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Acting Reports Clearance Officer, Centers for Disease Control and Prevent.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0479]

Mark E. Van Wormer: 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 FD&C Act) permanently debarring Mark E. Van Wormer, MD, 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 Dr. Van Wormer was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Dr. Van Wormer was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. In a January 1, 2011, letter to FDA, Dr. Van Wormer notified FDA that he did not plan to seek a hearing and therefore has waived his right to a hearing concerning this action.

DATES: This order is effective March 10, 2011.

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, 301–796–4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C 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 FD&C Act.

On December 13, 2007, the U.S. District Court, District of New Mexico, entered judgment against Dr. Van Wormer for felony misbranding a drug while held for sale in violation of 21 U.S.C. 333(a)(2), 331(k) and 352(i)(3).

FDA's finding that debarment is appropriate is based on the felony conviction referenced herein for conduct relating to the regulation of a drug product. The factual basis for the conviction is as follows: Dr. Van Wormer is a physician licensed by the New Mexico State Board of Medicine, and he owned and operated the Union County Medical Center, also known as the Union County Medical, Diagnostic Imaging and Laser Surgery Center, PC, and the Physicians GreatSkin® Clinic.

From on or about January 13, 2004, through on or about November 9, 2004, Dr. Van Wormer advertised the use of Allergan's approved BOTOX for use in treatment of forehead wrinkles. However, during that time he knowingly used TRI-toxin, an unapproved botulinum toxin type A product, that he purchased from Toxin Research International, Inc. (TRI), a company in Tucson, AZ.

Dr. Van Wormer purchased approximately 20 vials of the TRI-toxin, which he injected into his patients. He did not inform his patients that they were being injected with an unapproved substance, and patients were charged as if they were receiving the approved drug product. Dr. Van Wormer injected approximately 120 patients with the unapproved TRI-toxin.

As a result of his convictions, on December 17, 2010, FDA sent Dr. Van Wormer a notice by certified mail 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 FD&C Act, that Dr. Van Wormer was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Dr. Van Wormer 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. Dr. Van Wormer submitted a letter dated January 1, 2011, acknowledging receipt of the proposal to debar and noting that he did not plan to seek a further hearing regarding the matter and thereby has waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Mark E. Van Wormer has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding and based on his notification of acquiescence, Dr. Van Wormer 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 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* section 306(c)(1)(B), (c)(2)(A)(ii), (c)(2)(B) of the FD&C Act and section 201(dd) of the FD&C 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 Dr. Van Wormer, in any capacity during Dr. Van Wormer's 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 Dr. Van Wormer provides services in any capacity to a person with an approved or pending drug product application during his period of debarment, he 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 Dr. Van Wormer during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Dr. Van Wormer for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2010–N–0479 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: *February 16, 2011.*

Howard Sklamberg,

Director, Office of Enforcement, Office of Regulatory Affairs.

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