The Report will provide ADD an overview of program trends and achievements and will enable ADD to respond to administration and congressional requests. It will also be used to submit an Annual Report to Congress.

Respondents: State, Local or Tribal Govt.; individuals or households; and not-for-profit institutions.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
DD P&A PPR	55	1	40	2,200

Estimated Total Annual Burden Hours: 2,200.

Title: State Developmental Disabilities Council Annual Program Performance Report.

Description: Section 107 of the DD Act requires the State DD Councils of each State to prepare and transmit to the Secretary, DHHS, an annual Report for the preceding fiscal year. It is to describe the activities and resultant accomplishments carried out with Part B funds received for the Federal fiscal year, and the general situation in the State for individuals with developmental disabilities. The information is necessary for annual technical assistance and monitoring, as well as preparation of the Secretary's Annual Report to the President, the Congress, and the National Council on Disabilities.

Respondents: State, Local or Tribal Govt.; individuals or households; and not-for-profit institutions.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
DD Council PPR	55	1	44	2,420

Estimated Total Annual Burden Hours: 2,420.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: November 22, 1996.

Douglas J. Godesky,

Reports Clearance Officer.

[FR Doc. 96–30455 Filed 11–27–96; 8:45 am]

BILLING CODE 4184–01–M

Food and Drug Administration

[Docket No. 96E–0196]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for DOMITOR® 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 DOMITOR® (medetomidine hydrochloride). DOMITOR® is indicated as a sedative and analgesic in dogs over 12 weeks of age to facilitate clinical examinations, clinical procedures, minor surgical procedures not requiring muscle relaxation, and minor dental procedures not requiring intubation. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for DOMITOR® (U.S. Patent No. 4,544,664) from ORION-YHTYMA OY and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated August 20, 1996, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of DOMITOR® 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 DOMITOR® is 4,000 days. Of this time, 2,294 days occurred during the testing phase of the regulatory review period, while 1,706 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 8, 1985. FDA has verified the applicant's claim that April 8, 1985, was the date the investigational new animal drug application became effective.

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*: July 19, 1991. The applicant claims July 2, 1991, as the date the new animal drug application (NADA) for DOMITOR® (NADA 140–999) was initially submitted. However, a review of FDA records reveals that the date of FDA's official acknowledgement letter assigning a number to the NADA was July 19, 1991, which is considered to be the initially submitted date for the NADA.

3. *The date the application was approved*: March 19, 1996. FDA has verified the applicant's claim that NADA 140–999 was approved on March 19, 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 1,095 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before January 28, 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 May 28, 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: November 20, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96–30388 Filed 11–27–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96E–0194]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for DOMITOR® 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.

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