consistent with product labeling (21 CFR 211.170).

FDA estimates that annually approximately 74 outsourcing facilities (''No. of Recordkeepers'' in table 1, row 13) will individually establish and maintain approximately 12 procedures and records for reserve samples (''Records per Recordkeeper'' in table 1, row 13) for drug products. FDA also estimates that preparing and maintaining these procedures and records as described in the guidance will take approximately 0.5 hours for each record (''Average Burden per Recordkeeping'' in table 1, row 13).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Quality assurance activities	74	13	962	3	2,886
Facility design	74	20	1,480	1.5	2,220
Control systems and procedures for maintaining suitable facilities.	74	6	444	5	2,220
Environmental and personnel monitoring	74	1,200	88,800	0.25 (15 minutes)	22,200
Containers and closures	74	300	22,200	0.25 (15 minutes)	5,550
Equipment	74	150	11,100	0.25 (15 minutes)	2,775
Components	74	150	11,100	4	44,400
Production and process controls	74	1,325	98,050	0.25 (15 minutes)	24,513
Release testing	74	1,725	127,650	1.5	191,475
Laboratory controls	74	200	14,800	0.5 (30 minutes)	7,400
Stability/Expiration dating	74	75	5,550	5	27,750
Packaging and labels	74	20	1,480	5.5	8,140
Reserve samples	74	12	888	0.5 (30 minutes)	444
Total					341,973

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Type of disclosure	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Notification that a drug product fails to meet a sterility criterion.	10	1	10	5	50
An expiration date is added to the drug product's label.	74	540	39,960	0.25 (15 minutes)	9,990
Total					10,040

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of reporting	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notification to FDA that a drug product fails to meet a sterility criterion	10	1	10	5	50

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: December 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26724 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–1990]

Su-Chiao Kuo: 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. Su-Chiao Kuo 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. Kuo 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. Kuo was given notice of the proposed

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]

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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