



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Advisory Committee; Dermatologic and Ophthalmic 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 Dermatologic and Ophthalmic 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 Dermatologic and Ophthalmic Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the October 7, 2028, expiration date.

DATES: Authority for the Dermatologic and Ophthalmic Drugs Advisory Committee will expire on October 7, 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, 21 CFR 14.40(b), and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Dermatologic and Ophthalmic 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 dermatologic and ophthalmic disorders and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of at least twelve voting members including two Chairpersons. Subject to legal and regulatory requirements, members and the Chairpersons are selected by and serve at the discretion of the Commissioner or designee. Each member, including the Chairpersons, will be selected from among authorities knowledgeable in the fields of dermatology, ophthalmology, dentistry, immunology, 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).

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 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/dermatologic-and-ophthalmic-drugs-advisory-committee/dermatologic-and-ophthalmic-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 Dermatologic and Ophthalmic 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 dermatologic and ophthalmic 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 annual budget for this committee is \$136,830

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 and supplies for meetings, is \$26,233

c. Proposed payments to members

The estimated payment to members is \$15,000

d. Proposed number of members

The anticipated number of members is twelve.

e. Reimbursable costs

The estimated annual reimbursable costs, including travel and related expenses for members, is \$32,069.

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 dermatologic and ophthalmic 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 dermatology, ophthalmology, dentistry, immunology, epidemiology or statistics, and related specialties, as well as needed consumer and industry representation. FDA also follows the requirements in section 505(n)(3) of the Federal Food, Drug, and Cosmetic Act 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

- 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
- 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 Electronic Product Radiation Safety Standards 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 Dermatologic and Ophthalmic 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 in the practice of dermatologic and ophthalmic disorders and related specialties.

The topics considered by the Dermatologic and Ophthalmic Drugs Advisory Committee require specialized expertise in the fields of dermatology, ophthalmology, dentistry, immunology, epidemiology or 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, the Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC) has held two advisory committee meetings on March 28-29, 2023, and January 9, 2023.

On March 28-29, 2023, the DODAC met jointly with the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee to discuss proposed changes to the iPLEDGE Risk Evaluation and Mitigation Strategy (REMS) requirements to minimize burden on patients, pharmacies, and prescribers while maintaining safe use of isotretinoin oral capsules for patients. The committee assembled was proposed with two voting questions: (1) whether the iPLEDGE

REMS should retain the 19-day lockout period requirement before patients can take an additional pregnancy test to be eligible to receive isotretinoin, and (2) when should the REMS require prescribers to document counseling for patients who cannot become pregnant in the iPLEDGE system. Respectively, majority of the members vote “No” (4 Yeses, 17 Noes, 1 Abstention) to a 19-day lockout period requirement before patients can take an additional pregnancy test to be eligible to receive isotretinoin, and 10 members favored the first option for REMS to require prescribers to document counseling patients who cannot become pregnant with the first prescription as part of patient enrollment. Regarding recommendations on the pregnancy registry requirement and ways in which it could be streamlined to encourage more participation to yield high-quality data, members agreed it is not necessary to continue to collect “follow-up data” (i.e., pregnancy and fetal outcome information) and that more effective communication and transparency are needed regarding how patients’ data will be used if they participate in the iPLEDGE Pregnancy Registry.

Impact: On February 6, 2026, the Agency approved modification to the iPLEDGE Risk Evaluation and Mitigation Strategy (REMS) to minimize burden on patients, prescribers, and pharmacies while maintaining the use of isotretinoin.

On January 9, 2023, the DODAC met to discuss supplemental biologics license application (sBLA) 125387, aflibercept solution for intravitreal injection, submitted by Regeneron Pharmaceuticals, Inc. The supplement was submitted in response to FDA’s pediatric written request. FDA’s written request was for studies of aflibercept in the treatment of retinopathy of prematurity. Two Discussion Questions were proposed to the panel: (1) Discuss how the studied use of aflibercept in the treatment of retinopathy of prematurity can best be communicated to physicians and the caregivers of these

premature infants, and (2) how it should be labeled in a real-world setting. Regarding the first speaking point, the committee acknowledged the benefits of using anti-vascular endothelial growth factor (anti-VEGF) for the treatment of retinopathy of prematurity (ROP), which is evident by the data shown and concluded that due to the general circumstances that the use of this product is made quickly in a neonatal intensive care unit, the instructions for administration must be clearly labeled in the package insert. The second discussion point, the Committee made recommendations on how the instructions should be centralized in the insert for easy a find, advised what would be classified as clear instructions for practitioners, appropriate dosing and safety precautions for pediatric use.

Impact: The FDA officially approved Eylea (aflibercept 0.4 mg) on February 8, 2023, as the first pharmacologic treatment for ROP in preterm infants – the first pediatric approval for this indication.

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 Dermatologic and Ophthalmic 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 dermatologic and ophthalmic 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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