4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-0008]

Advisory Committee; Obstetrics, Reproductive and Urologic Drugs Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Obstetrics, Reproductive and Urologic Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Obstetrics, Reproductive and Urologic Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the March 23, 2028, expiration date.

DATES: Authority for the Obstetrics, Reproductive and Urologic Drugs Advisory Committee will expire on March 23, 2026, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Advisory Committee Oversight and Management Staff, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, (301) 796-7973, ACOMSSubmissions@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 21 CFR 14.40(b) and 41 CFR 102-3.65, and following approval by the Department of Health and Human Services and review by the General Services Administration, FDA is announcing the renewal of the Obstetrics, Reproductive and Urologic Drugs Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner.

The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drug products for use in the practice of obstetrics, gynecology, urology and related specialties, and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of at least six voting members including the Chair. Subject to legal and regulatory requirements, members and the Chair are selected by and serve at the discretion of the Commissioner or designee. Each member, including the Chair, will be selected from among authorities knowledgeable in the fields of obstetrics, gynecology, urology, epidemiology, or statistics and related specialties.

Members may be invited to serve for terms of up to four years, or for less time in the discretion of the Commissioner or designee. Non-Federal members of this committee will serve as Special Government Employees or representatives. Federal members will serve as Regular Government Employees or Ex-Officios.

In addition to the voting members, the Commissioner or designee may identify consumer and/or industry representatives to join the Committee (or serve as alternate representatives) as non-voting representative member(s), via a process consistent with legal and regulatory requirements. Individuals currently employed at FDA-regulated companies, such as pharmaceutical and medical device manufacturers, shall not be selected to serve as members of the Committee unless this Committee is expected to address issues for which inclusion of an industry representative is required by statute. If this Committee includes an industry representative, the Commissioner or designee will determine whether to invite them to participate in meetings on a case-by-case basis, according to applicable legal and regulatory requirements.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees to serve temporarily as voting members and to designate

Special Government Employees to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members), or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking.

A quorum for the Committee is a majority of the current voting members present at the time, provided that FDA may specify a quorum that is less than a majority of the current voting members because of the size of the Committee and the variety in the types of issues that it will consider, or other reason determined appropriate in accordance with legal and regulatory requirements. 21 CFR §14.22(d).

Members appointed to an advisory committee serve for the duration of the committee, or until their terms expire, they resign, or they are removed from membership by the Commissioner or designee. Committee members' terms may be ended prior to their date of expiration, for reasons determined to be good cause. Good cause includes excessive absenteeism from committee meetings, a demonstrated bias that interferes with the ability to render objective advice, failure to abide by established procedures, or violation of other applicable rules and regulations.

Further information regarding the most recent charter and other information can be found at https://www.fda.gov/advisory-committees/human-drug-advisory-committees/obstetrics-reproductive-and-urologic-drugs-advisory-committee-formerly-bone-reproductive-and or by contacting the Advisory Committee Oversight and Management Staff (see FOR FURTHER INFORMATION CONTACT). Because the committee's name and description of duties remain unchanged, 21 CFR 14.100 will not be amended.

RENEWAL REQUIREMENTS AND JUSTIFICATION: The Commissioner has determined that renewal of the Obstetrics, Reproductive and Urologic Drugs Advisory Committee is in the public interest. This determination is based on the Committee's essential role in providing independent expert advice on complex scientific and regulatory matters related to obstetrics,

gynecology, urology and related specialties, the continued need for specialized expertise in this therapeutic area, and the Committee's demonstrated value in supporting FDA's regulatory mission. The following information supports this determination in accordance with applicable legal and regulatory requirements.

PUBLIC INTEREST DETERMINATION

FDA estimates the following annual operating costs and staff years associated with this committee.

(1) Annual budget and expected costs: $88,775

(i) Federal personnel (based on full-time equivalent (FTE) usage basis) and other Federal internal costs.

The estimated person years of Federal staff support required is 0.25 at an estimated annual cost of $50,739

(ii) Proposed payments to members and number of members; and

The estimated annual payment to members is $9,212 for twelve (12) committee members[1]

(iii) Reimbursable costs.

The estimated annual reimbursable costs, including travel and related expenses for members, is $16,140.

(2) If applicable, the total dollar value of grants expected to be recommended during the fiscal year.

N/A.

(3) Criteria for selecting members to ensure the committee has the necessary expertise and fairly balanced membership.

Ensuring Necessary Expertise:

Members must have background, education, and experience commensurate with the committee's function of advising FDA on the existing and relevant evidence of benefits and risks of marketed

[1] This number of committee members is an estimate that includes potential additional temporary voting members who may participate in specific advisory committee meetings.

and investigational human drug products for use in the practice of obstetrics, gynecology, urology and related specialties. Scientific and technical competence is critical. Nominees should be acknowledged experts with demonstrated skills in critical evaluation of data and effective communication. As outlined in the committee charter, the membership should include authorities knowledgeable in the fields of obstetrics, gynecology, urology, epidemiology, or statistics and related specialties, as well as needed consumer and industry representation. FDA also follows the requirements in section 505(n)(3) regarding membership of drug product advisory committees. (21 U.S.C. 355(n)(3)).

