filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: June 18, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11604 Filed 6–24–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–FDA–2025–N–0008]

Request for Nominations for Voting Members on the Tobacco Products Scientific Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for members to serve on the Tobacco Products Scientific Advisory Committee (TPSAC), in the Center for Tobacco Products. FDA seeks to include the views of qualified individuals on its advisory committees, and therefore encourages nominations of appropriately qualified candidates. Specifically, TPSAC is seeking to fill 5 vacancies with physicians, dentists, scientists, or health care professionals practicing in the area of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, engineering, or any other relevant specialty. Included in the 5 vacancies is 1 vacancy for a representative of the general public, and 1 vacancy for an employee of a state or local government or of the Federal Government.

DATES: Nominations received on or before June 25, 2025 will be given first consideration for membership on the Tobacco Products Scientific Advisory Committee. Nominations received after August 25, 2025 will be considered for nomination to the committee as later vacancies occur.

ADDRESSES: All nominations for membership should be sent electronically by logging into the FDA Advisory Nomination Portal: *http://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.

FOR FURTHER INFORMATION CONTACT:

Regarding all nomination questions for membership, the primary contact is:

Rachel Jang, PharmD, Office of Science, Center for Tobacco Products, Food and Drug Administration, Center for Tobacco Products, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1373 (choose Option 5), *email: TPSAC@fda.hhs.gov*. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's website at: *http://www.fda.gov/AdvisoryCommittees/default.htm*.

SUPPLEMENTARY INFORMATION: FDA is requesting nomination for voting members on the Tobacco Products Scientific Advisory Committee.

I. General Description of the Committee Duties

The Tobacco Products Scientific Advisory Committee advises the Commissioner of FDA or designee in discharging responsibilities related to the regulation of tobacco products. The Tobacco Products Scientific Advisory Committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information and recommendations to the Commissioner of Food and Drugs.

II. Criteria for Voting Members

The Committee consists of 12 members including the Chair. Members and the Chair are selected by the Commissioner or designee from among individuals knowledgeable in the fields of medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products. Almost all non-Federal members of this committee serve as Special Government Employees. The Committee includes nine technically qualified voting members, selected by the Commissioner or designee. The nine voting members include seven members who are physicians, dentists, scientists, or health care professionals practicing in the area of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant specialty. The nine voting members also include one member who is an officer or employee of a state or local government or of the Federal Government, and one member who is a representative of the general public. Members will be invited to serve for terms of up to 4 years.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the advisory committee. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address and/or home address, telephone number, and email address if available. Nominations must also 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. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: June 18, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11600 Filed 6–24–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2022–E–2187; FDA–2022–E–2190; FDA–2022–E–2191; FDA–2022–E–2192; FDA–2022–E–2193]

Determination of Regulatory Review Period for Purposes of Patent Extension; [EDWARDS SAPIEN 3 TRANSCATHETER PULMONARY VALVE]

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for EDWARDS SAPIEN 3 TRANSCATHETER PULMONARY VALVE and is publishing this notice of