

of October 6, 1972, that the charter for the Advisory Council for the Elimination of Tuberculosis (ACET) of the Centers for Disease Control and Prevention, Department of Health and Human Services, has been renewed for a 2-year period, through March 15, 2003.

For further information, contact Ronald O. Valdiserri, M.D., Executive Secretary, Advisory Council for the Elimination of Tuberculosis, CDC, 1600 Clifton Road, NE, M/S E-07, Atlanta, Georgia 30333, telephone 404/639-8002 or fax 404-639-8600.

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 26, 2001.

Carolyn J. Russell,

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

[FR Doc. 01-7874 Filed 3-30-01; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice Regarding Requirement for Submission of List of Ingredients Added to Tobacco in Cigarettes; Amendment

AGENCY: Centers for Disease Control and Prevention (CDC), HHS.

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Office on Smoking and Health (OSH), is amending the ingredient list due date referenced in the "Notice Regarding Requirement for Submission of List of Ingredients Added to Tobacco in Cigarettes; Amendment" published in the **Federal Register** on Tuesday, November 8, 1994.

FOR FURTHER INFORMATION CONTACT: Lawrence W. Green, Dr.P.H., Acting Director, Office on Smoking and Health, telephone (770) 488-5701.

SUPPLEMENTARY INFORMATION: On November 8, 1994, CDC published a notice changing the reporting date from December 31 to March 31 for submission of the list of ingredients

added to tobacco in cigarettes [59 FR 55669]. The following amendment is made to that notice:

On page 55670, first column, second paragraph, after "Dates:" change to read "upon initial importation and on March 31st every year thereafter."

Dated: March 26, 2001.

Joseph R. Carter,

Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01-7989 Filed 3-30-01; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice Regarding Requirement for Submission of List of Ingredients Added to Tobacco in the Manufacture of Smokeless Tobacco Products; Amendment

AGENCY: Centers for Disease Control and Prevention (CDC), HHS.

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Office on Smoking and Health (OSH), is amending the ingredient list due date referenced in the "Notice Regarding Requirement for Submission of List of Ingredients Added to Tobacco in the Manufacture of Smokeless Tobacco Products; Amendment" published in the **Federal Register** on Tuesday, November 8, 1994.

FOR FURTHER INFORMATION CONTACT: Lawrence W. Green, Dr.P.H., Acting Director, Office on Smoking and Health, telephone (770) 488-5701.

SUPPLEMENTARY INFORMATION: On November 8, 1994, CDC published a notice changing the reporting date from December 31 to March 31 for submission of the list of ingredients added to tobacco in the manufacture of smokeless tobacco products (59 FR 55670). The following amendment is made to that notice:

On page 55670, first column, fourth paragraph, after "Dates:" change to read "upon initial importation and on March 31st every year thereafter."

Dated: March 26, 2001.

Joseph R. Carter,

Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01-7990 Filed 3-30-01; 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 (DDC) and Protection and Advocacy (P&A) Formula Grant Programs for Fiscal Year 2002

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

ACTION: Notification of Fiscal Year 2002 Federal allotments to State Developmental Disabilities Councils and Protection and Advocacy formula grant programs.

SUMMARY: This notice sets forth Fiscal Year (FY) 2002 individual allotments and percentages 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 upon the FY 2001 Budget Request and are contingent upon congressional appropriations for FY 2002. If Congress enacts and the President approves a different appropriation amount, the allotments will be adjusted accordingly. The individual allotments will be available April 1, 2001 on the ADD homepage on the Internet: <http://www.act.dhhs.gov/programs/add/>.

EFFECTIVE DATE: October 1, 2001.

FOR FURTHER INFORMATION CONTACT: Doris Lee, Grants Fiscal Management Specialist, Office of Management Services, Administration for Children, Youth and Families, telephone (202) 205-4626.

