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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 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]

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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 effective date of the January 16 rule was February 15.
The new, delayed effective date of the January 16 rule was March 17.	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.

HeinOnline -- 66 Fed. Reg. 10815 2001

Correction of Publication

Accordingly FR document 01–2963, published on February 5, 2001, is corrected as follows: On page 8899, in the first column, the material in the **DATES** heading is corrected to read in its entirety as follows:

DATES: The effective date of the Acquisition of Title to Land in Trust rule, amending 25 CFR part 151, published in the **Federal Register** on January 16, 2001, at 66 FR 3452, is delayed for 60 days, from February 15, 2001, to a new effective date of April 16, 2001.

Dated: February 13, 2001.

Timothy S. Elliott,

Acting Deputy Solicitor.

[FR Doc. 01–4095 Filed 2–16–01; 8:45 am]

BILLING CODE 4310–02–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD01–00–234]

RIN 2115–AE47

Drawbridge Operation Regulations: Fort Point Channel, MA

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is changing the drawbridge operating regulations for the Northern Avenue Bridge, mile 0.1, across the Fort Point Channel at Boston, Massachusetts. This rule will revise the drawbridge operating regulations to provide bridge openings during times the bridge previously did not open and also place the bridge on an advance notice basis during times when there have been few requests to open the bridge. This action is expected to better meet the present needs of navigation.

DATES: This rule is effective March 22, 2001.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket (CGD01–00–234) and are available for inspection or copying at the First Coast Guard District, Bridge Branch Office, 408 Atlantic Avenue, Boston, Massachusetts 02110, 7 a.m. to 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. John W. McDonald, Project Officer, First Coast Guard District, (617) 223–8364.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On November 8, 2000, we published a notice of proposed rulemaking (NPRM) entitled Drawbridge Operation Regulations; Fort Point Channel, Massachusetts, in the **Federal Register** (65 FR 66939). We received six comment letters in response to the notice of proposed rulemaking. All the comment letters were in favor of the rule change. No public hearing was requested and none was held.

Background and Purpose

The Northern Avenue Bridge, mile 0.1, across the Fort Point Channel has a vertical clearance of 7 feet at mean high water and 17 feet at mean low water in the closed position. The existing operating regulations in 33 CFR 117.599 require the bridge to open on signal from 6 a.m. to 8 p.m. From 8 p.m. to 6 a.m., the bridge need not open for the passage of vessels. The Coast Guard received a request to change the operating regulations from a commercial tour boat operator and the mariners located at a marina upstream from the Northern Avenue Bridge. The mariners requested that the bridge be crewed and available to open for vessel traffic after 8 p.m. during the boating season. The bridge presently does not open from 8 p.m. to 6 a.m., daily.

The Coast Guard published a notice of temporary deviation and request for comments on April 27, 2000, in order to test an expanded operating schedule for the bridge and to provide immediate relief for the mariners during the summer of 2000. The deviation required the bridge to open on signal from 6 a.m. to 8 p.m. and from 8 p.m. to 6 a.m. to open on signal if at least a two-hour advance notice was provided by calling the number posted at the bridge. The Coast Guard received four letters in favor of expanding the operating hours for the bridge. After the comment period for the deviation concluded on September 30, 2000, the Coast Guard had discussions regarding the expansion of the operating hours for the bridge with officials from the City of Boston, the owner of the bridge. As a result of these discussions, the bridge owner agreed to crew the bridge additional hours as well as provide openings on an advance notice basis during times when the bridge is not crewed. The following schedule was established:

From May 1 through October 31, the draw shall open on signal from 7 a.m. to 11 p.m. From 11 p.m. to 7 a.m. the draw shall open on signal if at least a two-hour advance notice is given by calling the number posted at the bridge.

From November 1 through April 30, the draw shall open on signal from 7 a.m. to 3 p.m. From 3 p.m. to 7 a.m. the draw shall open on signal if at least a twenty-four hours advance notice is given by calling the number posted at the bridge.

The Coast Guard believes this is a reasonable operating schedule because the mariners will now be able to get bridge openings during the times the bridge is crewed or upon the required advance notice, and the bridge owner will not be required to crew the bridge during periods when there have been few requests to open the bridge.

Discussion of Comments and Changes

The Coast Guard received six comment letters all in favor of the rule change. No changes will be made to the final rule.

Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not "significant" under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). This conclusion is based on the fact that the bridge will be crewed at times to meet the needs of navigation and will be on an advance notice basis during the times when there have been few requests to open the bridge.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612) we considered whether this rule would have a significant economic impact on a substantial number of small entities. "Small entities" comprises small businesses, not-for profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This conclusion is based on the fact that the bridge will be crewed at times to meet the needs of navigation and will be on an advance notice basis during the times when there have been few requests to open the bridge.

Collection of Information

This rule calls for no new collection of information under the Paperwork

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