TABLE 4.—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICAL PRODUCTS[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Burden Hours
25.15(a) and (d)	415	1.68	699	8	5,592
25.40(a) and (c)	2	1	2	3,400	6,800
Total					12,392

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

Estimated Annual Reporting Burden for Animal Drugs

Under § 514.1(b)(14) (21 CFR 514.1(b)(14)), new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs), § 514.8(a)(1) supplemental NADAs and ANADAs, 21 CFR 511.1(b)(10) investigational new animal drug applications (INADs), 570.35(c)(1)(viii) generally recognized as safe (GRAS) affirmation petitions, and 571.1(c) food additive petitions must contain a claim for categorical exclusion under § 25.30 or § 25.33 or an EA under § 25.40. Since the last OMB approval of these collections of information, FDA's Center of Veterinary Medicine has received approximately 547 claims for categorical exclusion as required under § 25.15(a) and (d), and 19 EAs as required under § 25.40(a) and (c). Based on information provided by industry, FDA estimates that it takes sponsors/applicants approximately 8 hours to prepare a claim for a categorical exclusion and an average of 2,160 hours to prepare an EA.

TABLE 5.—ESTIMATED ANNUAL REPORTING BURDEN FOR ANIMAL DRUGS[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Burden Hours
25.15(a) and (d)	139	3.9	542	8	4,336
25.40(a) and (c)	14	1.4	19	2,160	41,040
Total					45,376

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

Based on information provided by industry, FDA estimates that the combined burden for the environmental impact considerations—part 25 is as follows:

TABLE 6.—ESTIMATED ANNUAL REPORTING BURDEN FOR ALL CENTERS[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Burden Hours
25.15(a) and (d)	2,735	17.5	10,768	29	81,032
25.40(a) and (c)	56	5.1	74	9,199	129,150
Total					210,182

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

In the **Federal Register** of March 17, 2003 (68 FR 12702), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Dated: June 19, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–16107 Filed 6–25–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0066]

Agency Information Collection Activities; Announcement of OMB Approval; Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 28, 2003 (68 FR 22388), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to,

a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0510. The approval expires on September 30, 2003. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: June 19, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–16110 Filed 6–25–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0267]

Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarketing Studies for Licensed Biological Products; Status Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to FDA regulations for the postmarketing studies for licensed biological products.

DATES: Submit written or electronic comments on the collection of information by August 25, 2003.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed extension of an existing collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

Postmarketing Studies for Licensed Biological Products; Status Reports (OMB Control Number 0910–0433)—Extension

Section 130(a) of the Food and Drug Administration Modernization Act (Public Law 105–115) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding a new provision (section 506B of the act (21 U.S.C. 356b)) requiring reports of postmarketing studies for approved human drugs and licensed biological products. Section 506B of the act provides FDA with additional authority to monitor the progress of postmarketing studies that applicants have made a commitment to conduct and requires the agency to make publicly available information that pertains to the status of these studies.

Under section 506B(a) of the act, applicants that have committed to conduct a postmarketing study for an approved human drug or licensed biological product must submit to FDA a status report of the progress of the study or the reasons for the failure of the applicant to conduct the study. This report must be submitted within 1 year after the U.S. approval of the application and then annually until the study is completed or terminated. The reporting requirements for applicants of approved new drug applications and abbreviated new drug applications are under § 314.81(b)(2)(vii) (21 CFR 314.81(b)(2)(vii)). The collection of information requirements for § 314.81(b)(2)(vii) are approved under OMB control number 0910–0001. The reporting requirements for applicants of approved biologics license applications (BLAs) or supplements to an application are under § 601.70 (21 CFR 601.70).

Section 601.70 requires applicants of approved biologics license applications or supplements to an application to submit to FDA postmarketing status reports for studies of clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology that are required by FDA or that an applicant of a BLA commits to conduct, in writing, at the time of approval of an application or a supplement to an application, or after approval of an application or a supplement. Information submitted in a status report for § 601.70(b) is limited to that which is needed to sufficiently identify each applicant that has committed to conduct a postmarketing study, the status of the study that is being reported, and the reasons, if any, for the applicant's failure to conduct, complete, and report the study. Previously, status reports were only for postmarketing studies in pediatric populations. Section 601.28(c) (21 CFR 601.28(c)) requires that the status of postmarketing pediatric studies be reported under § 601.70 rather than under § 601.28 and therefore, the information collection burden for postmarketing studies in pediatric populations is included under § 601.70.

Respondents to this collection of information are the applicants holding approved applications for licensed biological products that have committed to conduct postmarketing studies. Based on information obtained from FDA's Center for Biologics Evaluation and Research computerized application and license tracking database, the agency estimates that approximately 44 applicants with 65 approved BLAs have committed to conduct approximately