Supporting Statement

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

OMB No. 0910-0541

A. Justification

1. Need and Legal Basis

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."

2. Information Users

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.

3. Improved Information Technology

CFSAN currently accepts information supporting claims of categorical exclusion or an EA by e-mail. In addition, in the Federal Register of July 31, 2001 (66 FR 39517), FDA announced the availability of two draft guidances for industry entitled "Providing Regulatory Submissions to Office of Food Additive Safety in Electronic Format--General Considerations" and "Providing Regulatory Submissions to Office of Food Additive Safety in Electronic Format for Food Additive and Color Additive Petitions." These documents are the first in a series of guidance documents intended to provide guidance for industry regarding the preparation of regulatory submissions in electronic format to the Office of Food Additive Safety (OFAS), CFSAN. We expect that claims of categorical exclusion or EAs will be included along with other requested information in the electronic submissions discussed in these draft guidances.

4. Duplication of Similar Information

Two of the three categorical exclusions that require collection of information to support the exclusion (25 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 (25 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. 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 dealing with the requirements through the Division of Education and Communication in the Center for Food Safety and Applied Nutrition (CFSAN) and through the scientific and administrative staffs of the agency.

6. Less Frequent Collection

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

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. Federal Register Notice/Outside Consultation

In accordance with 5 CFR 1320.8(d), in the Federal Register of March 28, 2007 (72 FR 14581), FDA published a 60-day notice requesting public comment on the collection of information. No comments were received from the public.

9. Payment/Gift to Respondent

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

10. Confidentiality

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 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. Sensitive Questions

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

12. Burden Estimate (Total Hours and Wages)

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

Table 1 - Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Burden Hours
25.32(i)	52	3	156	1	156
25.32(o)	1	1	1	1	1

25.32(q)	7	2	14	1	14
Total					171

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

Description of Respondents: Respondents include businesses engaged in the manufacture or sale of food, food ingredients, and substances used in materials that come into contact with food.

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 three years. Please note that, in the past three 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 hours per response values, 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 the 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.

Costs to Respondents: Gathering the information discussed here and providing it to the agency may be done by a professional employee such as an environmental scientist. We are assuming that the hourly wage plus overhead for an environmental scientist is $50/hour. Based on that and on the burden hours calculated in Table 1 above (171), the annual cost to respondents is $8,550 (171 burden hours x $50/hour).

13. Capital Costs (Maintenance of Capital Costs)

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

14. Cost to Federal Government

At the agency, a professional employee reviews the submissions, which requires about one hour. Assuming that the aggregate professional hourly cost, including overhead, is $90, the annual cost to FDA is $15,390 (171 submissions x $90/hour).

15. Program or Burden Changes

The total annual burden has increased from 147 hours to 171 hours. This increase is due to an increase in the estimated number of respondents.

16. Publication and Tabulation Dates

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

17. Display of OMB Approval Date

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"

No exceptions to the certification statement identified in Item 19 of the instructions for completing OMB Form 83-I have been identified.