

and family practice. These physicians will be from all areas of the United States and, therefore, from diverse

geographic locations. There is no cost to respondents.

Respondents	No. of re-spondents	No. of responses/ re-spondent	Avg. burden/ response (in hours)	Total burden (in hours)
Physicians .....	2000	1	12/60	400
Total .....	.....	.....	.....	400

Dated: September 11, 2002.

**Nancy E. Cheal,**

*Acting Deputy Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[30DAY-27-02]

**Agency Forms Undergoing Paperwork Reduction Act Review**

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 498-1210. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503. Written comments should be received within 30 days of this notice.

*Proposed Project:* Anthropometric Survey of Respirator Users—NEW—The National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC). The mission of the National Institute for Occupational Safety and Health is to promote safety and health at work for all people through research and prevention.

The overall goal of the current project is to develop respirator fit-test panels that accurately represent today's workers who rely on respirators to prevent work-related respiratory illnesses, injuries, and death. The respirator fit-test panels currently used are 25-subject panels, developed by Los Alamos National Laboratory (LANL) based on data from the 1967-1968 survey of U.S. Air Force men and women. The half-mask panel is based on face length and lip length, and the

full-facepiece panel is based on face length and face width. These panels were established to represent the working population. The fit of respirators on these subject panels is assumed to be representative of the fit of respirators in the user populations. Respirators designed to fit these panels are also expected to accommodate at least 95 percent of the wearers. However, NIOSH research indicated that the LANL panel for full-facepiece respirators accommodated only 84 percent of current civilian subjects. Sizing data generated by the military for use in fitting respirators has been the normative basis for commercial respirator sizing. Anthropometric data developed for males of military age in the 1950's and 1960's is still in use today. Military populations cannot represent the worker population because of relatively strict anthropometric armed forces entry requirements and height/weight guidelines for troop retention. Personal protective equipment designed and sized for a military population may not provide the same level of protection to civilian workers because of the greater diversity in body size and shape seen in civilian populations. In addition, the demographics of the U.S. population have changed over the last 30 years. Thus, it is necessary to assess and refine the LANL fit-test panels.

This project will first develop an anthropometric database detailing the face-size distributions of respirator users using both traditional measurement methods and three-dimensional (3-D) scanning systems. The source population for this study will be the nationwide respirator users population. The databases will then be used to establish respirator fit-test panels that accurately represent today's workers. Three-dimensional anthropometry has only been available recently, and there is no track record of applying scan data to respirators. This study will provide preliminary data on which to develop methods for sizing and designing respirators and protective eyewear using 3-D scan data.

The subjects will be recruited from various industries in which workers rely on respirators to prevent work-related respiratory illnesses, injuries, and death (e.g., manufacturing, construction, mining, and health care). The project will also address emergency responders to chemical and biological terrorism and other crisis situations. Thus, subjects will also include law enforcement officers, firefighters, and health care workers. Height and weight plus 18 facial dimensions will be measured with traditional methods. A total of 4,000 subjects will be measured using traditional methods. Of those, 1,000 will be scanned using a 3-D head scanner (Cyberware Model 3030/RGB). The populations will be sampled by age, race and gender. A stratified sampling plan is being used with equal sample size in each cell (166). The strata consist of: 3 age groups (18-29, 30-44, and 45-65 years), 2 gender strata (male and female), and 4 ethnic groups (White, African Americans, Hispanic, and Others). The total number of cells is 24. The study will be conducted at five locations nationwide. Although test sites have yet to be determined, data collection is anticipated at two facilities in the western U.S., one in the central portion of the country, and at two locations in the east.

Information generated by this research project will benefit: (1) the participants and workers exposed to various gases and aerosols by improving fit and function of respirators worn during work; and (2) those involved in testing, certifying, and manufacturing respirators to be used in industry, by providing them with fit-test panels that accurately represent today's workers. The panels can be used for evaluating respirator facepiece fit characteristics. The long-term potential benefits are improved respirator quality and performance and increased worker protection. The total burden for this data collection is 1,083 hours.

Respondents	No. of respondents	No. of responses/ respondents	Avg. burden per response (in hours)
Workers (Data Collection #1) .....	1000	1	20/60
Workers (Data Collection #2) .....	3000	1	15/60

Dated: September 12, 2002.

