

the commodity to the buyer, and the segregation or allocation status of the commodity.

*Example 5:* Actual delivery will *not* have occurred if, within 28 days, an agreement, contract, or transaction for the purchase or sale of a commodity is rolled, offset, or otherwise netted with another transaction or settled in cash between the buyer and the seller, but the seller has not, in accordance with the methods described in Example 1 or 2, physically delivered the entire quantity of the commodity purchased by the buyer, including any portion of the purchase made using leverage, margin, or financing, and transferred title to that quantity of the commodity to the buyer, regardless of whether the agreement, contract, or transaction between the buyer and seller purports to create an enforceable obligation on the part of the seller, or a parent company, partner, agent, or other affiliate of the seller, to deliver the commodity to the buyer.

Issued in Washington, DC, on August 20, 2013, by the Commission.

**Christopher J. Kirkpatrick,**  
*Deputy Secretary of the Commission.*

### Appendix to Retail Commodity Transactions Under Commodity Exchange Act—Commission Voting Summary

On this matter, Chairman Gensler and Commissioners Chilton, O'Malia, and Wetjen voted in the affirmative. No Commissioners voted in the negative.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 175

#### Indirect Food Additives: Adhesives and Components of Coatings

##### CFR Correction

In Title 21 of the Code of Federal Regulations, Parts 170 to 199, revised as of April 1, 2013, on page 196, in § 175.320, in paragraph (c), in the first sentence, revise “tables 1 and 2 of § 176.17(c)” to read “tables 1 and 2 of § 176.170(c)”.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 510, 520, and 558

[Docket No. FDA-2013-N-0839]

#### New Animal Drugs; Withdrawal of Approval of New Animal Drug Applications; Diethylcarbamazine; Nicarbazin; Penicillin

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the withdrawal of approval of three new animal drug applications (NADAs) at the sponsors' request because the products are no longer manufactured or marketed.

**DATES:** This rule is effective September 3, 2013.

**FOR FURTHER INFORMATION CONTACT:** David Alterman, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6843, email: [david.alterman@fda.hhs.gov](mailto:david.alterman@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Phibro Animal Health Corp., 65 Challenger Rd., 3d Floor, Ridgefield Park, NJ 07660 has requested that FDA withdraw approval of NADA 098-371 for use of nicarbazin, penicillin, and roxarsone in 3-way, combination drug Type C medicated feeds for broiler chickens and NADA 098-374 for use of nicarbazin and penicillin in 2-way, combination drug Type C medicated feeds for broiler chickens because the products are no longer manufactured or marketed. Accordingly, 21 CFR 558.366 and 558.460 are being amended to reflect the withdrawal of approval.

R. P. Scherer North America, P.O. Box 5600, Clearwater, FL 33518 has requested that FDA withdraw approval of NADA 123-116 for Diethylcarbamazine Citrate Capsules used in dogs for the prevention of heartworm disease because the product is no longer manufactured or marketed. Accordingly, 21 CFR 520.622d is being amended to reflect the withdrawal of approval.

Following this withdrawal of approval, R. P. Scherer North America is no longer the sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for these firms.

Elsewhere in this issue of the **Federal Register**, FDA gave notice that approval

of NADA 098-371, NADA 098-374, and NADA 123-116, and all supplements and amendments thereto, is withdrawn. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these voluntary withdrawals of approval.

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.

#### List of Subjects

##### 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

##### 21 CFR Part 520

Animal drugs.

##### 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, and 558 are amended as follows:

#### PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

##### § 510.600 [Amended]

■ 2. In § 510.600, in the table in paragraph (c)(1), remove the entry for “R. P. Scherer North America”; and in the table in paragraph (c)(2), remove the entry for “011014”.

#### PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 520 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

##### § 520.622d [Removed]

■ 4. Remove § 520.622d.

#### PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 5. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** 21 U.S.C. 360b, 371.

##### § 558.366 [Amended]

■ 6. In § 558.366, in the table in paragraph (d), in the entry for “90.8 to 181.6 (0.01 to 0.02 pct)”, remove the

entries for “Penicillin 2.4 to 50” and “Penicillin 2.4 to 50 and roxarsone 22.7 to 45.4”.

**§ 558.460 [Amended]**

■ 7. In § 558.460, remove and reserve paragraph (d)(2)(iv).

Dated: August 19, 2013.

**Bernadette Dunham,**

*Director, Center for Veterinary Medicine.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 510 and 558**

[Docket No. FDA–2013–N–0002]

**Withdrawal of Approval of New Animal Drug Applications; Quali-Tech Products, Inc.; Bambermycins; Pyrantel; Tylosin; Virginiamycin**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the withdrawal of approval of four new animal drug applications (NADAs), held by Quali-Tech Products, Inc., at the sponsor’s request because the products are no longer manufactured or marketed.

**DATES:** The rule is effective September 3, 2013.

**FOR FURTHER INFORMATION CONTACT:** David Alterman, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6843, david.alterman@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:** Quali-Tech Products, Inc., has requested that FDA withdraw approval of the following four NADAs because the products, used to manufacture Type C medicated feeds, are no longer manufactured or marketed: NADA 097–980 for Quali-Tech TYLAN–10 (tylosin phosphate) Premix, NADA 118–815 for Q.T. BAN–TECH (pyrantel tartrate), NADA 132–705 for FLAVOMYCIN (bambermycins), and NADA 133–335 for STAFAC (virginiamycin) Swine Pak 10.

Elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of NADAs 097–980, 118–815, 132–705, and 133–335, and all supplements and amendments thereto, is withdrawn. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these voluntary withdrawals of approval.

Following these withdrawals of approval, Quali-Tech Products, Inc., will no longer be the sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for this firm.

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.

**List of Subjects**

*21 CFR Part 510*

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

*21 CFR Parts 558*

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner

of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 558 are amended as follows:

**PART 510—NEW ANIMAL DRUGS**

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

**§ 510.600 [Amended]**

■ 2. In § 510.600, in the table in paragraph (c)(1), remove the entry for “Quali-Tech Products, Inc.”; and in the table in paragraph (c)(2), remove the entry for “016968”.

**PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

■ 3. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** 21 U.S.C. 360b, 371.

■ 4. In § 558.95, revise paragraphs (a), (d)(1), (d)(2), (d)(3), (d)(4)(i), and (d)(4)(ii) to read as follows:

**§ 558.95 Bambermycins.**

(a) *Approvals.* See sponsors in § 510.600(c) of this chapter for use of Type A medicated articles as in paragraph (d) of this section:

(1) No. 016592: 2, 4, and 10 grams per pound for use as in paragraphs (d)(1), (d)(2), (d)(3), and (d)(4) of this section.

(2) Nos. 012286 and 017790: 2 grams for use as in paragraph (d)(2) of this section and 0.4 and 2 grams per pound for use as in paragraph (d)(3).

\* \* \* \* \*

(d) \* \* \*

(1) *Chickens.* Use in medicated feed as follows:

Bambermycins in grams/ton	Indications for use	Limitations	Sponsor
(i) 1 to 2 .....	Broiler chickens: For increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration .....	016592.
(ii) [Reserved].			

(2) *Turkeys.* Use in medicated feed as follows:

Bambermycins in grams/ton	Indications for use	Limitations	Sponsor
(i) 1 to 2 .....	Growing turkeys: For improved feed efficiency	Feed continuously as the sole ration .....	012286, 016592, 017790.
(ii) 2 .....	Growing turkeys: For increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration .....	012286, 016592, 017790.