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.

[FR Doc. 2023–24094 Filed 10–31–23; 8:45 am]

BILLING CODE 4164–01–P

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.*

FOR FURTHER INFORMATION CONTACT: Margaret Ames, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5213, Silver Spring, MD 20993, 301–796–5960, email: *Margaret.Ames@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency is requesting nominations for nonvoting industry representatives to the panels listed in table 1.

I. Medical Devices Advisory Committee

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The panels of the Medical Devices Advisory Committee engage in a number of activities to fulfill the functions the Federal Food, Drug, and Cosmetic Act (FD&C Act) envisions for device advisory panels. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, advises the Commissioner of Food and Drugs (the Commissioner) regarding recommended classification or reclassification of devices into one of three regulatory categories; advises on any possible risks to health associated with the use of devices; advises on formulation of product development protocols; reviews premarket approval applications for medical devices; reviews guidelines and guidance documents; recommends exemption of certain devices from the application of portions of the FD&C Act; advises on the necessity to ban a device; and responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices. The Committee also provides recommendations to the Commissioner or designee on complexity categorization of in vitro diagnostics under the Clinical Laboratory Improvement Amendments of 1988.

TABLE 1—PANELS AND FUNCTIONS

Panels	Function
Dental Products Panel	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational products for use in dentistry, endodontics, or bone physiology relative to the oral and maxillofacial area and makes appropriate recommendations to the Commissioner.
Ear, Nose, and Throat Devices Panel	Reviews and evaluate data concerning the safety and effectiveness of marketed and investigational ear, nose, and throat devices and makes appropriate recommendations to the Commissioner.
General and Plastic Surgery Devices Panel	Reviews and evaluate data concerning the safety and effectiveness of marketed and investigational general and plastic surgery devices and makes appropriate recommendations to the Commissioner.
Hematology and Pathology Devices Panel	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational *in vitro* devices for use in clinical laboratory medicine including pathology, hematology, histopathology, cytotechnology, and molecular biology and makes appropriate recommendations to the Commissioner.
Orthopedic and Rehabilitation Devices Panel	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational orthopedic and rehabilitation devices and makes appropriate recommendations to the Commissioner.

II. Qualifications

Persons nominated for the device panels should be full-time employees of firms that manufacture products that would come before the panel, or consulting firms that represent manufacturers, or have similar appropriate ties to industry.

III. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations, and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for a particular device panel. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

IV. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Nomination must include a current, complete résumé or curriculum vitae for each nominee including current business address and telephone number, email address if available, and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). Nominations must also specify the advisory panel for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the particular device panels listed in table 1. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.)

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees, and therefore encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5

U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: October 27, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–24123 Filed 10–31–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4319]

Determination That CALCIUM DISODIUM VERSENATE (Edetate Calcium Disodium) Injection, 200 Milligrams per Milliliter, and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363, *Stacy.Kane@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table are no longer being marketed.

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 008922	CALCIUM DISODIUM VERSENATE.	Edetate Calcium Disodium.	200 Milligrams (mg)/Milliliter (mL)	Injectable; Injection	Bausch Health US, LLC.
NDA 011722	TENUATE	Diethylpropion Hydrochloride.	25 mg	Tablet; Oral	Nostrum Labs., Inc.
NDA 012546	TENUATE DOSPAN	Diethylpropion Hydrochloride.	75 mg	Tablets, Extended-Release; Oral.	Do.
NDA 019117	FLUOCINONIDE	Fluocinonide	0.05%	Cream; Topical	Taro Pharms. U.S.A., Inc.
NDA 019796	ELOCON	Mometasone Furoate	0.1%	Lotion; Topical	Organon, LLC.
NDA 020489	ANDRODERM	Testosterone	2 mg/24 hours; 4 mg/24 hours	Film, Extended Release; Transdermal.	AbbVie Inc.
NDA 020884	AGGRENO$_X$	Aspirin; Dipyridamole	25 mg; 200 mg	Capsule, Extended Release; Oral.	Boehringer Ingelheim Pharms., Inc.
NDA 020903	REBETOL	Ribavirin	200 mg	Capsule; Oral	Merck Sharp and Dohme Corp.
NDA 020907	ACTIVELLA	Estradiol; Norethindrone Acetate.	0.5 mg; 0.1 mg	Tablet; Oral	Amneal Pharms., LLC.
NDA 020949	ACCUNEB	Albuterol Sulfate	Equivalent to (EQ) 0.021% Base; EQ 0.042% Base.	Solution; Inhalation	Mylan Specialty LP.
NDA 021022	PENLAC	Ciclopirox	8%	Solution; Topical	Valeant International Bermuda.
NDA 021449	HEPSERA	Adefovir Dipivoxil	10 mg	Tablet; Oral	Gilead Sciences, Inc.
NDA 022052	ZYFLO CR	Zileuton	600 mg	Tablet, Extended Release; Oral.	Chiesi USA, Inc.
NDA 022511	VIMOVO	Esomeprazole Magnesium; Naproxen.	EQ 20 mg Base; 375 mg; EQ 20 mg Base; 500 mg.	Tablet, Delayed Release; Oral.	Horizon Medicines LLC.
NDA 022569	LAZANDA	Fentanyl Citrate	EQ 0.1mg Base; EQ 0.3 mg Base; EQ 0.4 mg Base.	Spray, Metered; Nasal	BTcP Pharma, LLC.
NDA 202788	SUBSYS	Fentanyl	0.1 mg; 0.2 mg; 0.4 mg; 0.6 mg; 0.8 mg; 1.2 mg; 1.6 mg.	Spray; Sublingual	Do.
NDA 213645	DAPZURA RT	Daptomycin	500 mg/Vial	Powder; Intravenous	Baxter Healthcare Corp.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product