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.

[FR Doc. 2024–16629 Filed 7–26–24; 8:45 am]

BILLING CODE 4164–01–P

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

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.'' FDA 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 be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Shivana Srivastava, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5152, Silver Spring, MD 20993–0002, 301–796–8695, *shivana.srivastava@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On September 18, 2024, the PAC will meet to discuss post-marketing pediatric-focused safety reviews of the following products:

1. Center for Biologics Evaluation and Research
   a. AGRIFLU (influenza virus vaccine)
   b. CUTAQUIG (immune globulin subcutaneous (human)-hipp, 16.5%)
   c. XYNTHA (antihemophilic factor (recombinant), plasma/albumin Free)
2. Center for Drug Evaluation and Research
   a. AZSTARYS (serdexmethylphenidate/dexmethylphenidate)
   b. CAFCIT (caffeine citrate)
   c. CHANTIX (varenicline)
   d. CIMDUO, TEMIXYS (lamivudine/tenofovir disoproxil fumarate)
   e. CLEOCIN HYDROCHLORIDE (clindamycin hydrochloride), CLEOCIN PHOSPHATE (clindamycin phosphate), CLEOCIN PHOSPHATE IN DEXTROSE 5% IN PLASTIC CONTAINER (clindamycin phosphate), CLINDAMYCIN PHOSPHATE IN 0.9% SODIUM CHLORIDE (clindamycin phosphate)
   f. DYANAVEL XR (amphetamine)
   g. EVEKEO ODT (amphetamine sulfate)
   h. GATTEX (teduglutide)
   i. GILENYA (fingolimod) and TASCENSO ODT (fingolimod)
   j. JANUVIA (sitagliptin) and JANUMET (sitagliptin/metformin HCl), JANUMET XR (sitagliptin/metformin hydrochloride extended release)
   k. KAPSPARGO SPRINKLE (metoprolol succinate extended release)
   l. LITHIUM (lithium carbonate), (lithium oral solution)
   m. LOTEMAX (loteprednol etabonate)
   n. LUMASON (sulfur hexafluoride lipid-type A microspheres)
   o. MAVYRET (glecaprevir/pibrentasvir)
   p. MIRCERA (methoxy polyethylene glycol-epoetin beta)
   q. MULTRYS (trace elements), TRALEMENT (trace elements), ZINC SULFATE, SELENIOUS ACID
   r. MYDAYIS (mixed salts of a single-entity amphetamine)
   s. NATROBA (spinosad)
   t. PRADAXA (dabigatran etexilate)
   u. QELBREE (viloxazine extended-release)
   v. RIOMET ER (metformin hydrochloride extended-release)
   w. TEFLARO (ceftaroline fosamil)
   x. TIROSINT–SOL (levothyroxine sodium)
   y. TYBOST (cobicistat)
   z. ULTRAVATE (halobetasol propionate), LEXETTE (halobetasol propionate)
   aa. VEKLURY (remdesivir)
   bb. VYVANSE (lisdexamfetamine dimesylate)
   cc. XACIATO (clindamycin phosphate)
   dd. XEGLYZE (abametapir)
   ee. XELSTRYM (dextroamphetamine)
   ff. YERVOY (ipilimumab)
3. Center for Devices and Radiological Health
   a. CONTEGRA PULMONARY VALVED CONDUIT (Humanitarian Device Exemption (HDE))
   b. ENTERRA THERAPY SYSTEM (HDE)
   c. FLOURISH PEDIATRIC ESOPHAGEAL ATRESIA DEVICE (HDE)
   d. PLEXIMMUNE IN-VITRO DIAGNOSTIC TEST (HDE)
   e. PULSERIDER ANEURYSM NECK RECONSTRUCTION DEVICE (HDE)
   f. SONALLEVE MR–HIFU (HDE)

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website after the meeting. Background material and the link to the online meeting will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before September 9, 2024, will be provided to the committee. Written submissions may be made to the contact person on or before September 11, 2024. Oral presentations from the public will be scheduled between approximately 11 a.m. to 12 p.m. Eastern Standard Time on September 18, 2024. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time

requested to make their presentation on or before September 9, 2024. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 10, 2024.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Shivana Srivastava (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: July 24, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16618 Filed 7–26–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0846]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; National Agriculture and Food Defense Strategy Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by August 28, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://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. The OMB control number for this information collection is 0910–0855. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

National Agriculture and Food Defense Strategy Survey

OMB Control Number 0910–0855—Extension

We are seeking OMB approval of the National Agriculture and Food Defense Strategy (NAFDS) under section 108 of the Food Safety Modernization Act (FSMA). This is a voluntary survey of State, local, territorial, and/or tribal (SLTT) governments intended to gauge government activities in food and agriculture defense from intentional contamination and emerging threats. The collected information will be included in the mandatory NAFDS followup Report to Congress. The authority for us to collect the information derives from the Commissioner of Food and Drugs' authority provided in section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(C)).

Protecting the nation's food and agriculture supply against intentional contamination and other emerging threats is an important responsibility shared by SLTT governments as well as private sector partners. FSMA focuses on ensuring the safety of the U.S. food supply by shifting the efforts of Federal regulators from response to prevention and recognizes the importance of strengthening existing collaboration among all stakeholders to achieve common public health and security goals. FSMA identifies some key priorities for working with partners in areas such as reliance on Federal, State, and local agencies for inspections; improving foodborne illness surveillance; and leveraging and enhancing State and local food safety and defense capacities. Section 108 of FSMA–NAFDS requires HHS and the U.S. Department of Agriculture (USDA), in coordination with the Department of Homeland Security (DHS), to work together with SLTT to monitor and measure progress in food defense.

In 2015, the initial NAFDS Report to Congress detailed the specific Federal response to food and agriculture defense goals, objectives, key initiatives, and activities that HHS, USDA, DHS, and other stakeholders planned to accomplish to meet the objectives outlined in FSMA. The NAFDS charts a direction for how Federal agencies, in cooperation with SLTT governments and private sector partners, protect the nation's food supply against intentional contamination. Not later than 4 years after the initial NAFDS Report to Congress (2015), and every 4 years thereafter (*i.e.,* 2019, 2023, 2027, etc.), HHS, USDA, and DHS are required to revise and submit an updated report to the relevant committees of Congress.

FDA is the agency primarily responsible for obtaining the information from Federal and SLTT partners to complete the NAFDS Report to Congress. An interagency working group will conduct the survey and collect and update the NAFDS as directed by FSMA, including developing metrics and measuring progress for the evaluation process.

The survey of Federal and State partners will be used to determine what