UNITED STATES FOOD AND DRUG ADMINISTRATION

Generally Recognized as Safe (GRAS) Notices

OMB Control No. 0910-0342 - Revision

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection helps support implementation of statutory requirements that govern food additives. 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 the Food and Drug Administration (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 are set forth in 21 CFR part 170 for human food and 21 CFR part 570 for animal food. 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 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 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.

Food additives that are not determined to be GRAS must obtain premarket approval. The clarified criteria for GRAS status helps stakeholders draw more informed conclusions about whether the intended conditions of use of a substance in food for humans or animals complies with the FD&C Act, and the notification procedure enables stakeholders to be aware of whether we have questioned the basis of a conclusion of GRAS status.

As set forth in the regulations, a GRAS notice must include the following:

- signed statements and a certification;
- the identity, method of manufacture, specifications, and physical or technical effect of the notified substance;
- dietary exposure to the notified substance;
- self-limiting levels of use in circumstances where the amount of the notified substance that can be added to human food or animal food is limited because the food containing levels of the notified substance above a particular level would become unpalatable or technologically impractical;

- the history of consumption of the substance for food use by a significant number of consumers (or animals in the case of animal food) prior to January 1, 1958, if a conclusion of GRAS status is based on common use of the substance in food prior to 1958;
- a narrative that provides the basis for the notifier's conclusion of GRAS status, including why the scientific data, information, methods, and principles described in the notice provide a basis for the conclusion that the notified substance is generally recognized, among qualified experts, to be safe under the conditions of its intended use; and
- a list of the generally available data, information, and methods the notifier cites in the GRAS notice.

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 recommends proponents document the application of the GRAS panel policy to each GRAS panel member as part of the vetting process, although 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 (HFP), we offer Form FDA 3667 entitled, "*Generally Recognized as Safe (GRAS) 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 (COSM) (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 (CVM), respondents may continue to send GRAS notices in paper format, or as electronic files on physical media with paper signature page to FDA, as instructed in the *Federal Register* of June 4, 2010 (75 FR 31800).

We therefore request OMB approval for the information collection provisions found in parts 170 and 570 of our regulations; Form FDA 3667; and the associated guidance, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

We use the information collected through the GRAS notification procedures to complete our evaluation within specific timelines. The information submitted to FDA 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 regarding whether a substance is GRAS under the conditions of its intended use or is a food additive subject to premarket review.

The associated guidance assists respondents convening a GRAS panel. The information collection recommendations (establishment of a written GRAS panel policy, solicitation of information from prospective GRAS panel members about potential conflicts of interest and other sources of bias, and documentation of the application of the GRAS panel policy to each GRAS panel member) helps respondents to identify GRAS panel members who have appropriate and balanced expertise and reduce the risk that bias (or the appearance of bias) will affect the credibility of the GRAS panel's output.

Description of Respondents: Respondents to the collection of information are manufacturers of substances used in human food and animal food. 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 are from the private sector (for-profit businesses). 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.

3. Use of Improved Information Technology and Burden Reduction

The form, and elements prepared as attachments to the form, may be submitted in electronic format via COSM (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.

We acknowledge that technology may not be available to every notifier and, thus, do not require the submission of an electronic copy. Instead, a notifier may submit a GRAS notice either in an electronic format that is accessible for our evaluation or

on paper (for HFP, see § 170.210; for the CVM, see § 570.210). Based on our review of past GRAS submissions, we estimate 70% of submissions will be made electronically, while 30% will continue to be submitted on paper.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. Under the Meat and Poultry Inspection Acts, the United States Department of Agriculture's Food Safety and Inspection Service (USDA/FSIS) has regulatory authority for meat and poultry. FDA and USDA have signed a Memorandum of Understanding that provides for a coordinated evaluation process with FSIS when the intended conditions of use of a notified substance include use in a product or products subject to regulation by USDA under statutes that it administers (75 FR 81536 at 81541-81542).

5. Impact on Small Businesses or Other Small Entities

We estimate ten percent (10%) of respondents are small businesses; however, the regulations do not pose an undue burden on small entities. We assist small businesses in complying with our requirements through Regional Small Business Representatives and through scientific and administrative staffs within the agency. Assistance is also available for small businesses via the agency's website at https://www.fda.gov/industry/small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

GRAS notifications are submitted only once and enable us to determine whether the 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 procedure to complete our evaluation within the timelines specified in the regulations associated with parts 170 and 570.

