with FDA's decision regarding the petition may, under § 60.40 (21 CFR 60.40), request an informal hearing for reconsideration of the due diligence determination. Petitioners are likely to include persons or organizations having knowledge that FDA's marketing permission for that product was not actively pursued throughout the regulatory review period. The information collection for which an extension of approval is being sought is the use of the statutorily created due diligence petition.

Since 1992, five requests for revision of the regulatory review period have been submitted under § 60.24. One regulatory review period has been altered. No due diligence petitions have been submitted to FDA, under § 60.30, and consequently there have been no requests for hearings, under § 60.40, regarding the decisions on such petitions.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
60.24(a)	1	1	1	100	100
60.30	0	0	0	0	0
60.40	0	0	0	0	0
Total					100

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 29, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–20740 Filed 8–3–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0535]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by September 3, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collections of information to OMB for review and clearance.

Institutional Review Boards—(21 CFR 56.115)—(OMB Control Number 0910–0130)—Extension

When reviewing clinical research studies regulated by FDA, institutional review boards (IRB's) are required to create and maintain records describing their operations, and make the records available for FDA inspection when requested. These records include: (1) Written procedures describing the structure and membership of the IRB and the methods which the IRB will use in performing its functions; (2) the research protocols, informed consent documents, progress reports, and reports of injuries to subjects submitted by investigators to the IRB; (3) minutes of meetings showing attendance, votes and decisions made by the IRB, the number of votes on each decision for, against, and abstaining, the basis for requiring changes in or disapproving research; (4) records of continuing review activities; (5) copies of all correspondence between investigators and the IRB; (6) statements of significant new findings provided to subjects of the research; (7) and a list of IRB members by name, showing each member's earned degrees, representative capacity, and experience in sufficient detail to describe each member's contributions to the IRB's deliberations, and any employment relationship between each member and the IRB's institution. This information is used by FDA in conducting audit inspections of IRB's to determine whether IRB's and clinical investigators are providing adequate protections to human subjects participating in clinical research.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Recordkeeper	Total Hours
56.115	2,000	14.6	29,200	4.5	131,400

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Due to a typographical error, the total annual records were reported as 10,000 and the hours per recordkeeper were reported as 65 in a notice issued in the **Federal Register** of January 27, 1998 (63 FR 3902), which provided 60 days for public comment on this collection of information. The total annual records has been corrected to 29,200 and the

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