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)(ii)(I) of the FD&C
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)(ii)(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)(ii)(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
debarmed 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
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)(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.


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/AboutAdvisory
Committees/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: TPSACO@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 application (MRTPA), 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).


Leslie Kux, Associate Commissioner for Policy.

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.