

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 2003N-0267]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Postmarketing Studies for Licensed Biological Products; Status Reports**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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

**DATES:** Fax written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**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.

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

**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 223 postmarketing studies and would be required to submit an annual progress report on those postmarketing studies under § 601.70. Based on past experience with similar reporting requirements, the agency estimates that it takes an applicant approximately 24 hours (8 hours per study x 3) annually to gather, complete, and submit the appropriate information for each report (approximately two to four studies per report). Included in these 24 hours is the time necessary to prepare and submit two

copies of the annual progress report of postmarketing studies to FDA under § 601.70(d).

In the **Federal Register** of June 26, 2003 (68 FR 38066), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
601.70(b) and (d)	44	1.5	65	24	1,560

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: 1-9-04

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January 9, 2004.

*Jeffrey Shuren*

Jeffrey Shuren,  
Assistant Commissioner for Policy.

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