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 are to be notified no less than six (6) months before the beginning of the fiscal year in which such adjustment is to take effect. In relation to the State DDC allotments, the description 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 2002 allotments for 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, 2000 to the Social Security Bulletin" issued by the Social Security Administration;

B. State data on Average Per Capita Income are from Table 1—Personal Income and Per Capita Personal Income

by State and Region, 1996–99 of the "Survey of Current Business," October, 2000, issued by the Bureau of Economic Analysis, U.S. Department of Commerce; comparable data for the Territories also were obtained from the Department of Commerce October, 2000; and

C. State data on Total Population and Working Population (ages 18–64) as of July 1, 1999, are from the "Estimate of Resident Population of the U.S. by

Selected Age Groups and Sex," issued by the Bureau of the Census, U.S. Department of Commerce. Total population estimates for the Territories, as of 1999, are from the Statistical Abstract of the United States: 2000 issued by the Bureau of Census. The Territories working population was issued in the Bureau of Census report, "General Characteristics Report: 1980," which is the most recent data available from the Bureau.

TABLE 1.—FY 2002 ALLOTMENTS—ADMINISTRATION ON DEVELOPMENTAL DISABILITIES

	Developmental disabilities councils	Percentage
Total	¹ \$67,800,000	100.000000
Alabama	1,316,694	1.942027
Alaska	20,477	.620173
Arizona	965,108	1.423463
Arkansas	768,612	1.133646
California	5,876,564	8.667492
Colorado	732,816	1.080850
Connecticut	678,461	1.000680
Delaware	420,477	.620173
District of Columbia	420,477	.620173
Florida	2,856,147	4.212606
Georgia	1,657,371	2.444500
Hawaii	420,477	.620173
Idaho	420,477	.620173
Illinois	2,656,686	3.918416
Indiana	1,465,626	2.161690
Iowa	795,933	1.173942
Kansas	610,953	.901111
Kentucky	1,218,231	1.796801
Louisiana	1,414,383	2.086111
Maine	420,477	.620173
Maryland	926,442	1.366434
Massachusetts	1,311,359	1.934158
Michigan	2,378,843	3.508618
Minnesota	1,007,871	1.486535
Mississippi	938,115	1.383650
Missouri	1,326,270	1.956150
Montana	420,477	.620173
Nebraska	425,955	.628252
Nevada	420,477	.620173
New Hampshire	420,477	.620173
New Jersey	1,493,616	2.202973
New Mexico	462,147	.681633
New York	4,150,337	6.121441
North Carolina	1,817,454	2.680611
North Dakota	420,477	.620173
Ohio	2,870,118	4.233212
Oklahoma	912,780	1.346283
Oregon	703,155	1.037102
Pennsylvania	3,111,570	4.589336
Rhode Island	420,477	.620173
South Carolina	1,059,459	1.567300
South Dakota	420,477	.620173
Tennessee	1,443,822	2.129531
Texas	4,290,573	6.328279
Utah	521,763	.769562
Vermont	420,477	.620173
Virginia	1,374,780	2.027699
Washington	1,066,152	1.572496
West Virginia	765,828	1.129540
Wisconsin	1,284,774	1.894947
Wyoming	420,477	.620173
American Samoa	220,752	.325593
Guam	220,752	.325593
Northern Mariana Islands	220,752	.325593
Puerto Rico	2,373,546	3.500805

TABLE 1.—FY 2002 ALLOTMENTS—ADMINISTRATION ON DEVELOPMENTAL DISABILITIES—Continued

	Developmental disabilities councils	Percentage
Virgin Islands	220,752	.325593

¹ Allocations are computed based on the requirements of Section 122(a)(4)(B), Reduction of Allotment of the Act.