Regarding convening GRAS panels, data collection occurs intermittently, which includes a one-time collection of creating a written GRAS panel policy. A firm or other GRAS proponent that decides to follow the recommendations in the guidance would create a written GRAS panel policy, gather information from prospective members of each GRAS panel the proponent convenes, and then keep records of the application of the policy to each GRAS panel. If the collection is not conducted or is conducted less frequently, GRAS conclusions may lack evidence indicating the GRAS panel had appropriate, balanced expertise and was free of bias (or the appearance of bias) that could affect the credibility of the GRAS panel's output.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The information collection requirements are consistent with 5 CFR 1320.5, excepting indefinite extended retention of GRAS notification records. We believe this extended retention period is necessary because, under the regulations, notifiers submit a summary of information that provides the basis for a conclusion of GRAS status rather than the information itself. Although the regulations in 21 CFR parts 170 and 570 do not specify any timeframe to retain the data and information that supports the conclusion of GRAS status, preservation of the data and information that are the basis for the conclusion of GRAS status represents prudent practice for those who claim an exclusion from a statutory requirement regardless of whether the person subsequently notifies FDA.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), we published a 60-day notice for public comment in the *Federal Register* of June 27, 2025 (90 FR 27642). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In accordance with our public information regulations in 21 CFR 20.85 (Disclosure to other Federal government departments and agencies), we can share confidential commercial information with another Federal agency pursuant to a written agreement that the record will not be further disclosed. The MOU between FDA and USDA's FSIS provides for FDA to share with FSIS confidential commercial information in a submission such as a GRAS notice. We generally cannot share trade secret information with other Federal agencies under section 301(j) of the FD&C Act (21 U.S.C. 331(j)), and therefore we would need the notifier's authorization to share this information with FSIS.

For efficiency in administering the coordinated evaluation of a GRAS notice with FSIS, we have added a requirement for a notifier who submits a GRAS notice that we would send to FSIS to include in Part 1 of the GRAS notice a statement as to whether the notifier: (1) Authorizes us to send any trade secrets to FSIS; or (2) asks us to exclude any trade secrets from the copy of the GRAS notice that we will send to FSIS (see § 170.225(c)(11)). Under the provisions that make the coordinated evaluation of a GRAS notice with FSIS explicit, we will exclude any trade secrets unless the notifier has authorized us to send trade secret information to FSIS (see § 170.270). These provisions enable us, with the notifier's authorization, to share a GRAS notice that includes trade secret information with FSIS without first redacting the GRAS notice to remove the trade secret information and, thus, will reduce the time it takes for us to provide FSIS with a copy of the GRAS notice.

These provisions also clarify the notifier's expectations regarding whether we should share trade secret information with FSIS and, thus, require us to redact the trade secret information from the copy we send to FSIS when consistent with the notifier's express wishes.

Privacy Act

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

Related to this information collection request (ICR), the Food Applications Regulatory Management (FARM) System stores information submitted by industry for GRAS submissions. Appian Tempo is the software product used to manage and track the safety review processes performed by the Office of Food Chemical Safety, Dietary Supplements, and Innovation (OFCSDSI)/Office of Premarket Additive Safety (OPMAS). FARM receives industry submissions by paper, or electronic media (CD-ROM or DVD) or electronically through the FDA Electronic Submissions Gateway (ESG), or the Centralized Online Submission Module (COSM) (the subject of a separate assessment). Submitters provide their contact information as a practical requirement in order to communicate with FDA. The submissions may contain personally identifiable information (PII), which may include name of notifier (industry and/or citizen points of contact (POCs)) or its agent, and/or email address, mailing address, and/or phone number. PII is not shared with any other organization.

This ICR collects PII. PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted via Form FDA 3667 (Generally Recognized as Safe (GRAS) Notice) is name, phone number, mailing address, email address, and fax number. FDA determined that although PII is collected, it is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Freedom of Information Act

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

This information collection does not involve any questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden[1]

Activity; 21 CFR Section	No. of Respondents	No. 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			112		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	No. Of Recordkeepers	No. 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 in our estimate of the average burden per recordkeeping from 40 hours to 2 hours annually. We believe that respondents will have realized burden associated with the initial documentation of written GRAS panel policies and have modified our estimate to reflect burden associated with maintaining the applicable records

Table 3.--Estimated Annual Third-Party Disclosure Burden[1]

Activity; Guidance Document Section	No. of Respondents	No. 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 have made no change in our estimate associated with the disclosure recommendations discussed in the guidance document.

