DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0008]

Request for Nominations for Voting Members for the Patient Engagement Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is requesting nominations for voting members, excluding consumer and industry representatives, to serve on the Patient Engagement Advisory Committee (the Committee) in the Center for Devices and Radiological Health. Nominations will be accepted for upcoming vacancies effective with this notice. FDA seeks to include the views of members of all gender groups, 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.

DATES: Nominations received on or before June 4, 2024, will be given first consideration for membership on the Committee. Nominations received after June 4, 2024, will be considered for nomination to the Committee as later vacancies occur.

ADDRESSES: All nominations for membership should be submitted electronically, by logging into the FDA Advisory Committee Membership Nomination Portal (*https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm*) and selecting Academician/Practitioner from the dropdown menu (regardless of whether Academician/Practitioner accurately describes the nominee), 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 on 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: Letise Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5407, Silver Spring, MD 20993–0002, 301–796–8398, email: *Letise.Williams@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members to fill upcoming vacancies on the Patient Engagement Advisory Committee. This notice does not include consumer and industry representative nominations. The Agency will publish two separate notices announcing the vacancy of a representative of consumer interests and vacancy of representatives of interests of the device manufacturing industry.

I. General Description of the Committee Duties

The Committee provides relevant skills and perspectives to improve communication of benefits, risks, and clinical outcomes, and increase integration of patient perspectives into the regulatory process for medical devices. The Committee performs its duties by identifying new approaches, promoting innovation, recognizing unforeseen risks or barriers, and identifying unintended consequences that could result from FDA policy. The Committee provides advice on complex scientific issues related to medical devices, the regulation of devices, and their use by patients. Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient-reported outcomes, device-related quality of life measures, or health status issues are among the topics that may be considered by the Committee.

II. Criteria for Voting Members

The Committee consists of a core of nine voting members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities who are knowledgeable in areas such as clinical research, patient or caregiver experience, healthcare needs of patient groups in the United States, or are experienced in the work of patient and health professional organizations, scientific methodologies for patient-reported outcomes and other clinical outcome assessments, scientific methodologies for eliciting patient preferences, and strategies for communicating benefits, risks, and clinical outcomes to patients and research subjects, as well as other relevant areas. Members will be invited to serve for overlapping terms of up to 4 years. Prospective members should also have an understanding of the broad spectrum of patients in a particular disease area. Almost all non-Federal members of this Committee serve as Special Government Employees, with the exception of the representatives from industry.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the Committee. Self-nominations are also accepted. Nominations must include a cover letter; a current, complete résumé or curriculum vitae for each nominee, including current business and/or home address, telephone number, and email address if available; and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Nomination Portal (see **ADDRESSES**). Nominations must specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*) and 21 CFR part 14, relating to advisory committees.

Dated: April 2, 2024.

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–5257]

Robert Lance Shuffert: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Robert Lance Shuffert for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Shuffert was convicted of one felony count under Federal law for, with the intent to defraud and mislead, causing a drug to be misbranded while it was held for sale after shipment in interstate commerce. The factual basis supporting Mr. Shuffert's conviction, as described below, is conduct relating to