## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### National Institute for Occupational Safety and Health; Approval of Respiratory Devices Used to Protect Workers in Hazardous Environments

**AGENCY:** Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (DHHS).

**ACTION:** Notice of public meetings concerning quality assurance and administrative approval requirements for respiratory protective devices.

**DATES:** August 8, 2000, 9 a.m.–5 p.m., in the Washington DC Area. August 16, 2000, 9 a.m.–5 p.m., in the San Francisco, CA Area.

**PLACES:**

Washington DC Area—Quality Hotel & Suites; Courthouse Plaza, Jefferson Room, 1200 N. Courthouse Road, Arlington, VA 22201. Phone: 1–888–987–2555 or 703–524–4000. Phone by July 21, 2000 to receive the NIOSH group rate of $118.00.

San Francisco, CA Area—Embassy Suites, Ambassador Ballroom, 150 Anza Boulevard, Burlingame, California 94010. Phone: 650–340–0327. Phone by July 24, 2000 to receive the NIOSH group rate of $164.00.

The meetings will be open to the public, limited only by the space available. Each meeting room accommodates approximately 120 people.

Requests to make presentations at the public meetings should be mailed to the NIOSH Docket Officer, Robert A. Taft Laboratories, M/S C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513–533–8450, fax 513–533–8285, or e-mail to NIOCINDOCKET@CDC.GOV on or before July 30, 2000.

**SUMMARY:** The National Institute for Occupational Safety and Health (NIOSH) is in the process of developing a proposed rule on the quality assurance and administrative requirements for the approval of respirators and is seeking individual stakeholder input for this process. The purpose of these meetings is to provide an opportunity for an exchange of information between the Agency and respirator manufacturers, industry representatives, labor representatives, and others with an interest in respiratory protection. Attendees will be given an opportunity to ask questions; submit verbal and written comments they wish to have included in the regulatory record; and provide individual input into potential changes to the applicable regulations and policies.

**Discussion and Comment Topics**

NIOSH has not determined the final content of its proposed rulemaking but is considering the regulatory actions listed below. NIOSH is specifically asking for comments on these proposed actions, but would also welcome comments on additional areas that the commenters believe may need to be addressed.

*NIOSH is Considering*

(1) Proposing quality assurance requirements for the approval holder's manufacturing process that are consistent with international standards, specifically the International Organization for Standards (ISO) 9000 guidelines. These international standards would be supplemented by respirator-specific quality measures.

(2) Proposing new quality requirements, such as mandatory pre-approval audits for new manufacturing sites, more stringent quality sampling plans, critical classification of defects for all types of respirators, and records retention schedules;

(3) Proposing to enhance quality monitoring activities by NIOSH by increasing the frequency of both site and product audits, requiring an approval holder to supply free product audit samples for product audits, requiring approval holders to self-audit their product and present those results to NIOSH, accepting ISO certification in lieu of a NIOSH-performed site audit, employing contract laboratories to do certain tests for the approval program, and requiring the approval holder to report all customer complaints and non-compliance findings to NIOSH; and

(4) Implementing a new fee structure to recover costs of approval application processing (approximately a 2.5 times increase over the current application fees), approval records maintenance (a new annual fee of approximately $36 per approval), and auditing costs (a new charge computed based on the hourly rate of government personnel [approximately $50 per hour] plus expenses) for the chargeable services received by the applicant or approval holder.

Comments on the concepts presented in this notice should be mailed to the NIOSH Docket Office, Robert A. Taft Laboratories, M/S C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513–533–8450, fax 513–533–8285. Comments may also be submitted by e-mail to: NIOCINDOCKET@CDC.GOV. E-mail attachments should be formatted as WordPerfect 6/7/8/9 or Microsoft Word. Submitted comments should reference docket number, NIOSH–001, in the subject heading.

**FOR FURTHER INFORMATION CONTACT:** Matt Bowyer or Roland BerryAnn, NIOSH, 1095 Willowdale Road, Morgantown, West Virginia 26505–2888, telephone 304–285–5907, fax 304–285–6030 and/or E-mail:respcert@cdc.gov.

In addition to these public meetings, NIOSH invites individuals, organizations and companies to meet with the staff of its Respirator Branch. Requests for such meetings should be made on or before July 31, 2000 to Matt Bowyer or Roland BerryAnn. NIOSH will prepare summaries of these meetings and place them in the regulatory docket.

**Linda Rosenstock,**

*Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.*

[FR Doc. 00–16849 Filed 7–3–00; 8:45 am]

**BILLING CODE 4160–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 00N–1359]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Affirmation of Generally Recognized as Safe (GRAS) Status

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for reporting and recordkeeping, general and specific requirements, and availability of sample electronic product for manufacturers and distributors of electronic products.

**DATES:** Submit written comments on the collection of information by September 5, 2000.

**ADDRESSES:** Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:** Under the 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, including each proposed extension of an existing 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: (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.

**Affirmation of Generally Recognized As Safe (GRAS) Status (21 CFR 170.35(c)(1))—(OMB Control Number 0910–0132)—Extension**

Under authority of sections 201, 402, 409, and 701 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321, 342, 348, and 371), FDA reviews petitions for affirmation as GRAS that are submitted on a voluntary basis by the food industry and other interested parties. Under section 409 of the act, the agency has the authority to regulate food additives. Section 201(s) of the act, defines ''food additive'' and expressly excludes from the definition substances GRAS for use in food.

Specifically under section 201(s) of the act, a substance is GRAS if it is generally recognized among experts qualified by scientific training and experience to evaluate its safety, to be safe through either scientific procedures or common use in food. The act has historically been interpreted to permit food manufacturers to make their own determination that use of a substance in food is GRAS. To implement the GRAS provisions of the act, FDA has issued procedural regulations under § 170.35(c)(1) (21 CFR 170.35(c)(1)). These regulations establish a process by which a person may obtain FDA concurrence with a GRAS determination; this concurrence is referred to as ''GRAS affirmation.'' These regulations set forth the information to be submitted to FDA to obtain agency concurrence that a substance is GRAS (§ 170.35(c)(1)).

GRAS petitions are reviewed by FDA to ascertain whether the available data establish that the intended use of the substance is GRAS based upon either a history of the safe use of the substance, or upon widely available safety data (scientific procedures). The GRAS affirmation process is a voluntary one, and there is some risk that FDA may not agree with the petitioner's GRAS determination. The GRAS petition process does provide a public procedure for coordinating GRAS determinations. The process reduces the potential for public health problems when substances are marketed based upon unwarranted safety determinations and allows a food manufacturer to rely on the lawful status of a substance that has been affirmed by FDA as GRAS.

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 response | Total annual responses | Hours per response | Total hours |
|---|---|---|---|---|---|
| 170.35(c)(1) | 1 | 1 | 1 | 2,614 (average) | 2,614 |

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

FDA estimates that it may receive one GRAS petition annually. Although the burden varies with the type, size, and complexity of the petition submitted, GRAS petitions may involve analytical work, analysis of appropriate toxicological studies, and the work of drafting the petition itself. Since 1980, FDA has not received any petitions for affirmation of GRAS status under 21 CFR part 186—Indirect Food Substances Affirmed As Generally Recognized As Safe. Section 184.1(a) (21 CFR 184.1(a)) affirms the use of those substances affirmed as GRAS in 21 CFR part 184—Direct Food Substances Affirmed As Generally Recognized As Safe, for use as indirect food ingredients.

Dated: June 27, 2000.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 00–16812 Filed 7–3–00; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 00N–1224]**

### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Guidance for Industry: Submitting and Reviewing Complete Responses to Clinical Holds

**AGENCY:** Food and Drug Administration, HHS.