welfare, including traineeships with such stipends and allowances as may be permitted by the Department of Health and Human Services (DHHS). Specific priority areas for which grant awards are being solicited include:

99A: Adoption Opportunities

99A.1: Innovations for Increasing Adoptions of Minority Children
99A.2: Targeted Field-Initiated Research and Service Demonstrations
99A.3: Support for Improving Implementation of the Interstate Compact on the Placement of Children
99A.4: Collaborative Planning to Increase Inter-jurisdictional Adoptions

99B: Child Welfare National Resource Centers

99B.1: National Resource Center for Youth Development
99B.2: National Resource Center for Child Welfare Services and Information Technology
99B.3: National Resource Center for Foster Care and Permanency Planning
99B.4: National Resource Center for Organizational Improvement
99B.5: National Resource Center on Legal and Judicial Issues
99B.6: National Resource Center for Family-Centered Practice

99C: Child Welfare Training Discretionary Grants

99C.1: Training of Child Welfare Staff to Develop Child-focused Intervention Skills
99C.2: Training of Child Welfare Staff to Develop Cultural Competence Needed to Work with Tribal Children and Families

DATES: The date and time deadline for RECEIPT of applications by DHHS for new grants under this announcement 4:30 p.m. (Eastern Time Zone) on July 19, 1999.

FOR FURTHER INFORMATION: Copies of the program announcement will be automatically sent to all current Children's Bureau grantees, all organizations that applied for grant awards in FY 98 and all individuals and organizations that have asked to be placed on the mailing list for the FY 1999 announcement. Copies of the program announcement can be obtained by calling the ACYF Operations Center at 1–800–351–2293. A copy of this program announcement is also located under Policy and Funding Announcements at the Children's Bureau website at http://www.acf.dhhs.gov/programs/cb.

SUPPLEMENTARY INFORMATION: Grant awards of FY 1999 funds will be made by September 30, 1999. The estimated funds available for new awards is $10.6 million and the approximate number of new grants is estimated at 38.

(*Catalog of Federal Domestic Assistance.* Number 93.652, Adoption Opportunities Grants; Number 93.658, Foster Care; Number 93.556, Promoting Safe and Stable Families; and Number 93.648, Child Welfare Training)

Dated: May 13, 1999.

Patricia Montoya,

Commissioner, Administration on Children, Youth and Families.

[FR Doc. 99–12700 Filed 5–19–99; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Federal Allotments to State Developmental Disabilities Councils (DDCs) and Protection and Advocacy (P&A) Formula Grant Programs for Fiscal Year 2000

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

ACTION: Notification of Fiscal Year 2000 Federal Allotments to State Developmental Disabilities Councils and Protection and Advocacy Formula Grant Programs.

SUMMARY: This notice sets forth Fiscal Year 2000 individual allotments and percentages to States administering the State Developmental Disabilities Councils and Protection and Advocacy programs, pursuant to Section 125 and Section 142 of the Developmental Disabilities Assistance and Bill of Rights Act (Act). The allotment amounts are based on the 1999 Budget Request and are contingent upon Congressional appropriations for Fiscal Year 2000. If Congress enacts and the President approves a different appropriation amount, the allotments will be adjusted accordingly.

EFFECTIVE DATE: October 1, 1999.

FOR FURTHER INFORMATION CONTACT: Doris Lee, Grants Fiscal Management Specialist, Family Support Branch, Division of Formula, Entitlement and Block Grants, Office of Financial Operations, Administration for Children and Families, Department of Health and Human Services, 370 L'Enfant Promenade S.W., Washington, D.C. 20447, Telephone (202) 205–4626.

SUPPLEMENTARY INFORMATION: Section 125(a)(2) of the Act requires that adjustments in the amounts of State allotments may be made not more often than annually and that States are to be notified not less than six (6) months before the beginning of any fiscal year of any adjustments to take effect in that fiscal year. It should be noted that, as required by the Compact of Free Association, Palau is no longer eligible to receive funds. Also, 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 125(a)(5)).

