TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Tobacco Health Document Submissions and Form FDA 3743	10	3.2	32	50	1,600

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that a tobacco health document submission as required by section 904(a)(4) of the FD&C Act, will take approximately 50 hours per submission based on FDA experience. We anticipate documents will be submitted annually for a total of 10 respondents. FDA estimates the total annual reporting burden to be 1,600 hours.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: June 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11955 Filed 6–26–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0123]

Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Generally Recognized as Safe: Notifications and Convening Panels

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collections of information associated with provisions of the notification procedure for substances generally recognized as safe (GRAS) and with recommended activities found in the guidance for convening a GRAS panel.

DATES: Either electronic or written comments on the collection of information must be submitted by August 26, 2025.

ADDRESSES: You may submit comments as follows. 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 August 26, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2025–N–0123 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Generally Recognized as Safe: Notifications and Convening Panels.'' 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., 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.'' The Agency 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 to 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 this 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: 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: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Substances Generally Recognized as Safe: Notifications and Convening Panels—21 CFR 170, Subpart E and 21 CFR 570, Subpart E

OMB Control Number 0910–0342—Revision

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 GRAS by qualified experts. The GRAS provision of section 201(s) of the FD&C Act is implemented in 21 CFR part 170 (part 170) and 21 CFR part 570 (part 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 an administrative procedure for a proponent to notify 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 by a proponent is necessary to allow us to administer efficiently the various FD&C Act 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 support a GRAS conclusion, a proponent may convene a panel of qualified experts to provide evidence that generally available safety data and information about the intended use of the substance in food are generally accepted among experts, which is one of the criteria for eligibility for GRAS status (81 FR 54960 at 54975; August 17, 2016). FDA issued a guidance entitled ''Best Practices for Convening a Generally Recognized as Safe Panel'' (December, 2022) (*https://www.fda.gov/media/109006/download*) to assist persons who choose to convene a panel of experts in support of a conclusion that the use of a substance in food is GRAS. The guidance recommends specific content elements pertaining to recordkeeping and third-party disclosure. The guidance explains a recordkeeping recommendation for proponents to develop a written GRAS panel policy record describing how it will convene a panel. The proponent creates the written policy to fit its needs. The guidance discusses a third-party disclosure recommendation for prospective panel members to provide vetting information to proponents, to ascertain expertise, and reduce risk of bias. The guidance also explains a recordkeeping recommendation for proponents to document the application of the GRAS panel policy to each GRAS panel member as part of the vetting process. Respondents do not submit to FDA the recordkeeping or third-party disclosure information. The collections of information in the guidance are currently approved under OMB control number 0910–0911. Upon approval of the requested revision, we plan to discontinue OMB control number 0910–0911.

To assist respondents with submissions to the Human Foods Program, we offer Form FDA 3667 entitled ''Generally Recognized as Safe Notice'' (*https://www.fda.gov/media/85886/download*). The form, and elements prepared as attachments to the form, may be submitted in electronic format via the Centralized Online Submission Module (*https://www.fda.gov/food/registration-food-facilities-and-other-submissions/centralized-online-submission-module-cosm*), 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. For submissions to the Center for Veterinary Medicine, respondents may continue to send GRAS notices in paper format, or as electronic files on physical media with paper signature page to the Agency, as instructed in the **Federal Register** of June 4, 2010 (75 FR 31800).

Description of Respondents: The respondents to this collection of information are manufacturers of substances used in human food and animal food and feed. Respondents also include persons (''proponents'') who are responsible for a conclusion that a substance may be used in food on the basis of the GRAS provision of the FD&C Act when such persons convene a GRAS panel to evaluate whether the available scientific data, information, and methods establish that the substance is safe under the conditions of its intended use in human food or animal food. Respondents would also include members and prospective members of GRAS panels. The term ''GRAS panel'' is defined as a panel of individuals convened for the purpose of

evaluating whether the available scientific data, information, and methods establish that a substance is safe under the conditions of its intended use in food.

FDA estimates 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)	12	1	12	170	2,040
Total			125		19,040

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In row 2 of table 1, we are decreasing our estimate for the number of respondents submitting GRAS notices for animal food and animal feed from 25 to 12, which results in a decrease of 2,210 burden hours (4,250 hours minus 2,040 hours). This estimate is based on the number of submissions we received over the last 3 years.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity; guidance document section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Maintaining written GRAS panel policy; V. Recommendations	696	1	696	2	1,392
Application of written GRAS panel policy to GRAS panel members; V. Recommendations	94	6	564	16	9,024
Total			1,260		10,416

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Row 1 of table 2 reflects a decrease of the average burden per recordkeeping as compared to the corresponding estimate under OMB control number 0910–0911, which decreased from 40 hours to 2 hours per recordkeeping. When we issued the guidance for convening a GRAS panel, we estimated that a proponent would take 40 hours to create and establish a written GRAS panel policy. We presume that proponents will have now established their written GRAS panel policy and only needs to maintain it, which we estimate will take 2 hours for each proponent.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity; guidance document section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Potential GRAS panel members provide information to the proponents of GRAS conclusions; V. Recommendations	564	1	564	4	2,256

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We are revising the information collection to include related activities associated with the guidance for convening a GRAS panel, currently approved under OMB control number 0910–0911, ''Substances Generally Recognized as Safe: Best Practices for Convening a GRAS Panel.'' The revision will add 10,462 hours and 1,824 responses. This estimate is based on our experience with this information collection and the number of notifications received in the past 3 years.

Dated: June 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11960 Filed 6–26–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Purchased/Referred Care Delivery Area Re-Designation for the Chippewa Cree Tribe of the Rocky Boy's Reservation

AGENCY: Indian Health Service, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Indian Health Service (IHS) has decided to expand the geographic