

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]

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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.