STEL should not be exceeded during the work day, even if the cumulative exposure over the 8-hour TWA is not exceeded. CDC recommends a decrease in the GPL to 1×10^{-6} mg/m^3. The WPLs and GPLs values are approximately threefold lower than levels previously recommended by CDC in 1988. An immediately dangerous to life or health (IDLH) value of 0.1 mg/m^3 is recommended for GB. Recommended AELs for GA: Although not as well-studied as GB, GA is believed to be approximately equal in potency to GB. Therefore, CDC recommends the same exposure limits for GA as for GB. Recommended AELs for VX: CDC recommends that the VX WPL, expressed as an 8-hour TWA, be decreased to 1×10^{-6} mg/m^3. Additionally, CDC recommends a VX STEL of 1×10^{-5} mg/m^3. An excursion to the STEL should not occur more than one time per day (compared to four times per day for a typical STEL). The recommended WPL is a factor of 10 lower than the CDC's 1988 recommendation. CDC recommends that the GPL for VX be decreased to 6×10^{-7} mg/m^3 (a factor of five lower than CDC's 1988 recommendation). An IDLH value of 0.003 mg/m^3 is recommended for VX. CDC's final recommendations are summarized in Table 1 below.

TABLE 1.—FINAL RECOMMENDED AIRBORNE EXPOSURE LIMITS (AELS) FOR GA, GB, AND VX

AEL (mg/m^3)	General population limit (GPL)*	Worker population limit (WPL)*	Short-term exposure limit (STEL)* (Workers)	Immediately dangerous to life or health (IDLH) (Workers)
GA, GB	1×10^{-6}	3×10^{-5}	1×10^{-4}	0.1.
GA, GB—Previous (1988)	3×10^{-6}	1×10^{-4}		0.2 (Army)
VX	6×10^{-7}	1×10^{-6}	1×10^{-5} **	0.003
VX—Previous (1988)	3×10^{-6}	1×10^{-5}		0.02 (Army)
Averaging time	24 hours	8 hours	15 minutes	= 30 minutes
Monitoring Method for Recommended Exposure Criteria.	Historical monitor***	Historical monitor	Near-real-time monitor	Near-real-time monitor

* An additional reduction factor for statistical assurance of action at the exposure limit is not needed because of safety factors already built into the derivation of the exposure limit.

** VX STEL has been adjusted from 4×10^{-6} mg/m^3 (up to four times per day) as proposed in the **Federal Register** announcement to 1×10^{-5} mg/m^3 (not more than one time per day) based on technical capabilities of existing air-monitoring technologies.

*** Historical monitoring typically refers to long-term sampling and analytical methods. Air-monitoring results from historical methods are not known until laboratory analyses are complete. CDC does not specifically recommend the use of these AELs for uses other than transportation, worker protection during the destruction process, or general population protection. For example, the 8-hour WPL historically has been used for the Army-designated 3X decontamination, surveillance activities of leaking containers in storage, and charcoal unit mid-beds. CDC did not evaluate the applicability of the WPLs for these activities; the specific technical and safety requirements for each activity need to be considered individually. This announcement does not address the allowable stack concentration (ASC). The ASC is a ceiling value that serves as a destruction process source emission limit and not as a health standard. It typically is used for monitoring the furnace ducts and final exhaust stack, providing an early indication of an upset condition. Modeling of worst-case credible events and conditions at each installation should confirm that the WPL is not exceeded on-site or that the GPL is not exceeded at the installation boundary as a consequence of a release at or below the ASC.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and ATSDR.

Dated: September 11, 2003.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 03–23683 Filed 9–16–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0379]

Draft Guidance for Industry on Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition'' (the draft guidance). The draft guidance provides information to industry on how to prepare a claim of categorical exclusion or an environmental assessment (EA) for submission to the Center for Food Safety and Applied Nutrition (CFSAN) in notifications for food contact substances, food additive petitions, color additive petitions, requests for exemption from regulation as a food additive, generally recognized as safe (GRAS) petitions, and petitions for certain food labeling regulations.

