

information to be submitted. The environmental information to be submitted with petitions for certain food labeling regulations is listed in 21 CFR 101.12(h)(12), 101.69(h), and 101.70(f)F.

Thus, FDA collects information on the potential for environmental impacts of its actions in the form of environmental assessments and claims for categorical exclusions from interested parties who request agency action by submitting to the agency any of the above listed petitions, requests for exemption, or food contact substance notifications. After this information has been collected, the agency will use it to determine whether its action may significantly affect the quality of the human environment.

FDA has collected information from interested parties requesting agency action for many years. Over the years, this collected information has taken several different forms. The agency amended its environmental regulations in the 1997 rule to reduce the number

of NEPA evaluations by providing for categorical exclusions for additional classes of actions that do not individually or cumulatively have a significant affect on the quality of the human environment. In the 1997 rule, FDA also removed the formats for EAs from its regulations and, instead, now directs interested parties to the agency's Centers for information on what is needed in EAs. This draft guidance is FDA's current thinking on what information is needed for the environmental documentation of the actions that are most often requested. The draft guidance contains requests for certain information that has not been requested routinely in the past. FDA is now requesting that submitters provide certain information to support their claims that the categorical exclusions listed in § 25.32(i), (o), and (q) will be applicable to their requested actions. Since these informational requests are new, FDA is requesting approval from

OMB for this collection of information. The remainder of the environmental information requests are covered by the information collection approvals for the underlying actions, i.e., the OMB control number for food additive petitions is 0910-0016; for color additive petitions, 0910-0185; for requests for exemption from regulation as a food additive under § 170.39, 0910-0298; for notifications for food contact substances, 0910-0480; for GRAS affirmation petitions, 0910-0132; and for petitions for food labeling regulations, 0910-0183.

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.

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

Table 1.—Estimated Annual Reporting Burden¹

21 CFR Section	No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
25.32(i)	137	0.5	68	4	272
25.32(o)	1	1	1	1	1
25.32(q)	10	0.5	5	1	5
Total	148		74		278

¹There 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 since its environmental regulations were amended to include additional categorical exclusions. Please note that, since the agency revised its environmental regulations, 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. The hours per response were estimated as follows: First, FDA assumed that the new information it suggest be submitted in this guidance for each of these three categorical exclusions is readily available to the submitter. For the new information suggested for the exclusion in § 25.32(i), FDA expects that the submitter would gather information from appropriate persons in the submitter's company and to prepare this

information for attachment to the claim for categorical exclusion. FDA believes that this effort should take about 4 hours per submission. For the new information suggested for the exclusions in § 25.32(o) and (q), the submitters almost always would only copy existing documentation and attach it to the claim for categorical exclusion. FDA believes that this should take no longer than about 1 hour per submission.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at <http://www.cfsan.fda.gov/guidance.html>.

Dated: September 8, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Reimbursement Rates for Calendar Year 2003

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: Notice is given that the Director of Indian Health Service (IHS), under the authority of sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248(a) and 249(b)) and section 601 of the Indian Health Care Improvement Act (25 U.S.C. 1601), has approved the following rates for