Knott and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring Knott for 2 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Knott was convicted of a misdemeanor under Federal law for conduct relating to the regulation of a drug product under the FD&C Act and that the type of conduct underlying the conviction undermines the process for the regulation of drugs. In determining the appropriateness and period of Knott's debarment, FDA has considered the relevant factors listed in the FD&C Act. Knott has failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: The order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit applications for 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:

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Food and Drug Administration,

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SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(I)) permits FDA to debar an individual if it finds that the individual has been convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and if FDA finds that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

On August 11, 2009, in the U.S. district court for the northern district of New York, Knott pled guilty to a misdemeanor under the FD&C Act, namely misbranding a drug in violation of sections 301(k), 502(i)(3) and 303(a)(1) of the FD&C Act (21 U.S.C. 331(k), 352(i)(3), 333(a)(1)) and 18 U.S.C. 2. The basis for this conviction was conduct surrounding her role in the injection of patients seeking treatment with BOTOX/BOTOX Cosmetic (BOTOX) with a product, TRI-toxin, distributed by Toxic Research International, Inc. (TRI). BOTOX is a biological product derived from botulinum toxin type A that is manufactured by Allergan, Inc., and was approved by FDA for use on humans for the treatment of facial wrinkles in 1991.

According to the records of the criminal proceedings, Knott, in following a physician's instructions, ordered at least 31 vials of TRI-toxin, an unapproved drug product, which was represented by its distributor as "Botulinum Toxin Type A." Knott, a supervisory nurse in the medical practice, then instructed other nurses on how to dilute the TRI-toxin for injection into patients in accordance with orders from one or more physicians.

Knott is subject to debarment based on a finding, under section 306(b)(2)(B)(i) of the FD&C Act: (1) That she was convicted of a misdemeanor under Federal law for conduct relating to the regulation of a drug product under the FD&C Act and (2) that the type of conduct underlying the conviction undermines the process for the regulation of drugs. By letter dated November 30, 2010, FDA notified Knott of its proposal to debar her for 2 years from providing services in any capacity to a person having an approved or pending drug product application. In a letter dated February 3, 2011, through counsel, Knott requested a hearing on the proposal. In her request for a hearing, Knott acknowledges her conviction under Federal law, as alleged by FDA. However, she argues that she should not be debarred for several reasons, including several related to the factual basis set forth in the proposal to debar.

We reviewed Knott's request for a hearing and find that Knott has not created a sufficient basis for a hearing. Hearings are granted only if there is a genuine and substantial issue of fact. Hearings will not be granted on issues of policy or law, on mere allegations, denials, or general descriptions of positions and contentions, or on data and information insufficient to justify the factual determination urged (see 21 CFR 12.24(b)).

The Chief Scientist has considered Knott's arguments and concludes that they are unpersuasive and fail to raise a genuine and substantial issue of fact requiring a hearing.

II. Arguments

In support of her hearing request, Knott first asserts that section 306(b)(2)(B)(i) of the FD&C Act does not apply to her because she was never involved in the approval or regulation of drug products, nor was the underlying conduct of her conviction related to those activities. During her criminal proceedings, however, Knott pled guilty to misbranding and causing the misbranding of a drug in violation of sections 301(k), 502(i)(3) and 303(a)(1) of the FD&C Act by causing TRI-toxin, a drug not approved for use, to be offered for sale as an approved drug product, BOTOX. This conduct clearly relates to the regulation of drugs under the FD&C Act because it was in direct violation of the FD&C Act. The conduct also undermined the process for the regulation of drugs in that it permitted an unapproved drug to be substituted for an approved drug without the knowledge of the patient. As a result, Knott is subject to debarment under section 306(b)(2)(B)(i).

Knott next contends that she pled guilty to a misdemeanor violation under section 303(a)(1) of the FD&C Act, which is a strict liability offense, and that thus there was no demonstration or admission of criminal intent or knowledge underlying her conviction. She argues that, because she was not aware her conduct violated the FD&C Act, the conduct underlying her conviction could not undermine the process for regulation of drugs and she should not be debarred.

