United States Food and Drug Administration

Substances Generally Recognized as Safe (GRAS): Notification Procedures

OMB Control No. 0910-0342
RIN 0910-AJ02

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports agency rulemaking. 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 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 21 CFR part 170 for human food and 21 CFR part 570 for animal food. The provisions include an administrative procedure for a person to voluntarily notify FDA about a conclusion that a substance is GRAS under the conditions of its intended use in food for humans or animals.

The proposed rule, if finalized, would amend our regulations in parts 170 and 570 to require the submission of GRAS notices for the use of a human or animal food substance that is purported to be GRAS under the conditions of its intended use under section 201(s) of the FD&C Act. This proposed rule would require any person introducing a substance into interstate commerce under the GRAS provision of section 201(s) of the FD&C Act to notify FDA of the basis for their conclusion that the substance is GRAS under the conditions of its intended use unless an exception to the mandatory requirement to submit a GRAS notice applies. In short, the proposed rule would convert the voluntary GRAS notification program to a mandatory GRAS notification program. The proposed rule, if finalized, would, among other things, change the voluntary procedure to a requirement for notifying FDA about a conclusion that a substance is GRAS under the conditions of its intended use in human or animal food.

A GRAS notice will include the following information:

- 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 (and human exposures when used in food for food-producing animals);
- 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.

The proposed rule would establish certain exceptions to the requirement to submit a GRAS notice including a time-limited option to make a streamlined submission to FDA for certain substances already in interstate commerce instead of initially submitting a GRAS notice. The submission must include: (1) the name and address of the submitter; (2) the name of the substance, using an appropriately descriptive term; (3) the intended conditions of use of the substance, including the foods in which the substance is used or is in contact with, the levels of use, and the purposes for which the substance is used (and the target animal species for animal food as well as human exposures when used in food for food-producing animals); (4) evidence of presence in interstate commerce before the effective date of the final rule; and (5) if applicable, where FDA sent a cease to evaluate letter in response to a notifier's previous GRAS notice (GRN or AGRN), provide that file number (GRN No. or AGRN No.) as part of the submission.

The proposed rule would revise our procedural regulations for a Threshold of Regulation (TOR) exemption for human food to reflect updated scientific guidance and to include uses of substances in food and as a food contact substance. FDA has an existing information collection for information submitted in support of a TOR exemption for a food contact substance under OMB control number 0910-0495 (Food Contact Substances Notification System). The proposed rule would provide for manufacturers and suppliers of substances of food to also seek the TOR exemption. A request for a TOR exemption will include: (1) the chemical composition of the substance for which the request is made; (2) detailed information on the conditions of use of the substance; (3) a clear statement of the basis for the request for exemption from regulation as a food additive; (4) data that will enable FDA to estimate the daily dietary concentration resulting from the proposed use of the substance; (5) results of a literature search for toxicological data on the substance and its impurities; and (6) information on the environmental impact that would result from the proposed use.

2. Purpose and Use of the Information Collection

The information submitted to us in a GRAS notice is necessary to allow us to more efficiently determine if the use of a substance constitutes a food additive use that is subject to the premarket review and approval requirements of the FD&C Act. This will therefore enable FDA to more effectively regulate the safety of food substances and ultimately prohibit the use of unsafe food additives in food.

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

3. Use of Improved Information Technology and Burden Reduction

Respondents for human foods must submit data electronically using the Centralized Online Submission Module (COSM) (Form FDA 3667) (https://www.fda.gov/food/registration-food-facilities-and-other-submissions/centralized-online-submission-module-cosm) for GRAS notices, time-limited option information for certain substances already in interstate commerce, and requests for a TOR exemption. Notifiers may request HFP for a waiver to submit on paper at Office of Pre-market Additive Safety, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. While we do not expect COSM to reduce reporting time for respondents, use of the form helps to expedite our review of the information being submitted.

Respondents for animal foods may submit notices by mail in paper format, or as electronic files on physical media with paper signature page to FDA or email submissions to animalfood-premarket@fda.hhs.gov.

Based on our review of past 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).

