

to this database is essential for constructing the cohort of former workers and assessing the feasibility of conducting future health studies.

**Note:** Title 2 of the United States Code, Chapter 26, Section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

### C. Availability of Funds

Approximately \$100,000 is available in FY 2001 to fund one award to the Oregon Department of Human Services, Health Division. The award is expected to begin on or about September 30, 2001, and will be made for a 12-month budget within a project period of up to 2 years.

### D. Where To Obtain Additional Information

Program technical assistance may be obtained from:

Curtis Noonan, PhD, Epidemiologist,  
Division of Health Studies, Agency for  
Toxic Substances and Disease  
Registry, Executive Park, Building 4,  
Suite 1300, Atlanta, GA 30305,  
Telephone: (404) 498-0588, E-mail  
Address: cnoonan@cdc.gov

or

Maggie Warren, Funding Resource  
Specialist, Division of Health Studies,  
Agency for Toxic Substances and  
Disease Registry, 1600 Clifton Rd.,  
NE., Mail Stop E-31, Atlanta, GA  
30333, Telephone: (404) 498-0546, E-  
mail Address: mcs9@cdc.gov

Business management technical  
assistance may be obtained from: Nelda  
Y. Godfrey, Grants Management  
Specialist, Grants Management Branch,  
Procurement & Grants Office, Centers  
for Disease Control and Prevention,  
Room 3000, 2920 Brandywine Road,  
Atlanta, GA 30341-4146. Telephone  
number: (770) 488-2722. Email address:  
nag9@cdc.gov

Dated: August 7, 2001.

#### Georgi Jones,

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

[FR Doc. 01-20372 Filed 8-13-01; 8:45 am]

BILLING CODE 4163-70-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Toxic Substances and Disease Registry

[ATSDR-172]

#### Identification of Priority Data Needs for 10 Priority Hazardous Substances

**AGENCY:** Agency for Toxic Substances  
and Disease Registry (ATSDR), U.S.  
Department of Health and Human  
Services (HHS).

**ACTION:** Request for public comments on  
the identification of priority data needs  
for 10 priority hazardous substances,  
and an ongoing call for voluntary  
research proposals.

**SUMMARY:** This Notice makes available  
for public comment the priority data  
needs for 10 priority hazardous  
substances (see attached Table 1) as part  
of the continuing development and  
implementation of the ATSDR  
Substance-Specific Applied Research  
Program (SSARP). The Notice also  
serves as a continuous call for voluntary  
research proposals. The SSARP is  
authorized by the Comprehensive  
Environmental Response,  
Compensation, and Liability Act of 1980  
(Superfund) or CERCLA, and amended  
by the Superfund Amendments and  
Reauthorization Act of 1986 (SARA) (42  
U.S.C. 9604(i)). This research program  
was initiated on October 17, 1991. At  
that time, a list of priority data needs for  
38 priority hazardous substances was  
announced in the **Federal Register** (56  
FR 52178). The list was subsequently  
revised based on public comments and  
published in final form on November  
16, 1992 (57 FR 54150). In 1997, ATSDR  
finalized the priority data needs for a  
second list of 12 substances that was  
subsequently announced in the **Federal  
Register** (62 FR 40820).

Ten substances constitute the third  
list of hazardous substances for which  
priority data needs have been identified  
by ATSDR. In developing this list,  
ATSDR solicited input from the  
Environmental Protection Agency (EPA)  
and the National Institute of  
Environmental Health Sciences  
(NIEHS). The priority data needs  
documents are available for review by  
requesting them in writing from ATSDR  
(see **ADDRESSES** section of this Notice).

The exposure and toxicity priority  
data needs in this Notice were distilled  
from data needs identified in the  
agency's toxicological profiles via a  
logical scientific approach described in a  
"Decision Guide published" in the  
**Federal Register** on September 11, 1989  
(54 FR 37618). The priority data needs

represent essential information to  
improve the database to conduct public  
health assessments. Research to address  
these data needs will help determine the  
types or levels of exposure that may  
present significant risks of adverse  
health effects in people exposed to the  
subject substances.

