hours per recordkeeper has been corrected to 4.5. The recordkeeping requirement burden is based on the following formula: Approximately 2,000 IRB's review FDA-regulated research involving human subjects annually. The burden for each of the paragraphs under 21 CFR 56.115 has been considered as one for purposes of estimating the burden. Each paragraph cannot reasonably be segregated from one another because all are interrelated. FDA has about 2,000 IRB's in its inventory. The 2,000 IRB's meet on an average of 14.6 times annually. The mean number of IRB meetings per year was derived from a study conducted by the agency and published by the Office of Planning and Evaluation. The agency estimates that approximately 4.5 hours (h) of person time per meeting are required to transcribe and type the minutes of the meeting, to maintain records of continuing review activities, copies of all correspondence between the IRB and investigators, member records, and written IRB procedures which are approximately five pages per IRB.

Two comments were received in response to the January 27, 1998, **Federal Register** notice. Both comments were from major research universities and both contended that the estimate of approximately 4.5 h person-time of recordkeeping burden per meeting was a large underestimate.

One comment asserted that production and distribution of minutes took 40 h per meeting, and continual processing of documents received and generated by the IRB required 215 h. It is assumed that the latter number is calculated on a per month basis, as the comment also refers to holding five IRB meetings per month. The IRB reviews approximately 2,500 active projects, and processes approximately 5,000 required documents annually. An unquantified amount of additional time is said to be devoted to maintaining member lists, written procedures, and forms. The commenting university is among the top 20, or top 1 percent of IRB's in terms of the number of investigational new drug (IND) studies which it has reviewed. Studies other than those under IND are undoubtedly reviewed as well, but the number of IND studies is taken to be the best available workload measure. The median number of IND studies reviewed by IRB's is approximately 10. Setting aside IRB's which have reviewed three or fewer IND studies, which can be considered as inactive in reviewing FDA regulated studies, the commenting university is still almost at the 99th percentile and the median number of IND studies reviewed is 15. If, as assumed, IND workload is directly proportional to overall workload across all IRB's, the commenting university's workload is 30 times that of the median IRB.

The second commenting university claimed that 124.5 h were required for each meeting. This university is among the top 50 in terms of IND studies reviewed, and a similar analysis estimates its workload as approximately 21 times that of the median IRB.

Translating the first commenting university's workload to that of the median IRB, the comments indicate a workload of 40 h per meeting plus 215 h divided by 5 h continuous activity, or 81 h per meeting. Eighty-one hours divided by 30 h equals 2.7 h per meeting of the median IRB performing at the same level of efficiency. The second commenting university's workload translates to 124.5 h divided by 21 h, or 5.9 h per meeting of the median IRB performing at the same efficiency. Averaged, these estimated recordkeeping workloads translate to 2.7 h plus 5.9 h divided by 2 h, or 4.3 h per meeting.

This number compares with the FDA's estimate of 4.5 h per meeting and supports FDA's estimate, rather than disputing it as the raw numbers suggest. It is undeniable that the recordkeeping burden on the commenting universities is high, but it is also true that the commenting universities have among the busiest IRB's in the nation.

Dated: July 28, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–20741 Filed 8–3–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E–0338]

Determination of Regulatory Review Period for Purposes of Patent Extension: Anipryl®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Anipryl® 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

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 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 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 Anipryl® (selegiline hydrochloride). Anipryl® is indicated for the control of clinical signs associated with uncomplicated canine pituitary-dependent hyperadrenocorticism (PDH). Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Anipryl® (U.S. Patent No. 5,192,808) from Deprenyl Animal Health, Inc., and requested FDA's assistance in determining this patent's eligibility for

patent term restoration. In a letter dated November 7, 1997, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of Anipryl® 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 Anipryl® is 2,329 days. Of this time, 2,275 days occurred during the testing phase of the regulatory review period, 54 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 (the act) (21 U.S.C. 360b(j)) became effective*: January 15, 1991. The applicant claims December 21, 1990, as the date the investigational new animal drug application (INAD) became effective. However, FDA records indicate that the date of FDA's letter assigning a number to the INAD was January 15, 1991, which is considered to be the effective date for the INAD.

2. *The date the application was initially submitted with respect to the animal drug product under section 512(b) of the act*: April 7, 1997. The applicant claims April 2, 1997, as the date the new animal drug application (NADA) for Anipryl® (NADA 141–080) was initially submitted. However, a review of FDA records reveals that the date of FDA's official acknowledgement letter assigning a number to NADA 141–080 was April 7, 1997, which is considered to be the initially submitted date for NADA 141–080.

3. *The date the application was approved*: May 30, 1997. FDA has verified the applicant's claim that NADA 141–080 was approved on May 30, 1997.

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 448 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 5, 1998, 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 February 1, 1999, 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: July 8, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–20708 Filed 8–3–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E–0168]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for BeneFIX™ 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 biological product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biological product BeneFIX™ (coagulation factor IX (Recombinant)). BeneFIX™ is indicated for the control and prevention of hemorrhagic episodes in patients with hemophilia B, including the peri-operative management of hemophilia B patients undergoing surgery. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for BeneFIX™ (U.S. Patent No. 5,171,569) from British Technology Group Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 21, 1997, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of BeneFIX™ 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