DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 589

[Docket No. FDA–2002–N–0031] (formerly Docket No. 2002N–0273)

RIN 0910–AF46

Substances Prohibited From Use in Animal Food or Feed; Confirmation of Effective Date of Final Rule; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule; confirmation of effective date, that appeared in the **Federal Register** of Friday, April 24, 2009 (74 FR 18626) (the April 24, 2009, final rule; confirmation of effective date). That document had confirmed the effective date of April 27, 2009, for a final rule that published in the **Federal Register** of April 25, 2008 (73 FR 22720), entitled ''Substances Prohibited From Use in Animal Food or Feed.'' In the April 24, 2009, final rule; confirmation of effective date, the agency also established a compliance date of October 26, 2009, in order to allow additional time for renderers to comply with the new requirements. The April 24, 2009, final rule; confirmation of effective date was published with an inadvertent error in the ''Background'' section. This document corrects that error.

DATES: This correction is effective: May 5, 2009.

FOR FURTHER INFORMATION CONTACT: Joyce A. Strong, Office of Policy, Planning, and Preparedness (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. E9–9466, appearing on page 18626 in the **Federal Register** of Friday, April 24, 2009, the following correction is made:

On page 18626, in the third column, under ''I. Background,'' in the first paragraph, the first sentence ''In the **Federal Register** of April 25, 2008, FDA published a final rule entitled ''Substances Prohibited From Use in Animal Food or Feed)'' (referred to herein as the April 25, 2008, final rule), that would become effective 1 year after the April 27, 2009, date of publication.'' is corrected to read ''In the **Federal Register** of April 25, 2008, FDA published a final rule entitled ''Substances Prohibited From Use in Animal Food or Feed'' (referred to herein as the April 25, 2008, final rule), that would become effective 1 year after that publication.''

Dated: April 28, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–10138 Filed 5–4–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 601

[Docket No. FDA–2009–N–0100]

Revision of the Requirements for Publication of License Revocation

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is clarifying the regulatory procedures for notifying the public about the revocation of a biologics license to be consistent with current practices. FDA is amending the regulations in accordance with the agency's direct final rule procedures. Elsewhere in this issue of the **Federal Register**, we are publishing a companion proposed rule under FDA's usual procedures for notice and comment rulemaking to provide a procedural framework to finalize the rule in the event that we receive any significant adverse comments on the direct final rule. If we receive any significant adverse comments that warrant terminating the direct final rule, we will consider such comments on the proposed rule in developing the final rule.

DATES: This rule is effective September 17, 2009. Submit written or electronic comments on or before July 20, 2009. If FDA receives no significant adverse comments within the specified comment period, the agency will publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this direct final rule ends. If timely significant adverse comments are received, the agency will publish a document in the **Federal Register** withdrawing this direct final rule.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2009–N–0100, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Request for Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr., 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:

I. Background

In the **Federal Register** of January 25, 1977 (42 FR 4680), FDA issued a final rule revising, among other things, the procedures under part 601 (21 CFR part 601) for issuing, revoking, and suspending biologics licenses, and publishing license revocations. FDA revised these procedures in order to simplify and codify existing practices, establish new requirements where appropriate, and ensure that practices and procedures would be consistently applied throughout the agency.

A provision under the January 25, 1977, final rule provided that a ''Notice of revocation of a license, with statement of the cause therefor, shall be issued by the Commissioner and published in the **Federal Register**'' (§ 601.8). FDA interprets this requirement to apply only to a license which the Commissioner of Food and Drugs (the Commissioner) has found grounds to revoke under § 601.5(b). FDA has not routinely published, in the **Federal Register**, a notice of revocation of a biologics license resulting from a manufacturer's voluntary request for revocation for reasons unrelated to a finding by the Commissioner that reasonable grounds to revoke the license exist under § 601.5(b). Examples of situations in which a manufacturer might voluntarily request that a license be revoked include economic loss, change in product marketing strategy, lack of public need, corporate reorganization, or the emergence of innovative replacement products. FDA does not consider the revocation of licenses in such circumstances to require publication in the **Federal Register**. However, FDA may publish a notice of revocation for licenses revoked at the voluntary request of a manufacturer in situations where such notice is in the interest of public health.

II. Highlights of the Direct Final Rule

FDA is amending § 601.8 to read: ''The Commissioner, following revocation of a biologics license under 21 CFR 601.5(b), will publish a notice in the **Federal Register** with a statement of the specific grounds for the revocation.''

This amendment revises the existing regulation to clarify that FDA will publish a notice of license revocation in cases where the Commissioner has made a finding that reasonable grounds for revocation exist under § 601.5(b). This amendment also clarifies that the phrase ''with statement of the cause therefor,'' (§ 601.8) refers to the specific grounds for revocation enumerated in § 601.5(b). The rule, as amended, does not affect other regulations or procedures for notification of license revocation. The rule does not alter existing FDA practices for publishing notices of voluntary withdrawal, including notices of voluntary withdrawal of new drug applications.

