

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 601

[Docket No. 99N-1852]

OMB

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**Postmarketing Studies for Approved Human Drug and Licensed Biological Products;
Status Reports; Delay of Effective Date**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of effective date.

SUMMARY: In accordance with the memorandum of January 20, 2001, from the Assistant to the President and Chief of Staff, entitled "Regulatory Review Plan," published in the **Federal Register** on January 24, 2001 (66 FR 7702), this action temporarily delays for 60 days the effective date of the rule entitled "Postmarketing Studies for Approved Human Drug and Licensed Biological Products; Status Reports," published in the **Federal Register** on October 30, 2000 (65 FR 64607).

DATES: The effective date of the "Postmarketing Studies for Approved Human Drug and Licensed Biological Products; Status Reports," amending 21 CFR parts 314 and 601 published in the **Federal Register** on October 30, 2000 (65 FR 64607), is delayed for 60 days, from February 27, 2001, to a new effective date of April 30, 2001.

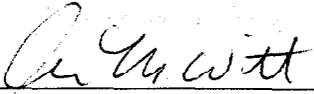
FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION: The rule concerns the requirements for annual postmarketing status reports for approved human drug and biological products, and requires applicants to submit annual status reports for certain postmarketing studies of licensed biological products. The rule describes the types of postmarketing studies covered by these status reports, the information to

be included in the reports, and the type of information that the Food and Drug Administration would consider appropriate for public disclosure. The rule will implement specific provisions of the Food and Drug Administration Modernization Act of 1997 (FDAMA). To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(A). Alternatively, the agency's implementation of this action without opportunity for public comment, effective immediately upon publication today in the **Federal Register**, is based on the good cause exceptions in 5 U.S.C. 553(b)(B) and (d)(3). Seeking public comment is impracticable, unnecessary and contrary to the public interest. The temporary 60-day delay in effective date is necessary to give Department of Health and Human Services (Department) officials the opportunity for further review and consideration of new regulations, consistent with the Assistant to the President's memorandum of January 20, 2001, sent to all executive departments and agencies. Given the imminence of the effective date, seeking prior public comment on this temporary delay would have been impractical, as well as contrary to the public interest in the orderly issuance and implementation of regulations. The imminence of the effective date is also good cause for making this action effective immediately upon publication. As originally published in the **Federal Register** on October 30, 2000, this rule would have required some firms to file annual progress reports for postmarketing study commitments shortly after February 27, 2001, if the anniversary date of U.S. approval of the application of the drug or licensed biological product under postmarketing study commitment fell on or shortly after February 27, 2001. An immediate effective date for this rule delaying implementation is necessary to assure that those applicants are not singled out and required to submit postmarketing study reports before Department officials have had the opportunity for further review and consideration of this regulation.

Dated: February 13, 2001
February 13, 2001.

cb016



Ann M. Witt,
Acting Associate Commissioner for Policy.

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**



[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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