The proposed rule would revise our procedural regulations for a Threshold of Regulation (TOR) exemption for human food to reflect updated scientific guidance and to include substances used in food and as a food contact substance (FCS.) FDA has an existing information collection for information submitted in support of a TOR exemption for a food contact substance under OMB control number 0910-0495 (Food Additives; Food Contact Substances Notification System). The proposed rule would allow manufacturers and suppliers to also seek the TOR exemption for substances used in food and is not duplicative of the information collected under OMB control number 0910-0495.

In addition, collections of information covered under OMB Control No. 0910-0546 and this rulemaking cover information collected under section 21 CFR 570. This rulemaking's collection of information for GRAS notification procedures for animal food (part 570, subpart E, sections 570.205 to 570.280) is different than the information collected under OMB No. 0910-0546 regarding investigational food

additive files under sections 570.17 (Investigational Food Additive Files, Moderate and Complex categories). Therefore, no duplicative collection of information exists between these two collections of information.

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 will be submitted only once and will enable FDA 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 this GRAS notification procedure to complete our evaluation within the timelines specified in the regulations associated with parts 170 and 570.

Regarding the TOR exemption for food substances, respondents will submit the required information on an occasional basis, as required by 21 CFR 170.39. Any restriction of the right to require certain types of data for requests submitted under this policy would significantly decrease the number of food substances exempted from the requirement that they be the subject of food additive petitions or GRAS notifications. Exemptions would be restricted to those situations which involve substances which are GRAS whose use was sanctioned prior to January 1, 1958, and substances approved for investigational use under section 409(j) of the FD&C Act. All other food substances would require premarket approval via the food additive petition process or the notification process.

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

The information collection requirements are consistent with 5 CFR 1320.5, except for 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.

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

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(B)), we solicited public comment on the information collection provisions in our proposed rule published in the *Federal Register* of August 11, 2026 (91 FR 51834).

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 will add 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.

Regarding TOR exemptions, requests for exemptions of food substances from the food additive listing regulation requirement often contain trade secret and commercial confidential information. Only information that is releasable under the agency's regulations (21 CFR part 20) would be released to the public. This information would also be safeguarded by section 301(j) of the FD&C Act and would be protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)).

A list of substances exempted under 21 CFR 170.39 will be placed on display at the Division of Dockets Management and will be available on the FDA website. This list will include the name of the company that made the request, the chemical name of the exempted substance and the specific use for which it has been exempted, as well as any appropriate limitations. It does not include any trade names or other confidential information. The agency's finding of no significant

environmental impact and the evidence supporting that finding, contained in an environmental assessment, are also available for public inspection at the Division of Dockets Management.

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.

The Freedom of Information Act (FOIA)

Under 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

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

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; 170.205-170.285 (part 170, subpart E)	194	1	194	180	34,920
Request for waiver to submit paper; §§ 170.39(d), 170.210, and 170.305(c)(3)	58	1	58	1	58
GRAS notification procedure for animal food; 570.205-570.280 (part 570, subpart E)	16	1	16	180	2,880
Threshold of regulation for substances used in food; § 170.39	7	1	7	48	336
Total					38,194

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

The burden estimates are consistent with the estimates found in the Preliminary Regulatory Impact Analysis (PRIA) (Docket No. FDA-2025-N-3262) (https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations). The existing information collection for voluntary GRAS notices OMB control number 0910-0342 (Substances Generally Recognized as Safe: Notification Procedure) estimates 100 firms for human foods and 12 firms for animal food that voluntarily submitted GRAS notices for a total of 112 firms. These annual estimates are based on our experience with the voluntary GRAS notice program, and we include with them with our annual estimates for additional firms that will submit GRAS notices to comply with the proposed rule, if finalized.

In Table 15 of the PRIA, we estimate that a total of approximately 98 additional firms, including GRAS substance producers and food manufacturers, will submit a GRAS notice annually. Of the new firms, we estimate that 94 produce human food, and 4 produce animal food. For this analysis, we estimate that 194 firms (100 voluntarily submitting + 94 due to rulemaking) annually will submit a GRAS notice for human food, and 16 firms (12 voluntarily submitting + 4 due to rulemaking) will submit a GRAS notice for animal food. In Table 14 of the PRIA, we estimate that it will take 180 hours to prepare and submit a GRAS notice for either human or animal food. Accordingly, we estimate the burden for submitting a GRAS notice to be 34,920 hours for human food (194 notices × 180 hours) and 2,880 hours for animal food (16 notices × 180 hours).

