

Because exposure to hazardous substances is of significant concern, ATSDR has been tabulating the substances to which people have been exposed at hazardous waste sites. Much interest has been focused on this tabulation. Therefore, ATSDR is announcing the publishing of this CEP report along with the CERCLA Priority List of Hazardous Substances. Since this CEP report focuses on documented exposure, it provides an important prioritization based on substances to which people are exposed.

The substances on the CEP report are similar to the substances on the CERCLA Priority List of Hazardous Substances. However, there are some substances that are on the CEP report, because they are frequently found in completed exposure pathways, but are not on the CERCLA Priority List because they have a very low toxicity (e.g., sodium). Since the CERCLA Priority List incorporates three different components (toxicity, frequency of occurrence, and potential for human exposure) to determine its priority substances,

substances with very low toxicity are not on the CERCLA Priority List and consequently are not the subject of toxicological profiles. In addition, since the Priority List is mandated by CERCLA, it only uses data from sites on the CERCLA National Priorities List, whereas the CEP report uses data from all sites with ATSDR activities that have a CEP. Of the 100 substances on the CEP report, the 25 substances found at the most number of sites in a CEP are presented below.

#### NUMBER OF SITES WITH SUBSTANCE IN A CEP

| Substance name                                | All sites | NPL sites |
|-----------------------------------------------|-----------|-----------|
| Lead .....                                    | 359       | 238       |
| Trichloroethylene .....                       | 319       | 271       |
| Arsenic .....                                 | 267       | 176       |
| Tetrachloroethylene .....                     | 236       | 190       |
| Cadmium .....                                 | 176       | 123       |
| Benzene .....                                 | 174       | 128       |
| Chromium .....                                | 169       | 113       |
| Volatile Organic Compounds, Unspecified ..... | 162       | 118       |
| Polychlorinated Biphenyls .....               | 152       | 104       |
| Mercury .....                                 | 136       | 82        |
| Zinc .....                                    | 134       | 83        |
| Manganese .....                               | 134       | 80        |
| 1,1,1-Trichloroethane .....                   | 125       | 106       |
| Copper .....                                  | 118       | 67        |
| Chloroform .....                              | 113       | 88        |
| 1,1-Dichloroethene .....                      | 105       | 91        |
| Methylene Chloride .....                      | 103       | 72        |
| Toluene .....                                 | 102       | 68        |
| Vinyl Chloride .....                          | 99        | 84        |
| Nickel .....                                  | 98        | 63        |
| Benzo (A) Pyrene .....                        | 98        | 54        |
| Polycyclic Aromatic Hydrocarbons .....        | 97        | 68        |
| Barium .....                                  | 96        | 54        |
| Antimony .....                                | 88        | 57        |
| 1,2-Dichloroethane .....                      | 86        | 71        |

**Note:** Sorted by the All Sites column. All Sites = all sites with ATSDR activities that have a CEP; NPL Sites = current and former sites on the National Priorities List, as mandated.

Dated: October 18, 2001.

**Donna Garland,**

*Deputy Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### National Center for Environmental Health; Meeting

The National Center for Environmental Health (NCEH) of the Centers for Disease Control and

Prevention (CDC) announces the following meeting:

**Name:** Applying Genetics and Public Health Strategies to Primary Immunodeficiency Diseases.

**Times and Dates:**

8 a.m.—6 p.m., November 8, 2001

8 a.m.—1 p.m., November 9, 2001

**Place:** Hyatt Regency, 285 Peachtree Street, Atlanta, Georgia 30309, Phone: 404-577-1234.

**Status:** Open to the public for observation and comment, limited only by the space available. The meeting room accommodates approximately 60 people.

**Purpose:** The purpose of the meeting is to identify a public health strategy for Primary Immunodeficiency (PI) Disease, including a public health assessment, examine laboratory issues including uses of genetic tests, to identify public health interventions to increase early recognition, to review efforts to increase awareness about these diseases among providers and the public, and to identify future public health strategies for assessment, intervention, and education.

**Matters to be Discussed:** The meeting objectives, although focused specifically on PI, also establish a framework useful for developing public health strategies for other common complex diseases. The objectives are: (1) To make a public health assessment of primary immunodeficiency diseases; (2) To examine uses of genetic tests and role in clinical practice; (3) To identify public health interventions to enhance early identification and intervention; (4) To review efforts to educate providers, patients and the public about primary immunodeficiency; and (5) To identify next steps for public health, including research priorities and workshop recommendations.

Agenda items are tentative and subject to change.

#### CONTACT PERSON FOR MORE INFORMATION:

Mary Lou Lindegren, M.D., Designated Federal Official, CDC, 4770 Buford Highway, NE, MS K-28, Atlanta, Georgia 30341-3724; telephone 770-488-3235, fax 770-488-3236; e-mail: mll3@cdc.gov.

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 the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: October 20, 2001.

**John Burckhardt,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 01N-0459]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling; Notification Procedures for Statements on Dietary Supplements

**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 collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the regulation requiring manufacturers, packers, and distributors of dietary supplements to notify FDA that they are marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in the Federal Food, Drug, and Cosmetic Act (the act).

**DATES:** Submit written or electronic comments on the collection of information by **DECEMBER 24, 2001.**

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. 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.

#### Food Labeling; Notification Procedures for Statements on Dietary Supplements—21 CFR Part 101.93 (OMB Control Number 0910-0331)—Extension

*Description:* Section 403(r)(6) of the act (21 U.S.C. 343(r)(6)) requires that the agency be notified by manufacturers, packers, and distributors of dietary supplements that they are marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in section 403(r)(6) of the act. Section 403(r)(6) of the act requires that the agency be notified, with a submission about such statements, no later than 30 days after the first marketing of the dietary supplement. Information that is required in the submission includes: (1) The name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) a signature of a responsible individual who can certify the accuracy of the information presented.

The agency established § 101.93 (21 CFR 101.93) as the procedural regulation for this program. Section 101.93 provides details of the procedures associated with the submission and identifies the information that must be included in order to meet the requirements of section 403 of the act.

*Description of Respondents:* Businesses or other for-profit organizations.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|----------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 101.93         | 2,500              | 1                             | 2,500                  | .75                | 1,875       |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The agency believes that there will be minimal burden on the industry to generate information to meet the

requirements of section 403 of the act in submitting information regarding section 403(r)(6) of the act statements on

labels or labeling of dietary supplements. The agency is requesting only information that is immediately