

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for Office of Management and Budget Review; Community Services Block Grant (CSBG) Model Tribal Plan Applications (New Collection)**

**AGENCY:** Office of Community Services, Administration for Children and Families, U.S. Department of Health and Human Services.

**ACTION:** Request for public comments.

**SUMMARY:** The Office of Community Services (OCS), Administration for Children and Families (ACF), requests an approval of the Community Services Block Grant (CSBG) Model Tribal Plan.

**DATES:** *Comments due within 30 days of publication.* OMB must make a decision

about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

**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](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. You can also obtain copies of the proposed collection of information by emailing [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). Identify all emailed requests by the title of the information collection.

**SUPPLEMENTARY INFORMATION:**

*Description:* Section 677 of the CSBG Act requires Indian tribes or tribal organizations to submit an application and plan (CSBG Model Tribal Plan). The CSBG Model Tribal Plan must meet statutory requirements prior to OCS awarding CSBG tribal grant recipients with CSBG funds. Tribal grant recipients have the option to submit a detailed plan annually or biannually. Tribal grant recipients that submit a biannual plan must provide an abbreviated plan the following year if substantial changes to the initial plan will occur. The CSBG Model Tribal Plan has been used in previous years without OMB approval. To come into compliance with the PRA, ACF is submitting the CSBG Model Tribal Plan as a new request to OMB.

*Respondents:* Tribal grant recipients (tribes and tribal organizations)

**ANNUAL BURDEN ESTIMATES**

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
CSBG Model Tribal Plan .....	66	1	10	660

*Authority:* Sec. 677, Pub. L. 105–285, 112 Stat. 2742 (42 U.S.C. 9911).

Mary C. Jones,  
*ACF/OPRE Certifying Officer.*

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**BILLING CODE 4184–27–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2022–N–0622]

**Advisory Committee; Pulmonary-Allergy Drugs Advisory Committee; Renewal**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; renewal of Federal advisory committee.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the renewal of the Pulmonary-Allergy 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 Pulmonary-Allergy Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The

new charter will be in effect until the May 30, 2026, expiration date.

**DATES:** Authority for the Pulmonary-Allergy Drugs Advisory Committee will expire on May 30, 2026, unless the Commissioner formally determines that renewal is in the public interest.

**FOR FURTHER INFORMATION CONTACT:**

Takyiah Stevenson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 240–402–2507, [PADAC@fda.hhs.gov](mailto:PADAC@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 Pulmonary-Allergy 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 pulmonary disease and diseases with allergic and/or immunologic mechanisms and makes appropriate recommendations to the Commissioner of Food and Drugs.

Pursuant to its Charter, the Committee shall consist of a core of 11 voting members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of pulmonary medicine, allergy, clinical immunology, and epidemiology or statistics. Members will be invited to serve for overlapping terms of up to 4 years. 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. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting representative member who is identified with industry interests. There may also be an alternate industry representative.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) 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. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements.

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.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/advisory-committees/pulmonary-allergy-drugs-advisory-committee/pulmonary-allergy-advisory-committee-charter> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

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 <https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: July 24, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2024-N-3294]

#### Pediatric Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) announces a forthcoming public advisory committee meeting of the Pediatric Advisory Committee (PAC). The general function of the committee is to provide advice and recommendations to the FDA on pediatric regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

**DATES:** The meeting will be held virtually on September 18, 2024, from 10 a.m. to 4 p.m. Eastern Time.

**ADDRESSES:** All meeting participants will be joining this advisory committee meeting via an online platform and heard, viewed, captioned, and recorded via an online and/or video conferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2024-N-3294. The docket will close on September 17, 2024. Submit either electronic or written comments on this public meeting by September 17, 2024. 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 September 17, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or the delivery service acceptance receipt is before or on that date.

Comments received on or before September 9, 2024, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is canceled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

#### 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-2024-N-3294 for "Pediatric Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments." 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. EST, Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your