**ESTIMATED STATE MEDIAN INCOME FOR 4-PERSON FAMILIES, BY STATE, FISCAL YEAR 1998—Continued**

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

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.


**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, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Brian J. Malikin, 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™ (benthoquatam). 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 investigational new drug application (IND) for IVY BLOCK™ (IND 20-532) was initially submitted. However, FDA records indicate that IND 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 IND 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 September 15, 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

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–P

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 on physicians,
practitioners, providers, and health care
entities which OIG has excluded from
participation 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
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 normally 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.


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