Chief Executive Officer (CEO). Insys developed and owned a drug called SUBSYS, a liquid formulation of fentanyl to be applied under the tongue. FDA approved SUBSYS for the management of breakthrough pain in adult cancer patients who are already receiving and are already tolerant to opioid therapy for their underlying persistent cancer pain. From 2012 and continuing through 2015, Mr. Kapoor oversaw a conspiracy whereby employees of Insys bribed medical practitioners in various states to get those practitioners to increase prescribing SUBSYS to their patients. Mr. Kapoor, along with his co-conspirators, measured the effect of these bribes on each practitioner's prescribing habits and on the revenue that each bribed practitioner generated for Insys. Mr. Kapoor, along with his co-conspirators, reduced or eliminated bribes paid to those practitioners who failed to meet the minimum prescription requirements or failed to generate enough revenue to justify additional bribes.

To further this conspiracy, Mr. Kapoor oversaw a scheme whereby Insys executives conspired to mislead and defraud health insurance providers to ensure those providers approved payment for SUBSYS. Insys achieved this goal by establishing the ''Insys Reimbursement Center,'' which was designed to shift the burden of seeking prior authorization for SUBSYS from practitioners to Insys. This allowed Insys to determine what medical information was presented to insurers. Mr. Kapoor and his co-conspirators directed Insys employees to mislead insurers to obtain payment authorization.

As a result of this conviction, FDA sent Mr. Kapoor by certified mail on July 16, 2020, a notice proposing to permanently debar him 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(a)(2)(B) of the FD&C Act, that Mr. Kapoor was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Mr. Kapoor 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 an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Mr. Kapoor received the proposal on July 27, 2020. Mr. Kapoor, through counsel, submitted a letter to FDA dated August 12, 2020, which commented on some of the factual circumstances surrounding the case. In the letter, he also stated that he did not intend to request a hearing nor, however, would he acquiesce to debarment. Since he did not request a hearing within the timeframe prescribed by regulation, Mr. Kapoor has waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Kapoor has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Mr. Kapoor, is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(B) and (c)(2)(A)(ii) 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 Mr. Kapoor, 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 Mr. Kapoor 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 application from Mr. Kapoor during his period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of section 306 of the FD&C Act, a ''drug product'' is defined as a drug subject to regulation under section 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) (see section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Any application by Mr. Kapoor for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2020–N–1337 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20.

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, 240–402–7500.

Dated: November 23, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26262 Filed 11–27–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4248]

Barry J. Cadden: 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 Barry J. Cadden 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. Cadden 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. Cadden was given notice of the proposed permanent debarment and an opportunity to request a hearing to show why he should not be debarred. As of July 9, 2020 (30 days after receipt of the notice), Mr. Cadden had not responded. Mr. Cadden's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is applicable November 30, 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, 240–402–7500, or at *https://www.regulations.gov*.

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 at 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 from providing services in any capacity to a person that has an approved or pending drug product application 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 June 27, 2017, Mr. Cadden was convicted as defined in section 306(l)(1) of the FD&C Act when judgment was entered against him in the U.S. District Court for the District of Massachusetts, after a jury verdict, for one count of racketeering in violation of 18 U.S.C. 1962(c), one count of racketeering conspiracy in violation of 18 U.S.C. 1962(d), 52 counts of mail fraud in violation of 18 U.S.C. 1341, and three counts of introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead-no prescriptions in violation of 21 U.S.C. 353(b)(1), 331(a), and 333(a)(2).

As contained in counts 1–2, 4–39, 41–56, 95, and 99–100 of the indictment, filed on December 16, 2014, Mr. Cadden was an owner and director of the New England Compounding Center (NECC), which held itself out as a compounding-only pharmacy, and he served as NECC's president, head pharmacist, and Manager of Record. In addition, Mr. Cadden was an owner and director of Medical Sales Management, Inc. (MSM), and served as MSM's Treasurer. MSM provided sales and administrative services to NECC for which MSM was paid a service fee. MSM's sales representatives sold drugs on behalf of NECC to customers throughout the country. In those capacities, Mr. Cadden instructed the MSM sales force to falsely represent to customers that NECC was providing the highest quality compounded medications, when in fact Mr. Cadden, among other things, failed to properly sterilize drug products consistent with applicable U.S. Pharmacopeia standards, failed to test purportedly sterile drugs, authorized the shipping of drugs before test results confirming their sterility were returned, never notified customers of nonsterile results, and compounded drugs with expired ingredients. Additionally, Mr. Cadden directed and authorized the shipping and mailing, in interstate commerce, of contaminated methylprednisolone acetate to NECC customers nationwide. Mr. Cadden also caused drugs to be introduced and delivered into interstate commerce without the valid prescription of a practitioner licensed by law to administer drugs, which act resulted in the drugs being misbranded. Further, Mr. Cadden defrauded the United States by interfering with and obstructing the lawful governmental functions of FDA by claiming to be a pharmacy dispensing drugs pursuant to valid, patient-specific prescriptions. In fact, NECC routinely dispensed drugs in bulk without valid, patient-specific prescriptions.

As a result of this conviction, FDA sent Mr. Cadden, by certified mail on June 2, 2020, a notice proposing to permanently debar him 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(a)(2)(B) of the FD&C Act, that Mr. Cadden was convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Mr. Cadden 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 an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Mr. Cadden received the proposal on June 9, 2020. Mr. Cadden did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Barry J. Cadden, has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Barry J. Cadden, is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(B) and 306(c)(2)(A)(ii) 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 Barry J. Cadden, 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 Mr. Cadden 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 from Mr. Cadden during his period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of section 306 of the FD&C Act, a ''drug product'' is defined as a drug subject to regulation under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262) (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Any application by Mr. Cadden for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2019–N–4248 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Dated: November 23, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26255 Filed 11–27–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1255]

Tuan Anh Tran: Final 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 Tuan Anh Tran for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Tran engaged in a pattern of importing or offering for import misbranded drugs (*i.e.,* in an amount, frequency, or dosage that is inconsistent with his personal or household use) that are not designated in an authorized electronic data interchange system as products