The Administration on Developmental Disabilities has updated the data elements for issuance of Fiscal Year 2000 allotments for the Developmental Disabilities formula grant programs. The data elements used in the update are:

A. The number of beneficiaries in each State and Territory under the Childhood Disabilities Beneficiary Program, December 1997, are from Table 5.J10 of the ''Social Security Bulletin: Annual Statistical Supplement 1998'' issued by the Social Security Administration. The number for the Northern Mariana Islands was obtained from the Social Security Administration;

B. State data on Average Per Capita Income are from Table SA05 of the ''Survey of Current Business,'' September 1997, issued by the Bureau of Economic Analysis, U.S. Department of Commerce; comparable data for the Territories also were obtained from that Bureau; and

C. State data on Total Population and Working Population (ages 18–64) as of July 1, 1997, are from the ''Estimates 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. Estimates for the Territories were issued for the first time since the 1990 Census Population Counts. The Territories' working populations were issued in the Bureau of Census report, ''General Characteristics Report: 1980,'' which is the most recent data available from the Bureau.

TABLE 1.—FY 2000 ALLOTMENT—ADMINISTRATION ON DEVELOPMENTAL DISABILITIES

	State developmental disabilities councils	Percentage
Total	[1] $64,803,000	100.000000
Alabama	1,262,258	1.947839
Alaska	403,093	.622028
Arizona	852,424	1.315408
Arkansas	736,835	1.137038
California	5,577,058	8.606173
Colorado	702,519	1.084084
Connecticut	636,590	.982346
Delaware	403,093	.622028
District of Columbia	403,093	.622028
Florida	2,738,067	4.225216
Georgia	1,588,851	2.451817
Hawaii	403,093	.622028
Idaho	403,093	.622028
Illinois	2,546,852	3.930145
Indiana	1,405,033	2.168160
Iowa	763,027	1.177456
Kansas	585,694	.903807
Kentucky	1,167,866	1.802179
Louisiana	1,355,909	2.092355
Maine	403,093	.622028
Maryland	888,140	1.370523
Massachusetts	1,232,540	1.901980
Michigan	2,260,428	3.488153
Minnesota	966,203	1.490985
Mississippi	899,331	1.387792
Missouri	1,271,438	1.962005
Montana	403,093	.622028
Nebraska	408,345	.630133
Nevada	403,093	.622028
New Hampshire	403,093	.622028
New Jersey	1,431,866	2.209567
New Mexico	443,040	.683672
New York	3,978,194	6.138750
North Carolina	1,742,316	2.688635
North Dakota	403,093	.622028
Ohio	2,751,460	4.245884
Oklahoma	875,043	1.350312
Oregon	674,084	1.040205
Pennsylvania	2,982,930	4.603074
Rhode Island	403,093	.622028
South Carolina	1,015,658	1.567301
South Dakota	403,093	.622028
Tennessee	1,384,131	2.135906
Texas	4,113,190	6.347222
Utah	500,192	.771866
Vermont	403,093	.622028
Virginia	1,317,943	2.033768
Washington	1,022,074	1.577202
West Virginia	728,693	1.124474
Wisconsin	1,231,658	1.900619
Wyoming	403,093	.622028
American Samoa	211,625	.326567
Guam	211,625	.326567
Northern Mariana Islands	211,625	.326567
Puerto Rico	2,275,418	3.511285
Virgin Islands	211,625	.326567

[1] Allocations are computed based on the requirements of Section 125(a)(3)(B)—Reduction of Allotment of the Act.

