DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0736]

Gregory Settino: 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) permanently debarring Gregory Settino 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. Settino was convicted of a felony under Federal law for conduct that relates to the regulation of any drug product under the FD&C Act. Mr. Settino 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 August 15, 2022 (30 days after receipt of the notice), Mr. Settino had not responded. Mr. Settino's failure to respond and request a hearing within the prescribed timeframe constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is applicable October 18, 2022.

ADDRESSES: Submit applications for special 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–4144), 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 April 20, 2022, Mr. Settino was convicted, as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for the Eastern District of New York, when the court accepted his plea of guilty and entered judgment against him for the felony offense of theft of medical products in violation of 18 U.S.C. 670.

As described in the indictment in his case, filed on September 20, 2020, from approximately 2012 to January 2020, Mr. Settino was the production supervisor of manufacturing for Luitpold Pharmaceuticals, Inc. (Luitpold), which was renamed American Regent, Inc. (American Regent) in January 2019. Luitpold and American Regent manufactured an injectable equine drug called ADEQUAN, which is administered to horses with degenerative joint disease. In his capacity as a production supervisor, Mr. Settino supervised the manufacture of pre-retail medical products including ADEQUAN. From approximately 2012 to January 2020, Mr. Settino stole thousands of bottles of ADEQUAN from Luitpold and American Regent and then sold the stolen ADEQUAN for a total of more than $600,000. As contained in the sentencing memoranda from his case, filed on March 31, 2022, and April 19, 2022, Mr. Settino resold the stolen drugs, many of which were expired, to horse trainers and veterinarians at New York area racetracks.

Based on this conviction, FDA sent Mr. Settino by certified mail on July 11, 2022, 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. Settino was convicted, as set forth in section 306(l)(1) of the FD&C Act, of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act. The proposal also offered Mr. Settino 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. Settino received the proposal on July 15, 2022. He 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. Settino has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act.

As a result of the foregoing finding, Mr. Settino is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, applicable (see **DATES**) (see section 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 in any capacity the services of Mr. Settino 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. Settino 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. Settino 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 sections 306 and 307 of the FD&C Act, a ''drug product'' is defined as a ''drug subject to regulation under section 505, 512, or 802 of this 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. Settino for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2022–N–0736 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: October 13, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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