State Capitol, Salt Lake City, Utah 84114, Telephone: (801) 538–1535, FAX: (801) 538–1547

Vermont

Nancy McAvoy, State Single Point of Contact, Pavilion Office Building, 109 State Street, Montpelier, Vermont 05609, Telephone: (802) 828–3326, FAX: (802) 828–3339

West Virginia

Fred Cutlip, Director, Community Development Division, W. Virginia Development Office, Building #6, Room 553, Charleston, West Virginia 25305, Telephone: (304) 558–4010, FAX: (304) 558–3248

Wisconsin

Martha Kerner, Section Chief, State/Federal Relations, Wisconsin Department of Administration, 101 East Wilson Street—6th Floor, P.O. Box 7868, Madison, Wisconsin 53707, Telephone: (608) 266–2125, FAX: (608) 267–6931

Wyoming

Sheryl Jeffries, State Single Point of Contact, Herschler Building, 4th Floor, East Wing, Cheyenne, Wyoming 82002, Telephone: (307) 777–7574, FAX: (307) 638–8967

Territories

Guam

Mr. Giovanni T. Sgambelluri, Director, Bureau of Budget and Management Research, Office of the Governor, P.O. Box 2950, Agana, Guam 96910, Telephone: 011–671–472–2285, FAX: 011–671–472–2825

Puerto Rico

Norma Burgos/Jose E. Caro, Chairwoman/Director, Puerto Rico Planning Board, Federal Proposals Review Office, Minillas Government Center, P.O. Box 41119, San Juan, Puerto Rico 00940–1119, Telephone: (809) 727–4444, (809) 723–6190, FAX: (809) 724–3270, (809) 724–3103

North Mariana Islands

State Single Point of Contact, Planning and Budget Office, Office of the Governor, Saipan, CM, Northern Mariana Islands 96950

Virgin Islands

Jose George, Director, Office of Management and Budget, #41 Norregade Emancipation Garden Station, Second Floor, Saint Thomas, Virgin Islands 00802

Please direct all questions and correspondence about intergovernmental review to:

Linda Clarke, Telephone: (809) 774–0750, FAX: (809) 776–0069

Certification Regarding Environmental Tobacco Smoke

Public Law 103–227, Part C—Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor facility owned or leased or contracted for by an entity and used routinely or regularly for the provision of health, day care, education, or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract, loan, or loan guarantee. The law does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, and portions of facilities used for inpatient drug or alcohol treatment. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to $1,000 per day and/or the imposition of an administrative compliance order on the responsible entity.

By signing and submitting this application the applicant/grantee certifies that it will comply with the requirements of the Act. The applicant/grantee further agrees that it will require the language of this certification be included in any subawards which contain provisions for children's services and that all subgrantees shall certify accordingly.

[FR Doc. 96–6260 Filed 3–15–96; 8:45 am]

BILLING CODE 4184–01–P

Food and Drug Administration

[Docket No. 95E–0364]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for IMMITICIDE® 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 animal 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 animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal 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 an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA recently approved for marketing the animal drug product IMMITICIDE® (melarsomine dihydrochloride). IMMITICIDE® is indicated for the treatment of stabilized Class 1, 2, and 3 heartworm disease caused by immature (4-month old, stage L_5) to mature adult infections of *Dirofilaria immitis* in dogs. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for IMMITICIDE® (U.S. Patent No. 4,514,390) from Rockefeller University and the Patent and Trademark Office requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated November 24, 1995, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of IMMITICIDE® represented the first commercial marketing 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 IMMITICIDE® is 2,650 days. Of this time, 2,037 days occurred during the testing phase of the regulatory review period, while 613 days occurred during the approval phase. These periods of

time were derived from the following dates:

1. *The date an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act became effective*: April 20, 1988. FDA has verified the applicant's claim that the date the investigational new drug application became effective was April 20, 1988.

