

Services, 370 L'Enfant Promenade SW., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the Federal Register. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should 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: March 12, 1997.

Bob Sargis,

Acting Reports Clearance Officer.

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Office of Community Services

State Median Income Estimates for Four-Person Families (FY 1998); Notice of the Fiscal Year (FY) 1998 State Median Income Estimates for Use Under the Low Income Home Energy Assistance Program (LIHEAP) Administered by the Administration for Children and Families, Office of Community Services, Division of Energy Assistance

AGENCY: Administration for Children and Families (ACF), DHHS.

ACTION: Notice of estimated state median income for FY 1998.

SUMMARY: This notice announces the estimated median income for four-person families in each state and the District of Columbia for FY 1998 (October 1, 1997 to September 30, 1998). In the past, the date for adoption of the state median income estimates has been the first day of the fiscal year after their publication. Beginning with the state median income estimates for FY 1996, the adoption date for the estimates was changed to be consistent with the adoption date for the poverty income guidelines. Therefore, LIHEAP grantees may adopt the state median income estimates at any time between the date of this publication and the first day of FY 1998, at the LIHEAP grantee's option. This means that LIHEAP grantees could also choose to implement this notice during the period between the heating and cooling seasons. However, by October 1, 1997, or by the beginning of a grantee's fiscal year, whichever is later, LIHEAP grantees using state median income estimates

must adjust their income eligibility criteria to be in accord with the FY 1998 state median income estimates.

This listing of estimated state median incomes concerns maximum income levels for households to which LIHEAP grantees may make payments under LIHEAP.

EFFECTIVE DATE: The estimates are effective at any time between the date of this publication and October 1, 1997, or by the beginning of a LIHEAP grantee's fiscal year, whichever is later.

FOR FURTHER INFORMATION CONTACT:

Leon Litow, Administration for Children and Families, HHS, Office of Community Services, Division of Energy Assistance, 5th Floor West, 370 L'Enfant Promenade, SW., Washington, DC 20447; Telephone: (202) 401-5304; Internet E-Mail: llitow@acf.dhhs.gov

SUPPLEMENTARY INFORMATION: Under the provisions of section 2603(7) of Title XXVI of the Omnibus Budget Reconciliation Act of 1981 (Pub. L. 97-35, as amended), we are announcing the estimated median income of a four-person family for each state, the District of Columbia, and the United States for FY 1998 (the period of October 1, 1997, through September 30, 1998).

Section 2605(b)(2)(B)(ii) of the LIHEAP statute provides that 60 percent of the median income for each state, as annually established by the Secretary of Health and Human Services, is one of the income criteria that LIHEAP grantees may use in determining a household's eligibility for LIHEAP.

LIHEAP is currently authorized through the end of FY 1999 by the Human Services Amendments of 1994, Public Law 103-252, which was enacted on May 18, 1994.

Estimates of the median income of four-person families for each state and the District of Columbia for FY 1998 have been developed by the Bureau of the Census of the U.S. Department of Commerce, using the most recently available income data. In developing the median income estimates for FY 1998, the Bureau of the Census used the following three sources of data: (1) The March 1996 Current Population Survey; (2) the 1990 Decennial Census of Population; and (3) 1995 per capita personal income estimates, by state, from the Bureau of Economic Analysis of the U.S. Department of Commerce.

Like the estimates for FY 1997, the FY 1998 estimates include income estimates from the March Current Population Survey that are based on population controls from the 1990 Decennial Census of Population. Previous income estimates from the March Current Population Survey had

been based on population controls from the 1980 Decennial Census of Population. Generally, the use of 1990 population controls results in somewhat lower estimates of income.

For further information on the estimating method and data sources, contact Edward Welniak, Chief of the Income Statistics Branch, Housing and Household Economic Statistics Division, at the Bureau of the Census (301-763-8576).

A state-by-state listing of median income, and 60 percent of median income, for a four-person family for FY 1998 follows. The listing describes the method for adjusting median income for families of different sizes as specified in regulations applicable to LIHEAP, at 45 CFR 96.85(b), which was published in the Federal Register on March 3, 1988 at 53 FR 6824.

Dated: March 11, 1997.

Donald Sykes,

Director, Office of Community Services.

