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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Advisory Committee; Endocrinologic and Metabolic 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 Endocrinologic and Metabolic 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 Endocrinologic and Metabolic Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the August 27, 2028, expiration date.

DATES: Authority for the Endocrinologic and Metabolic Drugs Advisory Committee will expire on August 27, 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 41 CFR 102-3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Endocrinologic and Metabolic 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 available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of endocrine and metabolic disorders 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 endocrinology, metabolism, 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).

If functioning as a medical device panel, an additional non-voting representative member of consumer interests and an additional non-voting representative member of industry interests will be included in addition to the voting members.

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 end 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/endocrinologic-and-metabolic-drugs-advisory-committee/endocrinologic-and-metabolic-drugs-advisory-committee-charter 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 Endocrinologic and Metabolic Drugs Advisory Committee is in the public interest. This determination is based on the Committee's essential role in providing independent expert advice on the safety and effectiveness of marketed and investigational human drug products for use in the treatment of endocrine and metabolic disorders, 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 $99,088

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

      The estimated person years of Federal staff support is 0.25 at an estimated annual cost of $43,916.

   b. Other Federal internal costs

      The anticipated total value in USD of other internal costs, such as cost associated with IT supplies for meeting is $18,606

c. Proposed payments to members

The estimated annual payments to members are $8,936.

d. Proposed number of members

The anticipated number of members is six.

e. Reimbursable costs

The estimated annual reimbursable costs, including travel and related expenses for members is $13,004

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 for use in the treatment of endocrine and metabolic disorders 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 endocrinology, metabolism, 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:

- Anesthetic and Analgesic Drug Products Advisory Committee
- Antimicrobial Drugs Advisory Committee
- Blood Products 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 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
- Pediatric 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 and Electronic Product Radiation Safety Standards Advisory Committee
- Tobacco Products Scientific Advisory Committee
- Vaccines and Related Biological Products 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 Endocrinologic and Metabolic 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 treatment of endocrine and metabolic disorders.

The topics considered by the Endocrinologic and Metabolic Drugs Advisory Committee require specialized expertise in the fields of endocrinology, metabolism, statistics, 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 consultation is a committee renewal, a summary of the previous accomplishments of the committee and the reasons it needs to continue

Summary of previous Accomplishments:

For the last three years, EMDAC met four times:

On October 31, 2024, the committee discussed the clinical benefits of sotagliflozin oral tablets on hemoglobin A1c (A1C) in patients with estimated

glomerular filtration rates (eGFR) below 60 mL/min, and whether these benefits are greater in patients with type 1 diabetes (T1D) and chronic kidney disease (CKD) compared to those without CKD. Safety concerns were raised regarding the incidence and severity of diabetic ketoacidosis (DKA) in T1D patients with CKD treated with sotagliflozin. Following deliberation, the committee voted 11 to 3 that the available data did not demonstrate that the benefits of sotagliflozin outweigh the risks for the indication of improving glycemic control in patients with T1D and CKD.

On May 24, 2024, the committee discussed the safety and efficacy of biologics license application 761326 for NNC0148-0287 injection (insulin icodec), a long-acting insulin analog product, submitted by Novo Nordisk. The proposed indication is to improve glycemic control in adults with diabetes mellitus. The majority of the committee voted unfavorably, indicating that the Applicant did not demonstrate that the benefits of insulin icodec outweigh the risks for improving glycemic control in adults with Type 1 diabetes.

On September 21, 2023, the committee discussed the safety and efficacy of ITCA 650 (exenatide in DUROS device), a drug-device combination product that is the subject of a new drug application (NDA) submitted by Intarcia Therapeutics, Inc. (Intarcia) (NDA 209053), for the proposed indication, as an adjunct to diet and exercise, to improve glycemic control in adults with type 2 diabetes mellitus. The meeting was held pursuant to a March 24, 2023, letter from the Chief Scientist of

FDA, Dr. Namandjé N. Bumpus, wherein she granted Intarcia's request under 21 CFR 12.32(b)(3)(ii) for a public hearing before an advisory committee in lieu of a formal evidentiary hearing. Intarcia requested a public hearing before an advisory committee on CDER's proposal to refuse approval of Intarcia's NDA for ITCA 650 (see Docket No. FDA-2021-N-0874). Unanimously, the committee voted "No" that based on the data shown, the Applicant failed to demonstrate that the benefits of the ITCA 650 drug-device combination product outweigh its risks for the treatment of type 2 diabetes mellitus.

On June 28, 2023, the committee discussed new drug application (NDA) 215559, for palovarotene capsules, submitted by Ipsen Biopharmaceuticals, Inc. The proposed indication is the prevention of heterotopic ossification in adults and children (females aged 8 years and above and males 10 years and above) with fibrodysplasia ossificans progressiva (FOP). The majority of the Committee voted "Yes" that palovarotene was shown effective in FOP patients and the clinical benefits outweigh its risks for the treatment of patients diagnosed with FOP.

Impact: On August 16, 2023, the Agency approved Sohonos™ (palovarotene) capsules for the reduction in volume of new heterotopic ossification in adults and pediatric patients aged 8 years and older for females and 10 years and older for males with fibrodysplasia ossificans progressiva (FOP). This is the first and only drug (retinoid) of its class to show reduction of abnormal bone growth in FOP patients, while improving mobility and quality of life.

All meetings don't conclude with favorable recommendations, as shown above. Members may require more studies to inform recommendations on the benefits and risks of the product. But patients benefit from this committee's review and evaluation of drug products for endocrine and metabolic disorders/diseases. Future topics on which FDA may seek input from this committee include the following: obesity disorders in pediatrics, glycemic management in type 1 diabetes mellitus, type 2 diabetes, and other related issues.

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 Endocrinologic and Metabolic 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 treatment of endocrine and metabolic disorders 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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