

Avilamycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 13.6 to 40.9	Broiler chickens: For the prevention of mortality caused by necrotic enteritis associated with <i>Clostridium perfringens</i> in broiler chickens.	Feed as the sole ration for 21 consecutive days. To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 10 days of age.	000986
(ii) [Reserved].				

(2) Swine—

Avilamycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 73	Weaned pigs less than 14 weeks of age: For the reduction in incidence and overall severity of diarrhea in the presence of pathogenic <i>Escherichia coli</i> in groups of weaned pigs.	Feed as the sole ration for 21 consecutive days. To assure responsible antimicrobial drug use in pigs, do not administer to pigs 14 weeks of age or older.	000986
(ii) [Reserved].				

§ 558.274 [Amended]

■ 19. Effective September 8, 2016, in § 558.274, remove and reserve paragraphs (c)(1)(ii) and (c)(2)(ii).

■ 20. Effective September 8, 2016, in § 558.355, remove and reserve paragraph (f)(1)(xxviii) and revise paragraphs (f)(8)(i) and (ii).

The revisions read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(8) * * *

(i) Decoquinatone alone and in combination as in § 558.195.

(ii) Melengestrol acetate alone and in combination as in § 558.342.

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§ 558.363 [Amended]

■ 21. Effective September 8, 2016, in § 558.363, remove and reserve paragraph (d)(1)(vi).

§ 558.550 [Amended]

■ 22. Effective September 8, 2016, in § 558.550, remove and reserve paragraph (d)(1)(xxii).

§ 558.618 [Amended]

■ 23. In § 558.618, in paragraphs (e)(2)(ii) and (iii):

■ a. In the “Limitations” column, add “Tilmicosin as provided by Nos. 000986 or 016952; monensin as provided by No. 000986 in § 510.600(c) of this chapter.” to the end of the existing entries; and

■ b. In the “Sponsor” column, numerically add “016952”.

■ 24. Effective September 8, 2016, in § 558.625, revise paragraphs (b)(1), (f)(2)(i), (f)(2)(iii), and (f)(2)(vii) and remove paragraphs (f)(2)(viii) and (ix).
The revisions read as follows:

§ 558.625 Tylosin.

* * * * *

(b) * * *

(1) No. 000986: 40 and 100 grams per pound for use as in paragraph (f) of this section.

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(f) * * *

(2) * * *

(i) Decoquinatone alone and in combination as in § 558.195.

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(iii) Melengestrol acetate alone and in combination as in § 558.342.

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(vii) Zilpaterol alone and in combination as in § 558.665.

■ 25. Effective September 8, 2016, in § 558.630, revise paragraph (b)(1) to read as follows:

§ 558.630 Tylosin and sulfamethazine.

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(b) * * *

(1) No. 000986: 40 and 100 grams per pound for use as in paragraph (e) of this section.

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Dated: August 8, 2016.

Tracey H. Forfa,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 2016–19914 Filed 8–26–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2016–N–0002]

New Animal Drugs for Use in Animal Feed; Withdrawal of Approval of a New Animal Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of eight new animal drug applications (NADAs) at the sponsor's request because these products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective September 8, 2016.

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5761, sujaya.dessai@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285 has requested that FDA withdraw approval of the NADAs listed in the following table because the products are no longer manufactured or marketed:

File No.	Product name	21 CFR section
012–548 ¹	TYLOSIN (tylosin phosphate)/HYGROMIX (hygromycin B)	558.274
013–162 ¹	TYLAN TM (tylosin phosphate) Type A medicated article	558.625

File No.	Product name	21 CFR section
013-388 ¹	TYLAN (tylosin phosphate)/HYGROMIX (hygromycin B) Premix	558.274
015-166 ¹	TYLAN TM (tylosin phosphate) Type A medicated article	558.625
127-507 ¹	TYLAN 5 SULFA-G (tylosin phosphate and sulfamethazine), TYLAN 10 SULFA-G (tylosin phosphate and sulfamethazine), TYLAN 20 SULFA-G (tylosin phosphate and sulfamethazine), TYLAN 40 SULFA-G (tylosin phosphate and sulfamethazine).	558.630
141-164 ¹	TYLAN (tylosin phosphate)/COBAN (monensin)	558.355
141-170 ¹	TYLAN (tylosin phosphate)/MONTEBAN (narasin)	558.363
141-198 ¹	TYLAN TM (tylosin phosphate)/BIO-COX (salinomycin)	558.550

¹ These NADAs were identified as being affected by guidance for industry #213, "New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209," December 2013.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADAs 012-548, 013-162, 013-388, 015-166, 127-507, 141-164, 141-170, and 141-198, and all supplements and amendments thereto, is hereby withdrawn, effective September 8, 2016.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: August 8, 2016.

