

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA-2010-N-0441]
Anastasios Pappas: 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) debaring Anastasios Pappas, MD, for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on findings that Dr. Pappas 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. Dr. Pappas was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Pappas failed to respond. Dr. Pappas' failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective March 9, 2011.

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: 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(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 April 4, 2006, Dr. Pappas pleaded guilty to a misdemeanor offense of introducing and causing the introduction into interstate commerce of a misbranded drug in violation of 21 U.S.C. 352(o), 331(a) and 333(a)(1). On

August 14, 2006, the U.S. district court for the district of South Dakota, Southern Division, entered judgment against Dr. Pappas for misdemeanor misbranding.

FDA's finding that debarment is appropriate is based on the misdemeanor conviction referenced herein. The factual basis for the conviction is as follows: Dr. Pappas was a licensed dermatologist in the state of South Dakota and a partner with Dakota Dermatology in Sioux Falls, SD. Between August and November 2004, in the District of South Dakota and elsewhere, Dr. Pappas placed three orders for a total of six vials of botulinum toxin type A (TRI-toxin) from Toxin Research International (TRI). Between September and November 2004, Dr. Pappas administered TRI-toxin to patients. TRI was not duly registered with FDA and, therefore, the TRI-toxin is deemed misbranded under 21 U.S.C. 352(o).

As a result of his convictions, on November 16, 2010, FDA sent Dr. Pappas a notice by certified mail proposing to debar him for 5 years 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(b)(2)(B)(i)(I) of the FD&C Act, that Dr. Pappas was convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and the conduct that served as a basis for the conviction undermines the process for the regulation of drugs. The proposal also offered Dr. Pappas 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. Pappas failed to respond within the timeframe prescribed by regulation and therefore has waived his opportunity for a hearing and waived 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(b)(2)(B)(i)(I) of the FD&C Act, under authority delegated to him (Staff Manual Guide 1410.35), finds that Anastasios Pappas has been 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 that served as a basis for the conviction undermines the process for the regulation of drugs.

As a result of the foregoing finding, Dr. Pappas is debarred for 5 years 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* sections 306(c)(1)(B), (c)(2)(A)(iii), and 201(dd) of the FD&C Act (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 employs or retains as a consultant or contractor, or otherwise uses the services of Dr. Pappas, in any capacity during Dr. Pappas' 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. Pappas 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 (21 U.S.C. 335b(a)(7))). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Pappas during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Dr. Pappas for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) should be identified with Docket No. FDA-2010-N-0441 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.

[FR Doc. 2011-5309 Filed 3-8-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA-2010-N-0473]
David E. Berman: 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) debarring David E. Berman, MD, for 3 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 Dr. Berman 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. Dr. Berman was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Berman failed to respond. Dr. Berman's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective March 9, 2011.

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: 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(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 October 30, 2007, Dr. Berman pleaded guilty to a misdemeanor offense of the introduction into interstate commerce of a misbranded drug in violation of 21 U.S.C 331(a), 333(a)(1), and 352(i)(3), and judgment was entered against Dr. Berman by the U.S. District Court, Eastern District of Virginia.

FDA's finding that debarment is appropriate is based on the misdemeanor conviction referenced herein. The factual basis for the conviction is as follows: Dr. Berman is a medical doctor licensed by the Virginia Department of Health Professions, specializing in plastic surgery with an office in Sterling, VA. On or about January 16, 2004, and on or

about February 16, 2004, Dr. Berman caused TRI-toxin, an unapproved botulinum toxin type A product, to be introduced into interstate commerce by causing Toxin Research International, Inc., to ship vials of TRI-toxin from Arizona to the Eastern District of Virginia. TRI-toxin was a misbranded drug in that Dr. Berman offered it for sale to, and used it on, thirty of his patients as BOTOX Cosmetic. Dr. Berman did not disclose to his patients that he was using a substitute, unapproved, unlicensed, and less expensive botulinum toxin type A product. TRI-toxin was not duly registered with the FDA and, therefore, the TRI-toxin is deemed misbranded.

As a result of his convictions, on December 17, 2010, FDA sent Dr. Berman a notice by certified mail proposing to debar him for 3 years 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(b)(2)(B)(i)(I) of the FD&C Act, that Dr. Berman was convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and the conduct that served as a basis for the conviction undermines the process for the regulation of drugs. The proposal also offered Dr. Berman 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. Berman failed to respond within the timeframe prescribed by regulation and therefore has waived his opportunity for a hearing and waived 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(b)(2)(B)(i)(I) of the FD&C Act, under authority delegated to him (Staff Manual Guide 1410.35), finds that David E. Berman has been 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 that served as a basis for the conviction undermines the process for the regulation of drugs.

As a result of the foregoing finding, Dr. Berman is debarred for 3 years 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* sections 306(c)(1)(B), (c)(2)(A)(iii), and 201(dd) of the FD&C Act (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 employs or retains as a consultant or contractor, or otherwise uses the services of Dr. Berman, in any capacity during Dr. Berman'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. Berman 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. Berman during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Dr. Berman for termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2010-N-0473 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 R. Sklamberg,

Director, Office of Enforcement, Office of Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Joint Meeting of the Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.