SUBSTANCES GENERALLY RECOGNIZED AS SAFE: NOTIFICATION PROCEDURE

OMB No. 0910-0342

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) establishes a premarket approval requirement for "food additives;" section 201(s) of the act (21 U.S.C. 321) provides an exemption from 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. In April 1997, FDA proposed a voluntary procedure whereby manufacturers would notify FDA about a view that a particular use (or uses) of a substance is not subject to the statutory premarket approval requirements based on a determination that such use is GRAS (62 FR 18938, April 17, 1997). Proposed §§ 170.36 and 570.36 (21 CFR 170.36 and 570.36) provide a standard format for the voluntary submission of a notice. The notice would include a detailed summary of the data and information that support the GRAS determination, and the notifier would maintain a record of such data and information. FDA would make the information describing the subject of the GRAS notice, and the agency's response to the notice, available in a publicly accessible file; the entire GRAS notice would be publicly available consistent with the Freedom of Information Act and other Federal disclosure statutes.

FDA requests extension of OMB approval of the GRAS notification procedure set forth in proposed §§ 170.36 and 570.36.

2. Purpose and Use of the Information Collection

The information is used by FDA to evaluate whether the notice provides a sufficient basis for a conclusion of GRAS status and whether information in the notice or otherwise available to FDA raises issues of public health significance that lead the agency to question whether use of the substance is GRAS.

3. Use of Improved Information Technology and Burden Reduction

The proposed regulation does not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology as necessary for use by firms. Companies are free to use whatever forms of information technology may best assist them in preparing the notice and submitting it to FDA. The information in the notice will be narrative text that the agency would read rather than data that the agency would either analyze or store in a database format. FDA would print and copy any notice submitted electronically. Therefore, for efficient enforcement of the act, FDA is requiring the submission of paper copies of the notice. However, FDA is aware that there is an increasing interest in submitting an electronic copy of information prepared for regulatory purposes. Therefore, in the proposed rule FDA requested comment on whether it would be appropriate to require or recommend that the submission include an electronic copy, in addition to the three paper copies required under the

proposed regulation, of the information in the notice. FDA also specifically requested comment on the narrower question of whether it would be appropriate to require or recommend that the notifier include an electronic copy of the notice's "GRAS exemption claim," which would include succinct descriptions of the notified substance and applicable conditions of use, to maximize the agency's flexibility in making such claims publicly accessible. Most of the comments to the proposed rule encouraged FDA to recommend, but not require, submission of an electronic copy of the GRAS notice.

4. Efforts to Identify Duplication and Use of Similar Information

No duplication of Federal regulations is likely. 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. Recently, USDA/FSIS (64 FR 72167; December 23, 1999) and FDA (65 FR 51758; August 25, 2000) amended their regulations to harmonize and improve the efficiency of the procedures used by USDA/FSIS and FDA with respect to reviewing and approving the use of substances in meat and poultry. In general, USDA/FSIS evaluates food substances as to their suitability for specified uses in meat or poultry products. When USDA/FSIS receives a request to evaluate the suitability of a substance for use in meat or poultry products, USDA/FSIS consults with FDA about the regulatory status of the substance. When FDA receives a GRAS notice that includes a use in meat or poultry products, FDA consults with USDA/FSIS and provides to the notifier feedback from USDA/FSIS about the suitability of the substance for use in meat or poultry products. If USDA/FSIS informs FDA that the use of the substance in meat or poultry products requires rulemaking under the statutes that FSIS implements, FDA provides that information to the notifier. FDA and USDA have now signed a Memorandum of Understanding regarding these procedures [http://www.fsis.usda.gov/OA/topics/mou_fda.htm].

5. Impact on Small Businesses or Other Small Entities

The proposed notification procedures are no more burdensome for small businesses than for large. The proposed requirements are the minimum requirements to provide a sufficient basis for a conclusion of GRAS status. The proposed notification procedure would minimize the burden on all businesses, including small businesses, by providing that the notifier submit a detailed summary of the data and information, rather than the data and information itself, that are the basis for the conclusion of GRAS status.

6. Consequences of Collecting the Information Less Frequently

The data in a GRAS notification are submitted only once and therefore cannot be collected less frequently. If the information was not collected, FDA would utilize more resources answering questions about the regulatory status of substances that are not explicitly authorized by the agency's regulations

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

The proposed GRAS notification program does not involve submission of information more than quarterly, written responses to the agency in less than 30 days, submission of more than an original plus two paper copies of the notification, or the use of statistical methods not reviewed by OMB.

The proposed GRAS notification program would, however, require that records be retained for more than three years. Under the proposal, notifiers would supply a detailed summary of the information that provides the basis for a conclusion of GRAS status rather than the information itself. As a result, FDA proposed to require that the notifier retain the information that forms the basis for the conclusion of GRAS status and sign a statement that such information is available for FDA review and copying at reasonable times or will be sent to FDA upon request.

