request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is applicable December 11, 2018.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Division of Enforcement, Food and Drug Administration, 12420 Parklawn Dr., 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 debarment of an individual if FDA 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 November 19, 2013, in the United States District Court for the Northern District of Ohio, judgment was entered against Dr. Fishman after he entered a plea of guilty to one count of misbranding, in violation of section 301(a) of the FD&C Act (21 U.S.C. 331(a)), which is a misdemeanor offense under section 303(a)(1) of the FD&C Act (21 U.S.C. 333(a)(1)).

FDA's finding that debarment is appropriate is based on the misdemeanor conviction referenced herein. The factual basis for this conviction is as follows: Between January 10, 2006, and March 12, 2009, Dr. Fishman was a physician (oncologist) in Ohio. During this time, Dr. Fishman purchased and received oncology drugs, including TAXOTERE (docetaxel) and NOVANTRONE (mitoxantrone), from a drug distributor located in Canada. These new drugs originated outside the United States and were not approved by FDA for introduction or delivery for introduction into interstate commerce in the United States. Thus, Dr. Fishman caused the introduction or delivery for introduction into interstate commerce of prescription drugs that were misbranded for lacking adequate directions for use in their labeling.

As a result of this conviction, on July 27, 2018, FDA sent Dr. Fishman 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. Fishman was convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

The proposal offered Dr. Fishman 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. Fishman received the proposal on August 2, 2018. Dr. Fishman did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and has waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, under section 306(b)(2)(B)(i)(I) of the FD&C Act, under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Dr. David J. Fishman has been convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

As a result of the foregoing findings and in consideration of the factors described in section 306(c)(3) of the FD&C Act, Dr. David J. Fishman 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)(3), and 201(dd) (21 U.S.C. 321(dd)) of the FD&C Act). 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. Fishman in any capacity during his 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. Fishman 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. Fishman during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Dr. Fishman for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2018–N–1994 and sent to the Dockets Management Staff (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 will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26722 Filed 12–10–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4162]

The Tobacco Products Scientific Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Tobacco Products Scientific Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on February 6, 2019, from 8:30 a.m. to 5 p.m. and on February 7, 2019 from 8 a.m. to 1 p.m.

ADDRESSES: FDA White Oak Conference Center, Bldg. 31, Rm. 1503 (the Great Room), 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, email: *TPSAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). 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 website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On February 6–7, 2019, the Committee will convene for two sessions. The first session will convene on February 6, 2019, during which the Committee will discuss an amendment to the modified risk tobacco product applications (MRTPAs), submitted by Swedish Match North America for the following snus smokeless tobacco products:

- MR0000020: General Loose;
- MR0000021: General Dry Mint Portion Original Mini;
- MR0000022: General Portion Original Large;
- MR0000024: General Classic Blend Portion White Large-12ct;
- MR0000025: General Mint Portion White Large;
- MR0000027: General Nordic Mint Portion White Large-12ct;
- MR0000028: General Portion White Large; and
- MR0000029: General Wintergreen Portion White Large.

The second session will convene, after the first session has concluded, on February 6, 2019, and continue on February 7, 2019. During the second session the Committee will discuss the MRTPA, submitted by Altria Client Services LLC on behalf of U.S. Smokeless Tobacco Company LLC for the following smokeless tobacco product:

- MR0000108: Copenhagen Snuff Fine Cut.

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 website 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 website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. Written submissions may be made to the contact person on or before January 22, 2019. Oral presentations from the public for the first session will be scheduled between approximately 10 a.m. and 10:30 a.m. on February 6, 2019, and for the second session between approximately 8 a.m. and 8:30 a.m. on February 7, 2019. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement describing the general nature of the evidence or arguments they wish to present, the names and email addresses of proposed participants, and the session during which they would like to speak, on or before January 14, 2019. 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 January 15, 2019.

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 disabilities. If you require accommodations due to a disability, please contact Caryn Cohen (see: **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://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: December 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26721 Filed 12–10–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, MD 20857; (301) 443–6593, or visit our website at: *http://www.hrsa.gov/vaccinecompensation/index.html.*

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.,* provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of HHS, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.