TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

| Item | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours |
|---|---|---|---|---|---|
| 510(k) reviews | 35 | 4 | 140 | 10[2] | 350[2] |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Due to clerical error, the recordkeeping burden hours for 510(k) reviews that appeared in a notice issued in the FEDERAL REGISTER of May 22, 1998 (63 FR 28388) were incorrect. Table 2 of this document contains the correct estimates.

The burdens are explained as follows:

1. Reporting

a. *Requests for accreditation*: Under the agency's Third–Party Review Pilot Program, the agency received 37 applications for recognition as third-party reviewers, of which the agency recognized 7. Under this expanded program, the agency anticipates that it will not see a significant increase in the number of applicants. Therefore, the agency is estimating that it will receive 40 applications. The agency anticipates that it will accredit 35 of the applicants to conduct third-party reviews.

b. *510(k) reviews conducted by accredited third parties*: In 18 months under the Third–Party Review Pilot Program, FDA received only 22 510(k)'s that were requested and were eligible for review by third parties. Because the new program is not as limited in time, and is expanded in scope, the agency anticipates that the number of 510(k)'s submitted for third-party review will increase. The agency anticipates that it will receive approximately 140 third-party review submissions annually, i.e., approximately 4 annual reviews per each of the estimated 35 accredited reviewers.

2. Recordkeeping

Third-party reviewers are required to keep records of their review of each submission. The agency anticipates approximately 140 annual submissions of 510(k)'s for third-party review. The agency estimates that each third-party reviewer will require approximately 10 annual hours to maintain records of their reviews and reports.

Dated: July 24, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 98–20705 Filed 8–3–98; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 98N–0268]**

### 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, 301–827–4659.

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

### Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions—(21 CFR Part 60)—(OMB Control Number 0910–0233)—Extension

FDA's patent extension activities are conducted under the authority of the Drug Price Competition and Patent Term Restoration Act of 1984 and the Animal Drug and Patent Term Restoration Act of 1988 (35 U.S.C. 156). New human drug, animal drug, human biological, medical device, food additive, or color additive products regulated by FDA must undergo FDA safety, or safety and effectiveness review, before marketing is permitted. Where the product is covered by a patent, part of the patent's term may be consumed during this review, which diminishes the value of the patent. In enacting 35 U.S.C. 156, Congress sought to encourage development of new, safer, and more effective medical and food additive products. It did so by authorizing the U.S. Patent and Trademark Office (PTO) to extend the patent term by a portion of the time during which FDA's safety and effectiveness review prevented marketing of the product. The length of the patent term extension is generally limited to a maximum of 5 years, and is calculated by PTO based on a statutory formula. When a patent holder submits an application for patent term extension to PTO, PTO requests information from FDA, including the length of the regulatory review period for the patented product. If PTO concludes that the product is eligible for patent term extension, FDA publishes a notice which describes the length of the regulatory review period, and the dates used to calculate that period. Interested parties may request, under § 60.24 (21 CFR 60.24), revision of the length of the regulatory review period, or may petition, under § 60.30 (21 CFR 60.30), to reduce the regulatory review period by any time where marketing approval was not pursued with ''due diligence.'' The statute defines due diligence as ''that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.'' As provided in § 60.30(c), a due diligence petition ''shall set forth sufficient facts, including dates if possible, to merit an investigation by FDA of whether the applicant acted with due diligence.'' Upon receipt of a due diligence petition, FDA reviews the petition and evaluates whether any change in the regulatory review period is necessary. If so, the corrected regulatory review period is published in the **Federal Register**. A due diligence petitioner not satisfied

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]

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## 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