DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–0008]

Advisory Committee; Cardiovascular and Renal 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 Cardiovascular and Renal 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 Cardiovascular and Renal 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 Cardiovascular and Renal 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 Cardiovascular and Renal 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 cardiovascular and kidney diseases 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 cardiology, nephrology, 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/cardiovascular-and-renal-drugs-advisory-committee/cardiovascular-and-renal-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 Cardiovascular and Renal 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 cardiovascular and kidney diseases, 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 $80,651.

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 $18,529.

c. Proposed payments to members: The estimated annual payment to members is $4,468.

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 are $6,456.

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 cardiovascular and kidney diseases 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 cardiology, nephrology, 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 Cardiovascular and Renal 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 cardiovascular and kidney diseases.

The topics considered by the Cardiovascular and Renal Drugs Advisory Committee require specialized expertise in the fields of cardiology, nephrology, 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:

The Cardiovascular and Renal Drugs Advisory Committee convened twice during the last three years to discuss the drug safety and efficacy of two new drug applications that would impact the management of Barth Syndrome and cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis in adults. Both indications are rare life-threatening diseases that affect a small population. Both products (Forzinity and Onpattro) reviewed were found clinically beneficial to the populations studied and are currently approved for use. ForzinityTM was an ophan product seeking accelerated approval. ForzinityTM was approved on September 19, 2025; it is the first treatment for Barth's Syndrome.

Patients benefit from this committee's review and evaluation of cardiology, nephrology and related specialties. This Committee generally meets twice per fiscal year. There is no other committee within the Agency that can address related issues without diminishing the depth and relevance of the expert input provided to the Agency. Topics on which FDA may seek input from this committee include the following: IgA nephropathy, chronic kidney disease (CKD) across diverse patient populations, and difficult to manage (refractory and resistant) hypertension.

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 Cardiovascular and Renal 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 practice of cardiology and nephrology 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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Black Lung Clinics Program Performance Measures

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than September 21, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–9094.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Black Lung Clinics Program Performance Measures, OMB No. 0915–0292—Revision.

Abstract: The Black Lung Clinics Program (BLCP) is authorized under Sec. 427(a) of the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 937(a)) and accompanying regulations (42 CFR part 55a). The purpose of the BLCP is to reduce the morbidity and mortality associated with occupationally related coal mine dust lung disease through the screening, diagnosis, and treatment of active, inactive, retired, and/or disabled coal miners. HRSA currently collects information about BLCP awards using an OMB-approved set of performance measures and seeks to revise the approved collection. The proposed changes are a result of keeping this instrument relevant, responsive to the BLCP needs and to improve clarity and ease of reporting for respondents.

A 60-day notice published in the **Federal Register** on March 31, 2026, vol. 91, No. 61; pp. 16008–16009. There were no public comments.

Need and Proposed Use of the Information: HRSA has revised the performance measures which BLCP awardees will submit to HRSA on an annual basis. The purpose of the revised data collection is to assess BLCP awardees' progress toward meeting BLCP program goals (as stated in the authorizing statute) and how well each awardee is meeting the needs of these miners in their communities. The proposed changes include deleting five questions, adding three new questions, and changing three existing questions. These updates were made to streamline data collection and improve usability. Clinical diagnosis fields will be consolidated into a single datapoint, replacing separate fields for primary, secondary, and other diagnoses. The difference between these categories was often subjective, limiting HRSA's ability to use the data to monitor for black lung rates. Filling out three separate questions about diagnoses was also burdensome for clinics. Additionally, COVID-related data fields are removed due to decreased relevance, reducing the reporting burden on awardees. A new cardiology diagnosis field is added to better capture conditions closely linked to pulmonary disease and assist HRSA in tracking population needs and making relevant programmatic updates based on those needs. Benefits counseling measures are also enhanced to collect filing dates and case status details. This update will help HRSA track case timelines, which translates to better monitoring of implementation of benefits counseling services. These changes strengthen HRSA's monitoring and assessment of the impact of the BLCP program and ensure that funds are effectively used to provide services that meet the target population's needs. There is no change in the burden hours.

Likely Respondents: Respondents will be the BLCP award recipients.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.