The priority data needs identified in  
this Notice reflect the opinion of the  
agency, in consultation with other  
federal programs, of the research needed  
pursuant to ATSDR's authority under  
CERCLA. They do not represent the  
priority data needs for any other  
program.

Consistent with Section 104(i)(12) of  
CERCLA as amended [42 U.S.C.  
9604(i)(12)], nothing in this research  
program shall be construed to delay or  
otherwise affect or impair the authority  
of the President, the Administrator of  
ATSDR, or the Administrator of EPA to  
exercise any authority regarding any  
other provision of law, including the  
Toxic Substances Control Act of 1976  
(TSCA) and the Federal Insecticide,  
Fungicide, and Rodenticide Act of 1972  
(FIFRA), or the response and abatement  
authorities of CERCLA.

In developing this research program,  
ATSDR has worked with other federal  
programs to determine common  
substance-specific data needs, as well as  
mechanisms to implement research that  
may include authorities under TSCA  
and FIFRA, private-sector voluntarism,  
or the direct use of CERCLA funds.

When deciding the type of research  
that should be done, ATSDR considers  
the recommendations of the Interagency  
Testing Committee established under  
Section 4(e) of TSCA. Federally funded  
projects that collect information from 10  
or more respondents and that are  
funded by cooperative agreements are  
subject to review by the Office of  
Management and Budget (OMB) under  
the Paperwork Reduction Act. If the  
proposed project involves research on  
human subjects, the applicants must  
comply with Department of Health and  
Human Services regulations (45 CFR  
part 46) regarding the protection of  
human subjects. Assurance must be  
provided that the project will be subject  
to initial and continuing review by the  
appropriate institutional review  
committees. Overall, data generated  
from this research program will lend  
support to others conducting human  
health assessments involving these 10  
substances by providing additional  
scientific information for the risk  
assessment process.

The 10 substances, which are  
included in the ATSDR Priority List of  
Hazardous Substances established by

ATSDR and EPA (64 FR 56792, October 21, 1999), are:

- Asbestos
- Benzidine
- Chlorinated dibenzo-p-dioxins
- 1,2-dibromoethane
- 1,2-dichloroethane
- 1,1-dichloroethene
- Ethylbenzene
- Pentachlorophenol
- 1,1,2,2-tetrachloroethane
- Total xylenes

The priority data needs for these 10 substances are presented in Table 1. We invite comments from the public on individual data needs. After considering the comments, ATSDR will publish the final priority data needs for each substance. These priority data needs will be addressed by the mechanisms described in the "Implementation of Substance-Specific Applied Research Program" section of this **Federal Register** Notice.

This Notice also serves as a continuous call for voluntary research proposals. Private-sector organizations may volunteer to conduct research to address specific priority data needs in this Notice by indicating their interest through submission of a letter of intent to ATSDR (see **ADDRESSES** section of this Notice). A Tri-Agency Superfund Applied Research Committee (TASARC) comprised of scientists from ATSDR, the National Toxicology Program (NTP), and EPA will review all proposals.

The substance-specific priority data needs were based on, and determined from, information in corresponding ATSDR toxicological profiles. Background technical information and justification for the priority data needs in this Notice are in the priority data needs documents. These documents are available for review by requesting them in writing from ATSDR (see **ADDRESSES** section of this Notice).

**DATES:** Comments concerning the priority data needs for the 10 substances must be received by November 13, 2001. Regarding ATSDR's call for voluntary research proposals, the agency considers the voluntary research effort to be crucial to the continuing development of the Substance-Specific Applied Research Program, and believes this effort should be an open and continuous one. Therefore, private-sector organizations are encouraged to volunteer to conduct research to address identified data needs, beginning with the publication of this Notice and until that time when ATSDR announces that other research has been initiated for a specific data need.

