Therefore, approval of the applications listed in Table 1, and all amendments and supplements thereto, is hereby withdrawn as of June 8, 2026. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from Table 1. Introduction or delivery for introduction into interstate commerce of products listed in Table 1 without an approved new drug application or ANDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in Table 1 that are in inventory on June 8, 2026 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–09012 Filed 5–6–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–0008]

Advisory Committee; Blood 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 Blood 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 Blood Products Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the May 13, 2028, expiration date.

DATES: Authority for the Blood Products Advisory Committee will expire on May 13, 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 Blood Products Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises and informs the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drug and biological products for human use, as well as, when required, any other product under the regulatory authority of FDA. The Committee reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood, products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases, and as required, any other products for which FDA has regulatory responsibility. The Committee also advises the Commissioner of Food and Drugs of its findings regarding screening and testing (to determine eligibility) of donors and labeling of the products, on clinical and laboratory studies involving such products, on the affirmation or revocation of biological products licenses. The Committee may consider the quality and relevance of FDA's research program, which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner.

The Committee will function at times as a medical device panel under the Federal Food, Drug, and Cosmetic Act Medical Device Amendments of 1976. As such, the Committee recommends classification of devices subject to its review into regulatory categories; recommends the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category; advises on formulation of product development protocols and reviews premarket approval applications for those devices to recommend changes in classification as appropriate; recommends exemption of certain devices from the application of portions of the Act; advises on the necessity to ban a device; and responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices.

The Committee shall consist of a core of at least thirteen 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 clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, biological and physical sciences, biotechnology, computer technology, statistics, epidemiology, sociology/ethics, and related specialties.

Members will be invited to serve for terms of up to four years, or for less time at the discretion of the Commissioner or designee. Non-Federal members of this committee will serve either 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 consultants 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/blood-vaccines-and-other-biologics/blood-products-advisory-committee* 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 Blood Products 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 blood products, 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 U.S.C. 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 U.S.C. 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 $131,660.

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

The estimated person years of Federal staff support required is 0.50 at an estimated cost of $76,713.

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 $26,452.

c. Proposed payments to members.

The estimated annual payment to members is $9,299.

d. Proposed number of members.

The anticipated number of members is 13.

e. Reimbursable costs.

The estimated annual reimbursable costs, including travel and related expenses for members, is $19,196.

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 safety, effectiveness, and appropriate use of blood, blood-derived products, and biotechnology products intended for the diagnosis, prevention, or treatment of human diseases, including donor screening and eligibility, product labeling, clinical and laboratory studies, and the approval or revocation of biological product licenses, as well as the quality and relevance of FDA's supporting research programs. 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 clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, biological and physical sciences, biotechnology, computer technology, statistics, epidemiology, sociology/ethics, and other related specialties, as well as needed consumer and industry representation. FDA also follows the requirements in section 505(n)(3) regarding membership of drug or biological product advisory committees. (21 U.S.C. 355(n)(3)). Because the BPAC will function at times as a medical device panel, FDA also considers the membership requirements in 21 U.S.C. 360(c).

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
- 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
- Obstetrics, Reproductive and Urologic Drug 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 Product Safety Standards AC
- Technical and Electronic Products Safety Standards Advisory Committee
- Tobacco 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 Blood Products Advisory Committee (BPAC) was established to review and evaluate available data concerning the safety, effectiveness, and appropriate use of blood, products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases, and make appropriate recommendations to the Commissioner of Food and Drugs. The Committee also advises the Commissioner of Food and Drugs of its findings regarding donor screening and testing, product labeling, clinical and laboratory studies involving such products, and the affirmation or revocation of biological product licenses.

No other FDA advisory committee is specifically focused on whole blood, blood components, plasma-derived products, and related biologics. These products raise unique scientific, technical, and public health issues involving donor eligibility and screening, transfusion-transmitted infectious disease risk, manufacturing controls, and clinical use that require the specialized expertise BPAC provides. At times, the Committee also functions as a medical device panel to address related device issues within its area of expertise.

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:

On May 9, 2024, the Committee met in open session to discuss strategies to reduce the risk of transfusion-transmitted malaria by testing blood donations from donors at risk of malaria exposure.

Agency Action: In January 2025, FDA issued a draft guidance for industry proposing a selective testing strategy to reduce the risk of transfusion-transmitted malaria (TTM). The draft guidance outlines testing strategies for blood donations that considers:

Testing donations from donors with a history of malaria.

- One-time testing of donors who resided in a malaria-endemic country.
- Testing donors who traveled to a malaria-endemic region in the past 12 months.
- Testing donations collected in U.S. regions identified by FDA as having local malaria transmission.

The guidance document for blood establishments is now in the public comment phase. The guidance reflects the scientific and operational considerations discussed at the committee meeting and is intended to help blood establishments reduce the risk of malaria transmission through tailored testing.

The committee is critical for the review and evaluation of data on the safety and effectiveness, and appropriate use of blood products intended for use in the diagnosis, prevention, or treatment of human diseases.

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 section 505(n)(1) and (s)(1) of the Federal Food, Drug, and Cosmetic Act by providing expert scientific advice and recommendations. The BPAC is the only FDA advisory committee that provides specialized expertise in whole blood, blood components, plasma-derived products, and related biologics. These products raise unique scientific, technical, and public health issues involving donor eligibility and screening, transfusion-transmitted infectious disease risk, manufacturing controls, and clinical use.

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.

[FR Doc. 2026–09108 Filed 5–6–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Criteria for Determining Maternity Care Health Professional Target Areas

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of final response.

SUMMARY: HRSA published a 30-day public notice in the **Federal Register** on February 3, 2026, (**Federal Register** volume 91, number 22, pp. 4927–4931) soliciting feedback on updated criteria for determining maternity care target areas (MCTA). In particular, HRSA requested feedback on proposed changes to the criteria and point scales for MCTAs by removing the criterion for Social Vulnerability Index (SVI) and reallocating its two points as follows: one point to population-to-full-time equivalent maternity care health professional ratio and one point to score for travel time/distance to the nearest source of accessible care outside of the MCTA. This notice responds to the comments received during this 30-day public notice period and sets forth updated MCTA scoring criteria.

DATES: The proposed update to Maternity Care Health Professional Target Areas will be implemented starting August 15, 2026.

FOR FURTHER INFORMATION CONTACT: Matthew Patterson, Senior Advisor, Division of Policy and Shortage Designation, Bureau of Health Workforce, HRSA, Mail Stop 15SWH03, 5600 Fishers Lane, Rockville, Maryland 20857, phone number: (301) 594–5110, or *sdb@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

Background

Section 332 of the Public Health Service (PHS) Act (42 U.S.C. 254e) provides that the Secretary of HHS designate Health Professional Shortage