Tracey H. Forfa,
Deputy Director, Center for Veterinary Medicine.

[FR Doc. 2016-19915 Filed 8-26-16; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 97 and 160

[Docket No. USCG-2000-7080]

RIN 1625-AA25 [formerly RIN 2115-AF97]

Cargo Securing Manuals

AGENCY: Coast Guard, DHS.

ACTION: Correcting amendments.

SUMMARY: The Coast Guard published an interim rule in the **Federal Register** on May 9, 2016, that prescribes when and how the loss or jettisoning of cargo at sea must be reported. That rule contained a typographical error that erroneously revised a force majeure regulation instead of a notice of hazardous conditions regulation. This document corrects that error.

DATES: Effective August 29, 2016.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or

email Mr. Ken Smith, Office of Operating and Environmental Standards (CG-OES-2), Coast Guard; telephone 202-372-1413, email *Ken.A.Smith@uscg.mil*.

SUPPLEMENTARY INFORMATION:

Viewing Documents Associated With This Rule

To view the interim rule published on May 9, 2016, or other documents in the docket for the Cargo Securing Manuals rulemaking, go to *www.regulations.gov*, type the docket number, USCG-2000-7080, in the "SEARCH" box and click "SEARCH." Click on "Open Docket Folder" in the first item listed. Use the following link to go directly to the docket: *www.regulations.gov/document?D=USCG-2000-7080-0040*.

Background

In 2013 the Coast Guard proposed to revise 33 CFR 160.215, "Notice of hazardous conditions," as part of its supplemental notice of proposed rulemaking regarding cargo securing manuals (78 FR 68784, November 15, 2013). In 2015, a different rulemaking, regarding notices of arrival, redesignated § 160.215 as § 160.216, and inserted a provision on force majeure in § 160.215 (80 FR 5281, January 30, 2015). In 2016, the Coast Guard published an interim rule on cargo securing manuals that implemented changes it had proposed in 2013, including the amendment of § 160.215 (81 FR 27992, May 9, 2016). Because the 2016 rule amended § 160.215 when it should have amended the redesignated section, § 160.216, the force majeure provision was unintentionally removed and part 160 contained two consecutive sections on notice of hazardous conditions. It was an error for the interim rule to revise § 160.215 and replace the force majeure provision. This rule corrects that error and a cross-reference in 33 CFR 97.115 to § 160.215.

Need for Correction

As discussed above, the interim rule published May 9, 2016, incorrectly

replaced force majeure regulations in § 160.215, instead of amending notice of hazardous conditions regulations in § 160.216.

List of Subjects

33 CFR Part 97

Cargo stowage and securing, Cargo vessels, Hazardous materials, Incorporation by reference, Reporting and recordkeeping requirements.

33 CFR Part 160

Administrative practice and procedure, Harbors, Hazardous materials transportation, Marine safety, Navigation (water), Personally identifiable information, Reporting and recordkeeping requirements, Seamen, Vessels, Waterways.

For the reasons stated in the preamble, 33 CFR parts 97 and 160 are amended as follows:

PART 97—RULES FOR THE SAFE OPERATION OF VESSELS, STOWAGE AND SECURING OF CARGOES

- 1. The authority citation for part 97 continues to read as follows:

Authority: 46 U.S.C. 2103, 3306; E.O. 12234; Department of Homeland Security Delegation No. 0170.1(92)(a) and (b).

§ 97.115 [Amended]

- 2. In § 97.115(a), remove "160.215", and add, in its place, "160.216".

PART 160—PORTS AND WATERWAYS SAFETY—GENERAL

- 3. The authority citation for part 160 continues to read as follows:

Authority: 33 U.S.C. 1223, 1231; 46 U.S.C. Chapter 701; Department of Homeland Security Delegation No. 0170.1. Subpart C is also issued under the authority of 33 U.S.C. 1225 and 46 U.S.C. 3715.

§ 160.216 [Removed]

- 4. Remove § 160.216.

§ 160.215 [Redesignated as § 160.216]

- 5. Redesignate § 160.215 as § 160.216.