ESTIMATED STATE MEDIAN INCOME FOR 4-PERSON FAMILIES, BY STATE, FISCAL YEAR 1998 [1]—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.

[1] In 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.

[2] Prepared 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]

BILLING CODE 4184–01–P

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

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: March 6, 1997.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 97–6590 Filed 3–14–97; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Privacy Act of 1974; Altered System of Records

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notification of an altered system of records.

SUMMARY: In accordance with the requirements of the Privacy Act, the Health Resources and Services Administration (HRSA) is publishing notice of a proposal to add a new category of records to 09–15–0054, the National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners, HHS/HRSA/BHPr. HRSA proposes to add specific information already available to the public from the Health Care Financing Administration (HCFA) on physicians, practitioners, providers, and other health care entities which the Office of Inspector General (OIG), HHS has excluded from participation in and from recovering payment from the Medicare and Medicaid programs.

DATES: HRSA invites interested parties to submit comments on the proposed internal and routine use of this information on or before April 28, 1997. HRSA has sent a Report of Altered System to the Congress and to the Office of Management and Budget (OMB) on March 3, 1997. The alteration to the system will be effective 40 days from the date submitted to OMB unless HRSA receives comments which would result in a contrary determination.

ADDRESSEES: Please address comments on the altered system of records to the Health Resources and Services Administration (HRSA) Privacy Act Officer, Department of Health and Human Services, 5600 Fishers Lane, Room 14A–20, Rockville, Maryland 20857, telephone (301) 443–3780. This is not a toll-free number.

FOR FURTHER INFORMATION CONTACT: Director, Division of Quality Assurance, BHPr/HRSA. Room 8A–55, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland, telephone (301) 443–2300. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: The Office of the Inspector General, HHS, has the authority to exclude individuals/entities from participating in the Medicare and/or certain State health care plans under sections 1128(a), 1128(b), 1892, or 1156 of the Social Security Act. The exclusion also applies to all other Executive Branch procurement and non-procurement programs and activities. Disclosure of the OIG Exclusion List to HRSA is under authority of section 1106(a) of the Social Security Act, 42 CFR 401.105, and routine use exception of the Privacy Act (5 U.S.C. 522a(b)(3)). HCFA is authorized to provide certain specific information on physicians, practitioners, providers, and health care entities which OIG has excluded from participation in and from recovering payment from the Medicare and Medicaid programs. HCFA will retain full responsibility for the content and accuracy of HCFA Exclusion reports; the Data Bank will only act as a disclosure service. Notification of exclusion from HCFA programs is made by HCFA. Inquiries on the appropriateness or content of HCFA Exclusion Reports will be referred to HCFA for response. The National Practitioner Data Bank (Data Bank) will disclose such information to authorized health care industry queriers on request, using the Data Bank's fully automated and secure systems and procedures.

Editorial changes have been made throughout the system to enhance clarity and specificity and to accommodate normal updating changes.

The following notice is written in the present, rather than the future tense, to avoid the unnecessary expenditure of public funds to republish the notice after the routine use has become effective.

Dated: March 3, 1997.

Ciro V. Sumaya,

Administrator.

09–15–0054

SYSTEM NAME:

National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners, HHS/HRSA/BHPr.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

The SRA Corporation (the Contractor) operates the National Practitioner Data Bank (Data Bank) under contract with the Bureau of Health Professions (BHPr), Health Resources and Services Administration (HRSA). Records are located at the following address: National Practitioner Data Bank, PO Box 10832, Chantilly, VA 20151. For security reasons, the street address cannot be disclosed.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Health care practitioners including physicians, dentists, and all other health care practitioners (such as nurses, optometrists, pharmacists, and podiatrists), licensed or otherwise authorized by a State to provide health care services, on whose behalf a payment has been made as a result of a malpractice action or claim; physicians and dentists who are the subject of licensure disciplinary actions; and physicians, dentists and other health care practitioners who are on medical staffs or who hold clinical privileges, or who are members of professional societies, against whom certain adverse actions have been taken as a result of a professional review action.

CATEGORIES OF RECORDS IN THE SYSTEM:

1. *For malpractice payments.* Information on the physician, dentist or other licensed health care practitioner such as name; work address; home address, if known; Social Security number, if known, and obtained in accordance with section 7 of the Privacy Act of 1974; date of birth; name of each professional school attended and year of graduation; for each professional license: The license number, the field of licensure, and the name of the State or Territory in which the license is held; Drug Enforcement Administration registration number(s), if known; and name of each hospital with which the practitioner is affiliated, if known. Information on the person or entity making the payment, such as the name and address of the person or entity making the payment; and the name, title, and telephone number of the responsible official submitting the report on behalf of the entity.

Information on the payments, such as the date of the occurrence of the acts or omissions upon which the action or claim was based occurred; date and amount of payment; description of the