ESTIMATED STATE MEDIAN INCOME FOR 4-PERSON FAMILIES, BY STATE, FISCAL YEAR 1998¹

States	Estimated state median income 4-person families ²	60 percent of estimated state median income 4-person families
Alabama	\$42,617	\$25,570
Alaska	56,045	33,627
Arizona	44,526	26,716
Arkansas	38,520	23,112
California	51,519	30,911
Colorado	50,941	30,565
Connecticut	62,157	37,294
Delaware	54,519	32,711
District of Col ...	49,837	29,902
Florida	44,626	26,776
Georgia	48,850	29,310
Hawaii	54,749	32,849
Idaho	42,142	25,285
Illinois	53,807	32,284
Indiana	47,465	28,479
Iowa	47,314	28,388
Kansas	46,611	27,967
Kentucky	40,587	24,352
Louisiana	41,442	24,865
Maine	45,507	27,304
Maryland	60,239	36,143
Massachusetts ..	59,191	35,515
Michigan	52,955	31,773
Minnesota	54,396	32,638
Mississippi	37,328	22,397
Missouri	45,795	27,477
Montana	42,987	25,792
Nebraska	44,886	26,932
Nevada	50,064	30,038
New Hampshire ..	54,492	32,695
New Jersey	61,409	36,845
New Mexico	37,365	22,419
New York	50,672	30,403
North Carolina ...	47,367	28,420
North Dakota	43,483	26,090
Ohio	50,893	30,536

ESTIMATED STATE MEDIAN INCOME
FOR 4-PERSON FAMILIES, BY STATE,
FISCAL YEAR 1998¹—Continued

States	Estimated state median income 4-person families ²	60 percent of estimated state median income 4-person families
Oklahoma	42,124	25,274
Oregon	46,229	27,737
Pennsylvania	50,884	30,530
Rhode Island	51,362	30,817
South Carolina	44,048	26,429
South Dakota	42,269	25,361
Tennessee	44,312	26,587
Texas	43,977	26,386
Utah	45,611	27,367
Vermont	47,376	28,426
Virginia	50,032	30,019
Washington	51,415	30,849
West Virginia	39,731	23,839
Wisconsin	50,628	30,377
Wyoming	45,925	27,555

Note—FY 1998 covers the period of October 1, 1997 through September 30, 1998. The estimated median income for 4-person families living in the United States is \$49,687 for FY 1998. The estimates are effective for the Low Income Home Energy Assistance Program (LIHEAP) at any time between the date of this publication and October 1, 1997, or by the beginning of a LIHEAP grantee's fiscal year, whichever is later.

¹In accordance with 45 CFR 96.85, each state's estimated median income for a 4-person family is multiplied by the following percentages to adjust for family size: 52% for one person, 68% for two persons, 84% for three persons, 100% for four persons, 116% for five persons, and 132% for six persons. For family sizes greater than six persons, add 3% to 132% for each additional family member and multiply the new percentage by the state's estimated median income for a 4-person family.

²Prepared by the Bureau of the Census from the March 1996 Current Population Survey, 1990 Decennial Census of Population and Housing, and 1995 per capita personal income estimates, by state, from the Bureau of Economic Analysis.

[FR Doc. 97-6606 Filed 3-14-97; 8:45 am]

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Food and Drug Administration

[Docket No. 96E-0465]

Determination of Regulatory Review Period for Purposes of Patent Extension; IVY BLOCK™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for IVY BLOCK™ 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, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

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 IVY BLOCK™ (bentoquatam). IVY BLOCK™ is indicated to help protect against poison ivy, poison oak, and poison sumac rash when applied before exposure. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for IVY BLOCK™ (U.S. Patent No. 4,861,584) from United Catalysts, 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 January 13, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of IVY BLOCK™ 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 IVY BLOCK™ is 2,644 days. Of this time, 1,946 days occurred during the testing phase of the regulatory review period, while 698 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* June 2, 1989. The applicant claims May 27, 1989, as the date the investigational new drug application (IND) for IVY BLOCK™ (IND 33,133) became effective. However, FDA records indicate that the effective date for IND 33,133 was June 2, 1989, which was 30 days after FDA receipt of the IND on May 3, 1989.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* September 29, 1994. The applicant claims September 28, 1994, as the date the new drug application (NDA) for IVY BLOCK™ (NDA 20-532) was initially submitted. However, FDA records indicate that NDA 20-532 was submitted on September 29, 1994.

3. *The date the application was approved:* August 26, 1996. FDA has verified the applicant's claim that NDA 20-532 was approved on August 26, 1996.

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 1,825 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before May 16, 1997, 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 September 15, 1997, for a determination regarding whether the applicant for extension acted with due