

deposit bond in lieu of cash or other form of bid deposit.

B. Annual Reporting Burden

Respondents: 1000

Responses Per Respondent: 1

Total Responses: 1000

Hours Per Response: .25

Total Burden Hours: 250

Obtaining Copies of Proposals:

Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (VIR), 1800 F Street, NW., Room 4035, Washington, DC 20405, telephone (202) 208-7312. Please cite OMB Control No. 3090-0057, Standard Form 150, Deposit Bond-Individual Invitation, Sale of Government Personal Property, in all correspondence.

Dated: March 24, 2005

Michael W. Carleton,

Chief Information Officer.

[FR Doc. 05-6415 Filed 3-31-05; 8:45 am]

BILLING CODE 6820-89-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Interagency Committee on Smoking and Health: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Public Law 92-463) of October 6, 1972, that the charter for the Interagency Committee on Smoking and Health (ICSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services, has been renewed for a 2-year period through March 20, 2007.

For further information, contact Dana Shelton, Executive Secretary, Interagency Committee on Smoking and Health, Centers for Disease Control and Prevention, of the Department of Health and Human Services, CDC, 4770 Buford Highway, NE., M/S K-50, Atlanta, Georgia 30341-3717, telephone 770-488-5709 or fax 770/488-5767.

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: March 25, 2005.

Alvin Hall,

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

[FR Doc. 05-6450 Filed 3-31-05; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Federal Allotments to State Developmental Disabilities Councils and Protection and Advocacy Formula Grant Programs for Fiscal Year 2006

AGENCY: Administration on Developmental Disabilities (ADD), Administration for Children and Families, Department of Health and Human Services.

ACTION: Notification of Fiscal Year 2006 Federal Allotments to State Developmental Disabilities Councils and Protection and Advocacy Formula Grant programs.

SUMMARY: This notice sets forth Fiscal Year (FY) 2006 individual allotments and percentages of the total appropriation to States administering the State Developmental Disabilities Councils and Protection and Advocacy programs, pursuant to Section 122 and Section 142 of the Developmental Disabilities Assistance and Bill of Rights Act (Act). The allotment amounts are based on the FY 2006 President's Budget request and are contingent on congressional appropriations for FY 2006. If the Congress enacts a different appropriation amount in FY 2006, these allotments will be adjusted accordingly. The State allotments are available on the ADD homepage on the Internet: <http://www.acf.hhs.gov/programs/add/>.

EFFECTIVE DATE: October 1, 2005.

FOR FURTHER INFORMATION CONTACT:

Catherine Wade, Grants Financial Management Specialist, Office of Grants Management, Office of Administration, Administration for Children and Families, telephone (202) 401-5798.

SUPPLEMENTARY INFORMATION: Section 122(a)(2) of the Act requires that adjustments in the amounts of State allotments shall be made not more often than annually and that States must be notified no less than six (6) months before the beginning of the fiscal year in which such adjustment is to take effect. The Catalog of Federal Domestic Assistance (CFDA) number is 93.630. In relation to the State Developmental Disabilities Council allotments, the descriptions of service needs were reviewed in the State plans and are consistent with the results obtained from the data elements and projected formula amounts for each State (Section 122(a)(5)).

The Administration on Developmental Disabilities has updated the following data elements for issuance of Fiscal Year 2006 allotments for both of the Developmental Disabilities formula grant programs.

A. The number of beneficiaries in each State and Territory under the Childhood Disabilities Beneficiary Program are from Table 5.J10 of the "Annual Statistical Supplement, 2003, to the Social Security Bulletin" issued by the Social Security Administration;

B. State data on Average Per Capita Income are from Table B—Per Capita Personal Income, 2001–2003 of the "Survey of Current Business," September, 2004, issued by the Bureau of Economic Analysis, U.S. Department of Commerce. The most recent comparable data for the Territories were obtained from the Department of Commerce September 2004; and

C. State data on Total Population is based on "State Population Estimates: July 1, 2004" issued December 2004 by the U.S. Census Bureau. The State working population (ages 18–64) is based on the "Estimate of Resident Population of the U.S. by Selected Age Groups and Sex, July 1, 2003" issued September 2004 by the U.S. Census Bureau. Total population estimates for the Territories are based on "Global Population Profile: 2002" data issued March 2004 by the U.S. Census Bureau. The Territories working population is based on "Population and Housing Profile: 2000" issued by the U.S. Census Bureau from Census 2000 data.

