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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0621]

Advisory Committee; Anesthetic and Analgesic Drug Products 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 Anesthetic and Analgesic Drug Products 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 Anesthetic and Analgesic Drug Products Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the May 1, 2028, expiration date.

DATES: Authority for the Anesthetic and Analgesic Drug Products Advisory Committee will expire on May 1, 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. 1, Rm. 3215, Silver Spring, MD 20993-0002, (301) 796-8220, 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 Anesthetic and Analgesic Drug Products 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 available data concerning the safety and effectiveness of marketed and investigational human drug products including analgesics, e.g., abuse-deterrent opioids, novel analgesics, issues related to opioid abuse, and drug products for use in anesthesiology, 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 anesthesiology, analgesics (e.g., abuse deterrent opioids, novel analgesics, and issues related to opioid abuse) epidemiology or statistics, and related specialties.

Members will 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/anesthetic-and-analgesic-drug-products-advisory-committee or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

Renewal Requirements and Justification: The Commissioner has determined that renewal of the AADPAC 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 anesthesiology, analgesics, 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

Pursuant to 41 CFR § 102-3.60(a), to establish, renew, reestablish, or merge a discretionary (agency discretion) advisory committee, an agency must first consult with the General Services Administration's Committee Management Secretariat (the Secretariat) and, as part of the consultation, provide a written public interest determination approved by the head of the agency to the Secretariat with a copy to the Office of Management and Budget. In addition, pursuant to 41 CFR § 102-3.35, an agency shall follow the same consultation process and document in writing the same determination of need before creating a subcommittee under a discretionary committee that is not made up entirely of members of a parent advisory committee.

Information on the following factors for the committee is provided to the Secretariat to demonstrate that renewing the committee is in the public interest:

1. Annual budget

The overall budget for this committee is $126,950.

a. Federal personnel on a full-time equivalent (FTE) basis

The estimated person years of Federal staff support required is 0.25

b. Other Federal internal costs

The anticipated total value in dollars of other internal costs, such as costs associated with IT and supplies for meetings, is $21,700.

c. Proposed payments to members

The estimated annual payment to members is $8,473.

d. Proposed number of members

The anticipated number of members is 6.

e. Reimbursable costs

The estimated annual reimbursable costs, including travel and related expenses for members, is $45,902.

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 and investigational human drug products including analgesics, e.g., abuse-deterrent opioids, novel analgesics, issues related to opioid abuse, and drug products for use in anesthesiology. 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 anesthesiology, analgesics (e.g., abuse deterrent opioids, novel analgesics, and issues related to opioid abuse), 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.

4. List of all other Federal advisory committees of the agency FDA maintains the following Federal advisory committees:

• 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

• Genetic and Metabolic Disease Advisory Committee

• Medical Devices Advisory Committee

• National Mammography Quality Assurance Advisory Committee (Administratively Inactive)

• Nonprescription Drugs Advisory Committee

• Obstetrics, Reproductive and Urologic 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

• Psychopharmacologic Drugs Advisory Committee

• Pulmonary-Allergy Drugs Advisory Committee

• Risk Communication Advisory Committee (Administratively Inactive)

• Science Board to the Food and Drug Administration

• Technical Electronic Product Radiation Safety Standards Committee

• Tobacco Products Scientific Advisory Committee

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

The Anesthetic and Analgesic Drug Products Advisory Committee is the only FDA advisory committee that provides specialized expertise in anesthesiology, addiction medicine, and analgesics (e.g., abuse deterrent opioids, novel analgesics, and issues related to opioid abuse). The complexity of technical, clinical, and regulatory considerations in this therapeutic area exceeds the expertise of other advisory committees, necessitating the continuation of this dedicated committee.

6. If the consultation is a committee renewal, a summary of the previous accomplishments of the committee and the reasons it needs to continue

Patients benefit from this committee's review and evaluation of anesthetics and analgesic drugs. For example, in 2025, the committee met jointly with the Drug Safety and Risk

Management Advisory Committee and discussed the findings of the completed extended-release/long-acting opioid analgesic (ER/LA OA) post marketing requirements (PMRs) 3033-1 and 3033-2. These PMRs were prospective (3033-1) and retrospective (3033-2) epidemiologic studies that examined the serious risks and predictors of misuse, abuse, addiction, and fatal and non-fatal opioid overdose in patients with long-term use of opioid analgesics for management of chronic pain, including patients prescribed ER/LA OAs. The Committees discussed their interpretation of the findings from these PMRs on the incidence and prevalence of misuse, abuse, Opioid Use Disorder (OUD), and fatal and nonfatal overdose in patients using OAs long-term, their thoughts on the most important findings, as well as any novel findings they believed FDA should communicate to healthcare providers, patients, and other members of the public.

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

The Committee plays a critical role in enabling FDA to meet the requirements of section 505(n)(1) and (s)(1) of the Federal Food, Drug, and Cosmetic Act by providing expert scientific advice and recommendations. The Anesthetic and Analgesic Drug Products Advisory Committee is the only FDA advisory committee that provides specialized expertise in anesthesiology, addiction medicine, and analgesics. Without the Anesthetic and Analgesic Drug Products Advisory Committee, FDA's ability to obtain external input on issues related to the approval and regulation of anesthetics, addiction medicine and analgesics 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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