4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-4887]

John Warrington Kosolcharoen: 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 John Warrington Kosolcharoen from providing services in any capacity to a person that has an approved or pending drug product application including, but not limited to, a biologics license application (BLA). FDA bases this order on a finding that Mr. Kosolcharoen 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. Kosolcharoen was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of December 26, 2024 (30 days after receipt of the notice), Mr. Kosolcharoen has not responded. Mr. Kosolcharoen's failure to respond and request a hearing constitutes a waiver of Mr. Kosolcharoen's right to a hearing concerning this matter.

DATES: This order is applicable **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Any application by Mr. Kosolcharoen for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) may be submitted at any time as follows:

Electronic Submissions

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. An application submitted electronically, including attachments, to

https://www.regulations.gov will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on https://www.regulations.gov.

- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

- Mail/Hand Delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All applications must include the Docket No. FDA-2024-N-4887. Received applications will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states

"THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Field Enforcement, Office of Field Regulatory Operations, Office of Inspections and Investigations, Food and Drug Administration, at 240-402-8743, or 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 including, but not limited to, a BLA 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 30, 2024, Mr. Kosolcharoen was convicted as defined in section 306(l)(1) of the FD&C Act in the United States District Court for

the Central District of California when the court accepted his plea of guilty and entered judgment against him for the offense of introducing an unapproved new drug into interstate commerce with intent to defraud in violation of 21 U.S.C. 331(d), 333(a)(2), and 355(a). The underlying facts supporting the conviction are as follows:

As described in the plea agreement from his case, Mr. Kosolcharoen was the chief executive officer and sole owner of Liveyon, LLC (Liveyon). Genetech, Inc. (Genetech) was a company incorporated by another individual who described it as a "research lab" in the public filing. Mr. Kosolcharoen directed that other person to operate Genetech for the purpose of manufacturing ReGen, an injectable stem cell product made from human umbilical cord blood, for exclusive distribution by Liveyon to physicians to administer to patients to purportedly treat a variety of human diseases and illnesses. Mr. Kosolcharoen knew that Genetech and Liveyon were essentially formed and operated in concert solely to manufacture and distribute ReGen.

Beginning around May 2016, and continuing through April 2019, Mr. Kosolcharoen, together with others, fraudulently introduced ReGen and other stem cell derived Liveyon products into interstate commerce. Around July 2016, Mr. Kosolcharoen retained legal counsel and was advised that ReGen could not be manufactured or distributed without FDA's premarket approval. Nonetheless, Mr. Kosolcharoen sold ReGen and other stem cell derived Liveyon products without premarket approval. In November 2016, an FDA regulatory expert advised Mr. Kosolcharoen that ReGen could only be distributed for research use or for specific therapeutic applications that FDA had approved. Mr. Kosolcharoen then directed Liveyon's purchase orders to falsely state that the stem cell products were being sold "for research purposes only for investigational use."

Mr. Kosolcharoen began selling ReGen around November 2016. From November 2016 until October 2017, Mr. Kosolcharoen manufactured and distributed more than $5,000,000 worth of ReGen. However, Liveyon did not file its required annual registration with FDA until on or about October 9, 2017. In that registration submission Mr. Kosolcharoen caused a Liveyon

employee to include numerous false statements to mislead FDA. These false statements included that Liveyon was not a labeling product, that Liveyon products were not human cells, tissues, or cellular or tissue-based products (HCT/Ps) "regulated as drugs or biological drugs," that Liveyon was distributing HCT/Ps that met certain criteria that exempted them from FDA pre-market approval requirements, and that Liveyon was engaged in "satellite distribution only" of human umbilical cord blood products for allogenic use. In fact, Liveyon was the sole distributor of ReGen, which Genetech manufactured exclusively for Liveyon to be distributed to Liveyon's clinician-customers for treatment of their patients. Around September 12, 2018, Mr. Kosolcharoen introduced and delivered for introduction into interstate commerce, ReGen, an unapproved new drug, for non-research, clinical use for commercial profit, with a purchase order that falsely stated "Liveyon cells are sold for research purposes only." This conduct was undertaken knowingly and with intent to defraud as to material matters.

Mr. Kosolcharoen and others misrepresented in marketing materials that ReGen was suitable for the treatment of a variety of conditions, such as lung and heart diseases, autoimmune disorders, Alzheimer's disease, Parkinson's disease and other conditions. Liveyon marketed the products throughout the United States until about April 2019, using advertising materials that contained multiple false and misleading statements about their purported safety and effectiveness. Mr. Kosolcharoen and others fraudulently induced Liveyon customers into purchasing other stem cell derived Liveyon products that were ReGen's successors, by falsely reporting and concealing material facts regarding the outcome of an FDA inspection of Liveyon and nationwide recall of ReGen, by misleading the public about the severity and cause of adverse events suffered by Liveyon patients who were administered ReGen, and by hosting seminars to promote ReGen's successor products that were functionally identical to ReGen and that also were not FDA approved.

ReGen was administered to well more than 10 patients to whom Mr. Kosolcharoen and others mass marketed via internet and social media advertisements that falsely claimed ReGen

was a safe and effective, cheaper, and less invasive treatment alternative to surgery or other procedures for severe, serious, and chronic diseases and disorders that had left patients feeling they had no options.

As a result of this conviction, FDA sent Mr. Kosolcharoen, by certified mail, on November 20, 2024, 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 including, but not limited to, a BLA. The proposal was based on a finding, under section 306(a)(2)(B), that Mr. Kosolcharoen 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 informed Mr. Kosolcharoen of the proposed debarment and offered him 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 a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Kosolcharoen received the proposal and notice of opportunity for a hearing on November 26, 2024. Mr. Kosolcharoen failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Division of Field Enforcement Director, Office of Inspections and Investigations, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Director, Division of Enforcement finds that Mr. John Warrington Kosolcharoen has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Mr. Kosolcharoen is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application including, but not limited to, a BLA, effective (see DATES) (see sections 306(a)(2)(B) and 306(c)(2)(A)(ii) of the FD&C Act, (21 U.S.C. 335a(a)(2)(B) and

335a(c)(2)(A)(ii))). Any person with an approved or pending drug product application including, but not limited to, a BLA, who knowingly employs or retains as a consultant or contractor, or otherwise uses in any capacity the services of Mr. Kosolcharoen 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. Kosolcharoen provides services in any capacity to a person with an approved or pending drug product application including, but not limited to, a BLA during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act (21 U.S.C. 335b(a)(7))). In addition, FDA will not accept or review any abbreviated new drug application from Mr. Kosolcharoen 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 (21 U.S.C. 335a(c)(1)(B))). Note that, for purposes of sections 306 and 307 of the FD&C Act (21 U.S.C. 335a and 335b), a "drug product" is defined as a "drug subject to regulation under section 505, 512, or 802 of this 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))).

Dated: March 7, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025-04031 Filed: 3/12/2025 8:45 am; Publication Date: 3/13/2025]