DATES: Submit written or electronic comments on the draft guidance and the collection of information by November 17, 2003, to ensure their adequate consideration in preparation of a revised guidance, if warranted. However, you may submit comments at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition'' to the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 202–418–3100, premarkt@cfsan.fda.gov. Send two self-addressed adhesive labels to assist that office in processing your requests. See **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit written comments on the draft guidance and the collection of information provisions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Layla I. Batarseh, Center for Food Safety and Applied Nutrition (HFS–246), 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 202–418–3016 or 202–

418–3005, FAX 202–418–3030, Internet: *Layla.Batarseh@cfsan.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The National Environmental Policy Act of 1969 (NEPA) requires each Federal agency to assess, as an integral part of its decisionmaking process, the environmental impacts of its actions and requires that the interested and affected public be informed of environmental analyses. As an integral part of its regulatory procedures, FDA is obligated under NEPA to consider the environmental impact of agency 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, 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 and for which, therefore, neither an environmental impact statement nor an EA is required (62 FR 40570, July 29, 1997) (the 1997 rule). As a result of the 1997 rule, FDA no longer routinely requires submission of information about the manufacturing and production of FDA-regulated articles, which information includes a certification of compliance with Federal, State, and local environmental laws. As FDA stated in the 1997 rule (62 FR 40570 at 40585–40586), after reviewing hundreds of EA's, the agency found that articles produced in compliance with applicable emission and occupational safety requirements do not have significant environmental effects, provided that no extraordinary circumstances apply to the production site. FDA also has eliminated the previously required EA and abbreviated EA formats from the amended regulations. Instead, appropriate EA formats are to be presented in guidance documents. FDA believes that guidance documents provide the agency with greater flexibility to interpret requirements under its NEPA procedures in a manner that responds to the evolving nature of environmental science and the needs of industry and interested parties. Such guidance documents, which interpret and clarify existing requirements imposed by statute and regulation and do not themselves create requirements, are not subject to the notice and comment rulemaking provisions of the Administrative Procedure Act (5 U.S.C. 553) and are consistent with the Council on Environmental Quality regulations (40 CFR 1507.3) that encourage agencies to publish explanatory guidance for their own procedures and to revise them as necessary to ensure full compliance with the purposes and provisions of NEPA.

This draft guidance provides information on how to prepare claims of categorical exclusion and EAs for submission to CFSAN. The following topics are covered in this draft 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? (6) What suggestions does CFSAN have for preparing an EA? Although CFSAN encourages industry to use the EA formats described in this draft 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.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulations (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on the preparation of a claim of categorical exclusion or an environmental assessment for submission to CFSAN. It does not create or confer any rights, for or on any person, and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing the guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed in the title page of the guidance.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60–day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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

Description: FDA's regulation in § 25.20 specifies the types of actions related to food additive petitions, color additive petitions, requests for exemption from regulation as a food additive under § 170.39 (21 CFR 170.39), notifications for food contact substances under section 409(h) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(h)), GRAS affirmation petitions, and citizen petitions for certain food labeling regulations that require at least the preparation of an EA, unless the action qualifies for a categorical exclusion under § 25.30 or § 25.32. FDA's regulations in part 25 are based upon the requirements of NEPA (42 U.S.C. 4321 *et seq.*). The agency's collection of information on food additives and food-contact substances is based upon the requirements in section 409 of the act. Likewise, section 721 of the act (21 U.S.C. 379(e)) provides for the collection of information on color additives. The submission to FDA by interested parties of a GRAS affirmation petition is voluntary. The information to be submitted with a GRAS affirmation petition is listed in § 170.35 (21 CFR 170.35), including, in § 170.35(c)(1)(viii), the environmental

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 Burden[1]

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

[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 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.

[FR Doc. 03–23623 Filed 9–16–03; 8:45 am]

BILLING CODE 4160–01–S

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