

Dated: March 11, 2009.

Carol Waller Pope,

Acting Chairman.

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DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Parts 400, 407, 457

RIN 0563-AB73

General Administrative Regulations; Administrative Remedies for Non-Compliance; Correcting Amendments

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Final rule; correcting amendment.

SUMMARY: This document contains correcting amendments to the final regulations that were published December 18, 2008 (73 FR 76868-76891). These regulations pertain to Administrative Remedies for Non-Compliance and provide clarification of existing remedies.

DATES: *Effective Date:* March 19, 2009.

FOR FURTHER INFORMATION CONTACT: Cynthia Simpson, Director, Appeals, Litigation and Legal Liaison Staff, Risk Management Agency, United States Department of Agriculture, 1400 Independence Avenue, SW., Room 6603, Stop 0806, Washington, DC 20250, telephone (202) 720-0642.

SUPPLEMENTARY INFORMATION:

Background

The final regulation that is the subject of these correcting amendments was intended to add additional administrative remedies that are available as a result of the enactment of section 515(h) of the Federal Crop Insurance Act (Act) (7 U.S.C. 1515(h)), make such other changes as are necessary to implement the provisions of section 515(h) of the Act, and to clarify existing administrative remedies.

Need for Corrections

As published, the final regulation contained an error that may prove to be misleading and needs to be clarified.

On page 73 FR 76891 in § 407.9 item 22(a)(1) and § 457.8 item 27(e)(1)(i) the term "requirement of this title" is incorrect and should read "requirement of FCIC." Section 515(h) of the Act authorizes disqualification and the assessment of civil fine of persons who willfully and intentionally provide false or inaccurate information or fails to

comply with a requirement of FCIC. The term "requirement of this title" is confusing and provides no reference to a specific requirement.

List of Subjects in 7 CFR Parts 407 and 457

Administrative practice and procedures; Administrative remedies for non-compliance.

■ Accordingly, the 7 CFR part 407 and 457 is amended as follows:

■ 1. The authority citation for 7 CFR part 407 and 457 is revised to read as follows:

Authority: 7 U.S.C. 1506(l) and 1506(o).

PART 407—GROUP RISK PLAN OF INSURANCE REGULATIONS

■ 2. In § 407.9 amend item 22 by revising paragraph (a)(1) to read as follows:

§ 407.9 Group risk plan common policy.

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22. Remedial Sanctions

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(a) * * *

(1) The amount of the pecuniary gain obtained as a result of the false or inaccurate information provided or the noncompliance with a requirement of FCIC; or

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PART 457—COMMON CROP INSURANCE REGULATIONS

■ 3. In § 457.8 amend item 27 by revising paragraph (e)(1)(i) to read as follows:

§ 457.8 The application and policy.

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27. Concealment, Misrepresentation or Fraud.

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(e) * * *

(1) * * *

(i) The amount of the pecuniary gain obtained as a result of the false or inaccurate information provided or the noncompliance with a requirement of FCIC; or

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Signed in Washington, DC, on March 11, 2009.

William J. Murphy,

Acting Manager, Federal Crop Insurance Corporation.

[FR Doc. E9-5793 Filed 3-18-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA-2009-N-0665]

Implantation or Injectable Dosage Form New Animal Drugs; Tylosin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Elanco Animal Health. The supplemental NADA provides for changing scientific nomenclature for a bovine pathogen on labeling for tylosin injectable solution.

DATES: This rule is effective March 19, 2009.

FOR FURTHER INFORMATION CONTACT:

Cindy L. Burnsteel, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8341, e-mail: cindy.burnsteel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 12-965 for TYLAN (tylosin) Injection, an injectable solution used for the treatment of animal diseases associated with several bacterial pathogens. The supplemental NADA provides for changing a bovine pathogen name on product labeling. The supplemental NADA is approved as of February 24, 2009, and the regulations in 21 CFR 522.2640 and 522.2640a are amended to reflect the approval.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.