We estimate that approximately 58 respondents will request a waiver to submit in paper format either a GRAS notice, TOR exemption, or the time-limited option to submit information for certain substances already in interstate commerce for human food. This annual estimate is based on our experience with the voluntary

GRAS notice program and the annual estimate in the existing information collection approved under OMB control number 0910-0342, where we estimate that approximately 30 percent of submissions are in paper format annually. For this analysis, we will assume approximately 30 percent of firms will choose to submit in paper format. Thus, 30 percent of the estimated 194 firms for human food is about 58 (194 firms × 0.30). We believe respondents will need no longer than an hour to prepare such a request as respondents should already have any information needed to request a waiver. Accordingly, we estimate the annual burden to request a waiver to submit a GRAS notice for human food in paper format to be 58 hours.

The existing information collection for food contact substances covers TOR exemption under OMB control number 0910-0495 (Food Additives; Food Contact Substances Notification System). For this analysis, we will use the same annual estimates for TOR exemption from that information collection to apply to the TOR exemption for food substances. Thus, we estimate that 7 respondents annually will each submit 1 request for a TOR exemption, which will take approximately 48 hours to prepare and submit. Accordingly, we estimate the annual burden to request a TOR exemption for a food substance will be 336 hours (7 requests × 48 hours).

Table 2.--Estimated One-Time Reporting Burden[1]

Activity; 21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total One-Time Responses	Average Burden per Response	Total Hours
Time-limited option to submit information for certain substances already in interstate commerce for human food; § 170.305	967	2.5	2,418	32	77,376
Time-limited option to submit information for certain substances already in interstate commerce for animal food; § 570.305	62	2.5	155	32	4,960
Total					82,336

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

In Table 7 of the PRIA, we estimate that there are 1,028 unique firms with independent conclusions of GRAS status. Based on table 6 of the PRIA, we calculate that 94 percent of the independent conclusions of GRAS status are for human foods (1,885 human food independent conclusions of GRAS status ÷ 2,000 total human and animal independent conclusions of GRAS status). We assume the same distribution for the number of unique firms preparing a submission for certain substances purported to be GRAS based on an independent conclusion of GRAS status. Accordingly, we calculate the number of respondents preparing a submission for certain substances purported to be

GRAS based on an independent conclusion of GRAS status for human food to be 966 (1,028 × 0.94).

In Table 10 of the PRIA, we estimate that each respondent will prepare approximately 2.5 submissions for certain substances purported to be GRAS based on an independent conclusion of GRAS status that were already introduced into interstate commerce before the effective date of a final rule. In Table 10 of the PRIA, we estimate that there are 1,740 association expert panel-concluded GRAS substances. As discussed in the PRIA, this category includes substances evaluated by the Flavor and Extract Manufacturers Association and introduced into interstate commerce under section 201(s) of the FD&C Act but can include other independent conclusions of GRAS status made by other expert panels selected and convened by associations. For efficiency purposes, we assume that there will be one submission by one respondent to cover all submissions for certain substances purported to be GRAS based on an association expert panel GRAS conclusion that were already introduced into interstate commerce before the effective date of a final rule.

Accordingly, we calculate the total number of respondents to be 967 (966 respondents preparing a submission for certain substances purported to be GRAS based on an independent conclusion of GRAS status + 1 respondent preparing a submission for certain substances purported to be GRAS based on an association expert panel GRAS conclusion). Although we believe that one respondent will have one submission for 1,740 substances, we estimate that on average each respondent will submit 2.5 responses. Thus, we calculate that 2,418 submissions (rounded up from 2,417.5) will be submitted for certain substances purported to be GRAS based on an association expert panel GRAS conclusion that were already introduced into interstate commerce before the effective date of a final rule (967 respondents × 2.5 responses).

In Table 10 of the PRIA, we estimate that it will take approximately 32 hours (rounded up from 31.5) to prepare a submission for certain substances purported to be GRAS under section 201(s) of the FD&C Act that were already introduced into interstate commerce before the effective date of a final rule (we assume, in the PRIA, that a streamlined submission would require between 10 percent and 25 percent of the time expenditure of a GRAS notice (180 hours), with a central estimate of 17.5 percent to arrive at the estimate of 31.5 hours to prepare a streamlined submission (180 hours × 17.5 percent). Accordingly, we calculate the burden for this activity to be 77,376 hours (2,418 submissions × 32 hours). We believe that this will be a one-time burden because these streamlined submissions are time-limited and would only be available for 1 year after the effective date of a final rule.

