UNITED STATES FOOD AND DRUG ADMINISTRATION

Substances Generally Recognized as Safe (GRAS) Notification Procedures

OMB Control No. 0910-0342

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports agency regulations. 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, or we) 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 (21 U.S.C. 321(s)) provides an exclusion to the definition of "*food additive*," and thus from the premarket approval requirement, for uses of substances that are generally regarded as safe (GRAS) by qualified experts.

The GRAS provision of section 201(s) of the FD&C Act is implemented in 21 CFR part 170 for human food and 21 CFR part 570 for animal food. The regulations clarify the criteria when the use of a substance in food for humans or animals is not subject to the premarket approval requirements of the FD&C Act because the substance is GRAS under the conditions of its intended use. Part 170, subpart E and part 570, subpart E provide a standard format for the submission of a notice. This collection utilizes a voluntary procedure for notifying FDA about a conclusion that a substance is GRAS under the conditions of its intended use in human and 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. 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 assist respondents with the information collection we developed Form FDA 3667 entitled, "*Generally Recognized as Safe (GRAS) Notice*," which provides a standardized format for submitting the required information. We therefore request extension of OMB approval for the information collection provisions found in parts 170 and 570 of our regulations; Form FDA 3667, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

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 regarding whether a substance is GRAS under the conditions of its intended use or is a food additive subject to premarket review.

Description of Respondents: Respondents to the collection of information are manufacturers of substances used in human food and animal food and feed.

3. Use of Improved Information Technology and Burden Reduction

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 (see § 170.210(b)). Based on our review of past GRAS submissions, we estimate 70% of submissions will be made electronically, while 30% will continue to be submitted in letter format.

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. Our Regional Small Business Representatives assist small businesses in complying with FDA requirements. We also provide a Small Business Guide on our website at http://www.fda.gov/oc/industry/.

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 will 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.

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 part 170 and 21 CFR part 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 March 12, 2019 (84 FR 8876). No comments were received.

In the 60-day notice, an error in the burden hour calculation was made. We indicated in the notice that our burden was expected to increase by 8,500 hours due to a projected increase in the estimated number of GRAS submissions for human food. However, we did not indicate that we also expected a decrease of 46,725 one-time burden hours. This omission is explained in Item 15 of this supporting statement.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts are made to respondents.

10. Assurance of Confidentiality Provided to Respondents

In accordance with our public information regulations in § 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 amended MOU between FDA and USDA's FSIS now 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 will 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 will 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.

Information submitted to FDA in a GRAS notice may contain trade secret and commercial confidential information. As a result, all files are maintained in a secured area. Form FDA 3667, its instructions, and related guidance, provide instructions for assisting FDA with protecting confidential information. A notifier may choose to provide a redacted copy of the GRAS notice, identifying that information that the submitter views as trade secret or as confidential commercial or financial information.

Only information that is releasable under the agency's regulations in 21 CFR part 20 would be released to the public. This information is also safeguarded by Section 301(j) of the FD&C Act and would be protected from disclosure under FOIA under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)).

Privacy Act

This ICR request does not contain any personally identifiable information and does include a form; however, the form does not include information that requires a Privacy Act Statement under section 5 U.S.C. § 552a(e)(3).

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 Costs

12a. Annualized Hour Burden Estimate

Reporting

Table 1 shows the estimated annual reporting burden associated with the information collection. The petition process was replaced with a GRAS notification procedure. The level of effort required by a firm to reach a conclusion that a substance is GRAS for its intended use remains unchanged. However, it is required that firms submit some additional information to support the conclusions found within their notices. The additional information might include an amendment (§§ 170.260 and 570.260); a supplement (§§ 170.280 and 570.280); a request for FDA to cease to evaluate a GRAS notice (§§ 170.260 and 570.260); an incorporation into a GRAS notice (§§ 170.215 and 570.215); and, information required when the intended conditions of use of a notified substance includes use in a product subject to regulation by FSIS, including authorization to us to share any trade secrets with FSIS (§ 170.270). Because the amount of additional information may vary, we estimate that respondents will spend approximately 170 hours to prepare and submit each notice. Using 170 hours, we therefore estimate that the 100 notifiers for human food and 25 notifiers for animal food will expend 21,250 hours annually as shown, respectively, in rows 1 and 2.

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 through 170.270	100	1	100	170	17,000
GRAS notification procedure for animal food; 570.210 through 570.270	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.

Recordkeeping

This information collection also contains recordkeeping requirements. We believe that documentation used by respondents in support of a conclusion of GRAS status is information that is collected and retained as a part of usual and customary business practices for a firm engaged in the manufacture of substances used in human food and animal food. While we do not specify a timeframe to retain the data and information that support 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. Accordingly, no estimated burden is provided for these activities.

12b. Annualized Cost Burden Estimate

We estimate the annualized burden hour cost to respondents for this collection of information to be $1,164,800. 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 2019, which is $36.68/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 2019, which is $17.88/hour. To account for overhead, both salaries will be doubled (e.g., $73.36/hour for operations managers and $35.76/hour for clerical staff.) In addition, we estimate that the effort to process a GRAS application will be split evenly, 50% for managers and 50% for clerical staff. Therefore, the total cost of this collection of information to the public is estimated to be $1,159,400, which is the total annual cost of processing human and animal GRAS applications and is listed in table 2 below.

Table 2 – Estimated Annual Reporting Cost

Activity/Sections	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
GRAS notification procedure for human food; 170.210 through 170.270 (managers)	8,500	$73.36	$623,560.00
GRAS notification procedure for human food;170.210 through 170.270 (clerical)	8,500	$35.76	$303,960.00
GRAS notification procedure for animal food; 570.210 through 570.270 (managers)	2,125	$73.36	$155,890.00
GRAS notification procedure for animal food; 570.210 through 570.270 (clerical)	2,125	$35.76	$75,990.00
Total			$1,159,400

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/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 (FTE's) to the GRAS notification procedure for human foods. Due to the smaller number of notices anticipated for animal food, only 3 FTE are expected to be devoted to processing the notices submitted to CVM. Based on an average cost of $183,480 per fully supported position ($91,740 for GS 12 Step 4 in 2019 increased by 100 percent to account for overhead), the cost of processing GRAS notifications would be $1,284,360 per year ($183,480 x 7).

15. Explanation for Program Changes or Adjustments

This information collection reflects adjustments. We have removed one-time burden previously included and attributed to rulemaking because we believe respondents have realized burden associated with review of the new requirements. At the same time, we have received an increase in submissions since last OMB review. Cumulatively these changes result in an overall reduction to the collection by 475 responses and 38,225 burden hours. We have also uploaded cost information that, although previously included, had not been reflected at www.reginfo.gov.

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 used 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.