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.

[FR Doc. 2011–5308 Filed 3–8–11; 8:45 am]

BILLING CODE 4160–01–P

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.

Name of Committees: Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 17, 2011, from 8 a.m. to 5 p.m. and on May 18, 2011, from 8 a.m. to 12 noon.

ADDRESSES: FDA is opening a docket for public comment on this meeting. The docket number is FDA–2011–N–0002. The docket will open for public comment on *March 9, 2011.* The docket will close on June 30, 2011. Interested persons may submit electronic or written comments regarding this meeting. Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments received will be posted without change, including any personal information provided. Submit a single copy of electronic comments or a paper copy of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this meeting notice. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Comments received on or before May 3, 2011, will be provided to the committee before the meeting.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel telephone number is 301–589–5200.

Contact Person: Diem-Kieu Ngo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., WO31–2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, e-mail: *diem.ngo@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On May 17 and 18, 2011, the committees will review pertinent pharmacokinetic (how drugs are absorbed, distributed, used, and eliminated by the body), safety and efficacy data, and discuss whether new dosing information for oral over-the-counter (OTC) drug products containing acetaminophen should be added to the label for children less than 2 years of age. In addition, the committees will consider adding a weight-based dosing regimen to the existing age-based dosing regimen for children 2 to 12 years of age. Dosing for children 12 years of age and older will not be discussed. Lastly, the committees will discuss ways that administration by caregivers can be improved so that medication errors can be minimized.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (*see* the **ADDRESSES** section of this document) on or before May 3, 2011, will be provided to the committees. Oral presentations from the public will be scheduled between approximately 3 p.m. and 5 p.m. on May 17, 2011. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 25, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 26, 2011.

FDA will work with sponsors of acetaminophen products who wish to make presentations to ensure that adequate time, separate from the 3 p.m. to 5 p.m. time slots for the general open public hearing, is provided. Sponsors interested in making formal presentations to the committees should notify the contact person on or before April 25, 2011. Sponsors with common interest are urged to coordinate their oral presentations.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Diem-Kieu Ngo at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 3, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–5284 Filed 3–8–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Neurological Devices Panel of the Medical Devices Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Neurological Devices Panel of the Medical Devices Advisory Committee. This meeting was announced in the **Federal Register** of February 7, 2011 (76 FR 6625). The amendment is being