

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notice that approval of NADAs 097–980, 118–815, 132–705, and 133–335, and all supplements and amendments thereto, is withdrawn.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.

(3) *Swine*. Use in medicated feed as follows:

Bambermycins in grams/ton	Indications for use	Limitations	Sponsor
(i) 2	Growing-finishing swine: For increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration	012286, 016592, 017790.
(ii) 2 to 4	Growing-finishing swine: For increased rate of weight.	Feed continuously as the sole ration	012286, 016592, 017790.

(4) *Cattle*. Use in medicated feed as follows:

Bambermycins in grams/ton	Indications for use	Limitations	Sponsor
(i) 1 to 4	Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency.	Feed continuously at a rate of 10 to 20 milligrams per head per day.	016592.
(ii) 2 to 40	Pasture cattle (slaughter, stocker, and feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain.	Feed continuously at a rate of 10 to 40 milligrams per head per day in at least 1 pound and not more than 10 pounds of feed. Daily bambermycins intakes in excess of 20 mg/head/day have not been shown to be more effective than 20 mg/head/day.	016592.

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§ 558.485 [Amended]

■ 5. In paragraph (b)(3) of § 558.485, remove “Nos. 016968, and 017790” and in its place add “No. 017790”.

§ 558.625 [Amended]

■ 6. In § 558.625, remove and reserve paragraph (b)(14).

§ 558.635 [Amended]

■ 7. In paragraph (a)(2) of § 558.635, remove “046573, 016968, and 017790” and in its place add “046573 and 017790”.

Dated: August 20, 2013.

Bernadette Dunham,
Director, Center for Veterinary Medicine.

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DEPARTMENT OF THE INTERIOR

Office of Natural Resources Revenue

30 CFR Part 1218

[Docket No. ONRR–2013–0001; DS63610300 DR2PS0000.CH7000 134D0102R2]

RIN 1012–AA14

Amendments to ONRR’s Service of Official Correspondence

AGENCY: Office of the Secretary, Office of Natural Resources Revenue (ONRR), Interior.

ACTION: Direct final rule.

SUMMARY: This rule will update the Service of Official Correspondence regulations in title 30 of the *Code of Federal Regulations* (CFR) to allow ONRR to serve official correspondence using any electronic method of delivery that provides for a receipt of delivery, or, if there is no receipt, the date of delivery otherwise documented.

DATES: This rule becomes effective on October 22, 2013 unless adverse comment is received by September 23, 2013. If adverse comment is received, ONRR will publish a timely withdrawal of the rule in the **Federal Register**.

ADDRESSES: You may submit comments on the rulemaking by any of the following methods. Please use the Regulation Identifier Number (RIN) “1012–AA14” as an identifier in your comment. See also Public Availability of Comments under Procedural Matters.

- Electronically, go to <http://www.regulations.gov>. In the entry titled “Enter Keyword or ID,” enter “ONRR–2013–0001” and then click “Search.” Follow the instructions to submit public comments. ONRR will post all comments.

- Mail comments to Armand Southall, Regulatory Specialist, ONRR, P.O. Box 25165, MS 61030A, Denver, CO 80225.

- Hand-carry comments, or use an overnight courier service, ONRR. Our courier address is Building 85, Room A–614, Denver Federal Center, West 6th Ave. and Kipling St., Denver, Colorado 80225.

FOR FURTHER INFORMATION CONTACT: For questions on technical issues, contact

Tim Calahan, Supervisor, ONRR, telephone (303) 231–3036, or email Timothy.Calahan@onrr.gov. For a paper copy of this rule, contact Armand Southall, Regulatory Specialist, ONRR, telephone (303) 231–3221; or email Armand.Southall@onrr.gov. The authors of this direct final rule are Sarah Inderbitzin and Timothy Calahan.

SUPPLEMENTARY INFORMATION:

I. Background

On August 31, 2006, the Mineral Management Service (MMS) established 30 CFR part 218, subpart H—Service of Official Correspondence. 71 FR 51749 (August 31, 2006). On September 30, 2010, by Secretarial Order No. 3306, the Secretary of the Department of the Interior transferred the royalty management functions of the Minerals Revenue Management, former arm of MMS, to the Office of Natural Resources Revenue (ONRR). As part of that reorganization, ONRR recodified the former 30 CFR part 218, subpart H, of chapter II to a new chapter XII in 30 CFR as part 1218, without substantive change. 75 FR 61051 (Oct. 4, 2010). Section 1218.540(a) deals specifically with methods of service of official correspondence on companies and reporting entities.

II. Explanation of Amendments

This direct final rule adds a new paragraph (4) to 30 CFR 1218.540(a) updating the Service of Official Correspondence regulations to allow ONRR to serve official correspondence using any electronic method of delivery