

verified the applicant's claim that the new drug application (NDA) for VALTREX® (NDA 20-487) was initially submitted on June 23, 1994.

3. *The date the human drug was approved:* June 23, 1995. FDA has verified the applicant's claim that NDA 20-487 was approved on June 23, 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 1,052 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before February 5, 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 June 5, 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: November 30, 1995.

Stuart L. Nightingale,
Associate Commissioner for Health Affairs.
[FR Doc. 95-29809 Filed 12-6-95; 8:45 am]
BILLING CODE 4160-01-F

[Docket No. 95E-0302]

Determination of Regulatory Review Period for Purposes of Patent Extension; ULTANE™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

FOR FURTHER INFORMATION CONTACT: Brain 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 ULTANE™ (sevoflurane). ULTANE™ is indicated for induction and maintenance of general anesthesia in adult and pediatric patients for inpatient and outpatient surgery. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ULTANE™ (U.S. Patent

No. 4,250,334) from Baxter International, 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 September 25, 1995, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ULTANE™ 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 ULTANE™ is 3,418 days. Of this time, 3,086 days occurred during the testing phase of the regulatory review period, while 332 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:* January 29, 1986. The applicant claims January 10, 1986, as the date the investigational new drug (IND) became effective. However, FDA records indicate that the correct IND effective date was January 29, 1985, which was 30 days after FDA receipt of IND 27,645 on December 30, 1985.

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:* July 11, 1994. The applicant claims July 8, 1994, as the date the new drug application (NDA) for ULTANE™ (NDA 20-478) was initially submitted. However, FDA records indicate that the applicant submitted NDA 20-478 on July 8, 1994, and the agency received the NDA on July 11, 1994, which is considered to be the NDA initially submitted date.

3. *The date the application was approved:* June 7, 1995. FDA has verified the applicant's claim that NDA 20-478 was approved on June 7, 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 1,826 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before February 5, 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 June 5, 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: November 30, 1995.
 Stuart L. Nightingale,
Associate Commissioner for Health Affairs.
 [FR Doc. 95-29808 Filed 12-6-95; 8:45 am]
BILLING CODE 4160-01-F

Health Resources and Services Administration

Agency Forms Undergoing Paperwork Reduction Act Review

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)-443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995: Health Education Assistance Loan (HEAL) Program Physician's Certification of Borrower's Total and Permanent Disability Form—New—This form, completed by the HEAL borrower, the borrower's physician, and the holder of the loan, is used to certify that the

HEAL borrower meets the total and permanent disability provisions. The PHS will use this form to obtain precise information about the disability claim which includes the following: (1) The borrower's consent to release medical records to the Department of Health and Human Services and to the holder of the borrower's HEAL loans, (2) pertinent information supplied by the certifying physician, (3) the physician's certification that the borrower is unable to engage in any substantial gainful activity because of a medically determinable impairment that is expected to continue for a long and indefinite period of time or to result in death, and (4) information from the lender on the unpaid balance. Failure to submit the required documentation will result in a disability claim not being honored.

Type of respondent	Number of respondents	Responses per respondent	Average burden per response	Total burden (hours)
Borrower	42	1.0	0.08	3
Physician	42	1.0	2.75	116
Lender	35	1.2	0.17	7

Estimated Total Annual Burden: 126 hours.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Allison Eydt, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: December 1, 1995.
 J. Henry Montes,
Associate Administrator for Policy Coordination
 [FR Doc. 95-29810 Filed 12-6-95; 8:45 am]
BILLING CODE 4160-15-P

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 36 U.S.C. 207 or pursuant to 42 U.S.C.

241 to achieve expeditious commercialization of results of federally-funded research and development.

ADDRESSES: Licensing information for the technologies referenced below may be obtained by contacting Stephen Finley, Ph.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804 (telephone 301/496-7056 ext 215; fax 301/402-0220).

cDNA Sequence of a Clone Encoding Arylalkylamine N-acetyltransferase

Klein et al. (NICHD)

[DHHS Reference No. E-161-95/0]

and

Human Gene Encoding Serotonin N-acetyltransferase

Klein et al. (NICHD)

[DHHS Reference No. E-222-95/0]

The identification of an arylalkylamine N-acetyltransferase (AA-NAT) mRNA in the brain and the cloning of ovine and human cDNAs encoding for the pineal enzyme

serotonin N-acetyltransferase. These findings open a new area of research—the importance of AA-NAT in the regulation of brain serotonin and the development of drugs which raise serotonin levels by inhibiting this enzyme. This enzyme is the rate-controlling step in the conversion of serotonin to melatonin. The hormone melatonin has been linked to controlling circadian rhythms. Development of regulators of the synthesis of the hormone melatonin may be the preferred route to controlling seasonal reproduction cycles or sleep cycles of vertebrates. Activators of the serotonin N-acetyltransferase may be beneficial to induce or enhance the quality of sleep at night. Inhibitors of serotonin N-acetyltransferase may lead to drugs that stimulate the levels of alertness and physical activity or delay the onset of fatigue. Licenses for the cDNAs encoding for this enzyme or the production of the enzyme are available.