Annual Responses: 8,090; *Total Annual Hours:* 74,038. (For policy questions regarding this collection, contact Kristy Holtje at 410–786–2209.)

Dated: December 29, 2020.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020–29116 Filed 12–31–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1415]

Sunrise Lee: 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 Sunrise Lee 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 Ms. Lee was convicted of a felony under Federal law for conduct that relates to the regulation of a drug product under the FD&C Act. Ms. Lee was given notice of the proposed permanent debarment and an opportunity to request a hearing to show why she should not be debarred. As of October 8, 2020 (30 days after receipt of the notice), Ms. Lee had not responded. Ms. Lee's failure to respond and request a hearing constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is applicable 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, (ELEM–4029) Division of Enforcement, 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 January 22, 2020, Ms. Lee was convicted as defined in section 306(*l*)(1) of the FD&C Act when judgment was entered against her in the U.S. District Court for the District of Massachusetts, after a jury verdict, on one count of Racketeering Conspiracy in violation of 18 U.S.C. 1962(d). The pattern of racketeering activity she was convicted of included engaging in multiple acts of mail fraud (18 U.S.C. 1341) and wire fraud (18 U.S.C. 1343).

The factual basis for this conviction is as follows: Ms. Lee held executive management positions, to include Regional Sales Manager for the Mid-Atlantic Region, Regional Director for the Central Region, and Regional Director for the West Region, of Insys Therapeutics Inc. (Insys), 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 2012 and continuing through 2015, Ms. Lee participated in a conspiracy whereby employees of Insys bribed medical practitioners in various states to get those practitioners to increase prescribing SUBSYS to their patients, many of whom did not have cancer. Ms. Lee, along with her 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. Ms. Lee, along with her 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, Ms. Lee's co-conspirators mislead and defrauded 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. Ms. Lee's co-conspirators directed Insys employees to mislead insurers to obtain payment authorization.

As a result of this conviction, FDA sent Ms. Lee by certified mail on August 3, 2020, a notice proposing to permanently debar her 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 Ms. Lee 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 Ms. Lee an opportunity to request a hearing, providing 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 an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Ms. Lee received the proposal on September 8, 2020. She did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and any contentions concerning her 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 Ms. Sunrise Lee 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, Ms. Lee 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 Ms. Lee 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 Ms. Lee 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 application from Ms. Lee during her 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) (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.