With regard to the confidentiality of the information or the submission of trade secrets or proprietary information, the agency expects that it may receive notifications containing trade secrets or confidential commercial information. Trade secrets and confidential commercial information are protected from disclosure under the Freedom of Information Act under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20). Consistent with confidentiality requirements, FDA will make accessible to the public the information in the "GRAS exemption claim" and the agency's response to the notice through an electronic inventory of GRAS notices posted on the agency's Web site at http://www.cfsan.fda.gov/~rdb/opa-gras.html. In addition, FDA posts on the agency's Web site the complete text of frequently requested GRAS notices (after removal of any trade secrets or other confidential information) (at http://www.cfsan.fda.gov/~prise/prisesum.html).

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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of February 11, 2009 (74 FR 6894). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

FDA proposed that a particular section (i.e., the "GRAS exemption claim") of a notice be immediately available for public disclosure on the date the notice is received. FDA also proposed that all remaining data and information in a notice will become available for public disclosure, in accordance with 21 CFR part 20, on the date of receipt of the notice. The general recognition standard signifies that neither the proposed use of the substance nor the critical information needed to establish its safety are confidential. Therefore, FDA presumes that a notice will not contain any information that is protected from public disclosure. Moreover, because a GRAS substance may be marketed without prior approval, FDA presumes that, in most cases, submission of a notice will not reflect the notifier's plans about the timing of commercialization, which is arguably confidential commercial information (21 CFR 20.61(b)), because a notifier may market a substance at any time before or after notifying FDA.

FDA is recommending that a notifier who considers that certain information that is contained in the submission should not be available for public disclosure identify as confidential the relevant portions of the submission for FDA consideration. FDA will review the identified information, determine whether that information is exempt from public disclosure under 21 CFR part 20, and release or protect the information in accordance with that determination.

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

Description of Respondents: Manufacturers of substances used in food and feed.

FDA estimates the burden of this collection of information as follows:

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.36	25	1	25	150	3,750
570.36	5	1	5	150	750
Total					4,500

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

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
170.36(c)(v)	25	1	25	15	375
570.36(c)(v)	5	1	5	15	75
Total					450

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

In the proposed rule, FDA estimated that the Center for Food Safety and Applied Nutrition (CFSAN) would receive approximately 50 GRAS notices per year and that the Center for Veterinary Medicine (CVM) would receive approximately 10 GRAS notices per year. Although FDA requested comment on this estimate, the comments did not provide useful information regarding this issue. Therefore, FDA evaluated the number of notices received by CFSAN to date. CFSAN received 274 GRAS notices during the 11-year period from 1998 through 2008, for an average of approximately 25 GRAS notices per year. Based on this experience, FDA is revising its estimate of the annual number of GRAS notices submitted to CFSAN to be 25 or less. FDA also is revising its estimate of the annual number of GRAS notices submitted to CVM to be 5 or less.

<u>Estimated Annualized Cost for the Burden Hours</u>

FDA estimates the annualized burden hour cost to respondents for this collection of information to be approximately $426,096. FDA estimates a respondent's average wage to be that of a Federal government employee at the GS-13/Step-2 rate for the Washington-Baltimore locality pay area for the year 2009, which is $43.04 per hour. To account for overhead, this cost is increased by 100 percent, which is $86.08 per hour. Thus, the annual wage cost for completion and submission of GRAS notifications is approximately $426,096 (4,950 hours x $86.08 per hour).

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no capital costs or operating and maintenance costs associated with this collection.

14. Annualized Cost to Federal Government

FDA is estimating that the agency will direct approximately 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 1 FTE is expected to be devoted to processing the notices submitted to CVM. Based on an average cost of $168,090 per fully supported position ($84,045 increased by 100 percent to account for overhead), the cost of processing GRAS notifications would be $840,450 per year ($168,090 x 5).

15. Explanation for Program Changes or Adjustments

The adjustment in burden is due to a decrease in the estimated number of respondents. FDA lowered its estimate of the number of respondents based on its experience with notices received from 1998 to 2008.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA proposed to make readily accessible to the public the information in a section of the notice called the "GRAS exemption claim" and the agency's response to the notice. At this time, FDA is making this information accessible through an electronic inventory of GRAS notices [http://www.cfsan.fda.gov/~rdb/opa-gras.html]. The entire GRAS notice is publicly available consistent with the Freedom of Information Act and other federal disclosure statutes. In addition, FDA posts on the agency's Web site the complete text of frequently requested GRAS notices (after removal of any trade secrets or other confidential information) (at http://www.cfsan.fda.gov/~prise/prisesum.html).

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

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

N/A.