

retrieved by name or other personal identifier) are matched with records of other Federal or non-Federal agencies. The Privacy Act requires agencies involved in a matching program to:

1. Enter into a written agreement, which must be prepared in accordance with the Privacy Act, approved by the Data Integrity Board of each source and recipient Federal agency, provided to Congress and the Office of Management and Budget (OMB), and made available to the public, as required by 5 U.S.C. 552a(o), (u)(3)(A), and (u)(4).

2. Notify the individuals whose information will be used in the matching program that the information they provide is subject to verification through matching, as required by 5 U.S.C. 552a(o)(1)(D).

3. Verify match findings before suspending, terminating, reducing, or making a final denial of an individual's benefits or payments or taking other adverse action against the individual, as required by 5 U.S.C. 552a(p).

4. Report the matching program to Congress and the OMB, in advance and annually, as required by 5 U.S.C. 552a(o) (2)(A)(i), (r), and (u)(3)(D).

5. Publish advance notice of the matching program in the **Federal Register** as required by 5 U.S.C. 552a(e)(12).

This matching program meets these requirements.

Barbara Demopolos,

Privacy Act Officer, Division of Security, Privacy Policy and Governance, Office of Information Technology, Centers for Medicare & Medicaid Services.

Participating Agencies

The Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) is the recipient agency, and the Department of Defense (DoD), Defense Manpower Data Center (DMDC) is the source agency.

Authority for Conducting the Matching Program

The principal authority for conducting the matching program is 42 U.S.C. 18001, *et seq.*

Purpose(s)

The purpose of the matching program is to provide CMS with DoD data verifying individuals' eligibility for coverage under a DoD Health Benefit Plan (*i.e.*, TRICARE), when requested by CMS and state-based administering entities (AE) for the purpose of determining the individuals' eligibility for insurance affordability programs under the Patient Protection and Affordable Care Act (PPACA). CMS and the requesting AE will use the DoD data

to determine whether an enrollee in private health coverage under a qualified health plan through a federally-facilitated or state-based health insurance exchange is eligible for coverage under TRICARE, and the dates the individual was eligible for TRICARE coverage. DoD health benefit plans provide minimum essential coverage (MEC), and eligibility for such plans precludes eligibility for financial assistance in paying for private coverage. CMS and AE will use the DoD data to authenticate identity, determine eligibility for financial assistance (including an advance tax credit and cost-sharing reduction, which are types of insurance affordability programs), and determine the amount of any financial assistance.

Categories of Individuals

The categories of individuals whose information is involved in the matching program are: (1) active duty service members and their family members and (2) retirees and their family members whose TRICARE eligibility records at DoD match data provided to DoD by CMS (submitted by AEs) about individual consumers who are applying for or are enrolled in private health insurance coverage under a qualified health plan through a federally-facilitated or state-based health insurance exchange.

Categories of Records

The categories of records used in the matching program are identity records and minimum essential coverage (MEC) period records. To request information from DoD, CMS will submit a request to DoD that may contain, but is not limited to, the following specified data elements in a fixed record format: Social Security Number (SSN), first name, middle name, surname (last name), date of birth, gender, and requested Qualified Health Plan (QHP) coverage effective date and end date. When DoD is able to match the SSN and name provided by CMS and information is available, DoD will provide CMS with the following about each individual, as relevant: SSN, response code indicating enrollment in MEC under a TRICARE plan, and, as applicable, begin date(s) and end date(s) of enrollment in MEC under a TRICARE plan.

System(s) of Records

The records used in the matching program are disclosed from these systems of records, as authorized by routine uses published in the System of Records Notices (SORNs) cited below:

A. System of Records Maintained by CMS

CMS Health Insurance Exchanges System (HIX), CMS System No. 09–70–0560, last published in full at 78 FR 63211 (Oct. 23, 2013), and amended at 83 FR 6591 (Feb. 14, 2018). Routine use 3 authorizes CMS' disclosures of identifying information about applicants to DoD for use in this matching program.

B. System of Records Maintained by DoD

The DoD system of records and routine use that support this matching program are Routine Use h in DMDC 02 DoD, Defense Enrollment Eligibility Reporting Systems (DEERS), last published at 87 FR 32384 (May 31, 2022). Routine use H supports DoD's disclosures to CMS.

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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 November 1, 2023.

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.

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-0008]

Request for Nominations on Public Advisory Panels of the Medical Devices Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is requesting that any industry organizations interested in participating in the selection of nonvoting industry representatives to serve on certain panels of the Medical Devices Advisory Committee (MDAC or the Committee) in the Center for Devices and Radiological Health (CDRH) notify FDA in writing. FDA is also requesting nominations for nonvoting industry representatives to serve on certain device panels of the MDAC in the CDRH. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current and upcoming vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to the FDA by December 1, 2023 (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by December 1, 2023.

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nomination should be sent to Margaret Ames (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives should be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: <https://www.accessdata.fda.gov/scripts/FACTRSportal/FACTRS/index.cfm> or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993-0002. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm>.