TABLE 1.—FY 2006 ALLOTMENTS; ADMINISTRATION ON DEVELOPMENTAL DISABILITIES

	Developmental disabilities councils	Percentage of total appropriation
Total	\$72,496,000	100.000000

TABLE 1.—FY 2006 ALLOTMENTS; ADMINISTRATION ON DEVELOPMENTAL DISABILITIES—Continued

	Developmental disabilities councils	Percentage of total appropriation
Alabama	1,303,749	1.798374
Alaska	461,733	.636908
Arizona	1,273,254	1.756309
Arkansas	798,009	1.100763
California	6,732,793	9.287124
Colorado	828,370	1.142642
Connecticut	684,377	.944020
Delaware	461,733	.636908
District of Columbia	461,733	.636908
Florida	3,607,497	4.976132
Georgia	1,886,710	2.602502
Hawaii	461,733	.636908
Idaho	461,733	.636908
Illinois	2,645,112	3.648632
Indiana	1,499,994	2.069071
Iowa	773,202	1.066544
Kansas	615,537	.849063
Kentucky	1,214,354	1.675063
Louisiana	1,373,991	1.895265
Maine	461,733	.636908
Maryland	1,016,990	.402822
Massachusetts	1,355,070	1.869165
Michigan	2,517,456	3.472545
Minnesota	1,031,889	1.423374
Mississippi	940,145	1.296823
Missouri	1,372,365	1.893022
Montana	461,733	.636908
Nebraska	461,733	.636908
Nevada	461,733	.636908
New Hampshire	461,733	.636908
New Jersey	1,574,549	2.171912
New Mexico	517,026	.713179
New York	4,224,169	5.826761
North Carolina	1,970,887	2.718615
North Dakota	461,733	.636908
Ohio	2,864,776	3.951633
Oklahoma	906,308	1.250149
Oregon	778,013	1.073181
Pennsylvania	3,084,849	4.255199
Rhode Island	461,733	.636908
South Carolina	1,122,357	1.548164
South Dakota	461,733	.636908
Tennessee	1,503,287	2.073614
Texas	4,731,591	6.526693
Utah	597,250	.823839
Vermont	461,733	.636908
Virginia	1,510,032	2.082918
Washington	1,185,511	1.635278
West Virginia	765,293	1.055635
Wisconsin	1,297,635	1.789940
Wyoming	461,733	.636908
American Samoa	240,458	.331685
Guam	240,458	.331685
Northern Mariana Islands	240,458	.331685
Puerto Rico	2,503,776	3.453675
Virgin Islands	240,458	.331685

TABLE 2.—FY 2006 ALLOTMENTS; ADMINISTRATION ON DEVELOPMENTAL DISABILITIES

	Protection and advocacy	Percentage of total appropriation
Total	¹ \$37,346,820	100.000000
Alabama	616,974	1.652012
Alaska	365,940	.979842
Arizona	593,445	1.589011
Arkansas	379,748	1.016815
California	3,183,331	8.523708

TABLE 2.—FY 2006 ALLOTMENTS; ADMINISTRATION ON DEVELOPMENTAL DISABILITIES—Continued

	Protection and advocacy	Percentage of total appropriation
Colorado	408,703	1.094345
Connecticut	376,728	1.008728
Delaware	365,940	.979842
District of Columbia	365,940	.979842
Florida	1,751,019	4.688536
Georgia	934,345	2.501806
Hawaii	365,940	.979842
Idaho	365,940	.979842
Illinois	1,281,999	3.432686
Indiana	722,342	1.934146
Iowa	368,535	.986791
Kansas	365,940	.979842
Kentucky	567,565	1.519714
Louisiana	629,491	1.685528
Maine	365,940	.979842
Maryland	478,650	1.281635
Massachusetts	602,505	1.613270
Michigan	1,164,400	3.117802
Minnesota	492,891	1.319767
Mississippi	436,384	1.168464
Missouri	660,742	1.769206
Montana	365,940	.979842
Nebraska	365,940	.979842
Nevada	365,940	.979842
New Hampshire	365,940	.979842
New Jersey	749,910	2.007962
New Mexico	365,940	.979842
New York	1,931,732	5.172414
North Carolina	984,385	2.635793
North Dakota	365,940	.979842
Ohio	1,350,619	3.616423
Oklahoma	420,929	1.127081
Oregon	391,212	1.047511
Pennsylvania	1,417,757	3.796192
Rhode Island	365,940	.979842
South Carolina	541,043	1.448699
South Dakota	365,940	.979842
Tennessee	718,684	1.924351
Texas	2,243,796	6.007997
Utah	365,940	.979842
Vermont	365,940	.979842
Virginia	726,148	1.944337
Washington	564,196	1.510694
West Virginia	388,931	1.041403
Wisconsin	611,617	1.637668
Wyoming	365,940	.979842
American Samoa	195,775	.524208
Guam	195,775	.524208
Northern Mariana Islands	195,775	.524208
Puerto Rico	1,090,269	2.919309
Virgin Islands	195,775	.524208
DNA People Legal Services ²	195,775	.524208

¹ In accordance with Public Law 106-402, Section 142(a)(6)(A), \$762,180 has been withheld to fund technical assistance. The statute provides for spending up to two percent (2%) of the amount appropriated under Section 142 for this purpose. Unused funds will be reallocated in accordance with Section 122(e) of the Act.

