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) (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Any application by Ms. Lee for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2020–N–1415 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: December 28, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–29044 Filed 12–31–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3794]

Jerrod Nichols Smith: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order permanently debarring Jerrod Nichols Smith 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. Smith was convicted of multiple felony counts under Federal law for conduct that relates to the regulation of a drug product under the Federal, Food, Drug, and Cosmetic Act (the FD&C Act). Mr. Smith was given notice of the proposed permanent debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of September 27, 2020 (30 days after receipt of the notice), Mr. Smith had not responded. Mr. Smith's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective January 4, 2021.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, 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 (ELEM–4029), Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8743, or at *debarments@fda.hhs.gov.*

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 July 16, 2018, Mr. Smith was convicted as defined in section 306(*l*)(1)(A) of the FD&C Act when judgment was entered against him in the U.S. District Court for the Middle District of Tennessee, Nashville Division, after a jury trial, to one count of conspiracy to commit mail fraud in violation of 18 U.S.C. 371, 15 counts of mail fraud in violation of 18 U.S.C. 1341, and one count of obstruction of justice in violation of 18 U.S.C. 1001.

The factual basis for these convictions is as follows: Mr. Smith was one of the owners and operators of Cumberland Distribution, Inc. (''Cumberland''), formerly known as Midwest Pharmacy, which was a wholesale drug distribution company incorporated in Nevada and Tennessee. Mr. Smith was engaged in the business of wholesale distribution of prescription drugs, as defined by 21 U.S.C. 353(e)(3)(B), to pharmacy customers throughout the United States. From December 2006 through August 2009, Mr. Smith, along with others, purchased millions of dollars of prescription drugs, through Cumberland. The vast majority of the prescription drugs purchased by Cumberland and received at the company's warehouse facilities were sold to Cumberland, directly and indirectly, by individuals and entities whom Mr. Smith knew were not licensed by any State to engage in the wholesale distribution of prescription drugs and were not otherwise authorized to distribute prescription drugs pursuant to 21 U.S.C. 353. These unauthorized sellers obtained their prescription drugs from various networks of street level drug diverters. Mr. Smith directed employees to take steps to conceal the true origins of the diverted prescription drugs shipped to the company's warehouse facilities before shipping them to pharmacy customers around the country. Such steps included, but were not limited to, falsification of documents concerning the chain of custody or pedigree of a drug. These falsified pedigree documents, which Mr. Smith provided to his pharmacy customers or maintained at Cumberland, inaccurately represented that the diverted products had been obtained from licensed wholesale distributors. Mr. Smith also used shell companies to receive and relabel diverted prescription drugs before sending them to Cumberland's warehouse facilities to create the false appearance that his company was purchasing prescription drugs from licensed wholesale distributors.

The diverted drugs included, but were not limited to, drugs used to treat human immunodeficiency virus/acquired immunodeficiency syndrome, antipsychotic medications, antidepressants, blood pressure medications, and diabetes medications. Numerous pharmacies reported problems with drugs they purchased from Cumberland, including prescription drug bottles containing the wrong medicine, the wrong dosage information, and foreign objects inside. At trial, several witnesses testified that at least one bottle of prescription drugs sold by Cumberland contained Tic Tacs instead of medicine. Through the course of this scheme, Mr. Smith's company had gross proceeds of approximately $58,984,912. His profits were approximately $14,689,782.

As a result of these convictions, FDA sent Mr. Smith 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. Smith 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. Smith 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.

Smith received the proposal on August 28, 2020. Mr. Smith 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 Mr. Smith has been convicted of multiple felonies 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. Smith is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see section 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. Smith, 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. Smith 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. Smith 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. Smith for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2019–N–3794 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: December 28, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–29052 Filed 12–31–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1372]

Alec Burlakoff: 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 Alec Burlakoff 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 Alec Burlakoff 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. Burlakoff was given notice of the proposed permanent debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of July 24, 2020 (30 days after receipt of the notice), Mr. Burlakoff had not responded. Mr. Burlakoff'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 January 4, 2021.

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.

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,* 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 January 23, 2020, Mr. Burlakoff 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 his plea of guilty, to one count of Racketeering Conspiracy in violation of 18 U.S.C. 1962(d). The pattern of racketeering activity he was convicted of included engaging in multiple acts of illegal distribution of a controlled substance (21 U.S.C. 841(a)(1)); mail fraud (18 U.S.C. 1341); wire fraud (18 U.S.C. 1343); honest services mail fraud (18 U.S.C. 1341 and 1346); and, honest services wire fraud (18 U.S.C. 1343 and 1346).

The factual basis for this conviction is as follows: Mr. Burlakoff held executive management positions at Insys Therapeutics Inc. (Insys), including Regional Sales Manager for the Southeast Region and Vice President of Sales. Insys is a Delaware Corporation, with headquarters in Chandler, Arizona. 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 May 2012 and continuing until December 2015, he participated in a conspiracy whereby employees of Insys bribed and provided kickbacks to medical practitioners in various states to get those practitioners to increase prescribing SUBSYS to their patients, many of whom did not have cancer. The bribes and kickbacks took various forms to include honoraria for the practitioners' participation in educational events, payment of the practitioner's staff salaries, and the completion of office tasks for the provider performed by Insys employees.

Mr. Burlakoff and his co-conspirators used pharmacy data acquired from third parties to identify practitioners who either prescribed unusually high volumes of rapid-onset opioids, or had demonstrated a capacity to prescribe unusually large volumes of rapid-onset opioids. In exchange for bribes and kickbacks to these targeted practitioners, the practitioners increased the number of new SUBSYS prescriptions they wrote and increased the dosage and number of units of SUBSYS for new and existing prescriptions. Many of the targeted practitioner's patients for