**ADDRESSES:** Submit comments to Dr. William Cibulas, Chief, Research

Implementation Branch, Division of Toxicology, ATSDR, 1600 Clifton Road, NE., Mailstop E-29, Atlanta, GA 30333. Use the same address for requests for priority data needs documents and submission of proposals to conduct voluntary research.

Comments on this Notice will be available for public inspection at ATSDR, Building 4, Suite 2400, Executive Park Drive, Atlanta, Georgia (not a mailing address), from 8 a.m. to 4:30 p.m., Monday through Friday, except for legal holidays.

**FOR FURTHER INFORMATION CONTACT:** Dr. William Cibulas, Chief, Research Implementation Branch, Division of Toxicology, ATSDR, 1600 Clifton Road, NE., Mailstop E-29, Atlanta, GA 30333, telephone (404) 498-0140.

#### **SUPPLEMENTARY INFORMATION:**

##### **Background**

The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (Superfund) or CERCLA, as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA) [42 U.S.C. 9604(i)], requires that ATSDR (1) develop jointly with EPA a list of hazardous substances found at National Priorities List (NPL) sites (in order of priority), (2) prepare toxicological profiles of these substances, and (3) assure the initiation of a research program to address identified priority data needs associated with the substances.

The Substance-Specific Applied Research Program (SSARP) was initiated on October 17, 1991. At that time, a list of priority data needs for 38 priority hazardous substances was announced in the **Federal Register** (56 FR 52178). The list was subsequently revised based on public comments and published in final form on November 16, 1992 (57 FR 54150). In 1997, ATSDR finalized the priority data needs for a second list of 12 substances and announced the list in the **Federal Register** (62 FR 40820). Currently, a total of 201 priority data needs have been identified for these 50 substances.

This ATSDR SSARP supplies necessary information to improve the database to conduct public health assessments. This link between research and public health assessments, and the process for distilling priority data needs for ranked hazardous substances from data needs identified in associated ATSDR toxicological profiles, are described in the ATSDR "Decision Guide for Identifying Substance-Specific Data Needs Related to Toxicological Profiles" (54 FR 37618, September 11, 1989).

##### **Implementation of Substance-Specific Applied Research Program**

In Section 104(i)(5)(D), CERCLA states that it is the sense of Congress that the costs for conducting this research program be borne by the manufacturers and processors of the hazardous substances under the Toxic Substances Control Act of 1976 (TSCA) and by registrants under the Federal Insecticide, Fungicide, and Rodenticide Act of 1972 (FIFRA), or by cost recovery from responsible parties under CERCLA. To execute this statutory intent, ATSDR developed a plan whereby parts of the SSARP are being conducted via regulatory mechanisms (TSCA/FIFRA), private-sector voluntarism, and through the direct use of CERCLA funds.

CERCLA also requires that ATSDR consider recommendations of the Interagency Testing Committee (ITC), established under Section 4(e) of TSCA, on the types of research to be done. ATSDR actively participates on this committee; however, none of the proposed 10 substances are now on the ITC priority testing list.

The mechanisms for implementing the SSARP are discussed next. The status of the SSARP in addressing priority data needs of the first 50 priority hazardous substances via these mechanisms was described in a **Federal Register** Notice on January 15, 1999 (64 FR 2760).

##### *A. TSCA/FIFRA*

In developing and implementing the SSARP, ATSDR and EPA established procedures to identify those priority data needs of common interest to multiple federal programs. Where practicable, these data needs will be addressed through a program of toxicologic testing under TSCA or FIFRA. This part of the research will be conducted according to established TSCA/FIFRA procedures and guidelines.

