

(with The CDM Group, Inc. as their subcontractor (#105-96-1930)) to collect descriptive information on Head Start families, and Westat, Inc. (with Ellsworth Associates as their subcontractor (#105-96-1912)) to collect information on Head Start performance measures. The design calls for three rounds of data collection. A nationally representative group of 2,400 families with children enrolled in approximately 160 centers in 40 Head Start programs will be identified in Spring, 1997. At that time, Head Start staff and parents will be interviewed, classroom observations will be completed, and children will be assessed. The second data collection period will occur in Fall, 1997. Again, staff and parents will be interviewed, and children will be assessed and observed in their

classrooms. At that time children from the Spring, 1997 sample that left Head Start to enter kindergarten following the 1996-97 Head Start year will be replaced by a representative sample of children just entering Head Start. All families, including those whose children entered kindergarten in Fall, 1997 will be tracked through the school year. The final data collection effort will occur in Spring, 1998 and involve all families and children identified in the earlier two data collection periods.

A subgroup of 120 families will be identified from the Spring and Fall, 1997 samples for participation in the Validation Substudy. The Validation Substudy data collection will require home visits to participating families at each major data collection point and a series of monthly contacts between data

collections periods. The monthly contacts will begin with the Spring, 1997 data collection and continue through December, 1998.

This schedule of data collection is necessitated by the mandates of the Government Performance and Results Act (GPRA) of 1993 (Public Law 103-62), which requires that the Head Start Bureau move expeditiously toward development and testing of Head Start Performance Measures, and by the 1994 reauthorization of Head Start (Head Start Act, as amended, May 18, 1994, Section 649 (d)), which requires assessment of Head Start's quality and effectiveness.

Respondents: Federal Government, Individuals or Households, and Not-for-profit institutions.

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Spring, 1997	7,840	1	0.652	5,110
Fall, 1997	8,400	1	0.648	5,440
Spring, 1998	11,460	1	0.654	7,500

Estimated Total Annual Burden Hours: 9,025.

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 20, 1996.
 Bob Sargis,
Acting Reports Clearance Officer.
 [FR Doc. 96-30145 Filed 11-25-96; 8:45 am]
BILLING CODE 4184-01-M

Food and Drug Administration

[Docket No. 96E-0315]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Nuflor® 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 Nuflor® (florfenicol). Nuflor® is indicated for treatment of bovine respiratory disease (BRD), associated with *Pasteurella haemolytica*, *P. multocida*, and *Haemophilus somnus*. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Nuflor® (U.S. Patent No. 4,235,892) from Schering Corp. and the Patent and Trademark Office requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated September 17, 1996, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of Nuflor® 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 Nuflor® is 4,209 days. Of this time, 4,205 days occurred during the testing phase of the regulatory review period, while 4 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:* November 23, 1984. FDA has verified the applicant's claim that November 23, 1984, was the date that 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:* May 28, 1996. FDA has verified the applicant's claim that May 28, 1996, was the date that the new animal drug application (NADA) for Nuflor® (NADA 141-063) was initially submitted.

3. *The date the animal drug was approved:* May 31, 1996. FDA has verified the applicant's claim that NADA 141-063 was approved on May 31, 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 1,096 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before January 27, 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 27, 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 18, 1996.
Stuart L. Nightingale,
Associate Commissioner for Health Affairs.
[FR Doc. 96-30196 Filed 11-25-96; 8:45 am]
BILLING CODE 4160-01-F

[Docket No. 96E-0263]

Determination of Regulatory Review Period for Purposes of Patent Extension; Buphenyl Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Buphenyl Powder 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 Buphenyl Powder (sodium phenylbutyrate). Buphenyl Powder is indicated for adjunctive therapy in the chronic management of patients with urea cycle disorders involving deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase, or argininosuccinic acid synthetase. Subsequent to this approval, the Patent and Trademark office received a patent term restoration application for