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 Pulmonary-Allergy 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 pulmonary disease and diseases with allergic and/or immunologic mechanisms 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/AdvisoryCommittees/default.htm.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–10410 Filed 5–22–26; 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; Drug Safety and Risk Management 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 Drug Safety and Risk Management 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 Drug Safety and Risk Management Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the May 31, 2028, expiration date.

DATES: Authority for the Drug Safety and Risk Management Advisory Committee will expire on May 31, 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 Drug Safety and Risk Management 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(s) about the scientific and medical evaluation of information with regard to safety, efficacy, and abuse potential of drugs or other substances, and makes recommendations as appropriate.

The Committee reviews and evaluates information on risk management, risk communication, and quantitative evaluation of spontaneous reports for drugs for human use and for any other product for which the Food and Drug Administration has regulatory responsibility. The Committee also advises the Commissioner of Food and Drugs regarding the scientific and medical evaluation of information gathered by the Department of Health and Human Services and the Department of Justice with regard to safety, efficacy, and abuse potential of drugs or other substances, and makes recommendations as appropriate to be taken by the Department of Health and Human Services with regard to the marketing, investigation, and control of such drugs or other substances. 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 shall consist 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 risk communication, risk management, drug safety, medical, behavioral, and biological sciences as they apply to risk management, and drug abuse.

Members may 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 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/human-drug-advisory-committees/drug-safety-and-risk-management-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 Drug Safety and Risk Management Advisory Committee is in the public interest. This determination is based on the Committee's essential role in providing independent expert advice on risk management, risk communication, and quantitative evaluation of spontaneous reports for drugs for human use and for any other product for which the Food and Drug Administration has regulatory responsibility, 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 $130,550.00.

- Federal personnel on a full-time equivalent (FTE) basis: The estimated person years of Federal staff support required is 0.25 at an estimated annual cost of $50,875.00.
- 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 $17,269.00.
- Proposed payments to members: The estimated annual payment to members is $13,404.00.
- Proposed number of members: The anticipated number of members is 6.
- Reimbursable costs: The estimated annual reimbursable costs, including travel and related expenses for members is $42,300.00.

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 and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of risk communication, risk management, drug safety, medical, behavioral, and biological sciences as they apply to risk management, and drug abuse. Nominees should be acknowledged experts with demonstrated skills in critical evaluation of data and effective communication. 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. Scientific and technical competence is critical. 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
- 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
- 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 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 Committee advises and informs the Commissioner or designee(s) about the scientific and medical evaluation of information with regard to safety, efficacy, and abuse potential of drugs or other substances, and makes recommendations as appropriate.

The Committee reviews and evaluates information on risk management, risk communication, and quantitative evaluation of spontaneous reports for drugs for human use and for any other product for which the Food and Drug Administration has regulatory responsibility. The Committee also advises the Commissioner of Food and Drugs regarding the scientific and medical evaluation of information gathered by the Department of Health and Human Services (HHS) and the Department of Justice with regard to safety, efficacy, and abuse potential of drugs or other substances, and makes recommendations as appropriate to be taken by HHS with regard to the marketing, investigation, and control of such drugs or other substances.

The topics considered by DSaRM require specialized expertise in risk communication, risk management, drug safety, medical, behavioral, and biological sciences as they apply to risk management, and drug abuse. Potential topics that may need committee input in the near future include topics related to drug safety and efficacy, risk management and potential abuse. This Committee generally meets as a Joint meeting when other Committees are tasked to evaluate risk management associated with products relating to their disease states. There is no other committee within the Agency that can address these issues 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:*

For the last three years, DSaRM has co-led three joint advisory committee meetings with: Anesthetic and Analgesic Drug Products Advisory Committee, Psychopharmacologic Drugs Advisory Committee, and Dermatologic and Ophthalmic Drugs Advisory Committee.

On May 5, 2025, the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee met jointly to discuss the findings of the completed extended-release/long-acting opioid analgesic (ER/LA OA) postmarketing requirements (PMRs) 3033–1 and 3033–2 (*https://www.fda.gov/media/95546/download*). These PMRs are 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 PMRs 3033–1 and 3033–2 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.

