4164-01-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 **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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.

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