12b. Annualized Cost Burden Estimate

Regarding GRAS notice submissions, we estimate the annualized burden hour cost to respondents to be $1,262,924. We estimate the average wage for an operations manager to be the equivalent of a Federal government employee at the GS-11/Step 4 rate for the Washington-Baltimore locality pay area for the year 2025, which is $44.59/hour. We also estimate the average wage rate for clerical staff to be the equivalent of a Federal government employee at the GS-4/Step 4 level for the Washington-Baltimore locality pay area for the year 2025, which is $21.74/hour. To account for overhead, both salaries will be doubled (i.e., $89.18/hour for operations managers and $43.48/hour for clerical staff). In addition, we estimate that the effort to prepare and submit a GRAS notification will be split evenly between managers and clerical staff.

Regarding the information collection related to convening GRAS panels, we estimate the annualized burden hour cost to respondents to be $2,199,680. We estimate the average wage for a proponent to be the equivalent of a Federal government employee at the GS-15/Step 4 rate for the Washington-Baltimore locality pay area for the year 2025, which is $88.34/hour. We also estimate the average wage rate for a potential GRAS panel member to be the equivalent of a Federal government employee at the GS-14/Step 6 level for the Washington-Baltimore locality

pay area for the year 2025, which is $79.65/hour. To account for overhead, both wages are doubled (i.e., $176.68/hour for proponents and $159.30/hour for potential GRAS panel members).

Therefore, the total cost of this collection of information to respondents is estimated to be $3,462,604, which is listed in Table 4 below.

Table 4.--Estimated Annual Cost Burden

Activity; 21 CFR Section or Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
GRAS notification procedure for human food; 170.210 through 170.270 (managers)	8,500	$89.18	$758,030
GRAS notification procedure for human food; 170.210 through 170.270 (clerical)	8,500	$43.48	$369,580
GRAS notification procedure for animal food; 570.210 through 570.270 (managers)	1,020	$89.18	$90,964
GRAS notification procedure for animal food; 570.210 through 570.270 (clerical)	1,020	$43.48	$44,350
Recordkeeping for maintaining and applying GRAS written policy; proponent	10,416	$176.68	$1,840,299
Submission of information to proponents; potential GRAS panel members	2,256	$159.30	$359,381
Total			$3,462,604

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

We estimate it will take 4 full-time equivalent positions (FTEs) to process a GRAS notification for human food. Due to the smaller number of notices anticipated for animal food, only 3 FTEs are expected to be devoted to processing notices for animal food. Based on an average cost of $223,086 per fully supported position ($111,543 for a GS-12/Step 4 for the Washington-Baltimore locality pay area in 2025 increased by 100 percent to account for overhead), the cost of processing GRAS notifications would be $1,561,602 per year ($223,086 × 7 FTEs).

15. Explanation for Program Changes or Adjustments

The information collection reflects changes and adjustments. We have consolidated activity attributable to our *Best Practices for Convening GRAS Panels* guidance while at the same time correcting an inadvertent calculation error in our summary burden table. The result is an increase of 1,811 responses and 10,462 hours, annually. We plan to discontinue OMB control number 0910-0911 upon approval of this request.

16. Plans for Tabulation and Publication and Project Time Schedule

We will make the following readily accessible to the public: (1) A list of filed GRAS notices, including the information described in certain of the signed statements that are included in Part 1 of a GRAS notice (i.e., § 170.225(c)(2) through (c)(5)); and (2) The text of any letter that we issue under § 170.265(b)(1) (our response to a GRAS notice based on our evaluation of the notice), § 170.265(b)(3) (a letter if we grant a request that we cease to evaluate a GRAS notice), or § 170.265(c) (a subsequent letter that we send about a GRAS notice). (See § 170.275(b).) We are not specifying that the mechanism for us to do so is through an "Inventory" because the procedure we use to make this information readily accessible to the public evolved over time and may continue to evolve.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Display of OMB expiration date is appropriate. We will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.