Impact: After reviewing those results, public comments, medical research and recognizing the absence of adequate and well-controlled studies on long-term opioid effectiveness, the FDA decided to require safety labeling changes to help health care professionals and patients make treatment decisions influenced by the latest evidence shown in the May 2025 Advisory Committee meeting. The FDA implemented safety labeling requirements to all opioid pain medications to further extrapolate on the risks associated with their long-term use. Letters were sent to relevant applicants outlining the required changes: Clearer Risk Information, Dosing Warnings, Clarified Use Limits, Treatment Guidance, Safe Discontinuation, Overdose Reversal Agents, Drug Interactions, more Risk Information with Overdose (toxic leukoencephalopathy) and Digestive Health. The companies were given 30 days to submit their labeling updates for review.

On November 19, 2024, the Drug Safety and Risk Management Advisory Committee and the Psychopharmacologic Drugs Advisory Committee met jointly to discuss the reevaluation of the Clozapine Risk Evaluation and Mitigation Strategy (REMS) and possible changes to minimize burden on patients, pharmacies, and prescribers while maintaining safe use of clozapine. The issues the Committees discussed included whether clozapine healthcare providers have sufficient knowledge and access to resources about the risk of neutropenia and need for absolute neutrophil count (ANC) monitoring, and whether ANC monitoring would be performed without the requirements of the REMS. The Committees were in near unanimous agreement (14 Noes and 1 Yes) that the following REMS requirements are not necessary to ensure safe use of clozapine: documentation of ANC results by providers and verification of those results by pharmacies, and requirements for education of healthcare providers about the risk of severe neutropenia and need for ANC monitoring.

Impact: As of February 24, 2025, the Agency no longer expects prescribers, pharmacies, and patients to participate in the REMS program for clozapine or to report results of absolute neutrophil count (ANC) blood tests before pharmacies dispense clozapine. FDA still recommends that prescribers monitor patients' ANC according to the monitoring frequencies described in the prescribing information.

On March 28–29, 2023, the Drug Safety and Risk Management Advisory Committee met jointly with the Ophthalmic Drugs 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 majority of the members (4 Yeses, 17 Noes, 1 Abstention) voted ''No'' to the question as to 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. Regarding the vote question as to when should the REMS require prescribers to document counseling for patients who cannot become pregnant in the iPLEDGE system, ten (10) members voted that the REMS should only require prescribers to document counseling patients who cannot become pregnant with the first prescription as part of patient enrollment; one (1) member voted that the requirement should remain the same because there was no data to inform a change, six (6) members voted that the requirement should be switched to every 120 days with two of these members commenting they were comfortable with documentation only at treatment initiation, and five (5) members voted that the requirement should be changed to another frequency. 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 9, 2026, the FDA approved significant modifications to the iPLEDGE REMS for isotretinoin oral capsules for patients by reducing burden on patients, prescribers, and pharmacists, effective August 8, 2026. The groundbreaking changes include allowing at-home pregnancy test, removing the 19-day lockout/waiting period and reducing document requirements for patient counseling.

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

The Committee advises and informs the Commissioner of Food and Drugs and appropriate designee(s) about the scientific and medical evaluation of all information about safety, efficacy, and abuse potential of drugs or other substances, and recommends actions to be taken. The recommendations of this Committee will help FDA make informed decisions about the product(s) or issues under consideration. However, the FDA will retain full regulatory decision-making authority on the issues associated with the product/s or issues under consideration. The committee also 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 Drug Safety and Risk Management Advisory Committee, FDA's ability to obtain external expert input on issues related to safety, efficacy, and abuse potential of drugs or other substances 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 (5 U.S.C. app.). 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. 2026–10371 Filed 5–22–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–5128]

Agency Information Collection Activities; Proposed Collection; Comment Request; Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection relating to human drug compounding.

DATES: Either electronic or written comments on the collection of information must be submitted by July 27, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 27, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2026–N–5128 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

1. Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly