Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition

OMB Control No. 0910-0541

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

As an integral part of its decision-making process, the Food and Drug Administration (FDA) is obligated under the National Environmental Policy Act of 1969 (NEPA) to consider the environmental impact of its actions, including allowing notifications for food contact substances to become effective and approving food additive petitions, color additive petitions, GRAS affirmation petitions, requests for exemption from regulation as a food additive, and actions on certain food labeling citizen petitions, nutrient content claims petitions, and health claims petitions. In 1997, FDA amended its regulations in part 25 (21 CFR part 25) to provide for categorical exclusions for additional classes of actions that do not individually or cumulatively have a significant effect on the human environment (62 FR 40570; July 29, 1997). As a result of that rulemaking, FDA no longer routinely requires submission of information about the manufacturing and production of FDA-regulated articles. FDA also has eliminated the previously required Environmental Assessment (EA) and abbreviated EA formats from the amended regulations. Instead, FDA has provided guidance that contains sample formats to help industry submit a claim of categorical exclusion or an EA to the Center for Food Safety and Applied Nutrition (CFSAN).

The guidance document entitled, "Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition" identifies, interprets, and clarifies existing requirements imposed by statute and regulation, consistent with the Council on Environmental Quality regulations (40 CFR 1507.3). It consists of recommendations that do not themselves create requirements; rather, they are explanatory guidance for FDA's own procedures in order to ensure full compliance with the purposes and provisions of NEPA.

FDA is requesting OMB approval of the voluntary information collection provisions contained in the guidance document entitled, "Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition, " found at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm081049.htm on the internet.

2. Purpose and Use of the Information Collection

The guidance provides information to assist in the preparation of claims of categorical exclusion and EAs for submission to CFSAN. The following questions are covered in this guidance: (1) What types of industry-initiated actions are subject to a claim of categorical exclusion? (2) What must a claim of categorical exclusion include by regulation? (3) What is an EA? (4) When is an EA required by regulation and what format should be used? (5) What are extraordinary circumstances?

and (6) What suggestions does CFSAN have for preparing an EA? Although CFSAN encourages industry to use the EA formats described in the guidance because standardized documentation submitted by industry increases the efficiency of the review process, alternative approaches may be used if these approaches satisfy the requirements of the applicable statutes and regulations.

An FDA-regulated firm submitting a notification, petition, or other form of request for agency action may choose to submit a claim of categorical exclusion or an EA. In doing so, the firm will collect the information about their product as recommended by the guidance. FDA will review the information collected to determine that the firm's requested action is in compliance with the purposes and provisions of NEPA.

Description of Respondents: The likely respondents include businesses engaged in the manufacture or sale of food, food ingredients, and substances used in materials that come into contact with food. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

CFSAN currently accepts information supporting claims of categorical exclusion or an EA by e-mail. The agency estimates that about twenty-five percent (25%) are submitted electronically.

4. Efforts to Identify Duplication and Use of Similar Information

Two of the three categorical exclusions that require collection of information to support the exclusion (21 CFR 25.32(o) and 25.32(q)) are based upon environmental reviews performed by other federal agencies. Accordingly, the guidance suggests that submitters provide FDA copies of certain information that has been provided to, or has been generated by, the other federal agencies. The duplicative information is necessary to support the claimed exclusion based on the other agency's environmental review. With regard to the third categorical exclusion (21 CFR 25.32(i)), FDA is the only federal agency that collects information and data to support this exclusions. There is no similar information or data that can be used or modified for this purpose.

5. Impact on Small Businesses or Other Small Entities

FDA estimates that ten percent (10%) of respondents are small businesses. There is no known way to minimize the burdens on a small business wishing to submit a request for action to the agency. FDA aids small businesses in complying with its requirements through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. If the information collection being considered here was not conducted, the agency might have difficulty determining if the categorical exclusion being claimed in a submission was, in fact, warranted. This difficulty could cause the agency to not be in compliance with its NEPA responsibilities.

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

The recommended information collection contained in the guidance does not involve more than quarterly submission of information to the agency, written responses to the agency in less than 30 days, submission of more than an original and 2 copies, retention of records for more than three years, or the use of statistical methods. However, a firm's submission of a claim of categorical exclusion or an EA may contain trade secret and commercial confidential information. This information is protected by FDA as set out below in the response to question 10.

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

In accordance with 5 CFR 1320.8(d), in the Federal Register of October 28, 2013 (78 FR 64218), FDA published a 60-day notice requesting public comment on the collection of information. The agency received one comment that was not responsive to the comment request on the information collection provisions.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

Information submitted to FDA in a claim of categorical exclusion or an EA may contain trade secret and commercial confidential information. As a result, all files are maintained in a secured area. The guidance provides instructions for assisting FDA with protecting confidential information. It states, "Data and information that are protected from disclosure under 18 U.S.C. 1905, 21 U.S.C. 331(j) or 360j(c) shall be submitted separately in a confidential section of the submission and shall be summarized, to the extent possible, in the EA (21 CFR 25.51)." 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 Federal Food, Drug, and Cosmetic 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)).

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

Description of Respondents: The likely respondents include businesses engaged in the manufacture or sale of food, food ingredients, and substances used in materials that come into contact with food. Respondents are from the private sector (for-profit businesses).

12 a. Annualized Hour Burden Estimate

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

Table 1.--Estimated Annual Reporting Burden[1]					
21 CFR Part 25/ Environmental Impact Considerations	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
25.32(i)	42	1	42	1	42
25.32(o)	1	1	1	1	1
25.32(q)	2	1	2	1	2
Total					45

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

The above estimates for respondents and numbers of responses are based on the annualized numbers of petitions and notifications qualifying for § 25.32(i) and (q) that the agency has received in the past 3 years. Please note that, in the past 3 years, there have been no submissions that requested an action that would have been subject to the categorical exclusion in § 25.32(o). To avoid counting this burden as zero, FDA has estimated the burden for this categorical exclusion at one respondent making one submission a year for a total of one annual submission.

To calculate the estimate for the values for Average Burden per Response, we assumed that the information requested in this guidance for each of these three categorical exclusions is readily available to the submitter. For the information requested for the exclusion in § 25.32(i), we expect that submitter will need to gather information from appropriate persons in the submitter's company and to prepare this information for attachment to the claim for categorical exclusion. We believe that this effort should take no longer than 1 hour per submission. For the information requested for the exclusions in § 25.32(o) and (q), the submitters will almost always merely need to copy existing documentation and attach it to the claim for categorical exclusion. We believe that collecting this information should also take no longer than 1 hour per submission.

12 b. Annualized Cost Burden Estimate

Gathering the information discussed here and providing it to the agency may be done by a professional employee such as an environmental scientist. FDA estimates that the average hourly wage for this employee would be equivalent to a GS-11/Step-1 level in the locality pay area of Washington-Baltimore in 2013, approximately $29.93/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $59.86/hour. The overall estimated cost incurred by the respondents is $2,693.70 (45 burden hours x $59.86/hr = $2,693.70).

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 collection.

14. Annualized Cost to the Federal Government

At the agency, a professional employee reviews the submissions, which requires about one hour. FDA estimates the hourly cost for review and evaluation of the submissions to be $48.35 per hour, the GS-13/Step-5 rate for the Washington-Baltimore locality pay area for the year 2013. To account for overhead, this cost is increased by 100 percent, making the total cost $96.70 per hour. Thus, FDA estimates the cost to the Federal Government for the review of submissions to be $4,351.50 ($96.70/hour x 1 hour per submission x 45 submissions = $4,351.50).

15. Explanation for Program Changes or Adjustments

This collection of information has increased by 8 respondents, resulting in an increase of 8 burden hours. Thus, FDA has increased its annual burden estimate from 37 hours to 45 hours.

16. Plans for Tabulation and Publication and Project Time Schedule

The agency has no plans for publication of information from this information collection.

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

There are no exceptions to the certification.