be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Ms. Wendy Taylor.

Dated: November 17, 1998.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 98–31234 Filed 11–20–98; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Federal Allotments to States for Social Services Expenditures, Pursuant to Title XX, Block Grants to States for Social Services; Promulgation for Fiscal Year 2000

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

ACTION: Notice of correction.

SUMMARY: This notice corrects the most recent population statistics and revises the allotment amounts contained in the notice published on Tuesday, November 10, 1998 (63 FR 63062). The allotments to the States published herein are based upon the authorization set forth in section 2003(c) of the Act and are contingent upon Congressional appropriations for the fiscal year. If Congress enacts and the President approves an amount different from the authorization, the allotments will be adjusted proportionately.

FOR FURTHER INFORMATION CONTACT: John K. Jolley, (202) 401–5284.

SUPPLEMENTARY INFORMATION: Section 2003(c) of the Act authorizes $2.380 billion for Fiscal Year 2000 and provides that it be allocated as follows:

(1) Puerto Rico, Guam, the Virgin Islands, and the Northern Mariana Islands each receives an amount which bears the same ratio to $2.380 billion as its allocation for Fiscal Year 1981 bore to $2.9 billion.

(2) American Samoa receives an amount which bears the same ratio to the amount allotted to the Northern Mariana Islands as the population of American Samoa bears to the population of the Northern Mariana Islands determined on the basis of the most recent data available at the time such allotment is determined.

(3) The remainder of the $2.380 billion is allotted to each State in the same proportion as that State's population is to the population of all States, based upon the most recent data available from the Department of Commerce.

For Fiscal Year 2000, the allotments are based upon the Bureau of Census population statistics contained in its report ''Estimates of the Population of States: Annual Time Series, July 1, 1990 to July 1, 1997 (Press Release CB97–213 December 31, 1997), and ''1990 Census of Population and Housing'' (CPH–6–AS and CPH–6–CNMI) published April 1992, which are the most recent data available from the Department of Commerce at this time as to the population of each State and each Territory.

EFFECTIVE DATE: The allotments shall be effective October 1, 1999.

FISCAL YEAR 2000 FEDERAL ALLOTMENTS TO STATES FOR SOCIAL SERVICES—TITLE XX BLOCK GRANTS

Total	$2,380,000,000
Alabama	38,192,807
Alaska	5,385,371
American Samoa	88,560
Arizona	40,279,749
Arkansas	22,310,825
California	285,345,103
Colorado	34,425,700
Connecticut	28,916,527
Delaware	6,473,057
Dist. of Col.	4,677,934
Florida	129,584,949
Georgia	66,198,507
Guam	410,345
Hawaii	10,496,611
Idaho	10,699,999
Illinois	105,196,025
Indiana	51,855,203
Iowa	25,220,163
Kansas	22,947,519
Kentucky	34,558,345
Louisiana	38,484,625
Maine	10,982,974
Maryland	45,046,112
Massachusetts	54,101,318
Michigan	86,431,233
Minnesota	41,438,179
Mississippi	24,141,321
Missouri	47,769,749
Montana	7,772,975
Nebraska	14,652,809
Nevada	14,829,668
New Hampshire	10,372,809
New Jersey	71,212,474
New Mexico	15,298,346
New York	160,385,029
North Carolina	65,659,086
North Dakota	5,668,347
No. Mariana Islands	82,069
Ohio	98,917,513
Oklahoma	29,332,147
Oregon	28,677,766
Pennsylvania	106,292,554
Puerto Rico	12,310,345
Rhode Island	8,728,016
South Carolina	33,249,584
South Dakota	6,526,115
Tennessee	47,469,087
Texas	171,898,582
Utah	18,207,685
Vermont	5,208,512
Virgin Islands	410,345
Virginia	59,548,591
Washington	49,609,087
West Virginia	16,058,842
Wisconsin	45,718,178
Wyoming	4,244,629

Dated: November 17, 1998.

Donald Sykes,

Director, Office of Community Services.

[FR Doc. 98–31232 Filed 11–20–98; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0758]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Seroquel® 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 Seroquel® (quetiapine fumarate). Seroquel® is indicated for the management of the manifestations of psychotic disorders. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Seroquel® (U.S. Patent No. 4,879,288) from Zeneca Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 7, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Seroquel® 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 Seroquel® is 3,264 days. Of this time, 2,839 days occurred during the testing phase of the regulatory review period, while 425 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*: October 21, 1988. The applicant claims September 20, 1988, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 21, 1988, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: July 29, 1996. FDA has verified the applicant's claim that the new drug application (NDA) for Seroquel® (NDA 20–639) was initially submitted on July 29, 1996.

3. *The date the application was approved*: September 26, 1997. FDA has verified the applicant's claim that NDA 20–639 was approved on September 26, 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 1,651 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before January 22, 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 May 24, 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: November 4, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–31101 Filed 11–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Arthritis 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Arthritis 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 December 1, 1998, 8 a.m. to 5 p.m., and December 2, 1998, 8 a.m. to 4 p.m.

Location: Town Center Hotel, The Maryland Ballroom, 8727 Colesville Rd., Silver Spring, MD.

Contact Person: Kathleen R. Reedy or LaNise S. Giles, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12532. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug application (NDA) 20–998 Celebrex™ (celecoxib, Searle) for the treatment of acute or chronic signs and symptoms of osteoarthritis and rheumatoid arthritis and the management of pain.

Procedure: On December 1, 1998, from 8 a.m. to 5 p.m., the meeting is open to the public. 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 November 25, 1998. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 25, 1998, 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.