DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2558]

David Winne; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is denying a request for a hearing submitted by David Roy Winne (Winne) and is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Winne 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 Winne was convicted of multiple felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Winne was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Winne submitted a request for hearing but failed to file with the Agency information and analysis sufficient to create a basis for a hearing.

DATES: The order is applicable August 18, 2023.

ADDRESSES: Any application for termination of debarment by Winne under section 306(d) of the FD&C Act (21 U.S.C. 335a(d)) (application) may be submitted 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

Submit written/paper submissions as follows:

- *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–2022–N–2558. An application will be placed in the docket and, unless 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 application 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: Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, *Rachael.Linowes@fda.hhs.gov,* 240–402–5931.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act mandates permanent debarment 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 29, 2022, the U.S. District Court for the Southern District of New York entered a judgment against Winne, after a guilty plea, for one count of conspiracy to commit wire fraud in violation of 18 U.S.C. 1349 and one count of wire fraud in violation of 18 U.S.C. 1343. The court sentenced Winne to 6 months in prison on each count, to run concurrently; $1,431,524.00 in restitution; and upon his release from prison, a 2-year supervised release for each count, to run concurrently. The bases for his convictions stem from his employment as a technical director with AMA Laboratories (AMA) a consumer product testing company.

According to FDA's Office of Regulatory Affairs' (ORA's) proposal to debar, AMA, for a fee paid by consumer product companies, purported to test the safety and effectiveness of cosmetics, sunscreens, and other products on a specified number of volunteer panelists. ORA found that, from 1987 to April 2017, Winne and other AMA personnel defrauded AMA customers by testing products on fewer panelists than were agreed to and paid for by AMA's customers. Specifically, Winne and other AMA personnel falsely represented to AMA's customers that AMA had tested products on the number of pre-specified panelists and then sent those customers fraudulent test results, which included false data.

By letter dated January 24, 2023, ORA notified Winne of a proposal to permanently debar him from providing services in any capacity to a person having an approved or pending drug product application, based on the felony convictions and underlying conduct outlined above. In addition to outlining

the above information, ORA found that the felony convictions were for conduct relating to the regulation of drug products. The product testing at issue included drug products, specifically sunscreens.[1]

On March 14, 2023, Winne submitted a request for a hearing. Winne's request for a hearing does not provide any information or factual analysis rebutting the findings in ORA's proposal to debar him. Instead, Winne's request for a hearing raises three policy considerations. First, Winne admits his wrongdoing and confirms the appropriateness of debarment but asks FDA to consider a ''reduced decision'' due to his ability to ''make a significant difference in the industry by offering my unique perspective on clinical studies and clinical data.'' Second, Winne mentions the debarment of another individual linked to the same investigation and states that his actions stemmed from that individual's direction. Third, Winne asserts that he cooperated with Federal investigators throughout the investigation process.

Under the authority delegated to her by the Commissioner of Food and Drugs, the Chief Scientist has considered Winne's request for a hearing. Hearings are granted only if there is a genuine and substantial issue of fact. Hearings will not be granted on issues of policy or law, on mere allegations, denials or general descriptions of positions and contentions, or on data and information insufficient to justify the factual determination urged (see 21 CFR 12.24(b)). Winne has not raised a genuine and substantial issue of fact regarding whether he was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Rather, Winne affirms that he engaged in fraudulent conduct regarding the product testing that this conduct formed the factual basis of the felony convictions. Insofar as Winne intends to argue that he provided ''substantial assistance'' in the investigation or prosecution of qualifying offenses under section 306(d)(4)(C) of the FD&C Act, he may apply for special termination of his debarment. While the statute does not define substantial assistance, FDA ''considers a determination by the Department of Justice concerning the substantial assistance of a debarred individual conclusive in most cases.'' [2]

II. Findings and Order

The Chief Scientist, under section 306(a)(2) of the FD&C Act and under the authority delegated to her, finds that David Roy Winne has been convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. As a result of the foregoing findings, Winne is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application 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), effective (see **DATES**) (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application who knowingly uses the services of Winne, in any capacity during his period of 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 Winne, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, 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 submitted by or with the assistance of Winne during his period of debarment.

Dated: August 14, 2023.

Namandjé N. Bumpus,

Chief Scientist.

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BILLING CODE 4164–01–P

[1] *See* section 201(g) of the FD&C Act (21 U.S.C. 321(g)) (defining drugs, *inter alia,* to include products for use in preventing disease in man or intended to affect the structure or function of the body); ''Sunscreen Drug Products for Over-the-Counter Human Use,'' 43 FR 38206 at 38209 (August 25, 1978) (stating an FDA-convened panel's conclusion that ''products intended to be used for prevention of sunburn or any other such similar condition should be regarded as drugs''); *see also* 21 CFR 201.327 (2011) (outlining certain testing requirements for certain over-the-counter sunscreen drug products and declaring such products to be misbranded if SPF labeling claims not supported by adequate testing).

[2] ''Baldev Raj Bhutani; Denial of Hearing on Application for Special Termination of Debarment,'' 77 FR 75636 at 75638 (December 12, 2012) (citing ''Amirul Islam; Grant of Special Termination; Final Order Terminating Debarment,'' 68 FR 58352 (October 9, 2003)).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, Maryland 20857; (301) 443–6593, or visit our website at: *http://www.hrsa.gov/vaccinecompensation/index.html.*

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.,* provides that those seeking compensation are to file a petition with the United States Court of Federal Claims and to serve a copy of the petition to the Secretary of HHS, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the