TABLE 2.—FY 2000 ALLOTMENT—ADMINISTRATION ON DEVELOPMENTAL DISABILITIES

	Protection and advocacy	Percentage
Total	[1] $26,183,640	100.000000
Alabama	440,488	1.682302
Alaska	254,508	.972012
Arizona	366,883	1.401192

TABLE 2.—FY 2000 ALLOTMENT—ADMINISTRATION ON DEVELOPMENTAL DISABILITIES—Continued

	Protection and advocacy	Percentage
Arkansas	263,838	1.007644
California	2,238,705	8.550014
Colorado	281,419	1.074789
Connecticut	262,297	1.001759
Delaware	254,508	.972012
District of Columbia	254,508	.972012
Florida	1,107,462	4.229595
Georgia	615,186	2.349505
Hawaii	254,508	.972012
Idaho	254,508	.972012
Illinois	899,454	3.435176
Indiana	504,761	1.927772
Iowa	260,532	.995018
Kansas	254,508	.972012
Kentucky	407,830	1.557576
Louisiana	465,862	1.779210
Maine	254,508	.972012
Maryland	344,455	1.315535
Massachusetts	445,897	1.702960
Michigan	829,459	3.167852
Minnesota	348,788	1.332084
Mississippi	314,344	1.200536
Missouri	461,734	1.763445
Montana	254,508	.972012
Nebraska	254,508	.972012
Nevada	254,508	.972012
New Hampshire	254,508	.972012
New Jersey	524,188	2.001968
New Mexico	254,508	.972012
New York	1,392,058	5.316518
North Carolina	648,421	2.476436
North Dakota	254,508	.972012
Ohio	978,964	3.738838
Oklahoma	310,330	1.185206
Oregon	266,748	1.018785
Pennsylvania	1,028,682	3.998409
Rhode Island	254,508	.972012
South Carolina	369,392	1.410774
South Dakota	254,508	.972012
Tennessee	495,137	1.891017
Texas	1,546,785	5.907448
Utah	254,508	.972012
Vermont	254,508	.972012
Virginia	513,852	1.962493
Washington	396,806	1.515473
West Virginia	274,742	1.049289
Wisconsin	444,030	1.695830
Wyoming	254,508	.972012
American Samoa	136,161	.520023
Guam	136,161	.520023
Northern Mariana Islands	136,161	.520023
Puerto Rico	853,915	3.261254
Virgin Islands	136,161	.520023
DNA People Legal Services[2]	136,161	.520023

[1] In accordance with Public Law 104–183, Section 142(c)(5), $534,360 has been withheld for funding technical assistance. The statute provides for spending up to two percent (2%) of the amount appropriated under Section 143 to fund technical assistance. Unused funds will be reallotted in accordance with Section 142(c)(1) of the Act.

[2] American Indian Consortiums are eligible to receive an allotment under Section 142(c)(1)(A)(i).

Dated: May 13, 1999.

Sue E. Swenson,

Commissioner, Administration on Developmental Disabilities.

[FR Doc. 99–12699 Filed 5–19–99; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0754]

Determination of Regulatory Review Period for Purposes of Patent Extension; Omnicef® Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Omnicef® Tablets and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Omnicef® Tablets (cefdinir). Omnicef® Tablets is indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of specific microorganisms in specified conditions. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Omnicef® Tablets (U.S. Patent No. 4,559,334) from Warner-Lambert Co., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 14, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Omnicef® Tablets represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Omnicef® Tablets is 2,745 days. Of this time, 2,288 days occurred during the testing phase of the regulatory review period, while 457 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective:* June 1, 1990. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 1, 1990.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act:* September 4, 1996. FDA has verified the applicant's claim that the new drug application (NDA) for Omnicef® Tablets (NDA 50–739) was initially submitted on September 4, 1996.

3. *The date the application was approved:* December 4, 1997. FDA has verified the applicant's claim that NDA 50–739 was approved on December 4, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,601 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 19, 1999, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 16, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 4, 1999.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 99–12651 Filed 5–19–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0474]

Determination of Regulatory Review Period for Purposes of Patent Extension; Tazorac®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined