debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Kuo failed to request a hearing. Dr. Kuo's failure to request a hearing constitutes a waiver of her 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 January 14, 2014, in the United States District Court for the Northern District of Ohio, judgment was entered against Dr. Kuo after she 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 June 22, 2005, and November 18, 2008, Dr. Kuo was a physician (oncologist) in Ohio. During this time, Dr. Kuo purchased and received oncology drugs, including TAXOTERE (docetaxel) and ZOMETA (zoledronic acid), 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. Kuo 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 13, 2018, FDA sent Dr. Kuo a notice by certified mail proposing to debar her 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. Kuo 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. Kuo an opportunity to request a hearing, provided her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Dr. Kuo received the proposal on July 23, 2018. Dr. Kuo did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and has waived any contentions concerning her 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. Su-Chiao Kuo 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. Su-Chiao Kuo 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. Kuo in any capacity during her 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. Kuo provides services in any capacity to a person with an approved or pending drug product application during her period of debarment, she 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. Kuo during her period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Dr. Kuo for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2018–N–1990 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. 2018–26778 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–1994]

David J. Fishman: 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 (FD&C Act) debarring Dr. David J. Fishman for a period of 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. Fishman was convicted of a misdemeanor under the FD&C Act for causing the introduction or delivery for introduction into interstate commerce of prescription drugs that were misbranded. In addition, FDA has determined that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs. Dr. Fishman was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Fishman failed to request a hearing. Dr. Fishman's failure to

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]

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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.*