**Nancy E. Cheal,**

*Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 02N-0403]

#### Premarket Notification for Food Contact Substances; Public Meeting

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

**ACTION:** Notice of public meeting.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the following public meeting entitled "FDA Workshop on the Notification Process for Food Contact Substances." The purpose of the meeting is to discuss the food contact notification (FCN) process so that notifiers and/or their representatives, consumer interest groups, and other interested members of the general public can have a better understanding of the FCN process, the information requirements of an FCN, and the common deficiencies to be avoided.

**Date and Time:** The meeting will be held on Tuesday, October 15, 2002, from 8 a.m. to 5 p.m.

**Location:** The meeting will be held on the campus of the National Institutes of Health (NIH) in the Lister Hill Center Auditorium, Bldg. 38A, National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894. The NIH campus is accessible by the Washington, DC area Metrorail system using the Medical Center station. Attendees must bring photo identification to gain admittance.

**Contact:** William J. Trotter, Center for Food Safety and Applied Nutrition (HFS-275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202-418-3088, FAX 202-418-3131, or e-mail: [wjt@cfsan.fda.gov](mailto:wjt@cfsan.fda.gov).

**SUPPLEMENTARY INFORMATION:**

### I. Background

In November 1997, Congress passed the Food and Drug Administration Modernization Act (FDAMA) of 1997. Section 309 of FDAMA amended section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) to establish a notification process for food contact substances (FCSs). An FCS is defined as any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have a technical effect in such food (21 U.S.C. 348(h)(6)). Congress intended the notification process to be the primary route for authorizing the use of FCSs (21 U.S.C. 348(h)(3)(A)).

Under section 409(h) of the act, the notification process requires a manufacturer or supplier of an FCS to notify FDA at least 120 days prior to marketing an FCS for a new use. If FDA does not object to the notification within 120 days, the notification becomes effective (21 U.S.C. 348(h)(2)(A)) and the substance may be legally marketed for the requested use by the notifier (21 U.S.C. 348(a)(3)(B)).

In the **Federal Register** of May 21, 2002 (67 FR 35724), FDA published a final rule amending the food additive regulations regarding the premarket notification process for FCSs. The rule became effective on June 20, 2002, and required that a notification for an FCS must contain sufficient scientific information to demonstrate that the FCS that is the subject of the notification is safe for the intended use (21 U.S.C. 348(h)(1)). Since the inception of the FCN process in 1999, FDA has observed that FCNs frequently have deficiencies such that the FCNs are not complete. FDA is having this public meeting to discuss the data requirements for an FCN and the commonly observed deficiencies, and to assist notifiers and/or their representatives in submitting adequate and complete FCNs.

### II. Registration and Written Questions

Persons interested in attending the October 15, 2002, meeting should send their registration information (including name, title, business affiliation, address,

and telephone and fax numbers) and any questions they wish to have answered at the meeting to the contact person. To expedite processing, fax registration information to 202-418-3131 or e-mail: [wjt@cfsan.fda.gov](mailto:wjt@cfsan.fda.gov). There will be no registration charges for attending the meeting.

If you need special accommodations due to disability, please notify the contact person by October 1, 2002.

### III. Availability of Guidance Documents for FCNs

Administrative, chemistry, and toxicology guidance documents for FCNs are available at <http://www.cfsan.fda.gov/dms/opa-notf.html>.

### IV. Agenda and Goals

FDA will present what information the agency requires in an FCN to make it adequate and complete. Topics to be presented will be broadly divided among the general categories of administrative, chemical, toxicological, and environmental. There will also be workshops in which questions from the audience will be encouraged. The issues to be discussed include the following:

1. Administrative: Guidance document, number of copies of the FCN to submit and where to submit the FCN, common FCN deficiencies, Form 3480, confidentiality, one FCS per FCN, and conditions under which a food additive petition should be submitted;
2. Chemical: Guidance document, common FCN deficiencies, approaches for determining migrant levels in food, estimated daily intake, and cumulative estimated daily intake;
3. Toxicological: Guidance document, common FCN deficiencies, acceptable daily intake, risk assessments, structure activity relationships, and genetic toxicology; and

4. Environmental: Guidance document, common FCN deficiencies, the National Environmental Policy Act as applied to the notification process, categorical exclusions, and requirements for an environmental assessment.