##### *B. Private-Sector Voluntarism*

As part of the SSARP, on February 7, 1992, ATSDR announced a set of proposed procedures for conducting voluntary research (57 FR 4758). Revisions based on public comments were published on November 16, 1992 (57 FR 54160). ATSDR strongly encourages private-sector organizations to propose research to address data needs at any time until ATSDR announces that research has already been initiated for a specific data need. Private-sector organizations may volunteer to conduct research to address specific priority data needs identified in this Notice by indicating their interest through submission of a letter of intent.

The letter of intent should be a brief statement (1–2 pages) that identifies the priority data need(s) to be filled, and the methods to be used. The Tri-Agency Superfund Applied Research Committee (TASARC) will review these proposals and make recommendations to ATSDR regarding which specific voluntary research projects should be pursued and how they should be conducted with the volunteer organizations. ATSDR will enter into only those voluntary research projects that lead to high quality, peer-reviewed scientific work. Additional details regarding the process for voluntary research are in the **Federal Register** notices cited in this section.

*C. CERCLA*

Those priority data needs that are not addressed by TSCA/FIFRA or initial voluntarism will be considered for funding by ATSDR through its CERCLA budget. A large part of this research program is envisioned to be unique to CERCLA, for example, research on substances not regulated by other programs or research needs specific to public health assessments. Current examples of the direct use of CERCLA funds include interagency agreements with other federal agencies and cooperative agreements and grants with academic institutions.

Mechanisms to address these priority data needs may include a second call for voluntarism. Again, scientific peer review of study protocols and results would occur for all research conducted under this auspice.

**Substance-Specific Priority Data Needs**

The priority data needs are identified in Table 1. Unique identification numbers (37A through 46G) are assigned to the priority data needs for this list of 10 priority hazardous substances; the initial list of 38 substances has identification numbers 1A through 24C (64 FR 2760), and the second list of 12 substances has identification numbers 25A through 36G (64 FR 2760).

As previously stated, segments of the proposed research are unique to CERCLA and may be most appropriately addressed by ATSDR programs as follows.

ATSDR's responsibility as a public health agency addressing environmental health issues is, when appropriate, to collect human data to validate substance-specific exposure and toxicity assumptions. ATSDR will obtain this information by conducting exposure and health effects studies, and by establishing and using substance-specific subregistries of people enrolled in the agency's National Exposure Registry who are potentially exposed to

these substances. When a subregistry or a human exposure study is identified as a priority data need, the responsible ATSDR program will determine its feasibility, which depends on identifying appropriate populations and funding.

In addition, the need to collect, evaluate, and interpret environmental data from contaminated media around hazardous waste sites remains a priority data need for all 10 priority hazardous substances ATSDR has identified for this third set. However, some of this information has already been collected through individual state programs and the EPA's CERCLA activities; therefore, ATSDR will evaluate the extant information from these programs to better characterize the need for additional site-specific information.

ATSDR acknowledges that the conduct of human studies to determine possible links between exposure to hazardous substances and human health effects may be accomplished through mechanisms other than agency programs. We encourage private-sector organizations and other governmental programs to use ATSDR's priority data needs to plan their research activities, including identifying appropriate populations and conducting studies to answer specific human health questions.