Ensuring Fair Balance:

Appointments are made without discrimination. The committee is reviewed in totality for balance, characterized by inclusion of necessary knowledge, insight, and scientific perspective from the relevant community or expertise area. Nominations are sought from all geographic locations within the United States and its territories, and from diverse sources including professional and scientific societies, academia, government agencies, industry and trade associations, consumer and patient organizations, and current Agency staff.

Selection Process:

A Federal Register Notice is published annually soliciting nominations for vacancies. Agency Designated Federal Officers and Office/Division Directors review and evaluate prospective members for competence and suitability. Anyone may nominate an individual, including themselves, for committee membership.

(4) List of all other Federal advisory committees of the agency.

FDA maintains the following Federal advisory committees:

- Anesthetic and Analgesic Drug Products Advisory Committee
- Antimicrobial Drugs Advisory Committee
- Blood Products Advisory Committee
- Cardiovascular and Renal Drugs Advisory Committee

- Cellular Tissue and Gene Therapies Advisory Committee
- Dermatologic and Ophthalmic Drugs Advisory Committee
- Device Good Manufacturing Practice Advisory Committee
- Digital Health Advisory Committee
- Drug Safety and Risk Management Advisory Committee
- Endocrinologic and Metabolic Drugs Advisory Committee
- Gastrointestinal Drugs Advisory Committee
- Genetic and Metabolic Disease Advisory Committee
- Medical Devices Advisory Committee
- National Mammography Quality Assurance Advisory Committee (Administratively Inactive)
- Nonprescription Drugs Advisory Committee
- Oncologic Drugs Advisory Committee
- Patient Engagement Advisory Committee
- Pediatrics Advisory Committee
- Peripheral and Central Nervous System Advisory Committee
- Pharmacy Compounding Advisory Committee
- Pharmacy Compounding Drugs AC
- Psychopharmacologic Drugs Advisory Committee
- Pulmonary-Allergy Drugs Advisory Committee
- Risk Communication Advisory Committee (Administratively Inactive)
- Science Board to the Food and Drug Administration
- Technical and Electronic Products Safety Standards Advisory Committee
- Tobacco Products Scientific Advisory Committee

(5) Justification that the information or advice provided by the Federal advisory committee is not available from another Federal advisory committee, another Federal Government source, or any other more cost-effective and less burdensome source.

The Obstetrics, Reproductive and Urologic Drugs Advisory Committee provides independent expert advice to FDA on the safety and effectiveness of marketed and investigational human drug products for use in the practice of obstetrics, gynecology, urology and related specialties. The topics considered by the Obstetrics, Reproductive and Urologic Drugs Advisory Committee require specialized expertise in the practice of obstetrics, gynecology, urology and related specialties that is not within the primary scope of other FDA advisory committees. Potential topics that may need committee input include products related to the topics outlined in Section (6) below. These and other issues cannot be appropriately addressed by another standing committee without diminishing the depth and relevance of the expert input provided to the Agency.

(6) If the justification relates to a renewal, a summary of the previous accomplishments of the committee and the reasons it needs to continue.

Summary of Previous Accomplishments:

In 2022, the committee discussed the Makena (hydroxyprogesterone caproate injection) application. Approved in 2011 under accelerated approval, Makena was the only drug product approved to reduce the risk of recurrent preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. As a condition of Makena's approval, the applicant was required to conduct a confirmatory clinical trial ("the PROLONG" trial) to verify and describe the predicted clinical benefit to newborns. The committee discussed whether the PROLONG trial verified the clinical benefit of Makena and whether available evidence demonstrated that Makena was effective for its approved indication. The Committee discussed whether FDA should allow Makena to remain on the market while an appropriate confirmatory

study was being designed. Their recommendations informed FDA's decision to withdraw approval for Makena in 2023.

Patients benefit from this committee's review and evaluation of obstetrics, reproductive and urologic drugs. Topics on which FDA may seek input from this committee include the following:

- Contraception and family planning
- Treatment for endometriosis and adenomyosis
- Treatment of menstrual disorders
- Prevention of preterm birth
- Female and male infertility
- Female and male sexual dysfunction
- Testosterone for hypogonadism in men
- Lactation disorders
- Treatment of menopausal symptoms
- Medical treatment of cervical dysplasia associated with human papilloma virus infection
- Treatment of preeclampsia
- Bladder pain disorders
- Overactive bladder disorders
- Treatment of benign prostate disease

7. Explanation of why the committee/subcommittee is essential to the conduct of agency business

Reasons for Continuation:

The committee plays a critical role in enabling FDA to meet the requirements of sections 505(n)(1) and (s)(1) of the Federal Food, Drug, and Cosmetic Act by providing expert scientific advice and recommendations. Without the Obstetrics, Reproductive and Urologic Drugs Advisory Committee, FDA's ability to obtain external expert input on issues related to the

approval and regulation of the safety and effectiveness of marketed and investigational human drug products for use in the practice of obstetrics, gynecology, urology and related specialties would be significantly limited.

In conclusion, this public interest determination documents that renewing the committee is in the public interest, essential to the conduct of agency business, and that the information to be obtained is not already available through another advisory committee or source within the Federal Government.

This notice is issued under the Federal Advisory Committee Act as amended (5 U.S.C. 1001 et seq.). For general information related to FDA advisory committees, please visit us at http://www.fda.gov/AdvisoryCommittees/default.htm.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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