TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§§ 514.1 and 514.6; applications and amended applications.	187	0.07	13	212	2,756
§§ 514.1(b)(8) and 514.8(c)(1); [2] evidence to establish safety and effectiveness.	187	0.44	82	90	7,380
§ 514.5(b), (d), and (f); requesting presubmission conferences.	187	0.67	125	50	6,250
§ 514.8(b); manufacturing changes to an approved application.	187	2	374	35	13,090
§ 514.8(c)(1); labeling and other changes to an approved application.	187	0.06	11	71	781
§ 514.8(c)(2) and (3); labeling and other changes to an approved application.	187	0.84	157	20	3,140
§ 514.11; submission of data studies and other information.	187	0.13	24	1	24
§ 558.5(i); requirements for liquid medicated feed	187	0.01	2	5	10
Applications for conditional approval submitted under section 571 of the FD&C Act.	1	1	1	1	1
Form FDA 356V	187	36.5	6,825	0.75 (45 minutes)	5,118
VMF submissions	15	1	15	20	300
Total			7,628		38,849

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] NADAs and supplements regarding antimicrobial animal drugs that use a recommended approach to assessing antimicrobial concerns as part of the overall preapproval safety evaluation.

Although we have characterized the information collection activity as a reporting burden, we include in our estimate time required for searching data sources, and preparing and maintaining necessary and applicable records. As stated above, although we receive fewer than one submission annually when averaged over a 3-year period, we attribute one response and 1 hour annually to account for CNADA submissions.

We have adjusted our estimate of the information collection to reflect a decrease in burden associated with application submissions in acknowledgement of respondents' preference in using FDA's ''eSubmitter'' system, which automatically generates Form FDA 356v and allows respondents to complete the form and submit applications and associated information electronically.

Dated: June 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–12355 Filed 6–7–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1192]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substances Generally Recognized as Safe: Notification Procedure

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 July 8, 2022.

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 0910–0342. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *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.

Substances Generally Recognized as Safe: Notification Procedure—21 CFR Part 170, Subpart E and 21 CFR Part 570, Subpart E

OMB Control Number 0910–0342—Extension

The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that all food additives (as defined by section 201(s) (21 U.S.C. 321(s)) be approved by FDA before they are marketed. Section 409 of the FD&C Act (21 U.S.C. 348) establishes a premarket approval requirement for ''food additives.'' Section 201(s) of the FD&C Act provides an exclusion to the definition of food additive and, thus, from the premarket approval requirement for uses of substances that are generally recognized as safe (GRAS) by qualified experts. The GRAS provision of section 201(s) of the FD&C Act is implemented in parts 170

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 [1]

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

[1] 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]

BILLING CODE 4164–01–P

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,