

and 570 (21 CFR parts 170 and 570) for human food and animal food, respectively. Part 170, subpart E and part 570, subpart E provide a standard format for the submission of a notice. This collection utilizes a voluntary administrative procedure for notifying FDA about a conclusion that a substance is GRAS under the conditions of its intended use in human food or animal food. The information submitted to us in a GRAS notice is necessary to allow us to administer efficiently the FD&C Act's various provisions that apply to the use of substances added to food, specifically with regard to whether a substance is GRAS under the conditions of its intended use or is a food additive subject to premarket review. We use the information collected through the GRAS notification procedures to complete our evaluation within specific timelines.

To assist respondents with submissions to the Center for Food Safety and Applied Nutrition, we offer Form FDA 3667 entitled "Generally Recognized as Safe Notice" (<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM350015.pdf>). The form, and elements prepared as attachments to the form, may be submitted in electronic

format via the Electronic Submission Gateway (<https://www.fda.gov/industry/electronic-submissions-gateway>), or may be submitted in paper format, or as electronic files on physical media with paper signature page. While we do not expect Form FDA 3667 to reduce reporting time for respondents, use of the form helps to expedite our review of the information being submitted.

**Description of Respondents:** The respondents to this collection of information are manufacturers of substances used in human food and animal food and feed.

In the **Federal Register** of November 19, 2021 (86 FR 64945), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received one comment responsive to the four information collection topics solicited in the 60-day notice.

The comment offers that FDA underestimated the average burden per response for information collection activities related to animal food GRAS notices. It asserts that GRAS notices for animal food and feed require peer reviewed journal publications to support the safety of ingredients, rather than accepting additional ways to demonstrate general recognition of

safety of an ingredient for an intended use.

For any substance used in animal food to be GRAS under the conditions of its intended use, the data and information relied on to establish the safety of the use of the substance must be generally available, and that information can be in published scientific literature or other publicly available sources (e.g., textbooks, journal articles). While the notifier may conduct their own study and publish it in a peer reviewed journal, the information provided in a GRAS notice can include other generally available information (i.e., in the public domain). The notifier is not required to conduct de novo studies (and get that information published) in order to submit a GRAS notice. The regulations for human food GRAS notifications and animal food GRAS notifications are similar, thus the average burden provided for animal food GRAS notifications is therefore consistent with the estimates for GRAS notifications for human food. Therefore, the average burden hours for this collection remain unchanged.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
GRAS notification procedure for human food; 170.210–170.280 (part 170, subpart E) .....	100	1	100	170	17,000
GRAS notification procedure for animal food and animal feed; 570.210–570.280 (part 570, subpart E) .....	25	1	25	170	4,250
Total .....			125		21,250

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. This estimate is based on our experience with this information collection and the number of notifications received in the past 3 years, which has remained constant.

Dated: June 3, 2022.

**Lauren K. Roth,**

Associate Commissioner for Policy.

[FR Doc. 2022–12367 Filed 6–7–22; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2022–N–0691]

### Advisory Committee; Peripheral and Central Nervous System 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 Peripheral and Central Nervous System 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 Peripheral and Central Nervous System Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the June 4, 2024, expiration date.

**DATES:** Authority for the Peripheral and Central Nervous System Drugs Advisory Committee will expire on June 4, 2024, unless the Commissioner formally determines that renewal is in the public interest.

**FOR FURTHER INFORMATION CONTACT:** Jessica Seo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring,

MD 20993-0002, 301-796-7699, email: [PCNS@fda.hhs.gov](mailto:PCNS@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 Peripheral and Central Nervous System 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 data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of neurologic diseases.

The Committee shall consist of a core of nine voting members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of neurology, neuropharmacology, neuropathology, otolaryngology, epidemiology or statistics, and related specialties. 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, representatives or ex-officio members. Federal members will serve as Regular Government Employees or ex-officio members. 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.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/advisory-committees/peripheral-and-central-nervous-system-drugs-advisory-committee/peripheral-and-central-nervous-system-drugs-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 (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at <https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: June 3, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022-12368 Filed 6-7-22; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2021-M-0228, FDA-2021-M-0202, FDA-2021-M-0203, FDA-2021-M-0178, FDA-2021-M-0153, FDA-2021-M-0135, FDA-2021-M-0325, FDA-2021-M-0303, FDA-2021-M-0288, FDA-2021-M-0421, FDA-2021-M-0416, FDA-2021-M-0355, FDA-2021-M-0354, FDA-2021-M-0520, FDA-2021-M-0325, FDA-2021-M-0531, FDA-2021-M-0527, FDA-2021-M-0820, FDA-2021-M-0769, FDA-2021-M-0766, FDA-2021-M-0676, FDA-2021-M-0690, FDA-2021-M-0656, FDA-2021-M-0494, FDA-2021-M-0915, FDA-2021-M-0911, FDA-2021-M-0853, FDA-2021-M-0805, FDA-2021-M-1046, FDA-2021-M-1010, FDA-2021-M-0991, FDA-2021-M-0989, FDA-2021-M-0975, FDA-2021-M-0962, FDA-2021-M-1176, FDA-2021-M-1119, FDA-2021-M-1116, FDA-2021-M-0532, FDA-2021-M-1058, FDA-2021-M-1182, FDA-2021-M-1023, FDA-2021-M-1207, FDA-2021-M-1284, FDA-2021-M-1271, FDA-2021-M-1317, FDA-2021-M-1321, FDA-2021-M-1316, FDA-2021-M-1325, FDA-2021-M-1352, FDA-2022-M-0029, FDA-2022-M-0071, FDA-2022-M-0087, FDA-2022-M-0089, FDA-2022-M-0090, and FDA-2022-M-0171].

### Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is publishing a list of premarket approval applications (PMAs) that have been approved from January 1, 2021, through February 14, 2022. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the internet and the Agency's Dockets Management Staff. This is the last notice of this kind considering FDA's rule discontinuing the practice of publishing such summaries in the **Federal Register**. As

indicated in that rule, FDA will continue to publish to make available on the internet and place on public display summaries of safety and effectiveness for approved PMAs.

**ADDRESSES:** 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 Nos. FDA-2021-M-0228, FDA-2021-M-0202, FDA-2021-M-0203, FDA-2021-M-0178, FDA-2021-M-0153, FDA-2021-M-0135, FDA-2021-M-0325, FDA-2021-M-0303, FDA-2021-M-0288, FDA-2021-M-0421, FDA-2021-M-0416, FDA-2021-M-0355, FDA-2021-M-0354, FDA-2021-M-0520, FDA-2021-M-0615, FDA-2021-M-0531, FDA-2021-M-0527, FDA-2021-M-0820, FDA-2021-M-0769, FDA-2021-M-0766, FDA-2021-M-0676, FDA-