III. Legal Authority

FDA is issuing this regulation under the biological products provisions of the Public Health Service Act (42 U.S.C. 262 and 264) and the drugs and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (sections 201, 301, 501, 502, 503, 505, 510, 701, and 704) (21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 371, and 374). Under these provisions of the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act, we have the authority to issue and enforce regulations designed to ensure that biological products are safe, pure, and potent; and prevent the introduction, transmission, and spread of communicable disease.

IV. Rulemaking Action

In the **Federal Register** of November 21, 1997 (62 FR 62466), FDA described the agency's procedures for when and how we will employ direct final rulemaking. We have determined that this rule is appropriate for direct final rulemaking because it includes only noncontroversial amendments, and we anticipate no significant adverse comments. Consistent with our procedures on direct final rulemaking, FDA is publishing, elsewhere in this issue of the **Federal Register**, a companion proposed rule to amend § 601.8. The companion proposed rule provides a procedural framework within which the rule may be finalized in the event that the direct final rule is withdrawn due to any significant adverse comments. The comment period for the direct final rule runs concurrently with the companion proposed rule. Any comments received in response to the companion proposed rule will be considered as comments regarding the direct final rule.

A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants terminating a direct final rulemaking, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process in accordance with section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553). Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure.

A comment recommending a regulation change in addition to that in this rule will not be considered a significant adverse comment unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule that can be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of a significant adverse comment.

If any significant adverse comments are received during the comment period, FDA will publish, before the effective date of the direct final rule, a document withdrawing the direct final rule. If we withdraw the direct final rule, any comments received will be applied to the companion proposed rule and will be considered in developing a final rule using the usual notice-and-comment procedures under the APA (5 U.S.C. 552a *et seq*).

If FDA receives no significant adverse comments during the specified comment period, FDA intends to publish a document confirming the effective date within 30 days after the comment period ends. Additional information about direct rulemaking procedures is set forth in a guidance published in the **Federal Register** of November 21, 1997 (62 FR 62466).

V. Analysis of Impacts

A. Review Under Executive Order 12866, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act of 1995

FDA has examined the impacts of the direct final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this direct final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the direct final rule makes current regulations consistent with existing FDA practices and procedures, the agency certifies that this direct final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may

result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $130 million, using the most current (2007) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

B. Environmental Impact

The agency has determined under 21 CFR 25.31(h) that this action is of a type that does not individually or cumulatively have a significant adverse effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

C. Federalism

FDA has analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the direct final rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VI. Paperwork Reduction Act of 1995

This direct final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

VII. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 601 is amended as follows:

PART 601—LICENSING

■ 1. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: 15 U.S.C. 1451–1561; 21 U.S.C. 321, 351, 352, 353, 355, 356b, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263, 264; sec 122, Pub. L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

■ 2. Revise § 601.8 to read as follows:

§ 601.8 Publication of revocation.

The Commissioner, following revocation of a biologics license under 21 CFR 601.5(b), will publish a notice in the **Federal Register** with a statement of the specific grounds for the revocation.

Dated: March 25, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–10244 Filed 5–4–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2009–0024]

Drawbridge Operation Regulation; High Street Drawbridge, Alameda, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eleventh Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the High Street drawbridge across the Oakland Inner Harbor, mile 6.0, at Alameda, CA. The deviation is necessary to allow seismic retrofitting of the bridge. This deviation allows single leaf operation of the double leaf, bascule style drawbridge, during the deviation period.

DATES: This deviation is effective from 12:01 a.m. on May 1, 2009 until 11:59 p.m. on August 31, 2009.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of the docket USCG–2009–0024 and are available online by going to *http://www.regulations.gov*, selecting the Advanced Docket Search option on the right side of the screen, inserting USCG–2009–0024 in the Docket ID box, pressing Enter, and then clicking on the item in the Docket ID column. This material is also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule call David H. Sulouff, Chief, Bridge Section, Eleventh Coast Guard District, telephone (510) 437–3516. If you have questions on viewing the docket, call Renee Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION: The County of Alameda requested a temporary change to the operation of the High Street drawbridge across the Oakland Inner Harbor, mile 6.0, at Alameda, CA. The High Street drawbridge navigation span provides a horizontal clearance of 244 feet between pier fenders. During single leaf operation, horizontal clearance is reduced to approximately 100 feet. The drawbridge provides a vertical clearance of 16 feet above Mean High Water in the closed-to-navigation position and unlimited vertical clearance in the open-to-navigation position. As required by 33 CFR 117.181, the draw shall open on signal; except that, from 8 a.m. to 9 a.m. and 4:30 p.m. to 6:30 p.m. Monday through Friday except Federal holidays, the draw need not be opened for the passage of vessels. However, the draw shall open during the above closed periods for vessels which must, for reasons of safety, move on a tide or slack water, if at least two hours notice is given. The waterway is navigated by commercial, recreational, emergency and law enforcement vessels.

Between the hours of 7 a.m. and 9 p.m. Monday through Thursday, and between the hours of 7 a.m. and 3:30 p.m. on Friday, the drawspan may be operated, one leaf at a time, while the opposite leaf is seismically retrofitted. The drawbridge will be operated in the normal double leaf operation mode at night and on weekends, when work is not actually being performed on the bridge. The starting and ending dates for the project are from 12:01 a.m. on May