TABLE 2.—FY 2002 ALLOTMENTS—ADMINISTRATION ON DEVELOPMENTAL DISABILITIES

State	Protection and advocacy	Percentage
Total	¹ \$32,340,000	100.000000
Alabama	544,401	1.683367
Alaska	314,319	.971920
Arizona	454,324	1.404836
Arkansas	323,364	.999889
California	2,776,522	8.585411
Colorado	344,211	1.064351
Connecticut	326,619	1.009954
Delaware	314,319	.971920
District of Columbia	314,319	.971920
Florida	1,404,766	4.343741
Georgia	766,845	2.371197
Hawaii	314,319	.971920
Idaho	314,319	.971920
Illinois	1,113,210	3.442208
Indiana	631,366	1.952276
Iowa	320,978	.992511
Kansas	314,319	.971920
Kentucky	503,612	1.557242
Louisiana	557,936	1.725220
Maine	314,319	.971920
Maryland	427,672	1.322424
Massachusetts	550,395	1.701902
Michigan	1,047,124	3.237860
Minnesota	434,873	1.344691
Mississippi	387,714	1.198868
Missouri	574,279	1.775754
Montana	314,319	.971920
Nebraska	314,319	.971920
Nevada	314,319	.971920
New Hampshire	314,319	.971920
New Jersey	658,758	2.036976
New Mexico	314,319	.971920
New York	1,680,809	5.197307
North Carolina	810,417	2.505928
North Dakota	14,319	.971920
Ohio	1,207,229	3.732928
Oklahoma	380,649	1.177022
Oregon	329,527	1.018946
Pennsylvania	1,263,351	3.906466
Rhode Island	314,319	.971920
South Carolina	465,271	1.438686
South Dakota	314,319	.971920
Tennessee	619,765	1.916404
Texas	1,860,544	5.753074
Utah	314,319	.971920
Vermont	314,319	.971920
Virginia	637,072	1.969920
Washington	487,689	1.508006
West Virginia	338,198	1.045758
Wisconsin	548,445	1.695872
Wyoming	314,319	.971920
American Samoa	168,175	.520022
Guam	168,175	.520022
Northern Mariana Islands	168,175	.520022
Puerto Rico	897,039	3.288336
Virgin Islands	168,175	.520022
DNA People Legal Services ²	168,175	.520022

¹ In accordance with Public Law 106-402, Section 142(a)(6), \$660,000 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 142(c) of the Act.

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

Dated: March 21, 2001.

Sue Swenson,

*Commissioner, Administration on
Developmental Disabilities.*

[FR Doc. 01-7963 Filed 3-30-01; 8:45 am]

BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 23, 2001, 8 a.m. to 5 p.m.

Location: Holiday Inn, Kennedy Grand Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact: Megan Moynahan, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8517, ext. 171, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12625. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for a peripheral stent used in the treatment of stenotic or occluded femoral or popliteal arteries. Subsequently, the committee will discuss clinical study design issues for peripheral stents used in the treatment of stenotic or occluded iliac arteries. Background information and questions for the committee will be available to the public on April 20, 2001, on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 18, 2001. Oral presentations from the public will be scheduled between approximately 8

a.m. and 8:30 a.m. Near the end of the committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 18, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 26, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01-7995 Filed 3-30-01; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0129]

Medical Devices Draft Guidance for the Implementation of the Biomaterials Access Assurance Act of 1998; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Implementation of the Biomaterials Access Assurance Act of 1998." The Biomaterials Access Assurance Act of 1998 (BAA98) allows persons to petition FDA for a declaration stating that a biomaterials supplier should have registered as a medical device establishment or listed its products with FDA but has not done so. This draft guidance provides information that FDA believes should be included in the petition, the procedures FDA believes should be followed in submitting the petition, and the procedures that the Center for Devices and Radiological Health (CDRH) intends to adopt for addressing petitions for declaration. This guidance is neither final nor is it in effect at this time.

DATES: Submit written comments on the draft guidance by July 2, 2001. Submit written comments on the information collection requirements by June 1, 2001.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Implementation of the Biomaterials Access Assurance Act of 1998" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

Harold A. Pellerite, Center for Devices and Radiological Health (HFZ-300), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-4692, ext. 159.

SUPPLEMENTARY INFORMATION:

I. Background

BAA98 (21 U.S.C. 1601-1606) establishes a mechanism to protect some biomaterials suppliers of implanted medical devices from liability in civil suits for harm caused by an implant. However, biomaterials suppliers are not protected from liability when they fail to meet specifications, act as a manufacturer or seller of the implanted devices, or have substantial economic ties to either the manufacturer or seller. For the purposes of BAA98, a "biomaterials supplier" is defined as an entity that directly or indirectly supplies a component part or raw material for use in the manufacture of an implanted medical device. BAA98 also provides that a biomaterials supplier may be considered a manufacturer of a medical device if the supplier is the subject of an FDA declaration that states that the supplier was required to register, under section 510 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360), but failed to do so, or was required to list its device, under section 520(j) of the act (21 U.S.C. 360(j)), but failed to do so. BAA98 allows persons to petition FDA for a declaration stating that a biomaterials supplier should have registered or listed with FDA but has not done so.

The draft guidance discusses the prerequisites for filing a petition for declaration and suggests information to be included in the petition. The following three prerequisites must be