We estimate the remaining 62 respondents would be preparing a submission for certain substances purported to be GRAS based on an independent conclusion of GRAS status for animal food (1,028 unique firms with independent conclusions of GRAS status - 966 respondents preparing a submission for certain substances purported to be GRAS based on an independent conclusion of GRAS status for human food). In Table 10 of the PRIA, we estimate that each respondent will prepare approximately 2.5 submissions for certain substances purported to be GRAS based on an independent conclusion of GRAS status that were already introduced into interstate commerce before the effective date of the final rule. Provided that each respondent will prepare 2.5 submissions, we calculated that there will be 155 responses (62 respondents × 2.5 submissions per respondent). In Table 10 of the PRIA, we estimate that it will take approximately 32 hours (rounded up from 31.5) to prepare a submission for certain substances purported to be GRAS based on an independent conclusion of GRAS status that were already introduced into interstate commerce before the effective date of a final rule. Accordingly, we estimate the burden for this activity to be 4,960 hours (155 submissions × 32 hours). We believe that this will be a one-time burden because the option to make streamlined submissions would only be available for 1 year after the effective date of a final rule.

12b. Annualized Cost Burden Estimate

We estimate the annualized burden hour cost to respondents for this collection of information to be $7,971,854.20. In Tables 10 and 14 of the PRIA, we estimate the fully-loaded composite hourly wage for food manufacturing and chemical manufacturing managers and clerical staff preparing and submitting information to FDA to be approximately $65.59, which is comparable to a Federal government employee at the GS-13/Step 5 rate for the Washington-Baltimore locality pay area for the year 2026 ($66.14/hour). Therefore, the total cost of this collection of information to respondents is estimated to be $7,971,854.20 ($66.14 × 120,530 total burden hours).

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

In Table 15 of the PRIA, we estimate that it will cost FDA $1,909,528.05 to review GRAS notices for uses of substances that otherwise would have been the subject of an independent conclusion of GRAS status or association expert panel GRAS conclusion. In Table 11 of the PRIA, we estimate that it will cost FDA $22,867,147 to review submissions of certain information for substances purported to be GRAS based on an independent conclusion of GRAS status that were already introduced

into interstate commerce before the effective date of the final rule. For this analysis, we will use the estimated cost to FDA from the existing collection for TOR exemptions (OMB control number 0910-0495), which is $19,705. Thus, we estimate that the annual cost to the Federal Government for the proposed rule will be $24,796,380.05 ($1,909,528.05 for GRAS notices + $22,867,147 for substances already in market + $19,705 for TOR exemptions).

15. Explanation for Program Changes or Adjustments

Rulemaking will revise the scope of collection activity in OMB control no. 0910-0342. We also anticipate potential adjustments in OMB control numbers 0910-0495 and 0910-0546 as a result of the regulatory changes. However, we expect these to be one-time adjustments. We have revised our estimate adding 101,490 hours and 2,736 responses annually to reflect the information collection associated with new regulatory requirements.

Table 3.--Changes or Adjustments to Burden Estimates

Activity/CFR Section	Previously Approved Annual Burden Hours	Proposed Annual Burden Hours	Difference (Hours) (+/-)	Rationale for Change (Estimate Revision/Programmatic)
GRAS notification procedure for human food; 170.205-170.285 (part 170, subpart E)	17,000	34,920	+17,920	Voluntary submissions will become required submissions.
GRAS notification procedure for animal food; 570.205-570.280 (part 570, subpart E)	2,040	2,880	+840	Voluntary submissions will become required submissions.
Request for waiver to submit paper; §§ 170.39(d), 170.210, and 170.305(c)(3)	0	58	+58	New collection of information.
Threshold of regulation for substances used in food; § 170.39	0	336	+336	New collection of information.
Time-limited option to submit information for certain substances already in interstate commerce for human food; § 170.305	0	77,376	+77,376	A one-time new collection of information.
Time-limited option to submit information for certain substances already in interstate commerce for animal food; § 570.305	0	4,960	+4,960	A one-time new collection of information.
Total	19,040	120,530	+101,490	

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.