Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Lubna Merchant, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4418, Silver Spring, MD 20993, 301–796–3600; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 1, 2018, FDA published a notice with a 60-day comment period to request comments on the draft guidance for industry entitled ''Development of Shared System REMS.'' This draft guidance describes some of the possible benefits of a shared system REMS and provides general principles and recommendations to assist industry with the development of these programs. Section 610 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94, 133 Stat. 3524 (December 20, 2019)), amended section 505–1(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351–1(i)), regarding the requirement that a drug that is the subject of an abbreviated new drug application (ANDA) and its reference listed drug use a single, shared system for the elements to assure safe use unless FDA waives that requirement. We intend to revise the draft guidance accordingly. The Agency continues to recognize that shared system REMS may be in the interest of public health.

FDA is reopening the comment period until May 18, 2020. FDA is interested in receiving additional input regarding any further steps the Agency could take to facilitate successful formation of shared system REMS. In particular, FDA is seeking comment on the challenges and successes with: (1) Negotiating governance agreements among parties involved in a shared system REMS and (2) developing effective shared system REMS programs. The Agency believes that an additional 60 days will allow adequate time for interested persons to submit comments without compromising the timely publication of the final version of the guidance.

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Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or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

Dated: March 13, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–05712 Filed 3–18–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–N–0001, FDA–2020–N–0255, FDA–2020–N–0256, FDA–2020–N–0259, FDA–2018–N–4337]

March 10 Through April 30, 2020, Public Meetings; Postponement, Cancellation, or Remote Only

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration is announcing that certain meetings involving the Center for Drug Evaluation and Research (CDER) from March 10 through April 30, 2020, are postponed, cancelled, or modified to take place remotely.

DATES: For dates that have been either postponed or cancelled, see table 1 in the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Kim Thomas, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6282, Silver Spring, MD 20993–0002, 301–796–2357, *Kimberly.K.Thomas@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Certain public meetings involving CDER from March 10 through April 30, 2020, are postponed, cancelled, or modified to take place remotely due to extenuating circumstances. The meetings that are postponed or canceled as part of this notice are listed in table 1. If a meeting is rescheduled, information about the rescheduled meeting will be provided in the future. The meeting that will no longer take place in person and instead take place by webcast only as part of this notice is listed in table 2.[1]

[1] Up-to-date information about public meetings involving CDER is available on the internet at *https://www.fda.gov/drugs/news-events-human-drugs/meetings-conferences-workshops-drugs.*

TABLE 1—CDER MEETINGS POSTPONED OR CANCELLED

Meeting type	Meeting title	Original meeting date	Docket No.	**Federal Register** citation
Public Meeting	Patient-Focused Drug Development for Stimulant Use Disorder.	Mar. 10, 2020	FDA–2020–N–0259	85 FR 8877, Feb. 18, 2020.
Public Meeting	Patient-Focused Drug Development for Vitiligo	Mar. 30, 2020	FDA–2020–N–0255	85 FR 8004, Feb. 12, 2020.
Public Meeting	Scientific and Ethical Considerations for the Inclusion of Pregnant Women in Clinical Trials.	Apr. 16, 2020	FDA–2020–N–0001	85 FR 14207, Mar. 11, 2020.
Public Meeting	Prescription Drug User Fee Act of 2017; Electronic Submissions and Data Standards.	Apr. 22, 2020	FDA–2018–N–4337	85 FR 6547, Feb. 5, 2020.

TABLE 2—CDER MEETING HELD REMOTELY

Meeting type	Meeting title	Original meeting date	Docket No.	**Federal Register** citation	Remote information
Public Meeting	United States Food and Drug Administration and Health Canada Joint Regional Consultation on the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.	Apr. 3, 2020	FDA–2020–N–0256.	85 FR 13659, Mar. 9, 2020.	*https://www.fda.gov/drugs/news-events-human-drugs/health-canada-and-fda-joint-public-consultation-international-council-harmonisation-technical-0.*

Dated: March 16, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–05743 Filed 3–18–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3591]

Gerald Tighe: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Gerald Tighe 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 Mr. Tighe was convicted of a felony under Federal law for conduct that relates to the regulation of a drug product under the FD&C Act. Mr. Tighe was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Mr. Tighe failed to respond. Mr. Tighe's failure to request a hearing within the prescribed timeframe constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is applicable March 19, 2020.

ADDRESSES: Submit applications for special 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: Jaime Espinosa, Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, *debarments@fda.hhs.gov,* or 240–402–8743.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act. On July 14, 2017, Mr. Tighe pleaded guilty to one count of conspiracy to commit wire fraud, a felony offense, in violation of 18 U.S.C. 371. On December 19, 2017, judgment was entered against Mr. Tighe in the U. S. District Court for the Eastern District of New York.

The factual basis for this conviction is as follows: Mr. Tighe was the founder, sole owner, and president of Med Prep Consulting, Inc. (Med Prep), a medical drug repackager located and incorporated in New Jersey in 1994. Med Prep manufactured, repackaged, processed, packed, labeled, held, compounded, and distributed various drug products, including pain management medications, anesthesia and operating room drugs, and oncology and dialysis drugs. As president of Med Prep, Mr. Tighe was the highest-ranking corporate official, and he was responsible for and oversaw all aspects of its business, including its manufacturing and quality operations. Between approximately January 2007 and April 2013, Mr. Tighe knowingly and intentionally conspired with other individuals to devise a scheme and artifice to defraud healthcare providers and to obtain money and property from them by means of materially false and fraudulent pretenses, representations, and promises, and for the purpose of executing such scheme and artifice, and attempting to do so, to transmit and cause to be transmitted, by means of wire communication in interstate commerce, writings, signs, signals, pictures, and sounds.

Specifically, during this time period, Mr. Tighe conspired with others to introduce and introduced, or caused the introduction of, adulterated and misbranded drugs into interstate commerce, all with the intent to defraud and mislead healthcare providers. The adulterated drugs Mr. Tighe introduced or caused to be introduced into interstate commerce were adulterated because they were prepared, packed, and held under insanitary conditions and because the drugs consisted in whole or in part of a filthy, putrid, and decomposed substance. The misbranded drugs Mr. Tighe introduced or caused to