4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-5923]

Paul J. Elmer: 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 (the FD&C Act) permanently debarring Paul J. Elmer 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. Elmer 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. Elmer 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 March 11, 2020 (30 days after receipt of the notice), Mr. Elmer had not responded. Mr. Elmer'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 [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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.

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, 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 September 23, 2019, Mr. Elmer 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 Southern District of Indiana to one count of conspiracy in violation of 18 U.S.C. 371, three counts of introduction of adulterated drugs into interstate commerce in violation of 21 U.S.C. 331(a), 333(a)(1), and 351, and six counts of adulterating drugs while holding for sale after shipment in interstate commerce in violation of 21 U.S.C. 331(k), 333(a)(1), and 351.

The factual basis for this conviction is as follows: as contained in in counts 1 and 3-11 of the indictment, filed on February 7, 2019, Mr. Elmer was the president and owner of Pharmakon Pharmaceuticals, Inc. (Pharmakon). Pharmakon compounded sterile drugs for public, private, and military hospitals and medical centers located throughout the United States. In that capacity Mr. Elmer conspired to defraud the United States by interfering with and obstructing, through deceitful and dishonest means, the lawful functions of FDA and to commit an offense against the United States by corruptly influencing, obstructing, and impeding, and endeavoring to influence, obstruct, and impede, the due and proper administration of the law under which a pending proceeding was being had before an agency of the United States, specifically FDA inspections of

Pharmakon. Among other things, Mr. Elmer and his co-conspirators provided or directed others to provide false statements, during three inspections and in related correspondence, to FDA regarding the practices at Pharmakon. In addition, on three separate occasions Mr. Elmer introduced and delivered for introduction into interstate commerce, and caused to be introduced and delivered for introduction into interstate commerce, adulterated drugs which were adulterated because the drugs were purported to be and represented as drugs which were recognized in an official compendium and the strength of such drugs differed from the standard set forth in such compendium: fentanyl, promethazine, and morphine sulfate. On six other occasions Mr. Elmer caused drugs, that were being held for sale after the shipment of a drug component in interstate commerce, to become adulterated because the drugs were purported to be and represented as drugs which were recognized in an official compendium and the strength of such drugs differed from the standard set forth in such compendium: midazolam, fentanyl citrate, phenylephrine, and morphine sulfate.

As a result of this conviction, FDA sent Mr. Elmer by certified mail on February 3, 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. Elmer 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. Elmer 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. Elmer received the proposal on February 10, 2020. Mr. Elmer 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 Paul J. Elmer, 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, Paul J. Elmer, 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 Paul J. Elmer, 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. Elmer 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. Elmer 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. Elmer for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2019-N-5923 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 may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 17, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

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