2. *The date the application was initially submitted with respect to the animal drug product under section 512(b) of the Federal Food, Drug, and Cosmetic Act*: November 16, 1993. The applicant claims November 5, 1993, as the date the new animal drug application (NADA) for IMMITICIDE® (NADA 141–042) was initially submitted. However, a review of FDA records reveals that the date of FDA's official acknowledgment letter assigning a number to the NADA was November 16, 1993, which is considered to be the initially submitted date for the NADA.

3. *The date the animal drug was approved*: July 21, 1995. FDA has verified the applicant's claim that NADA 141–042 was approved on July 21, 1995.

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 1,095 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before April 17, 1996, 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 16, 1996, 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 8, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96–6454 Filed 3–15–96; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Special Projects of National Significance Health Care Services Demonstration Models for Youth Infected with HIV

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of extension of application due date.

SUMMARY: This notice extends the application due date for grants for Special Projects of National Significance, Health Care Services Demonstration Models for Youth Infected with HIV. The application due date is extended to June 5, 1996. All other aspects of the March 7, 1996, Federal Register notice (61 FR 9186) remain the same.

Dated: March 12, 1996.

Ciro V. Sumaya,

Administrator.

[FR Doc. 96–6455 Filed 3–15–96; 8:45 am]

BILLING CODE 4160–15–P

Office of Inspector General

Program Exclusions: February 1996

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of February 1996, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, Maternal and Child Health Services Block Grant and Block Grants to States for Social Services programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Subject city, State	Effective date
PROGRAM-RELATED CONVICTIONS	
ADAMS, LAURA L, INDIANAPOLIS, IN	3/13/96
BRISTER, LORI D, BRYAN, TX	3/03/96
BURNS, DOROTHY, BURTON, TX	3/03/96
CHAPMAN, JOSEPH B, AKRON, OH	3/14/96
COLSTON-BURLEY, PHYLLIS, BALTIMORE, MD	3/19/96
COTTEN, JUDITH A, BRYAN, TX	3/03/96
GLENN R WISCH, DMD, INC, FAIRLAWN, NJ	3/14/96
HEMPHILL, LAND, TEXARKANA, TX	3/03/96
HORWITZ, LAWRENCE, GLENVIEW, IL	3/06/96
JAIN, SWARAN K, LANSING, KS	3/06/96
JORDAN, BRUCE, TUSCALOOSA, AL	3/05/96
KING, JAMES B, NEWCOMERSTOWN, OH	3/14/96
LANE, ANGELA P, BALTIMORE, MD	3/19/96
LASTRES, CAROLS, MIAMI, FL	3/05/96
MALLORY, HERMAN C III, BALTIMORE, MD	3/19/96
MARTIN-DAVIS, PERLA, HIALEAH, FL,	3/05/96
MORFA, PERLA E, MIAMI, FL	3/05/96
NEWMAN, ALAN I, ELMIRA, NY	3/14/96
PLEASANT, NEAL HOWARD, FLORENCE, AZ	3/14/96
SANDERS, PATRICIA MAY, BRYAN, TX	3/03/96
SMITH, SANDRA, CEDAR PARK, TX	3/03/96
TAYLOR, TONY KURT, DENVER, CO	3/19/96
TERUEL, LORENZO, BUFFALO, NY	3/14/96
THOMAS, SHERI LYNN, ENFIELD, NC	3/05/96
TUNSTALLL, DAPHNE, HAVRE DE GRACE, MD	3/19/96
WISCH, GLENN R, FAIRLAWN, NJ	3/14/96
ZORTMAN, JOHN P, SLOAN, IA	3/06/96
PATIENT ABUSE/NEGLECT CONVICTIONS	
ABILA, ALFREDO GARCIA, BARSTOW, TX	3/03/96
AMADOR, BLANCA ROSIE, BROWNSVILLE, TX	3/03/96
ARMSTRONG, SHIRLEY ANDREWS, BURGAW, NC	3/05/96
BONNER, JIMMY, PINSON, AL	3/05/96
BRADFORD, PERCY LEE JR, BIRMINGHAM, AL	3/05/96