



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2022-N-2558]

#### David Winne: Grant of Special Termination; Final Order Terminating Debarment

**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) granting special termination of the debarment of David Winne with an effective date of August 18, 2024. FDA bases this order on a finding that Mr. Winne provided substantial assistance in the investigations or prosecutions of offenses relating to a matter under FDA's jurisdiction, and that special termination of Mr. Winne's debarment serves the interest of justice and does not threaten the integrity of the drug approval process.

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

**ADDRESSES:** Submit comments electronically at <https://www.regulations.gov>. Written comments may be submitted to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Jaime Espinosa, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, at 240-402-8743, or [debarments@fda.hhs.gov](mailto:debarments@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

In a *Federal Register* notice dated August 18, 2023 (88 FR 56636), David Winne was permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 306(a) of the FD&C Act (21 U.S.C. 335a(a)).

The debarment was based on FDA's finding that Mr. Winne was convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act. On September 7, 2023, Mr. Winne applied for special termination of debarment, under section 306(d)(4) of the FD&C Act.

Under section 306(d)(4)(C) of the FD&C Act, FDA may limit the period of debarment of a permanently debarred individual if the Agency finds that the debarred individual has provided substantial assistance in the investigation or prosecution of offenses described in section 306(a) or (b) of the FD&C Act or relating to a matter under FDA's jurisdiction. In addition, pursuant to section 306(d)(4)(D)(ii) of the FD&C Act, in cases of an individual FDA may limit the period of debarment to less than permanent but to no less than 1 year, whichever serves the interest of justice and protects the integrity of the drug approval process.

Special termination of debarment is discretionary with FDA. FDA generally considers a determination by the Department of Justice concerning the substantial assistance of a debarred individual conclusive in most cases. Mr. Winne cooperated with the United States Attorney's Office in the investigation of several individuals, as substantiated by a letter submitted by the United States Attorney's Office for the Southern District of New York to the sentencing judge in Mr. Winne's case and which was submitted to the Agency by Mr. Winne. His cooperation contributed to the successful prosecution of these individuals. Accordingly, FDA finds that Mr. Winne provided substantial assistance as required by section 306(d)(4)(C) of the FD&C Act.

The additional requisite showings, i.e., that termination of debarment serves the interest of justice and poses no threat to the integrity of the drug approval process, are difficult standards to satisfy. In determining whether these have been met, the Agency weighs the significance of all favorable and unfavorable factors in light of the remedial, public health-related purposes underlying debarment. Termination of debarment will not be granted unless, weighing all favorable and unfavorable information, there is a high level of assurance that the conduct that

formed the basis for debarment has not recurred and will not recur, and that the individual will not otherwise pose a threat to the integrity of the drug approval process.

The evidence FDA reviewed in support of termination shows that Mr. Winne was convicted for a first offense; that he has no prior or subsequent convictions for conduct described under the FD&C Act and has committed no other wrongful acts affecting the drug approval process. The evidence presented supports the conclusion that the conduct upon which Mr. Winne's debarment was based is unlikely to recur. For these reasons, the Agency finds that termination of Mr. Winne's debarment serves the interest of justice and will not pose a threat to the integrity of the drug approval process.

Under section 306(d)(4)(D) of the FD&C Act, the period of debarment of an individual who qualifies for special termination may be limited to less than permanent but to no less than 1 year. Mr. Winne's period of debarment, which commenced on August 18, 2023, has not lasted for at least 1 year. As such, his period of debarment cannot terminate until August 17, 2024. Accordingly, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(d)(4) of the FD&C Act and under authority delegated to the Assistant Commissioner, finds that David Winne's application for special termination of debarment should be granted, and that the period of debarment should terminate on August 18, 2024, thereby allowing him to provide services in any capacity to a person with an approved or pending drug product application after that date. As a result of the foregoing findings, David Winne's debarment is terminated effective August 17, 2024.

**Dated:** October 26, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*