

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Parts 314 and 601**

[Docket No. 99N-1852]

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.

Ann M. Witt,*Acting Associate Commissioner for Policy.*

[FR Doc. 01-4141 Filed 2-16-01; 8:45 am]

BILLING CODE 4160-01-S**DEPARTMENT OF THE INTERIOR****Bureau of Indian Affairs****25 CFR Part 151****RIN 1076-AD90****Acquisition of Title to Land in Trust; Delay of Effective Date; Correction****AGENCY:** Bureau of Indian Affairs, Interior.**ACTION:** Correction to final rule.

SUMMARY: This document corrects the final rule published on Monday, February 5, 2001 (66 FR 8899). The February 5th rule delayed the effective date of the rule entitled "Acquisition of Title to Land in Trust," published in the *Federal Register* on January 16, 2001, at 66 FR 3452.

EFFECTIVE DATE: February 20, 2001.

FOR FURTHER INFORMATION CONTACT: Terry Virden, Director, Office of Trust Responsibilities, Mail Stop: 4513-MIB, 1849 "C" Street NW., Washington, DC 20240; telephone: 202-208-5831; electronic mail: TerryVirden@BIA.GOV.

SUPPLEMENTARY INFORMATION: On January 20, 2001, the Assistant to the President and Chief of Staff signed a memo to the heads of all executive Departments and agencies entitled "Regulatory Review Plan." (This memo was published in the *Federal Register* on January 24, 2001, at 66 FR 7701). To comply with this memo, we must delay for 60 days the effective date of any final rule that was published but not yet effective on or before January 20, 2001. On February 5th we published a final rule to delay the effective date of a rule titled "Acquisition of Title to Land in Trust." (We published the original "Acquisition of Title to Land in Trust" rule in the *Federal Register* on January 16, 2001, at 66 FR 3452.) In the **DATES** section of our February 5th rule, we incorrectly stated two dates, as shown in the following table:

In the February 5 rule we said that	What we should have said was
The effective date of the January 16 rule was January 16. The new, delayed effective date of the January 16 rule was March 17.	The effective date of the January 16 rule was February 15. The new, delayed effective date of the January 16 rule was April 16.

The delayed effective date that we published on February 5 would postpone the effective date for only 30 days, rather than the required 60 days. In this correction, we are making the following changes to the rule that we published on February 5th:

(1) Correcting the original effective date of the January 16 rule from January 17, 2001 to February 15, 2001; and

(2) Correcting the delayed effective date of the January 16 rule from March 17, 2001, to April 16, 2001.

Need for Correction

As published, the final rule contains errors that may prove to be misleading and are in need of correction.