² American Indian Consortia are eligible to receive an allotment under Section 142(a)(6)(B) of the Act.

Dated: March 29, 2005.

Patricia A. Morrissey,

*Commissioner, Administration on
Developmental Disabilities.*

[FR Doc. 05-6483 Filed 3-31-05; 8:45 am]

BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0515]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Labeling Regulations

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 2, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Device Labeling Regulations— 21 CFR Parts 800, 801, and 809 (OMB Control Number 0910-0485)—Extension

Section 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352), among other things, establishes requirements for the label or labeling of a medical device so that it is not misbranded and subject to regulatory action. Certain provisions of section 502 of the act require that manufacturers, importers, and distributors of medical

devices disclose information about themselves or their devices on the labels or labeling of the devices. Section 502(b) of the act requires that, if the device is in a package, the label must contain the name and place of business of the manufacturer, packer, or distributor and an accurate statement of the quantity of the contents. Section 502(f) of the act provides that the labeling of a device must contain adequate directions for use. FDA may grant an exemption from the adequate directions for use requirement, if FDA determines that adequate directions for use are not necessary for the protection of the public health.

FDA regulations in parts 800, 801, and 809 (21 CFR parts 800, 801, and 809) require manufacturers, importers, and distributors of medical devices to disclose to health professionals and consumers specific information about themselves or their devices on the label or labeling of their devices. FDA issued these regulations under the authority of sections 201, 301, 502, and 701 of the act (21 U.S.C. 321, 331, 352, and 371). Most of the regulations in parts 800, 801, and 809 derive from the requirements of section 502 of the act, which provides, in part, that a device shall be misbranded if, among other things, its label or labeling fails to bear certain required information concerning the device, is false or misleading in any particular way, or fails to contain adequate directions for use.

Section 800.12 requires that packages of contact lens cleaning solutions include a tamper-resistant feature to prevent malicious adulteration. Sections 800.10(a)(3) and 800.12(c) require that the label of contact lens cleaning solutions contain a prominent statement alerting consumers to the tamper-resistant feature.

Section 800.10(b)(2) requires that the labeling of liquid ophthalmic preparations packed in multiple-dose containers include information as to duration of use and necessary warnings to afford adequate protection from contamination during use.

Section 801.1 requires that the label of a device in package form contain the name and place of business of the manufacturer, packer, or distributor.

Section 801.5 requires that the labeling of devices include directions under which the layman can use a device safely and for the purposes for which it is intended. Section 801.4 defines “intended use”. Where necessary, the labeling should include: (1) Statements of all conditions, purposes, or uses for which the device is intended, unless the device is a prescription device subject to the

requirements of § 801.109; (2) quantity of dose; (3) frequency of administration or application; (4) duration of administration or application; (5) time of administration, e.g. in relation to meals, onset of symptoms, etc.; (6) route of method or application; and (7) preparation for use.

Section 801.61 requires that the principal display panel of an over-the-counter (OTC) device in package form must include a statement of the identity of the device. The statement of the identity of the device must include the common name of the device followed by an accurate statement of the principal intended actions of the device.

Section 801.62 requires that the label of an OTC device in package form must include a declaration of the net quantity of contents. The label must express the net quantity in terms of weight, measure, numerical count, or a combination of numerical count and weight, measure, or size.

Section 801.109 establishes labeling requirements for prescription devices. A prescription device is defined as a device which, because of its potential for harmful effect, the method of its use or the collateral measures necessary to its use, is not safe except under the supervision of a practitioner licensed by law to use the device and, therefore, for which adequate directions for use by a layperson cannot be developed.

The label of the device must include: (1) The statement “Caution: Federal law restricts this device to sale by or on the order of a ‘_____’”. The blank is to be filled in by a term such as “physician,” “dentist,” or other appropriate term; and (2) the method of its application or use.

Labeling must include information for use, including indications, effects, routes, methods, frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented.

Information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device.

Section 801.110 establishes a labeling requirement for a prescription device delivered to the ultimate purchaser or user upon the prescription of a licensed practitioner. The device must be accompanied by labeling bearing the name and address of the licensed