TABLE 1.—SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS (PDN) FOR THIRD SET OF 10 PRIORITY HAZARDOUS SUBSTANCES

Substance	PDN ID	Priority data needs
Asbestos .....	37A	Epidemiologic studies of individuals occupationally exposed to asbestos levels lower than those experienced before the institution of current occupational standards governing the use of asbestos, but higher than current levels in the general population. These studies should be performed in conjunction with the immunotoxicity studies.
	37B	Immunotoxicity studies of individuals occupationally exposed to asbestos.
	37C	Development of human and rat lung retention models to aid in extrapolating between rat and human data.
	37D	Improved analytical methods for screening samples and determining the chemical structure of asbestos fibers. Also, techniques are needed to normalize studies in which different analytical methods were employed.
	37E	Exposure levels, fiber size distribution, and asbestos fiber type in areas with natural geologic deposits of friable asbestos and at hazardous waste sites. Also, techniques for estimating air levels of asbestos from soil concentrations and activity scenarios.
	37F	Exposure levels in humans living near hazardous waste sites and in other populations such as humans living in areas with naturally high levels of friable asbestos.
	37G	Potential candidate for subregistry of exposed persons.
Benzidine .....	38A	Dose-response data for acute-and intermediate-duration exposure via the oral route (the study of subchronic-duration exposure should include evaluation of reproductive and endocrine organ histopathology, lymphoid tissues histopathology as well as examination of relevant blood components, and nervous system histopathology).
	38B	Exposure levels in humans living near hazardous waste sites.
	38C	Exposure levels of children.
	38D	Potential candidate for subregistry of exposed persons.
Chlorinated dibenzo-p-dioxins .....	39A	Studies via oral exposure designed to assess childhood susceptibility.
	39B	Comparative toxicokinetic studies examining the relative absorption of CDDs across exposure routes and the relative contribution of each exposure route to total body burdens.
	39C	Exposure levels in humans living near hazardous waste sites.
	39D	Exposure levels of children.

TABLE 1.—SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS (PDN) FOR THIRD SET OF 10 PRIORITY HAZARDOUS SUBSTANCES—Continued

Substance	PDN ID	Priority data needs
1,2-Dibromoethane .....	40A	Dose-response data in animals for acute- and intermediate-duration exposure by the oral route (the study of intermediate-duration exposure should include neuropathology and observation for overt signs of neurotoxicity).
	40B	Multigeneration reproductive toxicity studies via oral exposure.
	40C	Developmental toxicity studies via oral exposure.
	40D	Immunotoxicity battery studies via oral exposure.
	40E	Exposure levels in humans living near hazardous waste sites and in other populations such as workers exposed to 1,2-dibromoethane.
	40F	Exposure levels of children.
	40G	Potential candidate for subregistry of exposed persons.
1,2-Dichloroethane .....	41A	Dose-response data in animals for acute-duration (14-day) exposure by the inhalation route, including a comparison of young and adult animals.
	41B	Dose-response data in animals for acute-duration (14-day) exposure by the oral route, including a comparison of young and adult animals.
	41C	Dose-response data in animals for intermediate-duration exposure by the inhalation route (the study should be performed in conjunction with the neurotoxicology battery of tests).
	41D	Neurotoxicology battery of tests following inhalation exposure.
	41E	Neurotoxicology battery of tests following oral exposure.
	41F	Dose-response data in animals for chronic-duration exposure by the oral route.
	41G	Developmental toxicity data for inhalation exposure (assessment of developmental cardiotoxicity and neurotoxicity).
	41H	Developmental toxicity data for oral exposure (assessment of developmental cardiotoxicity and neurotoxicity).
	41I	Additional analyses and studies for comparative toxicokinetics across species, ages, routes, and durations.
	41J	Children's susceptibility.
	41K	Exposure levels in humans living near hazardous waste sites.
1,1-Dichloroethene .....	41L	Exposure levels of children.
	41M	Potential candidate for subregistry of exposed persons.
	42A	Dose-response data in animals for acute-duration exposure by the inhalation route.
	42B	Dose-response data in animals for chronic-duration exposure by the inhalation route.
	42C	Dose-response data in animals for acute-and intermediate-duration exposure by the oral route.
	42D	Carcinogenicity studies in two species following inhalation exposure.
	42E	Reproductive toxicity studies assessing male and female end points following inhalation exposure.
	42F	Developmental toxicity studies following oral exposure.
	42G	Immunotoxicology battery of tests following oral exposure.
	42H	Battery of neurobehavioral tests following inhalation exposure.
	42I	Children's susceptibility.
	42J	Exposure levels in humans living near hazardous waste sites.
	42K	Exposure levels of children.
Ethylbenzene .....	42L	Potential candidate for subregistry of exposed persons.
	43A	Dose-response data for acute-duration exposure by the inhalation route.
	43B	Dose-response data for chronic-duration exposure by the inhalation route.
	43C	Dose-response data for acute- and intermediate-duration exposure by the oral route; the study of intermediate-duration exposure should include an evaluation of clinical signs of neurotoxicity and histopathology of reproductive organs, endocrine glands, and nervous system.
	43D	Multigeneration toxicity study examining reproductive end points and indicators of endocrine disruption following inhalation exposure.
	43E	Two-species developmental study with continued assessment of offspring during postnatal development following oral exposure.
	43F	Studies for comparative toxicokinetics.
	43G	Exposure levels in humans living near hazardous waste sites.
Pentachlorophenol .....	43H	Exposure levels in children.
	43I	Potential candidate for subregistry of exposed persons.
	44A	In vivo endocrine disruptor studies via oral exposure.
	44B	Multigeneration reproduction study involving multiple matings and examining male and female fertility via oral exposure.
	44C	Comparative toxicokinetic studies.
	44D	Exposure levels in humans living near hazardous waste sites.
	44E	Exposure levels of children through play activities near contaminated environmental media.
1,1,2,2-Tetrachloroethane .....	44F	Potential candidate for subregistry of exposed persons.
	45A	Two-species developmental toxicity study by the oral route.
	45B	Immunotoxicity battery following oral exposure.
	45C	Mammalian in vivo genotoxicity assays.
	45D	Exposure levels in humans living near hazardous waste sites.
	45E	Exposure levels of children.
	45F	Potential candidate for subregistry of exposed persons.
Total xylenes .....	46A	Dose-response data for chronic-duration exposure by the oral route. This study should be done in conjunction with the neurotoxicology battery of tests.
	46B	Neurotoxicology battery of tests following oral exposure.

