This document is scheduled to be published in the Federal Register on 2026-09-25 and available online at **https://www.federalregister.gov/d/2026-19654**, and on **https://govinfo.gov**

4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-7395]

Naveed Aslam: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Naveed Aslam 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 Dr. Aslam was convicted of a felony under Federal law for conduct that relates to the regulation of a drug product under the FD&C Act. Dr. Aslam was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of July 9, 2026 (30 days after receipt of the notice), Dr. Aslam has not responded. Dr. Aslam's failure to respond and request a hearing constitutes a waiver of Dr. Aslam'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 Dr. Aslam 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-2025-N-7395. 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. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." 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, 240-402-8743, or debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act 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 November 17, 2025, Dr. Aslam 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 Michigan, when the court entered judgment against him

after his plea of guilty to one count of the illegal sale or trade of prescription drugs, in violation of 21 U.S.C. 333(a)(2) (section 303(a)(2) of the FD&C Act), which constitutes a felony under Federal law.

The underlying facts supporting the conviction are as follows: As described in the Indictment and Plea Agreement in Dr. Aslam's case, Dr. Aslam was a licensed oncologist practicing medicine at Somerset Hematology Oncology, P.C. (Somerset). Dr. Aslam and Somerset were healthcare entities under 21 CFR 203.3(q) because Dr. Aslam, through Somerset, provided medical treatment to patients. Through Somerset, Dr. Aslam had access to several prescription cancer medications that he could buy from drug distributors, including Distributor-1, a publicly traded company that distributed prescription drugs including Enhertu®, Padcev®, Poteligo®, Tivdak®, and Trodelvy®.

Samer Youssef owned and operated SMA Patient Care LLC (SMA), which was both a retail pharmacy and engaged in the wholesale distribution of prescription drugs. SMA and its customers were not healthcare entities under 21 CFR 203.3(q). Youssef operated SMA with the assistance of Houda Bazzi. As part of Youssef and Bazzi's business, they learned about customers who wanted to purchase certain prescription drugs, and they worked to acquire the prescription drugs and re-sell them at a profit. Youssef and Bazzi, however, did not have access to several prescription cancer drugs.

Dr. Aslam came to an agreement with Youssef and Bazzi to purchase and acquire prescription cancer drugs for purposes of selling these drugs to and through SMA and its customers. But as a healthcare entity, it was unlawful for Dr. Aslam to buy and resell prescription cancer drugs because he was only allowed to buy drugs to administer to his patients. Thus, to obtain these prescription drugs from Distributor-1 for purposes of the illegal resale to SMA and its customers, Dr. Aslam made or caused to be made numerous false and misleading statements including that these drugs were to be purchased to treat patients pursuant to a valid prescription and that they would be resold in compliance with the law. Immediately after

receiving the prescription drugs, Dr. Aslam contacted Bazzi and Youssef, and they arranged to pick up the drugs from Somerset for resale to their customers.

From 2019 to 2023, Dr. Aslam used his medical license and arrangement with Distributor-1 to purchase more than 20 different prescription cancer drugs that he resold to and through SMA, including for example, Enhertu®, Poteligeo®, Tivdak®, and Trodelvy®. He did so without ensuring the drugs--many of which required special handling or were infusion drugs--were shipped properly. None of the prescription drugs were administered or intended to be administered to treat patients as required by law and the applicable contract terms with Distributor-1. Dr. Aslam profited from his purchase and resale of illegally purchased prescription cancer drugs by charging SMA more than he paid Distributor-1, sharing the profit when SMA resold the drugs for more than he charged SMA for the drugs, and receiving rebates and discounts from Distributor-1 based on the amount of qualifying drugs he purchased. During this time period, Dr. Aslam bought from Distributor-1 more than $16 million in prescription drugs that he resold to SMA. Based on a comparison of records showing how much Dr. Aslam paid Distributor-1 and how much SMA paid Dr. Aslam and Somerset, Dr. Aslam received $2,601,568.47 in proceeds from the sales.

As a result of this conviction, FDA sent Dr. Aslam, by certified mail, on June 1, 2026, 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 Dr. Aslam 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 Dr. Aslam 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. Dr. Aslam received the proposal and notice of opportunity for a hearing on June 9, 2026. Dr. Aslam 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 Dr. Naveed Aslam 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, Dr. Aslam 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 in any capacity the services of Dr. Aslam 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 Dr. Aslam 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 Dr. Aslam during his period of debarment, other than in connection with an audit under 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 [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))).

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-19654 Filed: 9/24/2026 8:45 am; Publication Date: 9/25/2026]