With respect to Knott's assertion that her offense was strict liability, section 306(b)(2)(B)(i) of the FD&C Act specifically provides for the debarment of individuals convicted of Federal misdemeanors related to the regulation of drug products under the FD&C Act. Given that misdemeanor violations of the FD&C Act itself are strict liability offenses, it stands to reason that criminal intent is not a critical component to debar an individual under

section 306(b)(2)(B)(i). The charge to which Knott pled guilty did not hinge on supervisory liability or a technical violation of the FD&C Act. The charge in the information to which she pled guilty alleged that she caused a drug to be misbranded by offering it for sale under the name of another drug, BOTOX. The criminal information further establishes that, over the course of 9 months, she took the affirmative steps of ordering the drug and assisting in the formulation of the drug for injection to at least 150 patients. That the charge did not require a showing of intent has little to no bearing on whether Knott should be debarred. An individual need not have criminal intent for his or her conduct to undermine the process for the regulation of drugs. Knott's conduct undermined the process for the regulation of drugs in that it permitted an unapproved drug to be substituted for an approved drug without the knowledge of the patient. Knott has not presented any genuine and substantial issues of fact with respect to whether the conduct underlying her conviction undermines the process for the regulation of drugs.

Finally, Knott argues that the considerations under section 306(c)(3) of the FD&C Act weigh against imposing debarment of any length or debarment beyond a minimal period and that FDA should exercise discretion and decline to debar her for that reason. As set forth in the proposal and summarized in this document, Knott pled guilty to a misdemeanor under the FD&C Act for her role in offering a drug under the name of another. Consistent with the proposal to debar, therefore, we find that the consideration in section 306(c)(3)(A) of the FD&C Act with respect to the nature and seriousness of the offense involved weighs in favor of debarring Knott for some period of time.

The record establishes that the medical practice of which Knott was a part ultimately took voluntary steps to mitigate the effect on the public health from its unlawful conduct (see section 306(c)(3)(C) of the FD&C Act). Moreover, the record reflects that she was merely following a

physician's orders and that thus she did not serve a managerial role in the offense (see section 306(c)(3)(B) of the FD&C Act). Finally, it is undisputed that she had no previous criminal convictions related to matters within the jurisdiction of FDA (see section 306(c)(3)(F) of the FD&C Act). These considerations counterbalance the nature and seriousness of her offense sufficiently to warrant decreasing the period of debarment from 5 years to 2 years, as recommended in the proposal to debar.

III. Findings and Order

Therefore, the Chief Scientist, under section 306(b)(2)(B)(i)(I) of the FD&C Act and under authority delegated to him by the Commissioner of Food and Drugs, finds: (1) That Knott has been convicted of a misdemeanor under Federal law for conduct relating to the development or approval of a drug product or otherwise relating to the regulation of a drug product under the FD&C Act and (2) that the conduct underlying the conviction undermines the process for the regulation of drugs. FDA has considered the relevant factors listed in section 306(c)(3) of the FD&C Act and determined that a debarment of 2 years is appropriate.

As a result of the foregoing findings, Knott is debarred for 2 years from providing services in any capacity to a person with an approved or pending drug product application under section 505, 512, or 802 of the FD&C 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 21 U.S.C. 335a(c)(1)(B), (c)(2)(A)(iii), and 321(dd)). Any person with an approved or pending drug product application, who knowingly uses the services of Knott, in any capacity during her period of debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Knott, 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 FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Knott during her period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Knott for termination of debarment under section 306(d) of the FD&C Act should be identified with Docket No. FDA-2010-N-0304 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. Persons with access to the Internet may obtain documents in the Docket at http://www.regulations.gov/.

Dated: November 29, 2012.

Jesse L. Goodman,

Chief Scientist.

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