TABLE 1.—SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS (PDN) FOR THIRD SET OF 10 PRIORITY HAZARDOUS SUBSTANCES—Continued

Substance	PDN ID	Priority data needs
	46C	Two-generation reproductive study following oral exposure.
	46D	Developmental toxicity study that includes neurodevelopmental end points following oral exposure.
	46E	Exposure levels in humans living near hazardous waste sites.
	46F	Exposure levels of children.
	46G	Potential candidate for subregistry of exposed persons.

Dated: August 7, 2001.

**Georgi Jones,**

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

[FR Doc. 01–20373 Filed 8–13–01; 8:45 am]

BILLING CODE 4163–70–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 01N–0335]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling; Nutrition Labeling of Dietary Supplements on a “Per Day” Basis

**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 a collection of information on nutrition labeling of dietary supplements on a “per day” basis.

**DATES:** Submit written or electronic comments on the collection of information by October 15, 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; Nutrition Labeling of Dietary Supplements on a “Per Day” Basis

Section 403(q)(5)(F) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(F)) provides that dietary supplements must bear nutrition labeling in a manner that is appropriate for the product and that is specified in regulations issued by FDA. FDA issued regulations establishing the requirements for dietary supplements in nutrition labeling in 21 CFR 101.36 in the September 23, 1997, final rule (62 FR 49826). FDA published a proposed rule in the **Federal Register** of January 12, 1999 (64 FR 1765), to amend its nutrition labeling regulations for dietary supplements. This amendment would provide that the quantitative amount and the percentage of the daily value of a dietary ingredient may be voluntarily presented on a “per day” basis in addition to the required “per serving” basis. The proposed rule stated that this voluntary information may be provided if a dietary supplement label recommends that the dietary supplement be consumed more than once per day. These proposed provisions are in response to a citizen petition submitted by a manufacturer and marketer of dietary supplements. This proposed action would provide suppliers of dietary supplements flexibility to present additional label information voluntarily to consumers.

*Respondent Description:* Suppliers of dietary supplements.

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