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

Buphenyl Powder (U.S. Patent No. 4,457,942) from Ucyclyd Pharma, 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 17, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Buphenyl Powder 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 Buphenyl Powder is 4,528 days. Of this time, 4,089 days occurred during the testing phase of the regulatory review period, while 439 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*: December 9, 1983. The applicant claims July 23, 1984, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 9, 1983.

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*: February 17, 1995. The applicant claims February 15, 1995, as the date the new drug application (NDA) for Buphenyl Powder (NDA 20–573) was initially submitted. However, FDA records indicate that NDA 20–573 was submitted on February 17, 1995.

3. *The date the application was approved*: April 30, 1996. FDA has verified the applicant's claim that NDA 20–573 was approved on April 30, 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 730 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. 96–30195 Filed 11–25–96; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

Notice of Open Meeting

Notice is hereby given of the fifth meeting of the Task Force on Genetic Testing of the National Institutes of Health-Department of Energy Joint Working Group on Ethical, Legal, and Social Implications of Human Genome Research (ELSI Working Group) on Monday, December 2, 1996, 1:00 pm to recess; Tuesday, December 3, 1996, 8:00 am to adjournment, at the Doubletree Inn at the Colonnade, 4 West University Parkway, Baltimore, Maryland, (410) 235–5400.

Contact Person: Neil Holtzman, M.D., M.P.H., Genetics and Public Policy Studies, The Johns Hopkins Medical Institutions, 550 North Broadway, Suite 511, Baltimore, Maryland 21205, (410) 955–7894.

The Task Force has developed Interim Principles primarily regarding scientific validation of new genetic tests; laboratory quality; and education, counseling, and delivery. At this meeting, the Task Force will consider recommendations to implement key Principles. The Interim Principles are available on the World Wide Web at: http://infonet.welch.jhu.edu/policy/genetics/

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Dr. Holtzman in advance of the meeting.

(Catalog of Federal Domestic Assistance Program No. 93.172, Human Genome Research)

Dated: November 19, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–30100 Filed 11–25–96; 8:45 am]

BILLING CODE 4140–01–M

National Cancer Institute; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting of the National Cancer Institute Special Emphasis Panel (SEP):

Name of SEP: Operation of Registry of Tumors in Lower Animals.

Date: December 9, 1996.

Time: 1:00 p.m. to 4:00 p.m.

Place: Executive Plaza North Conference Room F, 6130 Executive Boulevard, Rockville, MD 20857.

Contact Person: Lalita D. Palekar, Ph.D., Scientific Review Administrator, National Cancer Institute, 6130 Executive Blvd. MSC–7405, Bethesda, MD 20892, (301) 496–7575.

Purpose/Agenda: To evaluate and review responses to RFP NCI–CB–77021–34.

This notice is being published less than 15 days prior to the above meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

The meeting will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Numbers: 7 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower, 93.399, Cancer Control)

Dated: November 19, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–30104 Filed 11–25–96; 8:45 am]

BILLING CODE 4140–01–M